U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

Southeast Region • Atlanta Federal Center
Suite 16T70 • 61 Forsyth Street, S.W. • Atlanta GA 30303
Voice - (800) 368-1019 • TDD – (800) 537-7697
Fax - (202) 619-3818 • http://www.hhs.gov/ocr

November 7, 2022

VIA EMAIL

(b)(6)
(b)(6)

OCR Transaction Number: 04-22-452005-(b)(6) vs Humana/Medicaid

Dear Ms. (b)(6)

On November 8, 2021, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received your complaint alleging that Humana Medicaid (Humana/Covered Entity) discriminatorily denied coverage for health-related services based on her sex (gender identity) in violation of Section 1557 of the Patient Protection and Affordable Care Act (Section 1557). Specifically, you alleged that in October 2021, Humana denied your request to cover medically necessary transition-related surgery, ignored the medical necessity documentation provided, and deemed the procedure cosmetic.[1]

LEGAL AUTHORITY

OCR enforces federal civil rights laws which prohibit discrimination in the delivery of health and human services based on race, color, national origin, disability, age, sex, religion, and the exercise of conscience, and also enforces the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security and Breach Notification Rules.

OCR is responsible for enforcing Section 1557 of the Patient Protection and Affordable Care Act. Section 1557 provides that "an individual shall not, on the grounds prohibited under Title VI of the Civil Rights Act of 1964 (42 U.S.C. § 2000d et seq.) [race, color, or national origin], Title IX of the Education Amendments of 1972 (20 U.S.C. § 1681 et seq.) [sex], the Age Discrimination Act of 1975 (42 U.S.C. § 6101 et seq.) [age], or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. § 794 et seq.) [disability], be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance." As a health program or activity receiving FFA from HHS, the Covered Entity is obligated to comply with Section 1557.

BACKGROUND

The Complainant stated that that in October 2021, Humana denied her request to cover her medically necessary transition-related surgery, ignored the documentation provided by

[1] Allegations were summarized and do not include all claims made.

her doctors and deemed the procedure as cosmetic. The Complainant stated that she provided letters of recommendation for surgery written by two WPATH therapists; however, the Covered Entity disregarded the professionals' opinions and rejected her diagnosis of gender dysphoria as well as the therapists' recommendations for gender reassignment surgery.

The Complainant stated that she had been undergoing gender transition, including hormone replacement therapy, for over two years; yet the Covered Entity impermissibly delayed a medically necessary procedure which caused her mental and physical stresses.

CORRECTIVE ACTION

OCR initiated this investigation on December 17, 2021, by providing the Covered Entity with notice of the allegations. The Covered Entity has assured OCR of its intention not to discriminate against persons based on their gender identity and protected status. The Covered Entity provided documentation to OCR that it has voluntarily taken corrective measures to remedy the Complainant's situation.

In its February 25, 2022, response, the Covered Entity informed OCR that in making its decision to initially deny the services the Complainant requested, it evaluated the Complainant's medical record and followed the State of Florida standards of review, which does not require considering the recommendations or opinions of the treating physicians to be determinative of the medical necessity of services.

The Covered Entity stated that the Complainant appealed the denial, but its decision was upheld. The Complainant then appeal through the Medicaid Fair Hearing (MHP) process; however, on December 29, 2021, before the MHP process was completed, the Covered Entity's Regional Vice President of Health Services (RVPHS) conducted a full review of the Complainant's file and approved the requested services. The Covered Entity stated that the RVPHS has vast experience with the professional standards of care for gender reassignment processes and her analysis determined the requests met the medical necessity criteria. The Covered Entity notified the Complainant about its decision to reverse the initials denial on the same date.

On September 22, 2022, the Complainant informed OCR that she received the surgery for gender reassignment on July 21, 2022. The Complainant reported the Covered Entity has continued to comply with medically necessary treatments for follow up care and she is satisfied with the current conditions.

Conclusion

Based upon the Covered Entity's voluntary corrective actions described above, OCR finds that the complaint allegations have been resolved. Therefore, OCR is closing this complaint.

If you have any questions concerning this letter, please contact Beatriz Romero-Escobar, Senior Investigator, at (404) 562-4680 (Voice), (404) 562-7884 (TDD) or at Beatriz.romero@hh.gov.

Sincerely,

Barbara Stampul
Regional Manager

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

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November 7, 2022

VIA EMAIL

Troy Barsky
Crowell & Moring LLP
tbarsky@crowell.com

OCR Transaction Number: 04-22-452005-(b)(6) vs Humana/Medicaid

Dear Mr. Barsky:

On November 8, 2021, the U.S. Department of Health and Human Services (HHS), Office for Civil Rights (OCR), received the above referenced complaint filed by (b)(6) (Complainant) against Humana Medicaid (Humana/Covered Entity) alleging that the Covered Entity discriminatorily denied coverage for health-related services based on her sex (gender identity) in violation of Section 1557 of the Patient Protection and Affordable Care Act (Section 1557). Specifically, the Complainant alleged that in October 2021, the Covered Entity denied her request to cover medically necessary transition-related surgery, ignored the medical necessity documentation provided, and deemed the procedure cosmetic. [1]

LEGAL AUTHORITY

OCR enforces federal civil rights laws which prohibit discrimination in the delivery of health and human services based on race, color, national origin, disability, age, sex, religion, and the exercise of conscience, and also enforces the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security and Breach Notification Rules.

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[1] Allegations were summarized and do not include all claims made.

BACKGROUND

The Complainant stated that that in October 2021, Humana denied her request to cover her medically necessary transition-related surgery, ignored the documentation provided by her doctors and deemed the procedure as cosmetic. The Complainant stated that she provided letters of recommendation for surgery written by two WPATH therapists; however, the Covered Entity disregarded the professionals' opinions and rejected her diagnosis of gender dysphoria as well as the therapists' recommendations for gender reassignment surgery.

The Complainant stated that she had been undergoing gender transition, including hormone replacement therapy, for over two years; yet the Covered Entity impermissibly delayed a medically necessary procedure which caused her mental and physical stresses.

CORRECTIVE ACTION

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Conclusion

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If you have any questions concerning this letter, please contact Beatriz Romero-Escobar,

Senior Investigator, at (404) 562-4680 (Voice), (404) 562-7884 (TDD) or at Beatriz.romero@hh.gov.

Sincerely,

Barbara Stampul
Regional Manager

Sydney T. King, M.S., LPCC
The Self Collective, LLC
Sydney@TheSelfCollective.com
Ph: 614-427-0875; Fax: 614-421-7987

04/19/2022

To:
UK HealthCare
1000 S. Limestone
University of Kentucky
Lexington, KY 40536

Re:
(b)(6); (b)(7)(C) (he/they); DOB: (b)(6); (b)(7)(C)

Reason for Referral:
(b)(6); (b)(7)(C)

Dr. David Drake and Team:

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Please feel free to contact me should you have any questions or need any further information. Thank you in advance for the care that you will provide to (b)(6);

Sydney T. King, M.S., LPCC
Ohio #E.2001814

Sydney@TheSelfCollective.com
Ph: 614-427-0875

05/06/2022

WellCare of Kentucky
2480 Fortune Dr Ste 200
Lexington, KY 40509

Member Name: (b)(6); (b)(7)(C)
Member Number ID:
Provider Name:
Payer:

Plan name:

Contact Name: (b)(6); (b)(7)(C)
Contact Email: (b)(6); (b)(7)(C)
Contact Phone Number:
Contact Address:

Subject: Request for [LEVEL 2 Appeal]

To Whom It May Concern:

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Sincerely,

(b)(6); (b)(7)(C)

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
HEALTH SERVICES ADMINISTRATION HEARINGS BRANCH
ADMINISTRATIVE ACTION NO. HSAHB DMS 22-0323

(b)(6); (b)(7)(C)

APPELLANT

v.

WELLCARE OF KENTUCKY, INC. **APPELLEE**

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Sydney T. King, M.S., LPCC
The Self Collective, LLC
Sydney@TheSelfCollective.com
Ph: 614-427-0875; Fax: 614-421-7987

04/19/2022

To:
UK HealthCare
1000 S. Limestone
University of Kentucky
Lexington, KY 40536

Re:
(b)(6); (b)(7)(C) (he/they); DOB (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Please feel free to contact me should you have any questions or need any further information. Thank you in advance for the care that you will provide to (b)(6);

Sydney T. King, M.S., LPCC
Ohio #E.2001814

Sydney@TheSelfCollective.com
Ph: 614-427-0875

05/06/2022

WellCare of Kentucky
2480 Fortune Dr Ste 200
Lexington, KY 40509

(b)(6); (b)(7)(C)

Member Name:
Member Number ID:
Provider Name:
Payer:

Plan name:

Contact Name:
Contact Email:
Contact Phone Number:
Contact Address:

Subject: Request for [LEVEL 2 Appeal]

To Whom It May Concern:

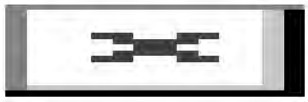
(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

From:	Lopez, Onelio (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=USER541E91E4 <Onelio.Lopez@HHS.GOV>
To:	OS - OCR ALL NATIONAL /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431c699b1f24e4199c55cf36517dcb4-OCRALLNAT.O <OCRALLNAT@hhs.gov>; OS - OCR ALL NATIONAL Contractors /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89387188969240b4ac04855d9722d3fe-OS - OCR AL <OS-OCRALLNATIONALContractors@hhs.gov>
CC:	Seeger, Rachel (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3090ef9b170d45969add4ff475a95583-Rachel Seeg <Rachel.Seeger@hhs.gov>
Subject:	OCR Weekly Media Clips: January 23 - 27, 2023
Date:	2023/01/27 15:36:14
Priority:	Normal
Type:	Note



OCR Weekly Media Clips

January 23 - 27, 2023

HHS PRESS RELEASES

Biden-Harris Administration to Launch Summit Series to Advance Asian American, Native Hawaiian, and Pacific Islander Economic Equity – 01/26/2023
WHIAANHPI will launch a series of regional economic summits to connect Asian American, Native Hawaiian, and Pacific Islander community members directly with federal leaders and resources. The events, set to kick off with an in-person summit at Philadelphia City Hall, are being held in collaboration with SBA, UST, HHS's OSDBU, the National Asian / Pacific Islander American Chamber of Commerce &Entrepreneurship, and local officials.

HHS Releases Report Detailing Biden-Harris Administration Efforts to Protect Reproductive Health Care Since Dobbs – 01/19/2023
HHS actions have been centered on six core priorities: 1) Protecting Access to Abortion Services; 2) Safeguarding Access to Birth Control; 3) Protecting Patient Privacy; 4) Promoting Access to Accurate Information; 5) Ensuring Nondiscrimination in Healthcare Delivery; and 6) Evidence-Based Decision Making at FDA. Click here to read the full report.

OCR IN THE NEWS

CIVIL RIGHTS

Feds, Catholic Group Urge 8th Circ. To Rehear TransRuling

LAW360, 01/24/2023 ***[Article and Court Briefs attached]***
In separate petition filings, the DOJ and the Catholic Benefits Association sought to alter a three-judge panel's **December 9 published opinion** in the lawsuit from religious groups that the federal government had appealed. While the DOJ sought an en banc rehearing with the goal of reversing the court's decision, the CBA wanted to broaden the religious groups' win by extending the injunction's application beyond what the panel decided, according to the parties' filings.

Anti-discrimination laws are faltering in the face of artificial intelligence; here's what to do about it
ABA Journal, 01/24/2023
"On the basis of." These four words from the Civil Rights Act of 1964 underlie the modern conception of illegal bias. From federal anti-discrimination statutes to state and local laws, this phrase nearly unites them all. The problem? As artificial intelligence systems automate more analyses, it is all too easy for decisions to become less transparent and decision-makers less accountable. Some conscientious developers are improving AI systems' technical transparency. But those advances are not universal, and they do not necessarily explain the processes behind those systems' outputs to the public or the courts.

When Lyndon B. Johnson Chose the Middle Ground on Civil Rights—and Disappointed Everyone
Smithsonian Magazine, 01/23/2023
Smithsonian takes a look back on the time of the years that preceded the signing of the Civil Rights Act of 1964. On August 7, 1957, Senate Majority Leader Lyndon B. Johnson voted yea on the first civil rights bill passed by Congress in 82 years. He was joined by 71 of his Senate colleagues, including 43 Republicans and 28 Democrats, 4 of them liberals from the South like Johnson himself. One month later, on September 9, President Dwight D. Eisenhower signed the Civil Rights Act of 1957. Limited in its scope and effectiveness, particularly when compared with legislation passed in the 1960s, the 1957 bill walked a treacherous tightrope that "was going to disappoint both the opponents of civil rights and the proponents of civil rights."

HIPAA

HHS Offers HIPAA Guidance on Online Tracking Technologies
Journal of Federal Action, March-April 2023, Pgs.117-125,
In this article, the authors discuss privacy issues between patients and healthcare companies relating to cookies, pixels, and other tracking technologies. The authors talk about the stance that HHS OCR has taken after getting involved in this public debate. This article covers the shift from whether tracking tools on websites and apps infringe on consumer privacy by allowing their information to be shared to claims that healthcare companies specifically are improperly disclosing patient confidence by integrating digital advertising, analytics, and security tools into the code on public websites. The authors explain the pushback that healthcare companies have shared, stating that these tools are ubiquitous on the internet and serve legitimate business purposes.

Exclusive: DeSantis is surveying number of students who received gender-affirming treatment, could be violating HIPPA
Newsbreak, 01/24/2023
Governor DeSantis and his administration are apparently conducting a poll to determine the number of students who have undergone gender reassignment surgery or similar procedures, which may violate HIPPA. Florida Governor Ron DeSantis has requested information from state

colleges regarding the number of students who have sought or received therapy for gender dysphoria. According to a released survey, this treatment may include sex reassignment surgery and hormone prescriptions, among other options, and claims to protect students' identities in completing the information.

2022 Healthcare Data Breach Report
HIPAA Journal, 01/24/2023
For the first time since 2015, there was a year-over-year decline in the number of data breaches reported to HHS' OCR, albeit only by 1.13%, with 707 data breaches of 500 or more records reported. Even with that reduction, 2022 still ranked as the second-worst-ever year in terms of the number of reported breaches. As the year drew to an end, data breach numbers started to decline from a high of 75 data breaches in October. In addition to the slight reduction in reported data breaches, there was also a drop in the number of breached records, which fell by 13.15% from 54.09 million records in 2021 to 51.9 million records in 2022.

Federal Fix to Telehealth Rules Would Secure Delivery System
Bloomberg Law, 01/23/2023
The pandemic has brought about a seismic shift to telehealth. State and federal regulators continue to scramble to implement more permanent and sustainable solutions that will allow ongoing and seamless delivery and payment for telehealth services. The renewed federal public health emergency declaration through April 2023 remains a vital policy. A Frankenstein-like quilt of federal and state laws, regulations, and waivers serves as a regulatory Band-Aid for telehealth.

NEWS OF INTEREST TO OCR

Medicare Invites Public Comment as it Considers National Coverage Determination for HIV PrEP
HIV.gov Blog
CMS announced that it had initiated a national coverage analysis for Medicare coverage of PrEP. The analysis, which involves reviewing the evidence and considering public comments, will inform NCD by the agency. The public comment period closes on February 11, 2023. Instructions on submitting comments can be found on this page of the CMS website. The USPSTF recently published a draft recommendation with a grade A for prescribing PrEP with effective antiretroviral therapy to persons at increased risk of HIV acquisition to decrease the risk of acquiring HIV infection. You can track the progress of the analysis on this page of CMS' website.

CHILD WELFARE

Unmet Needs: Critics Cite Failures In Health Care For Vulnerable Foster Children
Cobb County Courtier, 01/25/2023
One night last month, a 9-year-old boy who had autism and talked about killing himself was among about 70 foster care children and youth under state supervision sleeping in hotels across GA. GA's designated health insurer for foster care, Amerigroup Community Care, had denied the boy placement in a psychiatric residential treatment facility. He stayed in a hotel for more than a month before receiving a temporary emergency placement in a foster home. The boy and the other children staying in the hotels lacked permanent placements, and many weren't getting help for their complex mental and behavioral needs. The frustration over gaps in care had gotten so bad that Candice Broce, commissioner of the GA DHS, sent a scathing six-page letter to the state Medicaid agency in August — signaling an unusual interagency conflict.

Maryland's foster system sued over administration of psychotropic drugs to children
WAMU.org, 01/23/2023
The ACLU of Maryland, joined by other state and national nonprofits, has filed a class action lawsuit against the state for allegedly failing to conduct adequate oversight of psychotropic drug administration in children in Maryland's foster care system, potentially harming thousands of children. … The suit, filed by the ACLU, Disability Rights Maryland, and Children's Rights, alleges that over the course of a decade, the state's DHSS Administration has failed to maintain adequate medical records and has not established a policy of informed consent, where an adult responsible for the child could consult on their medications. It also alleged that the state had not built a secondary review system to ensure children's medications were properly prescribed. According to the suit, the alleged failures disproportionately harm and jeopardize Black children, who are overrepresented in the state's foster care system.

DISABILITIES

For People With Disabilities, Losing Abortion Access Can Be a Matter of Life or Death
Time Magazine, 01/24/2023
The fall of *Roe v. Wade*, and the subsequent wave of abortion bans and restrictions in US states, have grave implications for the estimated 26% of US adults with a disability. Pregnancy can be dangerous for anyone, but people who enter pregnancy with underlying health issues are at even greater risk. Ensuring all people, including those with disabilities, have access to essential medical care includes guaranteeing "the option of termination if it's better for their health." In addition, abortion bans represent a threat to bodily autonomy, "a core principle of the disability rights movement," as the AAPD wrote in a statement after a draft of the Supreme Court's decision to overturn *Roe* leaked last May. "Policies that restrict access to abortion will drastically exacerbate threats to the autonomy, health, and overall well-being of disabled people." Since then, a dozen US states-including many in the South, the US region with the highest rate of disability-have almost entirely banned abortion. For people with disabilities, those laws only compound long-standing obstacles to abortion care.

Senior Clinic At Alaska Regional To Close In February, Leaving Vulnerable Patients With Limited Options For Care
Anchorage Daily News, 01/23/2023
A longtime Anchorage medical clinic for seniors has announced it's closing at the end of February, prompting concern from patients and providers about dwindling healthcare options locally for some of Anchorage's most vulnerable residents.

GENERAL

Federal Workforce: Strengthening Diversity, Equity, Inclusion, and Accessibility
GAO Report: GAO-23-106254, 01/24/2023
Big Picture: As the nation's largest employer, the federal government strives to be a model for diversity, equity, inclusion, and accessibility (DEIA) and, according to EO 14035, to cultivate a workforce that draws from the full diversity of the nation. In this Snapshot, we highlight selected findings and recommendations we have made between 2017 and 2022 to enhance DEIA in the federal workforce.

HEALTH DISPARITIES

Maternal Deaths And Disparities Increase In Mississippi
AP, 01/27/2023
Deaths from pregnancy complications have become more prevalent in Mississippi, and racial disparities in the health of those who give birth have widened in recent years, according to a report released Thursday by the state's Department of Health. The Mississippi Maternal Mortality Report shows that the maternal mortality rate increased by 8.8% between 2013-2016 and 2017-2019, with the latter period being the most recent one analyzed by researchers.

LGBTQIA+

Judge Curbs Florida Probe Into US Medicine's Trans Treatment Standards
Washington Post, 01/26/2023
A legal battle over Florida's ban on Medicaid spending for gender-affirming medical care spilled into Washington on Thursday as a federal judge partially granted an urgent request by 18 American medical and mental health groups to quash subpoenas sent to them by the state after they opposed the prohibition. The professional associations accused Florida of targeting members such as the American Academy of Pediatrics, the American Psychological Association, and the Endocrine Society after they expressed the widely accepted medical view that care such as puberty blockers, hormones, and gender transition surgery can be an appropriate treatment for transgender youth and adults.

GOP State Lawmakers Push a Growing Wave of Anti-Transgender Bills
New York Times, 01/25/2023
Four states could ban transition care into young adulthood. Lawmakers in several others want to restrict drag shows in ways that could affect transgender performers broadly. It's part of a long-term plan. Over the past three years, Republican state lawmakers have put forward a barrage of bills to regulate the lives of transgender youths, restricting the sports teams they can play on, bathrooms they can use, and medical care they can receive. But even by those standards, the start of the 2023 legislative season stands out for the aggressiveness lawmakers are pushing into new territory. The bills they have proposed — more than 150 in at least 25 states — include bans on transition care into young adulthood; restrictions on drag shows using definitions that could broadly encompass performances by transgender people; measures that would prevent teachers in many cases from using names or pronouns matching students' gender identities; and requirements that schools out transgender students to their parents.

Appeals Court to hear arguments on transgender health care ban for state employees
The Pulse, 01/25/2023
The US Court of Appeals for the Fourth Circuit will hear oral arguments Wednesday in a case in which the state was found to have violated the rights of state employees and their families with a blanket exclusion of gender-affirming care for transgender people under the state health plan. Last year a federal judge in Winston-Salem ruled the ban violated the Equal Protection Clause of the US Constitution and Title VII of the Civil Rights Act of 1964 through discrimination based on sex and transgender status. That decision came just months after the US Supreme court denied the state's petition to review a lower court ruling that the state health plan wasn't entitled to sovereign immunity and could be sued for violating the nondiscrimination provisions of the ACA.

Reproductive Health

Lawsuits Show Focus Of Abortion Battle Shifting To Medication

Roll Call, 01/25/2023
The third — Alliance for Hippocratic Medicine v. FDA — could have the broadest impact of the three cases. In November, the conservative legal advocacy group Alliance Defending Freedom challenged the FDA's approval of mifepristone, citing concerns about its safety. ADF is seeking an emergency ruling to pull approval of the drug nationwide. "If the FDA were forced to withdraw its approval, that would mean that mifepristone would be taken off the shelves nationwide and would therefore decimate access to abortion to people across the country regardless of where they live or the laws of their state," said Jennifer Dalven, director of the reproductive freedom project at the ACLU, speaking in a press call last week.

Watch: Fifty Years After 'Roe,' Abortion Rights Battle Shifts To The States
KHN, 01/24/2023
Sunday marked the 50th anniversary of the Supreme Court's landmark ruling in Roe v. Wade, granting federal constitutional protection for the right to seek an abortion. Last year, a very different Supreme Court overturned Roe, erasing that federal right for women across the United States and giving individual states broad authority to regulate and restrict abortion within their borders. In this report co-produced by PBS NewsHour, KHN senior correspondent Sarah Varney joins "PBS News Weekend" anchor John Yang to discuss how abortion opponents and supporters are taking their campaigns to the states, the impact of abortion bans on medical care for women, and the emerging conflicts over medication abortion pills.

As States Seek To Limit Abortions, Montana Wants To Redefine What Is Medically Necessary
KHN, 01/24/2023
Montana's conservative leaders, stymied by the courts from passing laws that impose significant statewide abortion restrictions, seek to tighten the state's Medicaid rules to make it more difficult for low-income women to receive abortions. The Montana Department of Public Health and Human Services proposes to define when an abortion is medically necessary, limit who can perform such services, and require preauthorization for most cases.

Justice Department To Monitor New Anti-Abortion Bills In State Legislatures
CNN, 01/23/2023
Upcoming state-level pushes to restrict abortion access further will be on the radar of the US Justice Department, top DOJ officials said Monday as they touted the work the Biden administration has sought to do to shore up abortion access in the wake of the Supreme Court's Roe v. Wade reversal last year. "We've obviously been very active in monitoring what's happening in the states and locally, and given that most state legislatures now are coming back into session, we'll be continuing to do so and looking at any laws that may get passed that infringe on federal protections," said Associate Attorney General Vanita Gupta, who leads a department task force on reproductive rights that was launched after the Supreme Court's decision.

SEX-BASED HARASSMENT

Doctor Who Molested Patients Convicted Of Federal Sex Counts
AP, 01/25/2023
A gynecologist accused of molesting hundreds of patients during a decades-long career was convicted of federal sex crime charges Tuesday in a victory for accusers who were outraged when an initial state prosecution resulted in no jail time. Robert Hadden, 64, of Englewood, New Jersey, was convicted after less than a day of deliberations at a two-week trial in which nine former patients described how he abused them sexually during examinations when they were most vulnerable.

HIPAA

US Department of Justice Disrupts Hive Ransomware Variant
Justice News, 01/26/2023
DOJ announced its months-long disruption campaign against the Hive ransomware group, targeting over 1,500 victims in over 80 countries worldwide, including hospitals, school districts, financial firms, and critical infrastructure. Since late July 2022, the FBI has penetrated Hive's computer networks, captured its decryption keys, and offered them to victims worldwide, preventing them from paying the $130 million in ransom demanded. Since infiltrating Hive's network in July 2022, the FBI has provided over 300 decryption keys to Hive victims who were under attack. In addition, the FBI distributed over 1,000 additional decryption keys to previous Hive victims.

Feds Warn of Malicious Use of RMM Software in Callback Phishing Attacks
HIPAA Journal, 01/25/2023
Cybercriminals increasingly use legitimate remote monitoring and management (RMM) software in their attacks, according to a recent joint alert from the CISA, NSA, and MS-ISAC. The campaign was first identified in October 2022 and involves callback phishing. The emails used in this campaign are difficult for email security solutions to identify as malicious as they contain no malicious hyperlinks or attachments. The emails notify the recipient about an impending charge, and a phone number is provided for the user to call to avoid the charge being applied.

Downloaders, Ransomware, Among Top Healthcare Cyberattack Tactics in Q4
Health IT Security, 01/25/2023
Ransomware remained a primary healthcare cyberattack tactic in Q4 2022, BlackBerry noted in its news. Ransomware "still poses the biggest threat for the healthcare sector in particular," the report indicated. BlackBerry's Threat Research and Intelligence team leveraged data collected by its security solutions between September 1 and November 30, 2022, along with information from public and private intelligence sources. Throughout the 90-day period, researchers observed threat actors using a variety of tactics, from downloaders to ransomware, infostealers, and remote access Trojans (RATs).

VA: Contractors Have 1 Hour to Report a Security Incident
ISMG, 01/25/2023
Contractors for the Department of Veterans Affairs will have a single hour to report security and privacy incidents after their discovery under a finalized change to departmental regulations. A rule slated for publication in the Federal Register on Wednesday says the one-hour reporting requirement will apply to private sector entities handling "sensitive personal information." The department, the largest civilian government agency, defines that term broadly as including data safeguarded by HIPAA, proprietary information, or any information whose improper disclosure "could adversely affect the ability of VA to accomplish its mission." Any contractor reporting a breach under the updated VA acquisition regulations will also be subject to paying liquidated damages according to a formula the VA says "will be set forth in VA internal policy." In the event that a contractor could provide evidence of the value of actual damages, the department could be willing to accept that amount in lieu of liquidated damages.

Hacking Accounted For Nearly 80% of Healthcare Data Breaches Last Year
Health IT Security, 01/23/2023
Nearly 80% of healthcare data breaches reported to the HHS OCR in 2022 were attributed to hacking and IT incidents. Fortified Health Security noted in its "2023 Horizon Report," signifying

a 45% increase from just five years ago. Moreover, 70% of reported breaches (impacting more than 500 individuals each) affected healthcare providers, with business associates and health plans making up a much smaller portion of the total number of impacted entities. 51.4M healthcare records were breached in 2022, compared to 49.4M in 2021. As previously reported, many of the top ten largest healthcare data breaches reported to HHS in 2022 stemmed from third-party vendors, underscoring the need for better third-party risk management. Fortified Health Security suggested that these trends will continue into 2023 and beyond.

PATIENT SAFETY

The Persisting Risks Posed by Legacy Medical Devices
ISMG, 01/23/2023
Recently enacted US legislation requiring vendors to design cybersecurity into medical devices is a good first step, but healthcare delivery organizations, for many years to come, will continue to face serious risks involving older equipment still in use. The legislation, part of an omnibus funding bill signed into law by President Joe Biden in December, requires manufacturers to provide detailed assurance of device cybersecurity as part of their premarket product submissions to the FDA. Many of these older devices often lack encryption, contain hard-coded credentials, and pose other security concerns.

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Pride in Federal Service Meeting Notes

March 24, 2023
1pm EST

Registration Link: PFS Monthly Meeting
89 participants

Start time: 1:00pm ET

1. **Welcome: Robert Morris (he/him/his) and Matthew Toland (he/him/his), Co-Chairs**
    - Happy early Transgender Day of Visibility! Note: the 2023 PFS TDOV commemoration statement is copied below.

2. **Leadership Spotlight – Matt Lewis (he/him/his) lewis.james.m@dol.gov**
    - Matt Lewis, PFS Co-Chair of Community Outreach and Engagement, spoke about his roots growing up in a North Carolina Navy family. The importance of public service was ingrained in him from a young age. After realizing and accepting that he was gay, Matt met several important mentors in college but didn't start to live his life openly until his senior year of college at the University of Kentucky. Blessed to be accepted by his family and friends, Matt went on to work on several state and federal political campaigns during and after law school in Chapel Hill, NC. He then moved to Washington DC in 2005 to be closer to his sister and brother-in-law, who had just had their first child. Matt joined a law firm in DC, which afforded a good salary, but he didn't like the "cutthroat" atmosphere of private legal work or the workplace culture of the firm. After a year at the firm, Matt accepted his first federal government job with the Corporation for National and Community Service (CNCS) in the Agency's Department of Civil Rights as the Deputy Director and focused on EEO issue and processes, Civil Rights policies, and other DEIA initiatives with CNCS and the White House. He started Pride in National Service, the first LGBTQ+ ERG at CNCS and soon became involved in Fed GLOBE, the precursor to Pride in Federal Service (PFS). Matt went on to work at the US Patent and Trademark Office as an EEO Managing Attorney in the areas of EEO, Reasonable Accommodations, and Special Emphasis Programs. He later joined the EEOC and was appointed as an Administrative Law Judge where he presided over EEO Discrimination Hearings. While at the EEOC, he also participated in EEOC Pride where, among other things, he created LGBTQ+ programming for the EEOC and other Agencies. Matt next moved to the DOT Secretary's Office in 2019 where, as the Associate Director for EEO Compliance, he oversaw the EEO Investigations and EEO Compliance processes and worked in the Dept of Civil Rights developing anti-discrimination and harassment policies as well as LGBTQ+ policy and programming. While at DOT he was a member of DOT's Pride Group as well as their ERG Managerial Advisor. In 2022, Matt moved to his current position with the DOL's Secretary's Office where, as the Director of DOL's Workplace Equality Office, he advises and assists the Secretary and Deputy Secretary on all matters relating to civil rights responsibilities (DEIA, ADR, anti-harassment, etc.). Outside of his professional career, Matt volunteers on the Board of Directors for Team DC, a regional non-profit that overseas LGBTQ+ sports organizations in the DC area and plays various sports. While public service has been a cornerstone of Matt's life, he believes that we all have a unique journey that shapes who we are. "Don't let anyone tell you that your journey doesn't make a difference, because it does!"
3. **Gender Expansive and Transgender (G.E.T.) Work Group Updates – Ethan Seavey (he/him/his)**
    - This was Ethan's first PFS meeting—welcome! The purpose of the GET is to promote policy continuity among the agencies to ensure fair, equitable, and inclusive treatment and resource sharing throughout the community.
    - If you are interested in joining the group, please email GET co-leads: Ethan Seavey (he/him) ethan_seavey@fws.gov, Levi Teachey (he/him) levi_teachey@fws.gov, James Tiller (they/she)

tillerj@si.edu [currently working limited hours], Bali White (she/her) Bali.white@nih.gov! Allies are very welcome!

- The GET decentralizes our leadership structure as much as possible. This allows folks to bring their own project ideas to the table, and we let them run with them.
- Some of our current projects include:
    i. Addressing deadnaming within payroll and other official HR documents and databases
    ii. Name changes across federal agencies and in publications
    iii. Gender X marker in passports (note: we recently learned that the gender X marker may not be accepted by all countries, more will be forthcoming). International travel while on official government business involves issuance of a work passport (separate from a personal individual passport).
    iv. Supporting individuals as they transition at work (e.g., developing transition plans in collaboration with supervisors)
- Anti-trans laws and rhetoric are on the rise and are impacting our community. We are focused on fostering joy, health, and building community.
- James Tiller (they/she) tillerj@si.edu is seeking leave donations—if you are interested in donating leave, please contact James!
- DOI is hosting a summit on 3/28 in commemoration of Transgender Day of Visibility.
- FWS created some fabulous backgrounds for TDOV (see attached).

4. **Data Collection & Metrics - Christina Dragon (she/her/hers) christina.dragon@nih.gov**
    - If you haven't seen it yet, check out the Federal Evidence Agenda on LGBTQI+ Equity (link).
    - Agency SOGI data action plans due in early April. Please reach out to Christina if your agency needs more information on SOGI data or help with their SOGI data action plan.
    - PFS hosted an event on the Federal Evidence Agenda (see Training/Summit Update below).
    - An inter-agency work group is conducting research to understand more about how new state legislation might impact our willingness to disclose our identities depending on where we live. Info will be sent out in the next couple of weeks if you'd like to participate in this research.
5. **Policy – Nathan Harvey (he/him/his) nathan.harvey@usda.gov**
    - Our new subcommittees (Advocacy, Surveys, and Policy Development) are getting themselves organized, they recently held several startup meetings.
    - Advocacy Subcommittee
        i. Held initial subcommittee interest meeting in March
        ii. Looking to schedule regular standing meeting beginning toward end of April
        iii. Folks that are interested in participating please fill out this poll
    - Policy Development Subcommittee
        i. Pride in Federal Service FEHB Program Call Letter Summary
        ii. Kick-off meeting: When to meet poll will be circulated to those who expressed interest in the subcommittee, either March 24 or 25.
    - Survey Development Subcommittee
        i. Held first meeting in March to discuss our 2021 survey and lessons learned and timeline for developing this year's survey. We want our policy initiatives to be based on needs identified from our members.
        ii. Next Meeting: April 5, 2023, 12pm-1pm ET
    - Meeting minutes are attached.
6. **Communications Update – Orien Richmond (he/him/his) orien_richmond@fws.gov**
    - Current Membership – 738 email addresses!
    - Facebook Group is now live, join the community here: https://www.facebook.com/groups/2009564532512354/
    - Fill out the member survey to join the PFS email list.

7. **Outreach – Matt Lewis (he/him/his)** lewis.james.m@dol.gov
    - **DC Pride 2023.** Thanks to those who served on the DC Pride Committee last year. Saturday June 10th is the parade date; the Pride Festival is on the 11th. There is a $400 fee to enter the parade. ERGs are welcome to donate—please reach out to Matt if you can contribute.
    - **NY Pride.** The NY Pride Parade is June 26th. We are looking to help folks plan, also Atlanta Pride (Oct 14).
    - **Pride Guide.** Matt will compile federal agency Pride events happening throughout the country. Please send your events to Matt!
    - **April Happy Hour Mixer.** PFS will host a spring fling pre-Pride mixer. We want to engage everyone in the community. Late April, date TBD. Will be virtual.
    - **Night out at the Nationals.** June 6th vs Arizona Diamondbacks.
8. **Training/Summit Update – Val Johnson (she/her/hers)** valerie.r.johnson23.civ@us.navy.mil
    - We had an excellent summit on March 20th on the Federal Evidence Agenda and developing agency SOGI data action plans. We will be pushing out a recording of the presentation and the presentation slides that can be shared internally (with federal employees).
    - Thanks to everyone who has contacted me with interest in ideas for future summits. We are having a nice swing between policy and personal perspectives. The next summit will be focused on the intersection of LGBTQ+ identify and persons with disabilities in the federal workforce. Interested in the intersection of LGBTQ+ and Disabled communities in federal service as a summit session? Email me! valerie.r.johnson23.civ@us.navy.mil
9. **Bisexual Health Awareness Month – Victoria Montefusco (she/her/hers)**
    - Victoria Montefusco gave a fantastic presentation on health and the bisexual community, her slides are available here.
10. **Open Forum**
    - Question: question about travel - if people have an X marker on their passport - how do we put that in the travel system Concur? right now i think they only allow male and female. any idea if there's an update in that in the works?
    - LGBTQIA+ international travel information from the Dept of State can be found here.
    - On March 28th, FEMA will hold an event titled: Helping the LGBTQIA+ Community Before Disasters: Preparedness and Mitigation Considerations | FEMA.gov
    - Mark Hegedus, FTC, he/him: A shout out to Christina for her excellent program on SOGI data and the Federal Evidence Agenda this past Wednesday at the FTC. Thank you, Christina! I highly recommend her program if you are looking to educate your agency.
    - Denise Larison (USFWS, she/her, denise_larison@fws.gov) spoke about being a mom with a trans child and wanting to connect and create community with other parents of trans children, she will be speaking at the DOI TDOV event.
    - Briana: Some of us related to the GET working group are drafting a letter to Out & Equal requesting that they improve their accessibility practices with regard to disability access needs. If you also have had disability accommodations denied by O&E or had otherwise unpleasant experiences trying to get access needs met, please feel free to the GET leads so that when the letter is ready, we can ask for feedback from those most affected. Thank you!
    - Mahri Monson (they/them) OPM: 2022 White House TDOV Proclamation
    - Margaret Gentry: If anyone is interested in learning more history about the Lavender Scare, NARA has a good article on it: https://www.archives.gov/publications/prologue/2016/summer/lavender.html

End time: 2:01pm ET

2023 PFS TDOV Commemoration Statement

Each year on March 31, the world observes Transgender Day of Visibility (TDOV) to raise awareness about transgender people. In 2009, Rachel Crandall-Crocker, a transgender activist in Michigan, created this day to celebrate the successes of transgender, non-binary, and gender nonconforming people, highlight their contributions to society and raise awareness about the discrimination faced by this sector of the LGBTQI+ community.

Transgender Day of Visibility also recognizes the generations of struggle, activism, and courage that have brought our country closer to full equality for transgender and gender non-binary people in the United States and around the world. Their trailblazing work has given countless transgender individuals the bravery to live openly and authentically. This hard-fought progress is also shaping an increasingly accepting world in which peers at school, teammates and coaches on the playing field, colleagues at work, and allies in every corner of society are standing in support and solidarity with the transgender community.

In spite of our progress in advancing civil rights for LGBTQ+ Americans, too many transgender people — adults and youth alike — still face systemic barriers to freedom and equality. Transgender Americans of all ages face high rates of violence, harassment, and discrimination. Nearly one in three transgender Americans have experienced homelessness at some point in life. Transgender Americans continue to face discrimination in employment, housing, health care, and public accommodations. The crisis of violence against transgender women, especially transgender women of color, is a stain on our Nation's conscience.

On March 31, 2021 President Biden became the first U.S. President to issue a proclamation commemorating Transgender Day of Visibility, demonstrating the Administration's commitment to transgender, non-binary, and gender nonconforming people. Of note, the Administration seeks to make the federal government a model employer for transgender equality and visibility. To do so, federal agencies must build inclusive cultures for transgender, non-binary, and gender non-conforming employees by expanding the availability of gender-neutral facilities in buildings, ensuring transgender employees who wish to legally, medically, or socially transition

receive adequate support, advancing the use of non-binary gender markers and preferred pronouns, and increasing access to gender-affirming care and more inclusive health benefits.

Visibility sends a powerful message: **You Belong Here**! And so many transgender, non-binary, and gender nonconforming Americans are flourishing – seeing more representation on television and movie screens; enlisting to serve proudly and openly in our military; making policy at every level of government; and aiding our communities in countless other ways.

Yet, we are currently facing a growing backlash that targets the LGBTQI+ community, including, if not particularly, our transgender family members. In the first three months of 2023 alone, over 300 anti-LGBTQI+ bills have been filed so far, more than half of which specifically target transgender people.

This is why it is necessary for us to see all people through authentic, diverse, and accurate stories that reflect actual lived experiences. For those of us who do not identify as transgender, non-binary, or gender nonconforming, we must ally ourselves with our transgender family members, friends, and colleagues and hold space for them in recognition of their belonging and their many contributions. For additional information on how to be an ally, please visit the National Center for Transgender Equality's website here Additionally, The Library of Congress contains a collection of resources related to transgender and gender non-conforming research and histories for further reading.

On this Transgender Day of Visibility, Pride in Federal Service celebrates the bravery and resilience of our transgender, non-binary, and gender nonconforming members and the entire transgender community. As we celebrate this day, we are reminded that PFS values full inclusion and equality, and acknowledges the determination and courage it takes to live openly and authentically.

We remain Proudly Resilient,

Matthew Toland and Robert Morris
CO-Chairs, Pride in Federal Service

2022-2023 Pride in Federal Service Leadership Team

- Regional Chairs:
    i. Southeast - Robert Morris (he/him/his), Tennessee Valley Authority
    ii. Southwest/West - Matthew Toland (he/him/his), Housing & Urban Development
- Co-Chair, Data Collection & Metrics: Christina Dragon (she/her/hers), National Institute of Health
- Co-Chair, Policy: Nathan Harvey (he/him/his), U.S. Department of Agriculture
- Co-Chair, Community Outreach & Engagement: Matt Lewis (he/him/his), U.S. Department of Labor
- Co-Chair, Training & Summit: Valerie Johnson (she/her/hers), Department of the Navy
- Communications Director: Orien Richmond (he/him/his), U.S. Fish & Wildlife
- Advisors:
    i. Todd Denmark (he/him/his), U.S. Citizenship and Immigration Services (USCIS)
    ii. Mahri Monson, (they/them or she/her), OPM Liaison for Pride in Federal Service, OPM
    iii. Anthony Musa, (he/him/his), Past Chair Advisor, State Department
    iv. Brian S, (he/him/anything respectful), Past Data Collection & Metrics Co-Chair, Intelligence Community
    v. Maverick Hill, (he/him/his), Past Policy Co-Chair, U.S. Department of Agriculture
    vi. Mike Benardo, (he/him/his), Past Community Outreach & Engagement Co-Chair, FDIC
    vii. Thalia Lewis, (she/her/hers), Past Training & Summit Co-Chair, NOAA
    viii. Richard Hurtig, (he/him/his), Past Advisor, IRS Criminal Investigation
    ix. Meghan Walter, (she/her/hers), Past Advisor/Chair, U.S. Department of Agriculture

Pride in Federal Service FEHB Program Call Letter Summary

The Federal Employees Health Benefits Program Call Letter was released on the Office of Personnel Management's (OPM) website on March 1, 2023 and "sets forth the policy goals and initiatives for the FEHB Program for 2024." These goals and initiatives overlap with some of the same that Pride in Federal Service discussed in our recent policy recommendation document that was sent to OPM and discussed with OPM on December 5, 2022.

This summary focuses on the Call Letter sections PFS has prioritized: Section I. Fertility Benefits and Section IV. Advancing Biden-Harris Administration Priorities.

Section I. Fertility Benefits

This section is noteworthy because these are requirements for plan year 2024 and OPM rarely mandates benefits. OPM is requiring Carriers to:

1. cover artificial insemination (intrauterine insemination, intracervical insemination, and intravaginal insemination)
    a. Donor sperm **is not required** to be covered;
2. cover drugs associated with artificial insemination procedures;
3. cover IVF-related drugs for three cycles annually;
4. describe on consumer-facing materials (including FEHB Plan Brochure, carrier's website):
    a. Definition of infertility and
    b. The qualifications for infertility benefits;
5. provide medical policy easily accessible on Carrier's website.

Carriers can place utilization limits on these benefits (benefit maximums) and other cost sharing. OPM encourages but does not require additional benefits to be covered.

A **waiver to cost-neutrality is considered** by OPM to add these benefits. Cost-neutrality basically means that costs cannot increase beyond inflation across a Carrier's plans offerings for its service area. This waiver is considered for **infertility benefits only** and no other benefit described in the Call Letter.

Evaluation of Fertility Benefits

Overall, this represents major progress and will make an incredibly meaningful difference for a significant number of federal employees, including many PFS members who can avail themselves of the new coverage. The Call Letter specifically cites Mercer's 2021 Survey on

Fertility Benefits, a key resource that PFS provided to OPM, to illustrate the growth of fertility coverage among other employers. PFS considers this to be a victory from its advocacy, but has nonetheless identified some shortcomings:

1. Infertility definition. Infertility is commonly defined as the inability to achieve pregnancy after 1 year of regular, unprotected heterosexual intercourse (6 months if the woman is >35 years old). This would definitively exclude many couples in queer relationships. OPM is aware of this issue, but did not mandate a change in carriers definition. If the benefits described in Section I. Fertility Benefits are important to you, then pay *close attention* to the Carrier's infertility definitions posted on their website and, ideally, in their plan brochure. PFS will.
2. Third-party coverage. PFS is disappointed that the Call Letter did not require coverage of fertility benefits when the person receiving the fertility drugs or treatments on behalf of a covered family member(s) is not a covered individual (e.g., a covered family consisting of two cisgender men using a third-party surrogate who is not on the plan). PFS will review the upcoming Technical Guidance, and plan brochures during open season, for any additional benefits beyond those specified in the Call Letter.
3. Gestational Surrogacy. PFS is disappointed that OPM is not requiring nor specifically encouraging the coverage of gestational surrogacy expenses. PFS will continue to push for this coverage in future years.

Affinity Benefits

ART procedures are not required to be covered by OPM, but be sure to check with the plans you are considering if they cover these procedures or provide discounts. It should be available based on CPT-code (the codes the provider submits to billing and claims) – in fact, as a general rule, you should be able to request from the Carrier what CPT codes are covered for any benefit.

"OPM continues to strongly encourage FEHB Carriers to provide members with access to discounted or negotiated rates for non-covered ART procedures as previously referenced in Carrier Letter 2022-03."

Section IV. Advancing Biden-Harris Priorities

Gender-Affirming Care and Services

Nothing new is required to be covered or changes the way things are covered. It references their Carrier Letters 2021-05, 2022-03, and 2022-04. Furthermore, since cost-neutrality is not waived for this benefit, Carriers would need to show that expanding this benefit would not result in increased costs per 2019-01. To summarize those previous Carrier Letters, Carriers:

- **must** cover all services when medically necessary to all members, including those who are transgender (2021-05);[1]

[1] This was always a requirement since 2016, but this is just a clarification.

- **must** list all benefits for care, the prerequisites to be reimbursed for care, and any limitations (2021-05);
- **must** adopt an acceptable standard of care and mentions WPATH Standards of Care, Endocrine Society, and the Fenway Institute as examples (2022-03);[2]
- **must** provide Care Coordinators as an option for those diagnosed with gender dysphoria (2022-03);
- **must** use inclusive and gender-neutral language in FEHB Plan brochure and other member-facing materials including pronouns and gender identity on forms (2022-03);[3]
- **should** describe how members are directed to out-of-network providers;
- **must** cover iatrogenic infertility including for those who start or undergo medical and/or surgical gender transition (2022-03);
- **emphasized** non-discriminatory formulary design (2022-04).

Carrier Letter 2023-04 continues to emphasize the importance and now sets an "expectation that that Carriers remain current in their medical policies such that coverage decisions reflect up to date standards of care" and highlights a few items discussed in WPATH SOC-8 to "pay attention to" [footnotes contain WPATH SOC-8 examples/excerpts that OPM *might* be referring to]:

- Reduction in the number of required evaluation letters for initiation of treatment;[4]
- Medical necessity of facial gender affirming surgery;[5]
- Gender-affirming hormone therapy;[6] and
- Health care workforce cultural-awareness training.[7]

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[2] Carriers should remain current in their medical policies such that coverage decisions reflect up to date standards of care.

[3] OPM has yet to provide a template with its recommended terminology for FEHB Plan brochures.

[4] WPATH SOC-8, Statement 5.4 and 6.9. From two letters to one letter is required for gender-affirming genital reconstruction surgeries. A second can be indicated if there is a "clinical need."

[5] WPATH SOC-8, statement 2.1,

> Medically necessary gender-affirming interventions are discussed in SOC-8. These include but are not limited to hysterectomy +/- bilateral salpingo-oophorectomy; bilateral mastectomy, chest reconstruction or feminizing mammoplasty, nipple resizing or placement of breast prostheses; genital reconstruction, for example, phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty; hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process; gender-affirming facial surgery and body contouring; voice therapy and/or surgery; as well as puberty blocking medication and gender-affirming hormones; counseling or psychotherapeutic treatment as appropriate for the patient and based on a review of the patient's individual circumstances and needs.

Full, but not exhaustive, list of identified services in Appendix E.

[6] Lots of things discussed in WPATH SOC-8 (see Chapter 12) here including to not delay starting treatment for those who seek it; discussion on hormone therapy and puberty blockers for adolescents; that the hormone duration was reduced from 1 year to 6 months treatment (for adults) (5.6, 13.5, 13.6) prior to gonadectomy/ genital reconstructive surgeries unless hormone therapy is not desired or contraindicated. Remains at 1 year for adolescents (6.12g).

[7] From WPATH SOC-8, Chapter 4, "Education:"

As discussed in the footnotes, only a single letter is required for certain surgeries when it had been two evaluative letters. If surgery is on your list that involves a gonadectomy or chest surgery, then check the plan brochure or the Carrier's medical policy to ensure it has no more than 1 letter required. Again, this is not explicitly mandated by OPM, but this would reflect OPM's expectations.

Evaluation of Gender-Affirming Care and Services

PFS is disappointed that the medical policy was not explicitly stated to be reflected on their Carriers website since this is required for infertility benefits. While PFS would argue that either their medical policy for gender-affirming care needs to be linked or copied into the FEHB Plan Brochure due to the Carrier Letter 2021-05 requirement, there are numerous examples where it is clearly not sufficient. We are also disappointed that the utilization limitations (e.g., no reversals, no revisions, and once per lifetime) were not discussed in the Call Letter since these were also clarified since WPATH SOC-7 was released.[8]

We were also hopeful that there would be explicit discussion on the requirements for trans and gender expansive youth to gain access to care given the waive bills introduced and passed that block access to gender-affirming care, since it is not described in the FEHB Plan brochure, and many Carriers still specify "18 or older" in their medical policy. While some states have banned this care (or are introducing legislation to do so), OPM has federal preemption authority that FEHB Plans offered in those states must still cover this medically necessary care.[9] OPM can further discuss how families can be reimbursed for travel to another state to receive care.

Mental Health

- Mental Health: restated expectation for mental health parity laws, reimbursement rates, network adequacy, discusses new USPSTF recommendations that are required to be incorporated. Poor access to mental health providers is a concern that PFS highlighted in its policy recommendations. PFS is encouraged to see that mental health is addressed in the Call Letter, but notes that the Call Letter restates previous expectations and uses non-mandatory language.

4.1- We recommend all personnel working in governmental, nongovernmental, and private agencies receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity and respect.

4.2- We recommend all members of the health care workforce receive cultural-awareness training focused on treating transgender and gender diverse individuals with dignity during orientation and as part of annual or continuing education.

4.3- We recommend institutions involved in the training of health professionals develop competencies and learning objectives for transgender and gender diverse health within each of the competency areas for their specialty.

[8] See WPATH SOC-8 statement 5.7 for those detransitioning and WPATH's Recommended Transgender Medical Benefits dated June 6, 2018 and WPATH's **Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A** dated December 21, 2016.

[9] The law governing the FEHB Program at 5 U.S.C. §8902(m) gives FEHB contract terms preemptive authority over state laws regarding the nature or extent of coverage or benefits

What's Next?

OPM will release their Technical Guidance in a forthcoming carrier letter which will describe more in detail how to meet these requirements and what must be submitted in their proposals. This may strengthen some components or add some additional criteria for plan year 2024. Proposals are submitted to OPM around the beginning of June and negotiated between OPM's Contract Specialists in one of three Federal Employee Insurance Operations (FEIO) groups through July or August.

Additionally, OPM has in the past released separate carrier letters that have meaningful impact, sometimes in response to a ruling, legislation, or emergent industry development (e.g., 2022-17, Contraception post-overturning Roe, numerous COVID letters, and 2015-12, Covered Benefits for Gender Transition Services which coincided with the development of the Final Rule on Section 1557 published on May 18, 2016 declaring discrimination on the basis of gender identity is prohibited).

From: (b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) SUS (b)(6)

To: Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3e15a704cd4274bb9916d41a1923a9-Garcia, Art <Art.Garcia@HHS.GOV>

CC: (b) (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-(b)(6) (b)(6)

Subject: MW Region - GAC complaints

Date: 2022/11/08 10:30:50

Priority: Normal

Type: Note

Good morning,

Thanks for sending over new GAC complaints. We thought it would be a good idea to touch base on the cases, as well as your State Medicaid complaints. Below is a list of the GAC cases that we show for your Region.

I'm not sure if you want others to join the call, but it looks like the following times are available next week. Do any of these work? Thanks, (b)(6)

Wed. 11/16: 10-10:30am ET/9-9:30am CT
Fri. 11/18: 10-10:30am ET/9-9:30am CT; 11-11:30 ET/10-10:30 CT; 12-12:30pm ET/11-11:30am CT

Insurance Cases:

(b)(5)

(b)(5)

Medicaid Cases:

(b)(5)

From: Garcia, Art (HHS/OCR) <Art.Garcia@HHS.GOV>

Sent: Friday, November 4, 2022 9:37 AM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) (b)(6) (b)(6) (HHS/OCR)
(b)(6)
Cc: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) <Art.Garcia@HHS.GOV>
Subject: 05-23-503663

(b)(5)

Sender: (b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) SUS (b)(6)

Recipient: Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3e15a704cd4274bb9916d41a1923a9-Garcia, Art <Art.Garcia@HHS.GOV>; (b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91 (b)(6) (b)(6)

Sent Date: 2022/11/08 10:30:49

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FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

JOHN DOE, by his guardian and next friend, Susan Doe, on behalf of themselves and all others similarly situated, *Plaintiff-Appellant*, v. JAMI SNYDER, Director of the Arizona Health Care Cost Containment System, in her official capacity, *Defendant-Appellee*.	No. 21-15668 D.C. No. 4:20-cv-00335-SHR OPINION

Appeal from the United States District Court
for the District of Arizona
Scott H. Rash, District Judge, Presiding

Argued and Submitted November 19, 2021
Phoenix, Arizona

Filed March 10, 2022

Before: Richard R. Clifton, Consuelo M. Callahan, and Daniel A. Bress, Circuit Judges.

Opinion by Judge Callahan

SUMMARY*

Civil Rights

The panel affirmed the district court's order denying plaintiffs' motion for preliminary injunctive relief in a putative class action brought by two teenage transgender individuals alleging that a provision of Arizona law that precludes coverage for gender reassignment surgeries violates federal law and is unconstitutional.

Plaintiffs John Doe and D.H. sought a preliminary injunction compelling the Arizona Health Care Cost Containment System, Arizona's Medicaid program, to pay for their immediate male chest reconstruction surgeries and asserted that the exclusion of gender reassignment surgeries in Arizona Administrative Code R9-22-205(B)(4) constitutes sex discrimination. The district court determined that plaintiffs' request was for a mandatory injunction and denied the request based on a finding that plaintiffs had not shown that male chest reconstruction surgeries were medically necessary for them or safe and effective for correcting or ameliorating their gender dysphoria. Following the filing of the appeal, plaintiffs withdrew their motion for class certification and voluntarily dismissed plaintiff D.H. from the case and appeal.

The panel agreed with the district court that plaintiffs sought a mandatory injunction and noted that the standard for issuing a mandatory injunction is high. On this

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

preliminary record, given facts specific to remaining plaintiff Doe and the irreversible nature of the surgery, Doe had not shown that the district court's findings were illogical, implausible, or without support in inferences that could be drawn from the facts in the record. The panel noted that (1) defendants had proffered competing expert testimony challenging plaintiffs' assertion that top surgery was for them medically necessary, safe and effective; (2) Doe sought preliminary injunctive relief when he was a minor, which raised concerns as to whether he sufficiently appreciated the consequences of irreversible surgery; and (3) Doe had serious psychiatric issues distinct from, or related to, his gender dysphoria and his expert psychiatrist had not opined as to whether Doe himself was a suitable candidate for surgery and had not met or examined Doe.

Although the panel did not reach the merits of Doe's constitutional and statutory challenges, because there was ongoing litigation in the district court on Doe's claims and to ensure appropriate proceedings below, the panel noted two additional points. First, for Doe's claim under the Constitution's Equal Protection Clause, the panel noted that this court had already held in *Karnoski v. Trump*, 926 F.3d 1180 (9th Cir. 2019), that the level of scrutiny applicable to discrimination based on transgender status was "more than rational basis but less than strict scrutiny." Second, the district court's conclusion that the exclusion was not discriminatory as a threshold matter was based on an erroneous reading that *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), was limited to Title VII discrimination claims involving employment. The panel noted that Section 1557 of the Affordable Care Act provides that "an individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 . . . be excluded from participation in, be denied the benefits of, or be subjected to

discrimination under, any health program of activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). Given the similarity in language prohibiting sex discrimination in Titles VII and IX of the Education Amendment of 1972, the panel did not think *Bostock* could be limited in the manner the district court suggested.

COUNSEL

Asaf Orr (argued), Shannon Minter, and Christopher Stoll, National Center for Lesbian Rights, San Francisco, California; Brent P. Ray, King & Spalding LLP, Chicago, Illinois; Daniel C. Barr, Perkins Coie LLP, Phoenix, Arizona; Abigail K. Coursolle, National Health Law Program, Los Angeles, California; for Plaintiff-Appellant.

David T. Barton (argued) and Kathryn Hackett King, BurnsBarton PLC, Phoenix, Arizona; Logan T. Johnston, Johnston Law Offices, P.L.C., Phoenix, Arizona; for Defendant-Appellee.

Boyd Johnson, Jeannette Boot, Claire M. Guehenno, Cindy Pan and Wilmer Cutler Pickering, Hale and Dorr LLP, New York, New York, for Amici Curiae Pediatric Endocrine Society, World Professional Association for Transgender Health, and United States Professional Association for Transgender Health.

John C. Dwyer, Maureen P. Alger, Alexander J. Kasner, and Joshua S. Walden, Cooley LLP, Palo Alto, California; Peter C. Renn and Nora Huppert, Los Angeles, California; for Amici Curiae Transgender Youth Support Organizations.

Mary E. McAlister, Vernadette R. Broyles, and Joel H. Thornton, Child & Parental Rights Campaign, Inc., Johns Creek, Georgia, for Amici Curiae Keira Bell, Laura Becker, Sinead Watson, Kathy Grace Duncan, Laura Reynolds, Carol Freitas, and Detransvoices.org.

Cindy C. Albracht-Crogan, Cohen Dowd Quigley P.C., Phoenix, Arizona, for Amicus Curiae Society for Evidence Based Medicine.

Michael G. Moore, Esq., Law Office of Michael Garth Moore, Tucson, Arizona, for Amici Curiae Psychotherapeutic Experts in the Field of Treatment of Trans-Identified Children.

OPINION

CALLAHAN, Circuit Judge:

Plaintiffs John Doe and D.H, two teenage transgender individuals who were born female, filed this putative class action on behalf of themselves and others similarly situated, alleging that a provision of Arizona law that precludes coverage for gender reassignment surgeries violates federal law and is unconstitutional. They sought a preliminary injunction compelling the Arizona Health Care Cost Containment System (AHCCCS), Arizona's Medicaid program, to pay for their immediate male chest reconstruction surgeries. The district court denied their request for a mandatory preliminary injunction and Plaintiffs appealed.

Doe, the remaining Plaintiff,[1] asserts that the exclusion of gender reassignment surgeries in Arizona Administrative Code R9-22-205(B)(4) constitutes sex discrimination. In addition, Doe seeks a mandatory preliminary injunction, which may not be "granted unless extreme or very serious damage will result." *Marlyn Nutraceuticals, Inc. v. Mucos Pharma GmbH & Co.*, 571 F.3d 873, 879 (9th Cir. 2009) (quoting *Anderson v. United States*, 612 F.2d 1112, 1114 (9th Cir. 1980)) (cleaned up). We review the denial of a preliminary injunction for abuse of discretion and the district court's factual findings for clear error. *See Puente Arizona v. Arpaio*, 821 F.3d 1098, 1103 (9th Cir. 2016). "Clear error exists if the finding is 'illogical, implausible, or without support in inferences that may be drawn from the facts in the record.'" *Edmo v. Corizon, Inc.*, 935 F.3d 757, 784-85 (9th Cir. 2019) (quoting *La Quinta Worldwide LLC v. Q.R.T.M., S.A. de C.V.*, 762 F.3d 867, 879 (9th Cir. 2014)).

The district court denied the request for a mandatory preliminary injunction based on a finding that Plaintiffs had not shown that male chest reconstruction surgeries were medically necessary for them or safe and effective for correcting or ameliorating their gender dysphoria. On this preliminary record, given facts specific to Doe and the irreversible nature of the surgery, Doe has not shown that the district court's findings are "illogical, implausible, or without support in inferences that may be drawn from the facts in the record." Accordingly, we affirm the district court's denial of his request for a mandatory preliminary injunction.

[1] Following the filing of the appeal, Plaintiffs withdrew their motion for class certification and voluntarily dismissed D.H. from the case and appeal. Doe is now proceeding individually.

I

In August 2020, D.H., a seventeen-year-old transgender individual, and John Doe, a fifteen-year-old transgender individual, filed their complaint for declaratory and injunctive relief in the United States District Court for the District of Arizona. Plaintiffs were considered female at birth and have been undergoing medical treatment for gender dysphoria, including counseling and hormone therapy. They receive health coverage through the AHCCCS which covers their counseling and hormone therapy. Their health care providers recommend male chest reconstruction surgery to further alleviate their gender dysphoria. Their complaint alleged that a provision of Arizona law prohibits Medicaid coverage for "gender reassignment surgeries" (the "Challenged Exclusion"). Specifically, Arizona Administrative Code R9-22-205(B)(4) excludes the following from coverage:

> a. Infertility services, reversal of surgically induced infertility (sterilization), and *gender reassignment surgeries*;
>
> b. Pregnancy termination counseling services;
>
> c. Pregnancy terminations, unless required by state or federal law;
>
> d. Services or items furnished solely for cosmetic purposes; and
>
> e. Hysterectomies unless determined medically necessary.

(Emphasis added). Plaintiffs asserted that the Challenged Exclusion violates their civil rights under Section 1557 of the Patient Protection and Affordable Care Act (ACA), 42 U.S.C. § 18116; the Early and Periodic Screening, Diagnostic and Treatment requirements of the federal Medicaid Act, 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r); the comparability requirement of the Medicaid Act, 42 U.S.C. § 1396a(a)(10)(B); and the Equal Protection Clause of the Fourteenth Amendment to the Constitution.

Plaintiffs sought to represent a class of transgender individuals under the age of 21 who seek male chest reconstruction surgery (sometimes referred to as "top surgery"). [2] Along with their complaint, Plaintiffs filed a motion for preliminary injunction asserting that both Plaintiffs "urgently need male chest reconstruction surgery to alleviate their gender dysphoria" and that there is "broad consensus within the medical community that the surgery is a safe, effective, and medically necessary treatment for many

[2] The complaint sought the certification of the class, the appointment of Plaintiffs as representatives of the class, and the appointment of counsel for the class. It also sought preliminary and permanent injunctions on behalf of Plaintiffs, and all similarly situated individuals, and declaratory judgment that the denial of coverage for male chest reconstruction surgery violated the Medicaid Act, the ACA, and the Equal Protection Clause of the Fourteenth Amendment.

Plaintiffs defined the proposed class as "[a]ll transgender individuals under age 21 who are or will be enrolled in AHCCCS, have or will have a diagnosis of gender dysphoria, and are seeking or will seek coverage for male chest reconstruction surgery following a determination by their respective health care providers that the procedure is necessary to treat their gender dysphoria."

individuals with gender dysphoria, including adolescents."[3] The motion stated that the surgery is not cosmetic, but functional. It explained that "[a]s a result of the surgery, a transgender male's body matches the person's internal identity, thereby providing enormous psychological relief, and enables them to interact with others and to function in a male identity much more effectively and confidently." The motion further asserted that the surgery would eliminate the need for a chest binder, the extended use of which can cause difficulty breathing, exacerbate preexisting pulmonary conditions like asthma, and cause serious skin conditions.

The motion recited Plaintiffs' histories of gender dysphoria and their continued experiences of significant emotional distress and significant physical discomfort and pain. Both Plaintiffs had been taking testosterone for more than a year and had regularly worn their binders for far longer than the maximum daily time recommended by their health care providers. Both Plaintiffs also had various psychiatric issues. Doe had a referral letter for surgery from his mental health provider but was unable to schedule a surgical consult because he cannot afford the surgery and the AHCCCS will not cover it.

[3] Plaintiffs asserted that the "process of undergoing these treatments is called 'gender transition' and is guided by well-established, internationally recognized standards of care developed by the World Professional Association for Transgender Health (WPATH)." They further stated that the WPATH standards have been adopted by major professional associations of healthcare providers including the American Medical Association, American Psychological Association, the American Academy of Pediatrics, and the Endocrine Society.

II

The district court denied Plaintiffs' motion for a preliminary injunction. It noted the Ninth Circuit in *Monarch Content Management LLC v. Arizona Department of Gaming*, 971 F.3d 1021, 1027 (9th Cir. 2019), had quoted the Supreme Court's holding in *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 20 (2008), which stated that: "[a] plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." The district court determined that Plaintiffs' request was for a mandatory injunction because they sought "an injunction that not only enjoins Defendant from enforcing the law, but orders Defendant to take an affirmative action by providing coverage for a medical procedure that would be otherwise excluded, thus going well beyond the status quo." The court held that a request for a mandatory injunction was subject to heightened scrutiny and would be granted only when extreme or very serious damage would result that was not compensable in damages, and the merits of the case were not doubtful. *See Hernandez v. Sessions*, 872 F.3d 976, 999 (9th Cir. 2017); *Dahl v. HEM Pharms. Corp.*, 7 F.3d 1399, 1403 (9th Cir. 1993).

The district court first considered whether Plaintiffs had shown that top surgery was for them medically necessary, safe, and effective. Plaintiffs had submitted a number of declarations, including one from a psychiatrist who specializes in treating children and adolescents with gender dysphoria, and another from a plastic surgeon who specializes in gender reassignment surgery and would perform the surgeries for Plaintiffs. Both are members of

WPATH. According to the district court, the purpose of WPATH's "Standards of Care . . . is to assist health providers in delivering medical care to transgender people to provide them with safe and effective treatment for gender dysphoria, in order to maximize their overall health, psychological well-being and self-fulfillment." The district court noted that the psychiatrist had treated over 300 children and adolescents with gender dysphoria and considers male chest reconstruction surgery safe and effective for adolescents. The court observed that the psychiatrist opined that surgical treatment is necessary for some transgender youth, but that he had not met, examined, or consulted with Doe to determine whether surgery is medically necessary for him. The plastic surgeon had conducted virtual consultations with Plaintiffs and opined that they appear to be good candidates for male chest reconstruction surgery, that he is confident they are fully aware of the risks and benefits of the procedure, and that the surgery "is a safe, effective, and medically necessary treatment for each of them, assuming the absence of any pathology."

Defendant responded with declarations from two experts, an endocrinologist and a psychiatrist specializing in sexuality. The endocrinologist asserted that the purported "professional consensus" embodied in the WPATH's Standard of Care exists only within its confines and that there is no high-quality study showing male chest reconstruction surgery is safe, effective, or optimal for treating minors with gender dysphoria. He pointed to a 2016 decision by the Centers for Medicare & Medicaid Services that declined to issue a national coverage determination on gender reassignment surgery for Medicare beneficiaries with gender dysphoria because the clinical evidence was inconclusive for the Medicare population. The

endocrinologist opined that irreversible top surgery should not be performed on Plaintiffs because there is no way to predict whether they will outgrow their gender dysphoria and minors are "still undergoing brain development and as such they are immature with respect to intellect, emotion, judgment, and self-control."

Defendant's second expert had been an early member of WPATH but now alleged that "WPATH represents a self-selected subset of the mental health professions . . . [and] does not capture the clinical experiences of others." The psychiatrist asserted that WPATH "does not welcome skepticism, and therefore, deviates from the philosophical core of medical science." He opined that there is no reliable scientific data to support surgical intervention in adolescents with gender dysphoria, that the surgery will not eliminate the incongruence of female genitalia, and there is no reliable way to predict which patients' gender dysphoria will continue into adulthood.

Defendant also submitted a recent opinion from the United Kingdom's High Court of Justice, which reviewed a National Health Service clinic's practice of prescribing puberty-suppressing medication to individuals under age 18 with gender dysphoria. Although it heard evidence that such treatment was "required in accordance with the international frameworks of WPATH and the Endocrine Society," the United Kingdom court nonetheless concluded that treatment was "experimental or innovative in the sense that there are currently limited studies/evidence of the efficacy or long-term effects of the treatment." The district court noted that although the case did not involve surgery and was not controlling authority, it suggested that the "irreversible surgery Plaintiffs seek here is also experimental and perhaps risky." The district court determined that "Plaintiffs have

not clearly shown the surgery is medically necessary for them or that it is safe and effective for correcting or ameliorating their gender dysphoria."

The district court then turned to the controlling law. It noted that to prevail on their discrimination claim under the Equal Protection Clause and Section 1557 of the ACA, Plaintiffs had to show that (1) the AHCCCS is federally funded, (2) they were denied benefits on the basis of membership in a protected class (sex), and (3) the denial of benefits is a but-for cause of their injuries. The parties did not dispute that the AHCCCS received federal funds, but sharply disputed the other two elements.

Plaintiffs asserted that they were denied benefits and discriminated against by the AHCCCS, because they are transgender, citing *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020), and several cases from district courts in other states.

The district court did not find Plaintiffs' arguments compelling. First, it found their reliance on *Bostock* "unpersuasive" because the Supreme Court expressly limited its holding to Title VII claims involving employment and the case did not involve "a state Medicaid plan exclusion for surgical treatment for gender dysphoria in minors." The district court distinguished the cases from other district courts cited by Plaintiffs, noting that in those cases some coverages did not involve Medicaid, the plaintiffs were not minors, and the exclusions challenged were significantly different. The district court noted that in *Flack v. Wisconsin Department of Health Services*, 328 F. Supp. 3d 931 (W.D. Wis. 2018), the exclusion from Medicaid coverage included drugs and hormone therapy, whereas the Challenged Exclusion excluded only gender reassignment surgery, and did not exclude coverage for other treatments of gender

dysphoria such as hormone therapy. The district court agreed with Defendant that because the AHCCCS covers hormone treatment and mental health counseling for the treatment of gender dysphoria, Plaintiffs had failed to meet their high burden, especially because they "have not clearly shown the surgery they seek is safe and effective for treating gender dysphoria in adolescents." The district court further stated that because the AHCCCS covers certain treatments for gender dysphoria, Plaintiffs had not shown that the denial of coverage was based on sex rather than some other permissible rationale.

Finally, the district court addressed the balance of harm. Plaintiffs asserted that they would be irreparably harmed in the absence of an injunction both because such harm is presumed for violations of constitutional rights and because denying them surgery would cause them irreparable physical and emotional harm. The court noted that Defendant countered that Plaintiffs had not made the requisite showing of irreparable harm because: (1) "according to the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition ('DSM-5'), gender dysphoria does not persist into adulthood for most children and, specifically, '[i]n natal females persistence has ranged from 12% to 50%'"; (2) Plaintiffs had not demonstrated that they are capable of providing informed consent, given their significant psychological disorders that pre-date their gender dysphoria; (3) one of the Plaintiffs had "worn a binder for five years without developing any skin conditions or exacerbating his asthma, so irreparable harm is unlikely"; and (4) Doe's "long-standing and pre-existing 'chronic post-traumatic stress disorder from early life attachment trauma' . . . should be addressed before irreversible surgical procedures are employed." The district court further noted that Plaintiffs

had not provided a declaration from any medical doctor who is treating Doe.

The court found that Plaintiffs had not met their heightened burden, noting it is not clear that the injury was not capable of compensation as Plaintiffs could pay for the surgeries out-of-pocket and seek reimbursement; and that the preliminary injunctive relief sought was identical to the ultimate relief sought. The district court noted that "the relief sought would completely change, rather than preserve, the status quo." The court concluded that it would be "premature to grant such relief prior to discovery and summary judgment briefing."

In sum, the district court denied the request for a preliminary injunction finding that Plaintiffs had "not clearly shown that the surgery they seek is medically necessary for them, that it is a safe and effective treatment for gender dysphoria in adolescents, or that the Challenged Exclusion violates the Medicaid Act, Section 1557, or the Equal Protection Clause." Plaintiffs filed a timely notice of appeal. On appeal, they limit their challenge to Section 1557 and the Equal Protection Clause, and do not challenge the district court's ruling under the Medicaid Act.

III

We have jurisdiction under 28 U.S.C. § 1292(a)(1) to review the denial of a preliminary injunction, and we review such a denial for abuse of discretion. *Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1131 (9th Cir. 2011). As noted, for a preliminary injunction to issue, a plaintiff must establish a likelihood of success on the merits, irreparable harm in the absence of preliminary relief, a balance of equities in the movant's favor, and that the injunction is in the public interest. *Cal. Trucking Ass'n v. Bonta*, 996 F.3d

644, 652 (9th Cir. 2021) (citing *Winter*, 555 U.S. at 20). In addition, we have applied a "sliding scale" to this standard, allowing a stronger showing of one element to offset a weaker showing of another. *Alliance for the Wild Rockies*, 632 F.3d at 1131.

Although the district court held that Plaintiffs sought a mandatory preliminary injunction, their briefs argue that they seek "a quintessential prohibitory injunction" because they "seek to enjoin enforcement of the exclusion against them as individuals so that their coverage may be evaluated in the same way as any other request for coverage, without application of the exclusion." Doe argues that he has shown that he has been denied his right to equal protection under the law because his request has been denied solely based on the Challenged Exclusion and not on any individualized assessment.

In *Marlyn Nutraceuticals*, 571 F.3d at 879, we defined a mandatory injunction as one that goes beyond simply maintaining the status quo and orders the responsible party to take action pending the determination of the case on its merits. Here, rather than maintain the status quo pendente lite, Plaintiffs sought to compel Defendant to act prior to the entry of a final judgment. Thus, we agree with the district court that Plaintiffs sought a mandatory injunction.

The standard for issuing a mandatory preliminary injunction is high. "In general, mandatory injunctions 'are not granted unless extreme or very serious damage will result and are not issued in doubtful cases or where the injury complained of is capable of compensation in damages.'" *Id.*

(quoting *Anderson*, 612 F.2d at 1115).[4] Moreover, as the district court's evaluation of Plaintiffs' alleged harm is a factual determination, we review it for clear error, which exists "if the finding is 'illogical implausible, or without support in inferences that may be drawn from the facts in the record.'" *Edmo*, 935 F.3d at 784–85 (quoting *La Quinta Worldwide*, 762 F.3d at 879).

Here, Doe has not made a compelling showing of irreparable harm. Although his underlying claims alleged discrimination based on sex, the proffered reason for seeking preliminary injunctive relief was the alleged irreparable harm to him if his surgery was delayed. But to compel the issuance of a mandatory preliminary injunction, even where there has been a showing of likelihood of success on the underlying claim, a plaintiff need still show a likelihood of irreparable harm. *Marlyn Nutraceuticals*, 571 F.3d at 877. On appeal from the district court's finding of insufficient harm, Doe has the burden of showing that the district court's finding that there is not a likelihood of irreparable harm is illogical, implausible, or unsupported by the record. *Edmo*, 935 F.3d at 784–85.

Doe has not met his burden. First, although two experts testified that top surgery is safe and effective, even for adolescents, and has been approved by WPATH and most medical professional organizations, Defendant proffered competing expert testimony that WPATH's Standards of Care are not universally endorsed and questioning whether

[4] Based on this standard, we do not think that our "sliding scale" standard applies to this appeal. We read *Marlyn Nutraceuticals*, 571 F.3d at 879, as directing that on review of the denial of a mandatory preliminary injunction based on a factual evaluation of harm, weakness in a plaintiff's showing of harm cannot be offset by a stronger showing on the merits of the underlying legal claim.

there have been any high-quality studies showing that male chest reconstruction surgery is safe, effective, or optimal for treating gender dysphoria. For example, Defendant's expert noted that, as of 2016, the Centers for Medicare & Medicaid Services declined to issue a National Coverage Determination for gender reassignment surgery for Medicare patients with gender dysphoria "because the clinical evidence is inconclusive for the Medicare population." In its order, the district court explicitly noted that testimony in describing the evidence from Defendant's expert.

Second, when Doe sought preliminary injunctive relief, he was a minor. This gave rise to twin concerns: was his gender dysphoria permanent, and did he sufficiently appreciate the consequences of irreversible surgery? There are indications in the record and in the amici briefs filed in this appeal that some individuals who present as transgender during adolescence revert to their natal gender later on, regardless of whether they have had top surgery. Defendant argued, for instance, that gender dysphoria often resolves itself by adulthood and, specifically citing the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition, that "[i]n natal females, persistence has ranged from 12% to 50%." The district court explicitly noted that testimony as well in describing the evidence from Defendant's expert. Also, given the evidence presented that the human brain continues to mature well into a person's twenties, it was reasonable for a district court to question whether Doe appreciated the impact of irreversible surgery and to require further counseling before "authorizing" surgery.

Third, these concerns are reinforced by the apparent fact that Doe had serious psychiatric issues distinct from, or related to, his gender dysphoria. There were representations

before the district court that gender dysphoria might mask other psychiatric issues and that top surgery might not address those other issues. Relatedly, and significantly, Doe failed to provide a declaration from any psychiatrist or medical doctor who is treating him that attested to the necessity and suitability of the surgery in his particular case. And as the district court noted, Doe's expert psychiatrist had not opined as to whether Doe himself is a suitable candidate for surgery and had not met or examined Doe.

Our analysis highlights how *Edmo* is factually and procedurally distinguishable. There, the district court in a "carefully considered, 45-page opinion," supported by "detailed factual findings [that] were amply supported by its careful review of extensive evidence and testimony," determined that gender confirmation surgery was "medically necessary to treat Edmo's gender dysphoria." *Id.* at 780. Here, by contrast, the district court's 20-page order denying the motion for a preliminary injunction finds, based on a preliminary record, that "Plaintiffs have not clearly shown the surgery is medically necessary for them or that it is safe and effective for correcting or ameliorating their gender dysphoria."[5] This determination is not illogical,

[5] The cases cited by Plaintiffs from district courts in other states are similarly factually distinct. In *Flack*, both of the plaintiffs who sought injunctive relief were adults who had received treatment for gender dysphoria for a number of years. Indeed, one had already "had his uterus, fallopian tubes, ovaries and cervix removed through a hysterectomy with bilateral salpingo-oophorectomy." *Flack*, 328 F. Supp. 3d at 938; *See also Flack v. Wis. Dep't of Health Serv.*, 395 F. Supp. 3d 1001 (W.D. Wis. 2019) (granting summary judgment and enjoining the provision of Wisconsin law prescribing gender-conforming surgery and hormone therapy, but as to adults only). In *Boyden v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wis. 2018), the plaintiffs were adults and the court ruled on cross motions for summary judgment, not on a request for preliminary injunction. In *Kadel v. Folwell*, 446 F. Supp. 3d 1 (M.D.N.C. 2020), the

implausible, or unsupported by the record that was before the court at that time.

We hold only that even accepting the merits of Doe's underlying claim of discrimination, he has not shown that the district court's denial of a mandatory preliminary injunction was unreasonable or unsupported by the record.[6] Although we do not reach the merits of Doe's constitutional and statutory challenges, because there is ongoing litigation in the district court on Doe's claims and to ensure appropriate proceedings below, we note two additional points.

First, for Doe's claim under the Constitution's Equal Protection Clause, we have already held in *Karnoski v. Trump*, 926 F.3d 1180 (9th Cir. 2019), that the level of scrutiny applicable to discrimination based on transgender status is "more than rational basis but less than strict scrutiny." *Id.* at 1201. *Karnoski* considered a policy that "discriminate[d] on the basis of transgender status on its face." 926 F.3d at 1201 n.18. The district court here did not address *Karnoski* in its order denying Plaintiffs' motion for a preliminary injunction because it concluded that the exclusion was not discriminatory as a threshold matter.

Second, this conclusion was based on an erroneous reading of *Bostock*. In considering whether the Supreme

court denied the defendants' motion to dismiss and did not consider injunctive relief. In *Fletcher v. Alaska*, 443 F. Supp. 3d 1024 (D. Alaska 2020), the plaintiff was a transgender adult and the court granted summary judgment.

[6] The other criteria for injunctive relief, the balance of hardships and public interest, do not weigh strongly in favor of either party and do not raise concerns that are not addressed in our discussion above.

Court's decision in *Bostock* applied to Plaintiffs' claim under Section 1557 of the ACA, the district court found Plaintiffs' reliance on *Bostock* "unpersuasive" because, it reasoned, "[t]he Supreme Court expressly limited its holding to Title VII claims involving employers who discriminated against employees because of their gay or transgender status." A faithful application of *Bostock* causes us to conclude that the district court's understanding of *Bostock* was too narrow.

Interpreting language in Title VII that made it unlawful for an employer to take an adverse employment action or otherwise to discriminate "because of . . . sex," *Bostock* held that "it is impossible to discriminate against a person for being homosexual or transgender without discriminating against that individual based on sex." *Bostock*, 140 S. Ct. at 1741. Thus, firing a person based on his sexual orientation or transgender status is discrimination "because of sex."

Section 1557 of the ACA provides that "an individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program of activity, any part of which is receiving Federal financial assistance." 42 U.S.C. § 18116(a). Under Title IX, "[n]o person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681. We construe Title IX's protections consistently with those of Title VII. *See, e.g.*, *Emeldi v. Univ. of Or.*, 673 F.3d 1218, 1224 (9th Cir. 2012), *as amended*, 698 F.3d 715 (9th Cir. 2012) ("[T]he Supreme Court has often looked to its Title VII interpretations of discrimination in illuminating Title IX.'" (quotations omitted); *see also Franklin v.Gwinnett*

Cty. Pub. Schs., 503 U.S. 60, 75 (1992). Given the similarity in language prohibiting sex discrimination in Titles VII and IX, we do not think *Bostock* can be limited in the manner the district court suggested. *See also Bostock*, 140 S. Ct. at 1778–82 (Alito, J., dissenting) (anticipating that *Bostock* "is virtually certain to have far-reaching consequences" because "[o]ver 100 federal statutes prohibit discrimination because of sex," and listing in particular Title IX and the ACA). While the language in Title VII is "because of sex" and the language in Title IX is "on the basis of sex," *Bostock* used those phrases interchangeably throughout the decision. *See, e.g.*, *Bostock*, 140 S. Ct. at 1737–38, 1743–45, 1753.

To be sure, Defendant argues that the Challenge Exclusion does not discriminate based on sex because, in its view, Arizona only prohibits a medical procedure while allowing transgendered persons to receive other types of treatment. Doe responds that disallowing gender reassignment surgery should be treated as discriminating against transgender persons because they are the only ones seeking this surgery. The district court did not address this issue because it narrowly read *Bostock*. The district court may have opportunity to address this issue as the case proceeds.

IV

We review only the district court's denial of Doe's request for a mandatory preliminary injunction. A mandatory preliminary injunction will not issue unless extreme or very serious damage will otherwise result. *Marlyn Nutraceuticals*, 571 F.3d at 879. Here, the district court determined, based on the evidence before it, that Doe had not shown that the surgery was medically necessary and safe and effective for correcting or ameliorating his gender dysphoria. This factual determination is reviewed for clear

error, which exists "if the finding is 'illogical, implausible, or without support in inferences that may be drawn from the facts in the record.'" *Edmo*, 935 F.3d at 784–85 (quoting *La Quinta Worldwide*, 762 F.3d at 879). Because Doe has not met his burden of showing that the district court's denial of a mandatory preliminary injunction was clear error, the district court's order is **AFFIRMED**.

Each side shall bear its own costs.

United States Court of Appeals for the Ninth Circuit

Office of the Clerk
95 Seventh Street
San Francisco, CA 94103

Information Regarding Judgment and Post-Judgment Proceedings

Judgment

- This Court has filed and entered the attached judgment in your case. Fed. R. App. P. 36. Please note the filed date on the attached decision because all of the dates described below run from that date, not from the date you receive this notice.

Mandate (Fed. R. App. P. 41; 9th Cir. R. 41-1 & -2)

- The mandate will issue 7 days after the expiration of the time for filing a petition for rehearing or 7 days from the denial of a petition for rehearing, unless the Court directs otherwise. To file a motion to stay the mandate, file it electronically via the appellate ECF system or, if you are a pro se litigant or an attorney with an exemption from using appellate ECF, file one original motion on paper.

Petition for Panel Rehearing (Fed. R. App. P. 40; 9th Cir. R. 40-1)
Petition for Rehearing En Banc (Fed. R. App. P. 35; 9th Cir. R. 35-1 to -3)

(1) A. Purpose (Panel Rehearing):

- A party should seek panel rehearing only if one or more of the following grounds exist:
  - A material point of fact or law was overlooked in the decision;
  - A change in the law occurred after the case was submitted which appears to have been overlooked by the panel; or
  - An apparent conflict with another decision of the Court was not addressed in the opinion.
- Do not file a petition for panel rehearing merely to reargue the case.

B. Purpose (Rehearing En Banc)

- A party should seek en banc rehearing only if one or more of the following grounds exist:

- ► Consideration by the full Court is necessary to secure or maintain uniformity of the Court's decisions; or
- ► The proceeding involves a question of exceptional importance; or
- ► The opinion directly conflicts with an existing opinion by another court of appeals or the Supreme Court and substantially affects a rule of national application in which there is an overriding need for national uniformity.

(2) Deadlines for Filing:

- A petition for rehearing may be filed within 14 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the United States or an agency or officer thereof is a party in a civil case, the time for filing a petition for rehearing is 45 days after entry of judgment. Fed. R. App. P. 40(a)(1).
- If the mandate has issued, the petition for rehearing should be accompanied by a motion to recall the mandate.
- *See* Advisory Note to 9th Cir. R. 40-1 (petitions must be received on the due date).
- An order to publish a previously unpublished memorandum disposition extends the time to file a petition for rehearing to 14 days after the date of the order of publication or, in all civil cases in which the United States or an agency or officer thereof is a party, 45 days after the date of the order of publication. 9th Cir. R. 40-2.

(3) Statement of Counsel

- A petition should contain an introduction stating that, in counsel's judgment, one or more of the situations described in the "purpose" section above exist. The points to be raised must be stated clearly.

(4) Form & Number of Copies (9th Cir. R. 40-1; Fed. R. App. P. 32(c)(2))

- The petition shall not exceed 15 pages unless it complies with the alternative length limitations of 4,200 words or 390 lines of text.
- The petition must be accompanied by a copy of the panel's decision being challenged.
- A response, when ordered by the Court, shall comply with the same length limitations as the petition.
- If a pro se litigant elects to file a form brief pursuant to Circuit Rule 28-1, a petition for panel rehearing or for rehearing en banc need not comply with Fed. R. App. P. 32.

- The petition or response must be accompanied by a Certificate of Compliance found at Form 11, available on our website at www.ca9.uscourts.gov under *Forms*.
- You may file a petition electronically via the appellate ECF system. No paper copies are required unless the Court orders otherwise. If you are a pro se litigant or an attorney exempted from using the appellate ECF system, file one original petition on paper. No additional paper copies are required unless the Court orders otherwise.

Bill of Costs (Fed. R. App. P. 39, 9th Cir. R. 39-1)

- The Bill of Costs must be filed within 14 days after entry of judgment.
- See Form 10 for additional information, available on our website at www.ca9.uscourts.gov under *Forms*.

Attorneys Fees

- Ninth Circuit Rule 39-1 describes the content and due dates for attorneys fees applications.
- All relevant forms are available on our website at www.ca9.uscourts.gov under *Forms* or by telephoning (415) 355-7806.

Petition for a Writ of Certiorari

- Please refer to the Rules of the United States Supreme Court at www.supremecourt.gov

Counsel Listing in Published Opinions

- Please check counsel listing on the attached decision.
- If there are any errors in a published opinion, please send an email or letter **in writing within 10 days** to:
  - Thomson Reuters; 610 Opperman Drive; PO Box 64526; Eagan, MN 55123 (Attn: Maria Evangelista (maria.b.evangelista@tr.com));
  - and electronically file a copy of the letter via the appellate ECF system by using "File Correspondence to Court," or if you are an attorney exempted from using the appellate ECF system, mail the Court one copy of the letter.

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

Form 10. Bill of Costs

Instructions for this form: http://www.ca9.uscourts.gov/forms/form10instructions.pdf

9th Cir. Case Number(s)

Case Name

The Clerk is requested to award costs to *(party name(s))*:

I swear under penalty of perjury that the copies for which costs are requested were actually and necessarily produced, and that the requested costs were actually expended.

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Subject: FW: Recent comments related to coverage of gender-affirming care
Date: 2023/02/21 12:04:59
Priority: Normal
Type: Note

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
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Email: (b)(6)

From: Baker, Kellan <KBaker@whitman-walker.org>
Sent: Wednesday, February 8, 2023 4:34 PM
To: Rainer, Melanie Fontes (OS/OCR) <Melanie.Rainer@hhs.gov>; (b) (b)(6) (b)(6) (HHS/OCR)
(b)(6) (b)(6) Keene, Jamie D. EOP/WHO
(b)(6)
Subject: Recent comments related to coverage of gender-affirming care

Dear Melanie, (b)(6) Katie, and Jamie,

I hope you're well! I wanted to share the attached comments that relate to ongoing issues around coverage of gender-affirming care. I have shared these with colleagues at CMS as well but wanted to flag them for you all as well.

The comments cover the NBPP rule, particularly the proposal from CMS to create a risk adjustment HCC for gender dysphoria, and the EHB RFI. In the EHB RFI, we note that a scan we conducted earlier this year found blanket exclusions of gender-affirming care in 41 out of the 51 EHB benchmark plans. The language of these exclusions is reproduced in the comment for reference.

We look forward to working with the administration to address the pervasive problem of these exclusions, as well as to look for alternative means beyond risk adjustment to advance the accessibility and quality of coverage for transgender people.

All the best,
Kellan

Kellan E. Baker, PhD, MPH, MA
Executive Director, Whitman-Walker Institute
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Sent Date: 2023/02/21 12:05:05

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UNITED STATES OF AMERICA
BEFORE THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2024
Agency Docket No. CMS-9899-P, RIN 0938-AU97

Comments of the Federal LGBTQI Health Policy Roundtable and the LGBTQIA+ Primary Care Alliance

Pursuant to the Department's December 21, 2022, notice, 87 Fed. Reg. 244, the Federal LGBTQI Health Policy Roundtable and the LGBTQIA+ Primary Care Alliance submit these comments on the Department of Health and Human Services (hereinafter HHS or the Department) and Centers for Medicare & Medicaid Services (CMS) Notice of Benefit and Payment Parameters for 2024 under the Patient Protection and Affordable Care Act (ACA).

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Interest and Expertise of Commenters

The Federal LGBTQI Health Policy Roundtable is a coalition of community health centers and national advocacy organizations that share a focus on laws and policies that affect the health well-being of lesbian, gay, bisexual, transgender and nonbinary, queer, and intersex (LGBTQI) populations. Individually and collectively, our organizations work with agencies and offices within the Department – and with other parts of the Administration – to promote legal reforms and federal policies that advance the health and dignity of sexual and gender diverse people. Our community health center members provide primary health care, gender-affirming care, HIV specialty care, and mental health and substance use treatment services to many tens of thousands of individuals and families, many of whom identify as lesbian, gay, bisexual, transgender, queer, or nonbinary. These centers have years of experience helping patients navigate the complexities of the ACA and the health insurance marketplaces and to enroll in Qualified Health Plans (QHPs). Our membership also includes national advocacy organizations representing LGBTQI communities throughout the country.

The LGBTQIA+ Primary Care Alliance includes Federally Qualified Health Centers (FQHCs), State Primary Care Associations, community health centers, and other health care organizations and providers throughout the nation. Alliance members specialize in best practices for providing culturally responsive and compassionate health care and related services for persons identifying as lesbian, gay, bisexual, transgender and gender diverse, queer, intersex, and/or asexual or on the ace spectrum (LGBTQIA+). The Alliance members joining in these comments collectively serve several hundred thousand individuals and families every year, in the Northeast, Mid-Atlantic, Midwest, South, and West. Our members also advocate for federal, state, and local laws and public policies that advance the health and well-being of sexual and gender diverse people, with particular emphasis on persons of color, immigrants, people with disabilities and chronic illnesses, low-income individuals and families, transgender and gender diverse persons, sex workers, drug users, and other particularly marginalized communities.

Comments

Payment HCC for Gender Dysphoria

We appreciate the opportunity to respond to the request for information on a possible payment Hierarchical Condition Category (HCC) for gender dysphoria. Gender dysphoria is a recognized medical condition that can seriously affect the health and well-being of transgender people. While we share the goal of ensuring that people with gender dysphoria can access coverage for the medically necessary health care services they need which are robustly supported by the scientific literature and more than five decades of medical practice—we do not believe that an HCC for gender dysphoria is likely to serve that goal under current circumstances in the U.S. health care system. We are also concerned that risk adjustment for gender dysphoria may inappropriately reinforce the perception that transgender identity should inherently be pathologized as a medical

condition, rather than as a natural variation in human identity and experience. We therefore do not support further consideration of such an HCC at this time.

In considering the appropriateness of risk adjustment for gender dysphoria, we referred to the ten principles outlined by CMS in the 2014 Notice of Benefit and Payment Parameters Rule. Below we discuss each of the principles that led us to determine that an HCC for gender dysphoria is not warranted at this time.

Principle 1—Diagnostic categories should be clinically meaningful. Gender dysphoria is recognized as a serious medical condition in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) and the International Classification of Diseases (ICD), as well as by every major U.S. medical professional association. The primary means of coding for gender dysphoria in the U.S. is a series of mental health condition codes (F64.x) in the 10th edition of the ICD (ICD-10). A history of discriminatory insurance exclusions for the treatment of gender dysphoria, however, has long discouraged U.S. clinicians from using these codes, and some clinicians have resorted to using non-specific codes such as E34.9 (endocrine disorder, unspecified) to capture a need for gender-affirming care without flagging the patient as transgender. While there are indications that the F64.x series codes are being used more often as blanket exclusions of coverage for gender-affirming care receded over the past decade, the current political landscape in the U.S. is increasingly hostile to transgender people and their health care needs. As such, it is impossible to determine whether coding practices will reliably move in the direction of more consistent and accurate coding for gender dysphoria, or whether these codes will once again be avoided by many clinicians and patients potentially in differential patterns based on state laws for fear of triggering a transgender-specific coverage exclusion or disclosing a patient's transgender identity to state authorities.

Further, in the continuing absence of patient self-reported data on transgender status in most U.S. health care organizations, some clinicians append codes for gender dysphoria to claims for encounters where care is provided to a transgender person for purposes other than gender affirmation. The misapplication of these codes merely to identify a transgender person rather than to indicate the provision of a service to treat gender dysphoria dilutes the clinical relevance of these codes for risk adjustment purposes.

Finally, the existing codes do not differentiate among appropriate treatment courses for gender dysphoria or incongruence and thus do not specify uniform clinical trajectories that would justify risk adjustment. The expert *Standards of Care for the Health of Transgender and Gender Diverse People* (Version 8, 2022)[1] emphasizes that the course of care for gender dysphoria is highly individualized and that determinations of medical necessity should be made by providers in close consultation with individual patients: while some people with gender dysphoria may need mental

[1] World Professional Association for Transgender Health. (2022). Standards of Care for the Health of Transgender and Gender Diverse People (8th Version). 23 Int'l J. Trans. Health Supp. 1. https://doi.org/10.1080/26895269.2022.2100644

counseling, hormone therapy, and surgeries, others may need only some or none of these services. The course of care for gender dysphoria is also very different not only between individuals but by age: for pre-pubescent children, the only medical intervention that may be indicated is mental health counseling to assist the child and their family in exploring the child's gender through non-medical interventions such as social support. For adolescents, gender affirmation may include mental health support as well as puberty delay medications and eventually exogenous hormone therapy; surgeries are generally not indicated for adolescents and are only performed very rarely and in the presence of severe and debilitating gender dysphoria that is not alleviated by other care alone. For adults, the course of gender-affirming care may include a combination of mental health support, hormone therapy, and surgeries.

In the F64.x code series in the ICD-10, however, while support for children with gender dysphoria is captured in the code F64.2 (gender identity disorder of childhood), care for adolescents versus adults and between patients with differing degrees of clinical severity is not differentiated by the F64.0 (transsexualism), F64.8 (other gender identity disorder), and F64.9 (gender identity disorder, unspecified) codes. The ICD-11 code series maintains this approach with the codes HA60 (gender incongruence of adolescence or adulthood), HA61 (gender incongruence of childhood), and HA6Z (gender incongruence, unspecified). Moreover, the ICD-10 codes currently in use in the U.S. to describe the presence of gender dysphoria or a need for gender-affirming care also include the highly non-specific codes Z87.890 (personal history of sex reassignment) and F64.1 (dual-role transvestism).

For these reasons, we do not believe that coding for gender dysphoria/incongruence as reflected by the DSM-5, ICD-10, or ICD-11 frameworks currently captures discrete clinical trajectories to a degree sufficient to justify risk adjustment under this principle.

Principle 2—Diagnostic categories should predict medical expenditures. Putative claims of higher health care costs are routinely used against transgender people to argue that coverage for gender dysphoria is a burden on the health care system and should be restricted or eliminated. The available evidence shows, however, that removing exclusions of coverage for gender dysphoria from insurance plans is cost-neutral or extremely low-cost. The City and County of San Francisco initially raised premiums when they became the first major U.S. employers to remove blanket exclusions for gender-affirming care in 2001. But after five years, "beneficial cost data led Kaiser and Blue Shield to no longer separately rate and price the transgender benefit—in other words, to treat the benefit the same as other medical procedures such as gallbladder removal or heart surgery."[2] A 2013 survey of employers providing coverage for gender-affirming care to their employees found that two-thirds of the employers that provided information on the actual costs of utilization of gender dysphoria treatments reported zero costs, and those employers who reported

[2] City and County of San Francisco Human Rights Commission, *San Francisco City and County Transgender Health Benefit*
(Aug. 7, 2007), https://transhealthproject.org/documents/19/SF_transgender_health_benefit.pdf

some costs said that the costs were very low or minimal.[3] An analysis of gender-affirming care uptake by transgender people over 6.5 years in one California health plan found a utilization rate of 0.062 per 1,000 covered persons.[4] Estimates from other states show equally low utilization and related low costs, with North Carolina estimating costs at 0.011% to 0.027% of premiums;[5] Alaska, 0.03% to 0.05%;[6] and Wisconsin, "immaterial at 0.1% to 0.2% of the total cost."[7] Cost estimates under Wisconsin Medicaid were "actuarially immaterial, as they are equal to approximately 0.008% to 0.03%"[8] of Wisconsin's share of its Medicaid budget. Similarly, an analysis in the military context concluded that the financial cost of covering gender-affirming care was "too low to matter"[9] or, as military leadership noted, "'budget dust,' hardly even a rounding error."[10] This is because only a small percentage of the U.S. population is transgender, and, as noted above, not all transgender people need or use a full scope of services related to the treatment of gender dysphoria.

While we support continuing research to better understand patterns of utilization and expenditures in relation to gender dysphoria, we note that efforts to conduct this research can be susceptible to inherent bias that stems from the fact that, in the absence of self-reported demographic data on transgender status that can be linked to claims data, transgender people can only be identified through encounters with the health care system that result in the generation of claims and related costs. As such, claims data analyses may paint a distorted picture in which transgender people appear to use more health care services and incur higher costs in comparison to people who may have very low or zero utilization and who are presumed to be cisgender due to the absence of codes for gender dysphoria. Any future analyses assessing possible relationships between gender dysphoria and health care costs should rely on self-reported data on transgender status so that transgender and cisgender enrollees can be fairly compared, and they should use long time horizons and incorporate potential cost-savings in long-term mental health and surgical needs that may be realized by timely treatments such as puberty delay medications in adolescence.

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[3] Herman JL, The Williams Institute, *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings From a Survey of Employers* (Sept. 2013), https://escholarship.org/content/qt5z38157s/qt5z38157s.pdf?t=n2ff2l.

[4] State of California Department of Insurance, *Economic Impact Assessment: Gender Nondiscrimination in Health Insurance*, Reg. File No. REG-2011-00023 (Apr. 13, 2012), at 5, http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf

[5] Segal Consulting memorandum to Mona Moon, Executive Administrator of the North Carolina State Health Plan, re: Transgender Cost Estimate, Nov. 29, 2016, https://files.nc.gov/ncshp/documents/board-of-trustees/3aii-3-The-Segal-Company-Transgender-Cost-Estimate-Memorandum.pdf

[6] Plaintiffs' Motion for Partial Summary Judgment, *Fletcher v. Alaska*, No. 1:18-cv-00007-HRH (D. Alaska July 1, 2019), https://www.lambdalegal.org/sites/default/files/legal-docs/downloads/fletcher_ak_20190701_plaintiffs-motion-for-partial-summary-judgment.pdf

[7] *Boyden v. Conlin*, 341 F. Supp. 3d 979, 1000 (W.D. Wis. 2018).

[8] *Flack v. Wis. Dept of Health Servs.*, 395 F. Supp. 3d 1001, 1008 (W.D. Wis. 2019).

[9] Belkin A. Caring for our transgender troops – The negligible cost of transition-related care, 2015 *New Eng J Med* 373:1089-1092, at 1092, https://www.nejm.org/doi/full/10.1056/NEJMp1509230.

[10] Declaration of Raymond Edwin Mabus, Jr., Former U.S. Secretary of the Navy, in Support of Plaintiff's Motion for Preliminary Injunction, *Doe v. Trump*, No. 17-cv-1597-CKK (D.D.C.) filed Aug. 31, 2017, at 41), available at http://files.eqcf.org/wp-content/uploads/2017/09/13-Ps-App-PI.pdf

Principle 3 Diagnostic categories that will affect payments should have adequate sample sizes to permit accurate and stable estimates of expenditures. Transgender people are estimated to make up less than 1% of the U.S. population.[11] In claims data analyses, the prevalence of people presumed to be transgender based on the presence of codes for gender dysphoria is typically a tiny fraction of a percent.[12] When these already small cohorts are broken down by age to more accurately reflect potential differences in expenditures, the sample sizes for predicting costs become even smaller. Widespread and consistent collection of demographic data on transgender status, as recommended by a 2022 report from the National Academies of Sciences, Engineering, and Medicine,[13] and linkages of these data with information on health care utilization and expenditures are needed to even begin to build sample sizes that would be sufficient to satisfy this principle.

Principle 10—Discretionary diagnostic categories should be excluded from payment models. As discussed in relation to Principle 1, a great deal of variation currently exists in the degree to which clinicians are aware of the appropriate application of codes for gender dysphoria treatment. Moreover, given elements of the current U.S. political environment that increasingly threaten the safety of transgender people and the providers who care for them, coding practices are unlikely to soon stabilize across age groups, states, and insurance programs. Until transgender people are afforded sufficient protection from discrimination in health coverage and care—and until their health care needs are correctly viewed as legitimate and justified on the basis of the scientific literature that has established the medical necessity of this care—gender dysphoria codes will continue to be treated by providers and patients alike as not only discretionary but potentially dangerous.

Finally, we note that there is no inherent relationship between gender dysphoria/incongruence and any other diagnoses, which the ICD-11 further emphasized by moving gender incongruence from the mental and behavioral health chapter to a separate chapter on "conditions related to sexual health," where the only other entries are sexual dysfunctions and sexual pain disorders. Given the lack of a meaningful clinical relationship between gender dysphoria/incongruence and other conditions in the ICD-10 and ICD-11, these codes should not be combined with other diagnoses to form a broader HCC that is inclusive of gender dysphoria.

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[11] Herman JL, Flores AR, O'Neill KK. (2022). How Many Adults and Youth Identify as Transgender in the United States. Los Angeles: The Williams Institute. https://williamsinstitute.law.ucla.edu/publications/trans-adults-united-states/

[12] See, e.g., Jasuja GK, de Groot A, Quinn EK, et al. Beyond Gender Identity Disorder Diagnoses Codes: An Examination of Additional Methods to Identify Transgender Individuals in Administrative Databases. Med Care 2020;58(10):903–11.

[13] National Academies of Sciences, Engineering, and Medicine. (2022). Measuring Sex, Gender Identity, and Sexual Orientation. Washington, DC: National Academies Press. https://nap.nationalacademies.org/catalog/26424/measuring-sex-gender-identity-and-sexual-orientation

In sum, as long as transgender people continue to be the targets of state-sanctioned mistreatment and exclusion in health coverage and care, the primary means of ensuring access to gender-affirming care must be robust nondiscrimination protections that apply and are enforced nationwide. A strong bulwark of laws and policies protecting transgender people from discrimination in health care and coverage, as well as clear indications that regulators and carriers in states across the country understand and respect the medical necessity of gender-affirming care, are necessary prerequisites for any further consideration of an HCC for gender dysphoria.

Repeal of Prohibitions on Door-to-Door and Other Direct Contacts

We support lifting the prohibition of door-to-door canvassing by Navigators and Assisters. Whitman-Walker Health, (WWH), an LGBTQ+ serving FQHC in the Washington, DC area, has offered navigation services since before the ACA was implemented. We highlight their services as one of the nation's longest-running navigation providers.

We agree that door to door canvassing should include non-navigator assistance personnel sending highly trained Assisters/Navigators door to door is not an efficient use of resources but using non-Navigator support personnel help achieve community outreach and education goals and facilitates effective connections to Navigators via "warm hand offs" from educators to Assisters/Navigators. In recognition of their expanded role in assisting patients and clients in accessing social and health care services, these comments also call Navigators and Assisters, "Patient Benefit Insurance Navigators" (PBINs),

We support the view that repealing restrictions on an Exchange's ability to allow Navigators, non-Navigator assistance personnel, and certified application counselors to offer application or enrollment assistance by going door-to-door or through other unsolicited means of direct contact is a positive step that would enable Assisters to reach a broader consumer base in a timely manner—helping to reduce uninsured rates and health disparities by removing underlying barriers to accessing health coverage.

As part of an integrated service model, the PBIN team serves an important role to help ensure access to care by removing or addressing barriers to care from insurance or lack of insurance issues or cost of care issues. Specifically at WWH, the PBIN team helps WWH patients and DC area residents with health insurance eligibility, enrollment, and literacy, connecting people to Medicaid, Medicare, and Qualified Health Plans on the exchange, subsidies, and other insurance options for which they may be eligible. The PBIN team serve as certified DC Health Link Assisters, providing critical consumer outreach and enrollment assistance to uninsured and under-insured DC residents. Given WWH's patient population and geographic location, the PBIN team also counsels clients from Maryland and Virginia and receives calls from other areas for assistance and advice. The PBIN team works across three sites and manages an Insurance Helpline (where callers get immediately connected to a navigator for assistance). These avenues ensure that the navigators connect promptly and efficiently so that they can screen all patients and area consumers for eligible

insurance coverage, assist them in applying for benefits as applicable, and handle and resolve any eligibility or coverage issues.

Evidence shows that millions of people find the process of applying for and using health insurance overwhelming. Many lack basic health insurance literacy. Navigators can help demystify the complexity of applying for and using health insurance. They can also help reduce health disparities by improving health literacy in rural and underserved communities, including Black, Indigenous, and other communities of color. Questions and problems accessing care are not limited to the eligibility and enrollment issues. And with many people seeking assistance qualifying for Medicaid or subsidies, issues are not limited to open enrollment periods.

WWH's insurance navigation services are year-round services by trained experts who can help consumers break down barriers and promote access and health insurance literacy. Given this, it is vital that funding and the scope of services of Navigators include eligibility and enrollment, counseling and all the post-enrollment and access activities highlighted. We support expanded funding for Navigator services and ask that HHS intentionally recognizes that PBINs are trained experts on complex systems and supporting the professional development of expert navigators through year-long employment improves efficiency and supports innovation. Additionally, professional navigation should be available year-round to support continuous enrollment, special enrollment periods (SEP), and the full life cycle of consumers years as qualifying events occur. Funding only for open enrollment often results in temporary, seasonal jobs. Temporary employment misses the life cycle of qualifying events and fails to take advantage of the expanded access to SEPs proposed within the notice.

The Biden Administration has been supportive of market reforms that facilitate patient access to health insurance marketplaces, but navigator services are still not emphasized in a way that reflects their essential importance to consumer access. PBINs are service delivery and workforce specialists who unlock access to much needed health care services. As described briefly above, they operate year-round on the front-line of our operations, conducting more than just eligibility and enrollment screenings. PBINs also screen clients and patients for other needs, including health-harming legal issues that affect social determinants of health, like housing, employment, and education, and health related social needs like food security, transportation, and income. Given our focus on the LGBTQ community, PBINs also screen for alignment with name and gender marker on identity documents to ensure being asked for your insurance card and identification at a health visit isn't creating a barrier for people.

Expert navigators are trained to screen for social determinants of health and legal issues in the natural course of conversation when enrolling patients and clients, and to identify upstream issues to improve health. WWH navigation services are available in Spanish, English, and Amharic and are an essential part of a culturally competent practice. Screening for these additional barriers is organic, as the PBINs have much of this information from their screening for health insurance options - income, family size, immigration status, name, gender marker, employment status,

housing status. By using that information to identify potential other needs, the PBINs serve as a "upstream screener" and connector to other services like legal services who can assist to break down other systemic barriers critical to increased patient engagement, empowerment of consumers, and improving overall health care delivery. Conducting insurance navigation helps build health insurance literacy for our diverse patient population, helps give providers more care options when patients are insured, and helps our health center have stronger financial stability and long-term sustainability.

It is our experience that no matter someone's education, age, or computer literacy, people need navigation services. Despite the reforms that we have seen increasing enrollment periods, expanding tax credits for enrollees, protections from renewals and terminations of Medicaid during the COVID-19 public health emergency (PHE), and expansions of insurance coverage, consumer needs for Navigation services remain high and we are as busy as ever helping people navigate the very complicated health care system.

We support the proposal that changes rules to allow sharing information with Navigators of consumers who have been determined ineligible for Medicaid. The NPRM makes clear that consumers may only be approached when ineligible for Medicaid. Unfortunately, this regulation misses the opportunity to leverage PBIN expertise to support re-enrollment. Navigators need to be able to talk eligibility across options and engage by helping consumers to recertify Medicaid or discuss life events – new job/higher income, family size shift, etc – that may change eligibility. Sharing of information should be seen as part of supporting a "no wrong door" policy and a coordinated, robust screening process.

We support the change to allow Assisters and Navigators to offer application assistance door-to-door and through other unsolicited means at this stage of the implementation of the ACA. We agree that now that the Exchanges and their Assister programs have been in operation for almost 10 years, Assisters have more name recognition and consumer trust within the communities the Assisters serve. Accordingly, HHS believes that its previous concerns related to consumers' privacy and security interests and consumers not knowing what to expect when interacting with Assisters have been sufficiently mitigated with the measures HHS has enacted such that a blanket prohibition on unsolicited direct contact of consumers by Assisters for application or enrollment assistance is no longer necessary.

Regarding Providing Correct Information to the FFEs (§ 155.220(j))

We support a statutory requirement to

> "...explicitly require agents, brokers, or web-brokers assisting consumers with completing eligibility applications through the FFEs and SBE–FPs to confirm with those consumers the accuracy of the information entered on their applications prior to application submission or document the consumer has reviewed and confirmed the information to be accurate."

This regulation reasonably incentivizes the agent to take due care when engaging with clients and establishes a duty to confirm the information with the consumer. The rule seems likely to improve the accuracy of the information received in applications by establishing a second level of review and is constructed to support consumer-driven and informed consent of consumers as well.

The requirements on the documentation of consent seem carefully calibrated to balance the need for ease of understanding, storage of the information, and creating incentives for agents and brokers to explore and innovate new best practices for their business and the consumers they serve. The minimum standard of keeping records for 10 years helps establish consumer expectations and uniformity across brokers and agents.

Regarding Documenting Receipt of Consumer Consent (§ 155.220(j))

We are concerned about the security of consumer consent records and want to ensure strong data security and data hygiene standards are applied to any potentially sensitive information, including private health data. For example, is the consumer consent documentation kept, but not the underlying consumer application data? What happens to the consent confirmation? Is it encrypted, or otherwise kept physically and digitally secure? How long do brokers retain consumer application data? Under what conditions is this data kept? Large troves of consumer data retained by agencies and brokers represent a substantial risk to consumer privacy, which can be minimized by leveraging emergent best and promising practices on data retention and storage.

Regarding Failure to File and Reconcile Process (§ 155.305(f))

We agree that the costs of the current policy that ends a consumer's coverage are outweighed by the benefits of encouraging robust enrollment and participation in insurance programs. The proposed rule to not terminate because someone failed to file taxes for two years is an excellent addition. As noted, the IRS records may be inaccurate, and it is important that consumers not be improperly removed from a plan due to error on the part of the government.

Additionally, this change supports consumers who may not properly understand the consequences of failing to file, due perhaps historical expectations that lack of income negates the necessity to file taxes. In our practice, many consumers do not fully understand – even with coaching – the relationship between taxes and health insurance. The connection in many minds is non-obvious, complicated, and questionable. Finally, many people file late, some files years late after realizing they need to. This new language is a good relaxation of the original requirement to enhance consumer protections in support of continuity of coverage, and reduce the resources allocated to needless appeals. The proposed rule extending the grace periods instituted during the COVID-19 PHE will give consumers ample time to adjust to new requirements while Navigators and Assisters implement HHS's new flexibilities to engage in consumer education and the new requirements

that support accurate reporting of consumer data, ensuring the efficient administration of HHS resources.

Rather than provide an extra year of flexibility, we suggest that it may further support HHS's objectives to remove the penalty entirely. This would ensure that eligible consumers retain coverage under all circumstances. HHS should consider the impact of eliminating the penalty on the market and if HHS has a less restrictive means of administering the filing requirement. For example, consumers found to be ineligible for APTC could be charged premiums retroactively.

Regarding Income Inconsistencies (§§ 155.315 and 155.320)

We support the proposed regulation allowing self-attestation of projected income and family size in the absence of data from the IRS or when such data from the IRS fails to reflect a change of circumstance that is relevant to a consumer's eligibility for insurance affordability programs. Self-attestation and alternative documentation procedures support, to the greatest extent practicable, the inclusion of potentially eligible consumers in the insurance programs. This is an excellent use of Department resources as a high value is placed on consumer participation in insurance plans and incentivizes the IRS to provide timely information to the Exchange. The added flexibility supports an approach that meets consumers needs and balances the Department's interest in the judicious use of federal funds.

We support the range of additional flexibilities, especially the mandatory extension for consumers to provide documentation supporting their eligibility for advanced premium tax credits (APTCs) and cost sharing reductions (CSRs). Many patients who benefit most from these programs are working in households with multiple sources of income woven together to support a family. These beneficiaries are well-poised to benefit from these changes, and potentially deeply harmed when incorrectly removed from coverage. The additional flexibilities support consumers with the needed time to understand the requested information and gather it from across their household.

Annual Eligibility Redetermination (§ 155.335)

We support the proposed rule directing re-enrollment into lower or same cost, high generosity plans. This proposal is well calibrated to protect consumers who are most likely to need additional support and could benefit from the updated guided auto enrollment rules. As HHS notes, the proposed change will have a protective effect on consumers, likely lowering out of pocket costs while directing consumers to high-value products on the exchanges when they do not actively re-enroll themselves.

Special Enrollment Periods (§ 155.420)

We support the proposed change to requirements to allow a household to enter a special enrollment period based on a single member of that household having a qualifying event. This change supports

inclusion of households with different family structures and access to affordable insurance options for more consumers, especially those who move from Medicaid plans to marketplace plans. This will be particularly important for consumers facing the end of Medicaid enrollment flexibilities upon the expiration of the COVID-19 PHE, which is expected starting April 1, 2023. The proposed change more accurately reflects the lived experiences of consumers, in which often the changed circumstances of a single person within a household are part of a larger ecosystem of resources, income, and insurance products. For example, a qualifying event, like a birth, marriage, or job loss, may require a household to make changes to make certain other changes, and this expansion of SEP supports the lived experiences of many families.

Plan Display Error Special Enrollment Periods (§ 155.420(d))

We support the proposed changes to ensure that errors in Marketplace plan displays do not adversely affect consumers. We believe this change encourages the efficient operations of Marketplaces and the Exchanges while reducing the burden on consumers to prove an error occurred.

Prohibition of Mid-Plan Coverage Termination for Dependent Children Aging Out

We support the proposed prohibition on terminating coverage mid-year for dependent beneficiaries of plans who age out. This proposed change supports the industry standard of enrolling in health plans during the open enrollment periods at the end of each calendar year and creates stability for parents and families during transitions.

We see the coverage gap scenarios that HHS highlights in their NPRM. During the COVID-19 PHE-related SEP, Washington, DC's Marketplace exchange allowed consumers to essentially choose the effective date – not mid-month but retroactive, current, or prospective enrollment. Recognizing that mid-month enrollment is logistically difficult for insurers, an approach that allows for flexibility as to the effective date to meet the needs of consumers is balanced with the need for insurers to efficiently administer their plans.

Limitations on the Number of Non-Standardized Plans

We support the proposed rule to limit the number of non-standardized plans as reasonably designed to produce efficient health exchanges that are understandable and navigable by consumers. This proposed regulation may have a beneficial effect of reducing incentives for insurers to drive consumers from high value products through confusing marketing techniques. Combined with marketplace requirements based on meaningful differences, the proposed change reduces incentives to market a plethora of relatively cheap plans and supports innovation by insurers.

Network Adequacy (§ 156.230) and Essential Community Providers (§ 156.235)

We support the proposed changes to network adequacy and Essential Community Provider (ECP) standards. ECP requirements are a key feature of HHS regulations that ensure vulnerable communities, including low-income communities, LGBTQIA+ people, and communities of color are able to access health care services that are affordable and culturally and linguistically appropriate. Many LGBTQ+ serving health care centers are ECPs, and we support robust requirements that specialized ECPs with specific expertise be included in network adequacy requirements, including the proposed rule to create new standalone classes for ECPs for Substance Use Disorder (SUD) Treatment and Mental Health Facilities. We note that for patient access purposes, it is important that Mental Health Facilities and SUD Treatment centers used to satisfy the proposed requirements include facilities that are secular in nature, as many LGBTQIA+ people and racial and ethnic minority patients report discomfort with religiously affiliated programs.

We support the proposed changes to expand QHP requirements for contracting with Family Planning and FQHC ECPs to a 35% threshold. This ensures that network adequacy requirements result in meaningful coverage for underserved populations.

In the experience of WWH in Washington DC, low-income clients from Virginia and Maryland with exchange plans may find that WWH is excluded from their network because the plan issuer identifies the in-state ECPs, but not those in DC. HHS can provide clarification that a plan's service area and geographic distribution requirements include nearby metropolitan areas. Additionally, we propose a clarification that the threshold requirements do not prohibit adding to the plan's network, just removing providers from a plan's network.

In response to questions about ensuring network adequacy of certified QHPs, we recommend that HHS look to the requirements for Essential Health Benefits (EHBs) sold on state exchanges. The 10 categories of EHBs provide consumers with confidence to understand the quality of the insurance plans they are purchasing and provide market stability for insurers. Consumers would also benefit from plans having up-to-date information on available providers on insurers online network platforms. It may be helpful for consumers to understand whether an ECP is included or covered if the meaningful differences between network robustness is indicated by metal level.

Pricing Adjustment for the Hepatitis C Drugs

The Department's proposed rule to continue a market pricing adjustment specific to Hepatitis C drugs in models for the 2024 benefit year seems reasonably well calibrated to reduce the incentives that issuers will create discriminatory plans to drive away people living with or at risk for Hepatitis C. Virus (HCV). HCV cure therapies represent a breakthrough in HCV treatments as the NPRM notes, the costs are changing rapidly among drug products. A pricing adjustment for HCV drugs encourages formularies with sufficient access to all effective treatments for patients that need them.

Conclusion

The LGBTQI Health Policy Roundtable and the LGBTQIA+ Primary Care Alliance are pleased to participate in this important discussion. We would be happy to provide additional information or to assist CMS or the Department in any other way. For more information regarding any portion of these comments, please contact Benjamin Brooks, Associate Director of Policy and Education at Whitman-Walker Institute via bbrooks@whitman-walker.org.

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January 31, 2023

Ms. Chiquita Brooks-LaSure
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Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
PO Box 8010
Baltimore, MD 21244-1850

RE: Request for Information on the Essential Health Benefits (87 Fed. Reg. 74097, Dec. 2, 2022)

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to comment on the implementation of the Essential Health Benefits (EHB) provision of the Affordable Care Act (ACA). We believe that strong oversight by the Centers for Medicare & Medicaid Services (CMS) of the EHB standard is a critical component of ensuring that insurance coverage is adequate, comprehensive, and meaningful for consumers seeking health care and services. Upon careful consideration of this request for information, we continue to affirm our support of the EHB standard, and we respectfully request that CMS take steps to strengthen its enforcement of the EHB requirement and to help establish greater consistency in appropriate coverage of essential services in plans subject to this requirement. In particular, we note that the vast majority of state EHB benchmark plans across the country (41 out of 51 plans) continue to use discriminatory and outdated blanket exclusions of gender-affirming care. We urge you to take immediate action to ensure that all plans subject to the EHB requirement follow well-established standards of science and medical practice by removing these exclusions.

Whitman-Walker is a community health system that includes Whitman-Walker Health, a Federally Qualified Health Center with 50 years of experience serving the greater Washington, D.C. metropolitan area. Whitman-Walker Health has special expertise in LGBTQ care and HIV prevention and treatment, and our Legal Services Department, the nation's oldest medical–legal partnership, is a national leader in HIV law; gender identity and sexual orientation law; medical privacy law; and Medicaid, Medicare, and other public benefits health law. Our Public Benefits and Insurance Navigation Team, under the direction of senior Legal Services managers, served more than 2,000 clients over the last year in new cases related to insurance concerns.

Whitman-Walker Institute combines clinical and public health research, public policy advocacy, and professional and community education, with the goal of expanding the body of knowledge and science needed to advance health and well-being for our patients and communities. The Whitman-Walker Institute is home to the Out2Enroll initiative, a public–private partnership founded in 2013 to assist the U.S. Department of Health and Human Services (HHS) in connecting low- and middle-income LGBTQ people with quality, affordable insurance coverage through the Health Insurance Marketplaces. Out2Enroll has participated in enrollment activities, including advertising and community outreach, assister training, and Navigator program grant review, in every open enrollment period. Since 2017, we have also conducted annual research assessing the prevalence of transgender-specific exclusions in plans sold through HealthCare.gov. We are therefore particularly concerned with ensuring that all consumers, including

transgender consumers, can access coverage for medically necessary care through EHB-based plans and that they have the information they need to make informed plan choices.

Benefit Descriptions in EHB-Benchmark Plan Documents

CMS requests comment on whether states are generally effective enforcers of the EHB requirement and whether states may require additional guidance to ensure plans are correctly interpreting the scope of EHB benchmark plan coverage. In our experience working with consumers across the D.C. area, we see many instances of current and prospective enrollees being confused by what their EHB-based plan options cover, and we believe that the current approach of allowing states to simply rely on existing plan documents for describing the scope of coverage under EHB-compliant plans is inadequate. To assist consumers in understanding what their state's EHB benchmark covers, we urge CMS to develop a template for a standardized guide, similar to but more extensive than the Summary of Benefits and Coverage required for Marketplace plans, that every state must develop and publish. This guide should describe the baseline components of each state's EHB benchmark to a specified degree of detail so that consumers will be able to determine at least the minimum degree of coverage that their state makes available through EHB-compliant plans.

Typical Employer Plans

CMS requests comment on changes in the scope of benefits offered by employer plans since plan year 2014. An area of employer-sponsored coverage in which there has been substantial change since 2014 is coverage of gender-affirming care for transgender people. According to the Corporate Equality Index (CEI), which has tracked the status of employer-sponsored coverage for this care since 2002, 67 percent of the entire Fortune 500—and 86 percent of all CEI-rated businesses (1,088 of 1,271)—offered employee benefits with no transgender-specific exclusions in 2022.[1] In 2015, 54 percent (421 of 781) companies offered at least one fully inclusive plan to their employees, and by 2022 that number had reached 91 percent (1,160 out of 1,271).

Given that 41 out of 51 current state EHB benchmark plans maintain blanket exclusions of coverage for gender-affirming care (as described in more detail below), these benchmarks are clearly out of step with trends in employer coverage since 2014, and we strongly encourage CMS to use its EHB plan review authority to address this problem.

We also note that many employer-sponsored plans listed among the possible EHB benchmark plans at 45 C.F.R. § 156.100 have also removed transgender-specific exclusions since 2014. In 2016, the White House Office of Personnel Management (OPM) required all carriers in the Federal Employees Health Benefits Program (FEHBP) to remove blanket exclusions of services, drugs, or supplies related to the treatment of gender dysphoria. For plan year 2023, OPM instituted the following requirements for FEHB carriers:[2]

[1] Human Rights Campaign Foundation. (2022). Corporate Equality Index. https://reports.hrc.org/corporate-equality-index-2022

[2] United States Office of Personnel Management. (2022). Federal Benefits Open Season November 14, 2022 – December 12, 2022. https://cdn.govexec.com/media/gbc/docs/pdfs_edit/093022ew1.pdf

- Have adopted one or more recognized entities in order to guide evidence-based benefits coverage and medical policies pertaining to gender affirming care and services, such as the World Professional Association of Transgender Health (WPATH) Standards of Care, the Endocrine Society, and the Fenway Institute. These entities provide evidence-based clinical guidelines for health professionals to assist transgender and gender diverse people with safe and effective pathways that maximize their overall health, including physical and psychological well-being.
- Will provide individuals diagnosed with and/or undergoing evaluation for gender dysphoria the option to use a Care Coordinator to assist and support them as they seek gender-affirming care and services. If network providers are not available to provide medically necessary treatment of gender dysphoria, FEHB Carriers will provide members direction on how to find qualified providers with experience delivering this specialized care.
- Have reviewed their formularies to ensure that transgender and gender diverse individuals have equitable access to medications and provide coverage of medically necessary hormonal therapies for gender transition care.

Similarly, none of the plans offered by Kaiser Permanente—a leading HMO—through the federal HealthCare.gov marketplace for plan year 2023 include transgender-specific exclusions.[3] Among state employee benefit plans, 41 states and territories, including the District of Columbia, do not have transgender-specific exclusions in their plans; of these, 24 states and D.C. affirmatively spell out the gender-affirming services that their state employee plans cover.[4] These trends in employer-sponsored coverage strongly support federal action to clarify that EHB plans are not permitted to exclude gender-affirming care.

Review of EHB

CMS requests comment on whether enrollees are facing difficulty accessing needed services, whether EHB need to be modified or updated to account for changes in medicine and science, how EHB should be modified to address any gaps in coverage or changes to the evidence base, and how changes to EHB may affect actuarial value (AV) calculations.

Barriers of Accessing Services Due to Coverage or Cost

Whitman-Walker's attorneys and insurance navigators frequently encounter patients who are struggling to access services through EHB-compliant plans, particularly mental and behavioral health services. In some instances, plans do not have sufficient providers in their networks. In other cases, available providers are not prepared to work effectively with diverse patient populations: many providers lack cultural competency around working with LGBTQ patients, and it is also often difficult for patients to find providers with clinical competency around issues such as gender-affirming care. To address issues of network adequacy, the ACA requires Qualified Health Plans (QHPs) to meet network adequacy requirements and to contract with a minimum number of Essential Community Providers (ECPs), including FQHCs such as Whitman-Walker.

[3] Out2Enroll. (2022). Summary of Findings: 2023 Marketplace Plan Compliance with Section 1557 of the Affordable Care Act. https://out2enroll.org/2023-cocs/

[4] LGBT Movement Advancement Project. (2023). Equality Maps. https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/state_employees

To improve access to clinically and culturally competent care, particularly mental and behavioral health services, for diverse enrollees, CMS should extend the QHP network adequacy and ECP contracting requirements to all EHB-compliant plans. Though states are the primary enforcers of the EHB standard, federal oversight of network adequacy and ECP contracting requirements for all EHB-compliant plans can be accomplished in a manner similar to resumed federal oversight of these requirements for QHPs. Further, there should be no limitation on when providers, particularly ECPs, can be added to carrier networks.

Telehealth is also an important innovation that has helped improve access to services for many patients. From a clinic perspective, it also improves no-show rates and facilitates convenient appointment scheduling for patients. CMS should take steps to advance telehealth reimbursement parity nationwide beyond the Medicare program by requiring EHB-compliant plans to reimburse essential benefits provided via telehealth at the same rate as in-person visits.

Changes in Medical Evidence and Scientific Advancement

As noted above, a major area of change in the U.S. health insurance landscape since 2014 has been the expansion of coverage for gender-affirming care in many employer-sponsored plans, as well as through other types of coverage:

- Medicare rescinded its exclusion of gender-affirming care in 2014;[5]
- 46 states and territories, as well as D.C., do not have exclusions of gender-affirming care in their Medicaid programs;[6] and
- 24 states and D.C. have explicit laws or regulatory guidance in place prohibiting transgender-specific exclusions in state-regulated private insurance).[7]

The 2016 HHS regulation interpreting Section 1557 of the ACA also prohibited blanket exclusions of coverage for gender-affirming care; this provision of the regulation was removed in June 2020, but in 2021 HHS announced that it would enforce Section 1557 to include protections on the basis of gender identity,[8] and the July 2022 Notice of Proposed Rulemaking (NPRM) reinstates the prohibition on gender identity discrimination in health insurance coverage, including a ban on blanket exclusions of gender-affirming care.[9] Beyond the regulations, several courts have found that transgender-specific exclusions violate the

[5] See, e.g., Palmetto GBA. (2022). Billing and Coding: Gender Reassignment Services for Gender Dysphoria. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=53793

[6] LGBT Movement Advancement Project. (2023). Equality Maps. https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/medicaid

[7] LGBT Movement Advancement Project. (2023). Equality Maps. https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies/private_insurance

[8] Keith K. (2021). HHS Will Enforce Section 1557 to Protect LGBTQ People from Discrimination. *Health Affairs Blog*. https://www.healthaffairs.org/do/10.1377/forefront.20210511.619811/

[9] U.S. Department of Health and Human Services. (2022). HHS Announces Proposed Rule to Strengthen Nondiscrimination in Health Care. https://www.hhs.gov/about/news/2022/07/25/hhs-announces-proposed-rule-to-strengthen-nondiscrimination-in-health-care.html

statutory language of ACA Section 1557, which prohibits discrimination in health insurance coverage and health care on the basis of sex, among other protected characteristics.[10]

These advances place the EHB benchmark plans, of which 41 out of 51 have blanket exclusions, squarely out of step with both law and medical science, which is comprehensively summarized in the 8th version of the *Standards of Care for the Health of Transgender and Gender Diverse People* released by the World Professional Association for Transgender Health (WPATH) in September 2022.[11] In the appendix to this comment, we provide a full accounting of the illegal and unjustifiable exclusions present in these EHB benchmark plans.

Colorado proactively took the step in 2022 of removing the transgender-specific exclusion from its EHB benchmark plan, and we applaud CMS for approving Colorado's proposal. Taking a state-by-state approach to this issue, however, violates CMS's professed commitment to health equity and nondiscrimination by continuing to allow plans to discriminate against transgender EHB plan enrollees in a manner prohibited by federal law and by half of the states themselves. To achieve equity and parity for transgender enrollees across the country and to bring the EHB standard into alignment with medical evidence and with current practice in a wide variety of coverage programs and carrier offerings, CMS must require states to remove transgender-specific exclusions from their EHB benchmark plans.

Addressing Gaps in Coverage

In addition to the major gap in coverage for gender-affirming care described above, we frequently work with patients who are seeking coverage for fertility and family planning services. These services include in vitro fertilization (IVF) and other reproductive technologies; pharmaceutical and surgical abortion; and perinatal services provided by doulas, midwives, and other non-physician health care professionals. With regard to fertility services, we note that a number of states require coverage for these services, which historically have not been considered to be an essential health benefit. We further note that fertility is covered under the Americans with Disabilities Act (ADA) as a major life activity; though the ADA does not expressly require coverage of fertility services, a state adding these services to its EHB requirement to ensure fair treatment of people experiencing infertility is aligning its EHB requirement with relevant nondiscrimination law. To fully clarify that states are not required to defray these costs and to establish an equitable baseline for fertility coverage nationwide, we urge CMS to define the maternity care EHB category to include fertility services, and to do so in language that does not discriminate against same-sex couples seeking these services. This step will enhance equity by ensuring that all enrollees in EHB plans can access these important services. We further urge CMS to seek out other opportunities to expand coverage of a full range of fertility and family planning services offered by diverse categories of health care providers. One such opportunity is to explicitly clarify coverage for post-abortion care as an EHB requirement, as post-abortion care is critical in a post-*Roe v. Wade* landscape where many people may seek

[10] See, e.g., Pazanowski MA. (2022). North Carolina Transgender Surgery Ban Violates ACA, Court Rules. *Bloomberg Law.* https://news.bloomberglaw.com/health-law-and-business/transgender-state-employees-win-obamacare-claim-in-insurance-row

[11] World Professional Association for Transgender Health. (2022). Standards of Care for the Health of Transgender and Gender Diverse People (8th Version). *International J Transgender Health, 23*(Supp. 1), S1-S259. https://doi.org/10.1080/26895269.2022.2100644

self-managed abortions due to the complex abortion policy landscape. Often, the legality of post-abortion care is misunderstood, resulting in gaps in access to this care due to fear among patients, providers, and carriers of violating state abortion restrictions.

Actuarial and Cost-Sharing Limits

Putative claims of higher health care costs are routinely invoked to argue that coverage for gender-affirming care is too expensive to be feasible under AV limits. The available evidence shows, however, that removing exclusions of coverage for this care is cost-neutral or extremely low-cost. The City and County of San Francisco initially raised premiums when they became the first major U.S. employers to remove blanket exclusions for gender-affirming care in 2001. But after five years, "beneficial cost data led Kaiser and Blue Shield to no longer separately rate and price the transgender benefit—in other words, to treat the benefit the same as other medical procedures such as gallbladder removal or heart surgery."[12] A 2013 survey of employers providing coverage for gender-affirming care to their employees found that two-thirds of the employers that provided information on the actual costs of utilization of gender dysphoria treatments reported zero costs, and those employers who reported some costs said that the costs were very low or minimal.[13] An analysis of gender-affirming care uptake by transgender people over 6.5 years in one California health plan found a utilization rate of 0.062 per 1,000 covered persons.[14] Estimates from other states show equally low utilization and related low costs, with North Carolina estimating costs at 0.011% to 0.027% of premiums;[15] Alaska, 0.03% to 0.05%;[16] and Wisconsin, "immaterial at 0.1% to 0.2% of the total cost."[17] Cost estimates under Wisconsin Medicaid were "actuarially immaterial, as they are equal to approximately 0.008% to 0.03%"[18] of Wisconsin's share of its Medicaid budget. Similarly, an analysis in the military context concluded that the financial cost of covering gender-affirming care was "too low to matter"[19] or, as military leadership noted, "'budget dust,' hardly even a rounding error."[20] This is because

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[12] City and County of San Francisco Human Rights Commission, *San Francisco City and County Transgender Health Benefit*
(Aug. 7, 2007), https://transhealthproject.org/documents/19/SF_transgender_health_benefit.pdf

[13] Herman JL. (2013). *Costs and Benefits of Providing Transition-Related Health Care Coverage in Employee Health Benefits Plans: Findings from a Survey of Employers*. Los Angeles: The Williams Institute. https://escholarship.org/content/qt5z38157s/qt5z38157s.pdf?t=n2ff21

[14] State of California Department of Insurance. (2012). *Economic Impact Assessment: Gender Nondiscrimination in Health Insurance*, Reg. File No. REG-2011-0002. http://transgenderlawcenter.org/wp-content/uploads/2013/04/Economic-Impact-Assessment-Gender-Nondiscrimination-In-Health-Insurance.pdf

[15] Segal Consulting memorandum to Mona Moon, Executive Administrator of the North Carolina State Health Plan, re: Transgender Cost Estimate. (Nov. 29, 2016). https://files.nc.gov/ncshp/documents/board-of-trustees/3aii-3-The-Segal-Company-Transgender-Cost-Estimate-Memorandum.pdf

[16] Plaintiffs' Motion for Partial Summary Judgment, *Fletcher v. Alaska*, No. 1:18-cv-00007-HRH (D. Alaska July 1, 2019), https://www.lambdalegal.org/sites/default/files/legal-docs/downloads/fletcher_ak_20190701_plaintiffs-motion-for-partial-summary-judgment.pdf

[17] *Boyden v. Conlin*, 341 F. Supp. 3d 979, 1000 (W.D. Wis. 2018).

[18] *Flack v. Wis. Dept of Health Servs.*, 395 F. Supp. 3d 1001, 1008 (W.D. Wis. 2019).

[19] Belkin A. (2015). Caring for our transgender troops – The negligible cost of transition-related care. *New Eng J Med, 373*, 1089–1092. https://www.nejm.org/doi/full/10.1056/NEJMp1509230

[20] Declaration of Raymond Edwin Mabus, Jr., Former U.S. Secretary of the Navy, in Support of Plaintiff's Motion for Preliminary Injunction, *Doe v. Trump*, No. 17-cv-1597-CKK (D.D.C.) filed Aug. 31, 2017, at 41). http://files.eqcf.org/wp-content/uploads/2017/09/13-Ps-App-PI.pdf

only a small percentage of the U.S. population is transgender, and not all transgender people need or use a full scope of services related to gender affirmation.

Coverage of Prescription Drugs as EHB

CMS seeks comments on its approach to the EHB requirement's coverage of prescription drugs. We work with many patients who need medication for the prevention or treatment of HIV, and we note that insurance coverage of newer medications, particularly long-acting injectable options, often substantially lags behind the science. When these medications are covered, they are frequently placed in very high cost-sharing tiers and/or subjected to utilization management techniques such as step therapy. Long-acting injectable HIV medications can improve adherence and support viral suppression, particularly for patients with difficulty with oral medications.[21] To ensure that prescription drug coverage is sufficiently robust under EHB plans, we urge CMS to extend its approach to six protected categories of medications for plans participating in Medicare Part D to plans subject to the EHB requirement. Under this approach, EHB-compliant plans would be required to cover all medications in the six protected classes of immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics. Further, the prohibition on prior authorization or step therapy for antiretrovirals in the Part D program should be incorporated into the EHB requirement. Finally, we note that another major concern in prescription drug coverage is coverage of medication abortion. Particularly in the wake of the 2022 U.S. Supreme Court decision overturning abortion rights nationwide, we urge CMS to ensure that all EHB-compliant plans cover medication abortion without undue restrictions on prescribing and dispensing.

Conclusion

We thank you for the opportunity to comment on the EHB standard, which is a critical component of ensuring that the ACA delivers on its promise of higher-quality care for enrollees in the individual and small group markets across the country. We appreciate your consideration of our comments and look forward to continuing to work with CMS and its partners across HHS on improving our nation's health through the provision of equitable and timely access to high-quality, affordable health insurance coverage and care for all patients and consumers.

Sincerely Yours,

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Executive Director and Chief Learning Officer
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[21] Scarsi KK & Swindells S. (2021). The Promise of Improved Adherence with Long-Acting Antiretroviral Therapy: What Are the Data? *J Int Assoc Provid AIDS Care*, *20*, 23259582211009011. https://doi.org/10.1177/23259582211009011

Appendix

As noted above, Out2Enroll (a project of Whitman-Walker) conducts an annual assessment of plans sold through HealthCare.gov to identify plans that continue to exclude gender-affirming care, in violation of ACA Section 1557 and, in many cases, state law. We conducted a similar analysis of EHB benchmark plans and were surprised and dismayed to learn that 41 of 51 state EHB benchmarks have blanket exclusions of this care. We strongly urge CMS to take immediate action to clarify that these exclusions are prohibited in EHB-compliant plans, including the EHB benchmarks, and to require that they be removed before a plan can be approved as a benchmark.

State	Exclusion	Exclusion Language
Alabama	Yes	"HEALTH BENEFIT EXCLUSIONS Services or expenses for, or related to, sexual dysfunctions or inadequacies not related to organic disease (unless the injury results from an act of domestic violence or a medical condition) or which are related to surgical sex transformations"
Alaska	Yes	"WHAT'S NOT COVERED? Gender Transformations Treatment or surgery to change gender, including any direct or indirect complications and after effects thereof. Mental/Behavioral Health Outpatient Services: Exclusions: All medical services provided in preparation for or after gender reassignment surgery, also including the surgery medical counseling and hormone therapy, regardless of age."
Arizona	Yes	"9.1 Exclusions and General Limitations Any Services and Supplies which are not described as covered or are specifically excluded in any other Article of this Plan Description are excluded. In addition, the following are specifically excluded Services and Supplies: 16. Transsexual surgery including medical or psychological counseling and hormonal therapy in preparation for, or subsequent to, any such surgery."
Arkansas	Yes	"3.0 BENEFITS AND SPECIFIC LIMITATIONS IN YOUR PLAN 4. The following services and treatments are not covered. b. Sex Changes/Sex Therapy. Care, services or treatment for non-congenital transsexualism, gender dysphoria or sexual reassignment or change are not covered. This exclusion includes medications, implants, hormone therapy, surgery, medical or psychiatric treatment or other treatment of sexual dysfunction including Prescription Medication and sex therapy."
California	No	"Getting a Referral: Medical Group authorization procedure for certain referrals: Transgender surgery. If your treating Plan Provider makes a written referral for transgender surgical Services (genital surgery or mastectomy), the Medical Group's Transgender Surgery Review Board will authorize the Services if it determines that the Services meet the requirements described in the Medical Group's transgender surgery guidelines, which are available upon request"

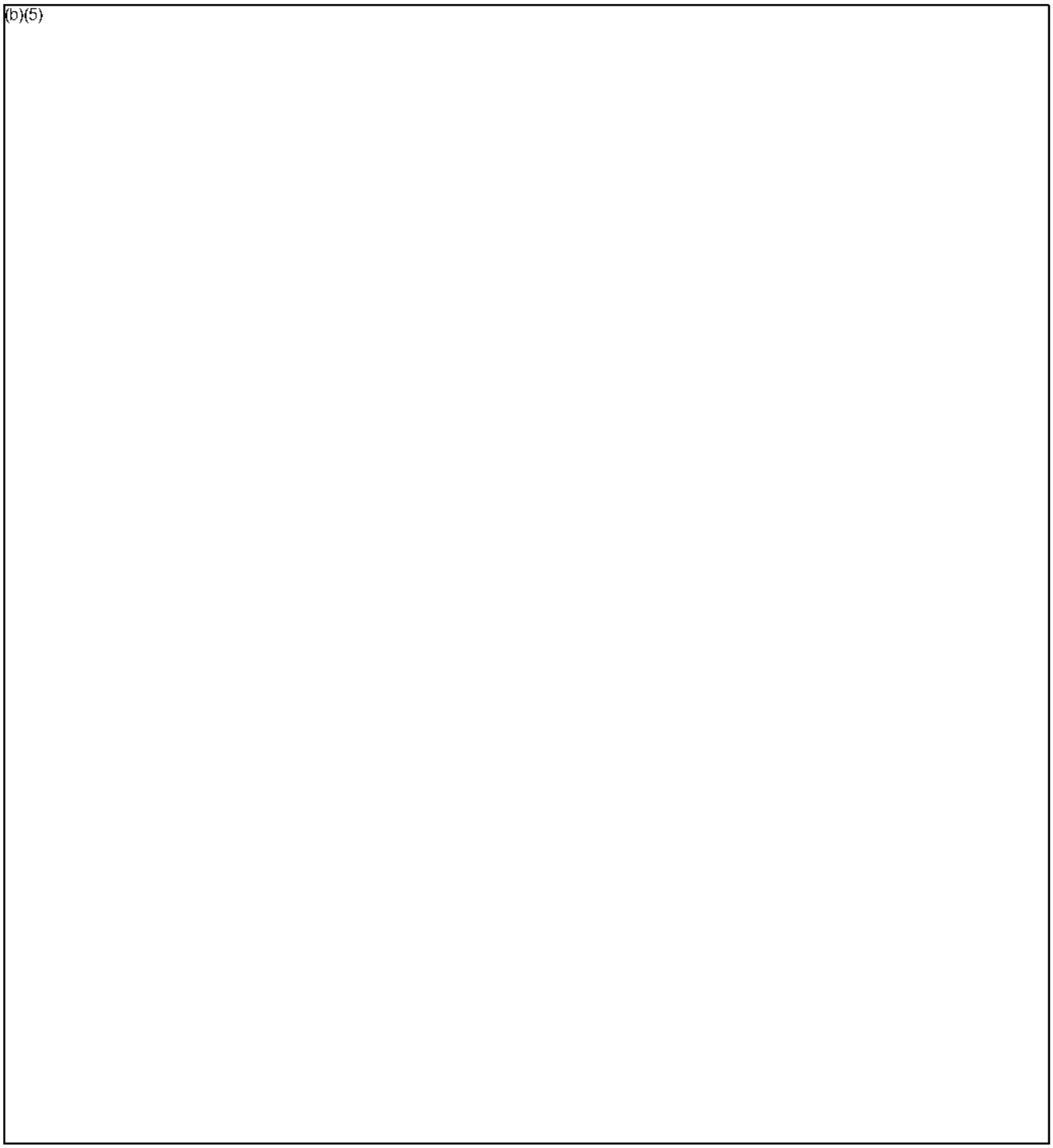
Colorado	No	"Gender Affirming Care Yes Covered" Medically-necessary treatment includes treatment for gender dysphoria and includes the following gender-affirming care services, at minimum: 1. Blepharoplasty (eye and lid modification) 2. Face/forehead and/or neck tightening 3. Facial bone remodeling for facial feminization 4. Genioplasty (chin width reduction) 5. Rhytidectomy (cheek, chin, and neck) 6. Cheek, chin, and nose implants 7. Lip lift/augmentation 8. Mandibular angle augmentation/creation/reduction (jaw) 9. Orbital recontouring 10. Rhinoplasty (nose reshaping) 11. Laser or electrolysis hair removal 12. Breast/Chest Augmentation, Reduction, Construction"
Connecticut	Silent	
Delaware	Yes	"WHAT IS NOT COVERED The following services and items are not covered. Certain mental health and substance abuse services, including treatment of sexual and gender identity disorders Change of sex surgery, except to correct congenital defect, or any medical services or pharmaceutical products related to gender identity disorder."
DC	Silent	
Florida	Yes	"Section 3. What Is Not Covered: Sexual Reassignment, or Modification Services including, but not limited to, any Health Care Service related to such treatment, such as psychiatric Services."
Georgia	Yes	"Limitations and Exclusions: Sex change services, regardless of any diagnosis of gender role or psychosexual orientation problems."
Hawaii	Yes	"Sexual Transformation: You are not covered for services and supplies related to sexual transformation regardless of cause. This includes, but is not limited to, sexual transformation surgery." "Sexual Identification Counseling: You are not covered for sexual identification counseling."
Idaho	Yes	"General Exclusions and Limitations: For any treatment of either gender leading to or in connection with transsexual Surgery, gender transformation, sexual dysfunction, or sexual inadequacy, including erectile dysfunction and/or impotence, even if related to a medical condition."
Illinois	Silent	

Indiana	Yes	"Non Covered Services/Exclusions: 53. Services and supplies related to sex transformation and/or the reversal thereof, or male or female sexual or erectile dysfunctions or inadequacies, regardless of origin or cause. This Exclusion includes sexual therapy and counseling. This exclusion also includes penile prostheses or implants and vascular or artificial reconstruction, Prescription Drugs, and all other procedures and equipment developed for or used in the treatment of impotency, and all related Diagnostic Testing."
Iowa	Yes	"Mental Health Services Not Covered: Sexual identification or gender disorders."
Kansas	Yes	"Benefits will not be provided for: 20. Services or supplies associated with sex changes/gender reassignment, and services related to sexual function, and any related complications."
Kentucky	Yes	"Section 2: Exclusions and Limitations M. Procedures and Treatments 8. Sex transformation operations and related services."
Louisiana	Yes	"LIMITATIONS AND EXCLUSIONS 6. Services, surgery, supplies, treatment, or expenses in connection with or related to, or complications from the following REGARDLESS OF CLAIM OF MEDICAL NECESSITY j. treatment related to sex transformations, sexual function, sexual dysfunctions or inadequacies."
Maine	Yes	"Sex Changes We do not provide Benefits for any services related to any transsexual operation."
Maryland	Yes	"Section 15 EXCLUSIONS AND LIMITATIONS: 15.33 Treatment leading to or in connection with transsexualism, or sex changes or modifications, including, but not limited to surgery."
Massachusetts	Silent	
Michigan	Yes	"Sex Change or Transformation Non-Covered Services Any procedure or treatment, including hormone therapy, designed to change your physical characteristics from your biologically determined sex to those of the opposite sex. This exclusion applies despite any diagnosis of gender role or psychosexual orientation problems."
Minnesota	No	"III. SERVICES NOT COVERED 17. Services and/or surgery for gender reassignment, except as determined medically necessary."
Mississippi	Yes	"Article XV LIMITATIONS AND EXCLUSIONS Benefits will not be provided for the following: A. 7. For treatment related to sex transformations, sexual function, sexual dysfunctions or inadequacies regardless of Medical Necessity."

Missouri	Yes	"What's Not Covered 39) Sex Change Services and supplies for a sex change and/or the reversal of a sex change." "What's Not Covered Under Your Prescription Drug Retail or Home Delivery (Mail Order) Pharmacy Benefit 22. Sex Change Drugs for sex change surgery."
Montana	Yes	"EXCLUSIONS AND LIMITATIONS 29. Services or supplies related to sexual reassignment and reversal of such procedures."
Nebraska	Yes	"EXCLUSIONS—WHAT'S NOT COVERED • Sex transformation surgery and related Services. • Prescription medications for the primary purpose of sex transformation, both prior to and after surgery."
Nevada	Yes	"Glossary: 13.70 "Mental Illness" means a pathological state of mind producing clinically significant psychological or physiological symptoms together with impairment in one or more major areas of functioning where improvement can reasonably be anticipated with therapy. Mental Illness does not include any Severe Mental Illness as defined in the EOC and otherwise covered under the Severe Mental Illness Covered Services section, or any of the following when they represent the primary need for therapy: Transsexualism, psychosexual identity disorder, psychosexual dysfunction of gender dysphoria."
New Hampshire	Yes	"What's Not Covered 35) Sex Change Services and supplies for a sex change and/or the reversal of a sex change. 21. Sex Change Drugs for sex change surgery."
New Jersey	Yes	"EXCLUSIONS Payment will not be made for any charges incurred for or in connection with: Surgery, sex hormones, and related medical, psychological and psychiatric services to change a Covered Person's sex; services and supplies arising from complications of sex transformation."
New Mexico	No	"Cosmetic Surgery: Medically necessary surgery performed to confirm a covered person's gender is not considered cosmetic surgery and will be covered."
New York	Yes	"Infertility Treatment: Exclusions and Limitations h. Sex change procedures."
North Carolina	Yes	"WHAT IS NOT COVERED? Treatment or studies leading to or in connection with sex changes or modifications and related care"
North Dakota	Yes	"Exclusions: No benefits are available for: 23. Treatment leading to or in connection with sex change or transformation surgery and related complications."

Ohio	Yes	"NON COVERED SERVICES/EXCLUSIONS: 51. Services and supplies related to sex transformation and/or the reversal thereof, or male or female sexual or erectile dysfunctions or inadequacies, regardless of origin or cause. This Exclusion includes sexual therapy and counseling. This exclusion also includes penile prostheses or implants and vascular or artificial reconstruction, Prescription Drugs, and all other procedures and equipment developed for or used in the treatment of impotency, and all related Diagnostic Testing."
Oklahoma	Yes	"Exclusions: S. For transsexual Surgery or any treatment leading to or in connection with transsexual Surgery."
Oregon	Silent	
Pennsylvania	Yes	"EXCLUSIONS – WHAT IS NOT COVERED Transsexual Surgery: For any procedure or treatment leading to or in connection with transsexual Surgery except for sickness or injury resulting from such Surgery."
Rhode Island	Yes	"4.33 Sex Transformations and Dysfunctions Health care services related to sex transformations are NOT covered. Health care services related to sexual dysfunctions or inadequacies, except services approved by us and necessary for the treatment of a condition arising out of organic dysfunctions, are NOT covered. (i.e., Therapeutic services will be covered when the cause of the dysfunction is physiological, not psychological.) This agreement does NOT cover sildenafil citrate (e.g., Viagra) or any therapeutic equivalents."
South Carolina	Yes	"Exclusions and Limitations Recreational, educational or play therapy; biofeedback; psychological or educational diagnostic testing to determine job or occupational placement or for other educational purposes, or to determine if a learning disorder exists; therapy for learning disorders, development speech delay, communication disorder, developmental coordination disorder, mental retardation, dissociative disorder, sexual and gender identity disorder, personality disorder and vocational rehabilitation unless specifically included in your Schedule of Benefits. Any services or supplies for the diagnosis or treatment of sexual dysfunction. This includes, but is not limited to: drugs, lab and X-ray tests, counseling, transsexual procedures or penile prostheses necessary due to any medical condition or organic disease. A penile prosthesis will be considered for payment only after Medically Necessary prostate Surgery."
South Dakota	Yes	"MENTAL HEALTH SERVICES Not Covered: Your benefits do not include coverage for the following: Sexual identification or gender disorders.
Tennessee	Yes	"V. Reconstructive Surgery Medically Necessary and Appropriate Surgical Procedures intended to restore

		normal form or function. 2. Exclusions c. Surgeries and related services to change gender (transsexual Surgery)."
Texas	Yes	"MEDICAL LIMITATIONS AND EXCLUSIONS 26. Any services or supplies provided for, in preparation for, or in conjunction with Transsexual surgery"
Utah	Yes	"6.4.3 Exclusions from coverage Relating to surgery: 10. Gender reassignment Surgery. 6.12.8 Exclusions from coverage Relating to prescription drug benefits: 26. Medications for sex change operations."
Vermont	No	"10. Cosmetic and Reconstructive Procedures: For purposes of this EHB Benchmark, "Reconstructive Procedures" are Medically Necessary procedures to correct gross deformities with physiological and functional impairments attributable to congenital defects, injury (including injuries occurring at birth), disease, or other health conditions (including gender dysphoria)." "16. Gender Dysphoria Medically Necessary treatment for gender dysphoria and related health conditions is covered to the extent required by 8 V.S.A. § 4724 and Insurance Bulletin 174."
Virginia	Yes	"What's Not Covered 38) Sex Change Services and supplies for a sex change and/or the reversal of a sex change."
Washington	Yes	"General Exclusions Sexual Reassignment Treatment and Surgery Treatment, surgery or counseling services for sexual reassignment."
West Virginia	Yes	"Exclusions / What Is Not Covered 28. Transsexual Surgery or any Treatment leading to or in connection with transsexual Surgery."
Wisconsin	Yes	"Section 2. Exclusions and Limitations M. Procedures and Treatments 8. Sex transformation operations and related services."
Wyoming	Yes	"g. Sex change operations and related expenses are not Covered Services."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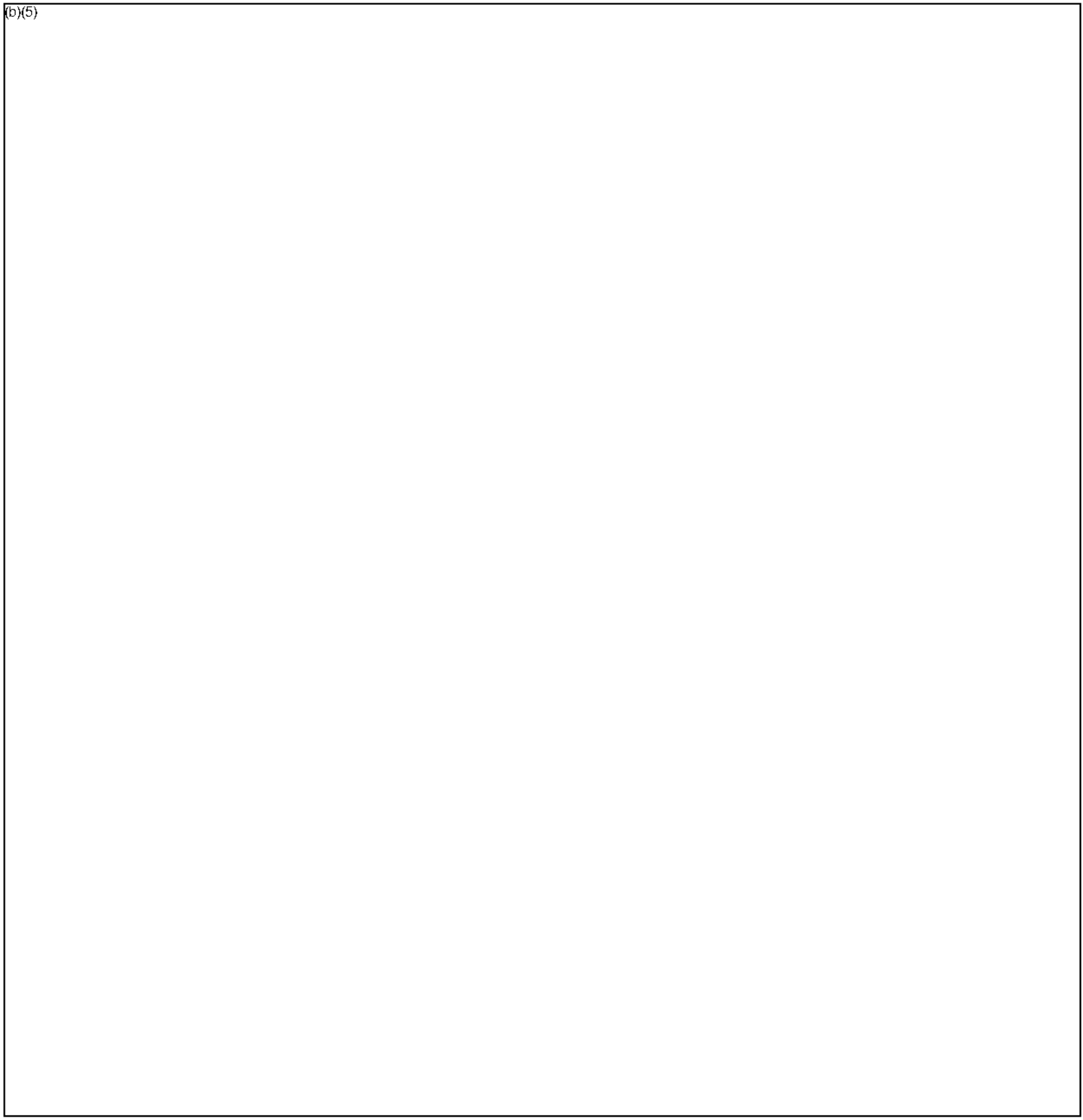
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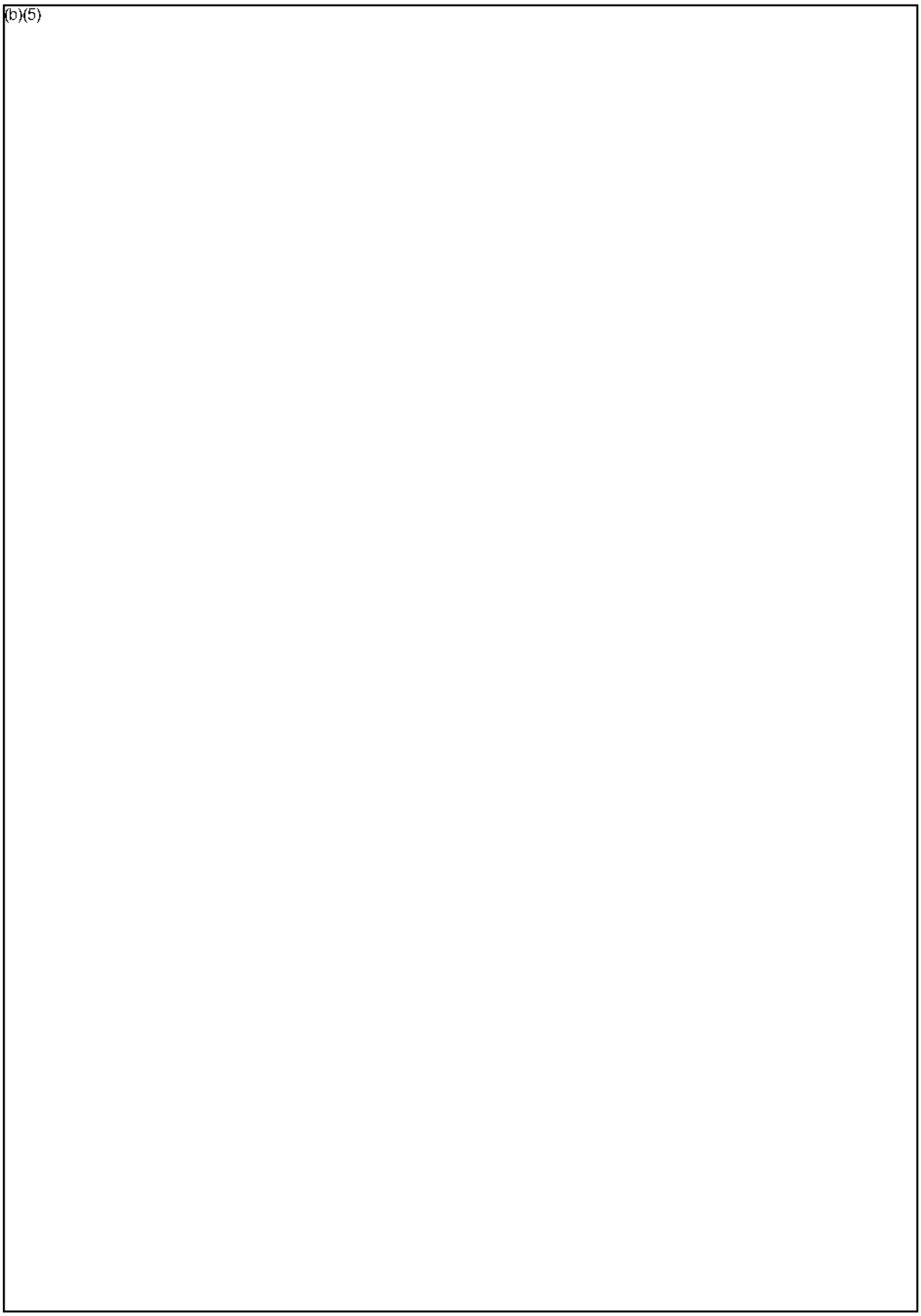
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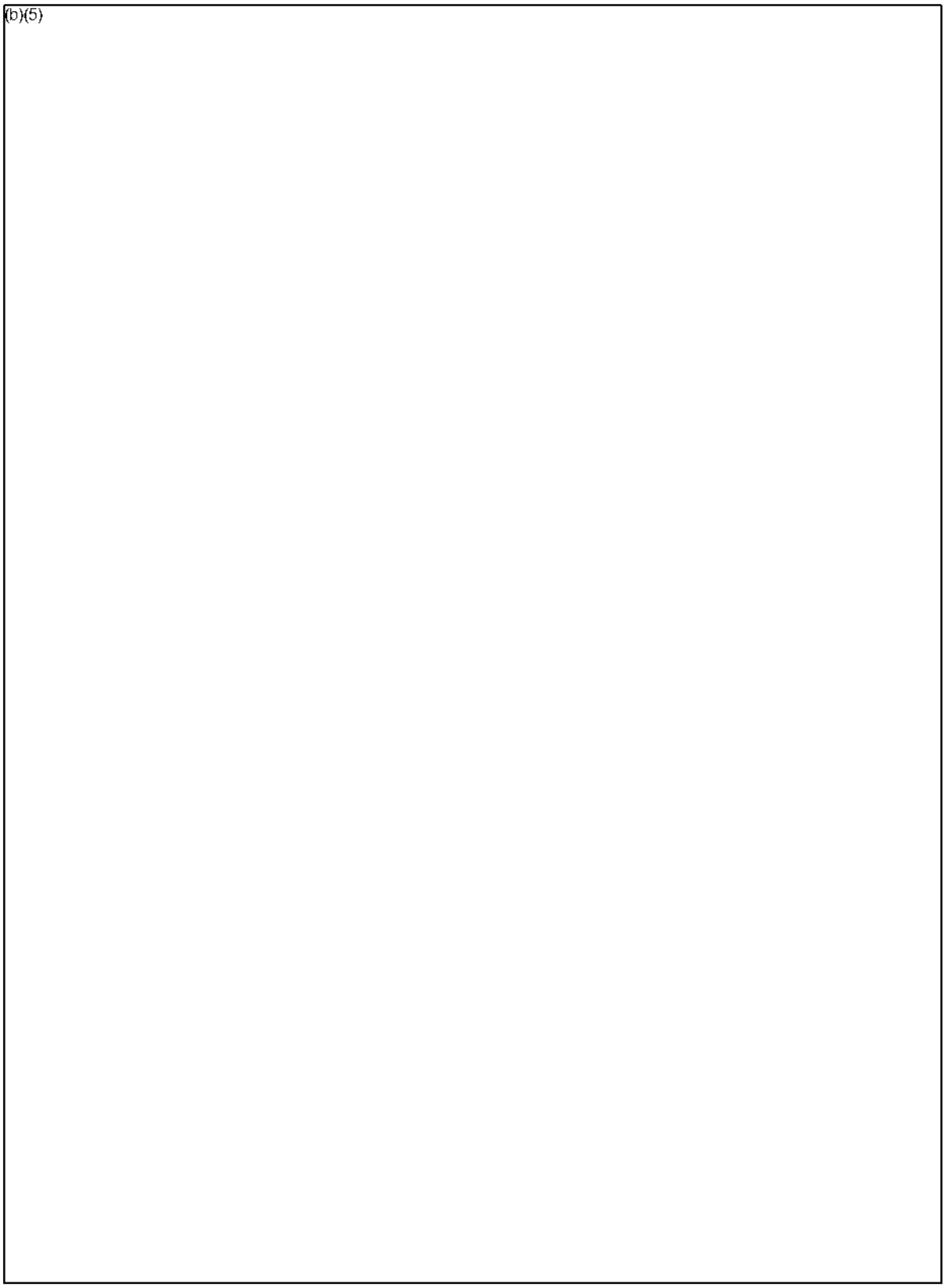
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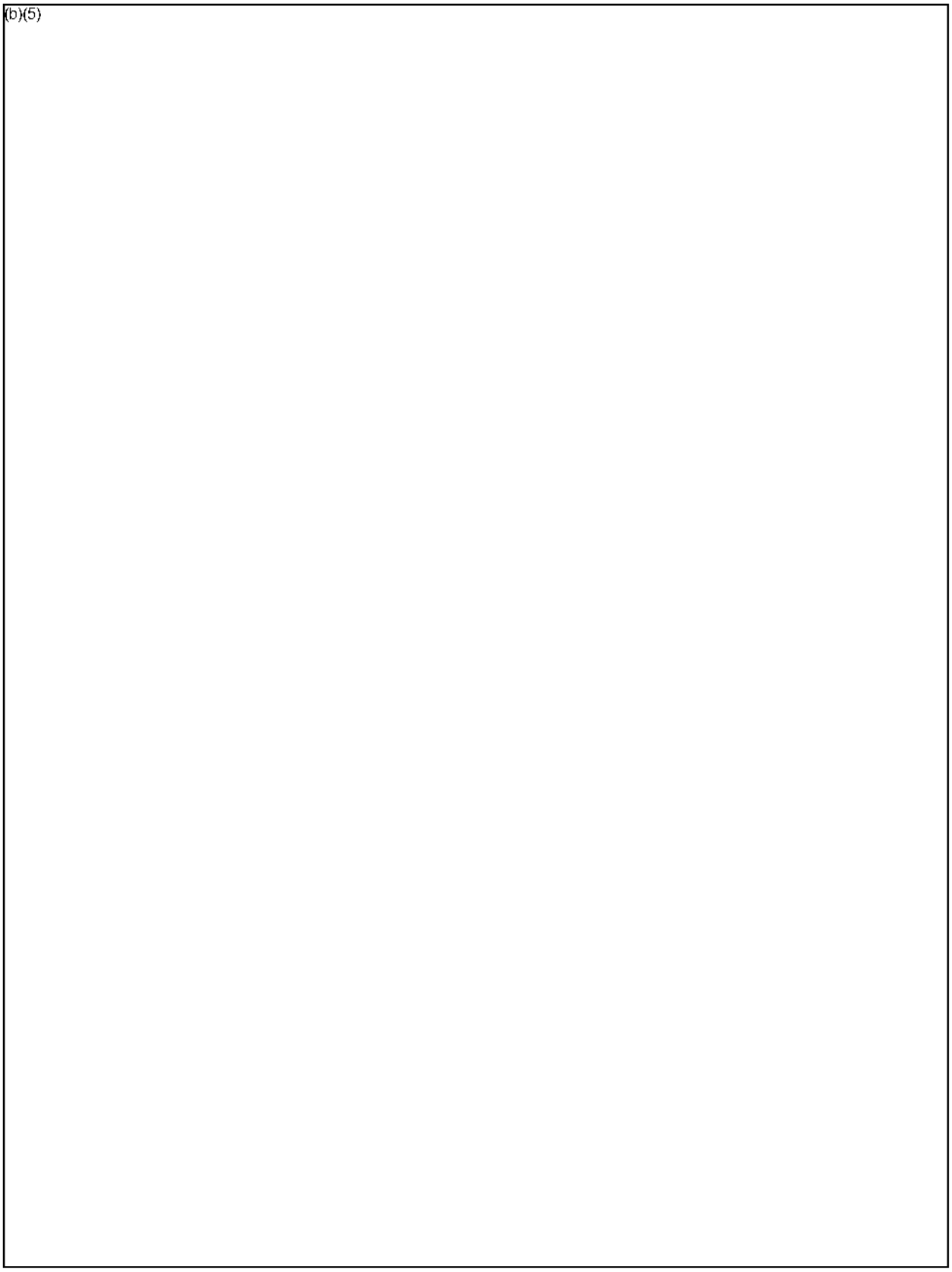
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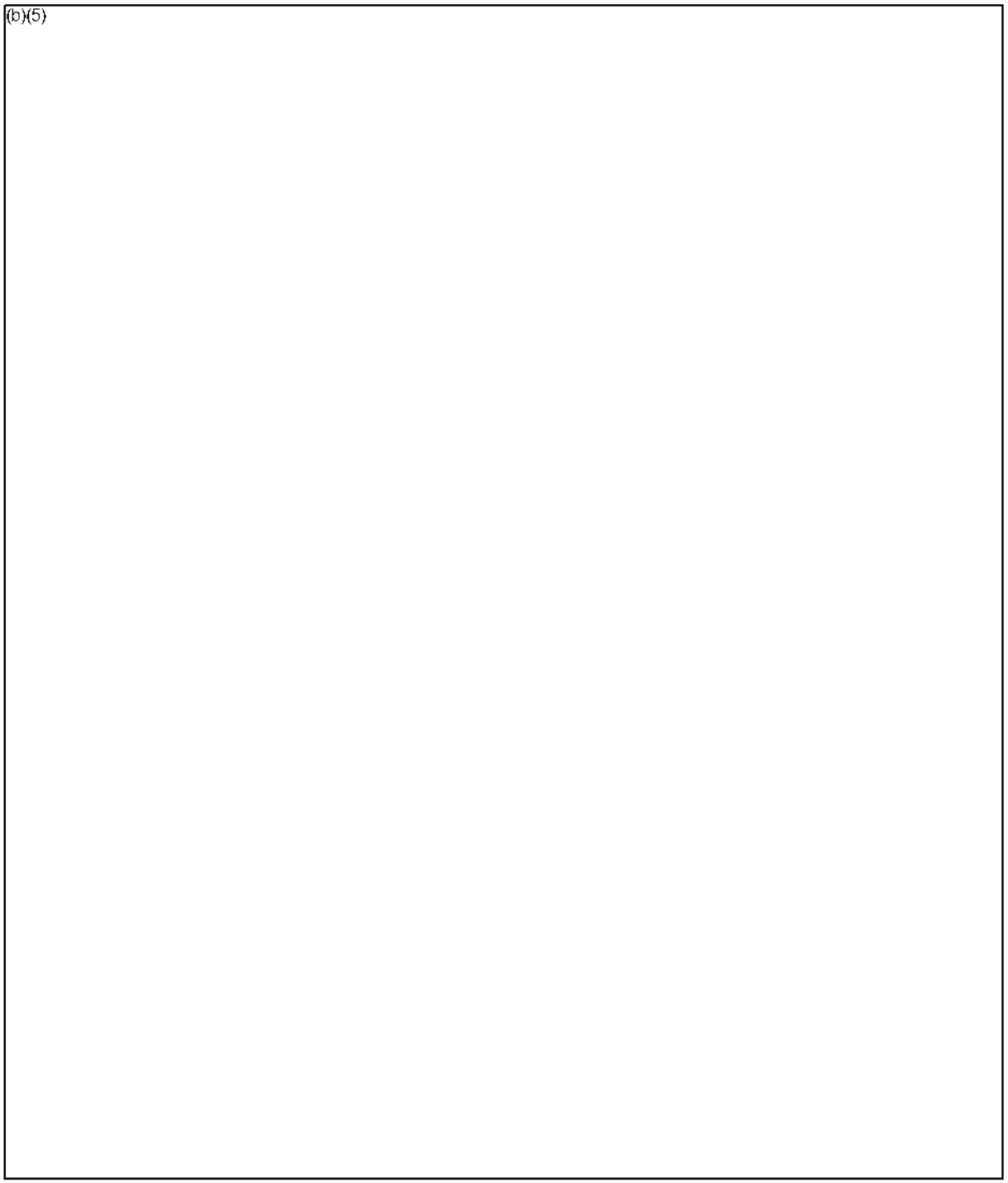
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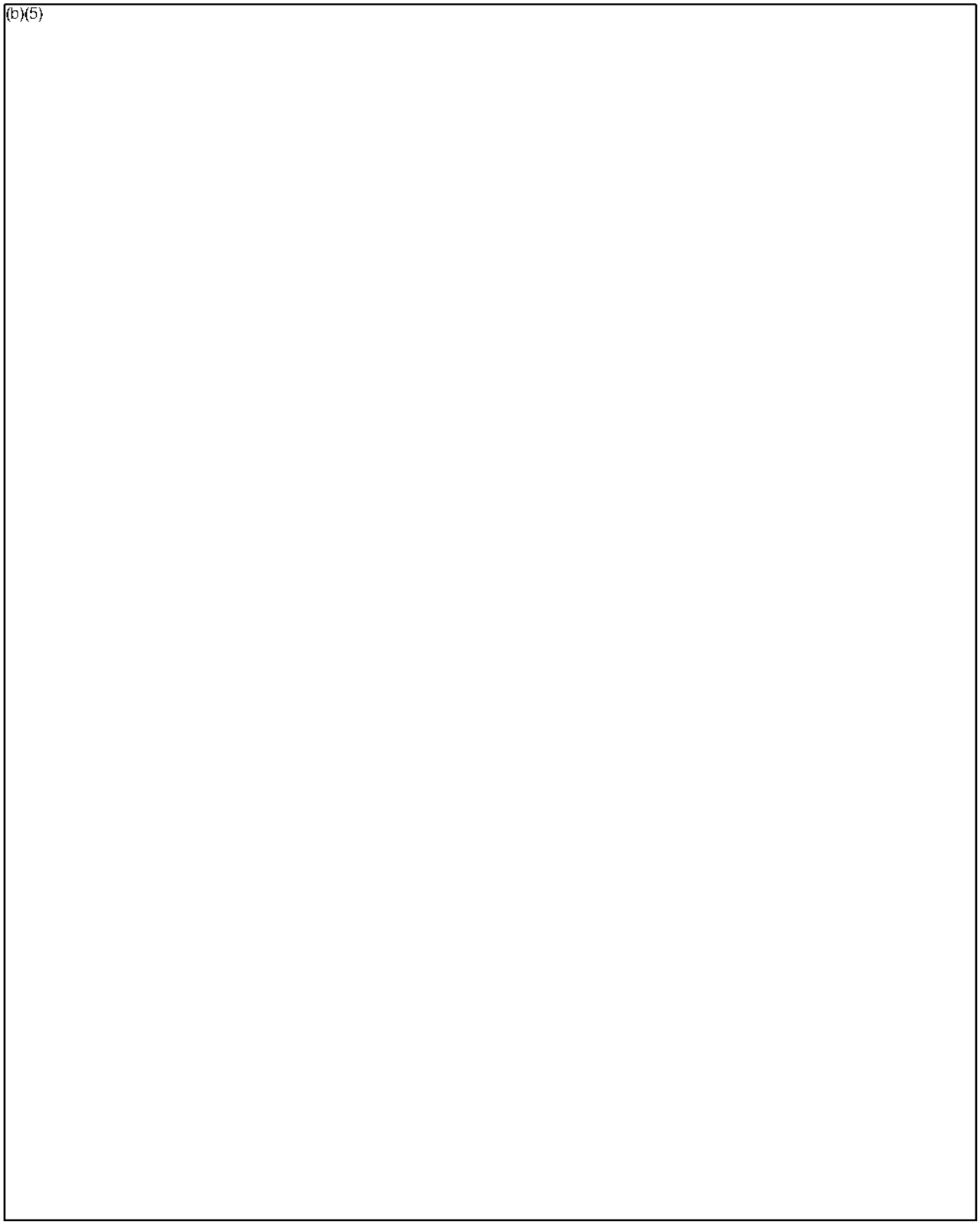
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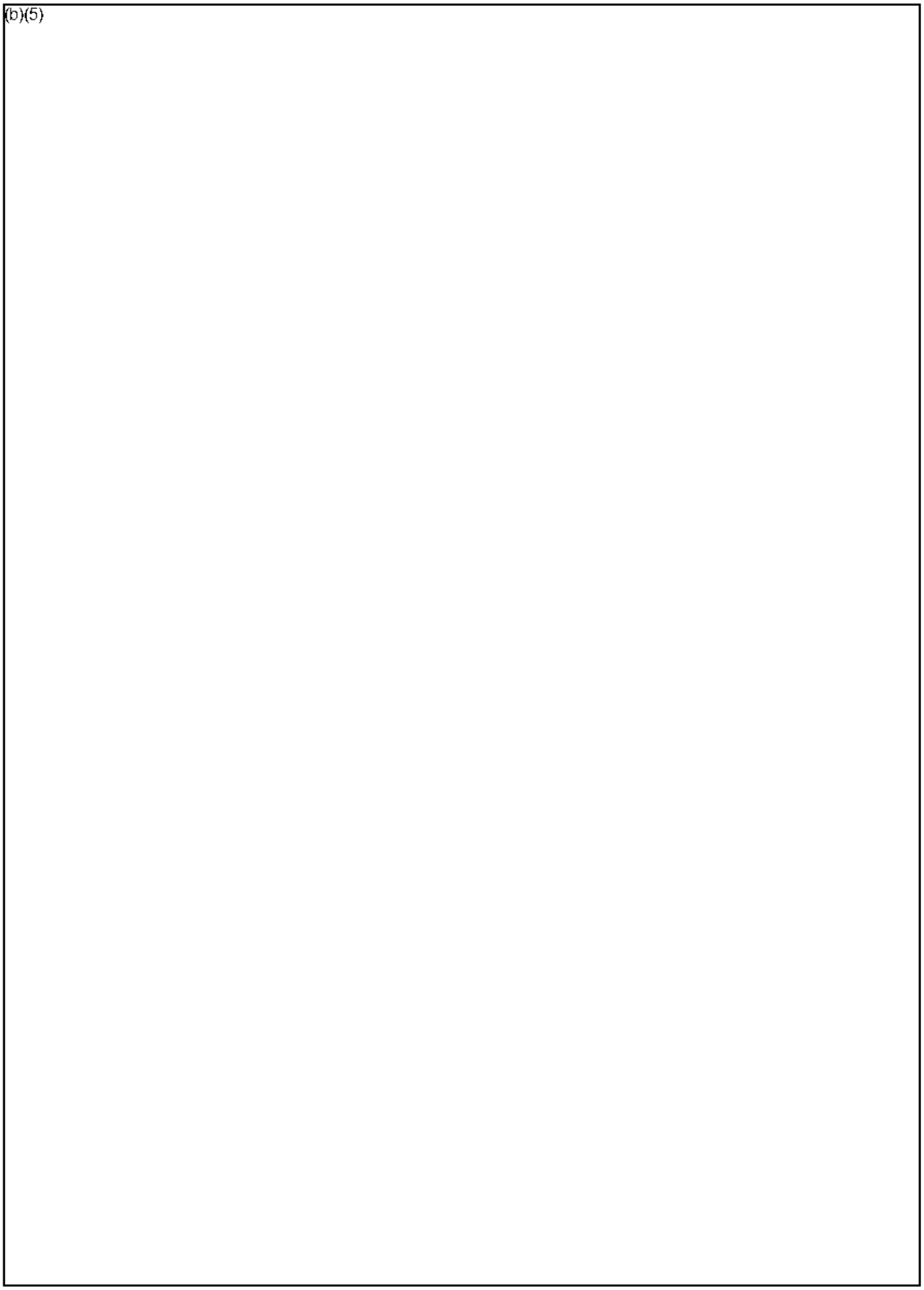
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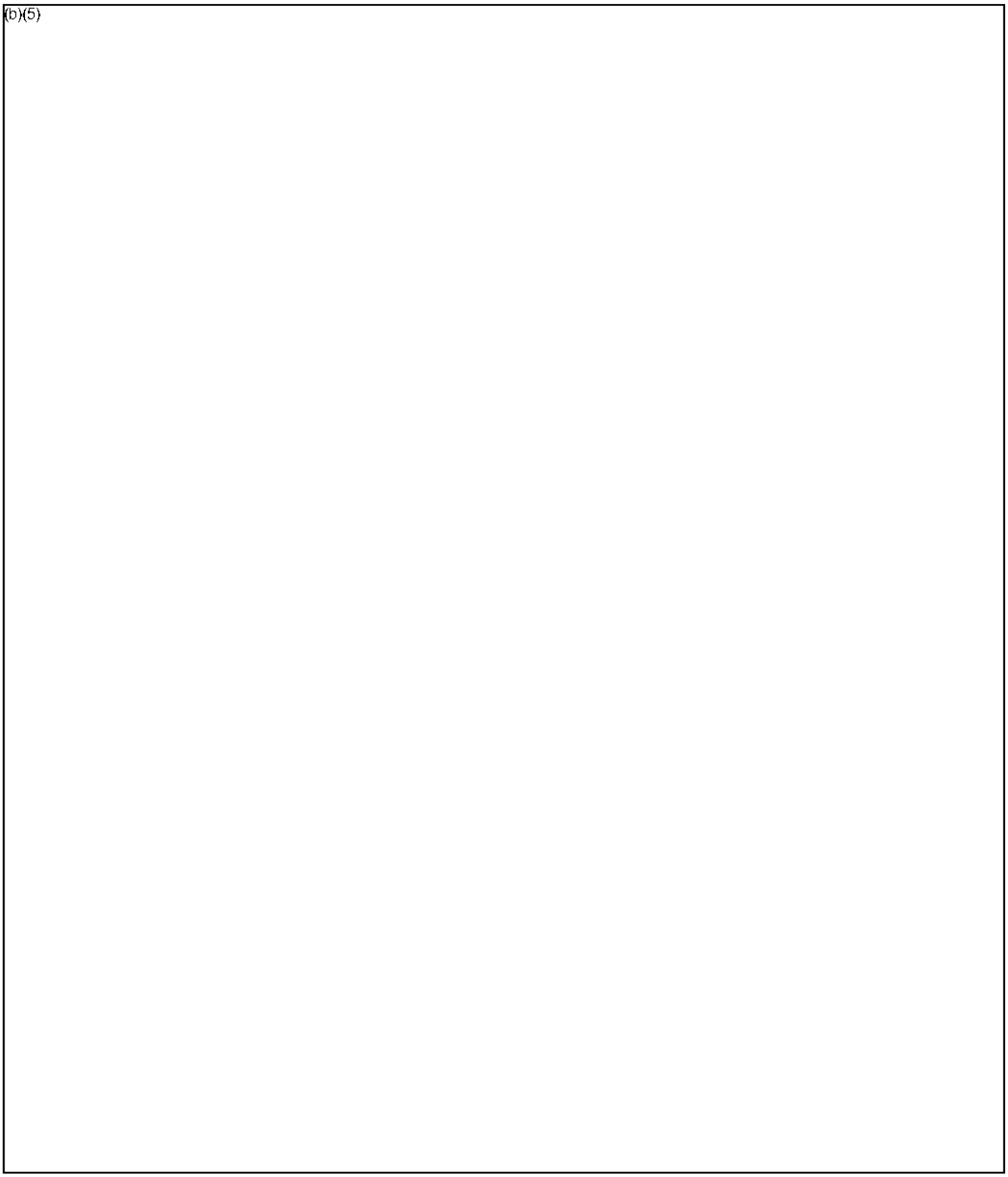
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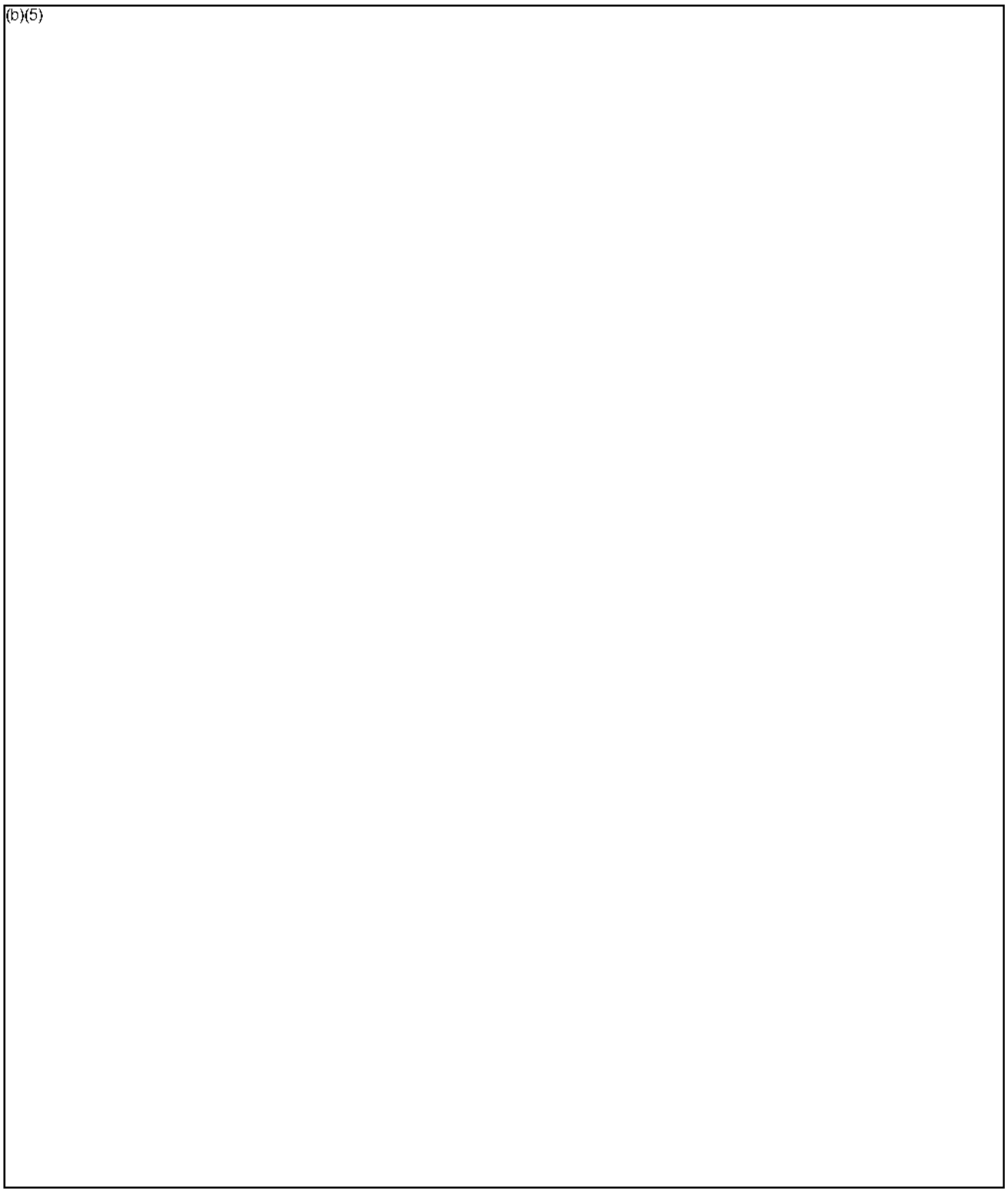
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From: (b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) SUS (b)(6)

To: (b) (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-(b)(6) (b)(6)
Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f3e15a704cd4274bb9916d41a1923a9-Garcia, Art <Art.Garcia@HHS.GOV>

Subject: RE: MW Region - GAC complaints

Date: 2022/11/16 09:05:47

Priority: Normal

Type: Note

Thanks (b)(6) I've cancelled the meeting.

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Tuesday, November 15, 2022 5:12 PM
To: (b)(6) (b)(6) (HHS/OCR) (b)(6) Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) <Art.Garcia@HHS.GOV>
Subject: RE: MW Region - GAC complaints
Importance: High

Hi folks – (b)(5)
(b)(5)
(b)(5) Thank you, (b)(6)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

-----Original Appointment-----
From: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Tuesday, November 8, 2022 6:31 PM
To: (b)(6) (b)(6) (HHS/OCR); Mitchell, Steven M (HHS/OCR); Garcia, Art (HHS/OCR); (b) (b)(6) (b)(6) (HHS/OCR)
Subject: MW Region - GAC complaints
When: Wednesday, November 16, 2022 10:00 AM-10:45 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

To discuss the following cases:

Insurance Cases:

(b)(5)

Medicaid Cases:

(b)(5)

(b)(5)

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2022 WL 17788148
United States District Court, W.D. Washington, at Tacoma.

C. P., BY AND THROUGH his parents, Patricia PRITCHARD and Nolle Pritchard, individually and on behalf of others similarly situated; and Patricia Pritchard, Plaintiff,
v.
BLUE CROSS BLUE SHIELD OF ILLINOIS, Defendant.

CASE NO. 3:20-cv-06145-RJB
|
Signed December 19, 2022

Attorneys and Law Firms

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Gwendolyn C. Payton, John R. Neeleman, Kilpatrick Townsend & Stockton LLP, Seattle, WA, Stephanie Bedard, Pro Hac Vice, Kilpatrick Townsend & Stockton LLP, Atlanta, GA, for Defendant.

ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

ROBERT J. BRYAN, United States District Judge

***1** This matter comes before the Court on the Defendant Blue Cross Blue Shield of Illinois' ("Blue Cross") Motion for Summary Judgment (Dkt. 87), and the Plaintiffs' Cross Motion for Summary Judgment (Dkt. 96), and Plaintiffs' motion to strike (Dkt. 126). The Court has considered the pleadings filed in support of and in opposition to the motions, oral argument heard on 12 December 2022, and the file herein.

In this case, Plaintiffs C.P., a transgender male, and his mother, Patricia Pritchard, claim that Blue Cross violated the anti-discrimination provision of the Affordable Care Act ("ACA"), 42 U.S.C. § 18116, when it administered discriminatory exclusions of gender-affirming care in a self-funded health care plans governed by the Employee Retirement Income Security Act of 1974 ("ERISA"). Dkt. 1. The Plaintiffs' motion to certify a class of similarly situated people was granted on November 9, 2022 (Dkt. 113) and amended on December 12, 2022 (Dkt. 143).

Blue Cross moves for summary judgment on Plaintiffs C.P. and Ms. Pritchard's claims. Dkt. 87. Plaintiffs C.P. and Ms. Pritchard cross move for summary judgment on their claims as well as the class claims. Dkt. 96. For the reasons provided below, Blue Cross's Motion for Summary Judgment (Dkt. 87) should be denied and Plaintiffs' Motion for Summary Judgment (Dkt. 96) and motion to strike (Dkt. 126) should be granted.

I. RELEVANT FACTS, PROCEDURAL HISTORY, AND STATUTORY BACKGROUND

A. FACTS

Named Plaintiffs are C.P., a boy of seventeen, and his mother, Ms. Pritchard. Dkt. 38. C.P. is a transgender male, which means that he has a male gender identity even though the sex assigned to him at birth was female. *Id.* C.P. has been living as a male since around 2015. Dkt. 94-1 at 135.

Ms. Pritchard receives health care coverage through her employer under the Catholic Health Initiatives ("CHI") Medical Plan ("the Plan") and C.P. is enrolled in that Plan as her dependent. Dkts. 81; 97-12 at 8. The Plan is "self-funded" - Ms. Pritchard's employer directly assumes financial responsibility for employees and their dependents' health care costs. Dkt. 88-1 at 11.

Defendant, Blue Cross, acts as the third-party claims administrator for the Plan. Dkt. 85-10. As a third-party administrator, it "assemble[s] a network of providers, process[es] claims, and handle[s] provider billing." Dkt. 88-1 at 11. Blue Cross is a division of Health Care Services

Corporation and is one of the largest administrators of insured and self-funded health plans in the nation. *Id.* at 206. It does not receive Federal financial assistance for its administration of self-funded plans, but does receives Federal financial assistance for other of its "products, such as Medicare supplemental coverage, Medicaid, Medicare Advantage and Prescription Drug insurance coverage, and Medicare/Medicaid dual eligibility." *Id.*

C.P. has gender dysphoria. Dkts. 38; 97-3 at 2. Gender dysphoria is a feeling of clinically significant stress and discomfort that can result from being transgender, or, more specifically, from having an incongruence between one's gender identity and the sex assigned to that person at birth. Dkt. 38. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition recognizes gender dysphoria as a medical condition that can be extremely serious, resulting in anxiety, depression, or even death. Dkt. 38 at 6.

***2** C.P. sought coverage for his first Vantas Implant (hormone therapy) in 2016. Dkt. 94-1 at 139. Blue Cross initially approved the treatment but later informed C.P.'s mother that it had made a mistake; it stated that the treatment was not covered under the Plan. Dkt. 94-1 at 137. Blue Cross paid for the treatment however, but indicated that later claims would be denied. *Id.* at 139. A few years later, in 2019, C.P. filed a claim for a second Vantas Implant and for chest reconstruction surgery; his claim was denied by Blue Cross because "[t]ransgender services [were] not covered under the terms of the Plan." *Id.*; 88-1 at 197; 94-3 at 2-10.

The relevant exclusionary language in the Plan in 2019 provided: "Transgender Reassignment Surgery Not Covered: Benefits shall not be provided for treatment, drugs, therapy, counseling services and supplies for, or leading to, gender reassigument surgery" ("Exclusion"). Dkt. 88-1 at 120. The Plan generally covers care for hormone treatments, mastectomies and chest reconstruction if that care is considered medically necessary for diagnosis other than for gender affirming care (like for breast cancer). Dkt. 85-8 at 12-13. The condition that triggers Blue Cross to apply the Exclusion is the diagnosis of gender dysphoria. *Id.* at 14.

After his claim was denied, C.P. received treatment – Ms. Pritchard paid $12,122.50 for the uncovered chest surgery and Vantas Implant. Dkt. 88-1 at 299.

B. PROCEDURAL HISTORY

Plaintiffs, including the class, bring a claims for violation of the antidiscrimination provision of the ACA. Dkt. 38. This provision is referred to in the case law and HHS regulations as "Section 1557" (although codified as 42 U.S.C. § 18116(a)), and this order will refer to it in the same manner. All Plaintiffs seek a declaration that Blue Cross violated Plaintiffs' rights under Section 1557 when it administered the Exclusion and other similar exclusions in other plans. Dkt. 38 at 21. They seek an order enjoining Blue Cross from "administering or enforcing health benefit plans that exclude coverage for gender-affirming health care, including applying or enforcing the Plan's Exclusion of services 'for, or leading to, gender reassignment surgery,' and other similar exclusions ... during the class period, now and in the future." *Id.* at 21-22. The Plaintiffs seek an order requiring Blue Cross to reprocess, "and when medically necessary and meeting the other terms and conditions under the relevant plans, provide coverage (payment) for all denied pre-authorizations and denied claims" that were based solely upon exclusions for gender affirming care. *Id.* at 22.

Ms. Pritchard brings a claim for financial harm. *Id.* C.P. and Ms. Pritchard bring claims for emotional distress damages, attorneys' fees, costs and expenses. *Id.*

In the December 12, 2022 Amended Order Certifying the Class, the class was certified as:

> All individuals who:
>
> (1) have been, are, or will be participants or beneficiaries in an ERISA self-funded "group health plan" (as defined in 29 U.S.C. § 1167(1)) administered by [Blue Cross] during the Class Period and that contains a categorical exclusion of some or all Gender-Affirming Health Care services; and
>
> (2) were, are, or will be denied pre-authorization or coverage of treatment with excluded Gender Affirming Health Care services

DEFINITIONS:

> "Class Period" means November 23, 2016 through the termination of the litigation.
>
> "Gender-Affirming Health Care" means any health care service—physical, mental, or otherwise—administered or prescribed for the treatment of gender dysphoria; related diagnoses such as gender identity disorder, gender incongruence, or transsexualism; or gender transition. This includes but is not limited to the administration of puberty delaying medication (such as gonadotropin-releasing hormone (GnRH) analogues); exogenous endocrine agents to induce feminizing or masculinizing changes ("hormone replacement therapy"); gender-affirming or "sex-reassignment" surgery or procedures; and other medical services or preventative medical care provided to treat gender dysphoria and/or related diagnoses, as outlined in World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version (2012).

***3** The class asserts claims that Blue Cross Blue Shield of Illinois violated the anti-discrimination provision of the Affordable Care Act, 42 U.S.C. § 18116, when it administered discriminatory exclusions of gender-affirming care in a self-funded health care plans governed by the Employee Retirement Income Security Act of 1974.

The class seeks declaratory relief. They seek an order enjoining Blue Cross Blue Shield of Illinois from administering or enforcing health benefit plans that exclude coverage for gender-affirming health care, including applying or enforcing the plans' exclusions of services for, or leading to, gender reassignment surgery,' and other similar exclusions during the class period, now and in the future. The class seeks an order requiring Blue Cross Blue Shield of Illinois to reprocess denied pre-authorizations and claims for gender affirming care under the relevant self-funded health care plans without applying the discriminatory exclusions, and when medically necessary and meeting the other terms and conditions of the relevant plans, provide coverage (payment) for those denied pre-authorizations and claims that were based solely on exclusions for gender affirming care.

Blue Cross Blue Shield of Illinois raises several defenses, including that the anti-discrimination provision of the Affordable Care Act, 42 U.S.C. § 18116 does not apply to it, and even if it did, its third-party administration of the exclusions was not discriminatory. Blue Cross Blue Shield also contends that it is protected by the Religious Freedom Restoration Act.

Dkt. 143.

C. SECTION 1557, REGULATIONS AND LITIGATION BACKGROUND

This case takes place in the midst of sharply divided regulatory and litigation background. A quick review of the statute, the U.S. Department of Health and Human Services ("HHS") regulations, and related litigation is helpful in understanding the parties' positions.

The starting point is the text of the antidiscrimination provision of the ACA. Again, this provision is referred to in the case law and HHS regulations as "Section 1557" (although codified as 42 U.S.C. § 18116(a)). Section 1557 provides:

> "[A]n individual shall not, on the ground prohibited under ... title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.... The enforcement mechanisms provided for and available under such ... title IX ... shall apply for purposes of violations of this subsection."

42 U.S.C. § 18116(a). Title IX provides that "[n]o person ... shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681.

1. 2016 Regulations

After passage of the ACA in 2010, HHS proposed, and then finalized, Section 1557 regulations on May 18, 2016 ("2016 Rule"). Non-Discrimination in Health Programs and Activities, 81 FR 31,375. While this order substantially complies with the 2016 Rule, a nationw injunction banning HHS from enforcing it is in place. *Franciscan All., Inc. v. Burwell*, 227 F.Supp.3d 660 (N.D. Tex. 2016) *as affirmed Franciscan All., Inc. v. Burwell*, 47 F.4th 368 (2022). Accordingly, the 2016 Rule does not impact this case.

2. 2020 Regulations

***4** Meanwhile, on June 12, 2020, under the Trump administration, HHS finalized regulations (2020 Rule), effective on August 18, 2020, that rescinded significant portions of the 2016 Rule. Non-Discrimination in Health Programs and Activities, 85 FR 37,178. Various cases have been filed to prohibit enforcement of the 2020 Rule and to reinstate portions of the 2016 Rule, in particular, challenging the definition of discrimination "on the basis of sex." *See e.g. Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, Case No. 1:20-cv-01630, 2020 WL 3444030 (D.D.C. June 22, 2020); *Walker v. Azar*, Case No. 1:20-cv-02834 (E.D.N.Y. June 26, 2020); *Boston All. of Gay, Lesbian, Bisexual & Transgender Youth v. U.S. Dep't of Health & Human Servs.*, Case No. 1:20-cv-11297, 2020 WL 3891426 (D. Mass. July 9, 2020). Injunctions prohibiting HHS from enforcing certain portions of the 2020 Rule's repeal of the 2016 Rule's definition of "on the basis of sex" are now in effect. *See Id.* This order does not comply with the 2020 Rule as provided in Section II. D. below.

3. 2021 HHS Notification and Proposed 2022 Regulations

On May 10, 2021, under the Biden administration, HHS issued a notice stating that it would interpret Section 1557's prohibition on sex discrimination to include discrimination on the basis of gender identity consistent with the U.S. Supreme Court's holding in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020). 86 FR 27,984. On August 4, 2022, HHS published a Proposed Rule that proposes repealing large portions of the 2020 Rule ("Proposed 2022 Rule"). Non-Discrimination in Health Programs and Activities, 87 FR 47,824. While the Proposed 2022 Rule is not yet adopted, this order is substantially consistent with it - but the Proposed 2022 Rule does not impact this case.

II. DISCUSSION

A. MOTION TO STRIKE

The Plaintiffs move to strike a newspaper article from the New York Times that was submitted by Blue Cross. Dkt. 126. "Generally, newspaper articles and television programs are considered hearsay under Rule 801(c) when offered for the truth of the matter asserted." *See Green v. Baca*, 226 F.R.D. 624, 637 (C.D. Cal. 2005). No exception to the hearsay rule was offered. The Plaintiffs' motion (Dkt. 126) should be granted.

B. SUMMARY JUDGMENT STANDARD

Summary judgment is proper only if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party is entitled to judgment as a matter of law when the nonmoving party fails to make a sufficient showing on an essential element of a claim in the case on which the nonmoving party has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1985). There is no genuine issue of fact for trial where the record, taken as a whole, could not lead a rational trier of fact to find for the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (nonmoving party must present specific, significant probative evidence, not simply "some metaphysical doubt."). Conversely, a genuine dispute over a material fact exists if there is sufficient evidence supporting the claimed factual dispute, requiring a judge or jury to resolve the differing versions of the truth. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986); *T.W. Elec. Serv. Inc. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

The determination of the existence of a material fact is often a close question. The court must consider the substantive evidentiary burden that the nonmoving party must meet at

trial, which is a preponderance of the evidence in most civil cases. *Anderson*, 477 U.S. at 254; *T.W. Elect.*, 809 F.2d at 630. The court must resolve any factual issues of controversy in favor of the nonmoving party only when the facts specifically attested by that party contradict facts specifically attested by the moving party. The nonmoving party may not merely state that it will discredit the moving party's evidence at trial, in the hopes that evidence can be developed at trial to support the claim. *T.W. Elect.*, 809 F.2d at 630 (relying on *Anderson*, 477 U.S. at 255). Conclusory, non-specific statements in affidavits are not sufficient, and "missing facts" will not be "presumed." *Lujan v. Nat'l Wildlife Fed.*, 497 U.S. 871, 888–89 (1990).

C. PLAINTIFFS' SECTION 1557 CLAIM

***5** The Plaintiffs' motion and Blue Cross's response raise issues of law. There are no serious fact issues before the Court.

Again, Section 1557 of the ACA provides:

> "[A]n individual shall not, on the ground prohibited under ... title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) ... be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.... The enforcement mechanisms provided for and available under such ... title IX ... shall apply for purposes of violations of this subsection."

42 U.S.C. § 18116(a). Title IX prohibits discrimination "on the basis of sex" in education. 20 U.S.C. § 1681.

To make a claim for sex discrimination under Title IX and by extension, under 1557 of the ACA, the Plaintiffs must show that: (1) Blue Cross operates "a health program or activity, any part of which is receiving Federal financial assistance;" (2) the Plaintiffs were excluded from participation in, denied the benefits of, or subjected to discrimination in the provision of that "health program or activity;" and (3) the latter occurred on the basis of sex. *See Schwake v. Ariz. Bd. of Regents*, 967 F.3d 940, 946 (9th Cir. 2020).

1. Provision of Any Health Program or Activity, Any Part of Which Receives Federal Financial Assistance

Under the plain language of Section 1557, Blue Cross's third party administrator activities constitute the operation of a "health program or activity." The phrase "any health program or activity," is not defined in the ACA but it is clearly broader in scope than only the provision of healthcare. The phrase is further defined in a clause in Section 1557's text: "including ... contracts of insurance." The plain language of Section 1557 indicates that a health insurance contract and the administration of a health insurance contract is a "health program or activity." *Schmitt v. Kaiser Found. Health Plan of Washington*, 965 F.3d 945, 951 (9th Cir. 2020)(holding that Section 1557 prohibits discrimination in the health care system which includes discrimination in health insurance contracts); *Kadel v. Folwell*, 2022 U.S. Dist. LEXIS 218104 *9 (M.D. N.C. Dec. 5, 2022).[1]

Further, while Blue Cross does not receive Federal financial assistance for its administration of self-funded plans, it receives Federal financial assistance for some of its other products including "Medicare supplemental coverage, Medicaid, Medicare Advantage and Prescription Drug insurance coverage, and Medicare/Medicaid dual eligibility." Dkt. 88-1 at 206. Section 1557's phrase "any health program or activity any part of which is receiving Federal financial assistance" plainly includes "all the operations of a business" principally engaged in providing health programs and activities. *T.S. by & through T.M.S. v. Heart of CarDon, LLC*, 43 F.4th 737, 743 (7th Cir. 2022); *Kadel* at *9-10.

***6** Accordingly, Blue Cross's third party administration activities are "health program[s] or activit[ies], ... part of which receives Federal financial assistance." The Plaintiffs are entitled to summary judgment on this element of their claim and Blue Cross's motion for summary judgment on this element should be denied.

2. Plaintiffs were Excluded from, Denied the Benefits of, or Subjected to Discrimination in the Provision of a "Health Program or Activity"

Parties do not dispute that Blue Cross denied C.P.'s claim for gender affirming surgery or that C.P.'s mother was "denied the benefits" her employer's sponsored health plan. Parties do not dispute that Blue Cross denied other class members gender affirming care under exclusions in other self-funded plans. This element is met. The Plaintiffs are entitled to summary judgment on this element and Blue Cross's motion on this element should be denied.

3. Discrimination Occurred on Basis of Sex

Section 1557 forbids sex discrimination based on transgender status. *Doe v. Snyder,* 28 F.4th 103, 114 (9th Cir. 2022). This holding from the Ninth Circuit is consistent with the Supreme Court's determination in *Bostock v. Clayton County, Georgia,* 140 S.Ct. 1731, (2020) which held that firing a person based on their transgender status is sex discrimination.

In its administration of the Plan, the trigger for application of the Exclusion and a denial of coverage was a diagnosis of "gender dysphoria" for C.P. and the other class members. Dkt. 85-8. "Gender dysphoria cannot be understood without referencing sex or a synonym." *See Kadel v. Fol*well, 2022 WL 11166311, at *4 (M.D.N.C. Oct. 19, 2022)(*internal quotation marks and citations omitted*). "[A] person cannot suffer from geoder dysphoria without identifying as transgeoder." *Fain v. Crouch*, 2022 WL 3051015, at 6 (S.D. West Virginia August 2, 2022). Accordingly, the administration of the Exclusion based on transgender status was discrimination "on the basis sex" contrary to Section 1557. The Plaintiffs' motion for summary judgment on this element should be granted and Blue Cross's cross motion for summary judgment on this element denied.

4. Conclusion on Plaintiffs' Section 1557 Claim

Blue Cross, as a third party administrator is engaged in a "health care program or activity" and receives Federal financial assistance. It is subject to Section 1557. Its denial of benefits under the Plaintiffs' plans based on their transgender status was discrimination on the basis of sex. Each of the elements of the claim are met and the Plaintiffs are entitled to summary judgment unless one or more of Blue Cross's defenses apply.

D. BLUE CROSS'S DEFENSES

Blue Cross contends that it is entitled to summary judgment based on various defenses. Each will be addressed.

1. Covered Entity Defense – "Health Program or Activity"

Blue Cross points to the 2020 Rule and argues that the Court should give HHS deference to its interpretation of Section 1557 in the 2020 Rule based on the deference doctrine announced in *Chevron, USA Inc. v. NRDC, Inc.*, 467 U.S. 837 (2014). Dkt. 87. It contends that Section 1557 does not apply to its third party administrator activities because those actions are not "healthcare activities" and because it does not receive any federal financial assistance for its third party administrator activities. Dkt. 87 at 18.

***7** As it relates to Blue Cross's argument here, the 2020 Rule provides that "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." 85 FR 37178, 37244-45; codified at 45 C.F.R. § 92.3. The 2020 Rule further provided that:

> As used in this part, "health program or activity" encompasses all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance as described in paragraph (a)(1) of this section. For any entity not principally engaged in the business of providing healthcare, the requirements applicable to a "health program or activity" under this part shall apply to such entity's operations only to the extent any such operation receives Federal financial assistance as described in paragraph (a)(1) of this section.

Id.

The HHS 2020 Rule, arguably in effect, is not entitled to deference in this case. In considering whether to accord an

agency's interpretation of a statute deference under *Chevron*, a two-part analysis is required. *Chevron* at 842. First, "is the question whether Congress has directly spoken to the precise question at issue." *Id.* If the intent of Congress is clear, the "unambiguously expressed intent of Congress" must be given effect by both the agency and the courts. *Id.* at 843. "If a statute is ambiguous, and if the implementing agency's construction is reasonable, *Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation." *Arizona v. Tohono O'odham Nation*, 818 F.3d 549, 556 (9th Cir. 2016).

In making the threshold determination under *Chevron* step one, whether statutory language is ambiguous or not "is determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole." *Corrigan v. Haaland*, 12 F.4th 901, 907 (9th Cir. 2021)(*cert. denied*, 211 L. Ed. 2d 607, 142 S. Ct. 901 (2022)). "[T]he starting point is the statutory text." *Tohono* at 556. As stated above, the plain language of the text includes insurance contracts and their administration as "health program[s] or activit[ies]."

Moreover, "[i]n making the threshold determination under *Chevron* step one, a reviewing court should not confine itself to examining a particular statutory provision in isolation. Rather, the meaning – or ambiguity – of certain words or phrases may only become evident when placed in context." *Corrigan* at 910. Further, "[i]n interpreting a statute, a court must also account for that statute's history and purpose." *Corrigan* at 912. "Congress enacted the ACA to increase the number of Americans covered by health insurance and decrease the costs of health care." *Schmitt* at 949. It enacted Section 1557 to prohibit discrimination in the health care system to increase access to services and insurance coverage. *Id.* at 951. "By extending nondiscrimination protections to individuals under 'any health program or activity,' Congress clearly intended to prohibit discrimination by any entity acting within the health system." *See Fain v. Crouch*, 545 F.Supp.3d 338, 342 (S.D.W. Va. 2021). Logically, this includes third party administrators of health insurance plans. To hold otherwise would thwart Congress's intent to prohibit discrimination in the provision of "health programs and activities." Clearly, application of the 2020 Rule is contrary to the statutory law, and the rule appears to be arbitrary, capricious and contrary to law. The statute, not the 2020 Rule, must be followed here.

2. Covered Entity Defense – Federal Financial Assistance

***8** Blue Cross argues that even if its third party administration of the Plan is providing a "health program or activity," it does not receive Federal financial assistance for that activity, so it is not covered under Section 1557. Blue Cross's argument is unpersuasive. "When the ACA was enacted in 2010, 'program or activity' was already a term of art with a clear meaning and a broad scope established by the provisions cited in Section 1557 that ban discrimination in connection with Federal financial assistance." *Heart of CarDon* at 742. The words "program or activity" must be read "in accordance with the prevailing understanding the term had under the law that Congress relied on when codifying section 1557." *Id.* Section 504 of the Rehabilitation Act, which is also incorporated into Section 1557, "defines 'program or activity' as 'all of the operations of' - among other entities - 'an entire corporation, partnership, or other private organization, ... which is principally engaged in the business of providing ... health care ... any part of which is extended Federal financial assistance.' " *Id.* (*citing* 29 U.S.C. § 794(b)(*emphasis added*)). "The meaning of 'program or activity' in Section 1557's other antidiscrimination provisions is materially identical." *Id.* (*citing* 20 U.S.C. § 1687; 42 U.S.C. § 6107(4); 42 U.S.C. § 2000d-4a). Section 1557's phrase "health programs or activities" plainly includes "all the operations" of Blue Cross including its involvement in "contracts of insurance." *Id.* at 743; *Kadel* at 10.

Blue Cross's motion for summary judgment based on the defense that it is not a covered entity should be denied. It operates "health program[s] or activit[ies]" and receives Federal financial assistance and so Section 1557 applies.

3. Plan Design Defense

Blue Cross maintains that it is entitled to summary judgment because it did not design the allegedly discriminatory Exclusion applicable to C.P. Dkt. 87. It points to comments to the 2016 Rules, 2020 Rules and 2022 Proposed Rules and

maintains that under each iteration of these rules, it is "only where the discriminatory terms of the group health plan originated with the third party administrator rather than with the plan sponsor [that] the third party administrator could be liable for the discriminatory design feature under Section 1557." Dkt. 87 at 10. There is no *Chevron* deference owed here to the various iterations of the rules or proposed rules because the statutory text is clear as is Congressional intent – there is no exclusion for third party administrators who did not draft the exclusion at issue.

Blue Cross contends that it is entitled to summary judgment because it is obligated under ERISA's command at 29 U.S.C. § 1104(a)(1)(D) to administer the Exclusion as written. Dkt. 87. Under ERISA, benefit plan decisions are required to be made in "accordance with the documents and instruments governing the plan." 29 U.S.C. § 1104(a)(1)(D). This provision of ERISA does not end the inquiry.

The Plaintiffs properly contend that whether Blue Cross provided the Exclusionary language or not is immaterial because Blue Cross has an independent duty to comply with Section 1557. Dkt. 96. The Plaintiffs point to ERISA's 29 U.S.C. § 1144(d) and argue that ERISA does not supplant Section 1557's antidiscrimination provisions. *Id.*

ERISA's Section 1144(d) provides that "[n]othing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States ... or any rule or regulation issued under any such law." Accordingly, ERISA expressly provides that it is not to be construed to impair laws like Section 1557. Harmonizing these provisions of ERISA, a third party administrator must make decisions in "accordance with the documents and instruments governing the plan," 29 U.S.C. § 1104(a)(1)(D), but that this requirement must not be construed to "invalidate or impair" Section 1557, 29 U.S.C. § 1144(d).

Blue Cross's third-party administration of the Plan and other self-funded plans are "health programs or activities" and it receives "Federal financial assistance" and so is covered by Section 1557. ERISA specifically provides that its requirements are not to be construed to invalidate or impair laws like Section 1557 and so ERISA's requirement that Blue Cross follow the Exclusion's language is no defense. Section 1557 supplements the ERISA requirements.

***9** Even if Blue Cross did not have an independent duty to comply with Section 1557, which it does, third party administrators can be liable under Section 1557 based on discriminatory terms in a self-funded plan even if the third party administrator provided the plan document "notwithstanding the fact that the [plan sponsor] subsequently adopted the plan and maintained control over its terms." *See, e.g.,* *Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017).

There are issues of fact as to whether the Plan design originated with Blue Cross. Blue Cross points to testimony that CHI drafted the gender reassignment surgery exclusion in the Plan. Dkt. 88-1 at 3. Plaintiffs points to the testimony of Laura Malec, another Blue Cross 30(b)(6) witness, who testified that of the 398 plans at issue, 378 (including the CHI Plan) contain the same or similar exclusionary language that is the "standard language" that Blue Cross "offers to employers when they want a gender affirming care exclusion." Dkt. 85-8 at 7. There are issues of fact as to whether the Exclusion's language originated from Blue Cross, but those issues need not be decided to justify denial of Blue Cross's motion for summary judgment on this issue.

4. Medical Consensus Defense

Blue Cross argues that the Exclusion does not discriminate "on the basis of sex" because "there is no medical consensus regarding gender-affirming treatment." Dkt. 87. Blue Cross's argument is unavailing. It did not base the decision to deny care on medical necessity but on C.P.'s and the other class members' transgender status. Further, it concedes that under its own medical necessity policy, C.P.'s request for hormone therapy and chest reconstruction would be considered "medically necessary." Dkt. 85 at 23, 25-26. Whether there is medical consensus about transgender care in general is immaterial as to whether Blue Cross discriminated against the Plaintiffs based on sex.

5. Religious Freedom Restoration Act

Blue Cross argues that it is entitled to summary judgment because it is protected by the Religious Freedom Restoration Act ("RFRA"). Dkt. 87. It maintains that RFRA exempts CHI's Plan based on CHI's sincerely-held religious beliefs. *Id.* Blue Cross argues that it does not violate Section 1557 if it administers an exempt plan. *Id.*

Under RFRA, "[g]overnment shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" unless the Government "demonstrates that application of the burden to the person – (1) is in furtherance of a compelling government interest; and (2) is the least restrictive means of furthering that compelling interest." 42 U.S.C. § 2000bb-1(a), (b). RFRA continues, "[a] person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." 42 U.S.C. § 2000bb-1(c)(*emphasis added*).

Blue Cross's motion for summary judgment based on RFRA should be denied. RFRA provides relief against the government and does not apply to disputes between private parties. *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 839 (9th Cir. 1999); *See Listecki v. Off. Comm. of Unsecured Creditors*, 780 F.3d 731, 736 (7th Cir. 2015)("Based on RFRA's plain language [and] its legislative history ... RFRA is not applicable in cases where the government is not a party"). The government is not a party here.

***10** Blue Cross's citation to *Burwell v. Hobby Lobby*, 573 U.S. 682 (2014) and other similar cases are unavailing. *Hobby Lobby* involved a challenge by employers to HHS rules requiring insurance coverage for birth control despite religious objection by employer. The government was a party in all of these cases – for example, Burwell was the Secretary of HHS. Blue Cross also acknowledges that it is not an entity with a "sincerely-held religious belief" (Dkt. 118).

Blue Cross argued at oral argument that while it is not asserting a claim or defense based on RFRA, Section 1557 and RFRA must be read together. While it is not wholly clear how that is to occur generally, in this case RFRA does not apply, Section 1557 does. The Court need not reach Blue Cross's arguments regarding its standing to assert CHI's religiously held beliefs.

There are many approaches and cases covering religious – and, perhaps, other, – reasons to avoid statutory or other legal obligations under the First Amendment to the U.S. Constitution (particularly when the government is involved). It is appropriate to consider such matters in protecting the U.S. Constitution's First Amendment establishment and free enterprise clauses. It cannot be, however, that Blue Cross can trump statutory anti-discrimination law with a potential religious protection claim from a co-contractor, without more, which allegedly frees that co-contractor and Blue Cross from obedience to the law. The law presented here does not clothe Blue Cross with the factual or legal basis to referee such claims of exemption from Section 1557. Perhaps, somehow, such an exemption may be legally reached, consistent with the First Amendment or other law, but the facts here do not support such a conclusion. Blue Cross is left with the obligation to obey Section 1557 as it stands.

6. Conclusion on Defenses

Blue Cross is not entitled to summary judgment on any of its defenses. None of its defenses apply.

E. BLUE CROSS'S MOTION FOR SUMMARY JUDGMENT ON NAMED PLAINTIFFS' CLAIM FOR EMOTIONAL DISTRESS DAMAGES

Blue Cross moves for summary judgment on Plaintiffs C.P. and Patricia Pritchard's emotional distress damages claim. Dkt. 87. That portion of the motion should be granted. Emotional distress damages are not recoverable in private actions to enforce the antidiscrimination provisions of the ACA. *Cummings v. Premier Rehab Keller, P.L.L.C.*, 142 S. Ct. 1562 (2022).

F. CONCLUSION

The conclusions herein are based on the preponderance of the evidence with no material facts in issue. This order addresses Blue Cross' duties under Section 1557 only, and

the Court is mindful that in reaching its conclusion here, Blue Cross was in the legal position of determining how to deal with the conflict between Section 1557, outlawing discrimination, and ERISA's command at 29 U.S.C. § 1104 (a)(1)(D) to administer plans, including discrimination, as written. The Court is satisfied that ERISA's command at 29 U.S.C. § 1104 (a)(1)(D) to administer the exclusions as written is subservient to Section 1557, outlawing discrimination, which is dominate. That finding leads to the ultimate conclusion of these summary judgment motions: Blue Cross, as a third party administrator, is a covered entity under Section 1557 and has discriminated against the Plaintiffs and the class Plaintiffs by denying them services for gender affirming care under individual and class Plaintiffs' insurance policies.

***11** The appropriate relief due, if any, will be addressed by motion practice, or at trial.

III. ORDER

Therefore, it is hereby **ORDERED** that:

- The Plaintiffs' motion to strike (Dkt. 126) **IS GRANTED**;
- Defendant Blue Cross's Motion for Summary Judgment (Dkt. 87) **IS GRANTED** as to the Plaintiffs' emotional distress claims and **DENIED** in all other respects; and
- The Plaintiffs' Cross Motion for Summary Judgment (Dkt. 96) **IS GRANTED** to the extent listed herein.

All Citations

Slip Copy, 2022 WL 17788148, 2022 Employee Benefits Cas. 452,660

Footnotes

[1] *Kadel* mirrors many of the thoughts in this order.

Date: 2022/02/16 09:47:29
Priority: Normal
Type: Note

Questions for melanie:

(b)(5)

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Sent Date: 2022/02/16 08:23:58
Delivered Date: 2022/02/16 09:47:29
Message Flags: Unread Unsent

To: Roman, David (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user5d5a5775 <David.Roman@hhs.gov>
Subject: RE: GAC Case Against Maryland Medicaid MCO
Date: 2022/06/14 09:27:34
Priority: Normal
Type: Note

Hi David,

(b)(6); (b)(7)(C)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Phone: (b)(6) (b)(6)
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From: Roman, David (OS/OCR) <David.Roman@hhs.gov>
Sent: Monday, June 13, 2022 4:25 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: FW: GAC Case Against Maryland Medicaid MCO

Hi (b)(6)

(b)(6); (b)(7)(C)

Best, David

From: Welch, Alisha (HHS/OCR) <Alisha.Welch@hhs.gov>
Sent: Thursday, June 9, 2022 12:39 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR) <David.Roman@hhs.gov>
Cc: Rahn Ballay, Jamie (HHS/OCR) <Jamie.Rahn@hhs.gov>; Smith, Marisa (HHS/OCR) <Marisa.Smith@HHS.GOV>
Subject: RE: GAC Case Against Maryland Medicaid MCO

Thanks. Will do!

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Thursday, June 9, 2022 3:39 PM
To: Welch, Alisha (HHS/OCR) <Alisha.Welch@hhs.gov>; Roman, David (OS/OCR) <David.Roman@hhs.gov>

Cc: Rahn Ballay, Jamie (HHS/OCR) <Jamie.Rahn@hhs.gov>; Smith, Marisa (HHS/OCR) <Marisa.Smith@HHS.GOV>
Subject: RE: GAC Case Against Maryland Medicaid MCO

Thanks, Alisha!

(b)(6); (b)(7)(C)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Welch, Alisha (HHS/OCR) <Alisha.Welch@hhs.gov>
Sent: Thursday, June 9, 2022 3:25 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Roman, David (OS/OCR) <David.Roman@hhs.gov>
Cc: Rahn Ballay, Jamie (HHS/OCR) <Jamie.Rahn@hhs.gov>; Smith, Marisa (HHS/OCR) <Marisa.Smith@HHS.GOV>
Subject: GAC Case Against Maryland Medicaid MCO

Hi (b)(6) and David:

I hope all is well with you (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

We would be happy to set up a time to discuss this complaint further

Thanks!

Alisha Welch
Acting Deputy Regional Manager
DHHS, Office for Civil Rights, Mid-Atlantic Region

801 Market Street, Suite 9300

Philadelphia, PA 19107

215-861-4439 (voice)

1-800-537-7697 (TTY)

215-861-4431 (fax)

Recipient:	Roman, David (OS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user5d5a5775 <David.Roman@hhs.gov>
Sent Date:	2022/06/14 09:28:01
Delivered Date:	2022/06/14 09:27:34
Message Flags:	Unread Unsent

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE FOR CIVIL RIGHTS (OCR)

Form Approved. OMB No. 0945-0002
Expiration Date: 11/30/2022

CIVIL RIGHTS & CONSCIENCE AND RELIGIOUS FREEDOM DISCRIMINATION COMPLAINT

YOUR FIRST NAME	YOUR LAST NAME
(b)(6); (b)(7)(C)	(b)(6); (b)(7)(C)

HOME PHONE (*Please include area code*)	WORK PHONE (*Please include area code*)
(b)(6); (b)(7)(C)	

STREET ADDRESS	CITY
(b)(6); (b)(7)(C)	(b)(6); (b)(7)(C)

STATE	ZIP	E-MAIL ADDRESS (*If available*)
(b)(6); (b)(7)(C)	(b)(6); (b)(7)(C)	(b)(6); (b)(7)(C)

Are you filing this complaint for someone else? ☐ Yes ☑ No

If Yes, whose civil or conscience and religious rights you believe were violated?

FIRST NAME	LAST NAME

I believe that I have been (or someone else has been) discriminated against on the basis of:

(b)(6); (b)(7)(C)

Who or what agency or organization do you believe discriminated against you (or someone else)?

PERSON / AGENCY / ORGANIZATION

Maryland Department of Health and it's agent Amerigroup Maryland, Inc., a Managed Care Organization

STREET ADDRESS	CITY
7550 Teague Road	Hanover

STATE	ZIP	PHONE (*Please include area code*)
Maryland	21076	(410) 859-5800

When do you believe that the civil rights or conscience and religious freedom discrimination occurred?

LIST DATE(S)

March 25, 2021 through October 12, 2021 (Ongoing)

Describe briefly what happened. How and why do you believe that you have been (or someone else has been) discriminated against? Please be as specific as possible. (*Attach additional pages as needed*)

See attached documents. Please direct all communications through my Attorneys: Mackenzie Dadswell, Esq. and Phillip Westry, Esq., FreeState Justice, 2526 St. Paul St., Baltimore, MD 21218. Tel. (410-625-5429). Email: mdadswell@freestate-justice.org and pwestry@freestate-justice.org.

Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.

SIGNATURE	DATE (mm/dd/yyyy)
(b)(6); (b)(7)(C)	4/8/2022

Filing a complaint with OCR is voluntary. However, without the information requested above, OCR may be unable to proceed with your complaint. We collect this information under authority of Section 1557 of the Affordable Care Act, Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, Title II of the Americans with Disabilities Act and their implementing regulations. It is illegal for a recipient of Federal financial assistance from HHS to intimidate, threaten, coerce, discriminate or retaliate against you for filing a complaint or for taking any other action to enforce your rights under these Federal civil rights laws. OCR also collects information under authority of Section 1553 of the Affordable Care Act, the Church Amendments, the Coats-Snowe Amendment, the Weldon Amendment, the Religious Freedom Restoration Act, as well as other Federal civil rights, conscience protections and religious liberty statutes. It may also be illegal for a recipient of Federal financial assistance from HHS to intimidate, threaten, coerce, discriminate or retaliate against you for filing this complaint or for taking any other action to enforce your rights under these Federal laws. We will use the information you provide to determine if we have jurisdiction and, if so, how we will process your complaint. Information submitted on this form is treated confidentially and is protected under the provisions of the Privacy Act of 1974. Names or other identifying information about individuals are disclosed when it is necessary for investigation of possible discrimination, for internal systems operations, or for routine uses, which include disclosure of information outside the Department of Health and Human Services (HHS) for purposes associated with civil rights compliance and as permitted by law. You are not required to use this form. You also may write a letter or submit a complaint electronically with the same information. To submit an electronic complaint, go to OCR's web site at: www.hhs.gov/ocr/civilrights/conscienceandreligiousfreedom/complaints/index.html. To mail a complaint, please see page 2 of this form for the mailing address.

The remaining information on this form is optional. Failure to answer these voluntary questions will not affect OCR's decision to process your complaint.

Do you need special accommodations for OCR to communicate with you about this complaint? (*Check all that apply*)

☐ Braille ☐ Large Print ☐ Computer ☐ Electronic Mail ☐ TDD ☐ Other (Specify): _____

☐ Sign language interpreter (specify language): _____

☐ Foreign language interpreter (specify language): _____

If we cannot reach you directly, is there someone we can contact to help us reach you?

FIRST NAME	LAST NAME

HOME PHONE (*Please include area code*)	WORK PHONE (*Please include area code*)

STREET ADDRESS	CITY

STATE	ZIP	E-MAIL ADDRESS (*If available*)

Have you filed your complaint anywhere else? If so, please provide the following. (*Attach additional pages as needed*)

NAME(S) OF PERSON / AGENCY / ORGANIZATION / COURT

DATE(S) FILED	CASE NUMBER(S) (If known)

To help us better serve the public; please provide the following information for the person you believe was discriminated against (you or the person on whose behalf you are filing).

ETHNICITY (*select one*)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

RACE (*select one or more*)

☐ American Indian or Alaska Native ☐ Asian ☐ Native Hawaiian or Other Pacific Islander

☐ Black or African American ☐ White ☐ Other (specify): _____

PRIMARY LANGUAGE SPOKEN (if other than English): _____

How did you learn about the Office for Civil Rights?

☐ HHS Website /Internet Search ☐ Family / Friend /Associate ☐ Religious /Community Org ■ Lawyer /Legal Org ☐ Customer Resp Cntr ☐ Employer

☐ Fed /State/Local Gov ☐ Healthcare Provider /Health Plan ☐ Conference /OCR Brochure ☐ Other(*specify*): _____

To submit a complaint, please type or print, sign, and return completed complaint form package (including consent form) to the OCR Headquarters address below.

U.S. Department of Health and Human Services

Office for Civil Rights
Centralized Case Management Operations
200 Independence Ave., S.W.
Suite 515F, HHH Building
Washington, D.C. 20201
Customer Response Center: (800) 368-1019
Fax: (202) 619-3818
TDD: (800) 537-7697
Email: ocrmail@hhs.gov

Burden Statement

Public reporting burden for the collection of information on this complaint form is estimated to average 45 minutes per response, including the time for reviewing instructions, gathering the data needed and entering and reviewing the information on the completed complaint form. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: HHS/OS Reports Clearance Officer, Office of Information Resources Management, 200 Independence Ave. S.W., Room 531H, Washington, D.C. 20201. **Please do not mail complaint form to this address.**

Form Approved: OMB No. 0945-0002
Expiration Date: 11/30/2022

COMPLAINANT CONSENT FORM

The Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) has the authority to collect and receive material and information about you, including personnel and medical records, when they are relevant to its investigation of your complaint.

To investigate your complaint, OCR may need to reveal your identity or identifying information about you to persons at the entity or agency under investigation or to other persons, agencies, or entities. In some circumstances, OCR may refer your complaint to another government agency, as warranted.

The Privacy Act of 1974 protects certain federal records that contain personally identifiable information about you and, with your consent, allows OCR to use your name or other personal information, if necessary, to investigate your complaint.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

Additionally, OCR may disclose information, including medical records and other personal information, which it has gathered during the course of its investigation in order to comply with a request under the Freedom of Information Act (FOIA) and may refer your complaint to another appropriate agency.

Under FOIA, OCR may be required to release information regarding the investigation of your complaint; however, we will make every effort, as permitted by law, to protect information that identifies individuals or that, if released, could constitute a clearly unwarranted invasion of personal privacy.

OCR will use any applicable protections in that law to safeguard information which could identify you, or other individuals, or that, if released, could constitute a clearly unwarranted invasion of personal privacy. OCR may be required to release some information regarding the investigation of your complaint under the Freedom of Information Act (FOIA), however, information concerning your complaint which could reveal your identity is protected from disclosure to third party requesters under FOIA.

Please read and review the documents entitled *Notice to Complainants and Other Individuals Asked to Supply Information to the Office for Civil Rights* and *Protecting Personal Information in Complaint Investigations* for further information regarding how OCR may obtain, use, and disclose your information while investigating your complaint.

In order to expedite the investigation of your complaint if it is accepted by OCR, please read, sign, and return one copy of this consent form to OCR with your complaint. Please make one copy for your records.

- As a complainant, I understand that in the course of the investigation of my complaint it may become necessary for OCR to reveal my identity or identifying information about me to persons at the entity or agency under investigation or to other persons, agencies, or entities.

- I am also aware of the obligations of OCR to honor requests under the Freedom of Information Act (FOIA). I understand that it may be necessary for OCR to disclose general information which it has gathered as part of its investigation of my complaint, excluding personally identifiable information.

- In addition, I understand that, as a complainant, I may be covered by the Department of Health and Human Services' (HHS) regulations which protect any individual from being intimidated, threatened, coerced, retaliated against, or discriminated against because he/she has made a complaint, testified, assisted, or participated in any manner in any mediation, investigation, hearing, proceeding, or other part of HHS's investigation, conciliation, or enforcement process.

After reading the above information, please check ONLY ONE of the following boxes:

☑ **CONSENT**: I have read, understand, and agree to the above and give permission to OCR to reveal my identity or identifying information about me in my case file to persons at the entity or agency under investigation or to other relevant persons, agencies, or entities during any part of HHS' investigation, conciliation, or enforcement process.

☐ **CONSENT DENIED**: I have read and I understand the above and do not give permission to OCR to reveal my identity or identifying information about me. I understand that this denial of consent is likely to impede the investigation of my complaint and may result in closure of the investigation.

Signature: (b)(6); (b)(7)(C) Date: 04/08/2022

**Please sign and date this complaint. You do not need to sign if submitting this form by email because submission by email represents your signature.*

Name (Please print): (b)(6); (b)(7)(C)

Address: (b)(6); (b)(7)(C)

Telephone Number: (b)(6); (b)(7)(C)

Form Approved: OMB No. 0945-0002
Expiration Date: 11/30/2022

NOTICE TO COMPLAINANTS AND OTHER INDIVIDUALS ASKED TO SUPPLY INFORMATION TO THE OFFICE FOR CIVIL RIGHTS

Privacy Act

The Privacy Act of 1974 (5 U.S.C. §552a) requires OCR to notify individuals whom it asks to supply information that:

— OCR is authorized to solicit information under:
(i) Federal laws barring discrimination by recipients of Federal financial assistance on grounds of race, color, national origin, disability, age, sex, religion under programs and activities receiving Federal financial assistance from the U.S. Department of Health and Human Services (HHS), including, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. §2000d *et seq.*), Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. §794), the Age Discrimination Act of 1975 (42 U.S.C. §6101 *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. §1681 *et seq.*), Sections 794 and 855 of the Public Health Service Act (42 U.S.C. §§295m and 296g); and Section 1557 of the Affordable Care Act (42 U.S.C. §18116);
(ii) Federal laws protecting rights of conscience and religious freedom in health and human services programs, such as Sections 1303(b)(4) and 1553 of the Affordable Care Act (42 U.S.C. §§18113, 18023(b)(4)), the Church Amendments (42 U.S.C. § 300a-7), the Coats-Snowe Amendment (42 U.S.C §238n), the Religious Freedom Restoration Act (42 U.S.C. § 2000bb *et seq.*), and the Weldon Amendment (*e.g.*, Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2019, Pub. L. No. 115-245, Div. B., §507(d)), and applicable regulations;
(iii) Titles VI and XVI of the Public Health Service Act (42 U.S.C. §§291 *et seq.* and 300s *et seq.*) and 42 C.F.R. Part 124, Subpart G (Community Service obligations of Hill-Burton facilities);
(iv) 45 C.F.R. Part 85, as it implements Section 504 of the Rehabilitation Act in programs conducted by HHS; and
(v) Title II of the Americans with Disabilities Act (42 U.S.C. §12131 *et seq.*) and Department of Justice regulations at 28 C.F.R. Part 35, which give HHS "designated agency" authority to investigate and resolve disability discrimination complaints against certain public entities, defined as health and service agencies of state and local governments, regardless of whether they receive federal financial assistance.

HIPAA Standards for the Privacy of Individually Identifiable Health Information (The Privacy Rule), 45 C.F.R. Part 160 and Subparts A and E of Part 164, Health Insurance Reform: Security Standards (The Security Rule), 45 C.F.R. Part 160 and Subparts A and C of Part 164, Breach Notification for Unsecured Protected Health Information (The Breach Rule), 45 C.F.R. Part 160 and Subparts A and D of Part 164, and Administrative Simplification: Enforcement, 45 C.F.R. Part 160, Subparts C, D, and E, which contains provisions relating to compliance and investigations, the imposition of civil money penalties, and procedures for hearings related to violations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. §1320d-2).

OCR will request information for the purpose of determining and securing compliance with the Federal laws listed above. Disclosure of this requested information to OCR by individuals who are not recipients of federal financial assistance is voluntary; however, even individuals who voluntarily disclose information are subject to prosecution and penalties under 18 U.S.C. § 1001 for making false statements.

Additionally, although disclosure is voluntary for individuals who are not recipients of federal financial assistance, failure to provide OCR with requested information may preclude OCR from making a compliance determination or enforcing the laws above.

OCR has the authority to disclose personal information collected during an investigation without the individual's consent for the following routine uses:

(i) to make disclosures to OCR contractors who are required to maintain Privacy Act safeguards with respect to such records;
(ii) for disclosure to a congressional office from the record of an individual in response to an inquiry made at the request of the individual;
(iii) to make disclosures to the Department of Justice to permit effective defense of litigation; and
(iv) to make disclosures to the appropriate agency in the event that records maintained by OCR to carry out its functions indicate a violation or potential violation of law.

Under 5 U.S.C. §552a(k)(2) and the HHS Privacy Act regulations at 45 C.F.R. §5b.11 OCR complaint records have been exempted as investigatory material compiled for law enforcement purposes from certain Privacy Act access, amendment, correction and notification requirements.

Freedom of Information Act

A complainant, the recipient or any member of the public may request release of OCR records under the Freedom of Information Act (5 U.S.C. §552) (FOIA) and HHS regulations at 45 C.F.R. Part 5. Generally, most records will be available only to the complainant if they are not privileged. Most or all records from a complaint file will be withheld to protect privacy.

Fraud and False Statements

Federal law, at 18 U.S.C. §1001, authorizes prosecution and penalties of fine or imprisonment for conviction of "whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry."

Form Approved: OMB No. 0945-0002
Expiration Date: 11/30/2022

PROTECTING PERSONAL INFORMATION IN COMPLAINT INVESTIGATIONS

To investigate your complaint, the Department of Health and Human Services' (HHS) Office for Civil Rights (OCR) will collect information from different sources. Depending on the type of complaint, we may need to get copies of your medical records, or other information that is personal to you. This Fact Sheet explains how OCR protects your personal information that is part of your case file.

HOW DOES OCR PROTECT MY PERSONAL INFORMATION?

OCR is required by law to protect your personal information. The Privacy Act of 1974 protects Federal records about an individual containing personally identifiable information, including, but not limited to, the individual's medical history, education, financial transactions, and criminal or employment history that contains an individual's name or other identifying information.

Under the Privacy Act, OCR will disclose your name or other personal information with a signed consent from you, and only when it is necessary to complete the investigation of your complaint or to enforce civil rights laws or when it is otherwise permitted by law.

Consent is voluntary, and it is not always needed in order to investigate your complaint; however, failure to give consent is likely to impede the investigation of your complaint and may result in the closure of your case.

CAN I SEE MY OCR FILE?

Under the Freedom of Information Act (FOIA), you can request a copy of your case file once your case has been closed; however, OCR can withhold information from you in order to protect the identities of witnesses and other sources of information. Additionally, some records may be withheld to protect OCR's deliberative process privilege or any other legally protected privilege.

CAN OCR GIVE MY FILE TO ANY ONE ELSE?

If a complaint indicates a violation or a potential violation of law, OCR can refer the complaint to another appropriate agency without your permission.

If you file a complaint with OCR, and we decide we cannot help you, we may refer your complaint to another agency, such as the Department of Justice.

CAN ANYONE ELSE SEE THE INFORMATION IN MY FILE?

Public access to OCR's files and records is controlled by the Freedom of Information Act (FOIA). Under FOIA, OCR may be required to release general information about this case upon public request. In the event that OCR receives such a request, we will apply every legal protection to information that identifies individuals.

If OCR receives protected health information about you in connection with a HIPAA investigation or compliance review, we will only share this information with individuals outside of HHS if necessary for our compliance efforts or if we are required to do so by another law.

DOES IT COST ANYTHING FOR ME (OR SOMEONE ELSE) TO OBTAIN A COPY OF MY FILE?

In most cases, the first two hours spent searching for document(s) you request under the Freedom of Information Act and the first 100 pages are free. Additional search time or copying time may result in a cost for which you will be responsible. If you wish to limit the search time and number of pages to a maximum of two hours and 100 pages; please specify this in your request. You may also set a specific cost limit, for example, cost not to exceed $100.00. For details, see HHS's FOIA page.

If you have any questions about this complaint and consent package, please contact OCR at www.hhs.gov/ocr/office/about/contactus/index.html.

OR

Contact the Customer Response Center at (800) 368-1019 (see contact information on page 2 of the Complaint Form).

2526 SAINT PAUL STREET
BALTIMORE, MD 21218
TEL (410) 625-LGBT (5428)
FAX (410) 625-7423
www.freestate-justice.org

Mackenzie Dadswell
Staff Attorney
mdadswell@freestate-justice.org

Description of Discrimination

(b)(6); (b)(7)(C)

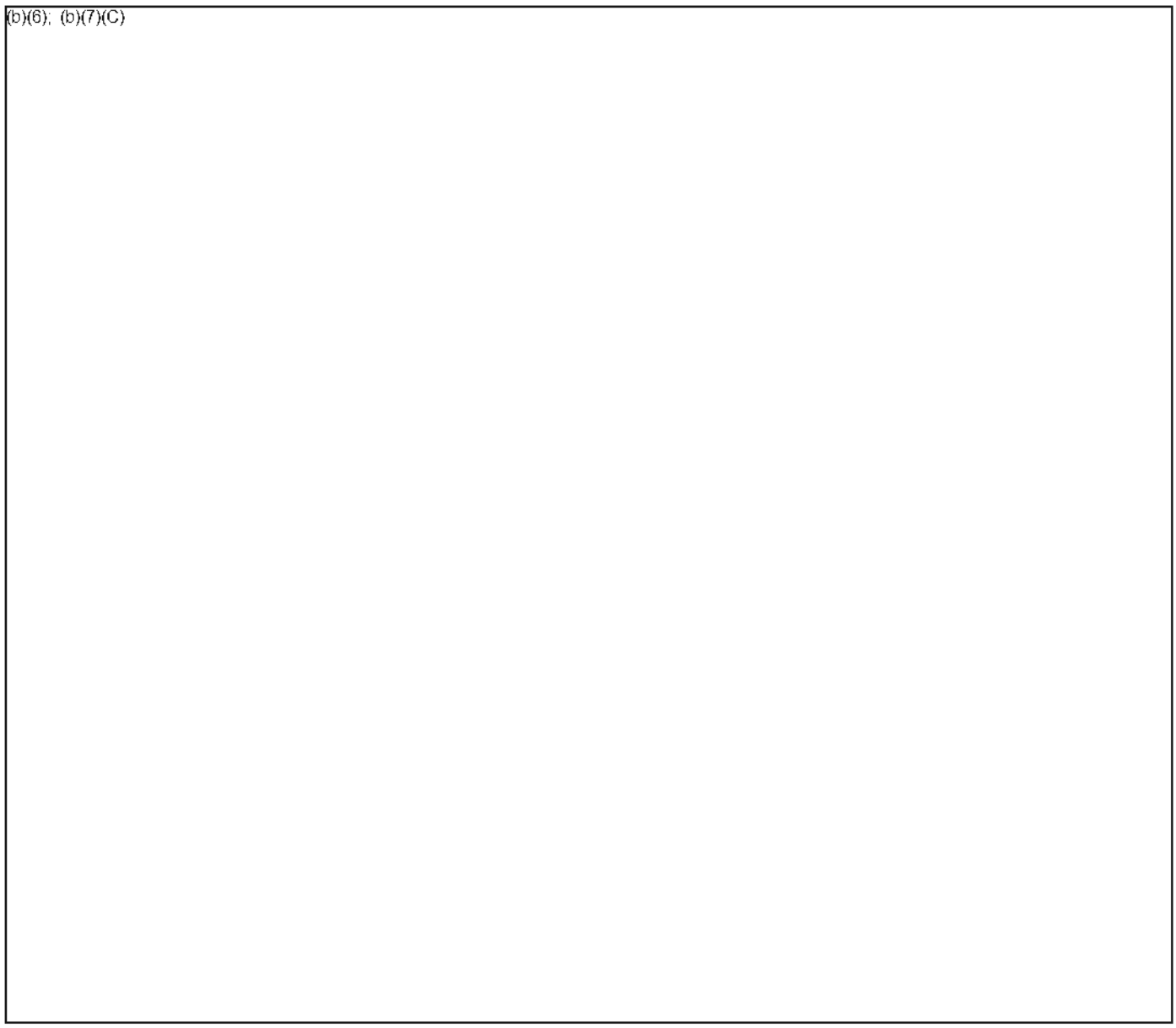
(b)(6); (b)(7)(C)

FREESTATE
2526 SAINT PAUL ST, BALTIMORE, MD 21218
(410) 625-5428 (410) 625-7423 www.freestate-justice.org

(b)(6); (b)(7)(C)

FREESTATE
2526 SAINT PAUL ST, BALTIMORE, MD 21218
(410) 625-5428 (410) 625-7423 www.freestate-justice.org

(b)(6); (b)(7)(C)



FREESTATE
2526 SAINT PAUL ST, BALTIMORE, MD 21218
(410) 625-5428 (410) 625-7423 www.freestate-justice.org

LOS
ANGELES
LGBT
CENTER

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T 323-993-7400

lalgbtcenter.org

/lalgbtcenter
@lalgbtcenter

Date: July 7, 2020
Re: (b)(6), (b)(7)(C)
DOB (b)(6), (b)(7)(C)

To Whom It May Concern,

(b)(6), (b)(7)(C)

LOS ANGELES LGBT CENTER

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T: 323-993-7400

lalgbtcenter.org

/lalgbtcenter
@lalgbtcenter

(b)(6), (b)(7)(C)

Please do not hesitate to contact us if further information is desired. We heartily thank you for the excellent service you provide to our clients.

Sincerely,

Elise S. Turen, PhD, ACS

Diane Kubrin, MFT#28532

LOS
ANGELES
LGBT
CENTER

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T: 323-993-7400

lalgbtcenter.org

/lalgbtcenter
@lalgbtcenter

Date: July 7, 2020
Re: (b)(6), (b)(7)(C)
DOB: (b)(6), (b)(7)(C)

To Whom It May Concern,

(b)(6), (b)(7)(C)

LOS ANGELES LGBT CENTER

(b)(6), (b)(7)(C)

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T: 323-993-7400

lalgbtcenter.org

/lalgbtcenter
#lalgbtcenter

Please do not hesitate to contact us if further information is desired. We heartily thank you for the excellent service you provide to our clients.

Sincerely,

Melissa Burroughs, LCSW 25259

LOS ANGELES LGBT CENTER

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T: 323-993-7400

lalgbtcenter.org

/lalgbtcenter
#lalgbtcenter

Date: 05/25/21

Re: (b)(6), (b)(7)(C)

DOB: (b)(6), (b)(7)(C)

To Whom It May Concern,

(b)(6), (b)(7)(C)

(b)(6); (b)(7)(C)

LOS ANGELES LGBT CENTER

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T: 323-993-7400

lalgbtcenter.org

/lalgbtcenter
#lalgbtcenter

Please do not hesitate to contact us if further information is desired. We heartily thank you for the excellent service you provide to our clients.

Sincerely,

Robin M. Cooper, Psy. D.

Robin M. Cooper, PsyD, PSY 25071

LOS ANGELES LGBT CENTER

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T: 323-993-7400

lalgbtcenter.org

/lalgbtcenter
#lalgbtcenter

Date: 05/25/21
Re: (b)(6); (b)(7)(C)
DOB: (b)(6); (b)(7)(C)

To Whom It May Concern,

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

LOS ANGELES LGBT CENTER

McDonald / Wright Building
1625 N. Schrader Boulevard
Los Angeles, CA 90028

T: 323-993-7400

lalgbtcenter.org

/lalgbtcenter
#lalgbtcenter

Please do not hesitate to contact us if further information is desired. We heartily thank you for the excellent service you provide to our clients.

Sincerely,

Toby Barron, LCSW #89672

Chase Brexton Health Care
Because everyone's health matters.

September 7, 2021

To Whom It May Concern:

Re: Assessment for Gender Affirmation Surgeries, Namely Facial Feminization Surgeries (FFS), and Electrolysis

Patient Name: (b)(6), (b)(7)(C)

DOB: (b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

1111 North Charles Street • Baltimore, MD 21201 • **T** 410-837-2050 • **F** 410-837-2071 • ChaseBrexton.org

(b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

Sincerely,

James A. Griffin, Ph.D.
Psychologist (MD Lic. #06113)
Center for LGBTQ Health Equity at Chase Brexton Health Care

(b)(6), (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6), (b)(7)(C)

Provider Notification of Determination

Member Name & DOB:	(b)(6), (b)(7)(C)
Member Amerigroup ID #:	
Reference ID#:	C10176203
Enter Contact & Fax#	Kim H 443-777-8667

(b)(6), (b)(7)(C)

Provider Notification of Determination

PRIVILEGED AND CONFIDENTIAL

The documents being transmitted may be confidential and may include Amerigroup member information that is legally privileged. This information is intended only for the use of the individual or entity named above. The authorized recipient of this information is prohibited from disclosing this information to any other party unless required to do so by law or regulation. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution or action taken on the contents of these documents is strictly prohibited. **If you have received this facsimile in error, please notify us immediately at 1-800-964-2112.** Please destroy all copies of the original message.

3/19/2021

MARYLAND Department of Health

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Robert R. Neall, Secretary

Date: June 23, 2021

(b)(6), (b)(7)(C)

Dear Ms. (b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

Sincerely,

Sharon Bryan, RN
Managed Care Administration

cc: Bernadette Benta, MSHA, BSN, RN – 201 West Preston Street Room 299, Baltimore, MD 2120
Kathy Harmon – Amerigroup Community Care, 7550 Teague Road, Ste. 500, Hanover, MD 21076
Dr. Gabriel A. Del Corral – 9103 Franklin Square Drive, Baltimore, MD 21237

Enclosures

(b)(6); (b)(7)(C)

	*	**NICOLAS ORECHWA,**
APPELLANT	*	**ADMINISTRATIVE LAW JUDGE**
v.	*	**THE MARYLAND OFFICE**
MARYLAND DEPARTMENT OF	*	**OF ADMINISTRATIVE HEARINGS**
HEALTH	*	**OAH No.: MDH-MCP-012-21-17696**

* * * * * * * * * * * * *

DECISION

STATEMENT OF THE CASE

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

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(b)(6); (b)(7)(C)

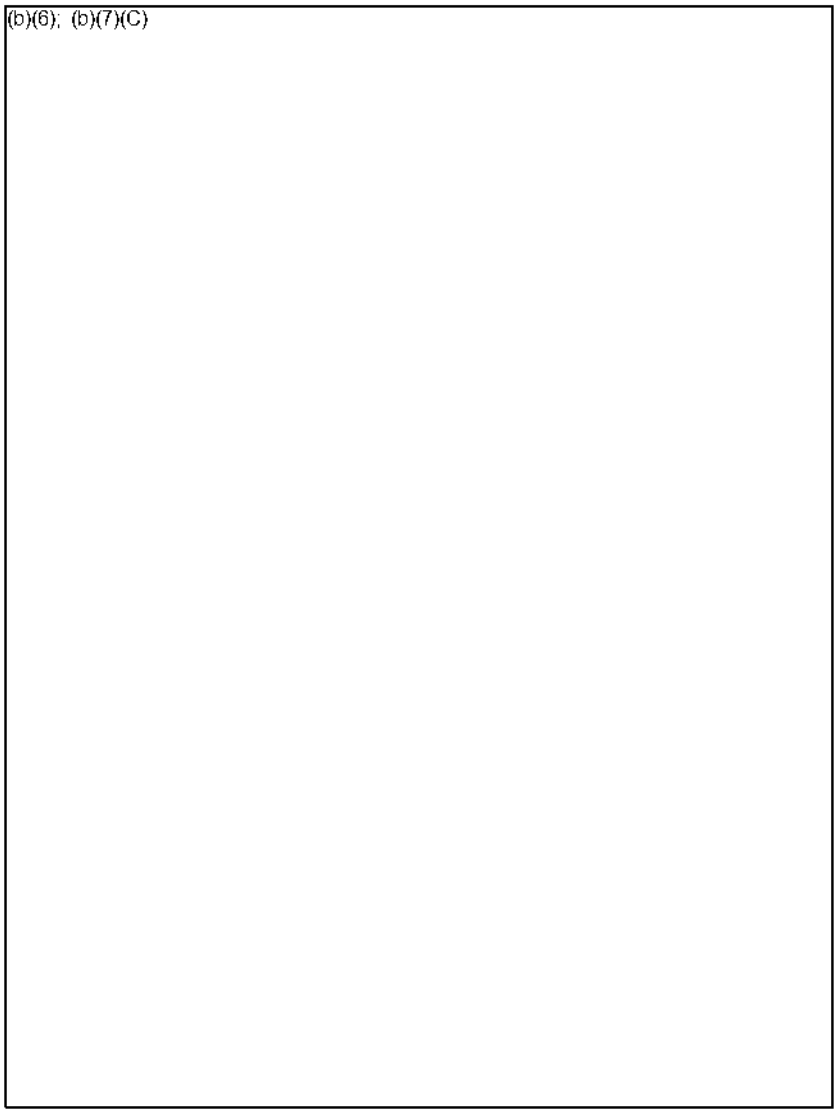
(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)


(b)(6); (b)(7)(C)

PT 37-16

STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

Office of Health Services
Medical Care Programs

MARYLAND MEDICAL ASSISTANCE PROGRAM
Managed Care Organizations Transmittal No. 110
March 10, 2016

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Mental Health Provider Certification for Gender Transition Treatment or Surgery (Optional Template)

Patient Name:
MA #:

I certify that:

☐ The patient is at least 18 years of age and has the capacity to make fully informed decisions and consent to treatment; The patient must provide evidence of two independent psychological assessments; at least one of the professionals must have a doctoral degree (Ph.D., M.D., Ed.D., D.Sc., D.S.W., or Psy.D).

The psychological assessment must indicate that the patient:

☐ Has a clear diagnosis of gender dysphoria with presence of symptoms > 2 years:

☐ The desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment;
☐ The gender dysphoria is not a symptom of another mental disorder; and
☐ The gender dysphoria causes clinically significant distress or impairment in social, occupational, or other important areas of functioning.

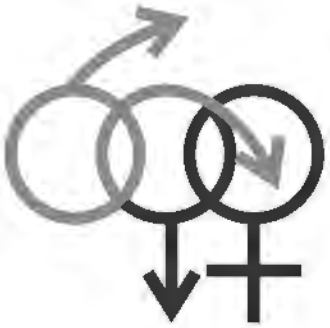
☐ Has lived for 12 months or more as opposite sex (desired gender) prior to the mental health professional recommending surgery; start date of living full time in the new gender-___/___/_____.

☐ Has no contraindicating mental health conditions; if the patient is diagnosed with severe psychiatric disorders and impaired reality testing (e.g., psychotic episodes, bipolar disorder, dissociative identity disorder, borderline personality disorder), the patient must be reasonably well controlled with psychotropic medications and/or psychotherapy before surgery is contemplated.

☐ Has expressed full understanding of the psychological, social, medical and financial implications of treatment, for now and the future, prior to referring for treatment or surgery.

_____ _____
Signature Date

_____ _____
Signature Date



WPATH
WORLD PROFESSIONAL ASSOCIATION for TRANSGENDER HEALTH

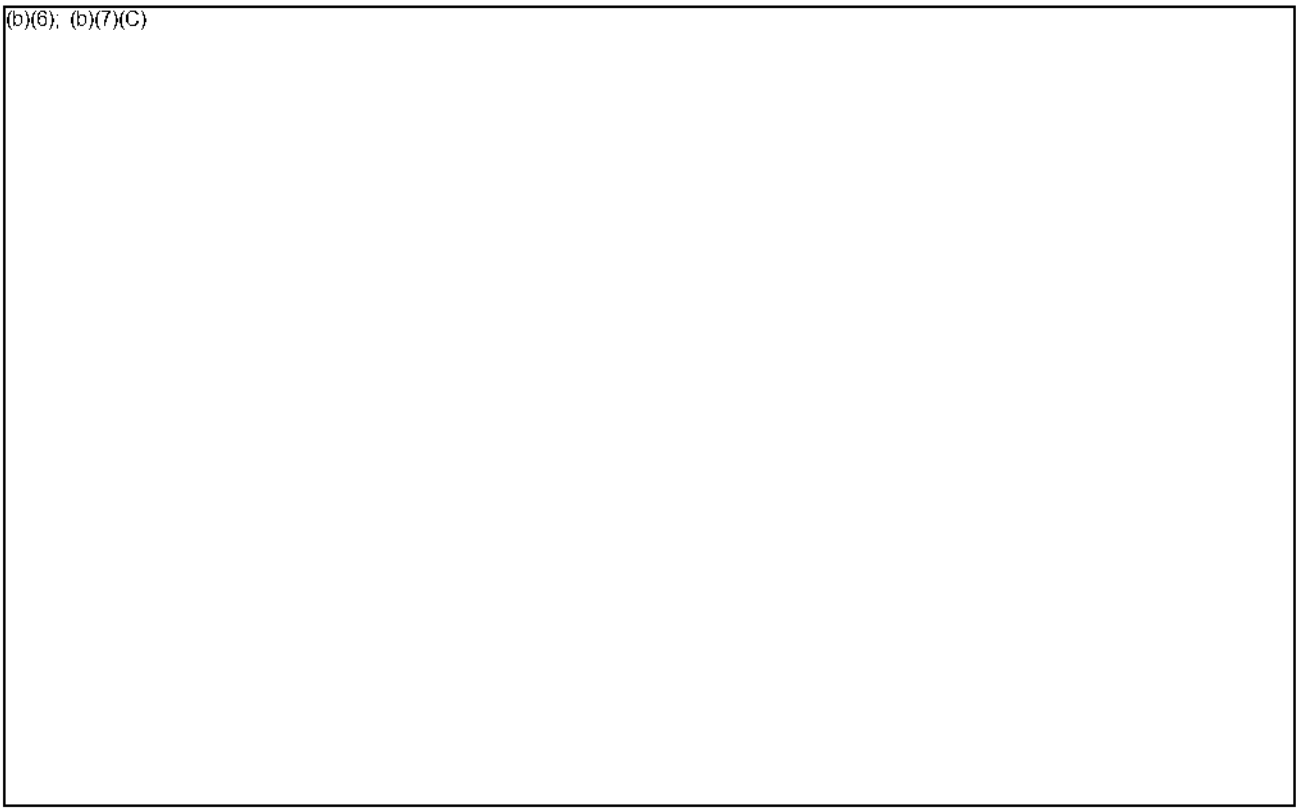
(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6), (b)(7)(C)

(b)(6), (b)(7)(C)

(b)(6); (b)(7)(C)


(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

From: Garcia, Art (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F3E15A704CD4274BB9916D41A1923A9-GARCIA, ART <Art.Garcia@HHS.GOV>

To: (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (b)(6) Sus (b)(6)
Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>

CC: (b) (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91 (b)(6) (b)(6)

Subject: RE: MW Region - GAC complaints

Date: 2022/11/08 10:31:54

Priority: Normal

Type: Note

All these times work for me, thank you.

From: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Tuesday, November 8, 2022 9:31 AM
To: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) <Art.Garcia@HHS.GOV>
Cc: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: MW Region - GAC complaints

Good morning,

Thanks for sending over new GAC complaints. We thought it would be a good idea to touch base on the cases, as well as your State Medicaid complaints. Below is a list of the GAC cases that we show for your Region.

I'm not sure if you want others to join the call, but it looks like the following times are available next week. Do any of these work? Thanks, (b)(6)

Wed. 11/16: 10-10:30am ET/9-9:30am CT
Fri. 11/18: 10-10:30am ET/9-9:30am CT; 11-11:30 ET/10-10:30 CT; 12-12:30pm ET/11-11:30am CT

Insurance Cases:

(b)(5)

(b)(5)

(b)(5)

Medicaid Cases:

(b)(5)

(b)(5)

From: Garcia, Art (HHS/OCR) <Art.Garcia@HHS.GOV>
Sent: Friday, November 4, 2022 9:37 AM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) (b)(6) (b)(6) (HHS/OCR)
(b)(6)
Cc: Mitchell, Steven M (HHS/OCR) <Steven.Mitchell@HHS.GOV>; Garcia, Art (HHS/OCR) <Art.Garcia@HHS.GOV>
Subject: (b)(5)

(b)(5)

Sender:	Garcia, Art (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3F3E15A704CD4274BB9916D41A1923A9-GARCIA, ART <Art.Garcia@HHS.GOV>
Recipient:	(b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (b)(6) Sus (b)(6) Mitchell, Steven M (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf53b56e8 <Steven.Mitchell@HHS.GOV>; (b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-(b)(6) (b)(6)
Sent Date:	2022/11/08 10:31:52
Delivered Date:	2022/11/08 10:31:54

From: (b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) (b)(6)

To: (b) (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91-(b)(6) (b)(6)

Subject: RE: NEED YOUR INPUT: (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Date: 2022/11/21 10:30:21

Priority: Normal

Type: Note

Thanks, I'll send it to them, copying you.

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)

Sent: Monday, November 21, 2022 10:08 AM

To: (b)(6) (b)(6) (HHS/OCR) (b)(6)

Subject: RE: NEED YOUR INPUT: (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: (b)(6) (b)(6) (HHS/OCR) (b)(6)

Sent: Thursday, November 17, 2022 7:14 PM

To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)

Subject: NEED YOUR INPUT: (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Hi (b)(6)

(b)(6); (b)(7)(C)

- • Case Summary:

(b)(6); (b)(7)(C)

Thanks, (b)(6)

From: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Thursday, November 17, 2022 6:46 PM
To: (b)(6) (b)(6) (HHS/OCR) (b)(6) hhs.gov>
Subject: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

From: Cameron, Emily (OS/OCR) <Emily.Cameron@hhs.gov>
Sent: Wednesday, November 16, 2022 5:29 PM
To: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: (b)(6); (b)(7)(C)

Hello,

(b)(6); (b)(7)(C)

Thanks for your help!

Emily Cameron, JD
She/Her
Supervisory Equal Opportunity Specialist
U.S. Department of Health &Human Services
Office for Civil Rights
Southwest Region • 1301 Young Street
Suite 106 - 1130 • Dallas, TX 75202
(214) 767-2010 • Toll Free – (800) 368-1019
Fax – (214) 767-0432 • TDD – (214) 767-8940
http://www.hhs.gov/ocr

Sender: (b)(6) (b)(6) (HHS/OCR) /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (b)(6) SUS (b)(6)

Recipient: (b) (b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bdec12ad0974eacababe032f2b37c91 (b)(6) (b)(6)

Sent Date: 2022/11/21 10:30:19
Delivered Date: 2022/11/21 10:30:21

ENSURING ACCESS TO QUALITY HEALTHCARE AND CRITICAL FAMILY BUILDING SERVICES FOR LGBTQIA+ FEDERAL EMPLOYEES

Policy Recommendations for the Office of Personnel Management

Written by the Pride in Federal Service Policy Committee[1]
November 2022

[1] The recommendations set forth in this document represent the personal opinions of the authors and do not represent an official opinion by the United States government. The authors are as follows: Jamie Tatti, Skylar Cushing, Nathan Harvey, Jonah Richmond, and Maverick Hill.

Contents

Background

The federal government is the nation's largest employer with more than 2.1 million civilian workers across the entire United States and its Federal Employee Health Benefit (FEHB) program is responsible for 8.2 million covered lives. According to data from the 2021-2022 Federal Employee Viewpoint Survey (FEVS),[2] around 7% of the federal workforce identify as "gay, lesbian, bisexual, transgender, or something else", a figure which is likely to be underestimated.[3] Although the Biden-Harris Administration has made significant strides forward, lesbian, gay, bisexual, transgender, queer, intersex, and asexual (LGBTQIA+[4]) federal workers continue to face significant barriers compared to their non-LGBTQIA+ federal colleagues and private sector counterparts. According to a 2021 survey conducted by Pride in Federal Service (PFS), LGBTQIA+ federal workers reported contemplating leaving federal service because of a lack of quality healthcare coverage, particularly with regard to gender-affirming care (GAC). PFS members also reported a need for family building services that reflect the unique needs of the LGBTQIA+ community.

The Biden-Harris Administration has called upon OPM to help prevent and combat discrimination against LGBTQIA+ federal employees and advance diversity, equity, inclusion, and accessibility (DEIA) throughout the federal workforce. Executive Order (EO) 14035 explicitly requires OPM to

> "ensure that LGBTQ+ employees (including their beneficiaries and their eligible dependents), as well as LGBTQ+ beneficiaries and LGBTQ+ eligible dependents of all Federal employees, have equitable access to healthcare and health insurance coverage: (i) the Director of OPM shall take actions to promote equitable healthcare coverage and services for enrolled LGBTQ+ employees (including their beneficiaries and their eligible dependents), LGBTQ+ beneficiaries, and LGBTQ+ eligible dependents, including coverage of comprehensive gender-affirming care, through the Federal Employees Health Benefits Program."

PFS appreciates OPM's request that carriers describe their review process of GAC Standards of Care (SOC), including the guidelines of the World Professional Association for Transgender Health (WPATH), the Endocrine Society, and Fenway Health in carrier

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[2] The Federal Employee Viewpoint Survey began allowing individuals to identify their sexual orientation and gender identify in 2012.

[3] The FEVS survey asked, "Are you transgender?" with "yes" or "no" options. This likely underestimates gender diverse individuals and non-binary individuals since many do not identify themselves as transgender and would not select this. Recent surveys show that more TGD people are self-identifying as such due to a variety of societal factors, including increased awareness and acceptance. Furthermore, nearly 2% of the population is intersex, but there was no question on the FEVS to capture this information. PrideVA and ORMDI collaborated to update VA's All Employee Survey to address this data collection issue, which was implemented in 2021. PrideVA (prideva*@* va.gov) would be happy to be a resource to OPM regarding inclusive language for surveys and forms.

[4] + indicates inclusion of all gender and sexual minorities including, for example, 2-spirit and pansexual.

letter 2022-03. WPATH released the 8th version of their SOC in September of 2022.[5] PFS sees SOC-8 as the clearest, evidence-based guide to quality healthcare delivery for the transgender and gender diverse (TGD) population available at this time. SOC-8 provides a roadmap to many of the equity challenges found in the PFS survey of federal employees seeking GAC for themselves and/or their dependents. Further, PFS believes that WPATH SOC-8 offers the only current SOC that aligns with OPM's criteria of an acceptable SOC for GAC as outlined in carrier letter 2022-03, which also addresses 2021-05 (See OPM May Already Require the Adoption of WPATH SOC, pg. 10 for details).

Equitable access to health insurance coverage for LGBTQIA+ individuals also requires coverage of Assisted Reproductive Technology (ART) procedures such as In Vitro Fertilization (IVF) and gestational surrogacy for couples who desire children but are unable to biologically reproduce without such medical procedures. Executive Order 14035 directs OPM to ensure that "federal benefits, programs, and services recognize the diversity of family structures." Many LGBTQIA+ individuals' family structures cannot access benefits provided in current FEHB plans that cover all or most of maternity care costs but no ART costs. This leads to a large, inequitable gap in coverage between non-LGBTQIA+ individuals and LGBTQIA+ individuals wishing to grow their families.

The call to action in EO 14035 is a historic moment for the federal workforce. OPM has an opportunity to position the federal government as *the* model employer that sets the example for other private and public sector employers in the United States and around the world. By adopting the two PFS policy recommendations set forth below, OPM can meet its mandate of ensuring LGBTQIA+ federal employees receive the benefits that reflect the diverse needs of the federal workforce.

Executive Summary

To address the challenges that LGBTQIA+ federal employees and their families face, PFS developed two policy recommendations that will address the current healthcare and family building-related deficiencies facing LGBTQIA+ FEHB enrollees and beneficiaries on their plans: 1) reduce barriers to care for LGBTQIA+ covered lives[6] and 2) promote quality healthcare for LGBTQIA+ covered lives. Implementing these recommendations will result in more equitable care and improved health for LGBTQIA+ federal employees, reduce undue cost and wait times, and improve recruitment and retention of qualified LGBTQIA+ employees.

[5] See WPATH SOC-8 available at https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644

[6] PFS recommendations apply to federal employees and other "covered lives," including retirees and other FEHB plan enrollees, and their beneficiaries and eligible dependents.

Discussion

BARRIERS TO CARE FOR LGBTQIA+ COVERED LIVES

Preauthorization Barriers

LGBTQIA+ federal employees face unique challenges, inequities, and disparities both in terms of their physical and mental health as well as their abilities to access health insurance and health care.[7] Research demonstrates that certain populations of the LGBTQIA+ community are more vulnerable to suffering from chronic health conditions such as a higher prevalence and earlier onset of disabilities, higher rates of illness and health challenges related to human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), substance abuse, mental illness, and sexual and physical violence.[8,9] Moreover, research suggests LGBTQIA+ people of color, particularly TGD people of color, face especially significant health disparities and obstacles to accessing insurance coverage and quality, affordable health care.[8,10]

Carrier preauthorization requirements currently create unnecessary hurdles for LGBTQIA+ covered lives. These hurdles contribute to significant expense and delay in receiving GAC, as documented in the PFS survey of employees seeking such care for themselves and/or their dependents. These requirements include:

- Inappropriate preauthorization criteria for GAC that can lead to claim denials:
    - *Sex markers:* Sex markers do not necessarily correspond with a person's anatomy or physiology. Markers can be legally changed and people may also have mixed sex attributes due to medical transition and/or intersex traits. A health care provider (HCP)'s assessment of a person's anatomy or physiology is the only accurate way to establish this data if needed for any purpose.
    - *Hormone levels and/or duration on hormone replacement therapy (HRT):* HRT may be contraindicated for individuals for medical reasons. Non-binary people, in particular, may not need HRT or may need HRT at a low dose, non-standard formulation or for a shorter duration than someone whose goals match stereotypical ideas of masculine or feminine bodily hormone changes.
    - *Duration of and/or plan for social transition:* WPATH SOC-8 recommends that limited duration of social transition or lack of plans for social transition

[7] See "Health Inequities in LGBT People and Nursing Interventions to Reduce Them: A Systematic Review" available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8624572/

[8] See "Social and Medical Gender Affirmation Experiences Are Inversely Associated with Mental Health Problems in a U.S. Non-Probability Sample of Transgender Adults" available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7494544/

[9] See "Health and Access to Care and Coverage for Lesbian, Gay, Bisexual, and Transgender Individuals in the U.S." available at https://files.kff.org/attachment/Issue-Brief-Health-and-Access-to-Care-and-Coverage-for-LGBT-Individuals-in-the-US

[10] See "The Report of the 2015 U.S. Transgender Survey" https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf

should not be considered exclusionary criteria for any GAC services or surgeries.

- Inappropriate Exclusionary Criteria for GAC:
    - *Age:* WPATH SOC-8 recommends against firm age requirements for GAC, stating instead biopsychosocial assessment including relevant mental health and medical professionals (including parent(s)/guardian(s) if feasible/not harmful), emotional and cognitive maturity needed to consent/assent to treatment (defined by Statement 6.12.c of WPATH SOC-8), achievement of Tanner stage 2 prior to initiating puberty suppressing treatment, and that the adolescent has "experienced several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones or surgeries." With the exception of phalloplasty, no blanket exclusions for GAC are recommended for pubescent youth under SOC-8.
    - *Revisions:* As with any surgery, gender-affirming surgeries may require revisions due to complications and unintended outcomes. Excluding coverage for needed surgical revisions can lead to exorbitant costs and/or make medically necessary care inaccessible to FEHB covered lives.
    - *Lifetime Maximums:* WPATH previously issued guidance in its model transgender medical benefits document explicitly stating that there are no lifetime maximums. Further, the implementation of a lifetime maximum is contrary to WPATH SOC-8's recommendations to promote access to medically necessary GAC.
    - *Reversals:* A clause excluding coverage of reversals of GAC procedures is very common in FEHB insurance plans. Though WPATH SOC-8 cites research that demonstrates desire for such reversals is exceedingly rare (termed "detransition"), access to such care should be available with a comprehensive multidisciplinary assessment. This would also impact gender fluid people who had previously transitioned and whose gender identity has changed.
    - *Harm Reduction:* An important addition to WPATH SOC-8 guidelines is the prevalence and dangers of Do-It-Yourself (DIY) gender-affirming interventions among TGD people without access to other means of care, including purchasing and self-administering unregulated hormones, undergoing self-surgery and injecting silicone with poor safety measures.[11] The Global Network of Sex Work Projects also notes that TGD people sometimes use sex work as a means of financing needed gender affirming care.[12] A 2015 survey of over 25,000 trans residents in the United States reported that "one in five (20%) respondents have participated in the underground economy for income at some point in their lives, including in sex work, drug sales, and other currently criminalized work, and 9% did so in the past year."[10] SOC-8 advises that flexibility in the SOC's authorization

[11] See note 5, WPATH SOC-8, Statement 2.3

[12] See "The Needs and Rights of Trans Sex Workers" available at https://www.nswp.org/sites/default/files/Trans%20SWs.pdf

requirements should exist so that access to GAC services and surgeries may be offered as a harm reduction strategy.

- Unnecessary Dependence on Mental Health Assessments: Many carriers require a diagnosis of gender dysphoria and letters by one or more mental health providers to initiate GAC services and qualify for surgeries. The duration required to assess for gender dysphoria can vary between mental health providers and carrier requirements. Access to in-network providers who can provide this diagnosis and relevant letters for care can be limited or non-existent, which can lead to patients incurring exorbitant cost. Availability of providers is also commonly limited leading to significant delays in obtaining needed care. WPATH SOC-8 states "we recommend health care professionals should not make it mandatory for transgender and gender diverse people to undergo psychotherapy prior to the initiation of gender-affirming treatment, while acknowledging psychotherapy may be helpful for some transgender and gender diverse people." The WPATH SOC-8 recommends the ICD-11 diagnostic code gender incongruence be used for GAC. For adults, this assessment is recommended to be performed by a single, licensed HCP with the appropriate education, role, and competencies as outlined in SOC-8.

Lack of Sufficient Provider Network

Even when insurance carriers agree to cover GAC, oftentimes a lack of providers who accept the insurance and are available to provide such care, which presents another pervasive barrier to accessing GAC.[13]

Coverage for travel and even relocation expenses are also needed for TGD people in states where GAC is banned[14] and TGD individuals and families are at increased risk of state and local punitive action,[15] which, in turn, can lead to increased risk of violence by individuals and group actors.[16]

Mental Health

LGBTQIA+ people, especially TGD people,[5,8] are affected by minority stress, resulting in increased mental health challenges including experiencing increased rates of substance

[13] See "Barriers to Gender-Affirming Care for Transgender and Gender Nonconforming Individuals" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5842950/

[14] See "Healthcare Laws and Policies" available at https://www.lgbtmap.org/equality-maps/healthcare_laws_and_policies

[15] See "Youth Access to Gender Affirming Care: The Federal and State Policy Landscape" available at https://www.kff.org/other/issue-brief/youth-access-to-gender-affirming-care-the-federal-and-state-policy-landscape/

[16] See "Violence Against Transgender People is on the Rise. Stopping it Requires a Holistic Solution" available at https://www.justsecurity.org/83597/violence-against-transgender-people-is-on-the-rise-stopping-it-requires-a-holistic-solution/

abuse[17] and suicide.[10,10,18] WPATH SOC-8 recommends that the family of a TGD child have access to mental health services that are affirming of the child's gender identity and community, as well as peer support networks. Additionally, TGD people are often required to meet with mental health providers in order to gain access to GAC. Poor access to and coverage of LGBTQIA+ competent mental health providers was documented in the PFS employee survey and is a widely discussed issue among TGD people.[19]

Outdated Appeals Processes

Insurance denials are an unfortunate norm for LGBTQIA+ individuals seeking needed healthcare. A 2015 survey of over 27,000 respondents found that "more than half (55%) of respondents who sought transition related surgery coverage were denied, and one quarter (25%) of those who sought coverage for hormones were denied" within the past year.[10] To make matters worse, the appeals process for insurance denials is severely outdated. In a PFS-conducted survey of federal employees who sought GAC services for themselves and/or their dependents, a prevalent theme in was a lack of understanding of how to appeal insurance denials, both to insurance providers (82% of respondents) and to OPM (95% of respondents). Most claim appeals processes rely on physical mail, which can delay receipt of critical documents, create unnecessary mailing and printing costs, and increase the risk of losing items. Well-designed, online systems in place of the current paper-based systems will create a streamlined, efficient, and cost-effective work process which will increase overall end-user satisfaction. Modernizing the claim appeals process, as well as making education and training on the process readily available, will help federal employees better navigate this process and reduce the associated negative health outcomes of delaying access to treatment.

QUALITY ISSUES IN HEALTHCARE FOR LGBTQIA+ COVERED LIVES

Sexual Health

Men who have sex with men (MSM),[20] transgender women and men,[21] and non-binary TGD people[22] are all populations at increased risk of exposure to HIV. The Centers for Disease Control (CDC) recommends annual screenings for populations at increased risk of

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[17] See "Substance Use and SUDs in LGBTQ* Populations" available at https://nida.nih.gov/research-topics/substance-use-suds-in-lgbtq-populations

[18] See "More than 60% of suicide attempts among LGBQ people happen within five years of realizing they are LGBQ" available at https://williamsinstitute.law.ucla.edu/press/suicide-coming-out-press-release/

[19] See Mental Health Care Is Crucial For Trans People So Why Is It So Hard To Find? https://www.refinery29.com/en-us/transgender-mental-health-care-access-issues

[20] See "Men Who Have Sex with Men (MSM)" available at https://www.cdc.gov/std/treatment-guidelines/msm.htm#:~:text=HIV%20Risk%20Among%20Men%20Who,one%20in%20253%20(191)

[21] See "The worldwide burden of HIV in transgender individuals: An updated systematic review and meta-analysis" available at https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0260063

[22] See "Sex, PrEP and HIV in trans and non-binary people" available at https://www.aidsmap.com/about-hiv/sex-prep-and-hiv-trans-and-non-binary-people

HIV infection[23] and access to interventions such as Pre-Exposure Prophylactics (PrEP) and Post-Exposure Prophylactics (PEP) for people at risk or recently exposed to HIV,[24] respectively. Lack of coverage and access to sexual health screenings and PrEP/PEP was identified as a major area of concern in the PFS survey of federal employees in need of gender-affirming healthcare for themselves and/or their dependents.

Inconsistent Coverage for Comprehensive Gender-Affirming Care

The 2021 McKinsey report Being Transgender at Work and the organization Out & Equal's[25] Toolkit for Change both align with Executive Order 14035 in emphasizing the importance of employers providing healthcare coverage inclusive of GAC for TGD covered lives. GAC is recognized by all major U.S. medical authorities, including the American Medical Association (AMA) and the American Psychological Association (APA),[26] as the only effective treatment for many with gender dysphoria and gender incongruence. Further, GAC is also recognized as vital to other associated outcomes including suicide prevention[8,27] and safety in public for TGD people.[5]

PFS conducted a review of all FEHB carrier plans for 2022 and found that, as with years prior, coverage of GAC procedures varies widely between plans with many coverage areas including few, if any, services beyond hormones, mastectomy and gender-affirming genital surgeries. No existing FEHB plans accessible to all eligible covered lives offer the full scope of medically necessary care outlined in WPATH SOC-8.[28] Transgender-specific exclusions have historically been utilized by public and private health insurers to deny TGD people coverage for medically necessary care related to gender affirmation or transition, even though many of the same services are commonly covered for cisgender people.[29,30] For example, such services and procedures include hormone therapy, mental health counseling, and surgeries—all regularly covered procedures for cisgender patients.

Despite genital surgeries (considered medically necessary by WPATH) being one of the most extensively covered surgeries in FEHB plans, modifications of secondary sex characteristics "are often of greater practical significance in the [TGD] patient's daily life" as stated in the WPATH Position on Medical Necessity (2016). Survey data of TGD people assigned male at birth demonstrates that hair removal is their most sought procedural treatment for gender dysphoria, followed by non-surgical voice therapy, facial feminization, breast augmentation, tracheal shave, orchiectomy, and, finally, vaginoplasty.[10] Participants assigned female at birth reported, on average, that chest

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[23] See "Recommendations for HIV Screening of Gay, Bisexual, and Other Men Who Have Sex with Men United States, 2017" available at https://www.cdc.gov/mmwr/volumes/66/wr/mm6631a3.htm

[24] See "Preventing New HIV Infections" available at https://www.cdc.gov/hiv/guidelines/preventing.html

[25] Out & Equal is the premier organization working exclusively on LGBTQ workplace equality. See https://outandequal.org/who-we-are/.

[26] See "Medical Organization Statements" available at https://transhealthproject.org/resources/medical-organization-statements/

[27] See note 5, S174, Statement 18.6

[28] While WPATH SOC-8 was released after 2022 plans were finalized and shortly before 2022 Open Season, the benefits indicated as medically necessary were nearly identical.

[29] See Supra Note 5, S22.

[30] See Trans Medicine by Stef M. Shuster

reduction/reconstruction is the procedure of highest importance, followed by hysterectomy, metoidioplasty, and phalloplasty.[10] WPATH SOC-8 provides a detailed list of medically necessary GAC procedures[31] and cites the research justifications for them.

PFS appreciates the discussion of "formulary access" for TGD people in Carrier Letter 2022-04 and the inclusion of the "Non-Discriminatory Formulary Design" in OPM Carrier Letter 2022-02. PFS believes affordable access to the full range of HRT and puberty suppressing medication (most clearly outlined in Fenway Health's 2021 Medical Care of Trans and Gender Diverse Adults) are fundamental to the TGD community's GAC needs. Clear evidence as to its medical necessity is outlined in WPATH SOC-8. Due to the need for HCPs to customize HRT to the individual physiology, medical needs, and treatment goals of the TGD patient, as illustrated in the aforementioned guides, PFS believes that access to the full range of hormones and administration methods is imperative. This includes medications with limited research support but common clinical application,[32] such as micronized progesterone, which may, for example, provide an avenue for sufficiently suppressing testosterone that remains elevated with the use of anti-androgens or as a non-surgical means of achieving breast growth.[33,34] Four respondents to the PFS survey specifically reported difficulty accessing HRT, with one explicitly naming difficulties in accessing Lupron/puberty suppressing medication. Due to survey limitations, the specific barriers and timing/access issues are unclear. Even so, further developments in care coordination, as discussed in OPM Carrier Letter 2022-04, and modernization of the claim appeal process would provide an improved structure for addressing these and other access issues on an ongoing basis.

OPM May Already Require the Adoption of WPATH SOC

OPM states in Call Letter 2022-03 that FEHB plan proposals "must adopt an acceptable standard of care" which are "based on credible scientific evidence published in peer-reviewed medical literature and generally recognized by the relevant medical community and physician specialty society recommendations."[35] Previously, in Carrier Letter 2021-05, OPM stated that "FEHB Carriers must provide benefits for all covered services when medically necessary for the covered member, including those who are transgender. FEHB Carriers must be sensitive to the fact that every individual with gender dysphoria has unique needs and the types of medically necessary services that the individual may require will be specific to that individual." To our knowledge, the only SOC that speaks to the medical necessity, timing, and indications for specific GAC services *and* meets OPM's aforementioned criteria of an acceptable standard of care is WPATH SOC-8. Without any

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[31] See Supra Note 5, S18 and Appendix E for overview.

[32] See "Evidence based medicine and justice: a framework for looking at the impact of EBM upon vulnerable or disadvantaged groups" available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1733835/pdf/v030p00141.pdf

[33] See "Medical Care of Trans and Gender Diverse Adults" available at https://fenwayhealth.org/wp-content/uploads/Medical-Care-of-Trans-and-Gender-Diverse-Adults-Spring-2021-1.pdf

[34] See "Overview of feminizing hormone therapy" available at https://transcare.ucsf.edu/guidelines/feminizing-hormone-therapy

[35] See Letter Number 2022-03, p. 6-7 available at https://www.opm.gov/healthcare-insurance/healthcare/carriers/2022/2022-03.pdf

other acceptable SOC that fulfills this function available, it follows that FEHB carriers are already required to adopt WPATH for the functions that no other acceptable standard of care have specified. Since only WPATH SOC-8 specifies medical necessity of specific GACs, an FEHB plan cannot exclude or deny a covered service on the basis of being TGD or seeking it as part of a gender transition/affirmation provided that the covered service is specified by WPATH as medically necessary.

For example, if a plan covers certain facial reconstruction surgeries, then the plan must make them available on their plan as part of a gender transition. Another example is if a plan offers breast reconstruction due to a diagnosis of breast cancer, then the plan must offer it due to diagnosis of gender dysphoria/incongruence. This requirement does not mandate a carrier to offer any GAC services specified by WPATH, nor does it prevent a carrier from denying a certain service due to an individualized evaluation of medical necessity. It does, however, prevent carriers from covering a service in one medically necessary context but never in another. Explicitly requiring FEHB carriers to adopt WPATH SOC-8 would ensure that the above requirements of Carrier Letter 21-05 and 22-03 are met.

To not adopt the aspects of medical necessity, timing, or indications for certain GAC services mentioned in the WPATH SOC-8 would leave a void carriers must fill with a generally acceptable SOC for those aspects not adopted. If an FEHB carrier wishes to depart from WPATH's SOC in this manner, then the carrier should be required to submit an alternate SOC to OPM for review that explains any departures from WPATH, how their chosen SOC satisfies OPM's criteria described in Call Letter 22-03, and how it appropriately addresses the void that would be left by WPATH. PFS would greatly appreciate being kept informed if OPM has already or later determines one or more SOC(s) fulfill both the aforementioned criteria specified in the carrier letters and the provision of details on indications, medical necessity and timing for GAC services (as in WPATH SOC-8).[36] PFS strongly recommends that only peer-reviewed research published by a credible source, and which does not undermine the "core principles"[37] of WPATH SOC-8, be eligible to inform departures from WPATH's SOC.[38]

Carriers Should Not Be Permitted to Rely on Sources that Do Not Meet OPM's Criteria for Generally Acceptable SOC

A health insurance carrier's policies for GAC services (in this document referred to as "medical policies") are often used in place of or as a proxy for WPATH SOC; thus, an insurance carrier's medical policy should be held to the same criteria for an acceptable

[36] 2022-03 Call Letter specifies WPATH, the Endocrine Society, and the Fenway Institute as acceptable entities for their acceptable SOC. WPATH endorsed Endocrine Society's guidelines for gender-affirming hormone therapy. See Chapter 12 and statement 5.6. WPATH also cites the Pediatric Endocrine Society.
[37] See Appendix WPATH SOC-8 Core Principles (S21)
[38] While WPATH acknowledges that their SOC are intended to be flexible clinical guidelines and mention that clinical departures from the SOC may come about in a few situations (including a research protocol; unique anatomic, social, or psychological situation; or an experienced health care professional's evolving method for handling a common situation), they require these departures be documented and explained to the patient. See Supra Note 5 "Flexibility in the SOC" on S56 of WPATH SOC-8.

standard of care. One potential source carriers may base their medical policies on are health technology assessments (HTAs), such as those published by Hayes, Inc. Their report on GAC[39] (in this document referred to as "Hayes"), however, does not meet OPM's above stated requirement for the basis of an acceptable SOC. Specifically, Hayes is not accessible to the public at a reasonable cost, is **not peer reviewed**, and **contradicts the growing medical consensus of the medical necessity of GAC**. These reasons alone are sufficient for OPM to require carriers to not base their medical policies on Hayes, though this is not to say that carriers should be prohibited from referencing it.[40]

What is the history of the development of Hayes and for what purpose was Hayes used before? Around 2005, *after* the implementation of Washington State's Department of Social and Health Services' (DSHS) regulations that made receiving GAC more difficult, DSHS commissioned the first Hayes report on GAC to question the safety and efficacy of GAC surgical treatment.[41] Hayes has historically made strong recommendations contrary to those of WPATH, the American Medical Association (AMA), and the American Psychological Association (APA) regarding the medical necessity of GAC. The Palm Center's 2018 evidence brief reviews the state of the evidence for GAC as well as erroneous reports used to undermine the conclusions of these respected medical authorities.[42] The paper documents its lack of peer-review, blatant omissions of strong evidence cited in APA's 2012 Task Force Report and patterns of misrepresenting the quality and conclusions of available research, illustrating a systematic bias to reach a conclusion favorable to rationalize denying care.[42] Hayes is referenced by carriers' medical policies on GAC and may be used to bolster their determination that a certain GAC procedure is not medically necessary in contradiction to WPATH SOC-8.[43] For example, Hayes was weaponized in the defense of firing Aimee Stephens, one of the underlying plaintiffs in the landmark Supreme Court case *Bostock v. Clayton County*,[44] after stating her intention to come to work dressed as a woman.[45] Ultimately, the Supreme Court sided with

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[39] See Sex Reassignment Surgery for the Treatment of Gender Dysphoria available at https://www.hayesinc.com/publications/evidence-analysis/health-technology-assessment/sex-reassignment-surgery-for-the-treatment-of-gender-dysphoria/dir-sex707/

[40] Examples of appropriate references to Hayes include using it to acknowledge other opinions or providing rationale for divergence from Hayes, as in this paper.

[41] Dean Spade; *Medicaid Policy & Gender-Confirming Healthcare for Trans People: An interview with Advocates*; Seattle Journal For Social Justice, Vol. 8, Issue 2, 2010. page 503. http://www.deanspade.net/wp-content/uploads/2010/07/SJSJ-MEdicaid-Final.pdf;

[42] See Transgender Troops are Medically Fit available at https://palmcenterlegacy.org/wp-content/uploads/2018/04/Transgender-troops-are-medically-fit-pdf.pdf. Note: this cannot be accessed through the firewall.

[43] See example: https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/gender-dysphoria-treatment.pdf effective date 11/2021, page 11of 17. UHC lists the conclusions reached by Hayes under "Clinical Evidence" and specific studies and conclusions are listed after. It is unclear if these summaries are quoted or paraphrased by Hayes (given it's unavailable). Given that UHC FEHB plans and this medical policy indicate that they view most GAC services as not medically necessary.

[44] 590 U.S. ___, 140 S. Ct. 1731 (2020), available at https://www.supremecourt.gov/opinions/19pdf/17-1618_hfci.pdf.

[45] See also *R. G. & G. R. Harris Funeral Homes, Inc. v. Equal Employment Opportunity Commission et al.*, on certiorari to the United States Court of Appeals for the Sixth Circuit., available at https://www.supremecourt.gov/DocketPDF/18/18-

Stephens, holding that transgender individuals cannot be fired because of their gender identity. Also of note, the Northwest Justice Project was able to successfully represent clients denied GAC under DSHS, but Medicaid recipients who did not have access to legal services were not successful.[41] This further illustrates access issues to GAC for those who cannot afford legal services.

PFS strongly recommends that FEHB carriers adopt WPATH SOC-8 in alignment with OPM's requirements of providing medically necessary care under the guidelines of a peer-reviewed SOC aligned with current medical guidelines and evidence.

Evidence Appraisal and Bias

SOC-8 asserts that "gender-affirming interventions are based on decades of clinical experience and research; therefore, they are not considered experimental, cosmetic, or for the mere convenience of a patient. They are safe and effective at reducing gender incongruence and gender dysphoria" and cites 25 studies to support this claim.[5] As mentioned, GAC is also endorsed by the APA, AMA, and most major U.S. medical institutions as medically necessary care for TGD individuals.[26] Claims to the contrary, for which Hayes is a prominent example, should therefore be scrutinized for bias. Evidence appraisal is an important method for evaluating treatment and allocation of resources within the process of creating an HTA, similar to evidence-based medicine.[46,47] While this process is undeniably important in establishing best practices in healthcare, it is not without bias. Resource allocation in scientific funding and profit-driven research creates significant disparities in the amount and level of research available on treatments and healthcare issues for marginalized people groups.[48] Research also suggests that even designing an HTA to focus exclusively on efficacious treatments can lead to policy decisions that undermine equity.[49] Since equity is not a variable in the analysis, it is not an outcome that is pursued.[49] HTAs should include consideration of physician specialty society recommendations, published SOCs and equity issues in their analysis and be carefully reviewed for bias when these elements are absent or contradict existing recommendations.

107/113262/20190822151939369_TO%20PRINT%2019-8-22%20Dr.%20Paul%20McHugh%20Amicus%20Brief%20FINAL.pdf

[46] See "Health technology assessment and evidence-based medicine: what are we talking about?" Available at https://pubmed.ncbi.nlm.nih.gov/19523187/

[47] See "EBM, HTA, and CER: Clearing the Confusion" available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2980346/

[48] See "Evidence based medicine and justice: a framework for looking at the impact of EBM upon vulnerable or disadvantaged groups" available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1733835/pdf/v030p00141.pdf

[49] See "Equity in HTA: what doesn't get measured, gets marginalised" available at https://ijhpr.biomedcentral.com/articles/10.1186/s13584-017-0162-3

Lack of Gender-Inclusive Language in All Federal Employee Benefits Healthcare Plans

As acknowledged in OPM Carrier Letter 2022-04, words are important. Language can reveal and enforce harmful stereotypes, or it can be used to challenge prevailing norms and conventions. By using gender inclusive language, we not only signal that we value equity we can also help speak it into being, advancing social progress for people of all genders. While the CDC supports the adoption of more inclusive language for LGBTQIA+ people through its public guidance, language specifying the use of "gender-affirming" when referring to GAC remains absent under the current guidance. PFS appreciates the actions taken by OPM thus far to establish standards of inclusive communication. PFS believe this additional change supports greater inclusion to TGD individuals who do not feel their transition related services constitute a reassignment of gender but merely an affirmation of their gender.

Lack of Coverage of Family Building Services for LGBTQIA+ Federal Employees

LGBTQIA+ people uniquely experience a high-cost barrier to building their families, either through adoption or Assisted Reproductive Technology (ART) procedures such as In Vitro Fertilization (IVF) and gestational surrogacy. Adoption costs are typically in the $30,000-$60,000 range,[50] and surrogacy can cost upwards of $120,000-$200,000.[51] ART is especially expensive for individuals who do not have the capacity to carry a child to term, including cisgender men in same sex relationships and those pursuing single fatherhood. The federal government lags behind many private sector employers in providing family-building benefits coverage. According to Mercer's 2021 Survey on Fertility Benefits, 61% of employers with 500 or more employees cover some type of infertility service. Meanwhile, the federal government's fertility benefits are extremely limited to cryopreservation in very limited circumstances and to some forms of artificial insemination. In stark contrast, most FEHB plans offer low or no cost maternity coverage, from which many LGBTQIA+ families are excluded, resulting in inequitable coverage that effectively discriminates against LGBTQIA+ employees and families.

PFS appreciates OPM's newly stated requirement in carrier letter 2022-03, requiring carriers to cover possible iatrogenic infertility, with the explicit inclusion of "infertility associated with medical and surgical gender transition treatment." However, to provide equitable reproductive coverage for individuals of all sexual orientations and gender identities, carriers must provide ART coverage to all individuals experiencing infertility, explicitly including those in same-sex partnerships or who are otherwise unable to reproduce without assistance due to their unique family structures as LGBTQIA+ individuals.[52] In addition to expanding the definition of infertility and fully covering ART

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[50] U.S. Department of Health and Human Services' Children's Bureau. *Factsheet for Families: Planning for Adoption: Knowing the Costs and Resources*. June 2022. Available at https://www.childwelfare.gov/pubpdfs/s_costs.pdf

[51] See Surrogacy Facts available at https://www.pbs.org/independentlens/blog/surrogacy-facts-and-myths-how-much-do-you-know/

[52] In 2020, RESOLVE: The National Infertility Association, NCLR (the National Center for Lesbian Rights), and Men Having Babies drafted an inclusive definition of "infertility" that is available online at: https://menhavingbabies.org/get-involved/advocacy/fertility-equality/

procedures, to achieve full equity for LGBTQIA+ employees, FEHB carriers should cover a third-party egg donor or gestational surrogate receiving the services in place of the covered individual (as is the case in live organ donation).

RESULTS

More Equitable Care for LGBTQIA+ Federal Employees

Adopting the recommendations below would significantly reduce unnecessary barriers to care and promote access to quality care for LGBTQIA+ federal employees. Operating on WPATH SOC-8 reduces stigmatizing protocols, treatment delays, and unnecessary costs for obtaining GAC.

Improved Health Outcomes

Increasing access and coverage to LGBTQIA+ competent medical and mental health providers will improve health outcomes for LGBTQIA+ employees.

Reduction in Cost and Wait Times for Medically Necessary Care

Consistent coverage of these services will improve health outcomes for employees, reduce the financial burden of seeking needed care out-of-pocket, and reduce wait times for TGD employees accessing medically necessary care.

Increased Hiring and Retention of Qualified LGBTQIA+ Employees

Reduced barriers to comprehensive gender-affirming healthcare and family building services promotes diversity and inclusion in the federal workforce, which helps the federal government hire and retain exceptionally qualified LGBTQIA+ employees. The PFS survey of federal employees in need of gender-affirming healthcare for themselves and/or their dependents found that:

> "nonfederal employers offer health insurance that provides more robust coverage of [gender-affirming healthcare], creating a strong incentive for individuals seeking such care for themselves or their dependents to choose careers outside the federal government. Some respondents reported that they considered careers outside the federal government for this reason, and we have no way to assess how many people might have left federal service to obtain needed healthcare."

Covering ART reduces high-risk pregnancies and associated costs, and benefits both LGBTQIA+ and non-LGBTQIA+ employees.

Providing equitable family-building coverage allows the federal government to stay competitive in attracting and retaining highly qualified LGBTQIA+ employees, be recognized as a "family friendly" employer, support DEIA efforts, and mitigate the cost of

high-risk pregnancies. With regard to this last point, data show that without insurance covering fertility treatments, employees paying out of pocket for these procedures typically try to maximize the chance of pregnancy by transferring multiple embryos, which can lead to multiple births, increasing the chances of pre-term births, low birth weights, and time spent in a neonatal intensive care unit—expenses that are ultimately covered by the employer's plan. According to the Mercer study cited above, since fertility coverage expenses are offset by a reduction in high-risk pregnancies, the vast majority of employers—97 percent—did not experience any increase in costs after providing fertility benefits.

Expanding FEHB to cover ART also benefits non-LGBTQIA+ women and cisgender heterosexual couples who experience difficulty conceiving or carrying a pregnancy to term, which, according to the Centers for Disease Control and Prevention, affects one in eight women of childbearing age.

Recommendations

RECOMMENDATION #1: REDUCE BARRIERS TO CARE FOR LGBTQIA+ COVERED LIVES

To reduce preauthorization barriers,[53] OPM should:

- Require FEHB carriers to adopt the ICD-11 diagnostic code "gender incongruence" (HA60 and HA6Z) and related assessment standards for billing and authorization of GAC. If carriers need time to implement this new diagnostic code, require they transition their assessment criteria for the existing diagnostic code "gender dysphoria" (F64) to that of "gender incongruence" (HA60 and HA6Z).

- Require that FEHB carriers not exceed the diagnosis and assessment requirements of WPATH SOC-8 for GAC procedures for the purpose of authorization. Of note, this includes changes to many current carrier authorization requirements, including but not limited to the following:

    - For Trans and Gender Diverse (TGD) adults, the full diagnosis and assessment criteria may be completed by either a competent medical or mental HCP. Psychotherapy is never a requirement for GAC and no more than one letter documenting that authorization criteria has been met may be required (and, again, the letter may be completed by either a competent medical or mental HCP).

    - Sex/gender markers on legal documents or paperwork, hormone levels and/or duration on a hormone treatment/hormone suppression, or duration of and/or plan for social transition are not acceptable criteria for GAC eligibility/authorization.

[53] See Preauthorization Barriers, p.5-7 for discussion

- Age-specific exclusions and parental/guardian consent are not appropriate authorization criteria. For adolescents, physiological attributes (Tanner stage 2) and a multidisciplinary assessment (that may involve parents/guardians if deemed not harmful to the adolescent's care) outlined in Chapter 6 of WPATH SOC-8 are the appropriate eligibility criteria for adolescent GAC.

- Disallow lifetime maximums and exclusions on revisions and reversals for GAC procedures in FEHB plans.

- Require carriers to allow for authorization of adult GAC under the rationale of harm reduction, requiring that assessment for this be allowed by either a single competent medical or mental HCP with a master's degree or greater per WPATH SOC-8.

To reduce care networks barriers,[54] OPM should:

- Require carriers to maintain an accurate and accessible list of all in-network mental and medical HCP who provide GAC.

- Require carriers to authorize robust, out-of-network coverage options for the assessment and provision of GAC, including but not limited to reimbursement-based coverage, for the purpose of reducing lengthy delays in the provision of such care.

- Require carriers to authorize robust, out-of-network coverage options, including but not limited to reimbursement-based coverage, for the provision of culturally competent psychotherapy.

- Require carriers to provide members navigating GAC decisions access to care coordinators with accurate information on in-network and out-of-network providers and coverage options for care.

- Create government-funded travel options for accessing GAC for FEHB covered lives needing access to GAC who are unable to access it due to state or local bans.

- Provide remote work and relocation options for TGD government employees affected by state or local bans on GAC.

To reduce claim appeals barriers,[55] OPM should:

- Create an easily accessible and user-friendly online platform for OPM claim appeals.

- Require FEHB carriers to create online platforms for claim appeals with clear links to the claim appeal page on the carrier home page and step by step instructions outlining how to successfully navigate the claim appeals process.

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[54] See Lack of Sufficient Provider Network, page 7 for discussion.

[55] See Outdated Appeals Processes, page 8-9 for discussion.

- Create a claims appeals homepage on the OPM website and keep updated information and training resources on the disputed claims process on the website.

- Implement methods to increase communication to consumers regarding the appeal process by OPM and also require implementation by carriers. Recommended methods include: reporting an estimated time in which someone submitting an appeal should receive an acknowledgment that it has been received, acknowledging the receipt of the appeal, reporting an expected wait time for an appeal verdict, providing instructions for follow-up, and requiring that FEHB plans include standardized verbiage on how an enrollee can appeal sustained FEHB coverage denials with OPM.

- Create highly visible annual awareness campaigns to improve consumer awareness of the claim appeal process with both OPM and where to find information on the appeal process in FEHB brochures.

RECOMMENDATION #2: PROMOTE QUALITY HEALTHCARE FOR LGBTQIA+ COVERED LIVES

To promote access to quality sexual health,[56] OPM should:

- Require FEHB carriers to cover all routine sexual health screenings, lab work, and PrEP/PEP interventions per CDC guidelines.

To ensure consistent coverage of comprehensive gender-affirming care,[57] OPM should:

- Require carriers to provide the full scope of GAC recommended by WPATH's SOC-8,[58] including initial/pre-op, preventative and follow-up care and related tests/examinations.[59]

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[56] See Sexual Health, page 8 for discussion.

[57] See Inconsistent Coverage for Comprehensive Gender-Affirming Care, page 9-10 for discussion.

[58] "Medically necessary gender-affirming interventions," as defined by SOC-8, "include but are not limited to hysterectomy +/- bilateral salpingo-oophorectomy; bilateral mastectomy, chest reconstruction or feminizing mammoplasty, nipple resizing or placement of breast prostheses; genital reconstruction, for example, phalloplasty and metoidioplasty, scrotoplasty, and penile and testicular prostheses, penectomy, orchiectomy, vaginoplasty, and vulvoplasty; hair removal from the face, body, and genital areas for gender affirmation or as part of a preoperative preparation process; gender-affirming facial surgery and body contouring; voice therapy and/or surgery; as well as puberty blocking medication and gender-affirming hormones; counseling or psychotherapeutic treatment as appropriate for the patient and based on a review of the patient's individual circumstances and needs." (See S18 and Appendix E for overview)

[59] See "Transgender Medical Benefits" available at https://www.wpath.org/media/cms/Documents/Public%20Policies/2018/6_June/Transgender%20Medical%20Benefits.pdf

- Require FEHB carriers to provide affordable coverage of the full scope of HRT and puberty suppressing medications and administration methods as outlined by Fenway Health's 2021 Medical Care of Trans and Gender Diverse Adults.[60]

- Enforce Carrier Letter 2021-05 that stipulates carriers "must provide benefits for all covered services when medically necessary" including the individualized needs of TGD people. Additionally, enforce Call Letter 2022-03 that requires carriers to "adopt an acceptable standard of care … based on credible scientific evidence published in peer-reviewed medical literature and generally recognized by the relevant medical community and physician specialty society recommendations."[61]

- Expand on Call Letter 2022-03 criteria for an acceptable SOC for GAC by also requiring adherence to WPATH SOC-8 "core principles"[62]

- Require carriers to adhere to a FEHB Plan Brochure Template that demonstrates an explicit statement of coverage outlining the full out-of-pocket cost for each gender-affirming procedure.

- Require carriers to adhere to a FEHB Plan Brochure Template that utilizes the term "gender-affirming" in place of words such as "reassignment" or "transformation" when referring to transition-related care.[63]

To promote equitable access to family building benefits and services for LGBTQIA+ federal employees,[64] OPM should:

- Require FEHB carriers to fully cover ART procedures such as IVF, artificial insemination, egg, embryo, and sperm retrieval, collection, cryopreservation, storage, thawing, and transfer, and gestational surrogacy. Carriers should also cover the cost of obtaining donor sperm, donor eggs, and fertility drugs.

- Require FEHB carriers to fully cover the diagnosis of infertility, using an inclusive definition that includes not only a medical disease or condition, but also a personal status (i.e., a person's inability to reproduce either as a single individual or with their partner without medical intervention). This means, for example, that a clinical diagnosis of infertility based on heterosexual intercourse would not be required for coverage.

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[60] Androderm patch, Androgel packets, Androgel actuated pump, Testim tubes, testosterone underarm solution, Testopel, testosterone undecanoate capsules (Jatenzo), Estradiol tablets, estradiol patches, estradiol gel, estradiol valerate, estradiol cypionate, spironolactone, finasteride, dutasteride, bicalutamide, GnRH agonists (leuprolide, triptorelin), micronized progesterone (Prometrium).

[61] See OPM May Already Require the Adoption of WPATH SOC, page 10-13 for discussion.

[62] See Appendix WPATH SOC-8 Core Principles (S21)

[63] See Lack of Gender-Inclusive Language in All Federal Employee Benefits Healthcare Plans, page 13 for discussion.

[64] See Lack of Coverage of Family Building Services for LGBTQIA+ Federal Employees, page 14 for discussion.

- Require FEHB carriers to cover a third-party egg donor or gestational surrogate receiving the services in place of the covered individual (as is the case in live organ donation).

Appendix

ABOUT PFS

PFS is an interagency work group focused on equal employment opportunity and engagement related to sexual orientation, gender identity, and gender expression. PFS contributes to achieving a diverse, qualified federal government workforce by establishing a network of practitioners, Special Emphasis Program Managers (SEPMs), Equal Employment Opportunity specialists, and Employee Resource Group leaders to collaborate on inclusive workplace policies and best practices for everyone regardless of sexual orientation, gender identity, and gender expression. The mission of PFS is to provide a forum for sharing best practices and resources and coordinating on federal diversity, equity, inclusion, and accessibility efforts related to equal opportunity for all members of the lesbian, gay, bisexual, transgender, queer, intersex, asexual plus (LGBTQIA+) community. PFS works to support equal employment opportunity and engagement for all applicants and employees, regardless of sexual orientation, gender identity, gender expression, race, ethnicity, sex, religion, national origin, disability status, or any other protected class or affinity. PFS is independent of any agency of the government and is nonpartisan and independent of any other non-profit, political or lobbying group, association, or organization.

PFS MEMBER SURVEY

In 2021, PFS conducted survey of federal employees about their experiences obtaining gender-affirming healthcare (GAHC) or transition-related care (TRC) for themselves or their dependents through their employer-based health plan. The survey results revealed serious deficiencies in benefits under the current FEHB program. Among other findings, our respondents identified several GAHC and TRC services that were unavailable via their Federal Employee Healthcare Benefits (FEHB) program. Some respondents did not seek medically necessary care because their insurance plan brochure excluded coverage of it; others filed claims that were denied. Other respondents reported significant out-of-pocket expenses. Few knew how to appeal claim rejections to their insurer or to OPM, indicating a need for targeted training.

WPATH SOC-8 CORE PRINCIPLES (S21)

General principles

- Be empowering and inclusive. Work to reduce stigma and facilitate access to appropriate health care, for all who seek it;

- Respect diversity. Respect all clients and all gender identities. Do not pathologize differences in gender identity or expression;

- Respect universal human rights, including the right to bodily and mental integrity, autonomy, and self-determination; freedom from discrimination and the right to the highest attainable standard of health.

Principles around developing and implementing appropriate services and accessible health care

- Involve TGD people in the development and implementation of services;
- Become aware of social, cultural, economic, and legal factors that might impact the health (and health care needs) of TGD people, as well as the willingness and capacity of the person to access services;
- Provide health care (or refer to knowledgeable colleagues) that affirms gender identities and expressions, including health care that reduces the distress associated with gender dysphoria (if this is present);
- Reject approaches that have the goal or effect of conversion, and avoid providing any direct or indirect support for such approaches or services

Principles around delivering competent services

- Become knowledgeable (get training, where possible) about the health care needs of transgender and gender diverse people, including the benefits and risks of gender-affirming care;
- Match the treatment approach to the specific needs of clients, particularly their goals for gender identity and expression;
- Focus on promoting health and well-being rather than solely the reduction of gender dysphoria, which may or may not be present;
- Commit to harm reduction approaches where appropriate;
- Enable the full and ongoing informed participation of transgender and gender diverse people in decisions about their health and well-being;
- Improve experiences of health services, including those associated with administrative systems and continuity of care.

Principles around working towards improved health through wider community approaches

- Put people in touch with communities and peer support networks;
- Support and advocate for clients within their families and communities (schools, workplaces, and other settings) where appropriate

CalOptima Health
A Public Agency
505 City Parkway West
Orange, CA 92868
☎ 714-246-8400
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caloptima.org

August 8, 2022

VIA ELECTRONIC MAIL

Eric Press
Equal Opportunity Specialist
Office for Civil Rights, Pacific Region
90 7th Street, Suite 4-100
San Francisco, California 94103
Eric.press@hhs.gov

RE: (b)(6); (b)(7)(C)

Dear Mr. Press:

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Subject: FW: [MARKETING EMAIL]Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban
Date: 2022/12/20 09:30:19
Priority: Normal
Type: Note

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Seeger, Rachel (HHS/OCR) <Rachel.Seeger@hhs.gov>
Sent: Tuesday, December 20, 2022 9:28 AM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Cc: Lopez, Onelio (HHS/OCR) <Onelio.Lopez@HHS.GOV>
Subject: RE: [MARKETING EMAIL]Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban

Hi (b)(6)

Please see the attached. We only have one Law360 subscription for the office, so please just let me know if you ever need anything. We have a very basic account, so not all content is accessible. That said, if I can pull an article and supporting materials, I will.

Best,
Rachel

From: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Tuesday, December 20, 2022 9:19 AM
To: Lopez, Onelio (HHS/OCR) <Onelio.Lopez@HHS.GOV>; Seeger, Rachel (HHS/OCR) <Rachel.Seeger@hhs.gov>
Subject: FW: [MARKETING EMAIL]Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban

Hi Onelio,

Apologies if you have already pulled the below article – if you have, can you please resend, and if not are you able to either get this article or one discussing the same case? If I recall we may not have law360 access…

Also – love to see these wins coming in!

Thank you!
(b)(6)

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: Benefits Law360 <news-alt@law360.com>
Sent: Tuesday, December 20, 2022 4:50 AM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: [MARKETING EMAIL]Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban

s Suit Challenging Trans Care Ban

londay sided with a transgender teenager who sued Blue Cross Blue Shield of Illinois for denying coverage for gender dysphoria- health care giant couldn't claim it was exempt from the Affordable Care Act's anti-bias policy.

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er's Suit Over Pension Payments

red UPS driver's lawsuit claiming he was shorted on his monthly pension payments, saying that a lower court jumped the gun ate.

ticle »

ealth Coverage Policy Is Illegal

ender bias complaint against a turbomachinery company at a New Hampshire state agency, alleging the company's blanket ban er dysphoria-related treatments is unlawful discrimination.

article »

COMPLIANCE

ions, Cigna Says Everybody Does It

ral judge that the U.S. Department of Justice's False Claims Act lawsuit accusing it of defrauding Medicare Advantage by challenging an "industry-wide practice."

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ercharging For Vets' Tuition

atically cheated the U.S. Department of Veterans Affairs out of millions of dollars by inflating reimbursements for veteran Justice has claimed in a suit filed in Michigan federal court.

article »

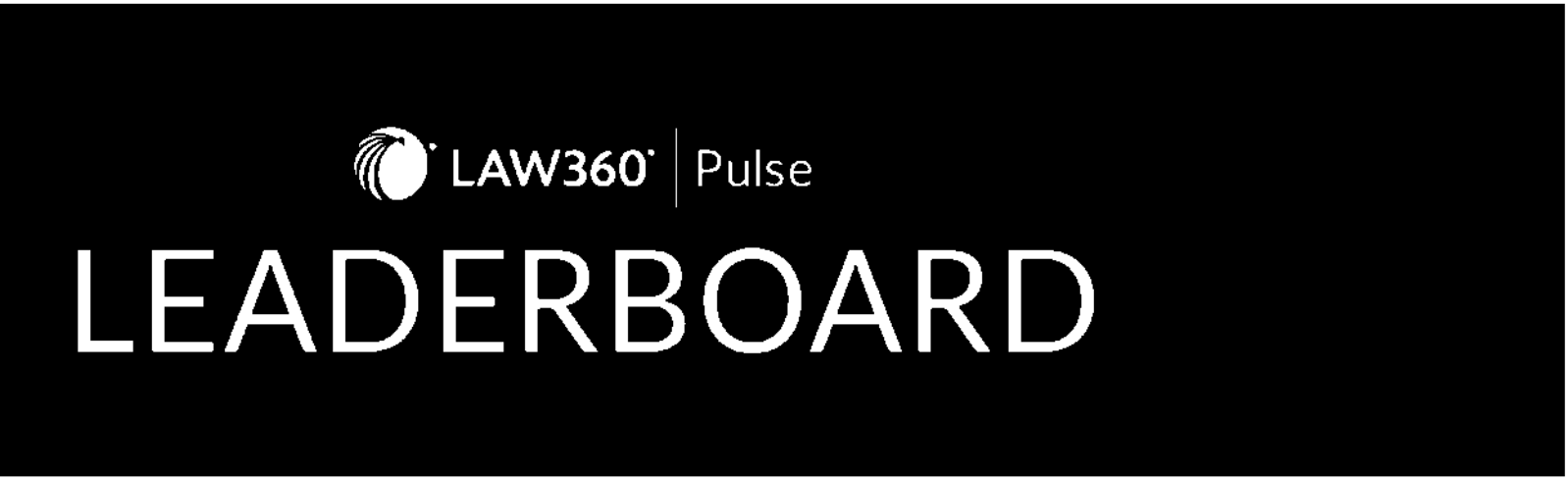
K Of $25M Post-IPO Drop Suit Deal

reliminary approval to Lyft's $25 million deal to end an investor class action alleging the company concealed sexual assault of its 2019 initial public offering, ruling Friday that the settlement is well within the range of approval.

le »

nt Laws In 2022 And Beyond

er drowning out other topics in Pennsylvania employment law, 2022 instead saw a variety of worker-friendly changes introduced nd that may continue to grow in 2023 under Gov.-elect Josh Shapiro, say J.T. Holt and Claire Throckmorton at Reed Smith.



Law360

r McKenzie's Bonus Scale

s Kellogg Hansen Todd Figel &Frederick PLLC are part of the latest round of law firms announcing their year-end bonuses, with rd set last month by Baker McKenzie.

To Refer Trump To DOJ

e Jan. 6 attack on the U.S. Capitol voted unanimously Monday to refer former President Donald Trump to the U.S. Department of the 2020 election, citing four criminal statutes it says he violated in the lead-up to and in the midst of the deadly insurrection.

Jackson To Take Senior Status

Jackson of the District of Columbia federal court will assume senior status in May, according to the Administrative Office of the udicial vacancies, giving President Joe Biden the opportunity to nominate another judge to the bench.

ct 'Supersized' Privilege Test

egal and nonlegal advice should not be shielded from grand jury subpoenas by a "supersized" attorney-client privilege unless the federal government told the U.S. Supreme Court.

e »

n Funder In Google Suit Fee Fight

e has backed a $1.8 million arbitration award in favor of a British litigation funder in its battle with a San Francisco law firm over patent infringement lawsuit against Google.

rticle »

e's Chancery Court

eady for the holidays this week, gifting one of their top justices to the Third Circuit, putting a bow on a multimillion-dollar fee c dispute for an arbitrator. Hope you enjoy the last wrap-up this year of last week's news from Delaware's Chancery Court.

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Teen Wins Blue Cross Bias Suit Challenging Trans Care Ban

By **Grace Elletson**

Law360 (December 19, 2022, 7:50 PM EST) -- A Washington federal judge on Monday sided with a transgender teenager who sued Blue Cross Blue Shield of Illinois for denying coverage for gender dysphoria-related treatments, ruling that the health care giant couldn't claim it was exempt from the Affordable Care Act's anti-bias policy.

A Washington federal judge found that Blue Cross Blue Shield of Illinois was not exempt from the ACA's anti-discrimination provision when it denied coverage to a transgender teen for gender dysphoria treatment. (iStock.com/jetcityimage)

U.S. District Judge Robert J. Bryan **granted** the teen, identified as C.P., and his mother, Patricia Pritchard, summary judgment in their class action lodged against Blue Cross' Illinois branch, after finding that the company couldn't evade the ACA's anti-discrimination provision, or Section 1557, as a third-party health plan administrator.

The ACA's anti-bias provision, "includes third party administrators of health insurance plans," Judge Bryan said. "To hold otherwise would thwart Congress's intent to prohibit discrimination in the provision of 'health programs and activities.'"

C.P. and his mother sued Blue Cross in November 2020. Pritchard enrolled in the Blue Cross health plan provided by her employer, Catholic Health Initiatives, which dictated that coverage would not be given for

any treatments of gender dysphoria, including therapy, hormones and gender-affirming surgery.

Pritchard said this policy forced her to spend over $12,000 out of pocket on treatments for her son. They secured class certification for the suit in November, and are representing all individuals who are participants in an Employee Retirement Income Security Act-backed health care plan administered by Blue Cross and were blocked from receiving coverage for gender-affirming care.

Blue Cross argued that the ACA's anti-discrimination provision does not apply to the company in this case because it only acted as a third-party administrator that did not have control over which areas of coverage Pritchard's employer provided. Judge Bryan turned to the ACA statute, instead of a rule instituted by the Trump administration in 2020 rolling back much of the law's anti-bias restrictions, to center on Congress' intent with the law.

Congress enacted Section 1557 of the ACA to prohibit discrimination in health care, Judge Bryan said. And by applying the section to "any health program or activity" Congress intended to block bias by any entity operating within the health system, he said, which includes third-party administrators.

He also rejected Blue Cross' attempt to evade the ACA's anti-bias provision by arguing that it was obligated under ERISA to administer the gender dysphoria treatment exclusion. Judge Bryan agreed with C.P. and Pritchard's argument that Blue Cross had an independent obligation to comply with the ACA's Section 1557.

"ERISA specifically provides that its requirements are not to be construed to invalidate or impair laws like Section 1557 and so ERISA's requirement that Blue Cross follow the exclusion's language is no defense," Judge Bryan said.

Blue Cross argued in a **mid-December hearing** that the Religious Freedom Restoration Act would allow CHI to enact the coverage exclusion based upon its sincerely held religious beliefs, and therefore allow Blue Cross to enforce the plan. But Judge Bryan didn't buy the claim. He said in his Monday order that the act applies to relief against the government, not private parties.

Attorney Eleanor Hamburger, who represents C.P. and Pritchard, said in a news release that the court has made clear that Blue Cross has a separate legal obligation to prevent discrimination.

"The court has pulled back the curtain and made it clear that BCBSIL cannot hide behind a defense that it was 'just following orders' from Pritchard's employer to apply the illegal exclusion," Hamburger said.

Pritchard said in the release that her son and other transgender youth deserve the ability to thrive and access the medical care they need.

"I'm relieved the court saw the justice in our claim, and hope that BCBSIL will not continue to throw obstacles in our way to access the care our son needs and is legally entitled to," Pritchard said.

Representatives for Blue Cross Blue Shield of Illinois did not immediately respond to requests for comment.

C.P. and Pritchard are represented by Eleanor Hamburger and Daniel S. Gross of Sirianni Youtz Spoonemore Hamburger PLLC, and by Omar Gonzalez-Pagan and Jennifer C. Pizer of Lambda Legal Defense and Education Fund.

Blue Cross Blue Shield of Illinois is represented by Gwendolyn C. Payton and John R. Neeleman of Kilpatrick Townsend & Stockton LLP.

The case is Pritchard et al. v. Blue Cross Blue Shield of Illinois, case number 3:20-cv-06145, in the U.S. District Court for the Western District of Washington.

--Additional reporting by Greg Lamm. Editing by Leah Bennett.

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C. P., by and through his parents, Patricia Pritchard and Nolle Pritchard, individually and on behalf of others similarly situated; and PATRICIA PRITCHARD,

Plaintiff,

v.

BLUE CROSS BLUE SHIELD OF ILLINOIS,

Defendant.

CASE NO. 3:20-cv-06145-RJB

ORDER ON CROSS MOTIONS FOR SUMMARY JUDGMENT

This matter comes before the Court on the Defendant Blue Cross Blue Shield of Illinois' ("Blue Cross") Motion for Summary Judgment (Dkt. 87), and the Plaintiffs' Cross Motion for Summary Judgment (Dkt. 96), and Plaintiffs' motion to strike (Dkt. 126). The Court has considered the pleadings filed in support of and in opposition to the motions, oral argument heard on 12 December 2022, and the file herein.

In this case, Plaintiffs C.P., a transgender male, and his mother, Patricia Pritchard, claim that Blue Cross violated the anti-discrimination provision of the Affordable Care Act ("ACA"),

42 U.S.C. § 18116, when it administered discriminatory exclusions of gender-affirming care in a self-funded health care plans governed by the Employee Retirement Income Security Act of 1974 ("ERISA"). Dkt. 1. The Plaintiffs' motion to certify a class of similarly situated people was granted on November 9, 2022 (Dkt. 113) and amended on December 12, 2022 (Dkt. 143).

Blue Cross moves for summary judgment on Plaintiffs C.P. and Ms. Pritchard's claims. Dkt. 87. Plaintiffs C.P. and Ms. Pritchard cross move for summary judgment on their claims as well as the class claims. Dkt. 96. For the reasons provided below, Blue Cross's Motion for Summary Judgment (Dkt. 87) should be denied and Plaintiffs' Motion for Summary Judgment (Dkt. 96) and motion to strike (Dkt. 126) should be granted.

I. RELEVANT FACTS, PROCEDURAL HISTORY, AND STATUTORY BACKGROUND

A. FACTS

Named Plaintiffs are C.P., a boy of seventeen, and his mother, Ms. Pritchard. Dkt. 38. C.P. is a transgender male, which means that he has a male gender identity even though the sex assigned to him at birth was female. *Id.* C.P. has been living as a male since around 2015. Dkt. 94-1 at 135.

Ms. Pritchard receives health care coverage through her employer under the Catholic Health Initiatives ("CHI") Medical Plan ("the Plan") and C.P. is enrolled in that Plan as her dependent. Dkts. 81; 97-12 at 8. The Plan is "self-funded" - Ms. Pritchard's employer directly assumes financial responsibility for employees and their dependents' health care costs. Dkt. 88-1 at 11.

Defendant, Blue Cross, acts as the third-party claims administrator for the Plan. Dkt. 85-10. As a third-party administrator, it "assemble[s] a network of providers, process[es] claims, and handle[s] provider billing." Dkt. 88-1 at 11. Blue Cross is a division of Health Care

Services Corporation and is one of the largest administrators of insured and self-funded health plans in the nation. *Id.* at 206. It does not receive Federal financial assistance for its administration of self-funded plans, but does receives Federal financial assistance for other of its "products, such as Medicare supplemental coverage, Medicaid, Medicare Advantage and Prescription Drug insurance coverage, and Medicare/Medicaid dual eligibility." *Id.*

C.P. has gender dysphoria. Dkts. 38; 97-3 at 2. Gender dysphoria is a feeling of clinically significant stress and discomfort that can result from being transgender, or, more specifically, from having an incongruence between one's gender identity and the sex assigned to that person at birth. Dkt. 38. The American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition recognizes gender dysphoria as a medical condition that can be extremely serious, resulting in anxiety, depression, or even death. Dkt. 38 at 6.

C.P. sought coverage for his first Vantas Implant (hormone therapy) in 2016. Dkt. 94-1 at 139. Blue Cross initially approved the treatment but later informed C.P.'s mother that it had made a mistake; it stated that the treatment was not covered under the Plan. Dkt. 94-1 at 137. Blue Cross paid for the treatment however, but indicated that later claims would be denied. *Id.* at 139. A few years later, in 2019, C.P. filed a claim for a second Vantas Implant and for chest reconstruction surgery; his claim was denied by Blue Cross because "[t]ransgender services [were] not covered under the terms of the Plan." *Id.*; 88-1 at 197; 94-3 at 2-10.

The relevant exclusionary language in the Plan in 2019 provided: "Transgender Reassignment Surgery Not Covered: Benefits shall not be provided for treatment, drugs, therapy, counseling services and supplies for, or leading to, gender reassignment surgery" ("Exclusion"). Dkt. 88-1 at 120. The Plan generally covers care for hormone treatments, mastectomies and chest reconstruction if that care is considered medically necessary for diagnosis other than for

gender affirming care (like for breast cancer). Dkt. 85-8 at 12-13. The condition that triggers Blue Cross to apply the Exclusion is the diagnosis of gender dysphoria. *Id.* at 14.

After his claim was denied, C.P. received treatment – Ms. Pritchard paid $12,122.50 for the uncovered chest surgery and Vantas Implant. Dkt. 88-1 at 299.

B. PROCEDURAL HISTORY

Plaintiffs, including the class, bring a claims for violation of the antidiscrimination provision of the ACA. Dkt. 38. This provision is referred to in the case law and HHS regulations as "Section 1557" (although codified as 42 U.S.C. § 18116(a)), and this order will refer to it in the same manner. All Plaintiffs seek a declaration that Blue Cross violated Plaintiffs' rights under Section 1557 when it administered the Exclusion and other similar exclusions in other plans. Dkt. 38 at 21. They seek an order enjoining Blue Cross from "administering or enforcing health benefit plans that exclude coverage for gender-affirming health care, including applying or enforcing the Plan's Exclusion of services 'for, or leading to, gender reassignment surgery,' and other similar exclusions . . . during the class period, now and in the future." *Id.* at 21-22. The Plaintiffs seek an order requiring Blue Cross to reprocess, "and when medically necessary and meeting the other terms and conditions under the relevant plans, provide coverage (payment) for all denied pre-authorizations and denied claims" that were based solely upon exclusions for gender affirming care. *Id.* at 22.

Ms. Pritchard brings a claim for financial harm. *Id.* C.P. and Ms. Pritchard bring claims for emotional distress damages, attorneys' fees, costs and expenses. *Id.*

In the December 12, 2022 Amended Order Certifying the Class, the class was certified as:

All individuals who:

> (1) have been, are, or will be participants or beneficiaries in an ERISA self-funded "group health plan" (as defined in 29 U.S.C. § 1167(1)) administered by [Blue Cross] during the Class Period and that contains a categorical exclusion of some or all Gender-Affirming Health Care services; and
>
> (2) were, are, or will be denied pre-authorization or coverage of treatment with excluded Gender Affirming Health Care services

DEFINITIONS:

> "Class Period" means November 23, 2016 through the termination of the litigation.
>
> "Gender-Affirming Health Care" means any health care service—physical, mental, or otherwise—administered or prescribed for the treatment of gender dysphoria; related diagnoses such as gender identity disorder, gender incongruence, or transsexualism; or gender transition. This includes but is not limited to the administration of puberty delaying medication (such as gonadotropin-releasing hormone (GnRH) analogues); exogenous endocrine agents to induce feminizing or masculinizing changes ("hormone replacement therapy"); gender-affirming or "sex-reassignment" surgery or procedures; and other medical services or preventative medical care provided to treat gender dysphoria and/or related diagnoses, as outlined in World Professional Association for Transgender Health, Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th Version (2012).

The class asserts claims that Blue Cross Blue Shield of Illinois violated the anti-discrimination provision of the Affordable Care Act, 42 U.S.C. § 18116, when it administered discriminatory exclusions of gender-affirming care in a self-funded health care plans governed by the Employee Retirement Income Security Act of 1974.

The class seeks declaratory relief. They seek an order enjoining Blue Cross Blue Shield of Illinois from administering or enforcing health benefit plans that exclude coverage for gender-affirming health care, including applying or enforcing the plans' exclusions of services for, or leading to, gender reassignment surgery,' and other similar exclusions during the class period, now and in the future. The class seeks an order requiring Blue Cross Blue Shield of Illinois to reprocess denied pre-authorizations and claims for gender affirming care under the relevant self-funded health care plans without applying the discriminatory

> exclusions, and when medically necessary and meeting the other terms and conditions of the relevant plans, provide coverage (payment) for those denied pre-authorizations and claims that were based solely on exclusions for gender affirming care.
>
> Blue Cross Blue Shield of Illinois raises several defenses, including that the anti-discrimination provision of the Affordable Care Act, 42 U.S.C. § 18116 does not apply to it, and even if it did, its third-party administration of the exclusions was not discriminatory. Blue Cross Blue Shield also contends that it is protected by the Religious Freedom Restoration Act.

Dkt. 143.

C. SECTION 1557, REGULATIONS AND LITIGATION BACKGROUND

This case takes place in the midst of sharply divided regulatory and litigation background. A quick review of the statute, the U.S. Department of Health and Human Services ("HHS") regulations, and related litigation is helpful in understanding the parties' positions.

The starting point is the text of the antidiscrimination provision of the ACA. Again, this provision is referred to in the case law and HHS regulations as "Section 1557" (although codified as 42 U.S.C. § 18116(a)). Section 1557 provides:

> "[A]n individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance . . . . The enforcement mechanisms provided for and available under such . . . title IX . . . shall apply for purposes of violations of this subsection."

42 U.S.C. § 18116(a). Title IX provides that "[n]o person . . . shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance." 20 U.S.C. § 1681.

1. 2016 Regulations

After passage of the ACA in 2010, HHS proposed, and then finalized, Section 1557 regulations on May 18, 2016 ("2016 Rule"). Non-Discrimination in Health Programs and

Activities, 81 FR 31,375. While this order substantially complies with the 2016 Rule, a nationwide injunction banning HHS from enforcing it is in place. *Franciscan All., Inc. v. Burwell*, 227 F.Supp.3d 660 (N.D. Tex. 2016) *as affirmed Franciscan All., Inc. v. Burwell*, 47 F.4th 368 (2022). Accordingly, the 2016 Rule does not impact this case.

2. 2020 Regulations

Meanwhile, on June 12, 2020, under the Trump administration, HHS finalized regulations (2020 Rule), effective on August 18, 2020, that rescinded significant portions of the 2016 Rule. Non-Discrimination in Health Programs and Activities, 85 FR 37,178. Various cases have been filed to prohibit enforcement of the 2020 Rule and to reinstate portions of the 2016 Rule, in particular, challenging the definition of discrimination "on the basis of sex." *See e.g. Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Human Servs.*, Case No. 1:20-cv-01630, 2020 WL 3444030 (D.D.C. June 22, 2020); *Walker v. Azar*, Case No. 1:20-cv-02834 (E.D.N.Y. June 26, 2020); *Boston All. of Gay, Lesbian, Bisexual & Transgender Youth v. U.S. Dep't of Health & Human Servs.*, Case No. 1:20-cv-11297, 2020 WL 3891426 (D. Mass. July 9, 2020). Injunctions prohibiting HHS from enforcing certain portions of the 2020 Rule's repeal of the 2016 Rule's definition of "on the basis of sex" are now in effect. *See Id.* This order does not comply with the 2020 Rule as provided in Section II. D. below.

3. 2021 HHS Notification and Proposed 2022 Regulations

On May 10, 2021, under the Biden administration, HHS issued a notice stating that it would interpret Section 1557's prohibition on sex discrimination to include discrimination on the basis of gender identity consistent with the U.S. Supreme Court's holding in *Bostock v. Clayton County*, 140 S. Ct. 1731 (2020). 86 FR 27,984. On August 4, 2022, HHS published a Proposed Rule that proposes repealing large portions of the 2020 Rule ("Proposed 2022 Rule"). Non-

Discrimination in Health Programs and Activities, 87 FR 47,824. While the Proposed 2022 Rule is not yet adopted, this order is substantially consistent with it - but the Proposed 2022 Rule does not impact this case.

II. DISCUSSION

A. MOTION TO STRIKE

The Plaintiffs move to strike a newspaper article from the New York Times that was submitted by Blue Cross. Dkt. 126. "Generally, newspaper articles and television programs are considered hearsay under Rule 801(c) when offered for the truth of the matter asserted." *See Green v. Baca*, 226 F.R.D. 624, 637 (C.D. Cal. 2005). No exception to the hearsay rule was offered. The Plaintiffs' motion (Dkt. 126) should be granted.

B. SUMMARY JUDGMENT STANDARD

Summary judgment is proper only if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The moving party is entitled to judgment as a matter of law when the nonmoving party fails to make a sufficient showing on an essential element of a claim in the case on which the nonmoving party has the burden of proof. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1985). There is no genuine issue of fact for trial where the record, taken as a whole, could not lead a rational trier of fact to find for the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986) (nonmoving party must present specific, significant probative evidence, not simply "some metaphysical doubt."). Conversely, a genuine dispute over a material fact exists if there is sufficient evidence supporting the claimed factual dispute, requiring a judge or jury to resolve

the differing versions of the truth. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 253 (1986); *T.W. Elec. Serv. Inc. v. Pacific Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

The determination of the existence of a material fact is often a close question. The court must consider the substantive evidentiary burden that the nonmoving party must meet at trial, which is a preponderance of the evidence in most civil cases. *Anderson*, 477 U.S. at 254; *T.W. Elect.*, 809 F.2d at 630. The court must resolve any factual issues of controversy in favor of the nonmoving party only when the facts specifically attested by that party contradict facts specifically attested by the moving party. The nonmoving party may not merely state that it will discredit the moving party's evidence at trial, in the hopes that evidence can be developed at trial to support the claim. *T.W. Elect.*, 809 F.2d at 630 (relying on *Anderson*, 477 U.S. at 255). Conclusory, non-specific statements in affidavits are not sufficient, and "missing facts" will not be "presumed." *Lujan v. Nat'l Wildlife Fed.*, 497 U.S. 871, 888–89 (1990).

C. PLAINTIFFS' SECTION 1557 CLAIM

The Plaintiffs' motion and Blue Cross's response raise issues of law. There are no serious fact issues before the Court.

Again, Section 1557 of the ACA provides:

> "[A]n individual shall not, on the ground prohibited under . . . title IX of the Education Amendments of 1972 (20 U.S.C. 1681 et seq.) . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance . . . . The enforcement mechanisms provided for and available under such . . . title IX . . . shall apply for purposes of violations of this subsection."

42 U.S.C. § 18116(a). Title IX prohibits discrimination "on the basis of sex" in education. 20 U.S.C. § 1681.

To make a claim for sex discrimination under Title IX and by extension, under 1557 of the ACA, the Plaintiffs must show that: (1) Blue Cross operates "a health program or activity, any part of which is receiving Federal financial assistance;" (2) the Plaintiffs were excluded from participation in, denied the benefits of, or subjected to discrimination in the provision of that "health program or activity;" and (3) the latter occurred on the basis of sex. *See Schwake v. Ariz. Bd. of Regents*, 967 F.3d 940, 946 (9th Cir. 2020).

1. Provision of Any Health Program or Activity, Any Part of Which Receives Federal Financial Assistance

Under the plain language of Section 1557, Blue Cross's third party administrator activities constitute the operation of a "health program or activity." The phrase "any health program or activity," is not defined in the ACA but it is clearly broader in scope than only the provision of healthcare. The phrase is further defined in a clause in Section 1557's text: "including . . . contracts of insurance." The plain language of Section 1557 indicates that a health insurance contract and the administration of a health insurance contract is a "health program or activity." *Schmitt v. Kaiser Found. Health Plan of Washington*, 965 F.3d 945, 951 (9th Cir. 2020)(holding that Section 1557 prohibits discrimination in the health care system which includes discrimination in health insurance contracts); *Kadel v. Folwell,* 2022 U.S. Dist. LEXIS 218104 *9 (M.D. N.C. Dec. 5, 2022).[1]

Further, while Blue Cross does not receive Federal financial assistance for its administration of self-funded plans, it receives Federal financial assistance for some of its other products including "Medicare supplemental coverage, Medicaid, Medicare Advantage and Prescription Drug insurance coverage, and Medicare/Medicaid dual eligibility." Dkt. 88-1 at

[1] *Kadel* mirrors many of the thoughts in this order.

206. Section 1557's phrase "any health program or activity any part of which is receiving Federal financial assistance" plainly includes "all the operations of a business" principally engaged in providing health programs and activities. *T.S. by & through T.M.S. v. Heart of CarDon, LLC*, 43 F.4th 737, 743 (7th Cir. 2022); *Kadel* at *9-10.

Accordingly, Blue Cross's third party administration activities are "health program[s] or activit[ies], . . . part of which receives Federal financial assistance." The Plaintiffs are entitled to summary judgment on this element of their claim and Blue Cross's motion for summary judgment on this element should be denied.

2. Plaintiffs were Excluded from, Denied the Benefits of, or Subjected to Discrimination in the Provision of a "Health Program or Activity"

Parties do not dispute that Blue Cross denied C.P.'s claim for gender affirming surgery or that C.P.'s mother was "denied the benefits" her employer's sponsored health plan. Parties do not dispute that Blue Cross denied other class members gender affirming care under exclusions in other self-funded plans. This element is met. The Plaintiffs are entitled to summary judgment on this element and Blue Cross's motion on this element should be denied.

3. Discrimination Occurred on Basis of Sex

Section 1557 forbids sex discrimination based on transgender status. *Doe v. Snyder*, 28 F.4th 103, 114 (9th Cir. 2022). This holding from the Ninth Circuit is consistent with the Supreme Court's determination in *Bostock v. Clayton County, Georgia*, 140 S.Ct. 1731, (2020) which held that firing a person based on their transgender status is sex discrimination.

In its administration of the Plan, the trigger for application of the Exclusion and a denial of coverage was a diagnosis of "gender dysphoria" for C.P. and the other class members. Dkt. 85-8. "Gender dysphoria cannot be understood without referencing sex or a synonym." *See Kadel v. Fol*well, 2022 WL 11166311, at *4 (M.D.N.C. Oct. 19, 2022)(*internal quotation marks*

and citations omitted). "[A] person cannot suffer from gender dysphoria without identifying as transgender." *Fain v. Crouch*, 2022 WL 3051015, at 6 (S.D. West Virginia August 2, 2022). Accordingly, the administration of the Exclusion based on transgender status was discrimination "on the basis sex" contrary to Section 1557. The Plaintiffs' motion for summary judgment on this element should be granted and Blue Cross's cross motion for summary judgment on this element denied.

4. Conclusion on Plaintiffs' Section 1557 Claim

Blue Cross, as a third party administrator is engaged in a "health care program or activity" and receives Federal financial assistance. It is subject to Section 1557. Its denial of benefits under the Plaintiffs' plans based on their transgender status was discrimination on the basis of sex. Each of the elements of the claim are met and the Plaintiffs are entitled to summary judgment unless one or more of Blue Cross's defenses apply.

D. BLUE CROSS'S DEFENSES

Blue Cross contends that it is entitled to summary judgment based on various defenses. Each will be addressed.

1. Covered Entity Defense – "Health Program or Activity"

Blue Cross points to the 2020 Rule and argues that the Court should give HHS deference to its interpretation of Section 1557 in the 2020 Rule based on the deference doctrine announced in *Chevron, USA Inc. v. NRDC, Inc.*, 467 U.S. 837 (2014). Dkt. 87. It contends that Section 1557 does not apply to its third party administrator activities because those actions are not "healthcare activities" and because it does not receive any federal financial assistance for its third party administrator activities. Dkt. 87 at 18.

As it relates to Blue Cross's argument here, the 2020 Rule provides that "an entity principally or otherwise engaged in the business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare." 85 FR 37178, 37244-45; codified at 45 C.F.R. § 92.3. The 2020 Rule further provided that:

> As used in this part, "health program or activity" encompasses all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance as described in paragraph (a)(1) of this section. For any entity not principally engaged in the business of providing healthcare, the requirements applicable to a "health program or activity" under this part shall apply to such entity's operations only to the extent any such operation receives Federal financial assistance as described in paragraph (a)(1) of this section.

Id.

The HHS 2020 Rule, arguably in effect, is not entitled to deference in this case. In considering whether to accord an agency's interpretation of a statute deference under *Chevron,* a two-part analysis is required. *Chevron* at 842. First, "is the question whether Congress has directly spoken to the precise question at issue." *Id.* If the intent of Congress is clear, the "unambiguously expressed intent of Congress" must be given effect by both the agency and the courts. *Id.* at 843. "If a statute is ambiguous, and if the implementing agency's construction is reasonable, *Chevron* requires a federal court to accept the agency's construction of the statute, even if the agency's reading differs from what the court believes is the best statutory interpretation." *Arizona v. Tohono O'odham Nation*, 818 F.3d 549, 556 (9th Cir. 2016).

In making the threshold determination under *Chevron* step one, whether statutory language is ambiguous or not "is determined by reference to the language itself, the specific context in which the language is used, and the broader context of the statute as a whole." *Corrigan v. Haaland*, 12 F.4th 901, 907 (9th Cir. 2021)(*cert. denied*, 211 L. Ed. 2d 607, 142 S.

Ct. 901 (2022)). "[T]he starting point is the statutory text." *Tohono* at 556. As stated above, the plain language of the text includes insurance contracts and their administration as "health program[s] or activit[ies]."

Moreover, "[i]n making the threshold determination under *Chevron* step one, a reviewing court should not confine itself to examining a particular statutory provision in isolation. Rather, the meaning – or ambiguity – of certain words or phrases may only become evident when placed in context." *Corrigan* at 910. Further, "[i]n interpreting a statute, a court must also account for that statute's history and purpose." *Corrigan* at 912. "Congress enacted the ACA to increase the number of Americans covered by health insurance and decrease the costs of health care." *Schmitt* at 949. It enacted Section 1557 to prohibit discrimination in the health care system to increase access to services and insurance coverage. *Id.* at 951. "By extending nondiscrimination protections to individuals under 'any health program or activity,' Congress clearly intended to prohibit discrimination by any entity acting within the health system." *See Fain v. Crouch,* 545 F.Supp.3d 338, 342 (S.D.W. Va. 2021). Logically, this includes third party administrators of health insurance plans. To hold otherwise would thwart Congress's intent to prohibit discrimination in the provision of "health programs and activities." Clearly, application of the 2020 Rule is contrary to the statutory law, and the rule appears to be arbitrary, capricious and contrary to law. The statue, not the 2020 Rule, must be followed here.

2. Covered Entity Defense – Federal Financial Assistance

Blue Cross argues that even if its third party administration of the Plan is providing a "health program or activity," it does not receive Federal financial assistance for that activity, so it is not covered under Section 1557. Blue Cross's argument is unpersuasive. "When the ACA was enacted in 2010, 'program or activity' was already a term of art with a clear meaning and a

broad scope established by the provisions cited in Section 1557 that ban discrimination in connection with Federal financial assistance." *Heart of CarDon* at 742. The words "program or activity" must be read "in accordance with the prevailing understanding the term had under the law that Congress relied on when codifying section 1557." *Id.* Section 504 of the Rehabilitation Act, which is also incorporated into Section 1557, "defines 'program or activity' as 'all of the operations of'- among other entities - 'an entire corporation, partnership, or other private organization, ... which is principally engaged in the business of providing ... health care... any part of which is extended Federal financial assistance.'" *Id.* (*citing* 29 U.S.C. § 794(b)(*emphasis added*). "The meaning of 'program or activity' in Section 1557's other antidiscrimination provisions is materially identical." *Id.* (*citing* 20 U.S.C. § 1687; 42 U.S.C. § 6107(4); 42 U.S.C. § 2000d-4a). Section 1557's phrase "health programs or activities" plainly includes "all the operations" of Blue Cross including its involvement in "contracts of insurance." *Id.* at 743; *Kadel* at 10.

Blue Cross's motion for summary judgment based on the defense that it is not a covered entity should be denied. It operates "health program[s] or activit[ies]" and receives Federal financial assistance and so Section 1557 applies.

3. Plan Design Defense

Blue Cross maintains that it is entitled to summary judgment because it did not design the allegedly discriminatory Exclusion applicable to C.P. Dkt. 87. It points to comments to the 2016 Rules, 2020 Rules and 2022 Proposed Rules and maintains that under each iteration of these rules, it is "only where the discriminatory terms of the group health plan originated with the third party administrator rather than with the plan sponsor [that] the third party administrator could be liable for the discriminatory design feature under Section 1557." Dkt. 87 at 10. There

is no *Chevron* deference owed here to the various iterations of the rules or proposed rules because the statutory text is clear as is Congressional intent – there is no exclusion for third party administrators who did not draft the exclusion at issue.

Blue Cross contends that it is entitled to summary judgment because it is obligated under ERISA's command at 29 U.S.C. § 1104(a)(1)(D) to administer the Exclusion as written. Dkt. 87. Under ERISA, benefit plan decisions are required to be made in "accordance with the documents and instruments governing the plan." 29 U.S.C. § 1104(a)(1)(D). This provision of ERISA does not end the inquiry.

The Plaintiffs properly contend that whether Blue Cross provided the Exclusionary language or not is immaterial because Blue Cross has an independent duty to comply with Section 1557. Dkt. 96. The Plaintiffs point to ERISA's 29 U.S.C. § 1144(d) and argue that ERISA does not supplant Section 1557's antidiscrimination provisions. *Id.*

ERISA's Section 1144(d) provides that "[n]othing in this subchapter shall be construed to alter, amend, modify, invalidate, impair, or supersede any law of the United States . . . or any rule or regulation issued under any such law." Accordingly, ERISA expressly provides that it is not to be construed to impair laws like Section 1557. Harmonizing these provisions of ERISA, a third party administrator must make decisions in "accordance with the documents and instruments governing the plan," 29 U.S.C. § 1104(a)(1)(D), but that this requirement must not be construed to "invalidate or impair" Section 1557, 29 U.S.C. § 1144(d).

Blue Cross's third-party administration of the Plan and other self-funded plans are "health programs or activities" and it receives "Federal financial assistance" and so is covered by Section 1557. ERISA specifically provides that its requirements are not to be construed to

invalidate or impair laws like Section 1557 and so ERISA's requirement that Blue Cross follow the Exclusion's language is no defense. Section 1557 supplements the ERISA requirements.

Even if Blue Cross did not have an independent duty to comply with Section 1557, which it does, third party administrators can be liable under Section 1557 based on discriminatory terms in a self-funded plan even if the third party administrator provided the plan document "notwithstanding the fact that the [plan sponsor] subsequently adopted the plan and maintained control over its terms." *See, e.g., Tovar* v. *Essentia Health,* 857 F.3d 771, 778 (8th Cir. 2017).

There are issues of fact as to whether the Plan design originated with Blue Cross. Blue Cross points to testimony that CHI drafted the gender reassignment surgery exclusion in the Plan. Dkt. 88-1 at 3. Plaintiffs points to the testimony of Laura Malec, another Blue Cross 30(b)(6) witness, who testified that of the 398 plans at issue, 378 (including the CHI Plan) contain the same or similar exclusionary language that is the "standard language" that Blue Cross "offers to employers when they want a gender affirming care exclusion." Dkt. 85-8 at 7. There are issues of fact as to whether the Exclusion's language originated from Blue Cross, but those issues need not be decided to justify denial of Blue Cross's motion for summary judgment on this issue.

4. Medical Consensus Defense

Blue Cross argues that the Exclusion does not discriminate "on the basis of sex" because "there is no medical consensus regarding gender-affirming treatment." Dkt. 87. Blue Cross's argument is unavailing. It did not base the decision to deny care on medical necessity but on C.P.'s and the other class members' transgender status. Further, it concedes that under its own medical necessity policy, C.P.'s request for hormone therapy and chest reconstruction would be considered "medically necessary." Dkt. 85 at 23, 25-26. Whether there is medical consensus

about transgender care in general is immaterial as to whether Blue Cross discriminated against the Plaintiffs based on sex.

5. Religious Freedom Restoration Act

Blue Cross argues that it is entitled to summary judgment because it is protected by the Religious Freedom Restoration Act ("RFRA"). Dkt. 87. It maintains that RFRA exempts CHI's Plan based on CHI's sincerely-held religious beliefs. *Id.* Blue Cross argues that it does not violate Section 1557 if it administers an exempt plan. *Id.*

Under RFRA, "[g]overnment shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability" unless the Government "demonstrates that application of the burden to the person – (1) is in furtherance of a compelling government interest; and (2) is the least restrictive means of furthering that compelling interest." 42 U.S.C. § 2000bb-1(a), (b). RFRA continues, "[a] person whose religious exercise has been burdened in violation of this section may assert that violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government." 42 U.S.C. § 2000bb-1(c)(*emphasis added*).

Blue Cross's motion for summary judgment based on RFRA should be denied. RFRA provides relief against the government and does not apply to disputes between private parties. *Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 839 (9th Cir. 1999); *See Listecki v. Off. Comm. of Unsecured Creditors*, 780 F.3d 731, 736 (7th Cir. 2015)("Based on RFRA's plain language [and] its legislative history . . . RFRA is not applicable in cases where the government is not a party"). The government is not a party here.

Blue Cross's citation to *Burwell v. Hobby Lobby*, 573 U.S. 682 (2014) and other similar cases are unavailing. *Hobby Lobby* involved a challenge by employers to HHS rules requiring

insurance coverage for birth control despite religious objection by employer. The government was a party in all of these cases – for example, Burwell was the Secretary of HHS. Blue Cross also acknowledges that it is not an entity with a "sincerely-held religious belief" (Dkt. 118).

Blue Cross argued at oral argument that while it is not asserting a claim or defense based on RFRA, Section 1557 and RFRA must be read together. While it is not wholly clear how that is to occur generally, in this case RFRA does not apply, Section 1557 does. The Court need not reach Blue Cross's arguments regarding its standing to assert CHI's religiously held beliefs.

There are many approaches and cases covering religious – and, perhaps, other, – reasons to avoid statutory or other legal obligations under the First Amendment to the U.S. Constitution (particularly when the government is involved). It is appropriate to consider such matters in protecting the U.S. Constitution's First Amendment establishment and free enterprise clauses. It cannot be, however, that Blue Cross can trump statutory anti-discrimination law with a potential religious protection claim from a co-contractor, without more, which allegedly frees that co-contractor and Blue Cross from obedience to the law. The law presented here does not clothe Blue Cross with the factual or legal basis to referee such claims of exemption from Section 1557. Perhaps, somehow, such an exemption may be legally reached, consistent with the First Amendment or other law, but the facts here do not support such a conclusion. Blue Cross is left with the obligation to obey Section 1557 as it stands.

6. Conclusion on Defenses

Blue Cross is not entitled to summary judgment on any of its defenses. None of its defenses apply.

E. BLUE CROSS'S MOTION FOR SUMMARY JUDGMENT ON NAMED PLAINTIFFS' CLAIM FOR EMOTIONAL DISTRESS DAMAGES

Blue Cross moves for summary judgment on Plaintiffs C.P. and Patricia Prichard's emotional distress damages claim. Dkt. 87. That portion of the motion should be granted. Emotional distress damages are not recoverable in private actions to enforce the antidiscrimination provisions of the ACA. *Cummings v. Premier Rehab Keller, P.L.L.C.*, 142 S. Ct. 1562 (2022).

F. CONCLUSION

The conclusions herein are based on the preponderance of the evidence with no material facts in issue. This order addresses Blue Cross' duties under Section 1557 only, and the Court is mindful that in reaching its conclusion here, Blue Cross was in the legal position of determining how to deal with the conflict between Section 1557, outlawing discrimination, and ERISA's command at 29 U.S.C. § 1104 (a)(1)(D) to administer plans, including discrimination, as written. The Court is satisfied that ERISA's command at 29 U.S.C. § 1104 (a)(1)(D) to administer the exclusions as written is subservient to Section 1557, outlawing discrimination, which is dominate. That finding leads to the ultimate conclusion of these summary judgment motions: Blue Cross, as a third party administrator, is a covered entity under Section 1557 and has discriminated against the Plaintiffs and the class Plaintiffs by denying them services for gender affirming care under individual and class Plaintiffs' insurance policies.

The appropriate relief due, if any, will be addressed by motion practice, or at trial.

III. ORDER

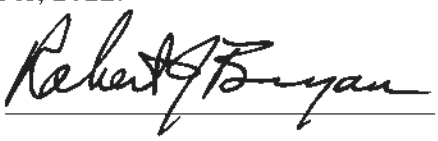
Therefore, it is hereby **ORDERED** that:

- The Plaintiffs' motion to strike (Dkt. 126) **IS GRANTED**;

- Defendant Blue Cross's Motion for Summary Judgment (Dkt. 87) **IS GRANTED** as to the Plaintiffs' emotional distress claims and **DENIED** in all other respects; and
- The Plaintiffs' Cross Motion for Summary Judgment (Dkt. 96) **IS GRANTED** to the extent listed herein.

The Clerk is directed to send uncertified copies of this Order to all counsel of record and to any party appearing pro se at said party's last known address.

Dated this 19th day of December, 2022.



ROBERT J. BRYAN
United States District Judge

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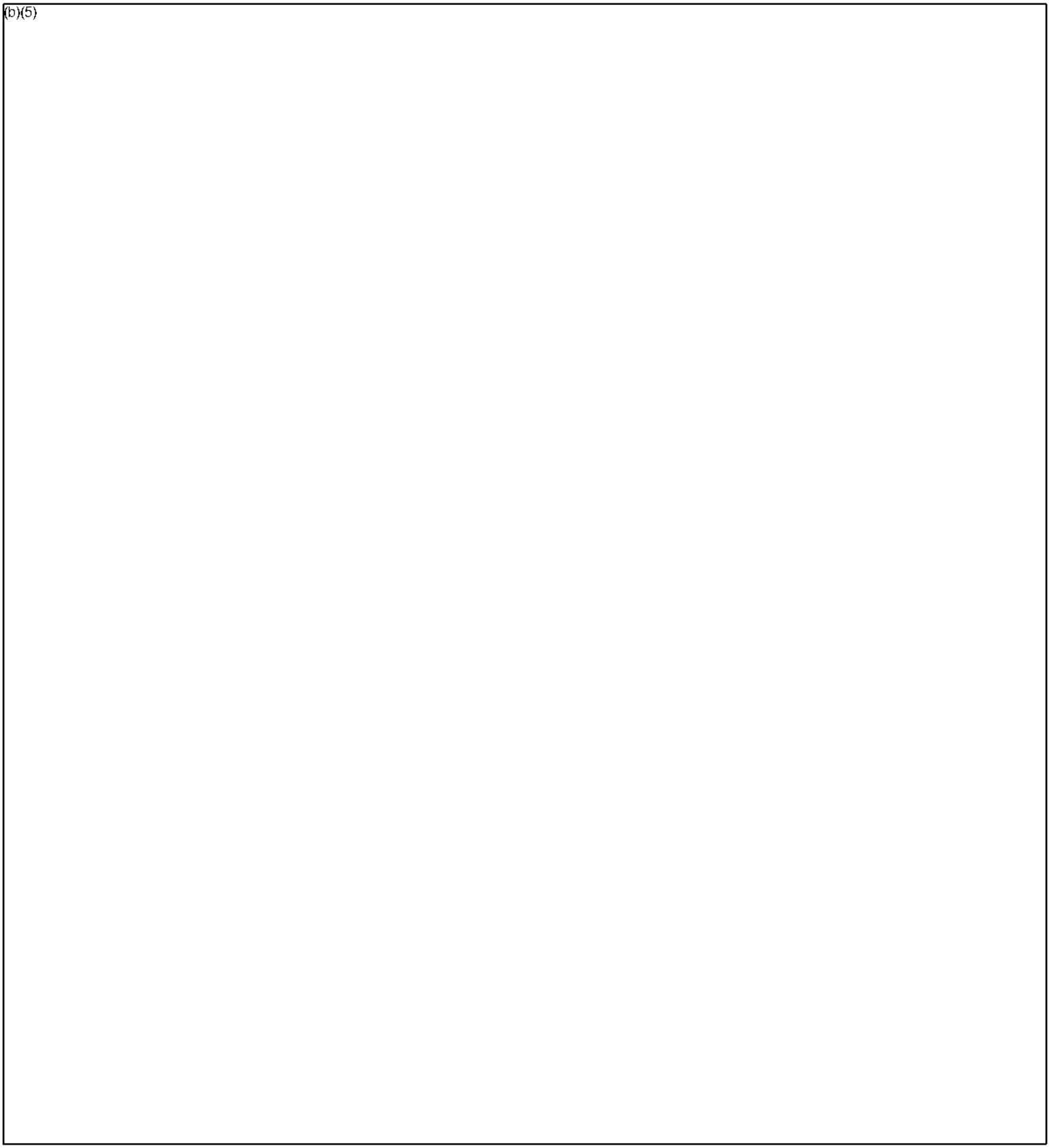
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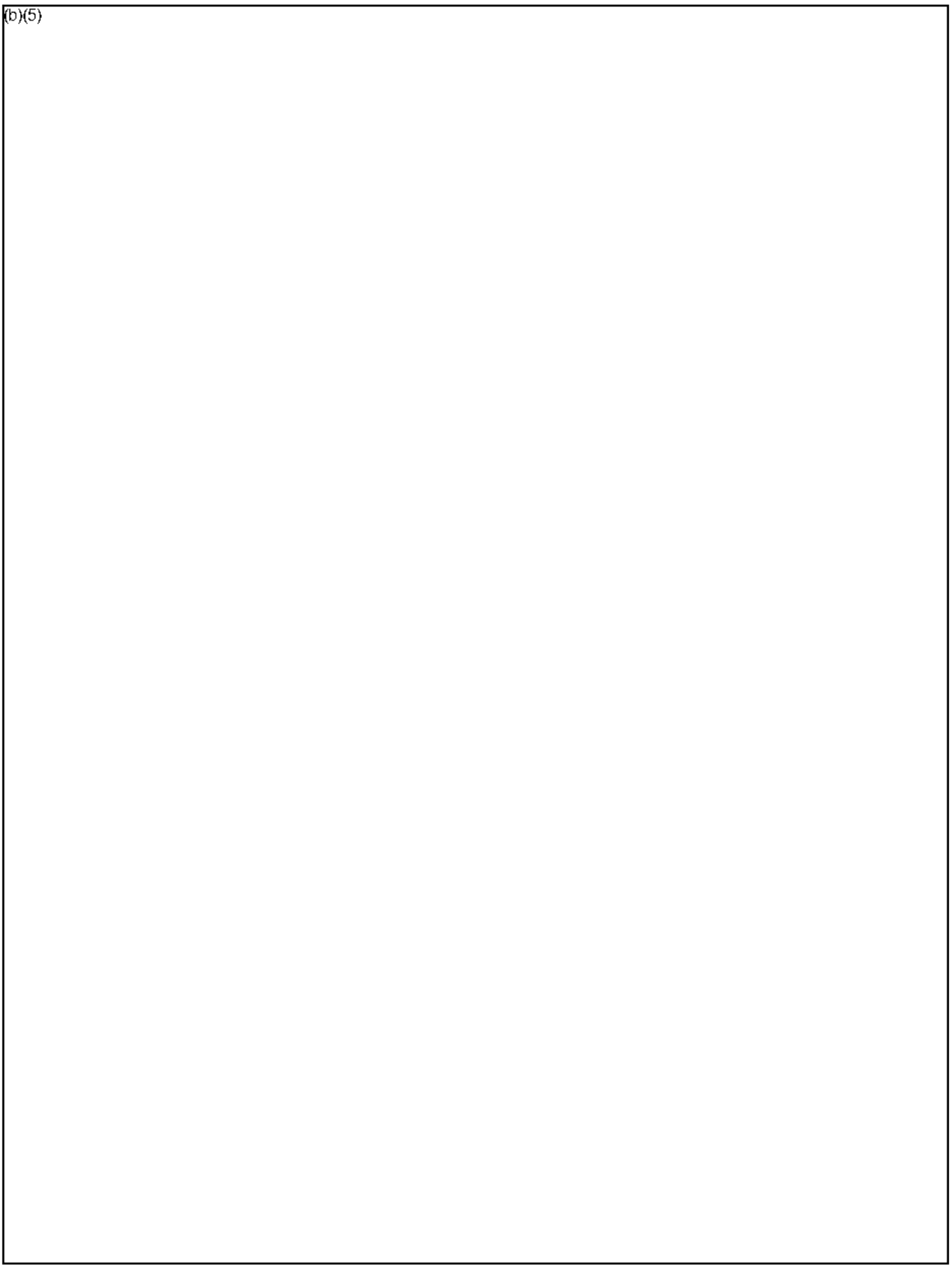
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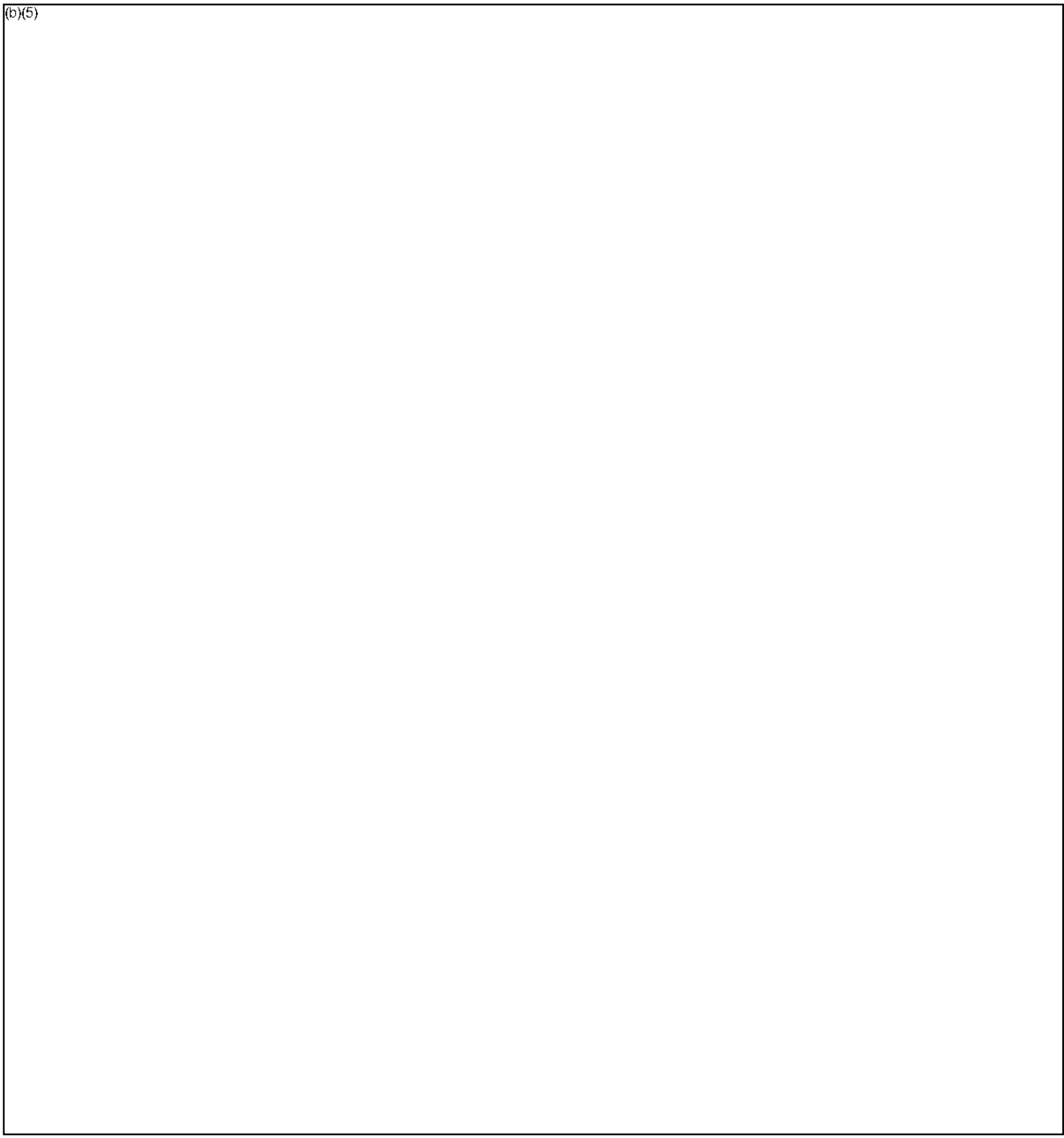
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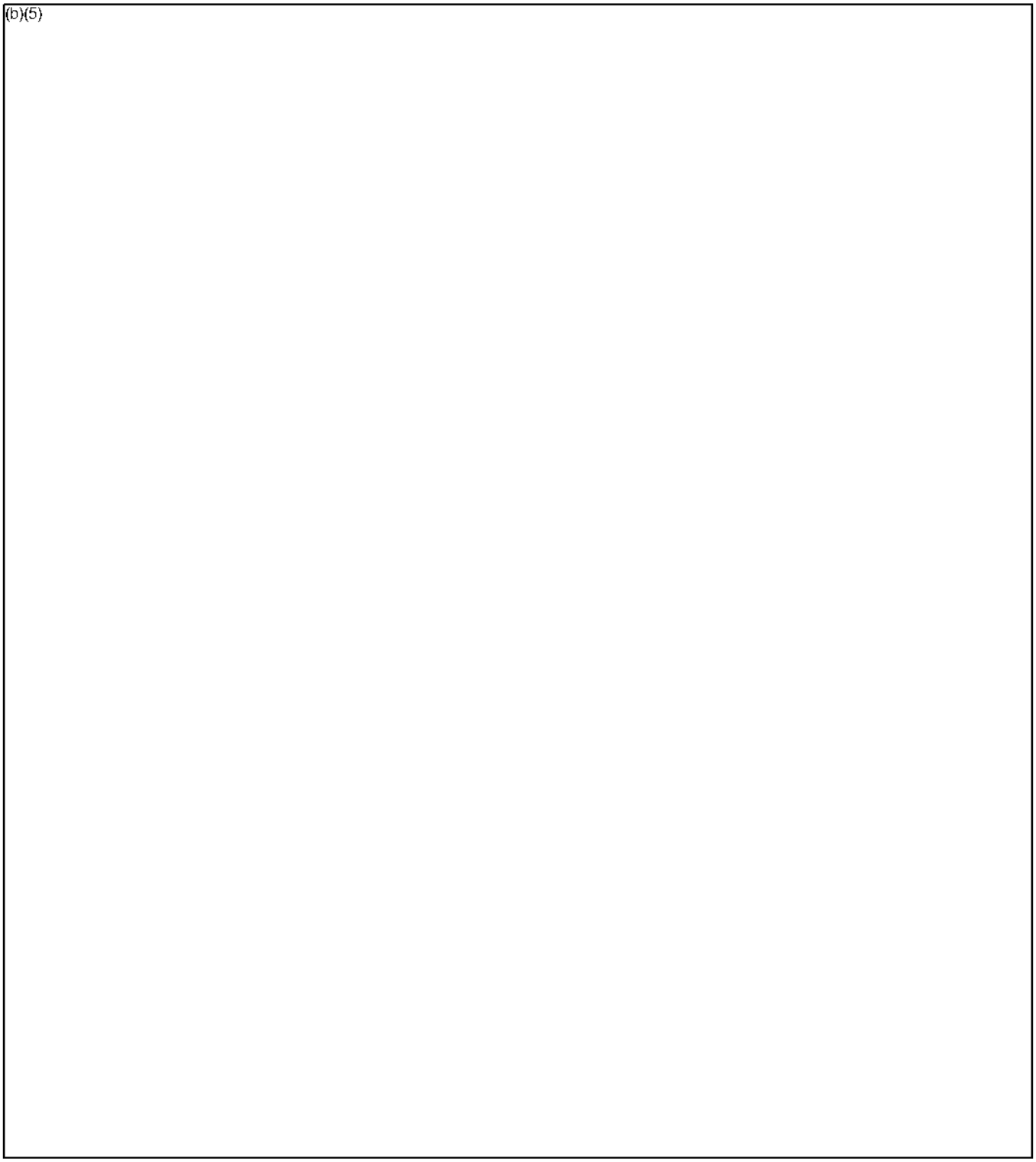
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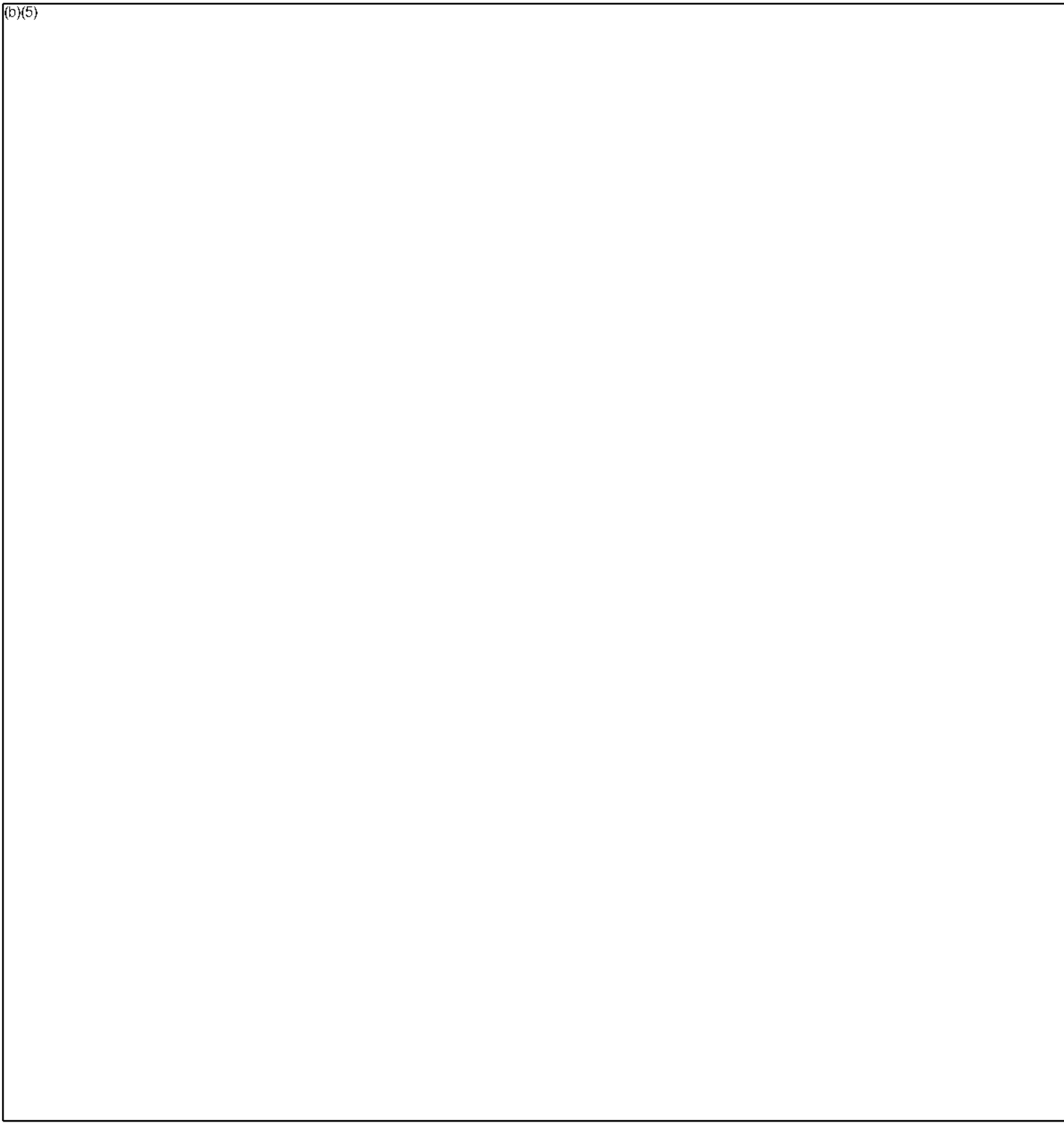
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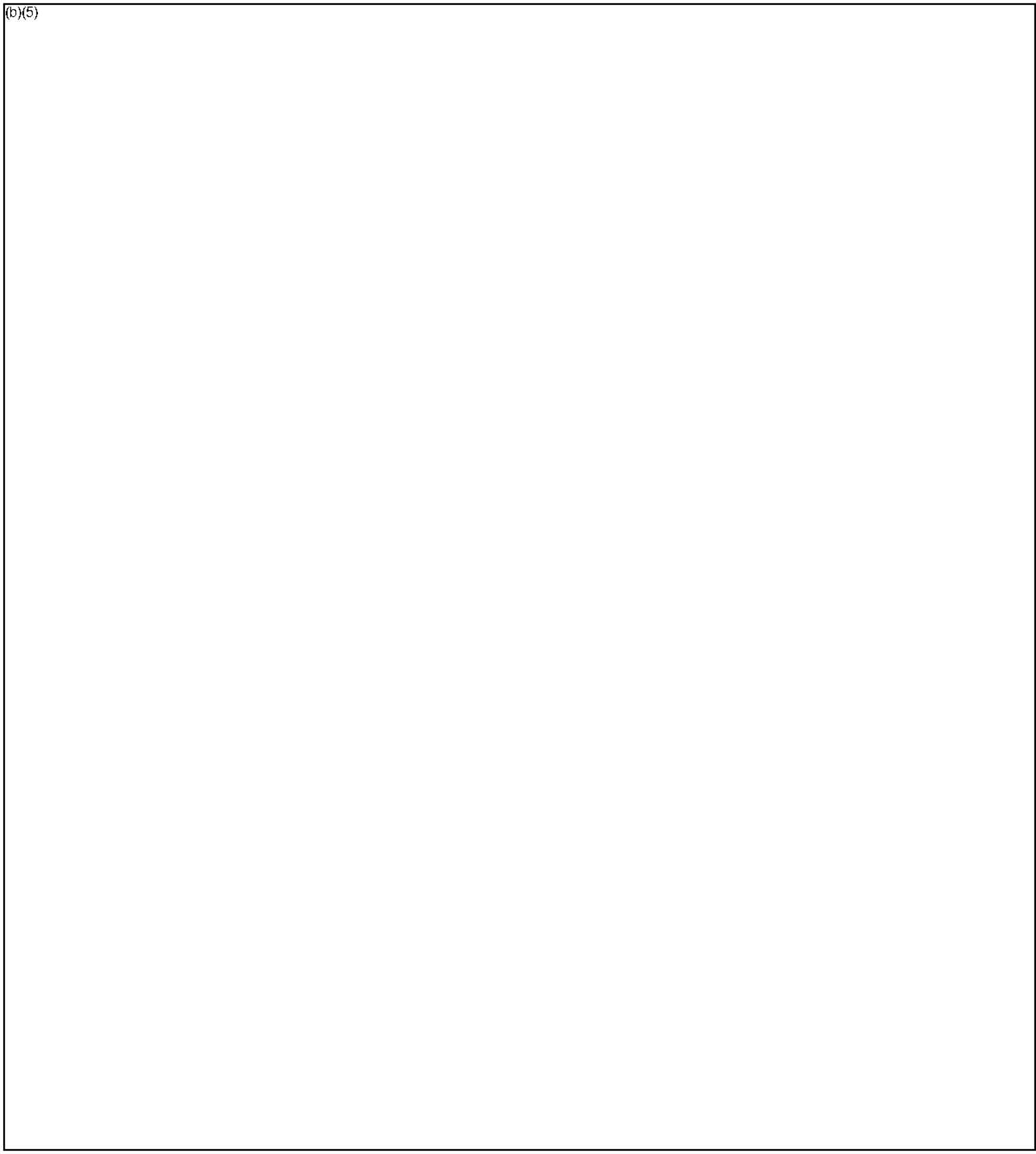
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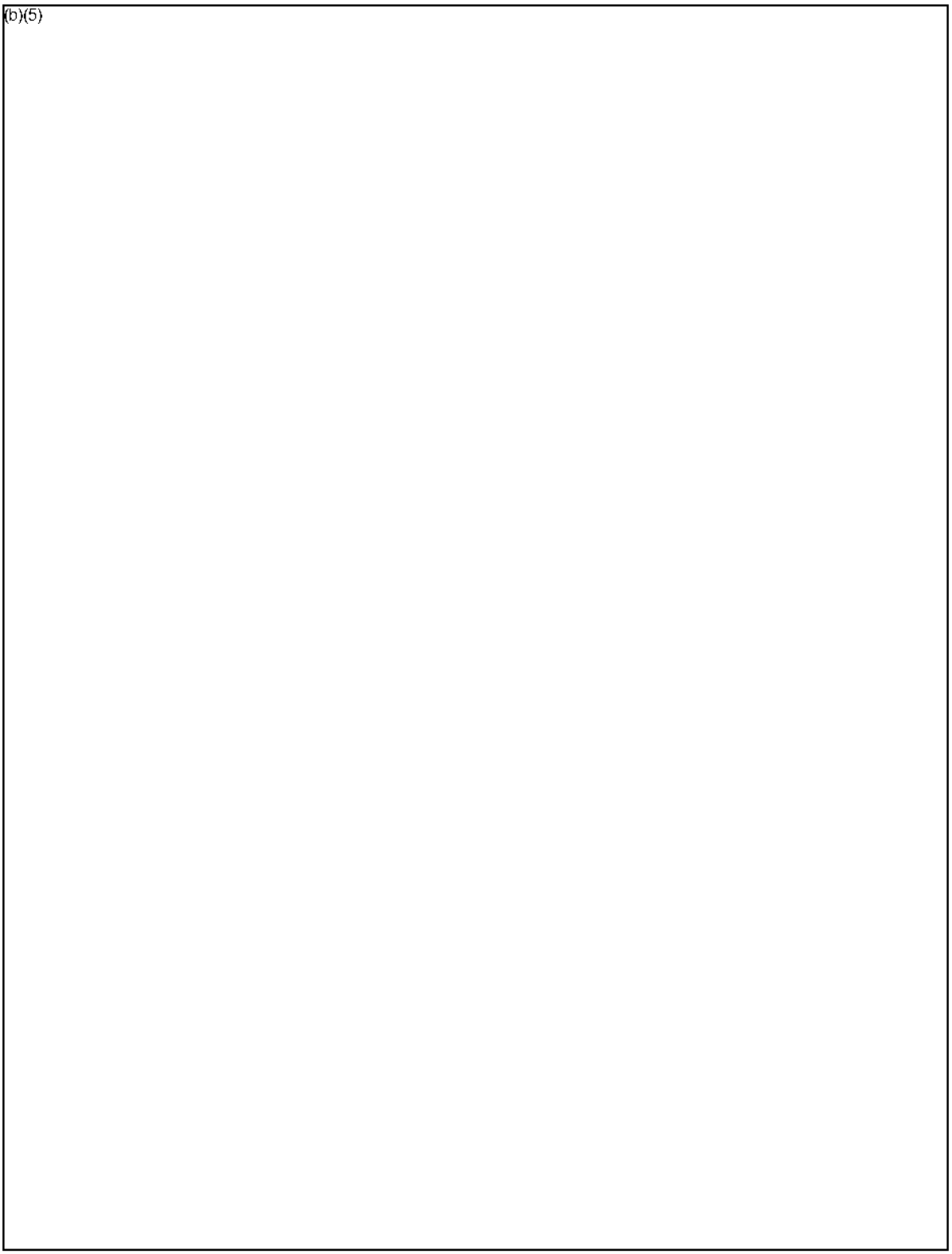
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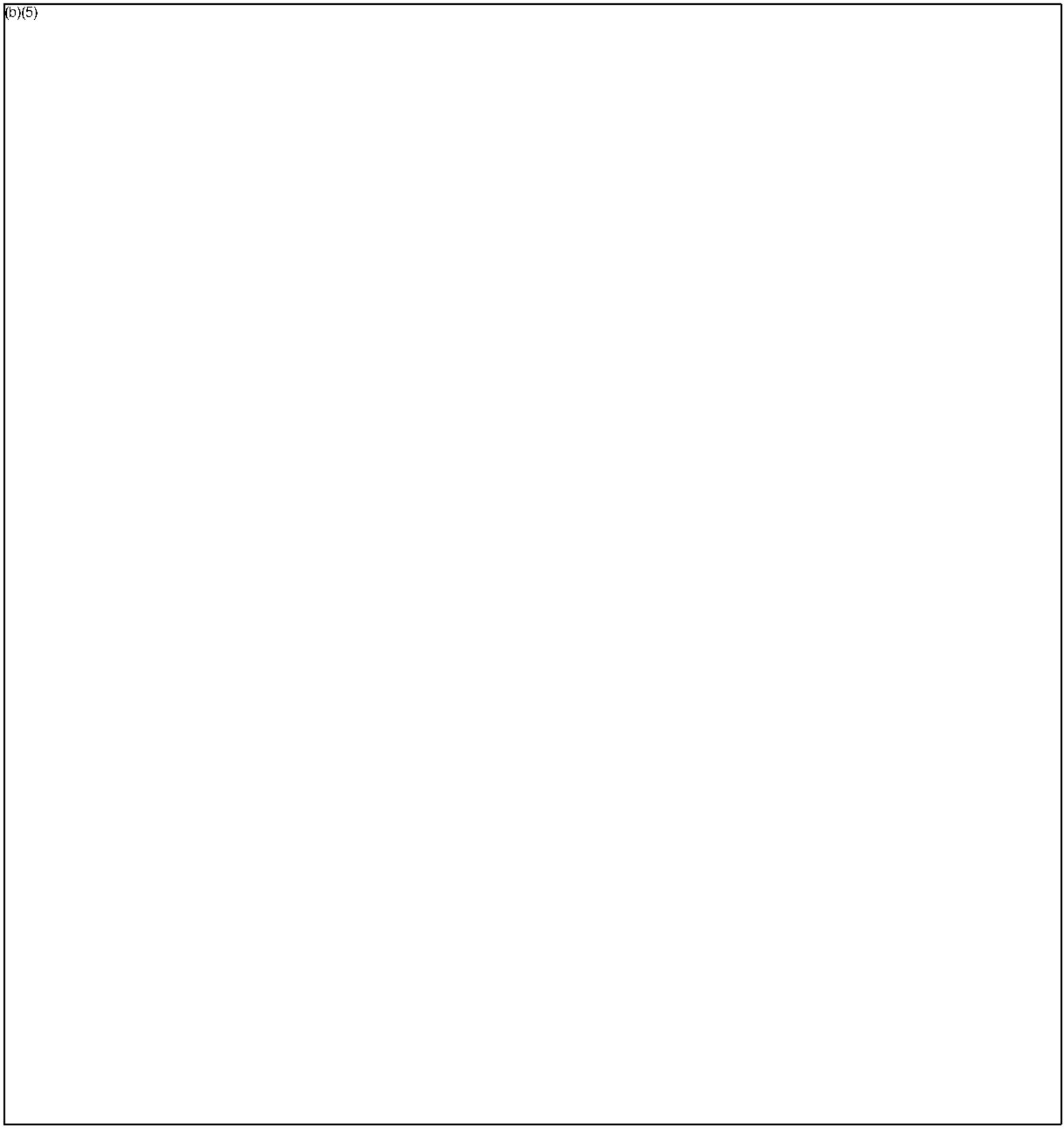
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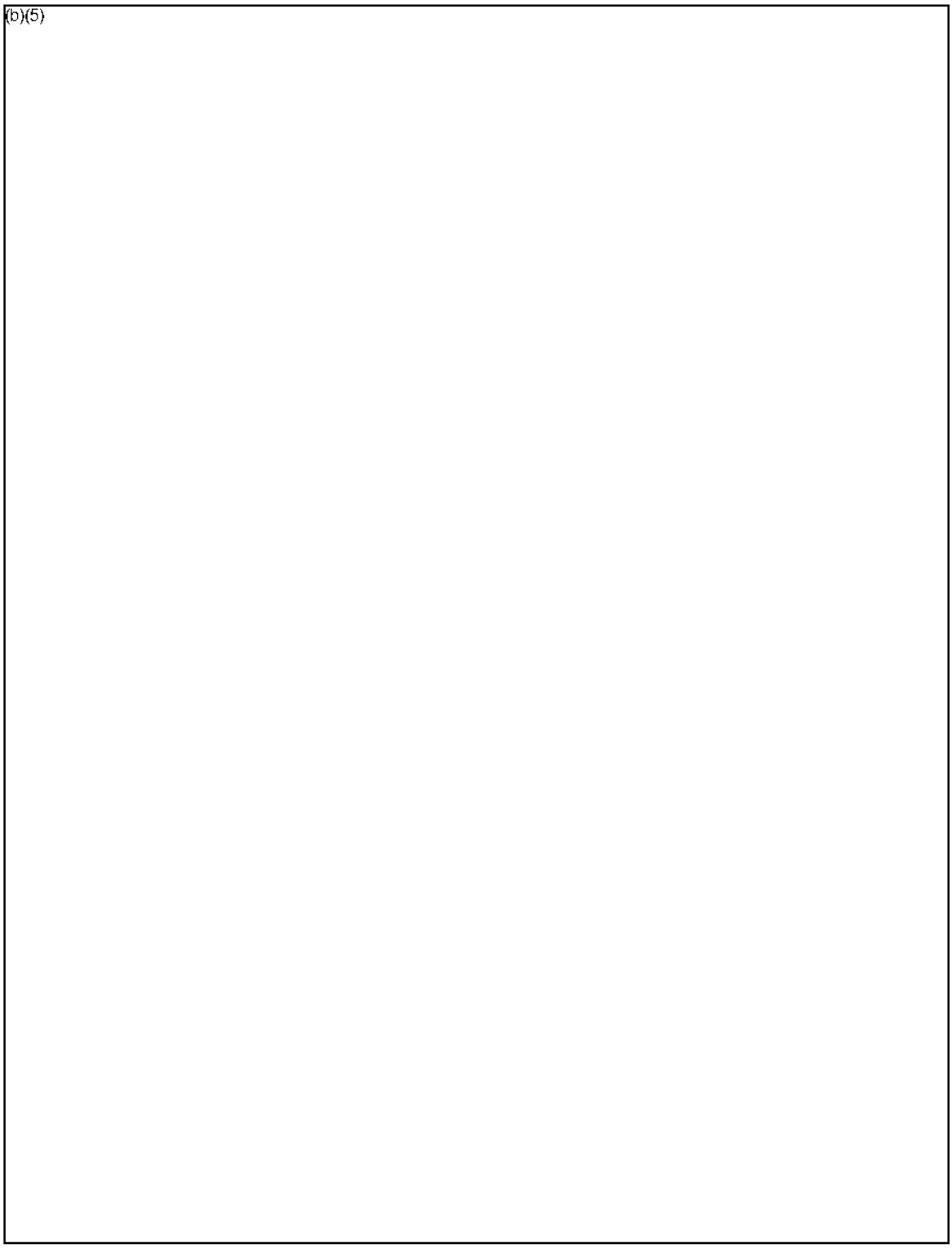
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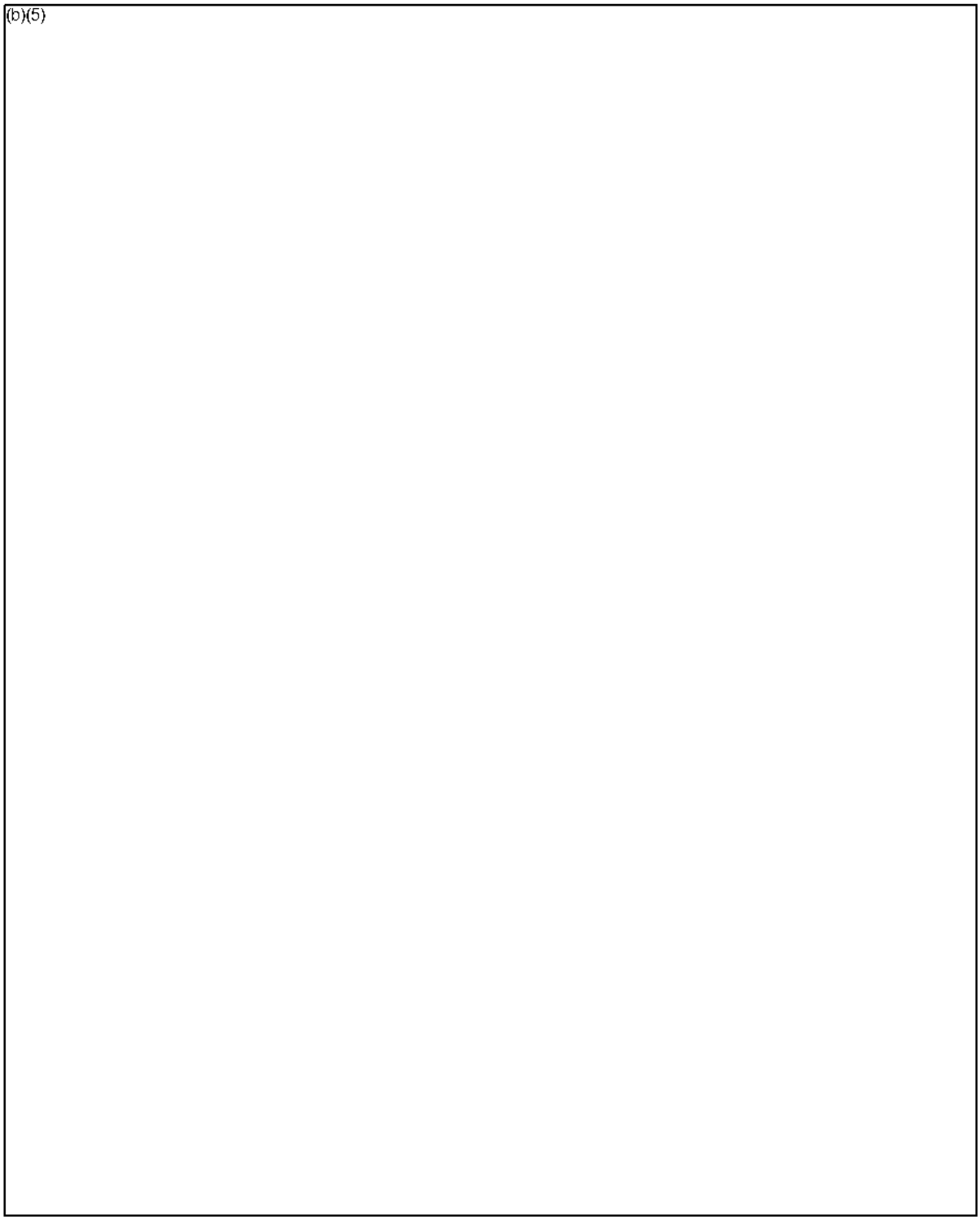
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Ms. Lisa J. Pino
Director
Office for Civil Rights
U.S. Department of Health and Human Services
200 Independence Ave. S.W.
Washington, DC 20201

Mr. James Harris
U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

February 14, 2022

Dear Ms. Pino & Mr. Harris,

As a follow up to the listening session on December 9, 2021, it is our pleasure to submit additional information and recommendations. We thank the Department of Health and Human Services (the Department) for its dedication to advancing the health and well-being of LGBTQI+ people. We urge the Department to strengthen the ACA Section 1557 implementing regulations so they better address the dire problem of discrimination against transgender and non-binary people in health care.

The Transgender Legal Defense & Education Fund (TLDEF) is a 501(c)(3) nonprofit whose mission is to end discrimination and achieve equality for transgender and non-binary people, particularly those in our most vulnerable communities. We provide legal representation to transgender individuals who have been subject to discrimination, focusing on the key issues of employment, education, public accommodations, and healthcare. We also provide public education on transgender rights.

Transgender Law Center (TLC) is the largest national trans-led nonprofit organization advocating for a world in which all people are free to define themselves and their futures. Grounded in legal expertise and committed to racial justice, TLC employs a variety of community-driven strategies to keep transgender and gender nonconforming people alive, thriving, and fighting for liberation. TLC works to improve health care access and health outcomes for transgender and non-binary people through our Helpdesk, impact litigation, education, and policy advocacy.

I. Transgender people face egregious discrimination in healthcare settings

Access to comprehensive and inclusive non-discriminatory health care is an urgent priority for transgender and non-binary communities[1]. Stigma and discrimination, and associated factors, jeopardize the health of transgender and non-binary people.[2] And far too many transgender people must postpone or

[1] In the context of this letter, the term transgender is inclusive of all gender identities other than cisgender, including non-binary gender identities, even when that is not explicitly named.
[2] Nat'l Acads. Of Scis. Engineering and Medicine, *Understanding the Health and Wellbeing of LGBTQI+ Populations* 317-318, (2020) at 317-318 (concluding that transgender and LGBQI people experience

forgo medical care because of cost.[3] At the same time, there is a dangerous trend of state legislatures pressing discriminatory, anti-transgender bills across the country.[4]

The ongoing COVID-19 pandemic makes access to health care more urgent for everyone, and transgender and non-binary people are no exception. Stigmatization of and discrimination against transgender people fosters an environment in which transgender and non-binary people are more likely to be exposed to the SARS-CoV-2 virus and more susceptible to serious COVID-19 illness.[5]

Transgender and non-binary people face pervasive discrimination by health care providers and health plans.[6] Following the previous Administration's announcement of a rollback of regulations explicitly protecting transgender and non-binary people from discrimination under Section 1557 of the Affordable Care Act, alarming levels of discrimination continued. Between June 2019 & June 2020 alone, nearly half of transgender and non-binary people, and a majority of transgender and non-binary people of color, faced discrimination by a health care provider, including 18% of respondents who had a provider deny them care entirely.[7] Though transgender-related care (also called gender affirming care) "is essential and medically necessary,"[8] denials of care remain commonplace.[9] Over 46% of transgender and non-binary people—56% of transgender and non-binary people color—had a health insurance company refuse coverage of gender affirming care.[10] Additionally, 48%—and 54% of people of color—had a health

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health disparities "driven by social forces, such as stigma, prejudice, and discrimination" that may be "compounded by intersecting stressors, such as racism, sexism, and xenophobia.")

[3] Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities* at 10 (2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/, (Between June 2019 and June 2020 alone, 51% of transgender people avoided needed medical and 40% preventative screenings care due to cost).

[4] ACLU, *Legislation Affecting LGBTQ Rights Across the Country,* https://www.aclu.org/legislation-affecting-lgbtq-rights-across-country (last accessed Feb. 4, 2022).

[5] Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities* at 2 (2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/. *See also,* Jody L. Herman & Kathryn K. O'Neill, *Vulnerabilities to COVID-19 Among Transgender Adults in the US* (April 2020), https://williamsinstitute.law.ucla.edu/publications/transgender-covid-19-risk/.

[6] James E. Sandy, et al., 2015 *U.S. Transgender Survey Report*, at 5, 92-103, (updated Dec. 2017) https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf (last visited Feb. 9, 2022).

[7] Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities* at 17-18 (2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/ (last viewed Feb. 9, 2022).

[8] National Academies of Sciences, Engineering, and Medicine, UNDERSTANDING THE WELLBEING OF LGBTQI+ POPULATIONS, at 380 (Washington, DC: 2020), https://www.nap.edu/catalog/25877/understanding-the-well-being-of-lgbtqi-populations.

[9] Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities* at 10 (2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/; Sandy E. James *et al., 2015 U.S. Transgender Survey Report,* at 93-95 (updated Dec. 2017), https://transequality.org/sites/default/files/docs/usts/USTS-Full-Report-Dec17.pdf (finding that of respondents who sought coverage for transgender-related care in the past year, 55% were denied coverage for surgery and 25% for hormones. Moreover, 25% of all respondents reported "problems with their insurance in the past year related to being transgender," including13% who were denied coverage for gender-coded care and 7% who were denied coverage for other routine health care.)

[10] *Id.*

insurance company cover only limited care or provide insufficient in-network providers.[11] Over 30% had an insurance company refuse to record their current name or gender.[12]

Providers have refused transgender patients routine preventative care such as cancer screening, and urgent care such as for a suspected infection or sexual assault forensic examinations.[13] Transgender & non-binary people also require[14] but often face barriers to obtaining reproductive health care.[15] Transgender people with limited English proficiency face additional challenges accessing health care.

TLDEF and TLC both devote significant resources to helping transgender and non-binary people overcome discrimination in health care. In 2021, TLC Helpdesk staff worked with 73 clients who had coverage for gender-affirming care denied by their insurance providers and have worked with approximately 300 transgender and non-binary people who have had issues with health care access over the last two years.

Sometimes, denials stem from insurance plans or insurance company medical policies that exclude coverage of transgender related care. Following the 2019 proposal and 2020 finalization of Section 1557 regulations ("the Rollback Rule"), we have seen a spike in such exclusions. [16] Many plans and insurance company medical policies cover limited transgender-related care but exclude treatments that are crucial for transgender women and transfeminine people, such as facial gender reassignment surgery.[17] For example, TLDEF represented transgender women from North Carolina denied coverage for facial gender reassignment surgery by their employer and Marketplace-based plans because of an insurance company medical policy that falsely labeled the surgeries not medically necessary.[18]

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[11] *Id.*

[12] *Id.*

[13] Sharita Gruberg et. al, *The ACA's LGBTQ Nondiscrimination Regulations Prove Crucial* (March 7, 2018), https://americanprogress.org/wp-content/uploads/2018/03/ACAnondiscrimination-brief2.pdf (last visited Feb. 9, 2022).

[14] Kerith Conron, et al., *Reproductive Health Care and LBT Adults*, Williams Institute (2020) https://williamsinstitute.law.ucla.edu/wp-content/uploads/LBT-Reproduction-Jul-2020.pdf.

[15] 15 National Academies, *Understanding the Well-Being of LGBTQI+ Populations*, 9, 303-305 (Washington, DC: National Academies Press 2020).
Laura Fix, et al., *Stakeholder Perceptions and Experiences Regarding Access to Contraception and Abortion for Transgender, Non-Binary, and Gender-Expansive Individuals Assigned Female at Birth in the U.S.*, Archives of Sexual Behavior (2020), https://link.springer.com/article/10.1007/s10508-020-01707-w

[16] *Summary of Findings: 2021 Marketplace Plan Compliance with 1557,* Out2Enroll (2020), https://out2enroll.org/out2enroll/wp-content/uploads/2020/11/Report-on-Trans-Exclusions-in-2021-Marketplace-Plans.pdf, (analyzing silver Marketplace plans and concluding that 7% of insurers reviewed used transgender-specific exclusions in their 2021 silver Marketplace plans, an increase from 3% of such exclusions in the 2020 plan year). *See also,* Anna Kirkland, et al., *Transition Coverage and Clarity in Self-Insured Corporate Health Insurance Benefit Plans,* 6 Transgender Health 207 (2021), https://www.liebertpub.com/doi/10.1089/trgh.2020.0067, (an analysis of 435 health plans offered 40 self-insured corporations found that 9% excluded all transgender related care).

[17] Anna Kirkland, et al., *Transition Coverage and Clarity in Self-Insured Corporate Health Insurance Benefit Plans,* 6 Transgender Health 207 at 211-212 (2021), https://www.liebertpub.com/doi/epdf/10.1089/trgh.2020.0067, (discussing excluded procedures and finding that "[m]ost exclusions are related to facial gender confirmation surgeries and hair removal, which are critically important to gender-affirming care and highly problematic to exclude.")

[18] *TLDEF Advocacy Brings Changes to Blue Cross Blue Shield of NC Coverage of Gender-Affirming Health Care* (July 13, 2021), https://www.transgenderlegal.org/stay-informed/tldef-advocacy-brings-

Moreover, some insurers impose onerous requirements for coverage of transgender-related care. For example, a major insurance company offering Marketplace plans in Arkansas makes a legal name change a prerequisite for gender affirming care.[19] This requirement has no basis in medicine. More than ever, the communities we serve need strong federal protections against this rise in legislated bigotry. In addition to being at odds with standards of care, intrusive, and rife with gender-stereotypes, the requirement may delay care or prevent people from obtaining care entirely because financial, legal, social barriers can prevent transgender people from changing their names and some transgender people do not want to change their names at all. TLDEF with the ACLU of Kansas recently advocated for removal of a similar requirement after it resulted in an initial denial of coverage and substantial delay in surgery for a transgender Kansan enrolled in a Marketplace plan.[20]

II. Recommendations for Proposed Rule

Reinstate previously prohibited categories of discrimination

The implementing regulations should clarify that the ban on discrimination on the basis of sex covers discrimination on the basis of sexual orientation, gender identity, sex characteristics, gender expression, transgender status, and pregnancy status. This properly includes disparate impact sex discrimination and should not allow for religious or abortion-based exceptions.

The rule HHS promulgated in 2016 interpreting the Affordable Care Act ("the 2016 Rule")[21] correctly defined discrimination on the basis of sex to include, but not be limited to, "discrimination on the basis of pregnancy, false pregnancy, termination or pregnancy, or recovery therefrom, childbirth or related medical conditions, sex stereotyping, and gender identity."[22] The 2016 Rule also recognized that Section 1557 not only prohibits intentional discrimination on the basis of sex, but also prohibits conduct, policies, and practices "that have the effect of subjecting individuals to discrimination on the basis of sex," that is, disparate impact sex discrimination.[23]

TLC and TLDEF strongly support the reimplementation of these regulations and recommend further clarifying what constitutes sex discrimination by explicitly adding transgender status, gender expression, and sex characteristics, including intersex traits, to prohibited forms of discrimination on the basis of sex.[24] Including transgender status and gender expression along with gender identity will

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changes-to-blue-cross-blue-shield-of-nc-coverage-of-gender-affirming-health-care/. Fortunately, after advocacy by TLDEF the insurer revised its policy to allow coverage for medically necessary facial gender reassignment surgery.

[19] Arkansas BlueCross BlueShield, Policy #2016024, Gender Reassignment Surgery for Gender Dysphoria, Initiated Jan. 2017, Last Review Oct. 2021, https://secure.arkansasbluecross.com/members/report.aspx?policyNumber=2016024 (visited Jan. 26, 2022).

[20] ACLU Kansas, *Blue Cross Blue Shield Kansas Changes Policy on Gender-Affirming Surgeries, ACLU of Kansas and TLDEF Urge Further Reforms* (Dec. 9, 2021), https://www.aclukansas.org/en/press-releases/blue-cross-blue-shield-kansas-changes-policy-gender-affirming-surgeries-aclu-kansas.

[21] Nondiscrimination in Health Programs and Activities, 81 Fed. Reg. 31,376 (May 18, 2016) (codified at 45 C.F.R. § 92 (2019)).

[22] 81 Fed. Reg. at 31,467 (codified as 45 C.F.R. § 92.4 (2019)).

[23] 81 Fed. Reg. at 31,467 (codified as 45 C.F.R. § 92.101(b)(3)(ii)(2019)).

[24] *See, e.g., Kadel v. Folwell*, 446 F. Supp. 3d 1, 14 (M.D.N.C. Mar. 11, 2020) (rejecting a motion to dismiss against the North Carolina state employee health plan under § 1557 and Title IX under a Price Waterhouse sex-stereotyping theory and also because the exclusion discriminates "based on employee's physical sex characteristics.") *Pritchard v. Blue Cross Blue Shield of Ill.*, 2021 WL 1758896, at *4 (W.D. Wash. May 4, 2021); *Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1015 (W.D. Wis.

strengthen protections for transgender people by clarifying legal obligations and leaving bad actors with fewer excuses for discrimination. Entities often perpetrate discrimination against transgender people because of their gender expression or belief that they are transgender rather than the transgender person's actual gender identity, which may be private information or unknown to the person discriminating against them. Inclusion of "gender identity" alone leaves room for confusion or evasion of legal obligations, particularly in typically sex-specific domains. For example, a New Jersey drug treatment facility defended its refusal to hire a transgender man as a male urine monitor by arguing that, "[w]hile New Jersey law prohibits discrimination on the basis of gender identity or expression, it does not expressly hold the same as to transgender status."[25] Including protections against discrimination based on transgender status, prevents bad actors from evading accountability for their discrimination through sleight of hand. Including transgender status aligns with the *Bostock* decision, which affirmed that discriminating against someone for being transgender is necessarily sex discrimination. [26] Such protections are already in place in New York and Colorado.[27]

Adding protections based on sex characteristics, including intersex status, is vital for preventing discrimination against intersex people, some of whom are also transgender. Intersex people also face pervasive health and health care disparities as well as barriers to receiving appropriate health care and coverage. While there is evidence of these disparities and barriers for intersex people, [28] the National Academies recently called for addressing a "significant gap" in data collection on intersex populations in

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2019) (finding a transgender exclusion in Medicaid discriminates on the basis of sex under § 1557 as detailed in *Flack*, 328 F. Supp. 3d at 951); *Boyden v. Conlin*, 341 F. Supp. 3d 979, 997 (W.D. Wisc. 2018) (applying § 1557 to Wisconsin state employee health plan); *Tovar v. Essentia Health*, 342 F. Supp. 3d 947, 954 (D. Minn. 2018)
(holding that employer and third-party administrator may be held liable under § 1557 for administering a self-funded plan containing an exclusion for "gender reassignment" treatment); *Cruz v. Zucker*, 116 F. Supp. 3d 334, 348 (S.D.N.Y. 2015) (entertaining a § 1557 sex discrimination claim for transgender people under Medicaid) *Rumble v. Fairview Health Servs.*, 2015 WL 1197415 (D. Minn. 2015).

[25] Memorandum of Law in Opposition to Plaintiff's Cross-Motion for Summary Judgment and in Further Support of Defendants' Motion for Summary Judgment at 4, *Devoureau vs. Camden Treatment Assoc.*, No. L-1825-11 (New Jersey Superior Ct. filed July 23, 2013).

[26] *Bostock v. Clayton County*, 140 S. Ct. 1731, 1747 (2020).

[27] N.Y. A04558A (Feb. 3, 2015), http://assembly.state.ny.us/leg/?default_fld=&bn=A04558&term=2015&Text=Y ("The term 'gender identity or expression' means a person's actual or perceived gender-related identity, appearance, behavior, expression, or other gender-related characteristic regardless of the sex assigned to that person at birth, including, but not limited to, the status of being transgender"); N.Y. Division of Human Rights, *Gender Identity Discrimination*, I.D. No. HRT-44-15-00033-P, New York Register (Nov. 4, 2015), http://docs.dos.ny.gov/info/register/2015/november4/pdf/rulemaking.pdf ("The term "sex" when used in the Human Rights Law includes gender identity and the status of being transgender."); N.Y. Exec. Law § 292(35) (defining gender identity to include actual or perceived gender expression and "status of being transgender"); Colo. Rev. Stat. § 24-34-301(7) (2015) (defining "sexual orientation" to include "transgender status").

[28] Rosenwohl-Mack A, et al., A national study on the physical and mental health of intersex adults in the U.S., PLoS ONE 5(10):e0240088 (2020); Zeeman, L., & Aranda, K., A Systematic Review of the Health and Healthcare Inequalities for People with Intersex Variance, Int. J. Environ. Res. Public Health, 17:6533 (2020); *National Academies, Understanding the Well-Being of LGBTQI+ Populations*, (Washington, DC: National Academies Press 2020).

reflection of the importance of this issue.[29] Express protections for intersex people are consistent with the reasoning of *Bostock,* which the Department of Justice stated in its updated *Title IX Legal Manual,* "applies with equal force to discrimination against intersex people."[30]

The implementing regulations should also clarify that discrimination based on pregnancy, false pregnancy, termination of pregnancy or recovery therefrom, and childbirth or related medical conditions is discrimination on the basis of sex. Before the ACA, insurers regularly rejected health coverage for a variety of "pre-existing conditions" tied to pregnancy, such as having had a Cesarean delivery or prior pregnancy.[31] Reproductive care can be especially challenging to access as a transgender or non-binary person,[32] and the updated rule should make clear that discrimination on this basis is discrimination on the basis of sex.

Broaden the scope of entities to which the regulations apply

The updated implementing regulations should reinstate applicability of section 1557's reach to all insurers and third party administrators.[33] Section 1557 itself unambiguously covers health insurance companies and third party administrators who receive federal financial assistance.[34] The Rollback Rule's narrowed definition of "health program or activity" removes many insurance plans which were covered by the 2016 regulation, even though they remain bound by the statute. This has generated confusion and uncertainty about providers' and insurers' legal obligations and runs counter to the purpose of the ACA.[35] It also makes it extremely difficult for transgender people to enforce their rights. The narrower definition leaves to the affected individual—who is also coping with the harms of a denial of service—the daunting task of understanding the intricacies of federal funding to ascertain whether Department's Office for Civil Rights ("OCR") can provide redress. And because the narrow definition hampers OCR's enforcement authority, many survivors of discrimination have no recourse to an administrative process. Their only option is to hire a lawyer and go to court or—more likely—go without relief.

We urge the Department to amend the definition of health program or activity to cover all health programs or activities who receive *any* federal financial assistance (including Medicaid, student health plans, and insurers), are administered by HHS, or established under Title I of the ACA. Equally crucial is that the rule apply to covered entities' entire operations. It should prohibit, for example, an insurer who issues plans on the ACA marketplace from discriminating in its services as third-party administrator for a self-funded plan. These changes are necessary to be consistent with the plain language of Section 1557 and achieve its purpose.

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[29] National Academies, *Understanding the Well-Being of LGBTQI+ Populations*, 67 (Washington, DC: National Academies Press 2020).

[30] US Department of Justice, *Title IX Legal Manual* (updated Aug. 12, 2021) (internal citations omitted), https://www.justice.gov/crt/title-ix#Bostock.

[31] *See* National Women's Law Center, Comment Letter on 2019 Proposed Rule at 2 (Aug. 13, 2019), https://bit.ly/2Zsrl2s.

[32] Laura Fix, et al., *Stakeholder Perceptions and Experiences Regarding Access to Contraception and Abortion for Transgender, Non-Binary, and Gender-Expansive Individuals Assigned Female at Birth in the U.S.*, Archives of Sexual Behavior (2020) https://link.springer.com/article/10.1007/s10508-020-01707-w (last visited Feb. 9, 2022).

[33] *See* 81 Fed. Reg. at 31,466 (codified as 45 C.F.R. § 92.2(a) (2019).

[34] Fain v. Crouch, No. CV 3:20-0740, 2021 WL 2657274, at *3 (S.D.W. Va. June 28, 2021)

[35] *See* 81 Fed. Reg. at 31,377; 156 Cong. Rec. S1842 (daily ed. Mar. 23, 2010).

Further clarify what constitutes sex discrimination

We recommend that the Section 1557 regulations both include a broad prohibition of discrimination and address with specificity forms of health care discrimination commonly perpetrated against transgender people.

The Department should reinstate the 2016 iteration of 45 C.F.R. § 92.206, which required covered entities to "provide individuals equal access to its health programs or activities without discrimination on the basis of sex," and "treat individuals consistent with their gender identity."[36] These broad rules against discrimination are crucial because they empower the Department to receive, consider, and respond flexibly and robustly on the specific facts of each case.

We also recommend specific prohibitions of discrimination. The regulations should make clear that it is a violation of Section 1557 for an insurance policy to include any blanket exclusion of gender affirming care. The 2016 Rule did so in its clarification prohibiting "a categorical coverage exclusion or limitation for all health services related to gender transition."[37] The updated rule should adopt a similar prohibition on transgender-related exclusions.

The updated rule should also make it clear that forms of discrimination beyond blanket exclusions for all transgender-related care also violate Section 1557. Even when plans allegedly cover gender affirming care, many transgender and non-binary people are denied care by providers or insurance companies deny them coverage for specific procedures, often because the insurance company deems them not medically necessary, despite the medical community's consensus in support of gender affirming care.[38] Surgical procedures, especially facial gender reassignment surgeries and breast augmentation, are commonly denied for these reasons. There is ample evidence that they are medically necessary and appropriate treatment for gender dysphoria.[39] And procedure specific exclusions are blatant sex and

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[36] *See* 81 Fed. Reg. at 31,471 (codified as 45 C.F.R. § 92.206 (2019)).

[37] 81 Fed. Reg. at 31,470 (codified at 45 C.F.R. § 92.207(b)(5)(2019)).

[38] *See* American Medical Association, *Issue Brief: Health insurance coverage for gender-affirming care of transgender patients*, https://www.ama-assn.org/system/files/2019-03/transgender-coverage-issue-brief.pdf; American Psychiatric Association, *Position Statement on Access to Care for Transgender and Gender Diverse Individuals* (2018) https://www.psychiatry.org/psychiatrists/cultural-competency/education/transgender-and-gender-nonconforming-patients/best-practices; American Psychological Association, *Guidelines for Psychological Practice with Transgender and Gender Nonconforming People* (Dec. 2015), https://www.apa.org/practice/guidelines/transgender.pdf; American Academy of Pediatrics, *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents* (2018) https://publications.aap.org/pediatrics/article/142/4/e20182162/37381/Ensuring-Comprehensive-Care-and-Support-for; American College of Obstetricians & Gynecologists, *Health Care for Transgender and Gender Diverse Individuals* (March 2021) https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.

[39] *See, e.g.,* WPATH, *Transgender Medical Benefits* at 4 (June 28, 2018), https://www.wpath.org/media/cms/Documents/Public%20Policies/2018/6_June/Transgender%20Medical%20Benefits.pdf; WPATH, *Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A.* at 3 (Dec. 21, 2016), https://www.wpath.org/media/cms/Documents/Web%20Transfer/Policies/WPATH-Position-on-Medical-Necessity-12-21-2016.pdf. For additional discussion of facial gender reassignment surgery and breast augmentation as treatment for gender dysphoria in transfeminine people see TLDEF, Literature Review: Medical necessity of facial gender reassignment surgery for transgender women (Sept. 10, 2020), https://transhealthproject.org/documents/34/Facial_surgery_medical_necessity_literature_review.pdf; and

disability discrimination.[40] Therefore, we urge the Department to state explicitly in its proposed rule that excluding coverage of medically necessary hormone therapy or surgery for the treatment of gender dysphoria are prohibited. Such a proposed rule should encompass both plans that categorically exclude all transgender-related care and plans that plans that categorically bar transgender people from specific procedures or treatments.

We also recommend the Department reinstate the 2016 iterations of 45 C.F.R. §§ 92.206, 92.207(b)(3), which protect access to care that is "gender-coded" or viewed as sex-specific.[41] Prior to the 2016 regulations, denials of care considered sex-specific care were rampant. For example, in 2012, a transgender woman who was denied coverage for a mammogram because her insurance company had recorded her sex as male, required TLDEF's assistance to have this critical, preventative procedure covered by her insurer.[42] Similarly, the Department's Office for Civil Rights investigated the discriminatory exclusion of transgender women from a CDC-funded mammogram program, resulting in the CDC issuing new guidance clarifying that transgender women can participate in the program.[43] Reinstating regulations covering gender-coded, or so called sex-specific care, is necessary to insuring transgender people receive equal access to basic preventative care including gynecological visits and preventative screenings.

The proposed rule should make clear that covered entities cannot refuse to let someone share single-sex spaces with others who share their affirmed gender because they are or are perceived to be transgender. Not having access to sex-appropriate hospital rooms, inpatient mental health facilities, and substance abuse treatment has dire consequences for transgender people. Unfortunately, sometimes hospitals and other health care providers, for example, place transgender women with men, instead of

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TLDEF, *Medical necessity of chest reassignment surgery to treat gender dysphoria in transgender women* (June 11, 2020), https://transhealthproject.org/documents/28/MTF_chest_reassignment_literature_review.pdf.

[40] Declaratory Ruling on Petition Regarding Health Insurers' Categorization of Certain Gender-Confirming Procedures as Cosmetic, Connecticut Commission on Human Rights and Opportunities, 26-27 (2020), https://www.glad.org/cases/challenging-insuranceexclusions-for-gender-affirming-medical-care, (holding that when the State or a municipality contracts for health insurance plans that contain categorical exclusions for treatments
related to gender dysphoria – and especially when the same treatments are covered for treatment of other conditions – it commits a discriminatory practice, as does the insurer.")

[41] 81 Fed. Reg. at 31,417 (codified at 45 C.F.R. 45 C.F.R. §§ 92.206, 92.207(b)(3) (2019)).

[42] Susan Donaldson James, *Transgender Woman Wins Insurance Coverage for Mammogram*, ABC News, May 1, 2012, https://abcnews.go.com/Health/transgender-woman-wins-health-coverage-mammogram/story?id=16246219.

[43] U.S. Dep't of Health and Human Services, *OCR Enforcement under Section 1557 of the Affordable Care Act Sex Discrimination Cases*, (Sept. 23, 2015), https://web.archive.org/web/20150923030557/http:/www.hhs.gov/ocr/civilrights/understanding/section1557/casesum.html.

with women.[44] Refusing to allow transgender people access to single sex-facilities is not only blatant sex discrimination but also jeopardizes their health and safety.[45]

Reinstate language accessibility obligations

We recommend that requirements to facilitate access to healthcare by persons speaking non-English languages contained in the 2016 Rule[46] be reinstated. Specifically, we ask that requirements to provide key notices and short statements informing individuals of their right to language assistance and how to seek it in multiple languages be reinstated. OCR should further repeal the standard that people are only entitled to receive notices in their language if a geographical threshold is met. People with limited English proficiency ("LEP") already face challenges navigating a complex healthcare system, especially when faced with medical or insurance terminology, and communication barriers between LEP patients and their providers create a heightened risk of poor health outcomes.[47] Depriving LEP patients of meaningful communication in key notices and of information about language assistance further exacerbates these issues.

HHS should make clear that LEP people should be meaningfully served by requiring statements informing people of their right to language assistance and key notices be provided in multiple languages. For example, people should receive notices of appeal in multiple languages so that LEP patients are able to understand the appeal process.

Reinstate a uniform enforcement scheme

Discrimination rarely acts upon one axis alone and Section 1557's regulations must acknowledge this. Section 1557 borrows the prohibited grounds of discrimination from four cross-referenced civil rights statutes.[48] The 2016 rule implemented a uniform enforcement system for discrimination on any ground identified in Section 1557, as that statute requires. In rescinding this system, the current rule requires entities subject to Section 1577, and patients, to navigate a confusing mix of legal standards and available remedies spread across the four referenced statutes. Rather than having to look to different

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[44] *See, e.g.,* Voluntary Resolution Agreement Between the U.S. Department of Health and Human Services Office for Civil Rights and the Brooklyn Hospital Center, Transaction Number: 12-147291 (2015), https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/vra.pdf; U.S. Dep't of Health and Human Services Office for Civil Rights, The Brooklyn Hospital Center Implements Non-Discriminatory Practices to Ensure Equal Care for Transgender Patients (July 14, 2015), https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/statement.pdf; NYC Commission on Human Rights, NYC Commission on Human Rights Charges Four Substance Abuse Centers with Discriminatory Intake Policies for Transgender Patients (July 13, 2017), https://www1.nyc.gov/assets/cchr/downloads/pdf/press-releases/Press%20Release%20-%20Substance%20Abuse%20Centers%20FINAL.pdf.

[45] *See, e.g., Wilson v. Phoenix House,* 978 N.Y.S.2d 748 (N.Y. Sup. Ct. Kings County 2013); *Grimm v. Gloucester Cty. Sch. Bd.,* 972 F.3d 586, 619 (4th Cir. 2020), *as amended* (Aug. 28, 2020), *cert. denied,* 141 S. Ct. 2878, 210 L. Ed. 2d 977 (2021).

[46] 81 Fed. Reg. at 31,415 (codified at 45 C.F.R. § 92.8 (2019)).

[47] *See* National Health Law Program, Comment Letter on 2019 Proposed Rule at 27 (Aug. 13, 2019), http://bit.ly/3gm1VdF.

[48] Race, color, or national origin, 42 U.S.C. § 18116(a), § 2000d, Title VI of the Civil Rights Act of 1964; sex, 20 U.S.C. § 1681(a), 1684, Title IX of the Education Amendments of 1972; age, 42 U.S.C. § 6101, Age Discrimination Act of 1975; disability, 29 U.S.C. § 794, Section 504 of the Rehabilitation Act.

regulatory schemes to seek redress, there should be one uniform enforcement scheme to allow intersectional claims that better reflect the reality of people's lives and experiences.

Ensure that people can enforce their rights by reinstating a private right of action and compensatory damages.

A robust enforcement scheme is necessary to ensure that anti-discrimination protections are effective and meaningful. To ensure this, the 2016 Rule explicitly provided that Section 1557 contains a private right of action and that Section 1557 plaintiffs may recover compensatory damages in judicial and administrative proceedings.[49] OCR should reinstate the private right of action as was previously codified in order to increase enforcement and incentivize compliance with Section 1557. Allowing people to vindicate their rights in court opens an important avenue to address discrimination and should be reinstated.

Remove Religious Exemptions

We urge the Department to repeal 45 C.F.R. § 92.6(b), the unlawfully broad religious exemption adopted in the Rollback Rule promulgated in 2020. As the Department correctly concluded in 2016, a religious exemption contravenes the express purpose of Section 1557 and violates the plain language of the statute.

A broad religious exemption threatens the health and well-being of LGBTQI patients and patients seeking reproductive health care. Unfortunately, some providers cite their religious beliefs as reason to mistreat or refuse to care for patients. [50] Providers have, because of their religious beliefs, denied transgender patients preventative care for HIV and mental health care, among other vitally important health care.[51] For some patients, particularly those in rural areas or with low-income, access to health care is so precarious that refusal by a religious provider means long delays, prohibitive cost, or worse forgoing care entirely.[52]

Other aspects of the health care landscape compound the harms of religious refusals. Religiously affiliated health care systems that follow "transgender exclusive ethical and religious directives"[53] have

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[49] *See* 81 Fed. Reg. at 31,417 (codified at 45 C.F.R. § 92.301(b), 92.302(d) (2019)).

[50] Ryan Thoreson, *You don't want Second Best: Anti-LGBT Discrimination in US Health Care* 18-23, Human Rights Watch (July, 2018), https://www.hrw.org/sites/default/files/report_pdf/us_lgbt0718_web.pdf.

[51] *Id.*

[52] Anna Maria Barry-Jester et al., Lois Uttley et al., "How Catholic Bishops Are Shaping Health Care In Rural America," *FiveThirtyEight* (July 25, 2018), https://fivethirtyeight.com/features/how-catholic-bishops-are-shaping-health-care-in-rural-america/ (describing geographic and financial barriers that result in patients being "functionally restricted to Catholic care"); *Growth of Catholic Hospitals and Health Systems: 2016 Update of the Miscarriage of Medicine Report,* at 5 (2016), http://static1.1.sqspcdn.com/static/f/816571/27061007/1465224862580/MW_Update-2016-MiscarrOfMedicine-report.pdf?token=cHO2jBYG017RabAXAdQXC4c9rps%3D (finding that in 2016 "46 sole community hospitals [were] Catholic owned or affiliated.")

[53] Caroline Medina et al., *Protecting and Advancing Health Care for Transgender Adult Communities* at 20 (2021), https://www.americanprogress.org/article/protecting-advancing-health-care-transgender-adult-communities/.

grown through mergers with nonsectarian systems.[54] Moreover, the COVID-19 pandemic has both overwhelmed our already overburdened health systems and increased the need for urgent or emergency medical care.[55] Both of these phenomena place transgender people and people seeking reproductive health care at greater risk of having no other resort if denied care by a religiously affiliated provider.

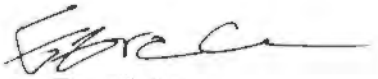
Secular health insurers have even claimed other entities' religious beliefs as basis to deny care to transgender people. Blue Cross Blue Shield of Illinois, an entity without religious affiliation, argued the Religious Freedom Restoration Act (RFRA) was grounds to dismiss a challenge to a categorical exclusion of all transgender related care in a plan it administered.[56] Over the last two years, TLC has worked with two transgender people whose insurance companies lacked any religious affiliation but nevertheless denied coverage for gender affirming because of the insureds' employers had religious objections to transgender people.

The religious exemption contained in 45 C.F.R. § 92.6(b) only causes additional harm by exacerbating the already serious threat of discrimination. It emboldens health care providers to deny patients care, jeopardizing the health and wellbeing of LGBTQI+ patients and people seeking reproductive health care. We urge the Department to remove the exemption. We also urge the Department to clarify that federal conscience statutes do not permit denials of necessary health care on the basis of the patient's sexual orientation, gender identity, transgender status, or intersex conditions.

III. Conclusion

Thank you again for the opportunity to provide information and recommendations to carry out the Department's statutory obligation to clarify and promulgate rules interpreting Section 1557. We appreciate the Department's dedication to equitable health care access, and once again urge the Department to strengthen the implementing regulations of Section 1557 so they better address the dire problem of discrimination against transgender and non-binary people in health care.

Sincerely,



Ezra Cukor
Senior Staff Attorney
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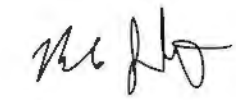

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[54] Julia Kaye et al., *Healthcare Denied: Patients and Physicians Speak Out About Catholic Hospitals and the Threat to Women's Health and Lives* at 22 (2016) https://www.aclu.org/report/report-health-care-denied?redirect=report/health-care-denied (finding a 22% increase in the number of Catholic hospitals from 2001-2016 and that "[o]ne in six hospital beds in this country is now in a facility that abides by Catholic restrictions on care.")

[55] Jenna Portnoy, "Patient safety a concern as emergency rooms fill up," *Washington Post* (Dec. 22, 2021), https://www.washingtonpost.com/dc-md-va/2021/12/22/emergency-departments-overwhelmed/ (COVID-19 surge overwhelms hospitals with dire consequences for patients, and even "[b]efore the pandemic, more than 90 percent of U.S. emergency departments already 'found themselves stressed beyond the breaking point at least some of the time.'")

[56] *Pritchard v. Blue Cross Blue Shield of Illinois,* 536 F.Supp. 3d 791, 797 (W.D.Wash., 2021) (finding that a transgender exclusion can give rise to a claim because a "claim of discrimination in violation of Section 1557" and rejecting RFRA defense.)

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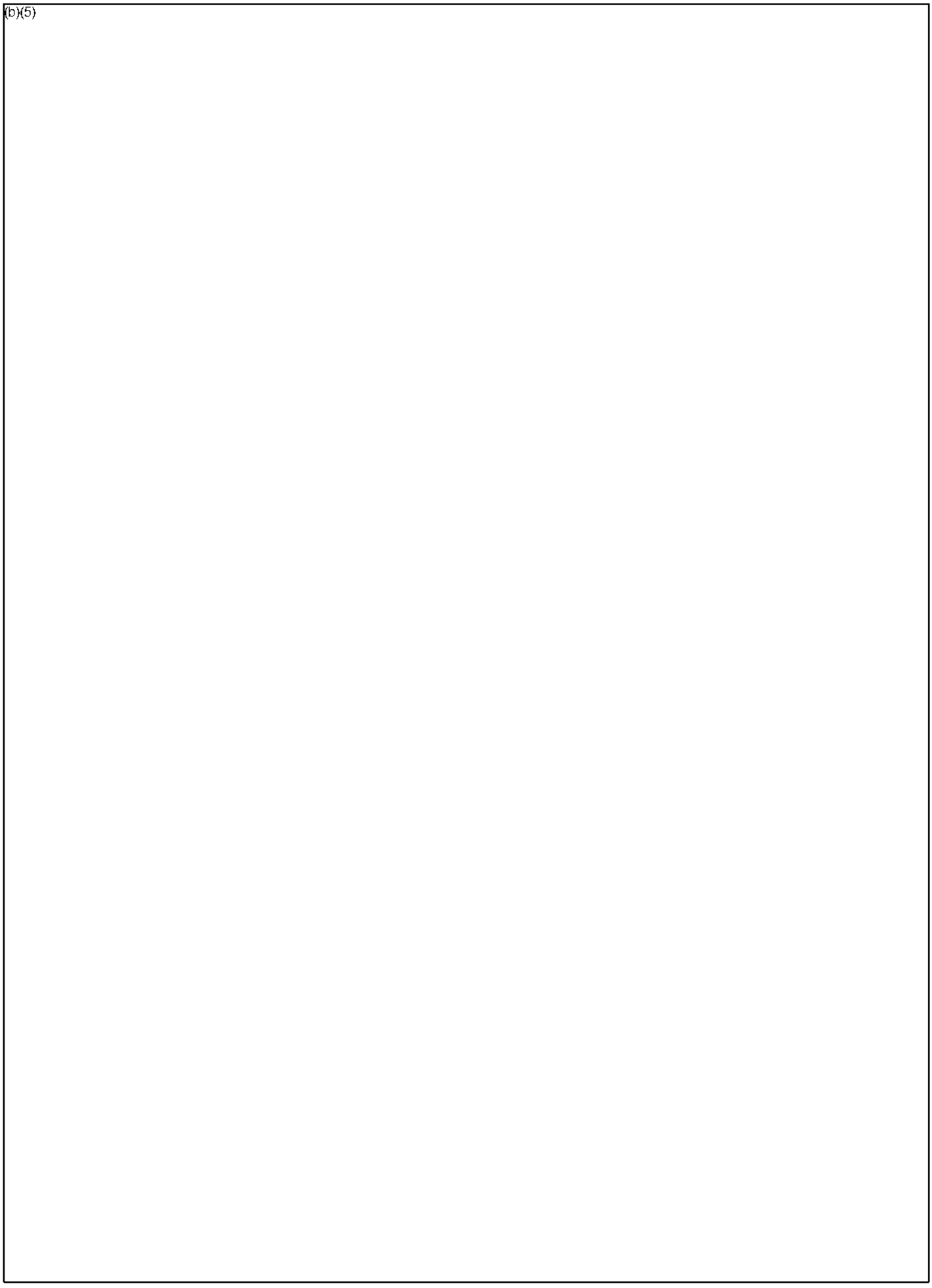
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The Cass Review

Independent review of gender identity services for children and young people: Interim report

February 2022

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Contents

About this report

This interim report represents the work of the independent review of gender identity services for children and young people to date. It reflects a point in time. It does not set out final recommendations; these will be developed over the coming months, informed by our formal research programme.

This Review is forward looking. Its role is to consider how to improve and develop the future clinical approach and service model. However, in order to do this, it is first necessary to understand the current landscape and the reasons why change is needed, so that any future model addresses existing challenges, whilst retaining those features that service users and the professionals supporting them most value.

This report is primarily for the commissioners and providers of services for children and young people needing support around their gender. However, because of the wide interest in this topic, we have included some explanations about how clinical service development routinely takes place in the NHS, which sets the context for some of our interim advice.

The care of this group of children and young people is everyone's business. We therefore encourage the wider clinical community to take note of our work and consider their own roles in providing the best holistic support to this population.

Since the Review began, it has focused on hearing a wide range of perspectives to better understand the challenges within the current system and aspirations for how these could be addressed. This report does not contain all that we have heard during our listening sessions but summarises consistent themes. These conversations will continue throughout the course of the Review and there will be further opportunities for stakeholders to engage and contribute.

It is important to note that the references cited in this report do not constitute a comprehensive literature review and are included only to clarify why specific lines of enquiry are being pursued, and where there are unanswered questions that will be addressed more fully during the life of the Review. A formal literature review is one strand of the Review's commissioned work, and this will be reported in full when complete.

A note about language

There is sometimes no consensus on the best language to use relating to this subject. The language surrounding this area has also changed rapidly and young people have developed varied ways of describing their experiences using different terms and constructs that are relevant to them.

The Review tries as far as possible to use language and terms that are respectful and acknowledge diversity, but that also accurately illustrate the complexity of what we are trying to describe and articulate.

The terms we have used may not always feel right to some; nevertheless, it is important to emphasise that the language used is not an indication of a position being taken by the Review. A glossary of terms is included.

The Review is cognisant of the broader cultural and societal debates relating to the rights of transgender adults. It is not the role of the Review to take any position on the beliefs that underpin these debates. Rather, this Review is strictly focused on the clinical services provided to children and young people who seek help from the NHS to resolve their gender-related distress.

A letter to children and young people

Children and young people accessing the NHS deserve safe, timely and supportive services, and clinical staff with the training and expertise to meet their healthcare needs.

Dr Hilary Cass

I understand that as you read this letter some of you may be anxious because you are waiting to access support from the NHS around your gender identity. Maybe you have tried to get help from your local services, or from the Gender Identity Development Service (GIDS), and because of the long waiting lists they have not yet been able to see you. I hope that some of you have had help – maybe from a supportive GP, a local Child and Adolescent Mental Health Service (CAMHS), or from GIDS.

I have heard that young service users are particularly worried that I will suggest that services should be reduced or stopped. I want to assure you that this is absolutely not the case – the reverse is true. I think that more services are needed for you, closer to where you live. The GIDS staff are working incredibly hard and doing their very best to see you as quickly as possible but providing supportive care is not something that can be rushed – each young person needs enough time and space for their personal needs to be met. So, with the best will in the world, one service is not going to be able to respond to the growing demand in a timely way.

I am advising that more services are made available to support you. But I must be honest; this is not something that can happen overnight, and I can't come up with a solution that will fix the problems immediately. However, we do need to start now.

The other topic that I know is worrying some of you is whether I will suggest that hormone treatments should be stopped. On this issue, I have to share my thoughts as a doctor. We know quite a bit about hormone treatments, but there is still a lot we don't know about the long-term effects.

Whenever doctors prescribe a treatment, they want to be as certain as possible that the benefits will outweigh any adverse effects so that when you are older you don't end up saying 'Why did no-one tell me that that might happen?' This includes understanding both the risks and benefits of having treatment and not having treatment.

Therefore, what we will be doing over the next few months is trying to make sense of all the information that is available, as well as seeing if we can plug any of the gaps in the research. I am currently emphasising the importance of making decisions about prescribing as safe as possible. This means making sure you have all the information you need – about what we do know and what we don't know.

Finally, some of you may want the chance to talk to me and share your thoughts about how services should look in the future. Over the coming months we will need your help and there will be opportunities to get involved with the Review, so please keep an eye on our website (www.cass.independent-review.uk), where we will provide updates on our work.

Dr Hilary Cass, OBE

Introduction from the Chair

Anyone with an interest in the care of gender-questioning children and young people, as well as those with lived experience, may have wondered what qualifies me to take on this Review, and whether I have a pre-existing position on this subject.

I am a paediatrician who was in clinical practice until 2018, my area of specialism being children and young people with disability. I have also held many management and policy roles throughout my career, most notably as President of the Royal College of Paediatrics and Child Health (RCPCH) from 2012-15.

Children's services are often at a disadvantage in healthcare because health services are usually designed around the needs of adults. As President of RCPCH, a key part of my role was to advocate for services to be planned with children and families at their heart.

I have not worked in gender services during my career, but my strong focus on hearing the voice of service users, supporting vulnerable young people, equity of access, and strong clinical standards applies in this area as much as in my other work.

With this in mind, the aim of the Review is to ensure that children and young people who are experiencing gender incongruence or gender-related distress receive a high standard of NHS care that meets their needs and is safe, holistic and effective.

I have previously set out the principles governing this Review process, namely that:

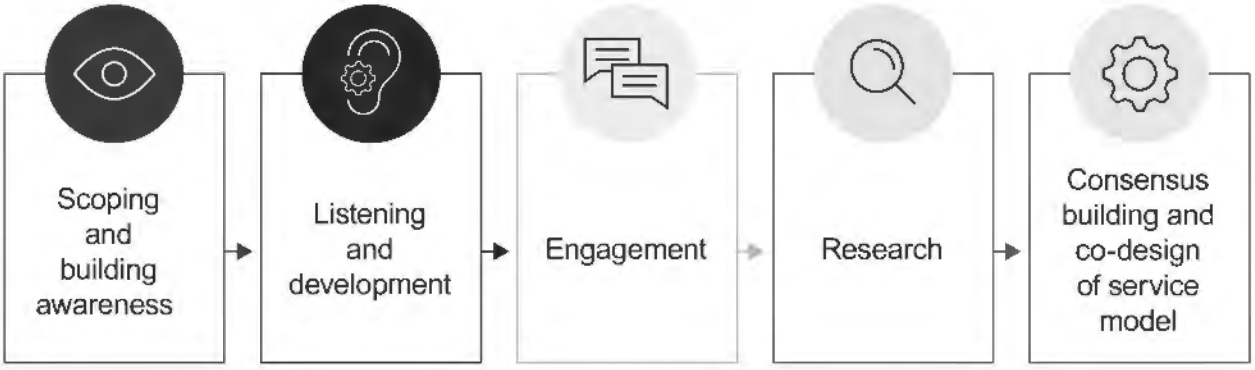
- The welfare of the child and young person will be paramount in all considerations.
- Children and young people must receive a high standard of care that meets their needs.
- There will be extensive and purposeful stakeholder engagement, including ensuring that children and young people can express their own views through a supportive process.
- The Review will be underpinned by research and evidence, including international models of good practice where available.
- There will be transparency in how the Review is conducted and how recommendations are made.
- There are no pre-determined outcomes with regards to the recommendations the Review will make.

The Review's terms of reference (**Appendix 1**) are wide ranging in scope, looking at different aspects of gender identity services across the whole pathway through primary, secondary and specialist services, up to the point of transition to adult services. This includes consideration of referral pathways, assessment, appropriate clinical management and workforce recommendations.

I have also been asked to explore the reasons for the considerable increase in the number of referrals, which have had a significant impact on waiting times, as well as the changing case-mix of gender-questioning children and young people presenting to clinical services.

The Review is taking an investigative approach to understanding what the future service model should look like for children and young people. This means that its outcomes are not being developed in isolation or by committee but rather through an ongoing dialogue aimed at building a shared understanding of the current situation and how it can and should be improved.

The key aspects of the approach to the Review are:



My starting point has been to hear from a variety of experts with relevant expertise and those with lived experience to understand as many perspectives as possible. To date, this has included hearing directly from those with lived experience, from professionals and support and advocacy groups. This listening process will continue.

We have been very fortunate in the generosity of all those who have been prepared to talk to the Review and share their experiences. In addition to some divergent opinions, there are also some themes and views which seem to be widely shared. The commitment of professionals at all levels is striking and I genuinely believe that with collective effort we can improve services for the children and young people who are at the heart of this Review.

These discussions have been valuable to get an in-depth sense of the current situation and different viewpoints on how it may be improved. However, it is essential that this initial understanding is underpinned by more detailed data and an enhanced evidence base, which is being delivered through the Review's academic research programme.

Providing this evidence base for the Review is going to take some time. I recognise there is a pressing need to enhance the services currently available for children, young people, their

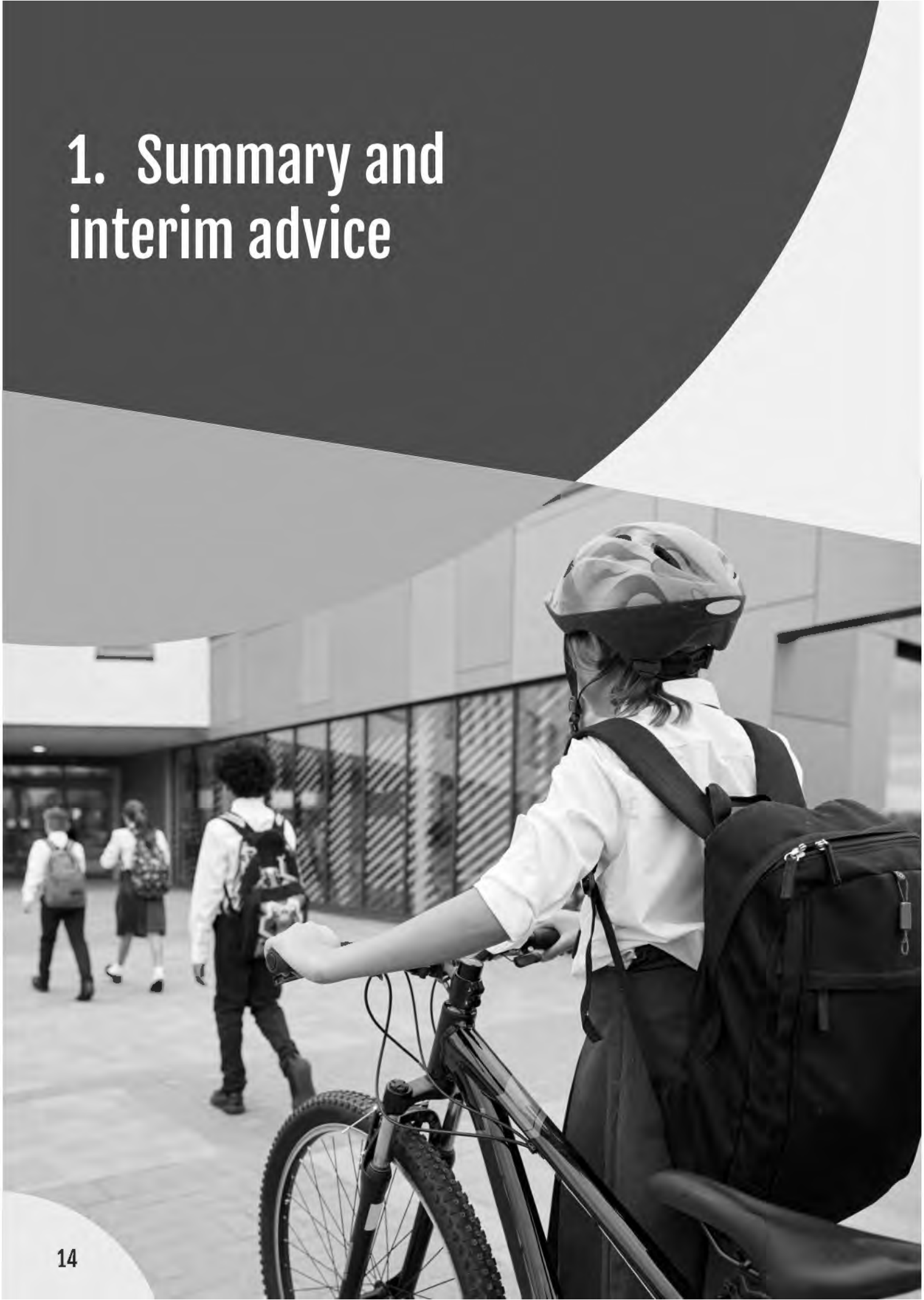
parents and carers, some of whom are experiencing considerable distress. Clinicians providing their treatment and care are also under pressure and cannot sustain the current workload. As such, I know the time I am taking to complete this Review and make recommendations will be difficult for some, but it is necessary.

I wrote to NHS England in May 2021 (**Appendix 2**) setting out some more immediate considerations whilst awaiting my full recommendations. This report builds on that letter and looks to provide some further interim advice.

Through our research programme, the Review team will continue to examine the literature and, where possible, will fill gaps in the existing evidence base. However, there will be persisting evidence gaps and areas of uncertainty. We need the engagement of service users, support and advocacy groups, and professionals across the wider workforce to work with us in the coming months in a collaborative and open-minded manner in order to reach a shared understanding of the problems and an agreed way forward that is in the best interests of children and young people.

My measure of success for this Review will be that this group of children and young people receive timely, appropriate and excellent care, not just from specialists but from every healthcare professional they encounter as they take the difficult journey from childhood to adulthood.

1. Summary and interim advice



Summary

1.1. In recent years, there has been a significant increase in the number of referrals to the Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust. This has contributed to long waiting lists and growing concern about how the NHS should most appropriately assess, diagnose and care for this population of children and young people.

1.2. Within the UK, the single specialist service has developed organically, and the clinical approach has not been subjected to some of the usual control measures that are typically applied when new or innovative treatments are introduced. Many of the challenges and knowledge gaps that we face in the UK are echoed internationally,[1] and there are significant gaps in the research and evidence base.

1.3. This Review was commissioned by NHS England to make recommendations on how to improve services provided by the NHS to children and young people who are questioning their gender identity or experiencing gender incongruence and ensure that the best model for safe and effective services is commissioned (**Appendix 1**).

1.4. This interim report represents the Review's work to date. It sets out what we have heard so far and the approach we are taking moving forward. There is still much evidence to be gathered, questions to be answered, and voices to be heard, and our perspective will evolve as more evidence comes to light. However, there is sufficient clarity on several areas for the Review to be able to offer advice at this stage so that action can be taken more quickly.

1.5. The Review is not able to provide definitive advice on the use of puberty blockers and feminising/masculinising hormones at this stage, due to gaps in the evidence base; however, recommendations will be developed as our research programme progresses.

Every gender-questioning child or young person who seeks help from the NHS must receive the support they need to get on the appropriate pathway for them as an individual.

Children and young people with gender incongruence or dysphoria must receive the same standards of clinical care, assessment and treatment as every other child or young person accessing health services.

[1] Vrouenraets LJ, Fredriks AM, Hannema SE, Cohen-Kettenis PT, de Vries MC (2015). Early medical treatment of children and adolescents with gender dysphoria: an empirical ethical study. J Adolesc Health 57(4): 367-73. DOI: 10.1016/.2015.04.004.

Conceptual understanding and consensus about the meaning of gender dysphoria

1.6. In clinical practice, a diagnosis of gender dysphoria is currently based on an operational definition, using the criteria set out in DSM-5 (**Appendix 3**). Some of these criteria are seen by some as outdated in the context of current understanding about the flexibility of gender expression.

1.7. At primary, secondary and specialist level, there is a lack of agreement, and in many instances a lack of open discussion, about the extent to which gender incongruence in childhood and adolescence can be an inherent and immutable phenomenon for which transition is the best option for the individual, or a more fluid and temporal response to a range of developmental, social, and psychological factors. Professionals' experience and position on this spectrum may determine their clinical approach.

1.8. Children and young people can experience this as a 'clinician lottery', and failure to have an open discussion about this issue is impeding the development of clear guidelines about their care.

Service capacity and delivery

1.9. A rapid change in epidemiology and an increase in referrals means that the number of children seeking help from the NHS is now outstripping the capacity of the single national specialist service, the Gender Identity Development Service (GIDS) at The Tavistock and Portman NHS Foundation Trust.

1.10. The mix of young people presenting to the service is more complex than seen previously, with many being neurodiverse and/or having a wide range of psychosocial and mental health needs. The largest group currently comprises birth-registered females first presenting in adolescence with gender-related distress.

1.11. Until very recently, any local professional, including non-health professionals, could refer to GIDS, which has meant that the quality and appropriateness of referrals lacks consistency, and local service provision has remained patchy and scarce.

1.12. The staff working within the specialist service demonstrate a high level of commitment to the population they serve. However, the waiting list pressure and lack of consensus development on the clinical approach, combined with criticism of the service, have all resulted in rapid turnover of staff and inadequate capacity to deal with the increasing workload. Capacity constraints cannot be addressed through financial investment alone; there are some complex workforce (recruitment; retention; and training) and cultural issues to address.

1.13. Our initial work has indicated that many professionals working at primary and secondary level feel that they have the transferable skills and the commitment to offer more robust support to this group of children and young people, but are nervous about doing so, partly because of the lack of formal clinical guidance, and partly due to the broader societal context.

1.14. Primary and secondary care staff have told us that they feel under pressure to adopt an unquestioning affirmative approach and that this is at odds with the standard process of clinical assessment and diagnosis that they have been trained to undertake in all other clinical encounters.

1.15. Children and young people are waiting lengthy periods to access GIDS, during which time some may be at considerable risk. By the time they are seen, their distress may have worsened, and their mental health may have deteriorated.

1.16. Another significant issue raised with us is one of diagnostic overshadowing – many of the children and young people presenting have complex needs, but once they are identified as having gender-related distress, other important healthcare issues that would normally be managed by local services can sometimes be overlooked.

1.17. The current move to adult services at age 17-18 may fall at a critical time in the young person's gender management. In contrast, young people with neurodiversity often remain under children's services until age 19 and some other clinical services continue to mid-20s. Further consideration will be needed regarding the age of transfer to adult services.

Service standards

1.18. The Multi-Professional Review Group (MPRG), set up by NHS England to ensure that procedures for assessment and for informed consent have been properly followed, has stated that the following areas require consideration:

- From the point of entry to GIDS there appears to be predominantly an affirmative, non-exploratory approach, often driven by child and parent expectations and the extent of social transition that has developed due to the delay in service provision.
- From documentation provided to the MPRG, there does not appear to be a standardised approach to assessment or progression through the process, which leads to potential gaps in necessary evidence and a lack of clarity.
- There is limited evidence of mental health or neurodevelopmental assessments being routinely documented, or of a discipline of formal diagnostic or psychological formulation.
- Of 44 submissions received by the MPRG, 31% were not initially assured due to lack of safeguarding information. And in a number of cases there were specific safeguarding concerns. There do not appear to be consistent processes in place to work with other agencies to identify children and young people and families who may be vulnerable, at risk and require safeguarding.

- Appropriate clinical experts need to be involved in informing decision making.

1.19. Many of these issues were also highlighted by the Care Quality Commission (CQC) in 2020.[2]

International comparisons

1.20. The Netherlands was the first country to provide early endocrine interventions (now known internationally as the Dutch Approach). Although GIDS initially reported its approach to early endocrine intervention as being based on the Dutch Approach,[3] there are significant differences in the NHS approach. Within the Dutch Approach, children and young people with neurodiversity and/or complex mental health problems are routinely given therapeutic support in advance of, or when considered appropriate, instead of early hormone intervention. Whereas criteria to have accessed therapeutic support prior to starting hormone blocking treatment do not appear to be integral to the current NHS process.

1.21. NHS endocrinologists do not systematically attend the multi-disciplinary meetings where the complex cases that may be referred to them are discussed, and until very recently did not routinely have direct contact with the clinical staff member who had assessed the child or young person. This is not consistent with some international approaches for this group of children and young people, or in other multi-disciplinary models of care across paediatrics and adult medicine where challenging decisions about life-changing interventions are made.[4,5]

1.22. In the NHS, once young people are started on hormone treatment, the frequency of appointments drops off rather than intensifies, and review usually takes place quarterly. Again, this is different to the Dutch Approach.[6] GIDS staff would recommend more frequent contact during this period, but the fall-off in appointments reflects a lack of service capacity, with the aspiration being for more staff time to remedy this situation.

Existing evidence base

1.23. Evidence on the appropriate management of children and young people with gender incongruence and dysphoria is inconclusive both nationally and internationally.

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[2] Care Quality Commission (2021). The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report. London: CQC.
[3] de Vries ALC, Cohen-Kettenis PT (2012). Clinical management of gender dysphoria in children and adolescents: the Dutch approach. J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.
[4] Ibid.
[5] Kyriakou A, Nicolaides NC, Skordis N (2020). Current approach to the clinical care of adolescents with gender dysphoria. Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.
[6] de Vries ALC, Cohen-Kettenis PT (2012). Clinical management of gender dysphoria in children and adolescents: the Dutch approach. J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.

1.24. A lack of a conceptual agreement about the meaning of gender dysphoria hampers research, as well as NHS clinical service provision.

1.25. There has not been routine and consistent data collection within GIDS, which means it is not possible to accurately track the outcomes and pathways that children and young people take through the service.

1.26. Internationally as well as nationally, longer-term follow-up data on children and young people who have been seen by gender identity services is limited, including for those who have received physical interventions; who were transferred to adult services and/or accessed private services; or who desisted, experienced regret or detransitioned.

1.27. There has been research on the short-term mental health outcomes and physical side effects of puberty blockers for this cohort, but very limited research on the sexual, cognitive or broader developmental outcomes.[7]

1.28. Much of the existing literature about natural history and treatment outcomes for gender dysphoria in childhood is based on a case-mix of predominantly birth-registered males presenting in early childhood. There is much less data on the more recent case-mix of predominantly birth-registered females presenting in early teens, particularly in relation to treatment and outcomes.

1.29. Aspects of the literature are open to interpretation in multiple ways, and there is a risk that some authors interpret their data from a particular ideological and/or theoretical standpoint.

The mismatch between service user expectations and clinical standards

1.30. By the time children and young people reach GIDS, they have usually had to experience increasingly long, challenging waits to be seen.[8] Consequently, some feel they want rapid access to physical interventions and find having a detailed assessment distressing.

1.31. Clinical staff are governed by professional, legal and ethical guidance which demands that certain standards are met before a treatment can be provided. Clinicians carry responsibility for their assessment and recommendations, and any harm that might be caused to a patient under their care. This can create a tension between the aspirations of the young person and the responsibilities of the clinician.

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[7] National Institute for Health and Care Excellence (2020). Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria.
[8] Care Quality Commission (2021). The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report. London: CQC.

Interim advice

1.32. The Review considers that there are some areas where there is sufficient clarity about the way forward and we are therefore offering some specific observations and interim advice. The Review will work with NHS England, providers and the broader stakeholder community to progress action in these areas.

Service model

1.33. It has become increasingly clear that a single specialist provider model is not a safe or viable long-term option in view of concerns about lack of peer review and the ability to respond to the increasing demand.

1.34. Additionally, children and young people with gender-related distress have been inadvertently disadvantaged because local services have not felt adequately equipped to see them. It is essential that they can access the same level of psychological and social support as any other child or young person in distress, from their first encounter with the NHS and at every level within the service.

1.35. A fundamentally different service model is needed which is more in line with other paediatric provision, to provide timely and appropriate care for children and young people needing support around their gender identity. This must include support for any other clinical presentations that they may have.

1.36. The Review supports NHS England's plan to establish regional services, and welcomes the move from a single highly specialist service to regional hubs.

1.37. Expanding the number of providers will have the advantages of:

- creating networks within each area to improve early access and support;
- reducing waiting times for specialist care;
- building capacity and training opportunities within the workforce;
- developing a specialist network to ensure peer review and shared standards of care; and
- providing opportunities to establish a more formalised service improvement strategy.

Service provision

1.38. The primary remit of NHS England's proposed model is for the regional hubs to provide support and advice to referrers and professionals. However, it includes limited provision for direct contact with children and young people and their families.

1: The Review advises that the regional centres should be developed, as soon as feasibly possible, to become direct service providers, assessing and treating children and young people who may need specialist care, as part of a wider pathway. The Review team will work with NHS England and stakeholders to further define the proposed model and workforce implications.

2: Each regional centre will need to develop links and work collaboratively with a range of local services within their geography to ensure that appropriate clinical, psychological and social support is made available to children and young people who are in early stages of experiencing gender distress.

3: Clear criteria will be needed for referral to services along the pathway from primary to tertiary care so that gender-questioning children and young people who seek help from the NHS have equitable access to services.

4: Regional training programmes should be run for clinical practitioners at all levels, alongside the online training modules developed by Health Education England (HEE). In the longer-term, clearer mapping of the required workforce, and a series of competency frameworks will need to be developed in collaboration with relevant professional organisations.

Data, audit and research

1.39. A lack of routine and consistent data collection means that it is not possible to accurately track the outcomes and pathways children and young people take through the service. Standardised data collection is required in order to audit service standards and inform understanding of the epidemiology, assessment and treatment of this group. This, alongside a national network which brings providers together, will help build knowledge and improve outcomes through shared clinical standards and systematic data collection. In the longer-term, formalisation of such a network into a learning health system[9] with an academic host would mean that there was systematised use of data to produce a continuing research programme with rapid translation into clinical practice and a focus on training.

[9] Scobie S, Castle-Clarke S (2019). Implementing learning health systems in the UK NHS: Policy actions to improve collaboration and transparency and support innovation and better use of analytics. Learning Health Systems 4(1): e10209. DOI:10.1002/lrh2.10209.

5: The regional services should have regular co-ordinated national provider meetings and operate to shared standards and operating procedures with a view to establishing a formal learning health system.

6: Existing and future services should have standardised data collection in order to audit standards and inform understanding of the epidemiology, assessment and treatment of this group of children and young people.

7: Prospective consent of children and young people should be sought for their data to be used for continuous service development, to track outcomes, and for research purposes. Within this model, children and young people put on hormone treatment should be formally followed up into adult services, ideally as part of an agreed research protocol, to improve outcome data.

Clinical approach

Assessment processes

1.40. We have heard that there are inconsistencies and gaps in the assessment process. Our work to date has also demonstrated that clinical staff have different views about the purpose of assessment and where responsibility lies for different components of the process within the pathway of care. The Review team has commenced discussions with clinical staff across primary, secondary and tertiary care to develop a framework for these processes.

8: There needs to be agreement and guidance about the appropriate clinical assessment processes that should take place at primary, secondary and tertiary level.

9: Assessments should be respectful of the experience of the child or young person and be developmentally informed. Clinicians should remain open and explore the patient's experience and the range of support and treatment options that may best address their needs, including any specific needs of neurodiverse children and young people.

Hormone treatment

1.41. The issues raised by the Multi-Professional Review Group echo several of the problems highlighted by the CQC. It is essential that principles of the General Medical Council's Good Practice in Prescribing and Managing Medicine's and Devices[10] are closely followed, particularly given the gaps in the evidence base regarding hormone treatment. Standards for decision making regarding endocrine treatment should also be consistent with international best practice.[11,12,13]

10: Any child or young person being considered for hormone treatment should have a formal diagnosis and formulation, which addresses the full range of factors affecting their physical, mental, developmental and psychosocial wellbeing. This formulation should then inform what options for support and intervention might be helpful for that child or young person.

11: Currently paediatric endocrinologists have sole responsibility for treatment, but where a life-changing intervention is given there should also be additional medical responsibility for the differential diagnosis leading up to the treatment decision.

1.42. Paediatric endocrinologists develop a wide range of knowledge within their paediatric training, including safeguarding, child mental health, and adolescent development. Being party to the discussions and deliberations that have led up to the decision for medical intervention supports them in carrying out their legal responsibility for consent to treatment and the prescription of hormones.

12: Paediatric endocrinologists should become active partners in the decision making process leading up to referral for hormone treatment by participating in the multidisciplinary team meeting where children being considered for hormone treatment are discussed.

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[10] General Medical Council (2021). Good practice in prescribing and managing medicines and devices (76-78).
[11] Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, et al (2017). Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 102(11): 3869–903. DOI: 10.1210/jc.2017-01658.
[12] Cohen-Kettenis PT, Steensma TD, de Vries ALC (2001). Treatment of adolescents with gender dysphoria in the Netherlands. Child Adolesc Psychiatr Clin N Am 20: 689–700. DOI: 10.1016/j.chc.2011.08.001.
[13] Kyriakou A, Nicolaides NC, Skordis N (2020). Current approach to the clinical care of adolescents with gender dysphoria. Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.

1.43. Given the uncertainties regarding puberty blockers, it is particularly important to demonstrate that consent under this circumstance has been fully informed and to follow GMC guidance[14] by keeping an accurate record of the exchange of information leading to a decision in order to inform their future care and to help explain and justify the clinician's decisions and actions.

13: Within clinical notes, the stated purpose of puberty blockers as explained to the child or young person and parent should be made clear. There should be clear documentation of what information has been provided to each child or young person on likely outcomes and side effects of all hormone treatment, as well as uncertainties about longer-term outcomes.

14: In the immediate term the Multi-Professional Review Group (MPRG) established by NHS England should continue to review cases being referred by GIDS to endocrine services.

[14] General Medical Council (2020). Decision making and consent.

2. Context

Transgender, non-binary and gender fluid adults

2.1. NHS clinical services to support transgender adults with hormone treatment and subsequent surgery began in 1966.

2.2. Services were initially established within a mental health model, in conjunction with endocrinology and surgical services.

2.3. Currently, NHS services for transgender adults do not have adequate capacity to cope with demand.[15] In addition, the broader healthcare needs of this group are not well met. This is important in the context of the current generation of gender-questioning children and young people in that there are now two inflows into adult services – individuals transitioning in adulthood, and those moving through from children's services.

2.4. Legal rights and protections for transgender people lagged behind the provision of medical services, with the Gender Recognition Act 2004 coming into force in April 2005. Over the last few years, broader discussions about transgender issues have been played out in public, with discussions becoming increasingly polarised and adversarial. This polarisation is such that it undermines safe debate and creates difficulties in building consensus.

2.5. It is not the role of this Review to take any position on the cultural and societal debates relating to transgender adults. However, in achieving its objectives there is a need to consider the information and support that children and young people access from whatever source, as well as any pressures that they are subject to, before they access clinical services.

Terminology and diagnostic frameworks

2.6. The Office for National Statistics defines sex as "referring to the biological aspects of an individual as determined by their anatomy, which is produced by their chromosomes, hormones and their interactions; generally male or female; something that is assigned at birth".[16]

2.7. The Office for National Statistics defines gender as "a social construction relating to behaviours and attributes based on labels of masculinity and femininity; gender identity is a personal, internal perception of oneself and so the gender category someone identifies with may not match the sex they were assigned at birth".[17]

2.8. Societal attitudes towards gender roles and gender expression are changing. Children, teenagers and younger adults may more commonly see gender as a fluid, multi-faceted phenomenon which

[15] Gender Identity Clinic, The Tavistock and Portman NHS Foundation Trust. Waiting times.
[16] Office for National Statistics (2019). What is the difference between sex and gender?
[17] Ibid.

does not have to be binary, whereas older generations have tended to see gender as binary and fixed. It is not unusual for young people to explore both their sexuality and gender as they go through adolescence and early adulthood before developing a more settled identity. Many achieve this without experiencing significant distress or requiring support from the NHS, but this is not the case for all.

2.9. For those who require support from the NHS, there are two widely used frameworks which provide diagnostic criteria. The International Classification of Diseases (ICD), which is the World Health Organization (WHO) mandated health data standard, and the Diagnostic and Statistical Manual of Mental Disorders (DSM), which is the classification system for mental health disorders produced by the American Psychiatric Association. The current editions of these manuals – ICD-11 and DSM-5 – came into effect in January 2022 and 2013 respectively.

2.10. ICD-11[18] has attempted to depathologise gender diversity, removing the term 'gender identity disorders' from its mental health section and creating a new section for gender incongruence and transgender identities in a chapter on sexual health. These changes are part of a much broader societal drive to remove the stigma previously associated with transgender healthcare. ICD-11 defines gender incongruence as being "characterised by a marked incongruence between an individual's experienced/ expressed gender and the assigned sex." Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis. The full criteria for gender incongruence of childhood and gender incongruence of adolescence or adulthood are listed in **Appendix 3**.

2.11. DSM-5[19] is currently the framework used to diagnose gender dysphoria. This diagnostic category describes gender dysphoria as "the distress that may accompany the incongruence between one's experienced or expressed gender and one's assigned gender". A diagnosis of gender dysphoria is usually deemed necessary before a young person can access hormone treatment, and criteria are listed in **Appendix 3**.

Conceptual understanding of gender incongruence in children and young people

2.12. Children and young people presenting to gender identity services are not a homogeneous group. They vary in their age at presentation, their cultural background, whether they identify as binary, non-binary, or gender fluid, whether they are neurodiverse and in a host of other ways.

[18] World Health Organization (2022). International Classification of Diseases Eleventh Revision.
[19] American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Health Disorders: DSM-5™, 5th ed.

2.13. Some children and young people may thrive during a period of gender-questioning whilst for others it can be accompanied with a level of distress that can have a significant impact on their functioning and development.

2.14. Alongside these very varied presentations, it is highly unlikely that a single cause for gender incongruence will be found. Many authors view gender expression as a result of a complex interaction between biological, cultural, social and psychological factors.

2.15. Despite a high level of agreement about these points, there are widely divergent and, in some instances, quite polarised views among service users, parents, clinical staff and the wider public about how gender incongruence and gender-related distress in children and young people should be interpreted, and this has a bearing on expectations about clinical management.

2.16. These views will be influenced by how each individual weighs the balance of factors that may lead to gender incongruence, and the distress that may accompany it. Beliefs about whether it might be inherent and/or immutable, whether it might be a transient response to adverse experiences, whether it might be highly fluid and/or likely to change in later adolescence/early adulthood, etc will have a profound influence on expectations about treatment options.[20]

2.17. All of these views may be overlaid with strongly held concerns about children's and young people's rights, autonomy, and/or protection.

2.18. The disagreement and polarisation is heightened when potentially irreversible treatments are given to children and young people, when the evidence base underlying the treatments is inconclusive, and when there is uncertainty about whether, for any particular child or young person, medical intervention is the best way of resolving gender-related distress.

2.19. As with many other contemporary polarised disagreements, the situation is exacerbated when there is no space to have open, non-judgemental discussions about these differing perspectives. A key aim of this review process will be to encourage such discussions in a safe and respectful manner so that progress can be made in finding solutions.

[20] Wren B (2019). Notes on a crisis of meaning in the care of gender-diverse children. In: Hertzmann L, Newbigin J (eds) Sexuality and Gender Now: Moving Beyond Heteronormativity. Routledge.

3. Current services

Current service model for gender-questioning children and young people

3.1. Currently there are no locally or regionally commissioned services for children and young people who seek help from the NHS in managing their gender-related distress. Within primary and secondary care, some clinical staff have more interest and expertise in initial management of this group of young people, but such individuals are few and far between.

3.2. The pathway for NHS support around gender identity for children and young people is designated as a highly specialised service.[21] The Gender Identity Development Service (GIDS) at the Tavistock and Portman NHS Foundation Trust is commissioned by NHS England to provide specialist assessment, support and, where appropriate, hormone intervention for children and young people with gender dysphoria. It is the only NHS provider of specialist gender services for children and young people in England. The Trust runs satellite bases in Leeds and Bristol. Until recently GIDS accepted referrals from multiple sources, for example, GPs, secondary care, social care, schools, and support and advocacy groups, which is unusual for a specialist service.

3.3. Children and young people are assessed by two members of the GIDS team who may be any combination of psychologists, psychotherapists, family therapists, or social workers. If there is uncertainty about the right approach, individual cases may be discussed in a complex case meeting. Those deemed appropriate for physical interventions are referred on to the endocrine team; under the current Standard Operating Procedure (SOP), this decision requires a multi-disciplinary team (MDT) discussion within GIDS. A member of the GIDS team attends new appointments in the endocrine clinic, but they will not routinely be the member of staff who saw the young person for assessment. However, very recently a triage meeting has been piloted to enable endocrinologists to discuss upcoming appointments with the clinician who saw the young person for assessment. The young person then attends an education session prior to their endocrine appointment. The endocrinologist will assess any medical contraindications prior to seeking consent from the patient for any hormone treatments.

3.4. For many years, the GIDS approach was to offer assessment and support, and to only start puberty blockers when children reached sexual maturity at about age 15 (Tanner Stage 5) as the first step in the treatment process to feminise or masculinise the young person, with

[21] National Health Service Commissioning Board and Clinical Commissioning Groups (Responsibilities and Standing Rules) Regulations 2012.

oestrogen or testosterone given from age 16. Feminising/masculinising hormones are not given at an earlier stage because of the irreversibility of some of their actions in developing secondary sex characteristics of the acquired gender.[22,23]

3.5. In 1998, a new protocol was published by the Amsterdam gender identity clinic.[24] It was subsequently named the Dutch Approach.[25] This involved giving puberty blockers much earlier, from the time that children showed the early signs of puberty (Tanner Stage 2), to pause further pubertal changes of the sex at birth. This stage of pubertal development was chosen because it was felt that although many younger children experienced gender incongruence as a transient developmental phenomenon, those who expressed early gender incongruence which continued into puberty were unlikely to desist at that stage.

3.6. It was felt that blocking puberty would buy time for children and young people to fully explore their gender identity and help with the distress caused by the development of their secondary sexual characteristics. The Dutch criteria for treating children with early puberty blockers were: (i) a presence of gender dysphoria from early childhood; (ii) an increase of the gender dysphoria after the first pubertal changes; (iii) an absence of psychiatric comorbidity that interferes with the diagnostic work-up or treatment; (iv) adequate psychological and social support during treatment; and (v) a demonstration of knowledge and understanding of the effects of gonadotropin-releasing hormones (puberty blockers), feminising/masculinising hormones, surgery, and the social consequences of sex reassignment.[26]

3.7. Under the Dutch Approach, feminising/masculinising hormones were started at age 16 and surgery was permitted to be undertaken from age 18, as in England.

3.8. From 2011, early administration of puberty blockers was started in England under a research protocol, which partially paralleled the Dutch Approach (the Early Intervention Study). From 2014, this protocol was adopted by GIDS as routine clinical practice. Results of the Early Intervention Study were published in December 2021.[27]

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[22] Delemarre-van de Wall HA, Cohen-Kettinis PT (2006). Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects. Eur J Endocrinol 155 (Suppl 1): S131–7. DOI: 10.1530/eje.1.02231.

[23] de Vries ALC, Cohen-Kettenis PT (2012). Clinical management of gender dysphoria in children and adolescents: the Dutch approach. J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.

[24] Cohen-Kettenis PT, Van Goozen S (1998). Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. Eur Child Adolesc Psychiatry 7: 246–8. DOI: 10.1007/s007870050073.

[25] de Vries ALC, Cohen-Kettenis PT (2012). Clinical management of gender dysphoria in children and adolescents: the Dutch approach. J Homosex 59: 301–320. DOI: 10.1080/00918369.2012.653300.

[26] Ibid.

[27] Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, et al (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. PLoS One. 16(2):e0243894. DOI:10.1371/journal.pone.0243894.

3.9. However, the Dutch Approach differs from the GIDS approach in having stricter requirements about provision of psychological interventions. For example, under the Dutch Approach, if young people have gender confusion, aversion towards their sexed body parts, psychiatric comorbidities or Autism Spectrum Disorder (ASD) related diagnostic difficulties, they may receive psychological interventions only, or before, or in combination with medical intervention. Of note, in 2011, the Amsterdam team were reporting that up to 10% of their referral base were young people with ASD.[28]

Changing epidemiology

3.10. In the last few years, there has been a significant change in the numbers and case-mix of children and young people being referred to GIDS.[29] From a baseline of approximately 50 referrals per annum in 2009, there was a steep increase from 2014-15, and at the time of the CQC inspection of the Tavistock and Portman NHS Foundation Trust in October 2020 there were 2,500 children and young people being referred per annum, 4,600 children and young people on the waiting list, and a waiting time of over two years to first appointment.[30] This has severely impacted on the capacity of the existing service to manage referrals in the safe and responsive way that they aspire to and has led to considerable distress for those on the waiting list.

3.11. This increase in referrals has been accompanied by a change in the case-mix from predominantly birth-registered males presenting with gender incongruence from an early age, to predominantly birth-registered females presenting with later onset of reported gender incongruence in early teen years. In addition, approximately one third of children and young people referred to GIDS have autism or other types of neurodiversity. There is also an over-representation percentage wise (compared to the national percentage) of looked after children.[31]

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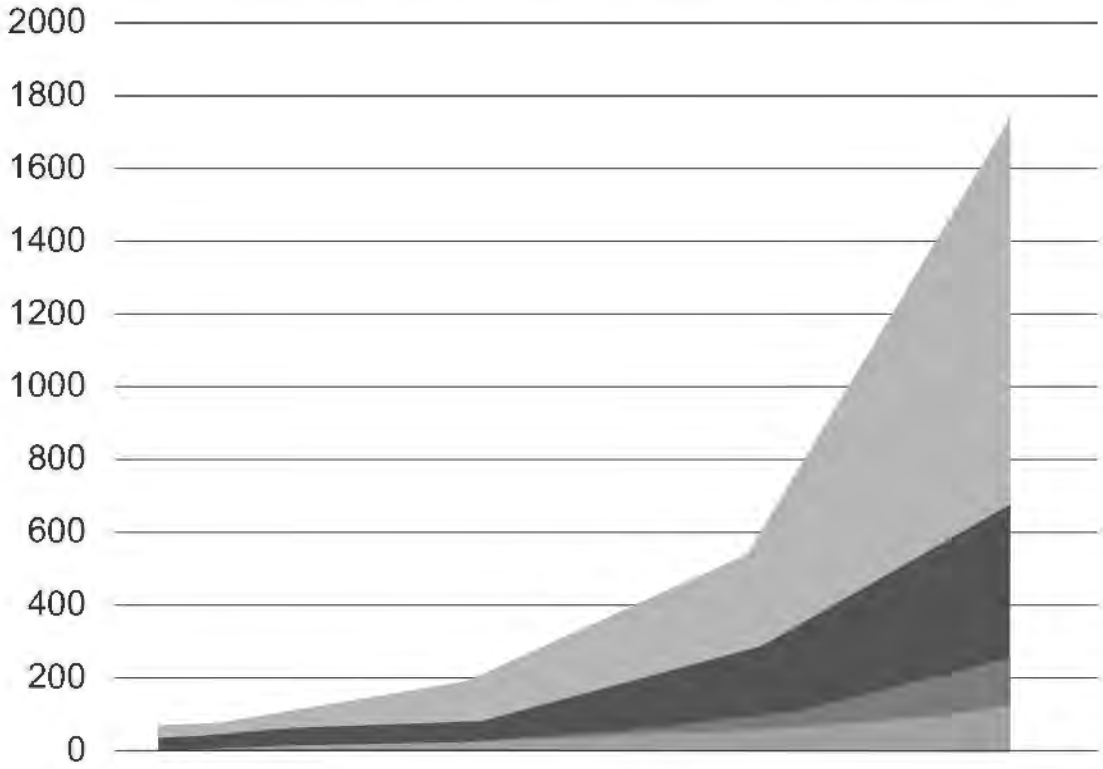
[28] Cohen-Kettenis PT, Steensma TD, de Vries ALC (2001). Treatment of adolescents with gender dysphoria in the Netherlands. Child Adolesc Psychiatr Clin N Am 20: 689–700. DOI: 10.1016/j.chc.2011.08.001.
[29] de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018). Sex ratio in children and adolescents referred to the gender identity development service in the UK (2009-2016). Arch Sex Behav 47(5): 1301–4.
[30] Care Quality Commission (2021). The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report. London: CQC.
[31] Matthews T, Holt V, Sahin S, Taylor A, Griksaitis (2019). Gender Dysphoria in looked-after and adopted young people in a gender identity development service. Clinical Child Psychol Psychiatry 24: 112-128. DOI: 10.1177/1359104518791657.

Figure 1: Sex ratio in children and adolescents referred to GIDS in the UK (2009-16)



	2009	2010	2011	2012	2013	2014	2015	2016
Adolescents F	15	48*	78*	141*	221*	314*	689*	1071*
Adolescents M	24	44*	41	77*	120*	185*	293*	426*
Children F	2	7	12	17	22	36	77*	138*
Children M	10	19	29	30	31	55*	103*	131

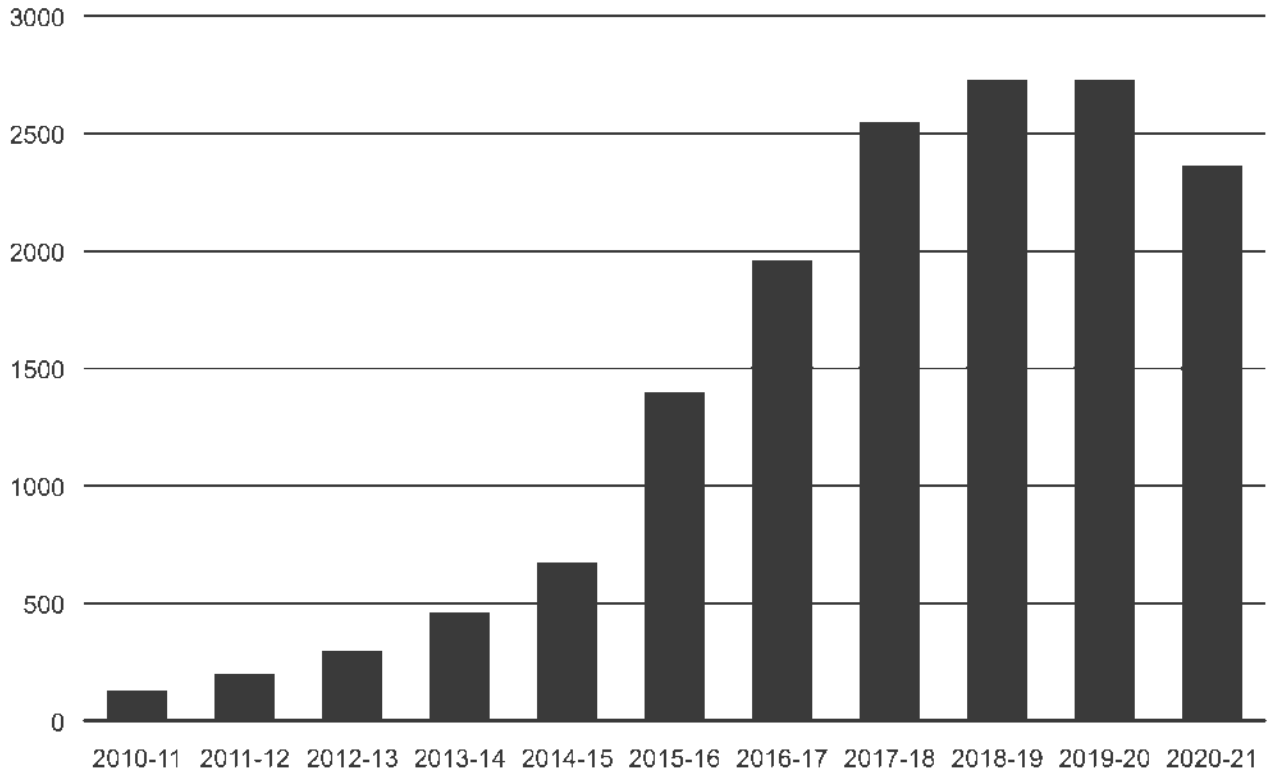
AFAB = assigned female at birth; AMAB = assigned male at birth

***Indicates** p<.05 which shows a significant increase of referrals compared to the previous year

Source: de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018).[32]

[32] de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018). Sex ratio in children and adolescents referred to the gender identity development service in the UK (2009-2016). Arch Sex Behav 47(5): 1301–4.

Figure 2: Referrals to GIDS, 2010-11 to 2020-21



Source: Gender Identity Development Service.[33]

3.12. In 2019, GIDS reported that about 200 children and young people from a referral base of 2,500 were referred on to the endocrine pathway. There is no published data on how the other children and young people from this referral baseline were managed, for example if: their gender dysphoria was resolved; they were still being assessed or receiving ongoing psychological support and input; they were not eligible for puberty blockers due to age; they were referred to endocrine services at a later stage; they were transferred to adult services; or they accessed private services.

Challenges to the service model and clinical approach

3.13. Over a number of years, in parallel with the increasing numbers of referrals, GIDS faced increasing challenges, both internally and externally. There were different views held within the staff group about the appropriate clinical approach, with some more strongly affirmative and some more cautious and concerned about the use of physical intervention. The complexity of the cases had also increased, so clinical decision making had become more difficult. There was also a high staff

[33] Gender Identity Development Service. Referrals to GIDS, financial years 2010-11 to 2020-21.

turnover, and accounts from staff concerned about the clinical care, which were picked up in both mainstream and social media. This culminated in 2018 with an internal report by a staff governor.

3.14. Following that report, a review was carried out in 2019 by the Trust's medical director. This set out the need for clearer processes for the service's referral management, safeguarding, consent, and clinical approach, and an examination of staff workload and support, and a new Standard Operating Procedure (SOP) was put in place.

NHS England Policy Working Group

3.15. In January 2020, a Policy Working Group (PWG) was established by NHS England to undertake a review of the published evidence on the use of puberty blockers and feminising/masculinising hormones in children and young people with gender dysphoria to inform a policy position on their future use. Given the increasingly evident polarisation among clinical professionals, Dr Cass was asked to chair the group as a senior clinician with no prior involvement or fixed views in this area. The PWG comprised an expert group including endocrinologists, child and adolescent psychiatrists and paediatricians representing their respective Royal Colleges, an ethicist, a GP, senior clinicians from the NHS GIDS, a transgender adult and parents of gender-questioning young people. The process was supported by a public health consultant and policy, pharmacy and safeguarding staff from NHS England.

3.16. NHS England uses a standardised protocol for developing clinical policies. The first step of this involves defining the PICO (the Population being treated, the Intervention, a Comparator treatment, and the intended Outcomes). This of itself was challenging, with a particular difficulty being definition of the intended outcomes of puberty blockers, and suitable comparators for both hormone interventions. However, agreement was reached on what should be included in the PICO and subsequently the National Institute for Health and Care Excellence (NICE) was commissioned to review the published evidence,[34,35] again following a standardised protocol which has strict criteria about the quality of studies that can be included.

3.17. Unfortunately, the available evidence was not strong enough to form the basis of a policy position. Some of the challenges and outstanding uncertainties are summarised as follows.

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[34] National Institute for Health and Care Excellence (2020). Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria.
[35] National Institute for Health and Care Excellence (2020). Evidence review: gender-affirming hormones for children and adolescents with gender dysphoria.

Feminising/masculinising hormones

3.18. Sex hormones have been prescribed for transgender adults for several decades, and the long-term risks and side effects are well understood. These include increased cardiovascular risk, osteoporosis, and hormone-dependent cancers.

3.19. In young people, consideration also needs to be given to the impact on fertility, with the need for fertility counselling and preservation.

3.20. The additional physical risk of starting these treatments at age 16+ rather than age 18+ is unlikely to add significantly to the total lifetime risk, although data on this will not be available for many years. However, as evidenced by take-up of treatment with feminising/masculinising hormones, where there is a high level of certainty that physical transition is the right option, the child or young person may be more accepting of these risks, which can seem remote from the immediate gender distress.

3.21. The most difficult question in relation to feminising/masculinising hormones therefore is not about long-term physical risk which is tangible and easier to understand. Rather, given the irreversible nature of many of the changes, the greatest difficulty centres on the decision to proceed to physical transition; this relies on the effectiveness of the assessment, support and counselling processes, and ultimately the shared decision making between clinicians and patients. Decisions need to be informed by long-term data on the range of outcomes, from satisfaction with transition, through a range of positive and negative mental health outcomes, through to regret and/or a decision to detransition. The NICE evidence review demonstrates the poor quality of these data, both nationally and internationally.

3.22. Regardless of the nature of the assessment process, some children and young people will remain fluid in their gender identity up to early to mid-20s, so there is a limit as to how much certainty one can achieve in late teens. This is a risk that needs to be understood during the shared decision making process with the young person.

3.23. It is also important to note that any data that are available do not relate to the current predominant cohort of later-presenting birth-registered female teenagers. This is because the rapid increase in this subgroup only began from around 2014-15. Since young people may not reach a settled gender expression until their mid-20s, it is too early to assess the longer-term outcomes of this group.

Puberty blockers

3.24. The administration of puberty blockers is arguably more controversial than administration of the feminising/ masculinising hormones, because there are more uncertainties associated with their use.

3.25. There has been considerable discussion about whether the treatment is 'experimental'; strictly speaking an experimental treatment is one that is being given as part of a research protocol, and this is not the case with puberty blockers, because the GIDS research protocol was stopped in 2014. At that time, the treatment was experimental and innovative, because the drug was licensed for use in children, but specifically for children with precocious puberty. This was therefore the first time it was used 'off-label' in the UK for children with gender dysphoria. If a drug is used 'off-label' it means it is being used for a condition that is different from the one for which it was licensed. The many uncertainties around the 'off-label' use were recognised, but given that this was not a new drug, it did not need Medicines and Healthcare products Regulatory Agency (MHRA) approval at that time.

3.26. The important question now, as with any treatment, is whether the evidence for the use and safety of the medication is strong enough as judged by reasonable clinical standards.

3.27. One of the challenges that NHS England's PWG faced in considering this question was the lack of clarity about intended outcomes, several of which have been proposed including:

- providing time/space for the young person to make a decision about continuing with transition;
- reducing or preventing worsening of distress;
- improving mental health; and
- stopping potentially irreversible pubertal changes which might later make it difficult for the young person to 'pass' in their intended gender role.

3.28. Proponents for the use of puberty blockers highlight the distress that young people experience through puberty and the risk of self-harm or suicide.[36] However, some clinicians do not feel that distress is actually alleviated until children and young people are able to start feminising/ masculinising hormones. The Review will seek to gain a better understanding of suicide data and the impact of puberty blockers through its research programme.

3.29. On the other hand, it has been asserted that starting puberty blockers at an older age provides children and young people with more time to achieve fertility preservation. In the case of birth-registered males, there is an argument that it also

[36] Turban JL, King D, Carswell JM, et al (2020). Pubertal suppression for transgender youth and risk of suicidal ideation. Pediatrics 145 (2): e20191725. DOI: 10.1542/peds.2019-1725.

allows more time to achieve adequate penile growth for successful vaginoplasty.

3.30. In the short-term, puberty blockers may have a range of side effects such as headaches, hot flushes, weight gain, tiredness, low mood and anxiety, all of which may make day-to-day functioning more difficult for a child or young person who is already experiencing distress. Short-term reduction in bone density is a well-recognised side effect, but data is weak and inconclusive regarding the long-term musculoskeletal impact.[37]

3.31. The most difficult question is whether puberty blockers do indeed provide valuable time for children and young people to consider their options, or whether they effectively 'lock in' children and young people to a treatment pathway which culminates in progression to feminising/ masculinising hormones by impeding the usual process of sexual orientation and gender identity development. Data from both the Netherlands[38] and the study conducted by GIDS[39] demonstrated that almost all children and young people who are put on puberty blockers go on to sex hormone treatment (96.5% and 98% respectively). The reasons for this need to be better understood.

3.32. A closely linked concern is the unknown impacts on development, maturation and cognition if a child or young person is not exposed to the physical, psychological, physiological, neurochemical and sexual changes that accompany adolescent hormone surges. It is known that adolescence is a period of significant changes in brain structure, function and connectivity.[40] During this period, the brain strengthens some connections (myelination) and cuts back on others (synaptic pruning). There is maturation and development of frontal lobe functions which control decision making, emotional regulation, judgement and planning ability. Animal research suggests that this development is partially driven by the pubertal sex hormones, but it is unclear whether the same is true in humans.[41] If pubertal sex hormones are essential to these brain maturation processes, this raises a secondary question of whether there is a critical time window for the processes to take place, or whether catch up is possible when oestrogen or testosterone is introduced later.

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[37] National Institute for Health and Care Excellence (2020). Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria.

[38] Brik T, Vrouenraets LJJJ, de Vries MC, Hannema SE (2020). Trajectories of adolescents treated with gonadotropin-releasing hormone analogues for gender dysphoria. Arch Sex Behav 49: 2611–8. DOI: 10.1007/ s10508-020-01660-8.

[39] Carmichael P, Butler G, Masic U, Cole TJ, De Stavola BL, Davidson S, et al (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. PLoS One. 16(2):e0243894. DOI:10.1371/journal.pone.0243894.

[40] Delevichab K, Klinger M, Nana OJ, Wilbrecht L (2021). Coming of age in the frontal cortex: The role of puberty in cortical maturation. Semin Cell Dev Biol 118: 64–72. DOI: 10.1016/j.semcdb.2021.04.021.

[41] Goddings A-L, Beltz A, Jiska S, Crone EA, Braams BR (2019). Understanding the role of puberty in structural and functional development of the adolescent brain. J Res Adolesc 29(1): 32–53. DOI: 10.1111/jora.12408.

3.33. An international interdisciplinary panel[42] has highlighted the importance of understanding the neurodevelopmental outcomes of pubertal suppression and defined an appropriate approach for investigating this further. However, this work has not yet been undertaken.

Initiation of Cass Review

3.34. Dr Cass' own reflections on the PWG process, the available literature, and the issues it highlighted were as follows:

- Firstly, that hormone treatment is just one possible outcome for gender-questioning children and young people. A much better understanding is needed about: the increasing numbers of children and young people with gender-related distress presenting for help; the appropriate clinical pathway for each individual; their support needs; and the full range of potential treatment options.
- Secondly, there is very limited follow-up of the subset of children and young people who receive hormone treatment, which limits our understanding about the long-term outcomes of these treatments and this lack of follow up data should be corrected.
- Thirdly, the assessment process is inconsistent across the published literature. The outcome of hormone treatment is highly influenced by whether the assessment process accurately selects those children and young people most likely to benefit from medical treatment. This makes it difficult to draw conclusions from published studies.

3.35. In light of the above, NHS England commissioned this independent review to make recommendations on how the clinical management and service provision for children and young people who are experiencing gender incongruence or gender-related distress can be improved.

CQC inspection

3.36. In October and November 2020, the Care Quality Commission (CQC) inspectors carried out an announced, focused inspection of GIDS due to concerns reported to them by healthcare professionals and the Children's Commissioner for England. Concerns related to clinical practice, safeguarding procedures, and assessments of capacity and consent to treatment.

[42] Chen D, Strang JF, Kolbuck VD, Rosenthal SM, Wallen K, Waber DP, et al (2020). Consensus parameter: research methodologies to evaluate neurodevelopmental effects of pubertal suppression in transgender youth. Transgender Health 5(4). DOI: 10.1089/trgh.2020.0006.

3.37. The CQC report, published in January 2021,[43] gave the service an overall rating of inadequate. The report noted the high level of commitment and caring approach of the staff but identified a series of issues that needed improvement. In addition to the growing waiting list pressures, the CQC identified problems in several other areas including: the assessment and management of risk; the variations in clinical approach; the lack of clarity and consistency of care plans; the lack of any clear written rationale for decision making in individual cases; and shortfalls in the multidisciplinary mix required for some patient groups. Recording of capacity, competency and consent had improved since the new SOP in January 2020; however, there remained a culture in which staff reported feeling unable to raise concerns.

3.38. The CQC reported that when it inspected GIDS, there did not appear to be a formalised assessment process, or standard questions to explore at each session, and it was not possible to tell from the notes why an individual child might have been referred to endocrinology whilst another had not. Current GIDS data demonstrate that a majority of children and young people seen by the service do not get referred for endocrine treatment, but there is no clear information about what other diagnoses they receive, and what help or support they might need.

3.39. Since the CQC report, NHS England and The Tavistock and Portman NHS Foundation Trust management team have been working to address the issues raised. However, whilst some problems require a focused Trust response, the waiting list requires a system-wide response. This was noted in the letter from the Review to NHS England in May 2021 (**Appendix 2**).

Legal background

3.40. This section sets out the chronology of recent case law. In October 2019, a claim for Judicial Review was brought against The Tavistock and Portman NHS Foundation Trust. The claimants' case was summarised by the High Court as follows: "The claimants' case is that children and young persons under 18 are not competent to give consent to the administration of puberty blocking drugs. Further, they contend that the information given to those under 18 by the defendant [GIDS] is misleading and insufficient to ensure such children or young persons are able to give informed consent. They further contend that the absence of procedural safeguards, and the inadequacy of the information provided, results in an infringement of the rights of such children and young persons under Article 8 of the European Convention

[43] Care Quality Commission (2021). The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report. London: CQC.

for the Protection of Human Rights and Fundamental Freedoms."[44]

3.41. In December 2020, three judges in the High Court of England and Wales handed down judgment in *Bell v Tavistock.*[45] (Most cases in the High Court are heard by a single judge sitting alone, and when a case is heard by more than one judge in the High Court, it is described as the Divisional Court.) The Divisional Court recognised that the Tavistock's policies and practices as set out in the service specification were not unlawful. However, the Court made a declaration that set out in detail a series of implications of treatment that a child would need to understand to be *Gillick* competent[46] to consent to puberty blockers. Specifically, because most children put on puberty blockers go on to have feminising/ masculinising hormones, the judgment said a child would need to understand not only the full implications of puberty blocking drugs, but also the implications of the full pathway of medical and surgical transition. The judges concluded that it will be "very doubtful" that 14-15 year-olds have such competence, and "highly unlikely" that children aged 13 or under have competence for that decision. Under the Mental Capacity Act 2005, 16-17 year-olds are presumed to have capacity, and they are effectively treated as adults for consent to medical treatment under the Family Law Reform Act 1969 section 8, but the judges suggested that it would be appropriate for clinicians to involve the court in any case where there were doubts as to whether the proposed treatment would be in the long term best interests of a 16-17 year-old.

3.42. Following the Divisional Court judgment in *Bell v Tavistock*, a claim was brought against the Tavistock in the High Court Family Division by the mother of a child for a declaration that she and the child's father had the ability in law to consent on behalf of their child to the administration of puberty blockers *(AB v CD)*.[47] The Court concluded that "the parents' right to consent to treatment on behalf of the child continues even when the child is *Gillick* competent to make the decision, save where the parents are seeking to override the decision of the child" [para 114] and that there is no "general rule that puberty blockers should be placed in a special category by which parents are unable in law to give consent" [para 128].

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[44] Bell v Tavistock. [2020] EWHC 3274 (Admin).
[45] Ibid.
[46] Gillick v West Norfolk and Wisbech AHA [1986] AC 112.
[47] AB v CD & Ors [2021] EWHC 741.

3.43. Subsequently, the Tavistock appealed the Divisional Court's earlier decision in *Bell v Tavistock* and was successful.[48] The Court of Appeal held that it was not appropriate for the Divisional Court to provide the guidance about the likelihood of having *Gillick* competence at particular ages, or about the need for court approval [para 91]. The Court of Appeal went on to say "The Divisional Court concluded that Tavistock's policies and practices (as expressed in the service specification and the SOP) were not unlawful and rejected the legal criticism of its materials. In those circumstances, the claim for judicial review is dismissed." [para 91]. However, clinicians should "take great care before recommending treatment to a child and be astute to ensure that the consent obtained from both child and parents is properly informed" [para 92].

3.44. The Court of Appeal in *Bell v Tavistock* recognised the lawfulness of treating children for gender dysphoria in this jurisdiction. Recognising the divergences in medical opinion, morality and ethics, it indicated that the question of whether treatment should be made available is a matter of policy "for the National Health Service, the medical profession and its regulators and Government and Parliament" [para 3].

3.45. Following the Divisional Court decision in *Bell v Tavistock*, new referrals for puberty blockers were suspended and a requirement was put in place that children currently on puberty blockers were reviewed with a view to court proceedings for a judge to determine the best interests for children in whom these medications were considered essential. This requirement was changed following *AB v CD*, with the reinstatement of the hormone pathway in March 2021. However, an external panel, the Multi Professional Review Group (MPRG), was established to ensure that procedures for assessment and for informed consent had been properly followed. The outcome of the *Bell* appeal has not changed this requirement, which is contingent not just on the legal processes but on the concerns raised by CQC regarding consent, documentation and clarity about decision making within the service.[49]

[48] EWCA [2021] Civ 1363.
[49] Care Quality Commission (2021). The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report. London: CQC.

The Multi-Professional Review Group

3.46. NHS England has established a Multi-Professional Review Group (MPRG) to review whether the agreed process has been followed for a child to be referred into the endocrinology clinic and to be prescribed treatment. The Review has spoken directly to the MPRG, which has reported its observations of current practice.

3.47. The MPRG has stated that its work has been impeded by delays in the provision of clinical information, the lack of structure in the documentation received, and gaps in the necessary evidence. This means that when reviewing the documents provided it is not always easy to determine if the process for referral for endocrine treatment has been fully or safely followed for a particular child or young person.

3.48. The MPRG indicates that there does not appear to be a standardised approach to assessment. They are particularly concerned about safeguarding shortfalls within the assessment process. There is also limited evidence of systematic, formal mental health or neurodevelopmental assessments being routinely documented, or of a discipline of formal diagnostic formulation in relation to co-occurring mental health difficulties. This issue was also highlighted by the Care Quality Commission (CQC).[50]

3.49. Additionally, there is concern that communications to GPs and parents regarding prescribed treatment with puberty blockers sometimes come from non-medical staff.

[50] Care Quality Commission (2021). The Tavistock and Portman NHS Foundation Trust Gender Identity Service Inspection Report. London: CQC.

4. What the review has heard so far

Listening sessions

4.1. Since its establishment, the Review has met with an extensive range of stakeholders, including professionals, their respective governing organisations and those with lived experience, both directly and through support and advocacy groups, to understand the broad range of views and experiences surrounding the delivery of gender identity services.

What we have heard from service users, their families and support and advocacy groups

Issues for children and young people

4.2. What we understand most clearly from all we have heard is that at the centre of a difficult and complex debate are children, young people and families in great distress. We have heard concerns about children and young people facing the stress of being on a prolonged waiting list with limited support available from statutory services, lack of certainty about when and if they might reach the top of that list and subsequent impacts on mental health. Also, the particular issues that have followed the *Bell v Tavistock* litigation.

4.3. We have heard about the anxiety that birth-registered males face as they come closer to the point where they will grow facial hair and their voice drops, and the fear that it will make it harder for them to pass as a transgender woman in later life. We have also heard about the distress experienced by birth-registered females as they reach puberty, including the use of painful, and potentially harmful, binding processes to conceal their breasts.

4.4. When children and young people are able to access the service, there is often a sense of frustration with what several describe as the "gatekeeping" medical model and a "clinician lottery". This can feel like a series of barriers and hurdles designed to add to, rather than alleviate, distress. Most children and young people seeking help do not see themselves as having a medical condition; yet to achieve their desired intervention they need to engage with clinical services and receive a medical diagnosis of gender dysphoria. By the time they are seen in the GIDS clinic, they may feel very certain of their gender identity and be anxious to start hormone treatment as quickly as possible. However, they can then face a period of what can seem like intrusive, repetitive and unnecessary questioning. Some feel that this undermines their autonomy and right to self-determination.

4.5. We have heard that some young people learn through peers and social media what they should and should not say to therapy staff in order to access hormone treatment; for example, that they are advised not to admit to previous abuse or trauma, or uncertainty about their sexual orientation. We have also heard that many of those seeking NHS support identify as non-binary, gender non-conforming, or gender fluid. We understand that some

young people who identify as non-binary feel their needs are not met by clinical services unless they give a binary narrative about their gender preferences.

Issues for parents

4.6. We have also heard about the distress parents may feel as they try to work out how best to support their children and how tensions and conflict may arise where parents and their children have different views. For example, some parents have highlighted the importance of ensuring that children and young people are able to keep their options fluid until such time as it becomes essential to commit to a hormonal course of action, whilst their children may want more rapid hormone intervention.

4.7. We have heard about families trying to balance the risks of obtaining unregulated and potentially dangerous hormone supplies over the internet or from private providers versus the ongoing trauma of prolonged waits for assessment.

4.8. Parents have also raised concerns about the vulnerability of neurodiverse children and young people and expressed that the communication needs of these children and young people are not adequately reflected during assessment processes or treatment planning.

4.9. GIDS has always required consent/assent from both the child and parents/carers and has sought ways to resolve family conflict, which in the worst-case scenario can lead to family breakdown. It has been highlighted to us that the future service model should provide more targeted support for parents and carers.

Service issues

4.10. Another significant issue raised with us is one of diagnostic overshadowing – many of the children and young people presenting have complex needs, but once they are identified as having gender-related distress, other important healthcare issues that would normally be managed by local services can sometimes be subsumed by the label of gender dysphoria. This issue is compounded by the waiting list, which means that there can be a significant period of time without appropriate assessment, treatment or care.

4.11. Stakeholders have spoken of the need for appropriate assessment when first accessing NHS services to aid both the exploration of the child or young person's wellbeing and gender distress and any other challenges they may be facing.

Information

4.12. We have also heard about the lack of access to accurate, balanced information upon which children, young people and their families/carers can inform their decisions.

4.13. We have heard that distress may be exacerbated by pressure to identify with societal stereotyping and concerns over the influence of social media, which can be seen to perpetuate unrealistic images of gender and set unhealthy expectations, especially given how long

children and young people are waiting to access services.

Other issues

4.14. Several issues that were raised with us are not explored further in this interim report, but we have taken note of them. These will be considered further during the lifetime of the Review and include:

- The important role of schools and the challenges they face in responding appropriately to gender-questioning children and young people.
- The complex interaction between sexuality and gender identity, and societal responses to both; for example, we have heard from young lesbians who felt pressured to identify as transgender male, and conversely transgender males who felt pressured to come out as lesbian rather than transgender. We have also heard from adults who identified as transgender through childhood, and then reverted to their birth-registered gender in teen years.
- The issues faced by detransitioners highlight the need for better services and pathways for this group, many of whom are living with irreversible effects of transition but for whom there is no clear access to services as they fall outside the responsibility of NHS gender identity services.
- The age at which adult gender identity clinics can receive referrals, with concerns about the inclusion of 17-year-olds. The service offer in adult services is perceived to be quite different from that of GIDS, and young people presenting later may therefore not be afforded the same level of therapeutic input under the adult service model. There is also concern about the impact on the young person of changing clinicians at a crucial point in their care. The movement of young people with special educational needs between children's and adult services raises particular concerns.

What we have heard from healthcare professionals

Lack of professional consensus

4.15. Clinicians and associated professionals we have spoken to have highlighted the lack of an agreed consensus on the different possible implications of gender-related distress – whether it may be an indication that the child or young person is likely to grow up to be a transgender adult and would benefit from physical intervention, or whether it may be a manifestation of other causes of distress. Following directly from this is a spectrum of opinion about the correct clinical approach, ranging broadly between those who take a more gender-affirmative approach to those who take a more cautious, developmentally-informed approach.

4.16. Speaking to current and ex-GIDS staff, we have heard about the pressure on GIDS clinicians, many of whom feel overwhelmed by the numbers of children and young people being referred and who are demoralised by the media coverage of their service. Although the clinical team attempt to manage risk on the waiting list by engaging with local services, there is limited capacity and/or capability to respond appropriately to the needs of this group in primary and secondary care. The Review has already referred to this issue as the most pressing priority in its letter to NHS England (**Appendix 2**), alongside potential risks relating to safeguarding and/or mental health issues, and diagnostic overshadowing.

4.17. With respect to GIDS, we have been told that although there are forums for staff to discuss difficult cases with senior colleagues, it is still difficult for staff to raise concerns about the clinical approach. Also that many individuals who are more cautious and advocate the need for an exploratory approach have left the service.

Consistency and standards

4.18. GIDS staff have confirmed that judgements are very individual, with some clinicians taking a more gender-affirmative approach and others emphasising the need for caution and for careful exploration of broader issues. The Review has been told that there is considerable variation in the approach taken between the London, Leeds and Bristol teams.

4.19. Speaking to professionals outside GIDS, we have heard widespread concern about the lack of guidance and evidence on how to manage this group of young people.

4.20. Some secondary care providers told us that their training and professional standards dictate that when working with a child or young person they should be taking a mental health approach to formulating a differential diagnosis of the child or young person's problems. However, they are afraid of the consequences of doing so in relation to gender distress because of the pressure to take a purely affirmative approach. Some clinicians feel that they are not supported by their professional body on this matter. Hence the practice of passing referrals straight through to GIDS is not just a reflection of local service capacity problems, but also of professionals' practical concerns about the appropriate clinical management of this group of children and young people.

4.21. GPs have expressed concern about being pressurised to prescribe puberty blockers or feminising/masculinising hormones after these have been initiated by private providers.

4.22. This also links to professional concerns about parents being anxious for hormone treatment to be initiated when the child or young person does not seem ready.

Other issues

4.23. We have also heard that parents and carers play a huge role and are instrumental in helping young people

to keep open their developmental opportunities. In discussion with social workers, we heard concerns about how looked after children are supported in getting the help and support they need.

4.24. Therapists who work with detransitioners and people with regret have highlighted a lack of services and pathways and a need for services to support this population. There is also the need for more research to understand what factors contribute to the decision to detransition.

4.25. The importance of broad holistic interventions to help reduce distress has been emphasised to the Review, with therapists and other clinicians advocating the importance of careful developmentally informed assessment and of showing children and young people a range of different narratives, experiences and outcomes.

4.26. Clinicians have raised concerns about children and young people's NHS numbers being changed inconsistently, as there is no specific guidance for GPs and others as to when this should be done for this population and under what consent. This has implications for safeguarding and clinical management of these children and young people and it also makes it difficult to do research exploring long-term outcomes.

4.27. As with the comments made by service users, their families and support and advocacy groups, we have heard similar views from professionals about the transition from children's to adult services, and the role of schools.

Structured engagement with primary, secondary and specialist clinicians

4.28. The Review's letter to NHS England (**Appendix 2**) set out some of the immediate issues with the current provision of gender identity services for children and young people and suggested how its work might help with the challenging problem of establishing an infrastructure outside GIDS. This included looking at the capacity, capability and confidence of the wider workforce and how this could be built and sustained, and the establishment of potential assessment frameworks for use in primary and/or secondary care.

Professional panel – primary and secondary care

4.29. In order to understand the challenges and establish a picture of current competency, capacity and confidence among the workforce outside the specialist gender development service, an online professional panel was established to explore issues around gender identity services for children and young people. The role of the panel was aimed at better comprehending how it looks and feels for clinicians and other professionals working with these young people, as well as any broader thoughts about the work, and to start exploring how the care of these

children and young people can be better managed in the future.

4.30. The project was designed to capture a broad mix of professional views and experiences, recruiting from the professional groups that are most likely to have a role in the care pathway – GPs, paediatricians, child psychiatrists, child psychologists and child psychotherapists, nurses and social workers.

4.31. A total of 102 clinicians and other professionals were involved in the panel. The panel represented a balanced professional mix, and participant ages and gender were broadly representative of the overall sector workforce. Participants were self-selecting and were recruited via healthcare professional networks and Royal Colleges.

4.32. Each week the panel was set an independent activity comprised of two or more tasks. Additionally, a sub-set of the panel was invited to participate in focus groups at the midway and endpoint of the project. Activities were designed to capture an understanding of:

- experiences of working with gender-questioning children and young people and panel members' confidence and competence to manage their care;
- changes they may have experienced in the presentation of children and young people with gender-related distress;
- areas where professionals feel they require more information in order to support gender-questioning children and young people;
- where professionals currently go to find that information;
- the role of different professions in the care pathway;
- the role of professionals in the assessment framework; and
- what participants felt should be included in an assessment framework across the whole service pathway.

Gender specialist questionnaire

4.33. Having concluded the professional panel exercise, we wanted to triangulate what we had heard with the thoughts and views of professionals working predominantly or exclusively with gender-questioning children and young people.

4.34. To do this in a systematic way, we conducted an online survey which contained some service-specific questions, but also reflected and sought to test some of what we had heard from primary and secondary care professionals.

Findings

4.35. This structured engagement has yielded valuable insights from clinicians and professionals with experience working with gender-questioning children and young people both within and outside the specialist gender service. It has contributed to the thinking of the Review and informed some of the interim advice set out in this report.

4.36. There are a number of consistent messages arising from these activities:

- The current long waiting lists that gender-questioning children and young people and their families/carers face are unacceptable for all parties involved, including professionals.
- Many professionals in our sample said that not only are gender-questioning children and young people having to wait a long time before receiving treatment, but they also do not receive appropriate support during this waiting period.
- Another impact of the long wait that clinicians reported is that when a child or young person is seen at GIDS, they may have a more fixed view of what they need and are looking for action to be taken quickly. This reportedly can lead to frustration with the assessment process.
- When considering the more holistic support that children and young people may need, gender specialists further highlighted the difficulties that children and young people face accessing local support, for example, from CAMHS, whilst being seen at GIDS.
- It is clear from the professionals who took part in these activities that there is a strong professional commitment to provide quality care to gender-questioning children and young people and their families/carers. However, this research indicates that levels of confidence and competence do vary among primary and secondary care professionals in our sample.
- Concerns were expressed by professionals who took part in this research about the lack of consensus among the clinical community on the right clinical approach to take when working with a gender-questioning child or young person and their families/carers.
- In order to support clinicians and professionals more widely, participants felt there is a need for a robust evidence base, consistent legal framework and clinical guidelines, a stronger assessment process and different pathway options that holistically meet the needs of each gender-questioning child or young person and their families/carers.

4.37. There are also several areas where further discussion and consensus is needed:

- There is not a consistent view among the professionals participating in the panel and questionnaire about the nature of gender dysphoria and therefore the role of assessment for children and young people experiencing gender dysphoria.

- Some clinicians felt that assessment should be focused on whether medical interventions are an appropriate course of action for the individual. Other clinicians believe that assessment should seek to make a differential diagnosis, ruling out other potential causes of the child or young person's distress.
- There are different perspectives on the roles of primary, secondary and specialist services in the care pathway(s) and what support or action might best be provided at different levels.
- While there was general consensus that diagnostic or psychological formulation needs to form part of the assessment process, there were differing views as to whether a mental state assessment is needed, and should it be, where in the pathway and by whom this should be done.

4.38. It is important to note that the information gathered represents the views and insights of the panel participants and survey respondents at a moment in time and findings should be read in the context of a developing narrative on the subject, where perspectives may evolve. This relates to both the experiences of professionals, but also the extent to which this subject matter is discussed in the public sphere.

4.39. The Review is grateful to all the participants for their time and high level of engagement. The Review will build on the work we have undertaken and, alongside our academic research, will continue with a programme of engagement with professionals, service users and their families, which will help to further develop the evidence base.

The full reports from the professional panel and gender specialist questionnaire are on the Review's website (https://cass.independent-review.uk/).

5. Principles of evidence based service development

Evidence based service development

5.1. This chapter integrates the information regarding the development of the current service (see Chapter 3) with the views we have heard to date (see Chapter 4) and sets this in the context of how evidence is routinely used to develop and improve services in the NHS.

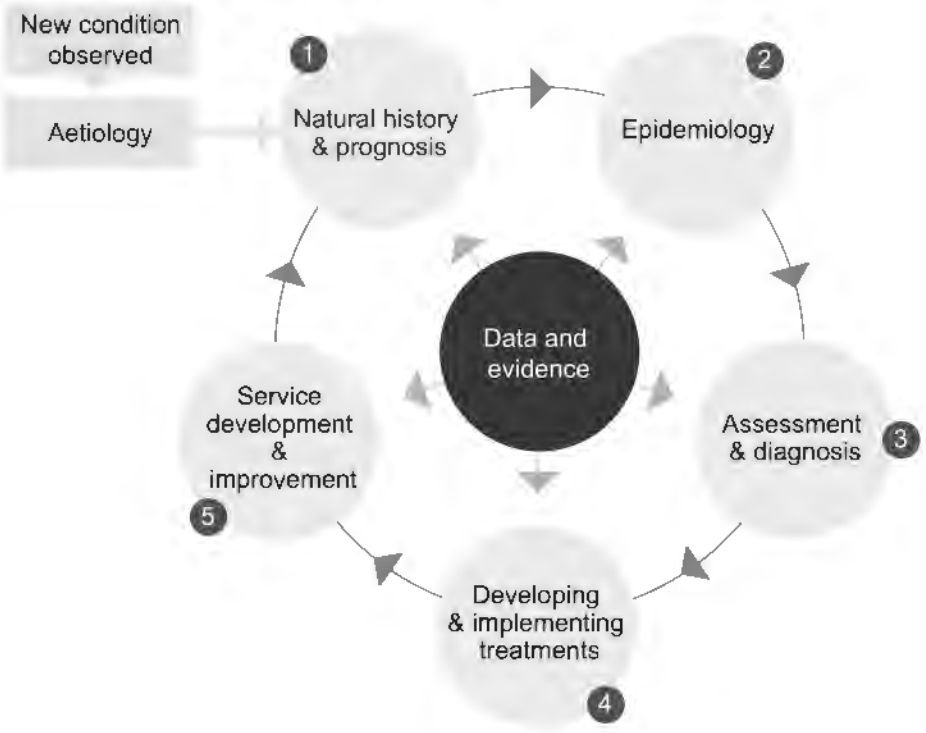
5.2. Some earlier information is necessarily repeated here, but this is with the intention of providing a more accessible explanation of the standards and processes which govern clinical service development. This is essential to an understanding of the rationale for the Review's recommendations.

5.3. Because the specialist service has evolved rapidly and organically in response to demand, the clinical approach and overall service design has not been subjected to some of the normal quality controls that are typically applied when new or innovative treatments are introduced. This Review now affords everyone concerned the opportunity to step back and consider from first principles what this cohort of children and young people now need from NHS services, based on the evidence that exists, or additional evidence that the Review hopes to collect.

5.4. In **Appendix 4** we have described the service development process for three different conditions which may help to illustrate what would be expected to happen at each different stage of developing a clinical service. The steps may proceed in a different sequence for different conditions, but each step is important in the development of evidence based care.

5.5. We recognise that for some of those reading this report it may feel wrong to compare gender incongruence or dysphoria to clinical conditions, and indeed this approach would not be justified if individuals presenting with these conditions did not require clinician intervention. However, where a clinical intervention is given, the same ethical, professional and scientific standards have to be applied as to any other clinical condition.

Key stages of service development



New condition observed: This often begins with a few case reports and then clinicians begin to recognise a recurring pattern and key clinical features, and to develop fuller descriptions of the condition.

Aetiology: Clinicians and scientists try to work out the cause of the condition or the underlying physical or biological basis. Sometimes the answers to this are never found.

Natural history and prognosis: It is important to understand how a condition usually evolves over time, with or without treatment. The latter is important if treatment has limited efficacy and the condition is 'self-limiting' (that is, it resolves without treatment), because otherwise there is a risk that treatments create more difficulties than the condition itself.

5.6. The first UK service for gender-questioning children and young people was established in 1989. At that time there were very few children and young people being seen by medical services internationally. The most common presentation in the early years of the service was of birth-registered

boys who had demonstrated gender incongruence from an early age.[51,52,53]

5.7. There is extensive literature discussing the possible aetiology of gender incongruence. Based on the available evidence, many authors would suggest that it is likely that biological, cultural, social and psychological factors all contribute. The examples in **Appendix 4** show that this is not an uncommon situation; many conditions do not have a single clear causation – they are in other words 'multifactorial'.

5.8. Regardless of aetiology, the more contentious and important question is how fixed or fluid gender incongruence is at different ages and stages of development, and whether, regardless of aetiology, can be an inherent characteristic of the individual concerned. There is a spectrum of academic, clinical and societal opinion on this. At one end are those who believe that gender identity can fluctuate over time and be highly mutable and that, because gender incongruence or gender-related distress may be a response to many psychosocial factors, identity may sometimes change or the distress may resolve in later adolescence or early adulthood, even in those whose early incongruence or distress was quite marked. At the other end are those who believe that gender incongruence or dysphoria in childhood or adolescence is generally a clear indicator of that child or young person being transgender and question the methodology of some of the desistance studies. Previous literature has indicated that if gender incongruence continues into puberty, desistance is unlikely.[54,55] However, it should be noted that these older studies were not based on the current changed case-mix or the different socio-cultural climate of recent years, which may have led to different outcomes. Having an open discussion about these questions is essential if a shared understanding of how to provide appropriate assessment and treatment is to be reached.

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[51] Zucker KJ (2017). Epidemiology of gender dysphoria and transgender identity. Sex Health 14(5): 404–11. DOI:10.1071/SH1.

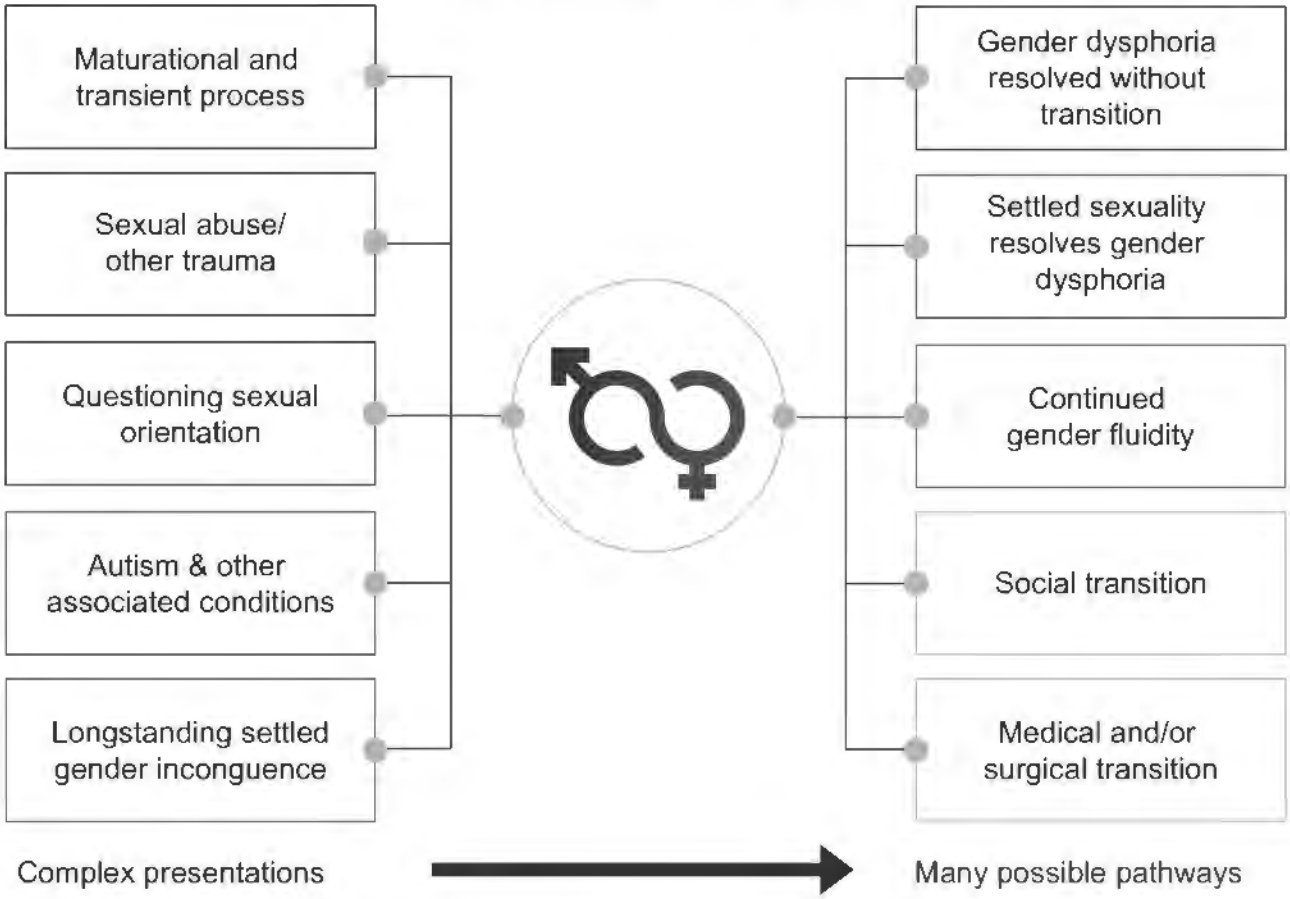
[52] Zucker KJ, Lawrence AA (2009). Epidemiology of gender identity disorder: recommendations for the Standards of Care of the World Professional Association for Transgender Health. Int J Transgend 11(1): 8-18. DOI: 10.1080/15532730902799946.

[53] de Graaf NM, Giovanardi G, Zitz C, Carmichael P (2018). Sex ratio in children and adolescents referred to the gender identity development service in the UK (2009-2016). Arch Sex Behav 47(5): 1301–4.

[54] Steensma TD, Biemond R, de Boer F, Cohen-Kettenis PT (2011). Desisting and persisting gender dysphoria after childhood: a qualitative follow-up study. Clin Child Psychol Psychiatry 16(4): 485-97. DOI: 10.1177/135910451037803.

[55] Steensma TD, McGuire JK, Kreukels BPC, Beekman AJ, Cohen-Kettenis PT (2013). Factors associated with desistence and persistence of childhood gender dysphoria: a quantitative follow-up study. J Am Acad Child Adolesc Psychiatry 52: 582-590. DOI: 10.1016/j.jaac.2013.03.016.

Complex presentations and complex pathways – exemplars, not comprehensive lists



Epidemiology: Epidemiologists collect data to find out how common a condition is, who is most likely to be affected, what the age distribution is and so on. This allows health service planners to work out how many services are needed, where they should be established, and what staff are needed.

They also report on changes in who is most affected, which may mean that either the disease is changing, or the susceptibility of the population is changing.

5.9. As previously indicated, the epidemiology of gender dysphoria is changing, with an increase in the numbers of birth-registered females presenting in early teens.[56,57] In addition, the majority of children and young people presenting to GIDS have other complex mental health issues and/or neurodiversity.[58] There is also an over-representation of looked after children.[59]

5.10. There are several implications arising from the change in epidemiology:

- Firstly, the speed of change in the numbers presenting means that services have not kept pace with demand.
- Secondly, the cohort that the original Dutch Approach was based on is different from the current more complex NHS cohort, and also from the current case-mix internationally, and therefore it is difficult to extrapolate from older literature to this current group.
- Thirdly, different subgroups may have quite different needs and outcomes, and these must be built into any service design, so that it works for all children and young people.

5.11. At present we have the least information for the largest group of patients – birth-registered females first presenting in early teen years. Since the rapid increase in this group began around 2015, they will not reach late 20s for another 5+ years, which would be the best time to assess longer-term wellbeing.

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[56] Steensma TD, Cohen-Kettenis PT, Zucker KJ (2018). Evidence for a change in the sex ratio of children referred for gender dysphoria: Data from the Center of Expertise on Gender Dysphoria in Amsterdam (1988-2016). Journal of Sex & Marital Therapy 44(7): 713–5. DOI: 10.1080/0092623X.2018.1437580.

[57] de Graaf NM, Carmichael P, Steensma TD, Zucker KJ (2018). Evidence for a change in the sex ratio of children referred for Gender Dysphoria: Data from the Gender Identity Development Service in London (2000–2017). J Sex Med 15(10): 1381–3. DOI: 10.1016/j.jsxm.2018.08.002.

[58] Van Der Miesen AIR, Hurley H, De Vries ALC (2016). Gender dysphoria and autism spectrum disorder: A narrative review. Int Rev Psychiatry 28: 70-80. DOI: 10.3109/09540261.2015.1111199.

[59] Matthews T, Holt V, Sahin S, Taylor A, Griksaitis (2019). Gender Dysphoria in looked-after and adopted young people in a gender identity development service. Clinical Child Psychol Psychiatry 24: 112-128. DOI: 10.1177/1359104518791657.

Assessment and diagnosis: Clinicians will usually take a history from (that is, of their symptoms) and examine the patient (that is, for signs and symptoms), and where appropriate undertake a series of investigations or tests, to help them reach an accurate diagnosis.

Sometimes the whole process of making a diagnosis through talking to the patient and asking them to complete formal questionnaires, examining them and/or undertaking investigations is called 'clinical assessment'.

As well as diagnosing and ruling out a particular condition, clinicians often need to consider and exclude other, sometimes more serious, conditions that present in a similar way but may need quite different treatment – this process is called 'differential diagnosis'.

5.12. For children and young people with gender-related distress, many people would dispute the notion that 'making a diagnosis' is a meaningful concept, arguing that gender identity is a personal, internal perception of oneself. However, there are several reasons to why a diagnostic framework is used:

- Firstly, the clinician will seek to determine whether the child or young person has a stable transgender identity, or whether there might be other causes for the gender-related distress.
- Secondly, the clinician will determine whether there are other issues or diagnoses that might be having an impact on the young person's mental health. The Dutch Approach suggesting that these should be addressed prior to or alongside initiation of any medical treatments.
- Thirdly, in any situation where life-altering treatments are being administered, the clinician holds the responsibility for ensuring that they are being administered based on an appropriate decision making process. Therefore, it is usual practice for a diagnosis of gender dysphoria to be made prior to referring for any physical treatments.

5.13. When the word 'diagnosis' is used, people often associate this with the use of blood tests, X-rays, or other laboratory tests. As set out in the **Appendix 4**, the public is very familiar with diagnosis of Covid-19 and understands that there need to be tests that give a high degree of certainty about whether an individual is Covid-19 positive or not. False positive lateral flow tests are rare, but caused problems for schools, while PCR has been treated as the 'gold standard' test for accuracy.

5.14. When it comes to gender dysphoria, there are no blood tests or other laboratory tests, so assessment and diagnosis in children and young people with gender-related distress is reliant on the judgements of experienced clinicians. Because medical, and subsequently possibly surgical treatments will follow, it may be argued that a highly sensitive and specific assessment process is required. The assessment should be able to accurately identify those children or young people for whom physical intervention is going to be the best course of action, but it is equally important that it identifies those who need an alternative pathway or treatment.

5.15. The formal criteria for diagnosing gender dysphoria (DSM-5) are listed in **Appendix 3**. However, there are two problems associated with the use of these criteria:

- Firstly, several of the criteria are based on gender stereotyping which may not be deemed relevant in current society, although the core criteria remain valid.
- Secondly, and more importantly, these criteria give a basis on which to make a diagnosis that a young person is clinically distressed by the incongruence between their birth-registered and their experienced gender, but they do not help in determining which factors may have led to this distress and how they might best be resolved.

5.16. At present, the assessment process varies considerably, dependent on the perceptions, experience and beliefs of different clinicians. There are some existing measurement tools, but it is suggested that these have substantial limitations.[60]

5.17. The challenges are similar to the early difficulties in diagnosing autism, as set out in **Appendix 4**. As with autism, the framework for assessment needs to become formalised so there are clearer criteria for diagnosis and treatment pathways which are shared more widely. These should incorporate not just whether the child or young person meets DSM-5 criteria for gender dysphoria, but how a broader psychosocial assessment should be conducted and evaluated, and what other factors need to be considered to gain a holistic understanding of the child or young person's experience. Professional judgement and experience will still be important, but if the frameworks and criteria for assessment and diagnosis were more consistent and reproducible, there would be a greater likelihood that two different people seeing the same child or young person would come to the same conclusion. This would also mean that any research on interventions or long-term outcomes would be more reliable because the criteria on which a diagnosis was made, and hence the patients within the sample, would have the same characteristics.

[60] Bloom TM, Nguyen TP, Lami F, Pace CC, Poulakis Z, Telfer N (2021). Measurement tools for gender identity, gender expression, and gender dysphoria in transgender and gender-diverse children and adolescents: a systematic review. Lancet Child Adolescent Health. 5: 582-588. DOI: 10.1016/s2352-4642(21)00098-5.

5.18. As outlined above, it is standard clinical practice to undertake a process called differential diagnosis. This involves summarising the main points of the clinical assessment, the most likely diagnosis, other possible diagnoses and the reasons for including or excluding them, as well as any further assessments that may be required to clarify the diagnosis and the treatment options and plan. This is important when a medical intervention is being provided on the basis of the assessment, so the process is robust, explicit and reproducible. These considerations need to be applied to the assessment of children and young people presenting with gender-related distress. In mental health services, practitioners may also undertake a diagnostic or psychological formulation, which is a holistic summary of how the patient is feeling and why, and how to make sense of it, and a plan for moving forward with management or treatment.

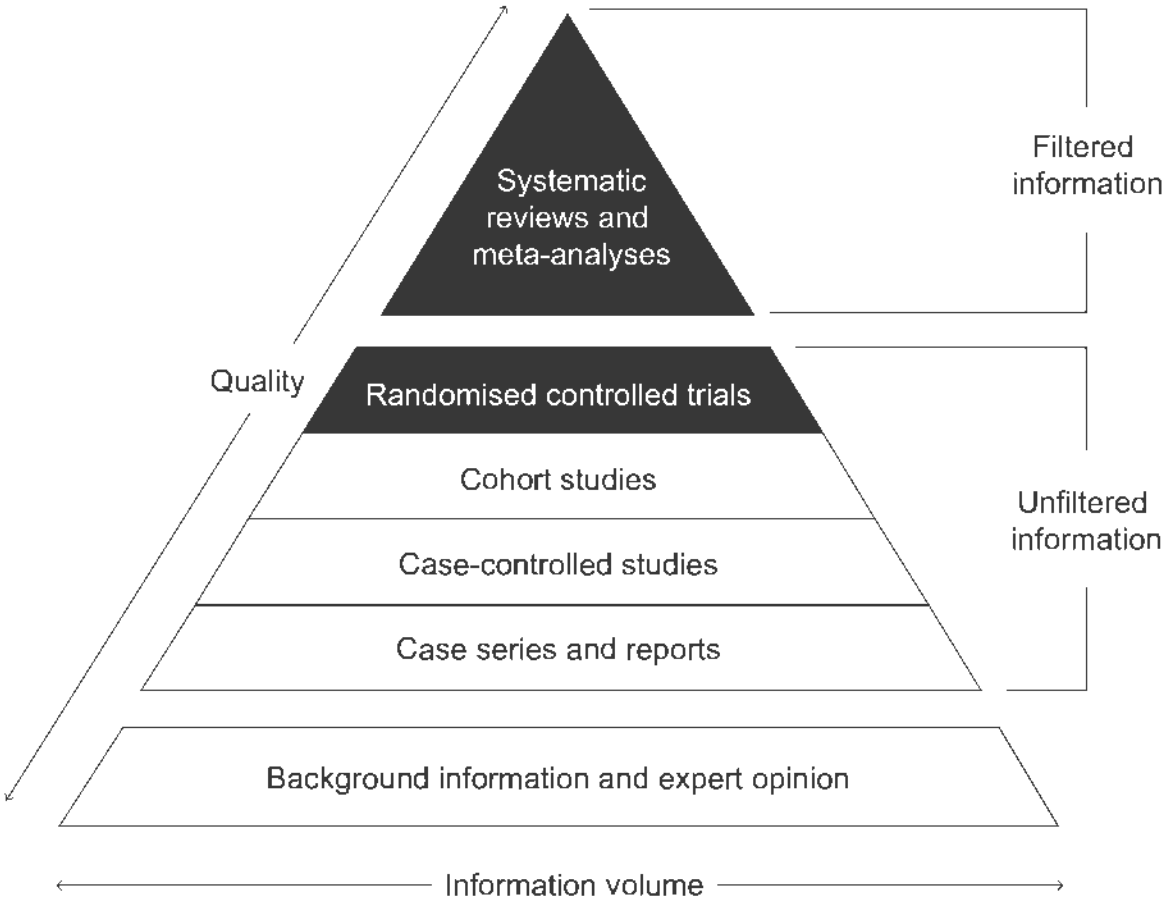
Developing and implementing new treatments: Clinicians and scientists work on developing treatments. This involves clinical trials and, where there are new treatments, comparing them to any existing treatments. Questions include: What are the intended outcomes or benefits of treatment? What are the complications or side effects? What are the costs? To initiate a new treatment, it must be both safe and effective. Questions of affordability can sometimes become controversial.

The best type of single study is considered to be the randomised controlled trial (RCT), but sometimes this is not feasible. Even where RCTs are not available, it is usual to at least have data on the outcomes of sufficient cases or cohorts to understand the risk/benefit of the treatment under consideration. As demonstrated in Fig. 4, the highest level of evidence is when the results of several different studies are pooled, but this is only useful if the individual studies themselves are of high quality.

In many instances, evidence is not perfect and difficult decisions have to be made. Where treatments are innovative or life-changing, the whole multi-disciplinary team will usually meet to consider the available options, and how to advise the child or young person and family so that a shared decision can be made. Sometimes an ethics committee is involved. This is one of the most challenging areas of medicine and is underpinned by GMC guidance.[61,62]

[61] General Medical Council (2020). Decision making and consent.
[62] National Institute for Health and Care Excellence (2021). Shared decision making.

Figure 3: Pyramid of standards of evidence



Source: Levels of evidence pyramid, OpenMD. Reproduced with permission[63]

5.19. There are three types of intervention or treatment for children and young people with gender-related distress, which may be introduced individually or in combination with one another:

- **Social transition** – this may not be thought of as an intervention or treatment, because it is not something that happens within health services. However, it is important to view it as an active intervention because it may have significant effects on the child or young person in terms of their psychological functioning.[64,65] There are different views on the benefits versus the harms of early social transition. Whatever position one

[63] OpenMD (2021). New Evidence in Medical Research.
[64] Sievert EDC, Schweizer K, Barkmann C, Fahrenkrug S, Becker-Hebly I (2020). Not social transition status, but peer relations and family functioning predict psychological functioning in a German clinical sample of children with Gender Dysphoria.Clin Child Psychol Psychiatry 26(1): 79–95. DOI: 10.1177/1359104520964530
[65] Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Colton K-M (2018). Prepubertal social gender transitions: What we know; what we can learn—A view from a gender affirmative lens. Int J Transgend 19(2): 251–68. DOI: 10.1080/15532739.2017.1414649.

takes, it is important to acknowledge that it is not a neutral act, and better information is needed about outcomes.

- **Counselling, social or psychological interventions** – these may be offered before, instead of, or alongside physical interventions. Again, they should be viewed as active interventions which require robust evaluation in their own right.
- **Physical treatments** – these comprise puberty blockers and feminising/masculinising hormones (administered by endocrinologists) and surgery. The latter is not considered as part of this Review since it is not available to those under age 18.

5.20. It should also be recognised that 'doing nothing' cannot be considered a neutral act.

5.21. The lack of available high-level evidence was reflected in the recent NICE review into the use of puberty blockers and feminising/masculinising hormones commissioned by NHS England, with the evidence being too inconclusive to form the basis of a policy position.[66,67] Assessing treatments for gender dysphoria has many of the same problems as assessing treatment for children with autism – it can take many years to get a full appreciation of outcomes and there may be other complicating factors in the child or young person's life during this period. However, this of itself is not an adequate reason for the major gaps in the international literature.

5.22. It is still common that drugs are not specifically licensed for children because the trials have only taken place on adults. This does not preclude their use or make their use inherently unsafe, particularly if they are used very commonly in children. However, where their use is innovative, patients receiving the drug should ideally do so under trial conditions.

5.23. The same considerations apply to 'off-label' drugs, where the drug is used for a condition different to the one for which it was licensed. This is the case for puberty blockers, which are licensed for use in precocious puberty, but not for puberty suppression in gender dysphoria. Again, it is important that it is not assumed that outcomes for, and side effects in, children treated for precocious puberty will necessarily be the same in children or young people with gender dysphoria.

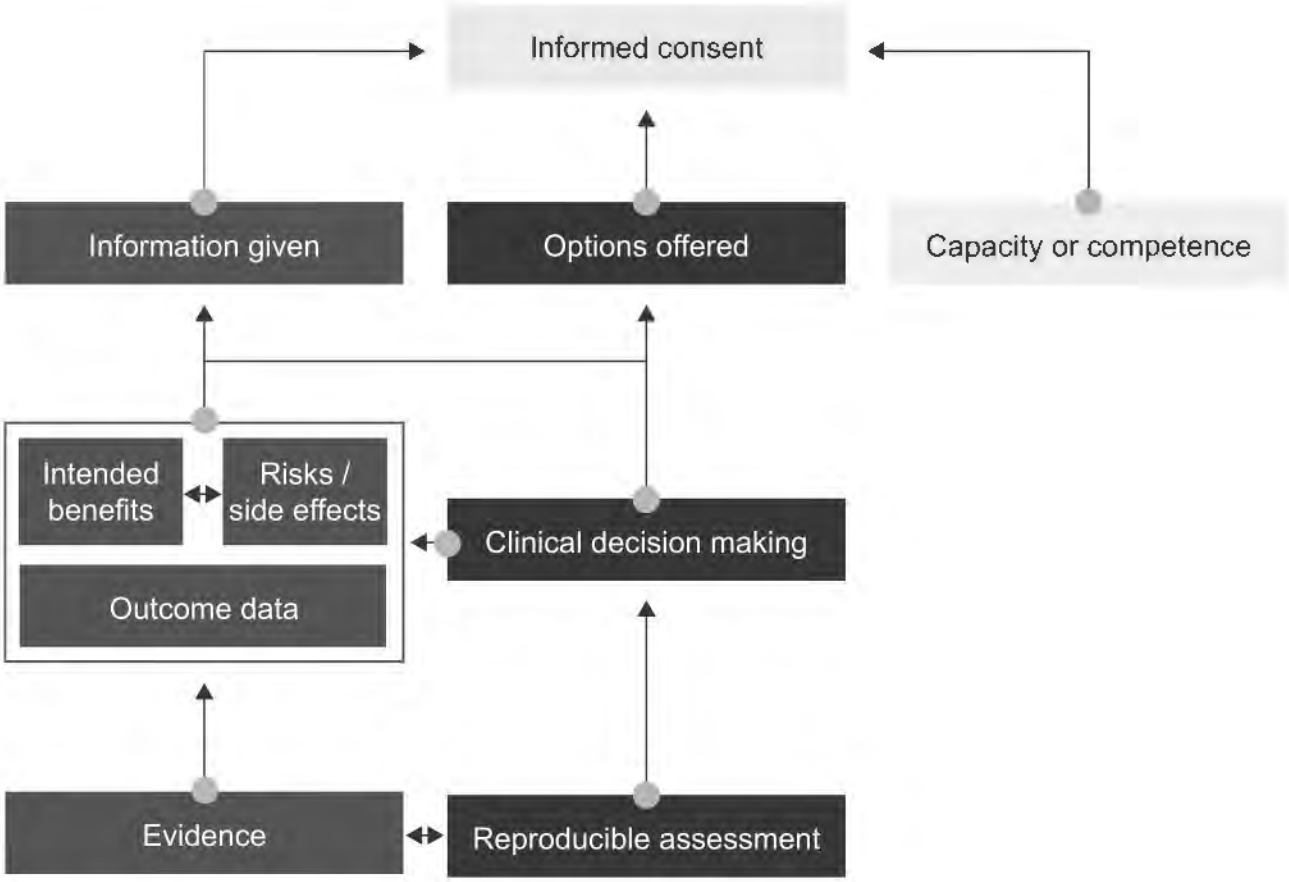
5.24. As outlined above, in other areas of practice where complex or potentially life-altering treatment is being considered for a child or young person, it is usual for the case to be discussed by an MDT including all professionals involved in their care. In gender services for children and young people in the Netherlands, as well as a number of other countries, there are full

[66] National Institute for Health and Care Excellence (2020). Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria
[67] National Institute for Health and Care Excellence (2020). Evidence review: gender-affirming hormones for children and adolescents with gender dysphoria.

MDT meetings, including psychiatrists and endocrinologists, to make decisions about suitability for hormone intervention and to review progress.[68,69]

5.25. Recent legal proceedings have examined the question of the competence and capacity of children and young people to consent to hormone treatment. However, there are some essential components that underpin informed consent; the robustness of the options offered to the patient, the information provided to them about those options, and their competence and capacity to consider them. The courts have given consideration to competence and capacity, and it is incumbent on this Review to consider the soundness of the decision making which underpins the options offered, and the quality and accuracy of the information provided about those options.

Elements of informed consent



[68] Kyriakou A, Nicolaides NC, Skordis N (2020). Current approach to the clinical care of adolescents with gender dysphoria. Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.
[69] Cohen-Kettenis PT, Steensma TD, de Vries ALC. Treatment of adolescents with gender dysphoria in the Netherlands. Child Adolesc Psychiatr Clin N Am 20. 689–700. 2001. DOI: 10.1016/j.chc.2011.08.001.

Service development and service improvement: Central to any service improvement is the systematic and consistent collection of data on outcomes of treatment. There is a process of continuous service improvement as new presentations or variations on the original condition are recognised, diagnosis or screening improves and/or trials on new treatments or variations on existing treatments are ongoing.

There should be consistent treatment protocols or guidelines in place, in order to make sense of variations in outcomes. Where possible, these should be compared between and across multiple different centres.

As time passes, services need to be changed or extended based on patient need, and on what resources are needed to deliver the available treatments. They need to be accessible where the prevalence of the condition is highest. The relevant workforce to deliver the service needs to be recruited and trained, contingent on the type of treatments or therapy that is required.

5.26. When a pioneering treatment or specialist service starts, it is often delivered in a single centre. Thereafter, additional centres take on the work as increasing numbers of patients need to access the treatment. Current provision of NHS specialist gender identity services for children and young people has remained concentrated within a single organisation, but demand has grown dramatically.

5.27. The situation has been exacerbated because there are not many local services seeing gender-questioning children at an earlier stage in their journey, which means that GIDS is carrying an unsustainable workload of increasingly complex young people.

5.28. As a condition evolves, rigorous data collection and quantitative research is an essential prerequisite to refining understanding and treatment. Historically, The Tavistock and Portman NHS Foundation Trust built its international reputation as the home of psychoanalysis, psychotherapy and family therapy, with a strong track record of publishing qualitative rather than quantitative research; consequently its approach to quantitative data collection about this important group of children and young people has been weak.

5.29. A further anomaly is a public perception that The Tavistock and Portman NHS Foundation Trust is the responsible organisation for leading the management of children receiving hormone treatment for their gender dysphoria. In reality, the hormone treatment is delivered by paediatric services in University College London Hospitals NHS Foundation Trust and The Leeds Teaching Hospitals NHS Trust.

5.30. In practice, it is important that for children and young people who need physical intervention, paediatric and mental health services are seen as equal partners, with seamless joint working and shared responsibility. When there were very small numbers of patients, it was easier for this to be achieved, but cross-site working with a very large caseload has made this more difficult to achieve, despite the best intentions of the staff.

5.31. Over the last two years there have been strong efforts on the part of The Tavistock and Portman NHS Foundation Trust to make practice within GIDS more consistent, with tighter procedures for case management, consent, and safeguarding. However, although this has resulted in better documentation, variations and inconsistencies in clinical decision making remain. In responding to a changing legal framework, some processes have become more cumbersome and complex, and the team are working hard to streamline the process.

5.32. Overall, GIDS faces a daunting task as a single provider in managing risk on the waiting list, seeing new referrals, reviewing and supporting those on hormone treatment, undertaking an ongoing transformation programme, recruiting and training new staff and trying to retain existing staff. This suggests that the current model is not sustainable and that another model is needed.

6. Interim advice, research programme and next steps

Dealing with uncertainty

6.1. As outlined throughout this report, there are major gaps in the research base underpinning the clinical management of children and young people with gender incongruence and gender dysphoria, including the appropriate approaches to assessment and treatment.

6.2. As with any other area of medicine, where there are gaps in the evidence base and uncertainties about the correct clinical approach, three tasks must be undertaken:

- Clinical services must be run as safely and effectively as possible, within the constraints of current knowledge; treatment options must be weighed carefully; and treatment decisions must be made in partnership between the clinicians and the children, young people and their families and carers, based on our current understanding about outcomes.
- Consistent data must be collected by clinical services, for both audit and research purposes so that knowledge gaps can be filled, alongside an active research programme.
- Where there is not an immediate prospect of filling research gaps, professional consensus should be developed on the correct way to proceed pending clearer research evidence, supported by input from service users.

6.3. The additional problem with the current service model is that safety and access are further compromised by the pace at which referrals have grown and outstripped capacity at tertiary level, and the lack of service availability at local level.

6.4. The Review's approach to these tasks is as follows:

- Our **interim advice** focuses on the issues of capacity, safety, and standards around treatment decisions, as well as data and audit.
- Our **research streams** will provide the Review with an independent collation of published evidence relevant to epidemiology, clinical management, models of care, and outcomes, as well as delivering qualitative and quantitative research relevant to the Terms of Reference of the Review. This offers a real opportunity to contribute to the international evidence base for this service area.
- There will be an ongoing and wide-ranging **programme of engagement** to address areas on which we will not be able to obtain definitive evidence during the lifetime of the Review.

Interim advice

6.5. The Review considers that there are some areas where there is sufficient clarity about the way forward and we are therefore offering some specific observations and interim advice. The Review will work with NHS England, providers and the broader stakeholder community to progress action in these areas.

Service model

6.6. It has become increasingly clear that a single specialist provider model is not a safe or viable long-term option in view of concerns about lack of peer review and the ability to respond to the increasing demand.

6.7. Additionally, children and young people with gender-related distress have been inadvertently disadvantaged because local services have not felt adequately equipped to see them. It is essential that they can access the same level of psychological and social support as any other child or young person in distress, from their first encounter with the NHS and at every level within the service.

6.8. A fundamentally different service model is needed which is more in line with other paediatric provision, to provide timely and appropriate care for children and young people needing support around their gender identity. This must include support for any other clinical presentations that they may have.

6.9. The Review supports NHS England's plan to establish regional services, and welcomes the move from a single highly specialist service to regional hubs.

6.10. Expanding the number of providers will have the advantages of:

- creating networks within each area to improve early access and support;
- reducing waiting times for specialist care;
- building capacity and training opportunities within the workforce;
- developing a specialist network to ensure peer review and shared standards of care; and
- providing opportunities to establish a more formalised service improvement strategy.

Service provision

6.11. The primary remit of NHS England's proposed model is for the regional hubs to provide support and advice to referrers and professionals. However, it includes limited provision for direct contact with children and young people and their families.

1: The Review advises that the regional centres should be developed, as soon as feasibly possible, to become direct service providers, assessing and treating children and young people who may need specialist care, as part of a wider pathway. The Review team will work with NHS England and stakeholders to further define the proposed model and workforce implications.

2: Each regional centre will need to develop links and work collaboratively with a range of local services within their geography to ensure that appropriate clinical, psychological and social support is made available to children and young people who are in early stages of experiencing gender distress.

3: Clear criteria will be needed for referral to services along the pathway from primary to tertiary care so that gender-questioning children and young people who seek help from the NHS have equitable access to services.

4: Regional training programmes should be run for clinical practitioners at all levels, alongside the online training modules developed by Health Education England (HEE). In the longer-term, clearer mapping of the required workforce, and a series of competency frameworks will need to be developed in collaboration with relevant professional organisations.

Data, audit and research

6.12. A lack of routine and consistent data collection means that it is not possible to accurately track the outcomes and pathways children and young people take through the service. Standardised data collection is required in order to audit service standards and inform understanding of the epidemiology, assessment and treatment of this group. This, alongside a national network which brings providers together, will help build knowledge and improve outcomes through shared clinical standards and systematic data collection. In the longer-term, formalisation of such a network into a learning health system[70] with an academic host would mean that there was systematised use of data to produce a continuing research programme with rapid translation into clinical practice and a focus on training.

5: The regional services should have regular co-ordinated national provider meetings and operate to shared standards and operating procedures with a view to establishing a formal learning health system.

6: Existing and future services should have standardised data collection in order to audit standards and inform understanding of the epidemiology, assessment and treatment of this group of children and young people.

[70] Scobie S, Castle-Clarke S (2019). Implementing learning health systems in the UK NHS: Policy actions to improve collaboration and transparency and support innovation and better use of analytics. Learning Health Systems 4(1): e10209. DOI:10.1002/lrh2.10209.

7: Prospective consent of children and young people should be sought for their data to be used for continuous service development, to track outcomes, and for research purposes. Within this model, children and young people put on hormone treatment should be formally followed up into adult services, ideally as part of an agreed research protocol, to improve outcome data.

Clinical approach

Assessment processes

6.13. We have heard that there are inconsistencies and gaps in the assessment process. Our work to date has also demonstrated that clinical staff have different views about the purpose of assessment and where responsibility lies for different components of the process within the pathway of care. The Review team has commenced discussions with clinical staff across primary, secondary and tertiary care to develop a framework for these processes.

8: There needs to be agreement and guidance about the appropriate clinical assessment processes that should take place at primary, secondary and tertiary level.

9: Assessments should be respectful of the experience of the child or young person and be developmentally informed. Clinicians should remain open and explore the patient's experience and the range of support and treatment options that may best address their needs, including any specific needs of neurodiverse children and young people.

Hormone treatment

6.14. The issues raised by the Multi-Professional Review Group echo several of the problems highlighted by the CQC. It is essential that principles of the General Medical Council's Good Practice in Prescribing and Managing Medicine's and Devices[71] are closely followed, particularly given the gaps in the evidence base regarding hormone treatment. Standards for decision making regarding endocrine treatment should also be consistent with international best practice.[72,73,74]

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[71] General Medical Council (2021). Good practice in prescribing and managing medicines and devices (76-78).
[72] Hembree WC, Cohen-Kettenis PT, Gooren L, Hannema SE, Meyer WJ, Murad MH, et al (2017). Endocrine treatment of gender-dysphoric/gender-incongruent persons: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab 102(11): 3869–903. DOI: 10.1210/jc.2017-01658.
[73] Cohen-Kettenis PT, Steensma TD, de Vries ALC (2001). Treatment of adolescents with gender dysphoria in the Netherlands. Child Adolesc Psychiatr Clin N Am 20: 689–700. DOI: 10.1016/j.chc.2011.08.001.
[74] Kyriakou A, Nicolaides NC, Skordis N (2020). Current approach to the clinical care of adolescents with gender dysphoria. Acta Biomed 91(1): 165–75. DOI: 10.23750/abm.v91i1.9244.

10: Any child or young person being considered for hormone treatment should have a formal diagnosis and formulation, which addresses the full range of factors affecting their physical, mental, developmental and psychosocial wellbeing. This formulation should then inform what options for support and intervention might be helpful for that child or young person.

11: Currently paediatric endocrinologists have sole responsibility for treatment, but where a life-changing intervention is given there should also be additional medical responsibility for the differential diagnosis leading up to the treatment decision.

6.15. Paediatric endocrinologists develop a wide range of knowledge within their paediatric training, including safeguarding, child mental health, and adolescent development. Being party to the discussions and deliberations that have led up to the decision for medical intervention supports them in carrying out their legal responsibility for consent to treatment and the prescription of hormones.

12: Paediatric endocrinologists should become active partners in the decision making process leading up to referral for hormone treatment by participating in the multidisciplinary team meeting where children being considered for hormone treatment are discussed.

6.16. Given the uncertainties regarding puberty blockers, it is particularly important to demonstrate that consent under this circumstance has been fully informed and to follow GMC guidance[75] by keeping an accurate record of the exchange of information leading to a decision in order to inform their future care and to help explain and justify the clinician's decisions and actions.

13: Within clinical notes, the stated purpose of puberty blockers as explained to the child or young person and parent should be made clear. There should be clear documentation of what information has been provided to each child or young person on likely outcomes and side effects of all hormone treatment, as well as uncertainties about longer-term outcomes.

[75] General Medical Council (2020). Decision making and consent.

14: In the immediate term the Multi-Professional Review Group (MPRG) established by NHS England should continue to review cases being referred by GIDS to endocrine services.

Research programme

6.17. The Review's formal academic research programme, comprising a literature review, quantitative analysis and primary qualitative research, has been based on the identified gaps in the evidence and the feasibility of filling them within the lifetime of the Review.

6.18. Initial work has identified the existing evidence base on epidemiology, natural history, and the treatment and outcomes of children and young people with gender dysphoria/gender-related distress. It has also assessed the feasibility of linking data between local, regional or national datasets in order to assess intermediate and longer-term outcomes.

Literature review

6.19. A literature review is being undertaken, which will interface with evidence gathering from the professional community (see qualitative research section below). Its aim is to systematically identify, collate and synthesise the existing evidence on the changing epidemiology of gender-related distress in children and young people and the appropriate social, clinical, psychological and medical management of that distress.

6.20. The literature review will capture primary studies of any design, including experimental, observational, survey and qualitative, and is looking to answer the following questions:

1. How has the population of children and young people presenting with gender dysphoria and/or gender-related distress changed over time?
2. What are the appropriate referral, assessment and treatment pathways for children and young people with gender dysphoria and/or gender-related distress?
3. What are the short-, medium- and long-term outcomes for children and young people with gender dysphoria and/or gender-related distress?
4. How do children and young people and their families negotiate distress, present this distress to services, and what are their expectations, following presentation?
5. How do children, young people and their families/carers experience referral, assessment and treatment? And how are these negotiated among children and young people, parents/carers, families and healthcare professionals?

6.21. A separate synthesis for each question will be undertaken. The systematic review has been registered on PROSPERO [ID:289659].

Quantitative research

6.22. The National Institute for Health and Care Excellence (NICE) recently published two evidence reviews.[76,77] These highlight shortcomings in the follow-up data collected about children and young people, when they are referred to a specialist gender identity service. The quantitative research will therefore focus on the collection and analysis of data to uncover patterns and quantify problems, thereby helping the Review to address some of these shortcomings.

6.23. The aim of the quantitative study is to supplement the material collected by the literature review, further examining the changing epidemiology of gender-related distress in children and young people, in addition to exploring the appropriate social, clinical, psychological and medical management. Its objectives are to:

a) describe the clinical and demographic characteristics of this population of children and young people and their clinical management in the GIDS service; and

b) assess the intermediate and longer-term outcomes of this population of children and young people utilising national healthcare data.

6.24. This research will provide an evidence base to facilitate informed decision making among children and young people and their families. It will also provide an evidence base for those responsible for commissioning, delivering and managing services.

Qualitative research

6.25. The qualitative research will capture a diverse range of trajectories experienced by gender-questioning children and young people, exploring a range of different experiences and outcomes. This will include talking to children and young people and their families/carers who are currently negotiating gender-related distress, young adults who have gone through the process of resolving their distress and care professionals.

[76] National Institute for Health and Care Excellence (2020). Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria.
[77] National Institute for Health and Care Excellence (2020). Evidence review: gender-affirming hormones for children and adolescents with gender dysphoria.

The objectives of the qualitative research are to:

1. Explore how children and young people understand, respond and negotiate gender-related distress within the context of their social networks, alongside the perspectives of young adults who experienced gender distress as children.
2. Examine the perspectives, understandings and responses of parents (or carers), including how they support their child.
3. Investigate how children, young people, young adults and their families experience(d) and negotiate(d) referral, assessment and possible treatment and intervention options.
4. Understand the role and experiences of care professionals who offer support, including identifying shared and potentially divergent views among care professionals, children and young people, and parents of what constitutes optimal care.

Progress

6.26. The literature review is already underway and is identifying relevant studies. Initial meetings have also taken place with voluntary organisations and other researchers working in the area to ensure there is no duplication and in recognition of research fatigue among this population.

6.27. Children and young people and young adults who have experienced gender-related distress are involved in the research programme. Their advice has been, and will continue to be, sought throughout this work, including in relation to the focus of the research and interpretation of findings and the design and content of dissemination materials.

6.28. Three research protocols have been produced setting out how the research will be undertaken, and the research team is currently gaining the necessary ethical and governance approvals to progress the study. The systematic review is published on the PROSPERO website and will be published on the Review website in due course, along with the qualitative and quantitative research proposals once ethical and governance approvals have been received.

6.29. The research findings will be subject to peer review through the publication process and various summaries, aimed at different audiences, will be available on the project website and distributed via support organisations. These summaries will also be made available on the Review website.

Ongoing engagement

6.30. In recognition that not all the published evidence is likely to be of high enough quality to form the sole basis for our recommendations, a consensus development approach will be used to synthesise the published evidence and research outputs of the academic work with stakeholder submissions and expert opinion.

6.31. Over the coming months, the Review will build on its engagement to date and, alongside the academic research programme, will continue informal and structured engagement with service users, their families, support and advocacy groups and professionals to test emerging thinking, provide opportunities for challenge and further develop the evidence base.

6.32. This review is an iterative process and we will share important findings when they become available. For the latest updates, please visit our website: https://cass.independent-review.uk/

6.33. We thank those who have participated in the Review to date and welcome engagement with us as work progresses towards final recommendations.

Glossary

Glossary

There is sometimes no consensus on the best language to use relating to this subject. The language surrounding this area has also changed rapidly and young people have developed varied ways of describing their experiences using different terms and constructs that are relevant to them.

The Review tries as far as possible to use language and terms that are respectful and acknowledge diversity, but that also accurately illustrate the complexity of what we are trying to describe and articulate.

The terms we have used may not always feel right to some; nevertheless, it is important to emphasise that the language used is not an indication of a position being taken by the Review. The glossary below sets out a description of some of the terms we have used in the Review.

Term		Description
Affirmative model		A model of gender healthcare that originated in the USA[78,79,80,81] which affirms a young person's subjective gender experience while remaining open to fluidity and changes over time. This approach is used in some key child and adolescent clinics across the Western world.
Assent		To agree to or approve of something (idea, plan or request), especially after thoughtful consideration.
Autonomy		Personal autonomy is the ability of a person to make their own decisions. In health this refers specifically to decisions about their care.

[78] Hidalgo MA, Ehrensaft D, Tishelman AC, Clark LF, Garofalo R, Rosenthal SM, et al (2013). The gender affirmative model: What we know and what we aim to learn [Editorial]. Human Dev 56(5): 285–290. DOI:10.1159/000355235.

[79] Chen D, Abrams M, Clark L, Ehrensaft D, Tishelman AC, Chan YM, et al (2021). Psychosocial characteristics of transgender youth seeking gender-affirming medical treatment: baseline findings from the trans youth care study. J Adol Health 68(6): 1104–11.

[80] Olson-Kennedy J, Chan YM, Rosenthal S, Hidalgo MA, Chen D, Clark L, et al (2019). Creating the Trans Youth Research Network: A collaborative research endeavor. Transgend Health 4(12): 304–12. DOI: 10.1089/trgh.2019.0024.

[81] Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Colton K-M (2018). Prepubertal social gender transitions: What we know; what we can learn—A view from a gender affirmative lens. Int J Transgend 19(2): 251–68. DOI: 10.1080/15532739.2017.1414649.

Term		Description
Best interests		Clinicians and the courts seek to act in the best interests of children and young people. For the Mental Capacity Act (MCA) 2005, decisions for someone who cannot decide for themselves must be made in their best interests. Under the Children Act 1989, in any decision of the court about a child (under 18), the welfare of the child must be paramount. For these purposes, there is little or no material difference between the welfare and best interests, and we have used "best interests" throughout the report. Although there is no standard definition of "best interests of the child," the General Medical Council advises that an assessment of best interests will include what is clinically indicated as well as additional factors such as the child or young person's views, the views of parents and others close to the child or young person and cultural, religious and other beliefs and values of the child or young person.[82]
		The MCA s4,[83] and extensive Court of Protection case law, deals with the approach to best interests under that legislation. Whether in the Court of Protection or the High Court, when the court is asked to make an assessment of a child or young person's best interests, it will consider their welfare/best interests in the widest sense. This will include not just medical factors but also social and psychological factors.
Case-mix		The mix of patients within a particular group.
Child and adolescent mental health services	CAMHS	NHS children and young people's mental health services.[84]

[82] General Medical Council (2018). 0-18 years – guidance for all doctors.
[83] Mental Health Law Online. MCA 2005 s4.
[84] Young Minds. Guide to CAMHS: a guide for young people.

Term		Description
Child and/or young person		In law, everyone under 18 years of age is a child (Children Act 1989) but we recognise that it may be more appropriate to refer to those approaching the age of 18 as a young person, and that such young people may not recognise themselves as a "child". In places, we have referred only to "young person", or only to "child", for example where treatment in question is only given towards the later stages of childhood, closer to the age of 18, or in reference to the parent/child relationship, in which they remain the parents' child, regardless of their age. Otherwise, we have used the phrase "child and/or young person" throughout the report for this reason only, and do not intend there to be a material difference between them other than that.
Cognitive		Relating to, or involving, the process of thinking and reasoning.
Consent		Permission for a clinical intervention (such as an examination, test or treatment) to happen. For consent to be 'informed', information must be disclosed to the person about relevant risks, benefits and alternatives (including the option to take no action), and efforts made to ensure that the information is understood. In legal terms, consent is seen as needing: 1 – capacity (or *Gillick* competence under 16) to make the relevant decision; 2 – to be fully informed (ie the information provided about the available options, the material risks and benefits of each option, and of doing nothing, "material" meaning (per the Montgomery Supreme Court judgment in 2015) what a reasonable patient would want to know, and what this patient actually wants to know, NOT what a reasonable doctor would tell them); and 3 – to be freely given (that is,without coercion).
Contraindications		A condition or circumstance that suggests or indicates that a particular technique or drug should not be used in the case in question.

Term		Description
Court of Appeal		(England and Wales) The Court of Appeal hears appeals against both civil and criminal judgments from the Crown Courts, High Court and County Court. It is second only to the Supreme Court.
Detransition/ detransitioners		Population of individuals who experienced gender dysphoria, chose to undergo medical and/or surgical transition and then detransitioned by discontinuing medications, having surgery to reverse the effects of transition, or both.[85]
Diagnostic and Statistical Manual of Mental Disorders Fifth edition	DSM-5	The American diagnostic manual used to diagnose mental health disorders, and commonly used in UK practice. See **Appendix 3**.
Diagnostic formulation		The comprehensive assessment that includes a patient's history, results of psychological tests, and diagnosis of mental health difficulties.
Divisional Court		(England and Wales) When the High Court of Justice of England and Wales hears a case with at least two judges sitting, it is referred to as the Divisional Court. This is typically the case for certain judicial review cases (as well as some criminal cases).
Dutch Approach		Protocol published in 1998 by the Amsterdam child and adolescent gender identity clinic.[86]
Endocrine treatment		In relation to this clinical area, this term is used to describe the use of gonadotropin-releasing hormones (see below) and feminising and masculinising hormones (see below).
Endocrinologist		An endocrinologist is a medical doctor specialising in diagnosing and treating disorders relating to problems with the body's hormones.
Endocrinology		The study of hormones.

[85] Littman L (2021). Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: a survey of 100 detransitioners. Arch Sex Abuse 50: 3353–69. DOI: 10.1007/s10508-021-02163-w

[86] de Vries ALC, Cohen-Kettenis PT (2012). Clinical management of gender dysphoria in children and adolescents: The Dutch approach. J Homosex 59: 301-320. DOI: 10.1080/00918369.2012.653300.

Term		Description
Epidemiology		Epidemiology is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems.[87]
Exploratory approaches		Therapeutic approaches that acknowledge the young person's subjective gender experience, whilst also engaging in an open, curious, non-directive exploration of the meaning of a range of experiences that may connect to gender and broader self-identity.[88,89,90,91]
Feminising and masculinising hormones (also known as cross-sex hormones, and gender affirming hormones).		Hormones given as part of a medical transition for gender dysphoric individuals, where sex hormones (testosterone for transgender males and oestrogen for transgender females).
Gender dysphoria		Diagnostic term used in DSM-5.[92] Gender dysphoria describes "a marked incongruence between one's experienced/expressed gender and assigned gender of at least 6 months duration" which must be manifested by a number of criterion – see **Appendix 3** for further detail.
Gender fluid		An experience of gender that is not fixed, but changes between two or more identities.
Gender identity		This term is used to describe an individual's internal sense of being male or female or something else.
Gender identity development		The developmental experience of a child or young person in seeking to understand their gender identity over time.
Gender Identity Development Service	GIDS	The service that NHS England commissions for children and adolescents with gender dysphoria.

[87] Centers for Disease Control and Prevention (2012). Principles of Epidemiology in Public Health Practice: An introduction to Applied Epidemiology and Biostatistics, 3rd ed.
[88] Di Ceglie D (2009). Engaging young people with atypical gender identity development in therapeutic work: A developmental approach. J Child Psychother 35(1): 3–12. DOI: 10.1080/00754170902764868.
[89] Spiliadis A (2019). Towards a gender exploratory model: Slowing things down, opening things up and exploring identity development. Metalogos Systemic Ther J 35: 1–9.
[90] Churcher Clarke A, Spiliadis A (2019). 'Taking the lid off the box': The value of extended clinical assessment for adolescents presenting with gender identity difficulties. Clin Child Psychol Psychiatry 24(2): 338–52. DOI:10.1177/1359104518825288.
[91] Bonfatto M, Crasnow E (2018). Gender/ed identities: an overview of our current work as child psychotherapists in the Gender Identity Development Service. J Child Psychother 44(1): 29–46. DOI:10.1080/007541 7X.2018.1443150.
[92] American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Health Disorders: DSM-5™, 5th ed.

Term		Description
Gender incongruence		Diagnostic term used in ICD-11.[93] Gender incongruence is characterised by "a marked and persistent incongruence between an individual's experienced gender and the assigned sex". See **Appendix 3** for further detail.
Gender-questioning		A broader term that might describe children and young people who are in a process of working out how they want to present in relation to their gender.
Gender-related distress		A way of describing distress that may arise from a broad range of experiences connected to a child or young person's gender identity development. Often used for young people whereby any formal diagnosis of gender dysphoria has not yet been made.
Gillick competence/ Fraser guidelines		A term derived from *Gillick v West Norfolk And Wisbech AHA*, 1984 that is used to decide whether a child or young person up to the age of 16 years is able to consent to their own medical treatment, without the need for parental permission or knowledge. A child or young person will be 'Gillick competent' for that decision if they have the necessary maturity and understanding to make the decision.
Gonadotropin-releasing hormone analogues (also known as the hormone blocker/s and puberty blocker/s)	GnRH	GnRH analogues competitively block GnRH receptors to prevent the spontaneous release of two gonadotropin hormones, Follicular Stimulating Hormone (FSH) and Luteinising Hormone (LH) from the pituitary gland. This arrests the progress of puberty.
General Practitioner	GP	GPs deal with a whole range of health problems and manage the care of their patients, referring onto specialists as appropriate.[94]
High Court		The third highest court in the UK. It deals with all high value and high importance civil law (non-criminal) cases and appeals of decisions made in lower courts. When the High Court sits with more than one judge, as required for certain kinds of cases, it is called the Divisional Court.
International Classification of Diseases, Version 11	ICD-11	ICD-11[95] is the World Health Organization (WHO) mandated health data standard used for medical diagnosis.

[93] World Health Organization (2022). International Classification of Diseases Eleventh Revision.
[94] NHS. GP services.
[95] World Health Organization (2022). International Classification of Diseases Eleventh Revision.

Term		Description
Looked after children		Children who are in the care of their Local Authority who may be living with foster parents or in a residential care setting.
Multi-disciplinary-team	MDT	The identified group of professional staff who provide a clinical service.
Neurodiverse		Displaying or characterised by autistic or other neurologically atypical patterns of thought or behaviour; not neurotypical.
Non-binary		A gender identity that does not fit into the traditional gender binary of male and female.[96]
Paediatrics		The branch of medicine dealing with children and their medical conditions.
Pass/passing		A person's gender being seen and read in the way they identify.
Precocious puberty		This is when a child's body begins changing into that of an adult (puberty) too soon – before age 8 in girls and before age 9 in boys.
Primary care		Primary care includes general practice, community pharmacy, dental and optometry (eye health) services. This tends to be the first point of access to healthcare.
Psychological formulation		A structured approach to understanding the factors underlying distressing states in a way that informs the changes needed and the therapeutic intervention for these changes to occur.
Psychosocial		Describes the psychological and social factors that encompass broader wellbeing.
Puberty blockers		See gonadotropin-releasing hormone above.
Secondary care		Hospital and community health care services that do not provide specialist care and are usually relatively close to the patient. For children this will include Child and Adolescent Mental Health Services (CAMHS), child development and general paediatric services.
Tanner Stage		Classification of puberty by stage of development. This ranges from Stage 1, before physical signs of puberty appear, to Stage 5 at full maturity.

[96] Twist J, de Graaf NM (2019). Gender diversity and non-binary presentations in young people attending the United Kingdom's National Gender Identity Development Service. Clin Child Psychol Psychiatry 24(2): 277–90. DOI: 10.1177/1359104518804311.

Term		Description
Tertiary care		Tertiary care is the specialist end of the NHS. These services relate to complex or rare conditions. Services are usually delivered in a number of hospitals/centres.
Transgender	trans	This is an umbrella term that includes a range of people whose gender identity is different from the sex they were registered at birth.
Transition		These are the steps a person may take to live in the gender in which they identify. This may involve different things, such as changing elements of social presentation and role and/or medical intervention for some.

Appendix 1

Terms of reference

TERMS OF REFERENCE FOR REVIEW OF GENDER IDENTITY DEVELOPMENT SERVICE FOR CHILDREN AND ADOLESCENTS

INTRODUCTION

1. NHS England is the responsible commissioner for specialised gender identity services for children and adolescents. The Gender Identity Development Service for children and adolescents is currently managed by the Tavistock and Portman NHS Foundation Trust.

2. In recent years there has been a significant increase in the number of referrals to the Gender Identity Development Service, and this has occurred at a time when the service has moved from a psychosocial and psychotherapeutic model to one that also prescribes medical interventions by way of hormone drugs. This has contributed to growing interest in how the NHS should most appropriately assess, diagnose and care for children and young people who present with gender incongruence and gender identity issues.

3. It is in this context that NHS England and NHS Improvement's Quality and Innovation Committee has asked Dr Hilary Cass to chair an independent review, and to make recommendations on how to improve services for children and young people experiencing issues with their gender identity or gender incongruence, and ensure that the best model/s for safe and effective services are commissioned.

REVIEW SCOPE

The independent review, led by Dr Cass, will be wide ranging in scope and will conduct extensive engagement with all interested stakeholders. The review is expected to set out findings and make recommendations in relation to:

i. Pathways of care into local services, including clinical management approaches for individuals with less complex expressions of gender incongruence who do not need specialist gender identity services;

ii. Pathways of care into specialist gender identity services, including referral criteria into a specialist gender identity service; and referral criteria into other appropriate specialist services;

iii. Clinical models and clinical management approaches at each point of the specialised pathway of care from assessment to discharge, including a description of objectives, expected benefits and expected outcomes for each clinical intervention in the pathway;

iv. Best clinical approach for individuals with other complex presentations.

v. The use of gonadotropin-releasing hormone analogues and gender affirming drugs, supported by a review of the available evidence by the National Institute for Health and Care Excellence; any treatment recommendations will include a description of treatment objectives, expected benefits and expected outcomes, and potential risks, harms and effects to the individual;

vi. Ongoing clinical audit, long term follow-up, data reporting and future research priorities;

vii. Current and future workforce requirements;

viii. Exploration of the reasons for the increase in referrals and why the increase has disproportionately been of natal females, and the implications of these matters; and,

TERMS OF REFERENCE FOR REVIEW OF GENDER IDENTITY DEVELOPMENT SERVICE FOR CHILDREN AND ADOLESCENTS

ix. Any other relevant matters that arise during the course of the review

4. In addition, and with support from the Royal College of Paediatrics and Child Health and other relevant professional associations, the Chair will review current clinical practice concerning individuals referred to the specialist endocrine service. It is expected that findings and any recommendations on this aspect of the review will be reported early in 2021 with the review's wider findings and recommendations delivered later in 2021.

5. The review will not immediately consider issues around informed consent as these are the subject of an ongoing judicial review. However, any implications that might arise from the legal ruling could be considered by the review if appropriate or necessary.

Appendix 2

Letter to NHS England from Dr Cass – May 2021

The Cass Review

Independent review into gender identity services for children and young people

Dr Hilary Cass
Chair
Review of GIDS for Children and Young People

John Stewart
National Director
Specialised Commissioning
NHS England and NHS Improvement

Sent by email

10 May 2021

Dear John

INDEPENDENT REVIEW INTO GENDER IDENTITY SERVICES FOR CHILDREN AND YOUNG PEOPLE

I am writing to update you on my current approach to the work of the independent review into gender identity services for children and young people. However, the most pressing issue is how we augment the immediate support for children and young people currently needing assessment and treatment, some of whom have already been waiting for an extended period for an appointment. I will therefore also make some suggestions about interim arrangements and ways in which the review team could help to support and strengthen these.

Commissioned research programme

As you know, a key principle of the review is that it should be evidence-based, and that final conclusions will be developed through a consensus development process contingent on the synthesised evidence.

I am pleased to see that the National Institute for Health and Care Excellence (NICE) evidence reviews of gonadotrophin releasing hormone analogues and gender affirming hormones for children and adolescents with gender dysphoria have now been published. Although this is a helpful starting point, despite following a standard and robust process the NICE review findings are not conclusive enough to inform policy decisions. As part of my review, I am therefore exploring other methodologies to give increased confidence and clarity about the optimal treatment approaches.

My team is commissioning a broader literature review of the existing evidence base on the epidemiology, management and outcomes of children with gender dysphoria. We are also commissioning qualitative and quantitative research, including considering other approaches which might be employed to understand the intermediate and longer-term outcomes of children with gender dysphoria. We intend to include a review of international models and data in this programme of work.

Addressing the immediate situation

Recognising that the outcome of the review is going to take some time, I have been reflecting on the recent court rulings on puberty blockers and consent and the Care Quality Commission (CQC) report on the Gender Identity Development Service (GIDS) run by the Tavistock and Portman NHS Foundation Trust. These significant developments have changed the context in which the review is taking place, and further added to the service pressures.

I note the proposal to establish an independent multidisciplinary professional review group to confirm decision-making has followed a robust process, which seems an appropriate interim measure pending further clarification of the legal situation.

I know that everyone concerned with the delivery of services – both commissioners and providers – are worried about the increasing number of children on the waiting list for assessment by the GIDS service and the resulting distress for the children and young people and their families. The difficulty in managing risk for those on the waiting list is exacerbated by the staff vacancies at GIDS, the increasing volume of new referrals, and the fact that the support and engagement from local services is highly variable and, in some cases, very limited.

Having a single provider may have been a logical position when the GIDS service was first set up, given that this is a highly specialised service that was seeing a relatively small number of cases each year. As the epidemiology has changed and there has been an exponential increase in numbers of children with gender incongruence or dysphoria, concentration of expertise within a single service has become unsustainable. At the same time, local services have not developed the skills and competencies to provide support for children on the waiting list and those with lesser degrees of gender incongruence who may not wish to pursue specialist medical intervention, and / or to provide help for children with additional complex needs.

I know from discussions we have had that your team is working hard to find some practical alternative arrangements, and that you have been in discussion with relevant professional bodies to come up with creative interim solutions while awaiting the outcome of my review.

The review team has also been in discussion with CQC, with the Tavistock and Portman NHS Foundation Trust and with colleagues within and external to NHS England and NHS Improvement to consider which aspects of this situation we can help with in the short to medium term, whilst keeping our focus on the longer-term questions of the appropriate clinical management and whole care pathway for these children and young people. In the past months I have also met with many groups and individuals with expertise and lived experience relevant to the review, including charities and support groups, Royal Colleges and healthcare professionals.

Recommendations to NHS England and NHS Improvement

I would encourage you to consider the following when developing an interim pathway for children and young people experiencing gender dysphoria:

- **Access and referral:** Children and young people need ready access to services. However, it is unusual for a specialist service to take direct referrals. The risk of having a national service as the first point of access is that assessment and treatment of children and young people who have the greatest need for specialist care is delayed because of the lack of differentiation of those on the waiting list. In addition, many children and

young people have complex needs, but once they are identified as having gender dysphoria, other important healthcare issues which would normally be managed by local services can sometimes be overlooked.

- **Assessment and management:** All children and young people who are referred to specialist services should have a competent local multi-disciplinary assessment and should remain under active holistic local management until they are seen at a specialist centre.

  I recognise that developing capacity and capability outside of the existing GIDS service to provide such initial assessment and support will be difficult to achieve at speed and will be incremental. This means that there will likely be a range of different models and options around the country, dependent on local resources, with some of the work being delivered through existing secondary service teams, and some being delivered at regional level. The support of wider services is vital.

- **Data:** The lack of systematic data collection is a significant issue. Therefore, when employing interim measures, I would suggest that particular attention is paid to the gathering of good quality data, which can then be used to inform the evidence base and future model of provision.

Actions for the review team

I would like to suggest how the review team might help with the challenging problem of growing an infrastructure outside of GIDS. From my conversations to date, I believe there are three barriers to the involvement of local services:

- **Capacity** – the staff most appropriately trained to be involved in initial assessment are those who are already most stretched within Child and Adolescent Mental Health Services (CAMHS) and paediatric services, and this situation has been significantly worsened through the impact of the Covid-19 pandemic on children's mental health. However, I know that there is substantial investment in CAMHS services, so close engagement with the relevant national policy teams at NHS England and NHS Improvement and at Health Education England (HEE) will be crucial.

- **Capability and confidence** – clinical teams outside of GIDS do not feel confident in initial assessment and support of children and young people with gender incongruence and dysphoria, in large part because they have not had the necessary training and experience, but also because of the societal polarisation and tensions surrounding the management of this group.

- **Lack of an explicit assessment framework** – currently expertise in assessment of children and young people presenting to GIDS is held in a small body of clinicians and their assessment processes have not been made explicit. The CQC report drew attention to the lack of structured assessment in the GIDS notes, and this is something that the Tavistock and Portman NHS Foundation Trust is already working to address internally. However, it is equally important to develop an initial assessment approach that can be used by first contact professionals, not just those working in the specialist service.

In the first instance, it is important that we test these assumptions with a range of clinical staff and ascertain whether there are other barriers that are preventing local engagement in this work. Then we would plan to prioritise a series of workshops, in collaboration with relevant professional groups, service users and close engagement with HEE. The purpose of these workshops would be to address identified barriers and develop:

- A framework for initial assessment of children and young people presenting with gender dysphoria.
- An approach to training for professionals at local and regional level.
- Some preliminary workforce recommendations, which will be particularly important in meeting the timelines of the three-year Comprehensive Spending Review.

These workshops will serve multiple purposes – firstly to support NHS England and NHS Improvement in the establishment of local and / or regional teams; secondly as an essential component of the work needed to inform the questions that the review is tackling; and thirdly to form the professional networks that will be needed to underpin future service and research networks.

Timelines

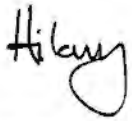
As you will recognise, setting up a complex national review is difficult and time consuming at the best of times. It requires a team to support the work and mechanisms for stakeholders to engage safely and with confidence. Starting a review in the midst of a pandemic is even more challenging.

I have committed to a review approach which is participative, consensus-based, evidence-based, transparent, and informed by lived and professional experience. This requires extensive engagement. Pending the appointment of our research team, the review has now launched its website and I have been proactively engaging with the stakeholder community.

It is critical that we get the approach right, particularly the engagement, the evidence review and the quantitative research given the gaps in the evidence highlighted through the NICE review, and this will take time.

My intention is that an interim report will be delivered in the summer, with a report next year setting out my final recommendations.

Yours sincerely



Dr Hilary Cass
Chair, Independent Review into Gender Identity Services for Children and Young People

Cc: Care Quality Commission
Health Education England
Tavistock and Portman NHS Foundation Trust

Appendix 3

Diagnostic criteria for gender dysphoria

DSM-5 diagnostic criteria for gender dysphoria

Gender Dysphoria in Children

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least six of the following (one of which must be Criterion A1):

1. A strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender).
2. In boys (assigned gender), a strong preference for cross-dressing or simulating female attire; or in girls (assigned gender), a strong preference for wearing only typical masculine clothing and a strong resistance to the wearing of typical feminine clothing.
3. A strong preference for cross-gender roles in make-believe play or fantasy play.
4. A strong preference for the toys, games, or activities stereotypically used or engaged in by the other gender.
5. A strong preference for playmates of the other gender.
6. In boys (assigned gender), a strong rejection of typically masculine toys, games, and activities and a strong avoidance of rough-and-tumble play; or in girls (assigned gender), a strong rejection of typically feminine toys, games, and activities.
7. A strong dislike of one's sexual anatomy.
8. A strong desire for the primary and/or secondary sex characteristics that match one's experienced gender.

B. The condition is associated with clinically significant distress or impairment in social, school, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as congenital adrenal hyperplasia or androgen insensitivity syndrome).

Gender Dysphoria in Adolescents and Adults

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least 6 months' duration, as manifested by at least two of the following:

1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).

3. A strong desire for the primary and/or secondary sex characteristics of the other gender.
4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

Specify if:

With a disorder of sex development (e.g., a congenital adrenogenital disorder such as congenital adrenal hyperplasia or androgen insensitivity syndrome).

Specify if:

Post transition: the individual has transitioned to full-time living in the desired gender (with or without legalization of gender change) and has undergone (or is preparing to have) at least one cross-sex medical procedure or treatment regimen – namely, regular cross-sex hormone treatment or gender reassignment surgery confirming the desired gender (e.g., penectomy, vaginoplasty in a natal male; mastectomy or phalloplasty in a natal female).

ICD-11: HA60 Gender incongruence of adolescence or adulthood

Gender Incongruence of Adolescence and Adulthood is characterised by a marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to 'transition', in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender. The diagnosis cannot be assigned prior the onset of puberty. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Exclusions:

Paraphilic disorders.

ICD-11: HA61 Gender incongruence of childhood

Gender incongruence of childhood is characterised by a marked incongruence between an individual's experienced/expressed gender and the assigned sex in pre-pubertal children. It includes a strong desire to be a different gender than the assigned sex; a strong dislike on the child's part of his or her sexual anatomy or anticipated secondary sex characteristics and/or a strong desire for the primary and/or anticipated secondary sex characteristics that match the experienced gender; and make-believe or fantasy play, toys, games, or activities and playmates that are typical of the experienced gender rather than the assigned sex. The incongruence must have persisted for about 2 years. Gender variant behaviour and preferences alone are not a basis for assigning the diagnosis.

Exclusions:

Paraphilic disorders.

Appendix 4

The standard approach to clinical service development

The standard approach to clinical service development

The three examples below illustrate the usual process of developing a clinical service: Covid-19 is included because this is a new condition that everyone is familiar with; childhood epilepsy because it is a complex condition with physical manifestations; and autism because it is a condition with neuro-behavioural manifestations.

By comparing these examples of clinical service development, it is possible to demonstrate some of the challenges in developing services for children and young people with gender incongruence or dysphoria, and to identify where there are gaps and questions that need to be addressed for this population, in order to ensure any future service model delivers the highest possible standards of care.

The stages below may proceed in a different sequence for different conditions, but each stage is important in the development of evidence based care.

Stage	Covid-19	Childhood Epilepsy	Autism
New condition is observed This often begins with a few case reports and then clinicians begin to recognise a recurring pattern and key clinical features, and to develop fuller descriptions of the condition.	Covid-19 is an example of a recent new condition that we all recognise, and this started with a few unusual cases of respiratory illness being described in Wuhan.	Childhood epilepsy has been recognised for centuries, but over the last century there has been growing understanding of the many different subtypes.	Individuals with autism have probably also existed for an indefinite period, but it wasn't until 1943 and 1944 that Leo Kanner and Hans Asperger wrote the first scientific accounts about the condition.

Stage	Covid-19	Childhood Epilepsy	Autism
Aetiology Clinicians and scientists try to work out the cause of the condition or the underlying physical or biological basis. Sometimes the answers to this are never found.	The cause of Covid-19 was identified at a very early stage as being due to a novel coronavirus, although it remains unclear where and how this originated.	It is now known that there are numerous different types of epilepsy, with many different causes – for example, epilepsy can be caused by specific epilepsy genes, by birth trauma, by metabolic conditions, by brain tumours and many other mechanisms. Epilepsies due to a change in the brain structure which occur after birth are called 'symptomatic' – they are a symptom of something else. Epilepsies for which there is no identified cause are called 'idiopathic'.	The first theory about the aetiology of autism was that it was caused by so called 'refrigerator parents'. This was inaccurate and damaging. It has subsequently been shown that there are many complex genetic and physical or chemical brain changes underpinning this condition.
Natural history and prognosis It is important to understand how a condition usually evolves over time, with or without treatment. The latter is important if treatment has limited efficacy and the condition is 'self-limiting' (that is, it resolves without treatment), because otherwise there is a risk that treatments create more difficulties than the condition itself.	Covid-19 is an example of a condition where there are quite polarised views about management based on its prognosis and natural history. A relatively small proportion of people are seriously affected and need treatment, and for the majority the natural history is that it will get better by itself. This has led some people to question the need for lockdowns, vaccinations and other measures which they see as impacting personal freedoms.	In epilepsy the natural history is very important. Some epilepsies get better through puberty and into adulthood, and some can get worse with hormonal changes. This is important to know when monitoring and reviewing drug treatment.	

Stage	Covid-19	Childhood Epilepsy	Autism
Epidemiology Epidemiologists collect data to find out how common a condition is, who is most likely to be affected, what the age distribution is and so on. This allows health service planners to work out how many services are needed, where they should be established, and what staff are needed. They also report on changes in who is most affected, which may mean that either the disease is changing, or the susceptibility of the population is changing.	Epidemiologists have been crucial in supporting the management of Covid-19 because they have extracted and analysed the data on which patients are at greater risk from the virus. This has been fundamental to planning a vaccination strategy and other protective measures.		The epidemiology of autism has changed considerably, with a dramatic increase in the numbers of children diagnosed over the last 20 years. This has had major implications for service provision. There is ongoing debate about the cause of the increase – whether it is because of greater awareness and better diagnosis, or because there are more children with autism. Current opinion favours the first option.

Stage	Covid-19	Childhood Epilepsy	Autism
Assessment and diagnosis Clinicians will usually take a history from (that is, of their symptoms) and examine the patient (that is, for signs and symptoms), and where appropriate undertake a series of investigations or tests, to help them reach an accurate diagnosis. Sometimes the whole process of making a diagnosis through talking to the patient and asking them to complete formal questionnaires, examining them and/or undertaking investigations is called 'clinical assessment'. As well as diagnosing and ruling out a particular condition, clinicians often need to consider and exclude other, sometimes more serious, conditions that present in a similar way but may need quite different treatment – this process is called 'differential diagnosis'.	PCR has been used as a 'gold standard' test for diagnosis of Covid-19 since the beginning of the pandemic. Lateral flow testing was developed to provide a quicker and cheaper option, but it demonstrates the limitations of testing; it is 99.68% specific, which is a very high specificity. This means there are only a tiny number of false positives. It has lower sensitivity at 76.8%, which means it will miss about a quarter of all cases, so giving many more false negatives, BUT it will only miss 5% of cases with high viral load.	Epilepsy can only be definitively diagnosed by either getting a really clear description of the events from a parent or carer, or seeing the child or young person having a seizure on a video. An EEG (brain wave tracing) and other tests can provide information about the type of epilepsy, but unless a seizure happens during the recording, it does not demonstrate that they actually have seizures – only that they may be susceptible to seizures.	In autism there are no blood tests or X-rays to make the diagnosis. It is a 'clinical' diagnosis, which means it is dependent on taking a standardised history from the parents, and performing standardised assessments on the child or young person to distinguish between autism and other possible diagnoses (for example, language disorder, social anxiety). In the early days, these standardised measures did not exist; the diagnosis was very dependent on experts who were used to diagnosing autism by making a clinical judgement about each child. This made it difficult to teach new people how to do this without a long apprenticeship, and also made it difficult to know whether two different experts would come to the same conclusion about the same child or young person. Standardisation of the questions and process made diagnosis more reliable and consistent, as did an improved evidence base. At the same time, because children with autism all present differently, the assessment had to be flexible enough to accommodate, for example, non-verbal children with severe learning disability, as well as high-functioning children with strong verbal skills.

Stage	Covid-19	Childhood Epilepsy	Autism
Differential diagnosis As well as making a positive diagnosis, clinicians often need to exclude other, sometimes more serious conditions that present in a similar way, but may need quite different treatment.		There are conditions that can be mistaken for epilepsy, so it is important to accurately diagnose whether seizures are happening and exclude other conditions (differential diagnoses) by carrying out relevant tests.	There are many conditions that may be mistaken for autism – for example, children who have language disorders, learning disability, severe social anxiety for other reasons, or ADHD can all appear to have autism. It is important to exclude these other conditions as well as making a positive diagnosis of autism. Sometimes these conditions can exist alongside autism, and management must then be planned to address all the child's difficulties.

Stage	Covid-19	Childhood Epilepsy	Autism
Developing and implementing new treatments Clinicians and scientists work on developing treatments. This involves clinical trials and, where there are new treatments, comparing them to any existing treatments. Questions include: What are the intended outcomes or benefits of treatment? What are the complications or side effects? What are the costs? To initiate a new treatment, it must be both safe and effective. Questions of affordability can sometimes become controversial. The best type of single study is considered to be the randomised controlled trial (RCT), but sometimes this is not feasible. Even where RCTs are not available, it is usual to at least have data on the outcomes of sufficient cases or cohorts to understand the risk/benefit of the treatment under consideration. As demonstrated in Fig. 3, the highest level of evidence is when the results of several different studies are pooled, but this is only useful if the individual studies themselves are of high quality.	Developing treatments for Covid-19 has been possible at speed because of the large numbers of patients, and the fact that outcomes can be observed on each patient within a matter of days to weeks. Because Covid-19 was a new condition, clinicians also started in a position of 'equipoise' which means that they did not have reason to believe any one treatment might be more effective than another; this made it ethical to have one group having a treatment and another group having a different treatment or a placebo. There are also really clear outcome measures, such as whether or not patients survive or need hospitalisation. This has facilitated a high level of evidence through randomised controlled trials (see diagram below).	Similar considerations apply to the treatment of epilepsy in that there are 'hard' outcome measures (for example, frequency of seizures), but it can take several months to determine whether a new drug is better than an existing one for any one patient, and some side effects may be longer-term, so trials can take several years. In addition, children with epilepsy may have very different conditions causing their seizures which can also make trials more challenging. In the most severe cases of epilepsy, surgery may be the best option for controlling seizures. This can be very radical in certain cases and have lifelong implications for how they function. These options, which have a cost as well as a benefit to the child, will only be offered after a multi-disciplinary team meeting, including the paediatricians, therapists, neuropsychologists, radiologists, neurophysiologists and neurosurgeons have all discussed whether the benefits will outweigh the costs.	Evaluating interventions for autism is the most difficult of these three examples. This is because it can take many years to see developmental outcomes; it is hard to get uniform groups of children; outcomes are extremely sensitive to the social (and historical) response of others; and many other things happen in children's lives (such as changes of school, other medications, new diets). Isolating the effect of the target treatment is therefore challenging.

Stage	Covid-19	Childhood Epilepsy	Autism
In many instances, evidence is not perfect and difficult decisions have to be made. Where treatments are innovative or life-changing, the whole multi-disciplinary team will usually meet to consider the available options, and how to advise the child or young person and family so that a shared decision can be made. Sometimes an ethics committee is involved. This is one of the most challenging areas of medicine and is underpinned by GMC guidance.[97, 98]	The UK has been internationally recognised for its Recovery Trial, led by Oxford University. This has recruited over 46,000 participants, and resulted in several treatments being approved. A key factor in this success was the willingness of patients to participate in these studies – with over 46,000 being recruited and consented.		

[97] General Medical Council (2020). Decision making and consent.
[98] National Institute for Health and Care Excellence (2021). Shared decision making.

Stage	Covid-19	Childhood Epilepsy	Autism
Service development and service improvement Central to any service improvement is the systematic and consistent collection of data on outcomes of treatment. There is a process of continuous service improvement as new presentations or variations on the original condition are recognised, diagnosis or screening improves and/or trials on new treatments or variations on existing treatments are ongoing. There should be consistent treatment protocols or guidelines in place, in order to make sense of variations in outcomes. Where possible, these should be compared between and across multiple different centres. As time passes, services need to be changed or extended based on patient need, and on what resources are needed to deliver the available treatments. They need to be accessible where the prevalence of the condition is highest. The relevant workforce to deliver the service needs to be recruited and trained, contingent on the type of treatments or therapy that is required.	Service development to manage Covid-19 has been on a scale unlike any normal new service development ever experienced. It has also demonstrated how other non-Covid services have had to evolve alongside, including the need for isolation, and/or PCR testing prior to routine clinical appointments, use of remote consultation and an array of other changes across the NHS. Continuous audit and monitoring of outcomes has resulted in major improvements in survival – for example, changing ventilation approach to include 'proning' (putting patients on their front while on the ventilator) and delaying fully intubated ventilation by giving mask ventilation for as long as possible.	Paediatric epilepsy is a good example of how a national approach can be taken to service improvement through the Epilepy12 programme.[99] This is a nationally co-ordinated audit which collects a standardised dataset, incorporating NICE standards, and is used to drive up standards of care for children and young people with epilepsy.	Improvement in autism services has been driven by the changing epidemiology, NICE standards, extensive training of the workforce and attempts to improve public understanding. Where previously diagnosis was undertaken in a few specialist centres, the rising waiting times and NICE standards on access, assessment and appropriate multi-professional provision have led to almost every community child development service having an autism assessment clinic or team. Services are able to self-assess against national standards to inform local improvement strategies.

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Review

Reconsidering Informed Consent for Trans-Identified Children, Adolescents, and Young Adults

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Abstract

In less than a decade, the western world has witnessed an unprecedented rise in the numbers of children and adolescents seeking gender transition. Despite the precedent of years of gender-affirmative care, the social, medical and surgical interventions are still based on very low-quality evidence. The many risks of these interventions, including medicalizing a temporary adolescent identity, have come into a clearer focus through an awareness of detransitioners. The risks of gender-affirmative care are ethically managed through a properly conducted informed consent process. Its elements—deliberate sharing of the hoped-for benefits, known risks and long-term outcomes, and alternative treatments—must be delivered in a manner that promotes comprehension. The process is limited by: erroneous professional assumptions; poor quality of the initial evaluations; and inaccurate and incomplete information shared with patients and their parents. We discuss data on suicide and present the limitations of the Dutch studies that have been the basis for interventions. Beliefs about gender-affirmative care need to be separated from the established facts. A proper informed consent process can both prepare parents and patients for the difficult choices that they must make and can ease professionals' ethical tensions. Even when properly accomplished, however, some clinical circumstances exist that remain quite uncertain.

Keywords: Informed consent | ethics | gender dysphoria | gender identity | detransition

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Introduction

Reconsideration of the meanings, purposes, indications, and processes of informed consent for transgender-identified youth is urgently needed. Parents of gender atypical children are considering social transition as early as preschool or grade school. Parents of preteens and teens are considering supporting their children's wishes to present in a new gender, take puberty blockers and cross-sex hormones, and plan for surgical alterations. College-aged youth are declaring new identities for the first time and obtaining hormones and surgery without their parents' knowledge.

When uncertain parents of children and teens consult their primary care providers, they are usually referred to specialty gender services. Parents and referring clinicians assume that specialists with "gender expertise" will undertake a thorough evaluation. However, the evaluations preceding the recommendation for gender transition are often surprisingly brief (Anderson & Edwards-Leeper, 2021) and typically lead to a recommendation for hormones and surgery, known as *gender-affirmative* treatment.

Despite the widely recognized deficiencies in the evidence supporting gender-affirmative interventions (National Institute for Health & Care Excellence, 2020a; 2020b), the process of obtaining informed consent from patients and their families has no established standard. There is no consensus about the requisite elements of evaluations, nor is there unanimity about how informed consent processes should be conducted (Byne et al., 2012). These two matters are inconsistent from practitioner to practitioner, clinic to clinic, and country to country.

Social transition, hormonal interventions, and surgery have profound implications for the course of the lives of young patients and their families. It is incumbent upon professionals that these consequences be thoroughly, patiently clarified over time prior to undertaking any element of transition. The informed consent process does not preclude transition; it merely educates the family about the state of the science underpinning the decision to transition. Social transition, hormones, and surgeries are unproven in a strict scientific sense, and as such, to be ethical, require a thorough and fully informed consent process.

Ethical Concerns About Inadequate Informed Consent

The concept of informed consent in medicine has roots in both ethical theory and law. The ethical foundation is centered in the principles of beneficence, justice, and respect for autonomy, while the legal issues have to do with questions of malpractice (Katz et al., 2016).

Patients consenting to treatment must meet age-based and decisional capacity requirements (Katz et al., 2016). Minors less than the age of consent participate in decision-making by providing *assent*—an agreement with the intervention. The limited maturational cognitive capacities of minors are the key reason why parents serve as the ethical and legal surrogates for medical decision-making, tasked with signing an informed consent document (Grootens-Wiegers, Hein, van den Broek, & de Vries, 2017).

The informed consent process consists of three main elements: a disclosure of information about the nature of the condition and the proposed treatment and its alternatives; an assessment of patient and caregiver understanding of the information and capacity for medical decision-making; and obtaining the signatures that signify informed consent has been obtained (Katz et al., 2016). The current expectation that clinicians and institutions are required to thoroughly inform their patients about the benefits, risks, and uncertainties of a particular treatment, as well as about alternatives, has a long legal history in the United States (Lynch, Joffe, & Feldman, 2018).

Ethical concerns about inadequate informed consent for trans-identified youth have several potentially problematic sources, including *erroneous assumptions* held by professionals; *poor quality of the evaluation process*; and *incomplete and inaccurate information* that the patients and family members are given.

These concerns are amplified by the *dramatic growth* in demand for youth gender transition witnessed in the last several years that has led to a perfunctory informed consent process. A rushed process does not allow for a proper discussion of not only the benefits, but the profound risks and uncertainties associated with gender transition, especially when gender transition is undertaken before mature adulthood.

a. *Dramatic growth in demand for services threatens true informed consent*

Gender identity variations were thought to be extremely rare a generation ago. While the incidence in youth had not been officially estimated, in adults it was 2-14 per 100,000 (American Psychiatric Association, 2013, p. 454). However, around 2006, the incidence among youth began to rise, with a dramatic increase observed in 2015 (Aitken et al., 2015, de Graaf, Giovanardi, Zitz, & Carmichael, 2018). Currently, 2-9% of U.S. high school students identify as transgender, while in colleges, 3% of males and 5% of females identify as gender-diverse (American College Health Association, 2021; Johns et al., 2019; Kidd et al., 2021).

Whereas previously most of the affected individuals identified as the opposite sex, there is now a growing trend toward identifying as *nonbinary*: neither male nor female or both male and female (Chew et al., 2020). A recent study reported that the majority of transgender-identifying youth (63%) now have a non-binary identity (Green, DeChants, Price, & Davis, 2021). Although the incidence of natal males asserting a trans identity in adolescence has significantly increased, the dramatic increase is driven primarily by the natal females requesting services (Zucker, 2017). Many suffer from significant comorbid mental health disorders, have neurocognitive difficulties such as ADHD or autism or have a history of trauma (Becerra-

Culqui et al., 2018; Kozlowska, McClure, et al., 2021).

The increase in rates of transgender identification is reflected in the numbers of youth seeking help from medical professionals. For example, according to data reported by the Tavistock gender clinic in the UK, in 2009, there were 51 requests for services (de Graaf et al., 2018); in 2019-2020, 2728 referrals were recorded—a 53-fold increase in just over a decade (Tavistock & Portman NHS Foundation Trust, 2020). The growing number of urban transgender health centers that have arisen in recent years (HRC, n.d.) reflects the increased demand for gender-related medical care among young people in North America Australia, and Europe.

This unprecedented increase has created pressure on institutions and practitioners to rapidly evaluate these youth and make recommendations about treatment. To respond to growing demand, an innovative *informed consent model of care* has been developed. Under this model, mental health evaluations are not required, and hormones can be provided after just one visit following the collection of a patient's or guardian's consent signature (Schulz, 2018). The provision of transition services under this model of care is available not just to those over 18, but for younger patients as well (Planned Parenthood League of Massachusetts, n.d.).

Although following the informed consent model of care for hormones and surgeries for youth may diminish clinicians' ethical or moral unease (Vrouenraets et al., 2020), we believe this model is the antithesis of true informed consent, as it jeopardizes the ethical foundation of patient autonomy. Autonomy is not respected when patients consenting to the treatment do not have an accurate understanding of the risks, benefits, and alternatives.

b. *Assumptions held by professionals influence the integrity of the informed consent process*

Gender-dysphoric children and teens can intensely occupy the belief that their lives will be immensely improved by transition. Clinicians who have embraced the gender-affirmative model of care operate on the assumption that children and teens know best what they need to be happy and productive (Ehrensaft, 2017). These professionals, responding to the youths' passionate pleas, see their role as validating the young person's fervent wishes for hormones and surgery and clearing the path for gender transition. In doing so, they privilege the ethical principle of respect for patient autonomy (Clark & Virani, 2021) over their obligations for beneficence and non-maleficence.

Many of the gender-affirmative clinicians subscribe to the theory of *minority stress* – the supposition that the frequently co-occurring psychiatric symptoms of gender-dysphoric individuals are a result of prejudice and discrimination brought about by gender non-conformity (Rood et al., 2016; Zucker, 2019), and that gender transition will ameliorate these symptoms. Some even claim that gender-affirmative care will successfully treat not only depression and anxiety but will also resolve neurocognitive deficits frequently present in gender-dysphoric individuals (Turban, 2018; Turban, King, Carswell, & Keuroghlian, 2020; Turban & van Schalkwyk, 2018). These latter assertions have proven controversial even among the proponents of gender-affirmative interventions (Strang et al., 2018; van der Miesen, Cohen-Kettenis, & de Vries, 2018). The minority stress theory as the sole explanatory mechanism for co-occurring mental health illness has also been questioned in light of the evidence that psychiatric symptoms frequently predate the onset of gender dysphoria (Bechard, VanderLaan, Wood, Wasserman, & Zucker, 2017; Kaltiala-Heino, Sumia, Työläjärvi, & Lindberg, 2015; Kozlowska, Chudleigh, McClure, Maguire, & Ambler, 2021). Other clinicians recognize the limits of gender-affirmative care and are aware that youth with underlying psychiatric issues are likely to continue to struggle post-transition (Kaltiala, Heino, Työläjärvi, & Suomalainen, 2020), but, unaware of alternative approaches such as gender-exploratory psychotherapy or watchful waiting (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Spiliadis, 2019), these well-meaning professionals continue to treat youth with gender-affirmative interventions despite lingering doubts.

It is common for gender-affirmative specialists to erroneously believe that gender-affirmative interventions are a *standard of care* (Malone, D'Angelo, Beck, Mason, & Evans, 2021; Malone, Hruz, Mason, Beck, et al:, 2021). Despite the increasingly widespread professional beliefs in the safety and efficacy of pediatric gender transition, and the endorsement of this treatment pathway by a number of professional medical societies, the best available evidence suggests that the benefits of gender-affirmative interventions are of very low certainty (Clayton et al., 2021; National Institute for Health & Care Excellence, 2020a; 2020b) and must be carefully weighed against the health risks to fertility, bone, and cardiovascular health (Alzahrani et al., 2019; Biggs, 2021; Getahun et al., 2018; Hembree et al., 2017; Nota et al., 2019). Recently, emphasis has also been placed on psychosocial risks and as yet unknown medical risks (Malone, D'Angelo, et al., 2021).

Five scientific observations question and refute the assumption that an individual's experience of incongruence of sex and gender identity is best addressed by supporting the newly assumed gender identity with psychosocial and medical interventions.

1. The most foundational aspect of the diagnoses of "gender dysphoria" (DSM-5) and "gender incongruence" (ICD-11), requisite for the provision of medical treatment, is in flux, as professionals disagree on whether the presence of distress is a key diagnostic criterion, as stated in the DSM-5, or is irrelevant, as is the case according to the latest ICD-11 criteria (American Psychiatric Association, 2013; World Health Organization, 2019). Further, these diagnoses have never been properly field-tested (de Vries et al., 2021).
2. There are no randomized controlled studies demonstrating the superiority of various affirmative interventions compared to alternatives. There isn't even agreement about which outcome measures would be ideal in such studies.
3. There are few long-term follow-up studies of various interventions using predetermined outcome measures at designated intervals. Studies that have been conducted are, at best, inconsistent. Higher quality studies with longer-follow-up fail to demonstrate durable positive impacts on mental health (Bränström & Pachankis, 2020a; 2020b).
4. Rates of post-transition desistance, increased mental suffering, increased incidence of physical illness, educational failure, vocational inconstancy, and social isolation have not been established.
5. Numerous cross-sectional and prospective studies of transgender adults consistently demonstrate a high prevalence of serious mental health and social problems as well as suicide (Asscheman et al., 2011; Dhejne et al., 2011). Controversies about how to deal with trans-identified youth must consider the well described vulnerabilities of transgender adults.

It is equally important to realize that to date, research about alternative approaches, such as psychotherapy or watchful waiting, shares the scientific limitations of the research of more invasive interventions: there are no control groups, nor is there systematic follow-up at predetermined intervals with predetermined means of measurement (Bonfatto & Crasnow, 2018; Churcher Clarke & Spiliadis, 2019; Spiliadis, 2019). Parents and patients need to be informed of this as well.

Perhaps the single most problematic assumption held by some gender clinicians is that the young patients have simply been "born in the wrong body." This assumption seemingly frees clinicians from having to contend with the ethical dilemmas of recommending body-altering interventions that are based on very low-quality evidence. Despite the principle of development that biology, psychosocial factors, and culture generate behavior, these clinicians may believe that atypical genders are created by biology. This reductionistic approach has been criticized repeatedly (Kendler, 2019).

While the origins of childhood or adolescent onset of gender incongruence have not yet been fully elucidated, brain studies of increasing technical sophistication have yet to demonstrate a distinct structure or pattern that accounts for an atypical gender identity, after statistically controlling for sexual orientation and exposure to exogenous hormones (Frigerio, Ballerini, & Valdés Hernández, 2021). Twin studies also demonstrate that while biology plays a role in one's experience of "gender incongruence," it is far from deterministic (Diamond, 2013).

A growing number of clinicians and researchers are noting that the dramatic rise of teens declaring a trans identity appears to be, at least in part, a result of peer influence (Anderson, 2022; Hutchinson, Midgen, & Spiliadis, 2020; Littman 2018; Littman, 2020; Zucker, 2019). Some have noted yet another influx of trans-identified youth emerging during the COVID lockdowns, and have hypothesized that increased isolation coupled with heavy internet exposure may be responsible (Anderson, 2022). While the research into the phenomenon of social influence as a contributor to trans identification of youth is still in its infancy, the possibility that clinicians are providing treatments with permanent consequences to address what may be transient identities in youth poses a serious ethical dilemma.

c. *Poor evaluations*

There is a growing recognition that rapid evaluations which disregard factors contributing to the development of gender dysphoria in youth are problematic. In November 2021, two-leaders of the World Professional Organization for Transgender Health (WPATH) warned the medical community that the "The mental health establishment is failing trans kids" (Anderson & Edwards-Leeper, 2021). Frequently, evaluations provided by gender clinicians may only ascertain the diagnosis of *gender dysphoria* (DSM-5) or its ICD-11 counterpart *gender incongruence*, and screen for conspicuous mental illness prior to recommending hormones and surgeries. These limited, abbreviated evaluations overlook, and as a result fail to address, the relevant issue of the forces that may have influenced the young person's current gender identity.

Confirming the young person's self-diagnosis of gender dysphoria or gender incongruence is easy. Clarifying the developmental forces that have influenced it and determining an appropriate intervention are not. Contextualizing these forces involves an understanding of child and adolescent developmental processes, childhood adversity, co-existing physical and cognitive disadvantages, unfortunate parental or family circumstances (Levine, 2021), as well as the role of social influence (Anderson, 2022; Anderson & Edwards-Leeper, 2021; Littman, 2018; 2021).

The poor quality of mental health evaluations has been a point of significant discontent for a growing number of parents of gender-dysphoric youth. Increasingly, parents have formed dozens of support groups in North America, Europe, Australia and New Zealand, united in their objections to the idea that the best or the only treatment for their gender-dysphoric children is affirmation (Genspect, 2021). These distressed parents, recognizing that their son or daughter may eventually decide to present to others as a trans person, want a psychotherapeutic investigation to understand what contributed to the development of this identity and an exploration of noninvasive treatment options. Frequently, they cannot find anyone in their community who does not recommend immediate affirmation.

The American Academy of Pediatrics' Committee of Bioethics recognizes that "parents...are better situated than others to understand the unique needs of their children and to make appropriate, caring decisions regarding their children's health care" (Katz et al., 2016). The plight of the families unable to find specialists capable of conducting thorough evaluations draws attention to the widespread acceptance of medical interventions for gender-dysphoric youth as the first line of treatment. The problem is that such care has been established through precedent rather than through scientific demonstrations of its efficacy. We contend that parents and patients have a right to know this, and that it is the professionals' responsibility and obligation to inform them of the state of knowledge in this arena of care.

d. *Incorrect information shared*

In sharing the information with patients and families, two key areas of uncertainty must be emphasized. The first one is the uncertain permanence of a child's or an adolescent's gender identity (Littman, 2021; Ristori & Steensma, 2016; Singh, Bradley, & Zucker, 2021; Vandenbussche, 2021; Zucker, 2017). The second is the uncertain long-term physical and psychological health outcomes of gender transition (National Institute for Health & Care Excellence, 2020a; 2020b). Unfortunately, gender specialists are frequently unfamiliar with, or discount the significance of, the research in support of these two concepts. As a result, the informed consent process rarely adequately discloses this information to patients and their families.

Problematically, it is common for gender clinicians to emphasize the risk of suicide if a young person's wish to transition gender is not immediately fulfilled. There is a significant amount of misinformation surrounding the question of suicidality of trans-identified youth (Biggs, 2022). Providers of gender-affirmative care should be careful not to unwittingly propagate misinformation regarding suicide to parents and youths. They should also be reminded that any conversations about suicide should be handled with great care, due to its socially contagious nature (Bridge et al., 2020; HHS, 2021).

i. High rate of desistance/natural resolution of gender dysphoria in children is not disclosed

There have been eleven research studies to date indicating a high rate of resolution of gender incongruence in children by late adolescence or young adulthood without medical interventions (Cantor, 2020; Ristori & Steensma, 2016; Singh et al., 2021). An attempt has been made to discount the applicability of this research, suggesting that the studies were based on merely gender non-conforming, rather than truly gender-dysphoric, children (Temple Newhook et al., 2018). However, a reanalysis of the data prompted by this critique confirmed the initial finding: Among children meeting the diagnostic criteria for "Gender Identity Disorder" in DSM-IV (currently "Gender Dysphoria in DSM-5), 67% were no longer gender-dysphoric as adults; the rate of natural resolution for gender dysphoria was 93% for children whose gender dysphoria was significant but subthreshold for the DSM diagnosis (Zucker, et al., 2018). It should be noted that high resolution of childhood-onset gender dysphoria had been recorded before the practice of social transition of young children was endorsed by the American Academy of Pediatrics (Rafferty et al., 2018). It is possible that social transition will predispose a young person to persistence of transgender identity long-term (Zucker, 2020).

The information regarding the resolution of gender dysphoria among those with adolescent-onset gender dysphoria, which is currently the predominant presentation, is less clear. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle, 2020; Littman, 2021; Vandenbussche, 2021). Previously, the rate of detransition and regret was reported to be very low, although these estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo, 2018). However, in the last several years since gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

According to a recent study from a UK adult gender clinic, 6.9% of those treated with gender-affirmative interventions detransitioned within only 16 months of starting treatment, and another 3.4% had a pattern of care suggestive of detransition, yielding a rate of probable detransition in excess of 10%. Another 21.7% of patients disengaged from the clinic without completing their treatment plan (Hall, Mitchell, & Sachdeva, 2021). While some of these individuals later reengaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for the average 5 years (17 months-10 years) prior to discontinuing.

Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: "Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields" (Boyd, Hackett, & Bewley, 2022 p.15). Indeed, given that regret may take up to 8-11 years to materialize (Dhejne, Öberg, Arver, & Landén, 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but two recently published studies examining detransitioner experiences report that detransitioners from the recently-transitioning cohorts feel they had been rushed to medical gender-affirmative interventions with irreversible effects, often without the benefit of appropriate, or in some instances any, psychologic exploration (Littman, 2021; Vandenbussche, 2021).

Clinicians should also disclose to patients and parents that there is no test which can accurately predict who will persist in their transgender identification upon reaching mature adulthood (Ristori & Steensma, 2016). Families should be made aware that a period of strong cross-sex identification in childhood is commonly associated with future homosexuality (Korte et al., 2008). Research in desistance confirms that the majority of youth whose gender dysphoria resolves naturally do indeed grow up to be gay, lesbian, or bisexual adults (Cantor, 2020, Appendix; Singh et al., 2021).

ii. Implications of very low-quality evidence that underlies the practice of pediatric gender transition are not explained

The evidence underlying the practice of pediatric gender transition is widely recognized to be of very low quality (Hembree et al., 2017). In 2020, the most comprehensive systematic review of evidence to date, commissioned by the UK National Health System (NHS) and conducted by the National Institute for

Health and Care Excellence (NICE), concluded that the evidence for both puberty blocking and cross-sex hormones is of very low certainty (National Institute for Health & Care Excellence, 2020a; 2020b).

According to the NICE review of evidence for puberty blockers, the studies "are all small, uncontrolled observational studies, which are subject to bias and confounding, and are of very low certainty as assessed using modified GRADE [Grading of Recommendations, Assessment, Development and Evaluations]. All the included studies reported physical and mental health comorbidities and concomitant treatments very poorly" (National Institute for Health & Care Excellence, 2020a, p.13). NICE reached similar conclusions regarding the quality of the evidence for cross-sex hormones (National Institute for Health & Care Excellence, 2020b).

Problematically, the implications of administering a treatment with irreversible, life-changing consequences based on evidence that has an official designation of "very low certainty" according to modified GRADE is rarely discussed with the patients and the families. GRADE is the most widely adopted tool for grading the quality of evidence and for making treatment recommendations worldwide. GRADE has four levels of evidence, also known as certainty in evidence or quality of evidence: very low, low, moderate, and high (BMJ Best Practice, 2021). When evidence is assessed to be "very low certainty," there is a high likelihood that the patients will not experience the effects of the proposed interventions (Balshem et al., 2011).

In the context of providing puberty blockers and cross-sex hormones, the designation of "very low certainty" signals that the body of evidence asserting the benefits of these interventions is highly unreliable. In contrast, several negative effects are quite certain. For example, puberty blockade followed by cross-sex hormones leads to infertility and sterility (Laidlaw, Van Meter, Hruz, Van Mol, & Malone, 2019). Surgeries to remove breasts or sex organs are irreversible. Other health risks, including risks to bone and cardiovascular health, are not fully understood and are uncertain, but the emerging evidence is alarming (Alzahrani et al., 2019; Biggs, 2021).

iii. The question of suicide is inappropriately handled

Suicide among trans-identified youth is significantly elevated compared to the general population of youth (Biggs, 2022; de Graaf et al., 2020). However, the "transition or die" narrative, whereby parents are told that their only choice is between a "live trans daughter or a dead son" (or vice-versa), is both factually inaccurate and ethically fraught. Disseminating such alarmist messages hurts the majority of trans-identified youth who are not at risk for suicide. It also hurts the minority who are at risk, and who, as a result of such misinformation, may forgo evidence-based suicide prevention interventions in the false hopes that transition will prevent suicide.

The notion that trans-identified youth are at alarmingly high risk of suicide usually stems from biased online samples that rely on self-report (D'Angelo et al., 2020; James et al., 2016; The Trevor Project, 2021), and frequently conflates suicidal thoughts and non-suicidal self-harm with serious suicide attempts and completed suicides. Until recently, little was known about the actual rate of suicide of trans-identified youth. However, a recent analysis of data from the biggest pediatric gender clinic in the world, the UK's Tavistock, found the rate of completed youth suicides to be 0.03% over a 10-year period, which translates into the annual rate of 13 per 100,000 (Biggs, 2022). While this rate is significantly elevated compared to the general population of teens, it is far from the epidemic of trans suicides portrayed by the media.

The "transition or die" narrative regards suicidal risk in trans-identified youth as a different phenomenon than suicidal risk among other youth. Making them an exception falsely promises the parents that immediate transition will remove the risk of suicidal self-harm. Trans patients themselves complain about the so-called "trans broken arm syndrome" – a frustrating pattern whereby physicians "blame" all the problems the patients are experiencing on their trans status, and a result, fail to perceive and respond to other sources of distress (Paine, 2021). Clinicians caring for trans-identified youth should be reminded that suicide risk in all patients is a multi-factorial phenomenon (Mars et al., 2019). To treat trans youths' suicidality as an exception is to deny them evidence-based care.

A recent study of three major youth clinics concluded that suicidality of trans-identifying teens is only somewhat elevated compared to that of youth referred for mental health issues unrelated to gender identity struggles (de Graaf et al., 2020). Another study found that transgender-identifying teens have relatively similar rates of suicidality compared to teens who are gay, lesbian and bisexual (Toomey, Syvertsen, & Shramko, 2018). Depression, eating disorders, autism spectrum conditions, and other mental health conditions commonly found in transgender-identifying youth (Kaltiala-Heino, Bergman, Työläjärvi, & Frisen, 2018; Kozlowska, McClure, et al., 2021; Morandini, Kelly, de Graaf, Carmichael, & Dar-Nimrod, 2021) are all known to independently contribute to the probability of suicide (Biggs, 2022; Simon & VonKorff, 1998; Smith, Zuromski, & Dodd, 2018).

The "transition or suicide" narrative falsely implies that transition will prevent suicides. Clinicians working with trans-identified youth should be aware that although in the short-term, gender-affirmative interventions can lead to improvements in some measures of suicidality (Kaltiala et al., 2020), neither hormones nor surgeries have been shown to reduce suicidality in the long-term (Bränström & Pachankis, 2020a; 2020b). Alarmingly, a longitudinal study from Sweden that covered more than a 30-year span found that adults who underwent surgical transition were 19 times more likely than their age-matched peers to die by suicide overall, with female-to-male participants' risk 40 times the expected rate (Dhejne et al., 2011, Table S1). Another key longitudinal study from the Netherlands concluded that suicides occur at a similar rate at all stages of transition, from pretreatment assessment to post-transition follow-up (Wiepjes et al., 2020). The data from the Tavistock clinic also did not show a statistically significant difference between completed suicides in the "waitlist" vs. the "treated" groups (Biggs, 2022). Luckily, in both groups, completed suicides were rare events (which may have been responsible for the lack of statistical significance). Thus, we consider the "transition or die" narrative to be misinformed and ethically wrong.

In our experience working with trans-identified youth, an adolescent's suicidality can sometimes arise as a response to parental distress, resistance, skepticism, or wish to investigate the forces shaping the new gender identity before social transition and hormone therapy. When mental health professionals or other healthcare providers fail to recognize the legitimacy of parental concerns, or label the parents as transphobic, this only tends to intensify intrafamilial tension. Clinicians would be well-advised that gender transition is not an appropriate response to suicidal intent or threat, as it ignores the larger mental health and social context of the young patient's life—the entire family is often in crisis. Trans-identified adolescents should be screened for self-harm and suicidality, and if suicidal behaviors are present, an appropriate evidence-based suicide prevention plan should be put in place (de Graaf et al., 2020).

The Dutch Study: the questionable basis for the gender affirmative model of care for youth

Few practitioners of gender-affirmative interventions, and even fewer patients and families, realize that the foundation of the practice of medically transitioning minors stems from a single Dutch proof of concept study, the outcomes of which were documented in two publications (de Vries, Steensma, Doreleijers, Cohen, & Kettenis, 2011; de Vries et al., 2014). The former (de Vries et al., 2011) reported on cases who underwent puberty blockade, while the latter (de Vries et al., 2014) reported on a subset of the cases who completed surgeries.

The Dutch study subjects' high level of psychological functioning at 1.5 years after surgery, which was the study end point, was an impressive feat. However, both of the studies suffer from a high risk of bias due to their study design, which is effectively a non-randomized case series—one of the lowest levels of evidence (Mathes & Pieper, 2017; National Institute for Health & Care Excellence, 2020a). In addition, the studies suffer from limited applicability to the populations of adolescents presenting today (de Vries, 2020). The interventions described in the study are currently being applied to adolescents who were not cross-gender identified prior to puberty, who have significant mental health problems, as well as those who have non-binary identities—all of these presentations were explicitly disqualified from the Dutch protocol. Despite these limitations, the Dutch clinical experiment has become the basis for the practice of medical transition of minors worldwide and serves as the basis for the recommendations outlined in the 2017 Endocrine Society guidelines (Hembree et al., 2017).

We contend that the Dutch studies have been misunderstood and misrepresented as providing evidence of the safety and efficacy of these interventions for all youth. It is important that both the strengths and the weaknesses of these two studies are understood, as to date, the Dutch experience presents the best available evidence behind the practice of pediatric gender transition.

Rationale for pediatric transition

Prior to the 1990s, gender transitions were typically initiated in mature adults (Dhejne et al., 2011)

However, it was noted that particularly for natal male patients, hormonal and surgical interventions failed to achieve satisfactory results, and patients had a "never disappearing masculine appearance" (Delemarre-van de Waal & Cohen-Kettenis, 2006). The lack of adequate cosmetic outcomes was thought to contribute to the frequently disappointing outcomes of medical gender transition, with persistently high rates of mental illness and suicidality post-transition (Delemarre-van de Waal & Cohen-Kettenis, 2006; Dhejne et al., 2011; Ross & Need, 1989).

In the mid 1990s, a team of Dutch researchers hypothesized that by carefully selecting a subset of gender-dysphoric children who would likely be transgender-identified for the rest of their lives, and by medically intervening before puberty left an irreversible mark on their bodies, the cosmetic outcomes would be improved—and as a result, mental health outcomes might be improved (Gooren & Delemarre-van de Waal, 1996).

Mixed study findings

In 2014, the Dutch research team published a key longitudinal study of mental health outcomes of 55 youths who completed medical and surgical transition (de Vries et al., 2014). The 2014 paper (sometimes referred to as the "Dutch study") reported that for youth with severe gender dysphoria that started in early childhood and persisted into mid-adolescence, a sequence of puberty blockers, cross-sex hormones, and breast and genital surgeries (including a mandatory removal of the ovaries, uterus and testes), with ongoing extensive psychological support, was associated with positive mental health and overall function 1.5 years post-surgery.

While the Dutch reported resolution of gender dysphoria post-surgery in study subjects, the reported psychological improvements were quite modest (de Vries et al., 2014). Of the 30 psychological measurements reported, nearly half showed no statistically significant improvements, while the changes in the other half were marginally clinically significant at best (Malone, D'Angelo, et al., 2021). The scores in anxiety, depression, and anger did not improve. The change in the Children's Global Assessment Scale, which measures overall function, was one of the most impressive changes—however it too remained in the same range before and after treatment (de Vries et al., 2014).

Problematic discordance between reduced gender dysphoria and lack of meaningful improvements in psychological measures

The discordance between the marked reduction in gender dysphoria, as measured by the UGDS (Utrecht Gender Dysphoria Scale), and the lack of meaningful changes in psychological function using standard measures, warrants further examination. There are three plausible explanations for this lack of agreement. Any one of these three explanations calls into question the widely assumed notion that the medical interventions significantly improve mental health or lessen or eradicate gender dysphoria.

One possible explanation is that gender dysphoria as measured by UGDS, and psychological function as measured by most standard instruments, are not correlated. This contradicts the primary rationale for providing gender-affirmative treatments for youth (which is to improve psychological health and functioning), and if true, ethically threatens these medical interventions. The other plausible explanation stems from the high psychological function of all the subjects at baseline; the subjects were selected because they were free from significant mental health problems (de Vries et al., 2014). As a result, there was little opportunity to meaningfully improve. This explanation highlights a key limitation in applying the study's results to the majority of today's gender-dysphoric youth, who often present with a high burden of mental illness (Becerra-Culqui et al., 2018; Kozlowska, McClure, et al., 2021). The study cannot be used as evidence that these procedures have been proven to improve depression, anxiety, and suicidality.

A third possible explanation for the discordance between only minor changes in psychological outcomes but a significant drop in gender dysphoria comes from a close examination of the UGDS scale itself and how it was used by the Dutch researchers. This 12-item scale, designed by the Dutch to assess the severity of gender dysphoria and to identify candidates for hormones and surgeries, consists of "male" (UGDS-aM) and "female" (UGDS-aF) versions (Iliadis et al., 2020). At baseline and after puberty suppression, biological females were given the "female" scale, while males were given the "male" scale. However, post-surgery, the scales were flipped: biological females were assessed using the "male" scale, while biological males were assessed on the "female" scale (de Vries et al., 2014). We maintain that this handling of the scales may have at best obscured, and at worst, severely compromised the ability to meaningfully track how gender dysphoria was affected throughout the treatment.

Consider this example. At baseline, a gender-dysphoric biological female would rate items from the "female" scale such as: "I prefer to behave like a boy" (item 1); "I feel unhappy because I have to behave like a girl" (item 6) and "I wish I had been born a boy" (item 12). Positive answers to these questions would have contributed to a high baseline gender dysphoria score. After the final surgery, however, this same patient would be asked to rate items from the "male" scale, including the following: "My life would be meaningless if I had to live as a boy" (item 1); "I hate myself because I am a boy" (item 6) and "It would be better not to live than to live as a boy" (item 12). A gender-dysphoric female would not endorse these statements (at any stage of the intervention), which would lead to a lower gender dysphoria score.

Thus, the detected drop in the gender dysphoria scores for biological males and females may have had less to do with the success of the interventions, and more to do with switching the scale from the "female" to the "male" version (and vice-versa) between the baseline and post-surgical period. This, too, may explain why no changes in gender dysphoria were noted between baseline and the puberty blockade phase, and were only recorded after the final surgery, when the scale was switched.

It must be considered that had the researchers administered the "flipped" scale earlier, at the completion of the puberty blocker stage, UGDS scale could have registered a reduction in gender dysphoria. Likewise, however, one must consider the possibility that had *both sets of scales* been administered to the same individual at baseline, a "reduction" in gender dysphoria could have been registered upon switching of the scale, *well before any interventions began*. The question here is whether the diminishment of quantitative measures of gender dysphoria is largely an artifact of what scale was used.

It must be noted that the UGDS measure has been demonstrated only to effectively differentiate between clinically referred gender-dysphoric individuals, non-clinically referred controls, and participants with disorders of sexual development, and was not designed to detect changes in gender dysphoria during treatment (Steensma, McGuire, Kreukels, et al. 2013). The presence of items such as "I dislike having erections" (item 11, UGDS-aM), which would have to be rated by birth-females, and "I hate menstruating because it makes me feel like a girl (item 10, UGDS-aF), which would be presented to birth-males, neither of which could be meaningfully rated by either at any stage of the interventions, further illustrates that UGDS has questionable validity for the purpose of detecting meaningful changes in gender dysphoria as a result of medical and surgical treatment.

The updated UGDS scale (UGDS-GS), developed by the Dutch after the publication of their seminal study, has eliminated the two-sex version of the scale in favor of a single battery of questions applicable to both sexes (McGuire et al., 2020). This change may lead to a more reliable measurement of treatment-associated changes in future research. Other gender dysphoria scales also exist (Hakeem, Črnčec, Asghari-Fard, Harte, & Eapen, 2016; Iliadis et al., 2020) and may or may not be better suited for the purposes of measuring the impact of medical interventions on underlying gender distress. Gender dysphoria, of course, may also prove to be a more complex concept than can be measured by any scale.

Other limitations

The two Dutch studies were conducted without a control group (de Vries et al., 2011; de Vires et al., 2014). Nor could the researchers control for mental health interventions, which all the subjects received in addition to hormones and surgery. The Dutch only evaluated mental health outcomes and did not assess physical health effects of hormones and surgery. The sample size was small: the final study reported the outcomes of only 55 children, and as few as 32 were evaluated on key measures of psychological outcomes.

It is important to realize that the Dutch sample was carefully selected, which introduced a source of bias, and also challenges the study's applicability. From the 196 adolescents initially referred, 111 were considered eligible to start puberty blockers, and of this group, only the 70 most mature and mentally stable who proceeded to cross-sex hormones were included in the study (de Vries et al., 2011). Of note, 97% of the selected cases were attracted to members of their natal sex at baseline. All were cross-sex identified, with no cases of nonbinary identities. The final study only followed 55, rather than the original 70 cases, further excluding from reporting the outcomes of subjects who had experienced adverse events, including: one death from surgery-related complications and three cases of obesity and diabetes that rendered subjects ineligible for surgery. Three more subjects refused to be contacted or dropped out of care, which may mask adverse outcomes (de Vries et al., 2014).

There is no knowledge of the fate of 126 patients who did not participate in the Dutch study. Longer term outcomes of the subjects who did participate are lacking. We are aware of only one case of long-term follow-up for a female-to-male patient treated by the Dutch team in the 1990s. The case study describing the subject's functioning at the age of 33 found that the patient did not regret gender transition. However, he reported struggling with significant shame related to the appearance of his genitals and to his inability to sexually function; had problems maintaining long-term relationships; and experienced depressive symptoms (Cohen-Kettenis, Schagen, Steensma, de Vries, & Delemarre-van de Waal, 2011). Notably, these problems had not yet emerged when the same patient was assessed at the age of 20, when he reported high levels of satisfaction in general, and was "very satisfied with the results [of the metoidioplasty]" in particular (Cohen-Kettenis & van Goozen, 1998, p.248). Since the last round of psychological outcomes of the individuals in the Dutch study was obtained when the subjects were around 21 years of age (de Vries et al., 2014), it raises questions how they will fare during the decade when new developmental tasks, such as career development, forming long-term intimate relationships and friendships, or starting families come into focus.

As to the unknown outcomes of the patients rejected by the Dutch protocol, one study did report on 14 adolescents who sought gender reassignment in the same clinic, but were disqualified from treatment due to "psychological or environmental problems" (Smith, Van Goozen, & Cohen-Kettenis, 2001, p. 473). The study found that at follow-up 1-7 years after the original application, 11 of the 14 no longer wished to transition, and 2 others only slightly regretted not transitioning (Malone, D'Angelo, et al., 2021; Smith et al., 2001). This further underscores the importance of conducting research utilizing control groups and following the subjects for an extended period.

A recent attempt to replicate the results of the first Dutch study (de Vries et al., 2011) found no demonstrable psychological benefit from puberty blockade, but did find that the treatment adversely affected bone development (Carmichael et al., 2021). The final Dutch study (de Vries et al., 2014) has never been attempted to be replicated with or without a control group.

The scaling of the Dutch Protocol beyond original indications

The medical and surgical sequence of Dutch protocol has been aggressively scaled worldwide without the careful evaluations and vetting practiced by the Dutch. The protocol's original investigators have recently expressed concern that the interventions they described have been widely adopted on four continents without several of the protocol's essential discriminatory features (de Vries, 2020).

The extensive multi-year multidisciplinary evaluations of the children have been abbreviated or simply bypassed. The medical sequence is routinely used for children with post-pubertal onset of transgender identities complicated by mental health comorbidities (Kaltiala-Heino et al., 2018), and not just for those high-functioning adolescents with persistent early life cross-identifications, as was required by the Dutch protocol (de Vries & Cohen-Kettenis, 2012). Further, it has become increasingly common to socially transition children before puberty (Olson, Durwood, DeMeules, & McLaughlin, 2016), even though this was explicitly discouraged by the Dutch protocol at the time (de Vries & Cohen-Kettenis, 2012).

In addition, medical transition is frequently initiated much earlier than recommended by the original protocol (de Vries & Cohen-Kettenis, 2012). The authors of the protocol were aware that most children would have a spontaneous realignment of their gender identity with sex by going through early- to mid-stages of puberty (Cohen-Kettenis, Delemarre-van de Waal, & Gooren, 2008). The average age of initiating puberty blockade in the Dutch study was around 15. In contrast, currently the age limit has been lowered to the age of Tanner stage II, which can occur as early as 8-9 years (Hembree et al., 2017). Irreversible cross-sex hormones, initiated in the Dutch study at the average age of nearly 17, are currently commonly prescribed to 14-year-olds, and this lower age threshold has been recommended by WPATH Standard of Care 8 draft, the final version of which is due to be released in early 2022. The fact that children are transitioned before their identity is tested against the biological reality and before natural resolution of gender dysphoria has had a chance to occur is a major deviation from the original Dutch protocol. Systematic follow-up, reassessments, and tracking and publishing of outcomes are not performed.

As the lead Dutch researchers have begun to call for more research into the novel presentation of gender dysphoria in youth (de Vries, 2020; Voorzij, 2021) and question the wisdom of applying the hormonal and surgical treatment protocols to the newly presenting cases, many recently educated gender specialists mistakenly believe that the Dutch protocol proved the concept that its sequence helps all gender-dysphoric youth. Although aware of the Dutch study's importance, they seem to be unaware of its agreed upon limitations, and the Dutch clinicians' own discomfort that most new trans-identified adolescents presenting for care today significantly differ from the population the Dutch had originally studied. These facts, of course, underscore the need for a robust informed consent process.

The recommendations for informed consent process for children, adolescents, and young adults

Consent for all stages of gender transition should be explicit, not implied

Noninvasive medical care or care that carries little risk of harm does not require a signed informed consent document; rather, consent is implied through the act of a patient presenting for care. For example, when a parent brings in a child for a skin laceration or abscess, consent for sutures or simple incision and drainage is implied. Similarly, when a child presents with pneumonia and is hospitalized, consent for chest x-ray, IV fluids, and antibiotics is also implied. It is assumed that patients or their guardians agree to the interventions and understand the benefits and risks. When risks are greater, such as prior to surgery, chemotherapy, or another invasive procedure, an informed consent document is signed. Such situations require an explicit, or express informed consent.

In the context of interventions for gender dysphoria or gender incongruence, the uncertainties associated with puberty blocking, cross-sex hormones, and gender-affirmative surgeries are well-recognized (Manrique et al., 2018; National Institute for Health & Care Excellence, 2020a; 2020b; Wilson et al., 2018). In these cases, consent should be explicit rather than implied because of the complexity, uncertainty, and risks involved.

Informed consent for social transition represents a gray area. Evidence suggests that social transition is associated with the persistence of gender dysphoria (Hembree et al., 2017; Steensma, McGuire, Kreukels, Beekman, & Cohen-Kettenis, 2013). This suggests that social gender transition is a form of a psychological intervention with potential lasting effects (Zucker, 2020). While the causality has not been proven, the possibility of iatrogenesis and the resulting exposure to the risks of future medical and surgical gender dysphoria treatments, qualifies social gender transition for explicit, rather than implied, consent.

Full unbiased disclosure of benefits, risks and alternatives is requisite

When mental health professionals are involved in evaluations and recommendations, the informed consent process begins either as part of an extended evaluation or is integrated in a psychotherapeutic process, separately or together, with the parents and patient. When pediatricians, nurse practitioners, or primary care physicians perform the initial evaluation, the informed consent process is more likely to be labeled as such in a briefer series of meetings.

In all settings, the informed consent discussions for gender-affirmative care should include three central ideas:

1. The decision to initiate gender transition may predispose the child to persist in their transgender identity long-term.
2. Many of the physical changes contemplated and undertaken are irreversible.
3. Careful long-term studies have not been done to verify that these interventions enable better physical and mental health or improved social functioning, or that they do not cause harm.

The informed consent process, culminating with a signed document, signifies that parents and patient have been educated about the short- and long-term risks, benefits and uncertainties associated with all relevant stages of the gender-affirmative interventions. The process must also inform the patients and families about the full range of alternative treatments, including the choice of not socially or medically treating the child's or adolescent's current state of gender/body incongruence.

Decisional capacity to consent needs to be assessed and family should be involved

Trans-identified youth typically present themselves as strongly desiring hormones and ultimately, surgery. It should not be assumed that their eagerness is matched with the capacity to carefully consider the consequences of their realized desires. Trans-identified youth younger than the age of consent should be part of the informed consent process, but they may not be mature enough to recognize or admit their concerns about the proposed intervention. For this reason, it is the parents who, after careful consideration, are responsible for signing an informed consent document.

The issue of the exact age at which adolescents are mature enough to consent to gender transition has proven contentious: courts have been asked to decide about competence to consent to gender-affirmative hormones for youth in the United Kingdom and Australia (Ouliaris, 2021). In the United States, the legal age for medical consent for gender-affirmative interventions varies by state.

When patients are age 18 and older, and in some jurisdictions as young as age 15 (Right to medical or dental treatment without parental consent, 2010), they do not legally require parental approval for medical procedures. But because an individual's change of gender has profound implications for parents, siblings, and other family members, it is usually prudent for clinicians to seek their input directly or indirectly during the informed consent process. This is done by requesting a meeting with the parents.

A recent study by a Dutch research team attempted to evaluate the decisional capacity of adolescents embarking on gender transition (Vrouenraets, de Vries, de Vries, van der Miesen, & Hein, 2021). The researchers administered the MacCAT-T tool, comprised of the *understanding*, *appreciating*, *reasoning*, and *expressing a choice* domains, to 74 adolescents who were 14.7 years old on average (with the minimum age of 10). They concluded that the adolescents were competent to consent to starting pubertal suppression, calling for similar research for the <12 group, particularly because "birth-assigned girls ... may benefit from puberty suppression as early as 9 years of age" (Vrouenraets et al., 2021 p.7).

This study suffers from two significant limitations involving the MacCAT-T tool. It was never designed for children. Rather, it was designed to assess medical consent capacities of adults suffering from conditions such as dementia, schizophrenia, and other psychiatric disorders. There is a fundamental lack of equivalency between consenting to treatment by adults with cognitive impairments and obtaining consent from healthy children whose age-appropriate cognitive capacities are intact, but who lack the requisite life experiences to consent to profound life-changing medical interventions. We doubt, for example, whether even highly intelligent children who have not had sexual experiences can meaningfully comprehend the loss of future sexual function and reproductive abilities.

In addition, even for adults, the MacCAT-T tool has been criticized for its exclusive focus on cognitive aspects of capacity, failing to account for the non-cognitive aspects such as values, emotions and other biographic and context specific aspects inherent in the complexity of the decision process in real life (Breden & Vollmann, 2004). Children's values and emotions undergo tremendous change during the process of maturation.

The authors' conclusion about their young patients' competence to consent should be compared with what a panel of judges wrote in the challenge to the Tavistock treatment protocol (Bell v Tavistock, 2020):

> ...the clinical intervention we are concerned with here is different in kind to other treatments or clinical interventions. In other cases, medical treatment is used to remedy, or alleviate the symptoms of, a diagnosed physical or mental condition, and the effects of that treatment are direct and usually apparent. The position in relation to puberty blockers would not seem to reflect that description. [para 135]
> ...we consider the treatment in this case to be in entirely different territory from the type of medical treatment which is normally being considered. [para 140]
> ... the combination here of lifelong and life changing treatment being given to children, with very limited knowledge of the degree to which it will or will not benefit them, is one that gives significant grounds for concern. [para 143]

It seems clear that perceptions of children as young as 10 years of age as medically competent vary by country, state, and the institution where the doctor works, and, by clinicians' beliefs about the long-term benefits of these interventions. We maintain that the claim that children can consent to extremely life-altering intervention is fundamentally a philosophical claim (Clark & Virani, 2021). Our view in this matter is that consent is primarily a parental function.

Informed consent should be viewed as a process rather than an event

Most institutions that care for transgender-identified individuals have devised obligatory consent forms that outline the risks and uncertainties of hormonal and surgical gender-affirmative interventions. However, the requisite signatures are frequently collected in a perfunctory manner (Schulz, 2018), akin to signatures collected ahead of a common surgical procedure. The purpose of such informed consent documents appears to be to protect practitioners from lawsuits, rather than attend to the primary ethical foundation of the process.

Although obtaining the signatures is important, the signed document should signify that the process of informed consent has been undertaken over an extended time period and is not simply quickly completed (Vrouenraets et al., 2021). We believe the latter approach poses an ethical concern (Levine, 2019).

The internal dynamics of the trans-identified young person and their families vary considerably. Parental capacities, their private marital and intrafamilial relationships, their cultural awareness, religious and political sensibilities all influence the amount of time necessary to undertake a thorough informed consent process. It is not prudent to suggest a specific duration for the process of informed consent, other than to emphasize that it requires a slow, patient, thoughtful question and answer period as the parents and patient contemplate the meaning of what is known and unknown and whether to embark on alternative approaches to the management of gender dysphoria before the age of full neurological maturity has been reached, mental health comorbidities have been addressed, and a true informed consent by the patient is more likely.

Final thoughts

Sixty years of experience providing medical and surgical assistance to transgender-identified persons have seen many changes in who is treated, when they are treated, and how they are treated. Today, the emphasis has shifted to the treatment of the unprecedented numbers of youth declaring a trans identity. As adolescents pursue social, medical, and surgical interventions, health care providers may experience unease about patients' cognitive and emotional capacities to make decisions with life-changing and enduring consequences. An unrushed informed consent process helps the provider, the parents, and the patient.

Three issues tend to obscure the salience of informed consent: conspicuous mental health problems, uncertainty about the minor's personal capacity to understand the irreversible nature of the interventions, and parental disagreement. Physical and psychiatric comorbidities can contribute to the formation of a new identity, develop as its consequence, or bear no connection to it. Assessing mental health and the minor's functionality is one of the reasons why rapid affirmative care may be dangerous for patients and their families. For example, when situations involve autism, learning disorders, sexual abuse, attachment problems, trauma, separation anxiety, previous depressed or anxious states, neglect, low IQ, past psychotic illness, eating disorders or parental mental illness, clinicians must choose between ignoring these potentially causative conditions and comorbidities and providing appropriate treatment before affirmative care (D'Angelo et al., 2020).

For youth less than the age of majority, informed consent via parents provides a legal route for treatment but it does not make the decision to socially transition, provide hormones, or surgically remove breasts or testes less fraught with uncertainty. The best that health professionals can do is to ensure that the consent process informs the patient and parents of the current state of science, which is sorely lacking in quality research. It is the professionals' responsibility to ensure that the benefits patients and parents seek, and the risks they are assuming, are clearly appreciated as they prepare to make this often-excruciating decision.

Young people who have reached the age of majority, but who have not reached full maturation of the brain represent a unique challenge. It is well-recognized that brain remodeling proceeds through the third decade of life, with the prefrontal cortex responsible for executive function and impulse control the last to mature (Katz et al., 2016). The growing number of detransitioners who had been old enough to legally consent to transition, but who no longer felt they were transgender upon reaching their mid-20's, raises additional concerns about this vulnerable age group (Littman, 2021; Vandenbussche, 2021).

When the clinician is uncertain whether a young person is competent to comprehend the implications of the desired treatment—that is, when informed consent cannot inform the patient—the clinician may need more time with the patient. When parents or guardians do not agree about whether to use puberty blockers or cross-sex hormones, clinicians are in an uneasy spot (Levine, 2021). This occurs in both intact and divorced families. Australia has given legal instructions to clinicians facing these uncertainties: the court is to be asked to decide (Ouliaris, 2021). The court system in the UK has been grappling with similar issues in recent years. While it is a rare case that ends up in a courtroom, clinicians devoted to a deliberate informed consent process are still likely to encounter ethical dilemmas that they cannot resolve.

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ORIGINAL PAPER

Individuals Treated for Gender Dysphoria with Medical and/or Surgical Transition Who Subsequently Detransitioned: A Survey of 100 Detransitioners

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Abstract
The study's purpose was to describe a population of individuals who experienced gender dysphoria, chose to undergo medical and/or surgical transition and then detransitioned by discontinuing medications, having surgery to reverse the effects of transition, or both. Recruitment information with a link to an anonymous survey was shared on social media, professional listservs, and via snowball sampling. Sixty-nine percent of the 100 participants were natal female and 31.0% were natal male. Reasons for detransitioning were varied and included: experiencing discrimination (23.0%); becoming more comfortable identifying as their natal sex (60.0%); having concerns about potential medical complications from transitioning (49.0%); and coming to the view that their gender dysphoria was caused by something specific such as trauma, abuse, or a mental health condition (38.0%). Homophobia or difficulty accepting themselves as lesbian, gay, or bisexual was expressed by 23.0% as a reason for transition and subsequent detransition. The majority (55.0%) felt that they did not receive an adequate evaluation from a doctor or mental health professional before starting transition and only 24.0% of respondents informed their clinicians that they had detransitioned. There are many different reasons and experiences leading to detransition. More research is needed to understand this population, determine the prevalence of detransition as an outcome of transition, meet the medical and psychological needs of this population, and better inform the process of evaluation and counseling prior to transition.

Keywords Gender dysphoria · Detransition · Transgender

Introduction

Detransition is the act of stopping or reversing a gender transition. The visibility of individuals who have detransitioned is new and may be rapidly growing. As recently as 2014, it was challenging for an individual who detransitioned to find another person who similarly detransitioned (Callahan, 2018). Between 2015 and 2017, a handful of blogs written by individual detransitioners started to appear online, private support groups for detransitioners formed, and interviews with detransitioners began to appear in news articles, magazines, and blogs (Anonymons, 2017; 4thwavenow, 2016; Herzog, 2017; McCann, 2017). Although few YouTube videos about detransition existed prior to 2016, multiple detransitioners started to post videos documenting their experiences in 2016 and the numbers of these videos continues to increase.[1] In late 2017, the subreddit r/detrans (r/detrans, 2020) was revitalized and in four years has grown from 100 members to more than 21,000 members. A member poll of r/detrans conducted in 2019 estimated that approximately one-third of the members responding to the survey were desisters or detransitioners (r/detrans, 2019). The Pique Resilience Project, a group of four detransitioned or desisted young women, was founded in 2018 as a way to share the experiences of detransitioners with the public (Pique Resilience Project, 2019). In late 2019, the Detransition Advocacy Network, a nonprofit organization to "improve the well-being of detransitioned people everywhere" was launched (The

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[1] A search of the word "detransition" in YouTube can be filtered by date of upload. https://www.youtube.com/results?search_query=%22detransition%22&sp=CAI%253D22.

Detransition Advocacy Network, 2020) and the first formal, in-person conference for detransitioned people was held (Bridge, 2020). In the face of this massive change, clinicians have called for more research into the experiences of detransitioners (Butler & Hutchinson, 2020; Entwistle, 2021; Marchiano, 2020).

Although there were rare published reports about detransitioners prior to 2016, most of the published literature about detransition is recent (Callahan, 2018; D'Angelo, 2018; Djordjevic et al., 2016; Kuiper & Cohen-Kettenis, 1998; Levine, 2018; Marchiano, 2017; Pazos Guerra et al., 2020; Stella, 2016; Turban & Keuroghlian, 2018; Turban et al., 2021; Vandenbussche, 2021). The prevailing cultural narratives about detransition are that most individuals who detransition will retransition and that the reasons for detransition are discrimination, pressures from others, and nonbinary identification (Turban et al., 2021). However, case reports are shedding light on a broader and more complex range of experiences that include trauma, worsened mental health with transition, re-identification with natal sex, and difficulty separating sexual orientation from gender identity (D'Angelo, 2018; Levine, 2018; Pazos Guerra et al., 2020).[2] Detransitioners and desisters, in their own words, have provided additional depth to the discussion, describing that:

(1) Trauma (including sexual trauma) and mental health conditions contributed to their transgender identification and transition (Callahan, 2018; Herzog, 2017; twitter.com/ftmdetransed & twitter.com/radfemjourney, 2019)
(2) Their dysphoria and transition were due to homophobia and difficulty accepting themselves as homosexual (Bridge, 2020; Callahan, 2018; upperhandMARS, 2020)
(3) Peers, social media, and online communities were influential in the development of transgender identification and desire to transition (Pique Resilience Project, 2019; Tracey, 2020; upperhandMARS, 2020)
(4) Their dysphoria was rooted in misogyny (Herzog, 2017)

Two recently published convenience sample reports provide additional context about the topic of detransition. First, Turban et al. (2021) analyzed data from the United States Trans Survey (USTS) (James et al., 2016). The USTS contains data from 27,715 transgender and gender diverse adults from the U.S. who were recruited through lesbian, gay, bisexual, transgender, queer (LGBTQ), and allied organization outreach. The USTS included the question, "Have you ever detransitioned? In other words, have you ever gone back to living as your sex assigned at birth, at least for a while?" with the multiple choice options of "yes," "no," and "I have never transitioned." For the 2,242 participants who answered "yes," Turban et al. analyzed the responses to the multiple choice question, "Why did you detransition? In other words, why did you go back to living as your sex assigned at birth? (Mark all that apply)." Although most of the offered answer options were about external pressures to detransition (pressure from spouse or partner, pressure from family, pressure from friends, pressure from employer, discrimination, etc.), participants could write in additional reasons that were not listed. Turban et al.'s sample included more natal males (55.1%) than natal females (44.9%). Roughly half (50.2%) had taken cross-sex hormones and 16.5% had obtained surgery. The findings revealed that most (82.5%) of the sample expressed at least one external factor for detransitioning and 15.9% expressed at least one internal factor (factors originating from self).

The second study by Vandenbussche (2021) recruited detransitioners from online communities of detransitioners and analyzed data for the participants who answered affirmatively to the question, "Did you transition medically and/or socially and then stopped?" The sample of 237 participants was predominantly natal female (92%), and from the U.S. (51%) and Europe (32%). Most (65%) had transitioned both medically and socially. Participants selected from multiple choice options to indicate why they detransitioned with options covering a range of experiences. Respondents also had the option to write in additional reasons. Frequently endorsed reasons for detransition included realizing that their gender dysphoria was related to other issues (70%); health concerns (62%); observing that transition did not help their dysphoria (50%); and that they found alternatives to deal with their dysphoria (45%). In contrast to Turban et al. (2021), external factors such as lack of support, financial concerns, and discrimination were less common (13%, 12%, and 10%, respectively). Many in the sample described that when they detransitioned they lost support or were ostracized from lesbian, gay, bisexual, and transgender (LGBT) communities, suggesting that many of the participants in Vandenbussche (2021) would not have been reached by the recruitment efforts of the USTS (James et al., 2016).

The objective of the current study was to describe a population of individuals who experienced gender dysphoria, chose to undergo medical and/or surgical transition and then detransitioned by discontinuing medications, having surgery to reverse the effects of transition, or both. In contrast to Turban et al. (2021) and Vandenbussche (2021), this study focused only on

[2] The debate about the terminologies used to describe an individual's sex (including "assigned sex at birth," "biological sex," "natal sex," "birth sex," "sex," etc.) is far from settled. Although some professionals have argued for the use of "assigned sex at birth," others argue that this terminology is misleading and not consistent with the events that occur at birth and prior to birth (Bouman et al., 2017; Byng et al., 2018; Dahlen, 2020; Griffin et al., 2020). Supporting the unsettled nature of the discussion, I received conflicting comments from the reviewers of this manuscript about my selection of natal sex terms–one reviewer asked that I justify my preference for natal sex over the other terminologies; another reviewer expressed support for my use of natal sex. I prefer to use "natal sex" and "birth sex" because they are accurate and objective. Further, I propose that "natal sex" and "birth sex" might be seen as reasonable, polite compromise terms between "biological sex" and "assigned sex at birth."

individuals who transitioned and detransitioned medically, surgically, or both. For the purpose of this study, medical transition refers to the use of puberty blockers, cross-sex hormones, or anti-androgens and surgical transition refers to any of a variety of surgical procedures (common surgical procedures include mastectomy, genital surgery, and breast augmentation). This study does not describe the population of individuals who undergo medical or surgical transition without issue nor is it designed to assess the prevalence of detransition as an outcome of transition. Instead, the goal was to identify detransition reasons and narratives in order to inform clinical care and future research.

Method

Participants and Procedure

During the recruitment period, 101 individuals who met the study criteria completed online surveys. Inclusion criteria were (1) completion of a survey via Survey Monkey; (2) answering that they had taken or had one or more of the following for the purpose of gender transition: cross-sex hormones, anti-androgens, puberty blockers, breast surgery, genital surgery, other surgery; and (3) answering that they had done any of the following for the purpose of detransitioning: stopped taking cross-sex hormones, stopped taking anti-androgens, stopped taking puberty blockers, had any surgery to reverse transition. One survey was excluded for nonsense answers leaving 100 surveys for analysis. The sample included more natal females (69.0%) than natal males (31.0%) with respondents who were predominantly White (90.0%), non-Hispanic (98.0%), resided in the U.S. (66.0%); had no religious affiliation (63.0%), and support the rights of gay and lesbian couples to marry legally (92.9%) (see Table 1). At the time of survey completion, the mean age of respondents was 29.2 years (SD = 9.1) though natal females were significantly younger ($M = 25.8$; SD = 5.0) than natal males ($M = 36.7$; SD = 11.4), $t(98) = -6.56$, $p < .001$. Prior to transitioning, natal females were more likely to report an exclusively homosexual sexual orientation and natal males were more likely to report an exclusively heterosexual sexual orientation.

A 115-question survey instrument with multiple choice, Likert-type, and open-ended questions was created by the author and two individuals who had personally detransitioned. The author had met both detransitioners by way of introductions from colleagues. The author and both individuals who had detransitioned created questions for the survey, provided feedback, and revised the survey questions collaboratively with a focus on content, clarity, and relevance to a variety of transition and detransition experiences. The survey instrument included two questions that were adapted from an online survey of female detransitioners (Stella, 2016). Once completed, the survey was uploaded onto Survey Monkey (SurveyMonkey, Palo Alto, CA) via an account that was HIPAA-enabled.

Recruitment information with a link to the survey was posted on blogs that covered detransition topics and shared in a private online detransition forum, in a closed detransition Facebook group, and on Tumblr, Twitter, and Reddit. Recruitment information was also shared on the professional listservs for the World Professional Association for Transgender Health, the American Psychological Association Section 44, and the SEXNET listserv (which is a listserv of sex researchers and clinicians) and the professionals on the listservs were asked to share recruitment information with anyone they knew who might be eligible. Efforts were made to reach out to communities with varied views about the use of medical and surgical transition and recruitment information stated that participation was sought from individuals regardless of whether their transition experiences were positive, negative or neutral. Potential participants were invited to share recruitment information with any potentially eligible person or community with potentially eligible people. The survey was active from December 15, 2016 to April 30, 2017 (4.5 months). The median time to complete a survey was 49 min; 50% of the surveys were completed between 32 and 71 min. There were no incentives offered for participating. Data were collected anonymously, without IP addresses, and stored securely with Survey Monkey.

Participation in this study was voluntary. Electronic consent was obtained from all participants in the following manner. The first page of the online survey informed respondents about the research purpose, potential risks and benefits, that participation was voluntary, and provided contact information for the researcher. Survey questions were only displayed if the participant clicked "agree" which indicated that they read the information, voluntarily agreed to participate and were at least 18 years of age.

Measures

Demographic and Baseline Characteristics

Information was collected about participant age, natal sex, race/ethnicity, country of residence, educational attainment, socioeconomic status, religion, attitudes about legal marriage for gay and lesbian couples, and where they first heard about the study. The term sexual orientation in this article is intended to refer to the natal sex of the participant and the natal sex of the individuals with whom they are sexually attracted. Participants were asked to select one or more labels for how they identified their sexual orientation prior to transition with options inclusive of participant sex (e.g., asexual female, bisexual female, heterosexual female, etc.). These responses were coded to be consistent with participant natal sex and were categorized into homosexual, heterosexual, bisexual, pansexual, asexual, and multiple. The multiple category included respondents who

Table 1 Demographic and baseline characteristics

	Natal female *N* (%) *N* = 69	Natal male *N* (%) *N* = 31
*Race/ethnicity**		
White	62 (89.9%)	28 (90.3%)
Multiracial	6 (8.7%)	3 (9.7%)
Other	4 (5.8%)	0 (0%)
Asian	1 (1.4%)	1 (3.2%)
Hispanic	1 (1.4%)	1 (3.2%)
Black	0 (0%)	0 (0%)
Country of residence		
USA	46 (66.7%)	20 (64.5%)
UK	8 (11.6%)	1 (3.2%)
Canada	5 (7.2%)	4 (12.9%)
Australia	2 (2.9%)	2 (6.5%)
Other	8 (11.6%)	4 (12.9%)
Education		
Bachelor's or graduate degree	29 (42.0%)	18 (58.1%)
Associates degree	3 (4.3%)	1 (3.2%)
Some college but no degree	28 (40.6%)	9 (29.0%)
High school graduate or GED	8 (11.6%)	2 (6.5%)
< High school	1 (1.4%)	0 (0%)
Other	0 (0%)	1 (3.2%)
Socioeconomic status compared to others in country of residence		
Above average (somewhat or very much)	19 (27.5%)	12 (38.7%)
About average	20 (29.0%)	7 (22.6%)
Below average (somewhat or very much)	27 (39.1%)	12 (38.7%)
Prefer not to say	3 (4.3%)	0 (0%)
Categorized sexual orientation (by natal sex) prior to transition[a]		
Homosexual	18 (26.1%)	2 (6.5%)
Heterosexual	6 (8.7%)	12 (38.7%)
Bisexual	15 (21.7%)	8 (25.8%)
Pansexual	4 (5.8%)	1 (3.2%)
Multiple	20 (29.0%)	5 (16.1%)
Asexual	6 (8.7%)	3 (9.7%)
Religious affiliation		
No religious affiliation	41 (59.4%)	22 (73.3%)
Liberal Christian	5 (7.2%)	3 (10.0%)
Liberal Jewish	5 (7.2%)	0 (0%)
Conservative Christian	1 (1.4%)	2 (6.7%)
Liberal Muslim	1 (1.4%)	0 (0%)
Conservative Jewish	0 (0%)	0 (0%)
Conservative Muslim	0 (0%)	0 (0%)
Other	16 (23.2%)	3 (10.0%)
Legal marriage for gay and lesbian couples		
Favor	65 (97.0%)	26 (83.9%)
Oppose	1 (1.5%)	5 (16.1%)
Don't know	1 (1.5%)	0 (0%)
Source where participant first heard about study		
Detransition blogs	26 (37.7%)	15 (48.4%)
Other social media	37 (53.6%)	11 (35.5%)
A person they know	3 (4.3%)	3 (9.7%)
Other	3 (4.3%)	2 (6.5%)

*May select more than one answer

[a]Natal females were more likely to express an exclusively homosexual sexual orientation prior to transition ($\chi^2 = 5.15$. The p-value is .023). Natal males were more likely to express an exclusively heterosexual sexual

Table 1 (continued)

orientation prior to transition ($\chi^2 = 13.05$. The p value is $< .001$). Natal sex differences were not significant for individuals expressing pre-transition sexual orientations of bisexual, pansexual, multiple, and asexual. For bisexual sexual orientation, $\chi^2 = 0.20$. For pansexual sexual orientation, $\chi^2 = 0.29$. For multiple sexual orientations reported, $\chi^2 = 1.88$. For asexual sexual orientation, $\chi^2 = 0.02$

selected more than one response where responses indicated more than one pattern of sexual attraction (e.g., lesbian female and heterosexual female). Other questions about baseline characteristics included questions about diagnosed psychiatric disorders and neurodevelopmental disabilities, trauma, and non-suicidal self-injury (NSSI) before the onset of gender dysphoria.

Gender Dysphoria Onset and Typologies

Participants were asked how old they were when they first experienced gender dysphoria and whether this was during childhood, at the onset of puberty, during puberty, or later. Respondents were categorized as having early-onset gender dysphoria if they indicated that their gender dysphoria began "during childhood" and late-onset gender dysphoria if their gender dysphoria began "at the onset of puberty" or later. To evaluate typologies, participants were characterized by Blanchard's (1985, 1989) typology as homosexual (if the sexual orientations listed prior to transition were exclusively homosexual) or non-homosexual which includes heterosexual, asexual, bisexual, pansexual, and multiple responses.

Transition

Participants were asked for their age and the year that they first sought care to transition, sources that encouraged them to believe that transition would be helpful to them, and whether they felt pressured to transition. The friendship group dynamics that were identified in previous work were assessed by asking respondents whether their friendship group mocked people who were not transgender, whether people in their pre-existing friend group transitioned before the participant decided to transition, and how participant popularity changed after announcing that they would transition (Littman, 2018). Questions were asked about participant experiences with clinicians, the social, medical, and surgical steps they took to transition, and the duration of time spent taking each medication.

Detransition

Participants were asked for their age and the year that they decided to detransition, how long they were transitioned before deciding to detransition, their reasons for wanting to detransition, what sources encouraged them to believe that detransition would be helpful to them, and whether they felt pressured to detransition. Participants were also asked which social, medical, and surgical steps they took to detransition and whether they contacted the doctor or clinic that they used for their transition to tell them that they detransitioned.

Transition and Detransition Narratives

In this article, "narratives" denote participant interpretations of their experiences and rationales surrounding their decisions to transition and detransition. To associate each participant survey with a set of relevant narratives, the data were reviewed with horizontal (beginning to end) passes and vertical passes for selected questions (these questions are listed in the supplemental materials). Surveys were coded as belonging to zero or more of the following narrative categories: discrimination, nonbinary, retransition, trauma and mental health, internalized homophobia, social influence, and misogyny. Each narrative and the responses that were associated with them are detailed below. Example quotes were selected with care taken to avoid quoting a participant more than once per narrative. Narratives are ordered and reported with the more commonly accepted narratives first and the newer narratives next.

The *discrimination* narrative was defined as when someone detransitioned due to experiencing discrimination or external social pressures. The *nonbinary* narrative consisted of answering that their current identification was "nonbinary/genderqueer" or providing open-text responses that described aspects of discovering or maintaining a nonbinary identification. Although there were no questions in the survey specifically asking about retransition, the *retransition* narrative was identified if participants expressed that they had retransitioned or resumed transition in any of the open-text responses in the survey. The *gender dysphoria was caused by trauma or a mental health condition* narrative was identified by selection for the answers, "what I thought were feelings of being transgender were actually the result of trauma," "what I thought were feelings of being transgender were actually the result of a mental health condition," "I discovered that my gender dysphoria was caused by something specific (ex. trauma, abuse, mental health condition)" or open-text responses consistent with these reasons. The *internalized homophobia/difficulty accepting oneself as a lesbian female, gay male, or bisexual person* narrative consisted of descriptions that the respondents' discomfort and distress about being lesbian, gay, or bisexual was related to their gender dysphoria, transition, or detransition, or that they assumed they were transgender because they did not yet understand themselves to be lesbian, gay or bisexual. The *social pressure to transition* narrative was identified with an affirmative

answer to whether they felt pressured to transition with an open-text response indicating that the pressure came from a person or gronp of people. The *misogyny* narrative was identified for natal female respondents with open-text responses using the word "misogyny" or expressing a hatred of femaleness.

Gender Identification at Start of Transition and at Survey Completion

Participants were asked how they identified their gender when they started their transition and at the time of survey completion. They were given options of female, male, nonbinary/genderqueer, trans man/FTM, trans woman/MTF, none of the above, and other. Responses were coded by natal sex and categorized as transgender, birth sex, nonbinary, and other. Answers that were combinations of the above categories were reported as combinations such as "birth sex and nonbinary."

Self-Appraisal of Transition and Detransition

One question asked if participants believe they were helped and another if they were harmed by their transition with options of "very much," "a little," or "not at all." These results were categorized into exclusively helped, exclusively harmed, and both helped and harmed. Participants were asked which of the following reflected their feelings about their transition: "I am glad that I transitioned," "I wish I had never transitioned," "Transitioning distracted me from what I should have been doing," "Transition was a necessary part of my journey." Participants were asked to rate their regret about their transition ("no regrets," "mild regrets," "strong regrets," and "very strong regrets") and were asked to indicate their satisfaction with their decisions to transition and detransition ("extremely satisfied," "very satisfied," "somewhat satisfied," "somewhat dissatisfied," "very dissatisfied," and "extremely dissatisfied"). Satisfaction options were collapsed into "satisfied" and "dissatisfied." In addition, participants were asked if they knew then what they know now, would they have chosen to transition.

Data Analysis

After data were cleaned, statistical analyses were performed using google sheets. Results are presented as frequencies, percentages, medians, means and standard deviations. *t* tests and chi-square tests were performed for selected variables and were considered significant for $p < .05$. Qualitative data were obtained from the open-text answers to questions that allowed participants to provide additional information. Selected open-text responses were categorized, tallied, and reported numerically. Salient respondent quotes and summaries from the qualitative data were selected to illustrate the quantitative results and to provide relevant examples.

Results

Before Transition

Mental health diagnoses and traumatic experiences before the onset of gender dysphoria. Table 2 shows data about psychiatric disorders, neurodevelopmental disabilities, NSSI, and trauma that were reported as occurring prior to the onset of gender dysphoria. Because these conditions and events occurred before participants began to feel gender dysphoric, they cannot be considered to be secondary to gender incongruence or transphobia.

Gender dysphoria onset and typology. Most participants (82.0%) were living with one or both parents when they first experienced gender dysphoria at a mean age of 11.2 years (SD = 5.6). The mean age of gender dysphoria onset was not statistically different between natal females ($M = 11.3$; SD = 5.4) and natal males ($M = 11.0$; SD = 5.9), $t(96) = 0.25$. By Blanchard typologies, 26.1% of natal females were exclusively homosexual and 73.9% non-homosexual while 6.5% of natal males were exclusively homosexual and 93.5% non-homosexual (Blanchard, 1985, 1989). Slightly more than half of the respondents (56.0%) experienced early-onset gender dysphoria and slightly less than half (44.0%) experienced late-onset gender dysphoria. Although late-onset gender dysphoria in natal females was largely absent from the scientific literature prior to 2012 (Steensma et al., 2013; Zucker & Bradley, 1995; Zucker et al., 2012a), 55.1% of the natal female participants reported that their gender dysphoria began with puberty or later. Because the information about the timing of gender dysphoria onset was obtained from participants reporting on their own experiences, it can be assumed that these cases were indeed late-onset rather than early-onset gender dysphoria that was concealed from parents and other people.

Transition reasons. Table 3 shows data about the reasons that individuals wanted to transition and the most frequently endorsed were: wanting to be perceived as the target gender (77.0%); believing that transitioning was their only option to feel better (71.0%); the sensation that their body felt wrong the way it was (71.0%), and not wanting to be associated with their natal sex (70.0%). Most participants believed that transitioning would eliminate (65.0%) or decrease (63.0%) their gender dysphoria and that with transitioning they would become their true selves (64.0%).

Sources of transition encouragement and friend group dynamics. Participants identified sources that encouraged them to believe transitioning would help them. Social media and online communities were the most frequently reported, including YouTube transition videos (48.0%), blogs (46.0%), Tumblr (45.0%), and online communities (43.0%) (see supplemental materials). Also common were people who the respondents knew offline such as therapists (37.0%); someone (28.0%) or a group of friends (27.0%) that they knew in-person. A subset of

Table 2 Mental health diagnoses and traumatic experiences prior to the onset of gender dysphoria

	Natal female *N* (%) *N* = 69	Natal male *N* (%) *N* = 31
*Diagnosed with a mental illness or neurodevelopmental disability**[a]		
Depression	27 (39.1%)	5 (16.1%)
Anxiety	22 (31.9%)	5 (16.1%)
Attention deficit hyperactivity disorder (ADHD)	10 (14.5%)	2 (6.5%)
Post-traumatic stress disorder (PTSD)	10 (14.5%)	1 (3.2%)
Eating disorders	10 (14.5%)	0 (0%)
Autism spectrum disorders	9 (13.0%)	1 (3.2%)
Bipolar disorder	9 (13.0%)	0 (0%)
Obsessive compulsive disorder	6 (8.7%)	3 (9.7%)
Borderline personality disorder	5 (7.2%)	0 (0%)
Schizophrenia or other psychotic disorders	1 (1.4%)	0 (0%)
None of the above	28 (40.6%)	17 (54.8%)
Other	7 (10.1%)	2 (6.5%)
Non-suicidal self-injury (NSSI)[b]		
Engaged in NSSI before the onset of gender dysphoria	19 (27.5%)	5 (16.1%)
Trauma[c]		
Experienced a trauma less than one year before the start of gender dysphoria	33 (47.8%)	4 (12.9%)

*May select more than one answer

[a]Natal sex difference for one or more pre-existing diagnoses (100-none of the above) was not significant [$\chi^2(1, 100) = 1.76$]

[b]Natal sex differences for NSSI before the onset of gender dysphoria was not significant ($\chi^2 = 1.52$)

[c]Experiencing a trauma less than one year before the start of gender dysphoria was statistically different [$\chi^2(1, 100) = 11.19, p < .001$] with natal females > natal males

Table 3 Transition reasons

	Natal female *N* (%) *N* = 69	Natal male *N* (%) *N* = 31
*Reasons for transition**		
I wanted others to perceive me as the target gender	53 (76.8%)	24 (77.4%)
I thought transitioning was my only option to feel better	50 (72.5%)	21 (67.7%)
My body felt wrong to me the way it was	50 (72.5%)	21 (67.7%)
I didn't want to be associated with my natal sex/natal gender	51 (73.9%)	19 (61.3%)
It made me uncomfortable to be perceived romantically/sexually as a member of my natal sex/natal gender	49 (71.0%)	18 (58.1%)
I thought transitioning would eliminate my gender dysphoria	43 (62.3%)	22 (71.0%)
I felt I would become my true self	42 (60.9%)	22 (71.0%)
I identified with the target gender	40 (58.0%)	24 (77.4%)
I thought transitioning would lessen my gender dysphoria	45 (65.2%)	18 (58.1%)
I felt I would fit in better with the target gender	36 (56.5%)	20 (64.5%)
I felt I would be more socially acceptable as a member of the target gender	38 (55.1%)	11 (35.5%)
I felt I would be treated better if I was perceived as the target gender	35 (50.7%)	14 (45.2%)
I saw myself as a member of the target gender	31 (44.9%)	18 (58.1%)
I thought transitioning would reduce gender-related harassment or trauma I was experiencing	35 (50.7%)	5 (16.1%)
I had erotic reasons for wanting to transition	9 (13.0)	12 (38.7%)
Other	9 (13.0%)	3 (9.7%)

*May select more than one answer

participants experienced the friendship group dynamics identified in previous work, including belonging to a friendship group that mocked people who were not transgender (22.2%), having one or more friend from the pre-existing friend group transition before the participant decided to transition (36.4%), and experiencing an increase in popularity after announcing plans to transition (19.6%) (Littman, 2018). Most did not have this experience (68.7%, 61.6%, and 62.9%, respectively).

Pressure to transition. More than a third of the participants (37.4%) felt pressured to transition. Natal sex differences in feeling pressured to transition were significant by chi-square test with natal females > natal males $\chi^2(1, 99) = 4.22$, $p = .04$. Twenty-eight participants provided open-text responses of which 24 described sources of pressure (17 described social pressures and 7 described sources that were not associated with other people). Clinicians, partners, friends, and society were named as sources that applied pressure to transition, as seen in the following quotes: "My gender therapist acted like it [transition] was a panacea for everything;" "[My] [d]octor pushed drugs and surgery at every visit;" "I was dating a trans woman and she framed our relationship in a way that was contingent on my being trans;" "A couple of later trans friends kept insisting that I needed to stop delaying things;" "[My] best friend told me repeatedly that it [transition] was best for me;" "The forums and communities and internet friends;" "By the whole of society telling me I was wrong as a lesbian;" and "Everyone says that if you feel like a different gender…then you just are that gender and you should transition." Participants also felt pressure to transition that did not involve other people as illustrated by the following: "I felt pressured by my inability to function with dysphoria" and "Not by people. By my life circumstances."

Experiences with clinicians. When participants first sought care for their gender dysphoria or desire to transition, more than half of the participants (53.0%) saw a psychiatrist or psychologist; about a third saw a primary care doctor (34.0%) or a counselor (including licensed clinician social worker, licensed professional counselor, or marriage and family therapist) (32.0%); and 17.0% saw an endocrinologist. For transition, 45.0% of participants went to a gender clinic (44.4% of those attending a gender clinic specified that the gender clinic used the informed consent model of care); 28.0% went to a private doctor's office; 26.0% went to a group practice; and 13.0% went to a mental health clinic (see supplemental materials).

The majority (56.7%) of participants felt that the evaluation they received by a doctor or mental health professional prior to transition was not adequate and 65.3% reported that their clinicians did not evaluate whether their desire to transition was secondary to trauma or a mental health condition. Although 27.0% believed that the counseling and information they received prior to transition was accurate about benefits and risks, nearly half reported that the counseling was overly positive about the benefits of transition (46.0%) and not negative enough about the risks (26.0%). In contrast, only a small minority found the counseling not positive enough about benefits (5.0%) or too negative about risks (6.0%) suggesting a bias toward encouraging transition.

Transition

Participants were on average 21.9 years old (SD = 6.1) when they sought medical care to transition with natal females seeking care at younger ages ($M = 20.0$; SD = 4.2) than natal males ($M = 26.0$; SD = 7.5), $t(97) = -5.07$, $p < .001$. Given that the majority of natal males were categorized as Blanchard typology non-homosexual, the finding that natal males sought medical care to transition at older ages than natal females is concordant with previous research (Blanchard et al., 1987). The average year for seeking care was more recent for natal females ($M = 2011$; SD = 3.8) than natal males ($M = 2007$; SD = 6.9), $t(96) = 2.78$, $p = .007$, and thus, there may have been differences in the care they received due to differences in the culture surrounding transition and the prevailing medical approaches to gender dysphoria for the time.

At the start of transitioning, nearly all (98.0%) of the participants identified as either transgender (80.0%), nonbinary (15.0%), or both transgender and nonbinary (3.0%). Participants identified which social, medical, and surgical steps they had taken to transition. Table 4 shows these steps, separated by natal sex where appropriate. Most respondents adopted new pronouns (91.0%) and names (88.0%), and the vast majority (97.1%) of natal females wore a binder. Most participants took cross-sex hormones (96.0%) and most natal males took anti-androgens (87.1%). The most frequent transition surgery was breast or chest surgery for natal females (33.3%). Genital surgery was less common (1.4% of natal females and 16.1% of natal males). Natal females took testosterone for a mean duration of 2.0 years (SD = 1.6). Natal males took estrogen for a mean duration of 5.1 years (SD = 5.9) and anti-androgens for 2.8 years (SD = 2.6). The minority of patients who took puberty blockers took them for a mean duration of less than a year ($M = 0.9$ years; SD = 0.6).

Detransition

Before deciding to detransition, participants remained transitioned for a mean duration of 3.9 years (SD = 4.1) with natal females remaining transitioned for a shorter period of time ($M = 3.2$ years; SD = 2.7) than natal males ($M = 5.4$ years; SD = 6.1), $t(96) = -2.40$, $p = .018$. When participants decided to detransition they were a mean age of 26.4 years old (SD = 7.4) though natal females were significantly younger ($M = 23.6$; SD = 4.5) than natal males ($M = 32.7$; SD = 8.8), $t(97) = -6.75$, $p < .001$. The mean calendar year when participants decided to detransition was 2014 ($M = 2014$; SD = 3.3), but the difference

Table 4 Steps taken for social, medical, and surgical transition

	N (%)
*Social transition**	
Pronouns	91 (91.0%)
Different name	88 (88.0%)
Clothes/hair/makeup	90 (90.0%)
Legal name change	49 (49.0%)
Gender/sex changed on government documents	36 (36.0%)
Voice training	20 (20.0%)
Natal female	
Wore a binder	67 (97.1%)
*Medical transition**	
Cross-sex hormones	96 (96.0%)
Puberty blockers	7 (7.0%)
Natal male	
Anti-androgens	27 (87.1%)
*Surgical transition**	
Face/neck surgery	5 (5.0%)
Natal female	
Breast/chest surgery	23 (33.3%)
Genital surgery (to create a penis)	1 (1.4%)
Natal male	
Breast implants	5 (16.1%)
Genital surgery (to create a vagina)	5 (16.1%)

*May select more than one answer

between natal females and natal males was not significant ($M = 2014$, SD = 3.3; $M = 2014$, SD = 3.5), $t(95) = 0.52$.

Respondents detransitioned for a variety of reasons and most (87.0%) selected more than one reason. The most frequently endorsed reason for detransitioning was that the respondent's personal definition of male and female changed and they became comfortable identifying with their natal sex (60.0%) (see Table 5). Other commonly endorsed reasons were concerns about potential medical complications (49.0%); transition did not improve their mental health (42.0%); dissatisfaction with the physical results of transition (40.0%); and discovering that something specific like trauma or a mental health condition caused their gender dysphoria (38.0%). External pressures to detransition such as experiencing discrimination (23.0%) or worrying about paying for treatments (17.0%) were less common.

Encouragement and pressure to detransition. Participants were asked to select sources that encouraged them to believe that detransitioning would help them. These included blogs (37.0%), Tumblr (35.0%), and YouTube detransition videos (23.0%) (see supplemental materials). At some point in their process, 23.2% felt pressured to detransition. There was no significant difference between natal females and natal males for feeling pressured to detransition, $\chi^2(1, 99) = 1.11$. Of the 21 open-text responses provided, 14 respondents expressed social pressure to detransition; three expressed internal pressure to detransition and four provided responses that were neither

Table 5 Reasons for detransitioning

	Natal female *N* (%) *N* = 69	Natal male *N* (%) *N* = 31
*Reasons for detransitioning**		
My personal definition of female or male changed and I became more comfortable identifying as my natal sex	45 (65.2%)	15 (48.4%)
I was concerned about potential medical complications from transitioning	40 (58.0%)	9 (29.0%)
My mental health did not improve while transitioning	31 (44.9%)	11 (35.5%)
I was dissatisfied by the physical results of the transition/felt the change was too much	35 (50.7%)	5 (16.1%)
I discovered that my gender dysphoria was caused by something specific (ex, trauma, abuse, mental health condition)	28 (40.6%)	10 (32.3%)
My mental health was worse while transitioning	27 (39.1%)	9 (29.0%)
I was dissatisfied by the physical results of the transition/felt the change was not enough	22 (31.9%)	11 (35.5%)
I found more effective ways to help my gender dysphoria	25 (36.2%)	7 (22.6%)
My physical health was worse while transitioning	21 (30.4%)	11 (35.5%)
I felt discriminated against	12 (17.4%)	11 (35.5%)
I had medical complications from transitioning	12 (17.4%)	7 (22.6%)
Financial concerns about paying for transition care	11 (15.9%)	6 (19.4%)
My gender dysphoria resolved	10 (14.5%)	5 (16.1%)
My physical health did not improve while transitioning	9 (13.0%)	2 (6.5%)
I resolved the specific issue that was the cause of my gender dysphoria	6 (8.7%)	4 (12.9%)
I realized that my desire to transition was erotically motivated	1 (1.4%)	5(16.1%)
Other	19 (27.5%)	6 (19.4%)

*May select more than one answer

or unclear. Regarding social pressure to detransition, seven participants expressed that the pressure came from partners, parents, or other family members as shown in the following example quotes: "I was threatened that if I did not immediately detransition I would NEVER see my [...] children again," "My father very much wanted me to desist," and "Parents constantly encouraging me to detransition." Five participants expressed societal pressure to detransition as expressed in the following quotes: "I did not pass, I was mocked in public, I could not get a job. It was not ok to be trans" and "Well, I mean basically the entire world was against me transitioning, so yeah." One participant felt pressured by doctors and another one from a blog.

Detransition steps. Table 6 shows data about the social, medical, and surgical steps participants took to detransition. Nearly all participants medically detransitioned by ceasing cross-sex hormones (95.0%). Social detransition steps were also common and included returning to the use of previously used pronouns (63.0%) and birth names (33.0%) and changing one's clothes and hair presentations (48.0%). Surgical detransition steps were less common (9.0%).

Finding better ways of coping with gender dysphoria. Participants were asked to select responses that that they considered to have been better ways for them to cope with their gender dysphoria. Responses included community (44.0%), mindfulness/meditation (41.0%), exercise (39.0%), therapy (24.0%), trauma work (24.0%), medication to treat a mental health condition (18.0%), and yoga (14.0%).

Table 6 Social, medical, and surgical detransition steps

	N (%)
*Social detransition**	
Previous pronouns	63 (63.0%)
Clothes/hair/makeup	48 (48.0%)
Birth name	33 (33.0%)
New name (not birth name)	24 (24.0%)
None of the above	2 (2.0%)
*Medical detransition**	
Stopped cross-sex hormones	95 (95.0%)
Stopped puberty blockers	4 (4.0%)
Started hormones consistent with natal sex	14 (14.0%)
Natal male	
Stopped anti-androgens	17 (54.8%)
*Surgical detransition**	
Surgery to reverse changes from transition	9 (9.0%)

*May select more than one answer

Transition and Detransition Narratives

Several transition and detransition narratives emerged from the data. A sizable minority of participants (41.0%) expressed more than one narrative in their responses.

The *discrimination and external pressures to detransition* narrative was described by 29.0% of participants. Examples include: "I had to detransition in order to get a job"; "I was afraid of being homeless and unable to support myself"; "I felt much happier with myself but I couldn't go anywhere without being afraid. I passed okay but not perfectly. I was stared down and sneered at in the women's clothes section, I wouldn't dare use a public toilet because I'd find either violent men or women who wished an encounter with a violent man on me."

A *nonbinary* narrative was expressed by 16.0% of participants. Some described that they discovered their nonbinary gender identity during their transition, as in the following quotes: "I still was uncomfortable with my body and figured I should stop and make sure I really wanted to keep going. I didn't and I decided I must be nonbinary, not FTM"; "Transitioning didn't do what I thought I wanted it to. I had transitioned to the wrong gender. I still felt wrong. Then, I realized I was not male, but genderqueer. I detransitioned to suit my true identity." And others described a consistent nonbinary identification, as in the following quote, "I identified the same way that I did before. I had gotten what I wanted out of HRT and was ready to stop taking it." (Cross-sex hormones are sometimes referred to as "hormone replacement therapy" and abbreviated as HRT).

Three participants (3.0%) expressed the *retransition* narrative in open-text answers indicating that they had retransitioned, including the following quotes: "I am now transitioning for a second time"; I retransitioned after 5 years of detransitioning"; and "Anyway, I retransitioned over 10 years after detransitioning."

Most participants (58.0%) expressed the *gender dysphoria was caused by trauma or a mental health condition* narrative which included endorsing the response options indicating that their gender dysphoria was caused by something specific, such as a trauma or a mental health condition. More than half of the participants (51.2%) responded that they believe that the process of transitioning delayed or prevented them from dealing with or being treated for trauma or a mental health condition. The following are example quotes that were in response to why participants chose to detransition: "I slowly began addressing the mental health conditions and traumatic experiences that caused such a severe disconnect between myself and my body..."; "I was starting to become critical of transition because I felt that many people were doing it out of self-hatred and started to realize that applied to me as well"; "I was deeply uncomfortable with my secondary sex characteristics, which I now understand was a result of childhood trauma and associating my secondary sex characteristics with those events."

Despite the absence of any questions about this topic in the survey, nearly a quarter (23.0%) of the participants expressed the *internalized homophobia and difficulty accepting oneself as lesbian, gay, or bisexual* narrative by spontaneously describing that these experiences were instrumental to their gender dysphoria, their desire to transition, and their detransition. All

of the participants in this category indicated that they were either same-sex attracted exclusively or were same-sex attracted in combination with opposite-sex attraction (such as bisexual, pansexual, etc.). The following responses were written in as "other" for the question about why participants transitioned: "Transitioning to male would mean my attraction to girls would be 'normal'"; "being a 'gay trans man' (female dating other females) felt better than being a lesbian, less shameful"; "I felt being the opposite gender would make my repressed same-sex attraction less scary"; "I didn't want to be a gay man." Some participants described that it took time for them to gain an understanding of themselves as lesbian, gay, or bisexual as seen in the following: "At the time I was trying to figure out my identity and felt very male and thought I was transgender. I later discovered that I was a lesbian…"; and "Well, after deep discovery, I realized I was a gay man and realized that a sexual trauma after puberty might [have] confused my thought. I wanted to live as a gay man again." Several natal female respondents expressed that seeing other butch lesbians would have been helpful to them as shown by the following: "What would have helped me is being able to access women's community, specifically lesbian community. I needed access to diverse female role-models and mentors, especially other butch women."

The *social influence* narrative was identified where participants added information to the question about if they had felt pressured to transition and the response described pressnre from a person or people. One-fifth (20.0%) of participants expressed that they felt pressured by a person or people to transition. Example quotes for social influence were described in a previous section.

Of the natal females, 7.2% expressed the *misogyny* narrative. Example quotes include: "…I realized how much of it [dysphoria] may have been caused by internalized misogyny and homophobia"; "Finally realizing there's nothing wrong or disgusting or weak about being female"; and "My transition was a desperate attempt to distance myself from womanhood and femaleness due to internalized lesbophobia and misogyny combined with a history of sexual trauma."

After Detransition

Disposition. At the time of survey completion, most participants had returned to identifying solely as their birth sex (61.0%) with an additional 10.0% identifying as their birth sex plus another identification. Fourteen percent of the participants identified solely as nonbinary with an additional 11.0% identifying as nonbinary plus a second identification. Eight percent of the participants identified solely as transgender with an additional 5.0% identifying as transgender plus another identification. Four percent of the responses did not fit into the above categories and were coded as "other." Figure 1 illnstrates the distribution of participants' current gender identification (post-detransition). Only 24.0% of participants had informed

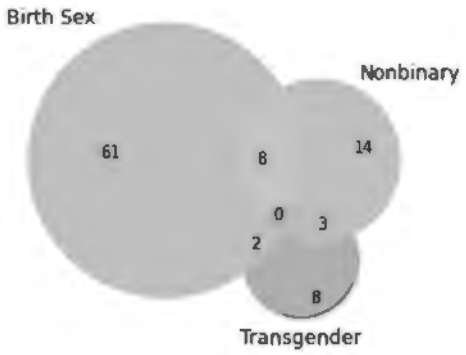

Fig. 1 Distribution of participants' current gender identification (after detransition) (n = 100). *Notes*: The sum of the numbers appearing in the "Birth Sex" circle indicates the number of participants who returned to identifying with their birth sex (71)—either as birth sex alone (61) or birth sex in addition to a second identification (10) represented in the overlap between two circles. For example, eight participants identify as their birth sex and as nonbinary. The sum of the numbers appearing in the "Nonbinary" circle indicates the number of participants who identify as nonbinary (25)—either as nonbinary alone (14) or nonbinary in addition to a second identification (11). The sum of the numbers appearing in the "Transgender" circle indicates the number of participants who identify as transgender (13)—either as transgender alone (8) or transgender in addition to a second identification (5). Four participants had responses that did not fit the categories above and were coded as "other"

the doctor or clinic that facilitated their transitions that they had detransitioned.

Self-appraisal of past transgender identification. Table 7 presents the data for responses endorsed by participants to reflect how they feel currently about having identified as transgender in the past. The statements most frequently selected included: "I thought gender dysphoria was the best explanation for what I was feeling" (57.0%), "My gender dysphoria was similar to the gender dysphoria of those who remain transitioned" (42.0%), "What I thought were feelings of being transgender actually were the result of trauma" (36.0%), "What I thought were feelings of being transgender actually were the result of a mental health condition" (36.0%).

Self-appraisal of transition and detransition. When asked to select which statement best reflects their feelings about their transition, nearly a third (30.0%) indicated that they wish they had never transitioned while 11.0% indicated they were glad they transitioned. Some (34.0%) selected the statement that transition "was a necessary part of [their] journey" but others (21.0%) indicated that the process of transitioning distracted them from what they should have been doing. Responses about whether transition helped or harmed them were also complicated. While 50.5% selected answers consistent with being both helped and harmed, 32.3% indicated that they were only harmed and 17.2% indicated that they were only helped. The majority of respondents were dissatisfied with their decision to transition (69.7%) and satisfied with their decision to detransition (84.7%). At least some amount of transition regret was

Table 7 Self-appraisal of past transgender identification

	Natal female *N* (%) *N* = 69	Natal male *N* (%) *N* = 31
*Self-appraisal about identifying as transgender in the past**		
I thought gender dysphoria was the best explanation for what I was feeling	39 (56.5%)	18 (58.1%)
My gender dysphoria was similar to the gender dysphoria of those who remain transitioned	32 (46.4%)	10 (32.3%)
What I thought were feelings of being transgender actually were the result of trauma	31 (44.9%)	5 (16.1%)
What I thought were feelings of being transgender actually were the result of a mental health condition	28 (40.6%)	8 (25.8%)
Someone else told me that the feelings I was having meant that I was transgender and I believed them	25 (36.2%)	10 (32.3%)
I still identify as transgender	20 (29.0%)	10 (32.3%)
I believed I was transgender then, but I was mistaken	16 (23.2%)	6 (19.4%)
I was transgender then but I am not transgender now	15 (21.7%)	7 (22.6%)
I formerly identified as transgender and now identify as genderqueer/nonbinary	12 (17.4%)	5 (16.1)
My gender dysphoria was different from the gender dysphoria of those who remain transitioned	11 (15.9%)	4 (12.9%)
I was never transgender	8 (11.6%)	3 (9.7%)
I thought I had gender dysphoria but I was mistaken	4 (5.8%)	4 (12.9%)
I never had gender dysphoria	1 (1.4)	2 (6.5%)
N/A as I did not identify as transgender in the past	0 (0%)	1 (3.2%)
Other	18 (26.1%)	5 (16.1%)

*May select more than one answer

common (79.8%) and nearly half (49.5%) reported strong or very strong regret. Most respondents (64.6%) indicated that if they knew then what they know now, they would not have chosen to transition.

Discussion

This study was designed to explore the experiences of individuals who obtained medical and surgical treatment for gender dysphoria and then detransitioned by discontinuing the medications or having surgery to reverse the changes from transition. The findings of this study, however, should not be assumed to be representative of all individuals who detransition. Although this study further documents that detransitioners exist, the prevalence of detransition as an outcome of transition is unknown. Only a small percentage of detransitioners (24.0%) informed the clinicians and clinics that facilitated their transitions that they had detransitioned. Therefore, clinic rates of detransition are likely to be underestimated and gender transition specialists may be unaware of how many of their own patients have detransitioned, particularly for patients who are no longer under their care.

This research demonstrates that the experiences of individuals who detransition are varied and the reasons for detransition are complex. Nearly all participants identified as transgender or nonbinary at the start of their transition and most sought transition because they did not want to be associated with their natal sex, their bodies felt wrong the way they were, and they believed that transition was the only option to relieve their distress. Some were helped by transition and only detransitioned because they were pressured to do so by people in their lives, society, or because they had medical complications. Some were harmed by transition and detransitioned because they concluded that their gender dysphoria was caused by trauma, a mental health condition, internalized homophobia, or misogyny—conditions that are not likely to be resolved with transition. These findings highlight the complexity of gender dysphoria and suggest that, in some cases, failure to explore co-morbidities and the context in which the gender dysphoria emerged can lead to misdiagnosis, missed diagnoses, and inappropriate gender transition. Some individuals detransitioned because their gender dysphoria resolved, because they found better ways to address their symptoms, or because their personal definitions of male and female changed and they became comfortable identifying as their natal sex.

The study sample was predominantly young natal females, many of whom experienced late-onset gender dysphoria which mirrors the recent, striking changes in the demographics of gender dysphoric youth seeking care as well as the youth described by their parents in Littman (2018) (see also Aitken et al., 2015; de Graaf et al., 2018; Zucker, 2019). Concerns have been raised that this new cohort of gender dysphoric individuals is unlike previous cohorts. Professionals have started to call for caution before treating this cohort with interventions with permanent effects because the etiologies, desistance and persistence rates,

expected duration of symptoms, and whether this new population is helped or harmed by gender transition is still unknown (D'Angelo et al., 2021; Kaltiala-Heino et al., 2018). The natal females and natal males in this sample differed on several dimensions, including that natal females were younger than natal males when they sought transition, when they decided to detransition, and at the time of survey completion. Natal females were more likely than natal males to have experienced a trauma less than one year before the onset of their gender dysphoria and were more likely to have felt pressured to transition. Compared to natal males, natal females remained transitioned for a shorter duration of time before deciding to detransition. Additionally, natal females transitioned more recently than natal males, so their experiences may vary due to changing trends in the clinical management of gender dysphoria and the cultural settings in which they became gender dysphoric.

The study findings covered a wide range of detransition experiences that are consistent with the diversity of experiences described in previously published clinical case reports and case series. Overlap of findings include: transition regret; absence of transition regret; re-identification with birth sex; continued identification as transgender; improvement or worsening of well-being with transition; retransitioning; detransitioning due to external social pressures; nonbinary identification; and recognizing and accepting oneself as homosexual or bisexual (D'Angelo, 2018; Djordjevic et al., 2016; Levine, 2018; Pazos Guerra et al., 2020; Turban & Keuroghlian, 2018; Turban et al., 2021; Vandenbussche, 2021). The population in this study is similar to the population in Vandenbussche in that both were predominantly natal females in their mid-20s. Because the current study recruited in 2016–2017 and Vandenbussche recruited in 2019, the similar mean age of participants may reflect the age of individuals who can be reached in online detransitioner communities. Several findings in this study were consistent with Vandenbussche's findings, including similar reasons for detransition (realizing that their gender dysphoria was related to other issues, finding alternatives to address gender dysphoria, gender dysphoria resolved, etc.). Although these two studies were recruited in different years, had different eligibility criteria, and included participants from several countries, it is possible that there may be some overlap of study populations.

The current study findings provide additional insight into the complex relationships between internalized homophobia, gender dysphoria, and desire to transition. Contrary to arguments against the potential role of homophobia in gender transitions (Ashley, 2020), participants reported that their own gender dysphoria and desire to transition stemmed from the discomfort they felt about being same-sex attracted, their desire to not be gay, and the difficulties that they had accepting themselves as lesbian, gay or bisexual. For these individuals, exploring their distress and discomfort around sexual orientation issues may have been more helpful to them than medical and surgical transition or at least an important part of exploration before making the decision to transition. This research adds to the existing evidence that gender dysphoria can be temporary (Ristori & Steensma, 2016; Singh et al., 2021; Zucker, 2018). It has been established that the most likely outcome for prepubertal youth with gender dysphoria is to develop into lesbian, gay, bisexual (LGB) (non-transgender) adults (Ristori & Steensma, 2016; Singh et al., 2021; Wallien & Cohen-Kettenis, 2008; Zucker, 2018). And, temporary gender dysphoria may be a common part of LGB identity development (Korte et al., 2008; Patterson, 2018). Therefore, intervening too soon to medicalize gender dysphoric youth risks iatrogenically derailing the development of youth who would otherwise grow up to be LGB non-transgender adults. Participants who detransitioned because they became comfortable identifying as their natal sex and because their gender dysphoria resolved further support that gender dysphoria is not always permanent.

The data in this study strengthen, with first-hand accounts, the rapid-onset gender dysphoria (ROGD) hypotheses which, briefly stated, are that psychosocial factors (such as trauma, mental health conditions, maladaptive coping mechanisms, internalized homophobia, and social influence) can cause or contribute to the development of gender dysphoria in some individuals (Littman, 2018). Littman also postulated that certain beliefs could be spread by peer contagion, including the belief that a wide range of symptoms should be interpreted as gender dysphoria (and proof of being transgender) and the belief that transition is the only solution to relieve distress. The current study supports the potential role of psychosocial factors in the development of gender dysphoria and further suggests, by participant responses that transitioning prevented or delayed them from addressing their underlying conditions, that maladaptive coping mechanisms may be relevant for some individuals. The potential role of social influence is demonstrated as well. First, when respondents were asked to describe how they currently feel about having identified as transgender in the past, more than a third endorsed the option, "Someone told me that the feelings I was having meant that I was transgender, and I believed them." Second, a subset of participants experienced the unique friendship group dynamics reported in Littman where peer groups mocked people who were not transgender and popularity within the friend group increased when respondents announced their plan to transition. Additionally, respondents identified several social sources that encouraged them to believe that transitioning would help them including: YouTube transition videos, blogs, Tumblr, and online communities. And finally, 20.0% of participants felt pressured to transition by social sources that included friends, partners, and society. More research is needed to further explore these hypotheses.

The current study and the Turban et al. (2021) analysis of the USTS data share some similarities and differences. Similarities include the use of convenience samples, targeted recruitment, and anonymous data collection. The findings of Turban et al. (including external pressures to detransition and transgender

identification after detransition) are a subset of the array of experiences described in the cnrrent study. The current stndy differed from James et al. (2016) and Turban et al. in that it enrolled participants based on the criterion of detransition after medical or surgical transition regardless of how they currently identified, recruited from communities with diverse perspectives about transition and detransition, used a precise definition for detransition that specifies the use of medication or surgery, and included answer options that were relevant to many different types of detransition experiences. In contrast, the USTS only enrolled transgender-identifying individnals regardless of whether they medically or surgically transitioned, recruited from communities likely to have similar perspectives about transition and detransition, and provided multiple choice answer options that were relevant to a narrower range of detransition experiences (James et al., 2016). Further, the definition used by the USTS for "detransitioned" (having "gone back to living as [their] sex assigned as birth, at least for a while") is quite vague. Although Turban et al. provide valuable information about the subset of transgender-identifying people who may have detransitioned, the current study provides a more comprehensive view of individuals who detransition after medical or surgical transition.

Over the past 15 years, there have been substantial changes in the clinical approach to gender dysphoric patients notable for a shift from approaches that employ thorough evaluations and judicious use of medical and surgical transition (the watchful waiting or Dutch approach, the developmentally informed approach, and the medical model of care) to approaches with minimized or eliminated evaluation and liberal use of transition interventions (the affirmative approach and the informed consent model of care) (Cavanaugh et al., 2016; de Vries & Cohen-Kettenis, 2012; Meyer et al., 2002; Rafferty et al., 2018; Schulz, 2018; Zucker et al., 2012b). This trend is prominent in the U.S. where the American Academy of Pediatrics endorsed the affirmative approach in 2018 and Planned Parenthood currently uses the informed consent model to provide medical transition in more than 200 clinics in 35 states (Planned Parenthood, 2021; Rafferty et al., 2018). It is plausible that an unintended consequence of these clinical shifts may be an increase in people who detransition. Many participants in this study believe that they did not receive an adequate evaluation by a clinician before transition. The definition of "adequate evaluation" was not provided in the survey and may be open to respondent interpretation. But given the complexities of the gender dysphoria described in the current study, one might consider a low bar of "adequate" to be the exploration of factors that could be misinterpreted as non-temporary gender dysphoria as well as factors that could be underlying causes for gender dysphoria. The most recently emerging approach to gender dysphoria is called the "exploratory approach" which is a neutral psychotherapeutic approach to help individuals gain a deeper understanding of their gender distress and the factors contributing to their dysphoria (Churcher Clarke & Spiliadis, 2019; Spiliadis, 2019). The study's findings suggest that an exploratory type of approach may have been beneficial to some of the respondents. Future research is needed to determine which patients are best treated by which approaches long term.

Patients considering medical and surgical interventions deserve accurate information about the risks, benefits, and alternatives to that treatment. In this sample, nearly half of the participants reported that the counseling they received about transition was overly positive about the benefits of transition and more than a quarter reported that the counseling was not negative enough about the risks. Several participants felt pressured to transition by their doctors and therapists. If these types of clinical interactions are verified, exploration is needed to determine the extent to which this situation occurs and what measures might be taken to ensure that clinicians provide patients with their options accurately and dispassionately.

There are several obstacles to obtaining accurate rates of detransition and desistance, including stigma and the low numbers of detransitioners who inform their clinicians that they detransitioned. One approach to bypass some of these barriers would be to incorporate non-judgmental questions about detransition and desistance into nationally representative surveys that collect health data. For example, the Behavioral Risk Factor Surveillance System contains an optional module about sexual orientation and gender identity that includes two questions to explore gender issues (Downing & Przedworski, 2018). By changing one existing question, "Do you consider yourself to be transgender?" into two questions, "Have you ever, at any point in your life, considered yourself to be transgender?" and "Do you currently consider yourself to be transgender?" and by adding a follow-up question if answers indicate past but not current transgender identification, "Did you ever take puberty blockers, cross-sex hormones, anti-androgens, or have any surgery as part of your transition?", valuable information about desistance, detransition, and current transgender identification could be obtained. These types of questions may also be of use in clinical practice and electronic medical records. The information gained about rates of detransition and desistance would enhance transgender healthcare by aiding informed consent processes at the start of any medical or surgical transition.

One of the strengths of this study is that it is one of the largest samples of detransitioners to date. Other strengths include the use of a precise definition for detransition, enrollment of detransitioners regardless of their post-detransition gender identification, recruitment from communities with likely divergent views about transition and detransition, and collaboration with two individuals who had detransitioned which helped to create a survey instrument with questions relevant to a variety of detransition experiences and enhanced the recruitment efforts.

There are several limitations to this study that should be considered when interpreting the findings. Like Vandenbussche (2021), James et al. (2016), and Turban et al. (2021), this study

used a cross-sectional design, anonymous surveying, and a convenience sample and therefore shares the same limitations that are inherent to these methodologies. These limitations include that conclusions about causation cannot be determined, identities of participants cannot be verified, and the findings of this study may not be generalizable to the entire population of people who detransition or to people outside of the countries where participants were from. Although this study reached out to communities with differing perspectives about transition and detransition, targeted recruitment and convenience samples always introduce the limitations associated with selection biases which should be addressed in future research. Finally, many of the participants in this study had less than ideal outcomes to their medical and surgical transitions, and it is possible that these experiences may have colored some of the responses.

Additional research is needed to determine the prevalence of detransition as an outcome of transition and to identify and meet the psychological and medical needs of the emerging detransitioned population. Because many individuals who detransition re-identify with their birth sex, are no longer connected to LGBT communities, and don't return to gender clinics, future research about detransition needs to expand recruitment efforts beyond gender clinics and transgender communities. The development and testing of non-medical interventions for gender dysphoria could provide valuable options to be used as alternatives or in conjunction with medical and surgical treatments. Because of the potential for some to experience trauma, mental health conditions, internalized homophobia, and misogyny as gender dysphoria, research needs to be conducted on the evaluation process before transition to find approaches that respectfully and collaboratively explore factors that might contribute to gender-related distress. There continues to be an absence of long-term outcomes evidence for youth treated with medical and surgical transition and a lack of information about the trajectories of youth experiencing late-onset gender dysphoria–research is needed to address these gaps. Continued work is needed to reduce rigid gender roles, increase representation of gender stereotype nonconformity, and to address discrimination and social pressures exerted against people who are transgender, lesbian, gay, bisexual, and gender stereotype non-conforming.

Conclusion

This study described individuals who, after transitioning with medications or surgery, have detransitioned. The prevalence of detransitioning after transition is unknown but is likely underestimated because most of the participants did not inform the doctors who facilitated their transitions that they had detransitioned. There is no single narrative to explain the experiences of all individuals who detransition and we should take care to avoid painting this population with a broad brush. Some detransitioners return to identifying with their birth sex, some assume (or maintain) a nonbinary identification, and some continue to identify as transgender. Some detransitioners regret transitioning and some do not. Some of the detransitioners reported experiences that support the ROGD hypotheses, including that their gender dysphoria began during or after puberty and that mental health issues, trauma, peers, social media, online communities, and difficulty accepting themselves as lesbian, gay, or bisexual were related to their gender dysphoria and desire to transition. Natal female and natal male detransitioners appear to have differences in their baseline characteristics and experiences and these differences should be further delineated. Future research about gender dysphoria and the outcomes of transition should consider the diversity of experiences and trajectories. More research is needed to determine how best to provide support and treatment for the long-term medical and psychological well-being of individuals who detransition. Findings about detransition should be used to improve our understanding of gender dysphoria and to better inform the processes of evaluation, counseling, and informed consent for individuals who are contemplating transition.

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Declarations

Conflict of interest The author has no relevant financial or non-financial conflicts of interest to disclose.

Consent to Participate Electronic consent was obtained from all participants included in the study. On the first page of the online survey, participants were informed of the research purpose and potential risks and benefits of participating, that their participation was voluntary, and were presented with a way to contact the researcher. The research survey questions were displayed only if the participant clicked "agree" which indicated that the participant read the information, voluntarily agreed to participate, and were at least 18 years of age.

Ethical Approval The research was determined to be Exempt Human Research by the Program for the Protection of Human Subjects of the Icahn School of Medicine at Mount Sinai in New York, NY. All procedures were performed in accordance with the ethical standards of the Program for the Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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National Academy of Medicine, France

Press Release

Medical Care of Children and Adolescents with Transgender Identity

This press release was adopted by the National Academy of Medicine, France on February 25, 2022, with 59 votes in favor, 20 votes against, and 13 abstaining. It was approved in its revised version by the Administrative Council on February 28, 2022.

Transgender identity is a feeling of identifying as a gender different from that assigned at birth, which is persistent and lasts more than 6 months. This experience can cause significant and prolonged distress, which can contribute to an increased risk of suicide. [a] No genetic predisposition has been found.

While this condition has long been recognized, a sharp increase in demand for medical interventions has been observed (1,2) first in North America, then in Northern Europe, and, more recently, in France, particularly among children and adolescents. A recent study of a number of high schools in Pittsburgh revealed a prevalence that is clearly higher than previously estimated in the United States (3): 10% of students declared themselves to be transgender or non-binary or were unsure of their gender.[b] In 2003, the Royal Children's Hospital in Melbourne diagnosed only one child with gender dysphoria, whereas today it treats nearly 200.

Whatever the mechanisms involved in adolescents - excessive engagement with social media, greater social acceptability, or influence by those in one's social circle - this epidemic-like phenomenon manifests itself in the emergence of cases or even clusters of cases in the adolescents' immediate surroundings (4). This primarily social problem is due, in part, to the questioning of an overly dichotomous view of gender identity by some young people.

The demand for medical interventions, due to the distress that this condition (which is not a mental illness per se) causes, leads to a growing supply of care in the form of consultations or care in specialized clinics. This involves many pediatric subspecialties. The psychiatric consultations are utilized first, and if the identity is authentic and the discomfort persists, endocrinology, gynecology and, ultimately, surgery become involved.

However, great medical caution must be taken in children and adolescents, given the vulnerability, particularly psychological, of this population and the many undesirable effects and even serious complications that can be caused by some of the therapies available. In this regard, it is important to recall the recent decision (May 2021) of the Karolinska University Hospital in Stockholm to prohibit the use of puberty blockers.

If France allows the use of puberty blockers or cross-sex hormones with parental authorization and no age limitations, the greatest caution is needed in their use, taking into account the side-effects such as the impact on growth, bone weakening, risk of sterility, emotional and intellectual consequences and, for girls, menopause-like symptoms.

As for surgical treatments, specifically mastectomy, which is allowed in France at the age of 14, and surgeries relating to the external genitalia (vulva, penis), it must be emphasized that these procedures are irreversible.

When medical care is provided for this reason, it is essential to ensure medical and psychological support, first for the affected children and adolescents, but also for their parents, especially since there is no test to distinguish between persisting gender dysphoria and transient adolescent dysphoria. Moreover, the risk of over-diagnosis is real, as evidenced by the growing number of young adults wishing to detransition.[c] It is, therefore, appropriate to extend the phase of psychological care as much as possible.

The National Academy of Medicine draws the medical community's attention to the growing demand for care in the context of transgender identity in children and adolescents, and recommends the following:

- Children and adolescents expressing a desire to transition, as well as their families, should receive extended psychological support;
- Should the desire to transition persist, the decision to treat with puberty blockers or cross sex-hormones must be considered carefully and within the framework of multidisciplinary consultations;
- Medical studies should include clinical information specifically adapted for informing and guiding young people and their families;
- Continued research into both, clinical and biological, as well as ethical aspects of this matter, still lacking in France, is needed;
- Parents addressing their children's questions about transgender identity or associated distress should remain vigilant regarding the addictive role of excessive engagement with social media, which is both harmful to the psychological development of young people and is responsible for a very significant part of the growing sense of gender incongruence.

Glossary:

a. Gender dysphoria is the medical term used to describe the distress resulting from the incongruence between the experienced gender and the gender assigned at birth (5).
b. A non-binary person is a person whose gender identity is neither male nor female.
c. A transgender person adopts the appearance and lifestyle of a sex different from that assigned at birth. Whether born a man or a woman, the transgender person modifies, or even rejects, his or her original sexual identity. The sex registered on their official documents does not match the appearance presented. This does not necessarily involve medical interventions.

Unofficial translation by the Society for Evidence-based Gender Medicine (SEGM), March 2, 2022.

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Researchers Found Puberty Blockers And Hormones Didn't Improve Trans Kids' Mental Health At Their Clinic. Then They Published A Study Claiming The Opposite. (Updated)

A critique of Tordoff et al. (2022)

Jesse Singal Apr 6 209 130

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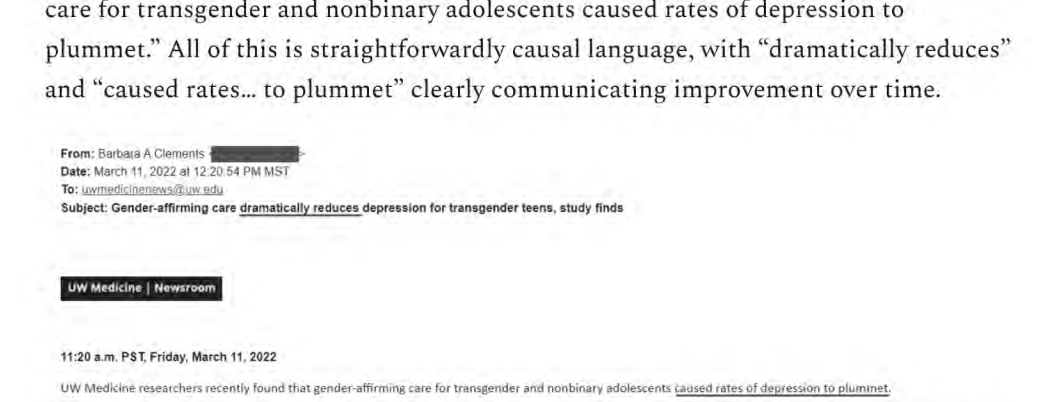
An article called "Mental Health Outcomes in Transgender and Nonbinary Youths Receiving Gender-Affirming Care" was published in JAMA Network Open late in February. The authors, listed as Diana M. Tordoff, Jonathon W. Wanta, Arin Collin, Cesalie Stepney, David J. Inwards-Breland, and Kym Ahrens, are mostly based at the University of Washington–Seattle or Seattle Children's Hospital.

In their study, the researchers examined a cohort of kids who came through Seattle Children's Gender Clinic. They simply followed the kids over time as some of them went on puberty blockers and/or hormones, administering self-report surveys tracking their mental health. There were four waves of data collection: when they first arrived at the clinic, three months later, six months later, and 12 months later.

The study was propelled into the national discourse by a big PR push on the part of UW–Seattle. It was successful — Diana Tordoff discussed her and her colleagues' findings on *Science Friday*, a very popular weekly public radio science show, not long after the study was published.

All the publicity materials the university released tell a very straightforward, exciting story: The kids in this study who accessed puberty blockers or hormones (henceforth GAM, for "gender-affirming medicine") had better mental health outcomes at the end of the study than they did at its beginning.

The headline of the emailed version of the press release, for example, reads, "Gender-affirming care dramatically reduces depression for transgender teens, study finds." The first sentence reads, "UW Medicine researchers recently found that gender-affirming care for transgender and nonbinary adolescents caused rates of depression to plummet." All of this is straightforwardly causal language, with "dramatically reduces" and "caused rates… to plummet" clearly communicating improvement over time.



The email continues:

> "Gender-affirming care is lifesaving care," said Arin Collin, a fourth-year medical student at the University of Washington School of Medicine, and one of the study authors. "This care does have a great deal of power in walking back baseline adverse mental-health outcomes that the transgender population overwhelmingly [experiences] at a very young age."

The web version has a softer headline but maintains an eye-grabbing opening: "In study findings published in JAMA Network Open, the investigators reported that gender-affirming care was associated with a 60% reduction in depression and a 73% drop in harmful or suicidal thoughts among the participants. They received their care at Seattle Children's Gender Clinic." When we talk about a "reduction" or a "drop," of course we mean "over time."

UW's publicity push included other media assets, including a video of Collin discussing the finding and a "Gender-Affirming Care for Adolescents soundbite log" Google document. In the log, Collin explains: "The results were very dramatic. We had a 56.7% baseline rate of depression, and a 43.4% baseline rate of suicidality – but receipt of any form of gender-affirming care, either or [sic] the puberty blockers or the gender-affirming hormones, was associated with a 60% reduction in depression and a 73% reduction in suicidality." Again, anyone reading this will interpret Collin's claim as "These kids had high baseline rates of depression and suicide, and then they were put on puberty blockers or hormones, and then those rates went down significantly."

To drive the point home further, Collin posted the study to /r/science on Reddit with the headline "Transgender and nonbinary youth who received gender affirming medical care experienced greatly reduced rates of suicidality and depression over the course of 12 months." The post has 13,400 upvotes and more than 1,700 comments, many of them remarking on what an important finding it is. Here Collin is plainly, indisputably arguing that the kids who went on GAM experienced mental health improvement during the study. (I reached out to Collin on Reddit but didn't hear back.) Collin also posted it to the /r/medicine subreddit with a more neutral headline, but echoed that same claim in a comment: "The short version is that transgender and nonbinary youth who received gender affirming care (defined as either Leuprolide, Testosterone, or Estradiol) of any sort experienced a 60% decrease in baseline depression and a 73% reduction in baseline suicidality over the course of 12 months."

It isn't just the publicity materials; the paper itself tells a similar story, at least a few times. The "Key Points" box found to the right of the abstract reads, "In this prospective cohort of 104 TNB [transgender and nonbinary] youths aged 13 to 20 years, receipt of gender-affirming care, including puberty blockers and gender-affirming hormones, was associated with 60% lower odds of moderate or severe depression and 73% lower odds of suicidality over a 12-month follow-up." The body of the paper also contains at least two sentences clearly claiming that the kids who went on blockers and hormones experienced improved mental health over time:

> Our findings are consistent with those of prior studies finding that TNB adolescents are at increased risk of depression, anxiety, and suicidality and studies finding long-term and short-term improvements in mental health outcomes among TNB individuals who receive gender-affirming medical interventions.
>
> …
>
> Our study provides quantitative evidence that access to PBs or GAHs in a multidisciplinary gender-affirming setting was associated with mental health improvements among TNB youths over a relatively short time frame of 1 year. [endnotes omitted]

What's surprising, in light of all these quotes, is that the kids who took puberty blockers or hormones **experienced no statistically significant mental health improvement during the study**. The claim that they *did* improve, which was presented to the public in the study itself, in publicity materials, and on social media (repeatedly) by one of the authors, is false.

It's hard even to figure this out from reading the study, which omits some very basic statistics one would expect to find, but the non-result is pretty clear from eTable 3 in the supplementary materials, which shows what percentage of study participants met the researchers' thresholds for depression, anxiety, and self-harm or suicidal thoughts during each of the four waves of the study:

eTable 3. Prevalence of Outcomes Over Time by Exposure Group

Time Point:	Baseline		3 Months		6 Months		12 Month	
Exposure:	*PB/GAH*	*None*	*PB/GAH*	*None*	*PB/GAH*	*None*	*PB/GAH*	*None*
N	7	92	44	38	59	24	57	6
Outcomes (no.,%)								
Moderate to Severe Depression	4 (57%)	54 (59%)	24 (55%)	29 (76%)	33 (56%)	13 (54%)	32 (56%)	5 (83%)
Moderate to Severe Anxiety	4 (57%)	47 (51%)	23 (52%)	23 (61%)	28 (48%)	10 (42%)	29 (51%)	4 (67%)
Self-harm or Suicidal Thoughts	3 (43%)	41 (45%)	13 (30%)	21 (55%)	25 (42%)	11 (46%)	21 (37%)	5 (83%)

At each time point, "PB/GAH" refers to the kids who reported being on puberty blockers or gender-affirming hormones, while "none" refers to the kids who reported no such treatment.

Among the kids who went on hormones, there isn't genuine statistical improvement here from baseline to the final wave of data collection. At baseline, 59% of the treatment-naive kids experienced moderate to severe depression. Twelve months later, 56% of the kids on GAM experienced moderate to severe depression. At baseline, 45% of the treatment-naive kids experienced self-harm or suicidal thoughts. Twelve months later, 37% of the kids on GAM did. These are not meaningful differences: The kids in the study arrived with what appear to be alarmingly high rates of mental health problems, many of them went on blockers or hormones, and they exited the study with what appear to be alarmingly high rates of mental health problems. (Though as I'll explain, because the researchers provide so little detailed data, it's hard to know exactly how dire the kids' mental health situations were.)

If there were improvement, the researchers would have touted it in a clear, specific way by explaining exactly how much the kids on GAM improved. After all, this is exactly what they were looking into — they list their study's "Question" as "Is gender-affirming care for transgender and nonbinary (TNB) youths associated with changes in depression, anxiety, and suicidality?" But they don't claim this anywhere — not specifically. They reference "improvements" twice (see above) but offer no statistical demonstration anywhere in the paper or the supplemental material. I wanted to double-check this to be sure, so I reached out to one of the study authors. They wanted to stay on background, but they confirmed to me that there was no improvement over time among the kids who went on hormones or blockers.

That's why I think the University of Washington–Seattle, JAMA Network Open, and the authors of this study are simply misrepresenting it. Anyone who reads their publicity materials, or who reads the study itself in a less-than-careful-manner, or who finds Collin's Reddit posts, will conclude that this study found that access to GAM improved trans kids' mental health outcomes over time.

But that simply didn't happen.

How The Authors Are Able To Claim The Treatments Worked

The researchers can't offer any specific statistical evidence that the kids who went on blockers and hormones improved over time. So instead, they claim that according to a statistical model they ran that supposedly adjusted for other, potentially confounding factors, the kids who went on GAM did better *than the kids in the sample who didn't*. In the abstract, they write: "After adjustment for temporal trends and potential confounders, we observed 60% lower odds of depression (adjusted odds ratio [aOR], 0.40; 95% CI, 0.17-0.95) and 73% lower odds of suicidality (aOR, 0.27; 95% CI, 0.11-0.65) among youths who had initiated PBs or GAHs compared with youths who had not." As the on-background researcher confirmed, this is an average of observations conducted at all time points in the study, not just a comparison between the baseline and 12-month observations.

"Mental health problems plummeted among kids who went on X" is a very different claim than "Kids who went on X didn't experience improved mental health, but had better outcomes compared to kids who didn't go on X." That difference matters a great deal here. After all, in the present debate over blockers and hormones, a very common refrain is that these medications are so powerfully ameliorative when it comes to depression and suicide that it is irresponsible to deny or delay their administration to kids. It's frequently argued that if kids don't have access to this medicine, they will be at a high risk of killing themselves. I don't know what this claim could possibly mean if it doesn't mean that upon starting blockers or hormones, a trans kid with elevated levels of depression or suicidal ideation will experience relief. These researchers, firmly enmeshed in this debate, found that kids who went on these medications did not experience relief — and yet they don't mention this worrisome fact anywhere in their paper.

Rather, they premise their argument on the fact that while the kids who went on GAM stayed stable, the kids who didn't go on GAM got worse. As the on-background researcher explained in an email, "[W]hen we adjusted our models for receipt of PB/GAH [that is, puberty blockers and gender-affirming hormones] we saw that depression and suicidality significantly worsened among youth who had not (yet) started PB/GAH at 3 and 6 months relative to baseline levels." So the action here, as the researcher admits, comes not from the kids in the treatment group getting better, but rather from the kids in the comparison group getting *worse*.

This brings us into very different territory, medicine-wise. Sure, there are some contexts where merely keeping someone stable might be considered a good outcome. If you give someone with stage IV cancer a drug and it keeps their tumors the same size for many months or even years, that's often a win. If you give an Alzheimer's patient a drug and it arrests their neurocognitive decline for a protracted period, that would be a win (I don't think we even have any drugs like this). But the point of puberty blockers and especially hormones is to make kids *better*, and they didn't get better in this study[1]. I'm not saying that improvement in a treatment group is necessary *and* sufficient for claiming a treatment works — you also need a control or comparison group (click the footnote for a brief explanation of what I mean here if this confuses you at all[2]) — but if you give someone medicine to treat something, and their symptom doesn't improve, shouldn't that cause you to question whether the treatment works?

The kids on GAM in this study didn't get better over time. So if we're going to accept the researchers' claim that their paper offers evidence that GAM works, that requires that we accept that the differences in outcomes between the GAM and no-GAM groups were *caused* — or mostly caused — by the latter group not accessing GAM. But why should we? There are many other potential explanations for this pattern of results, and they're mostly ignored by the researchers, with the exception of a couple points where they offer fairly generic assurances that they believe they have accounted for the possibility of omitted confounding variables.

Despite the fact that two of the authors worked at Seattle Children's Hospital, where the gender clinic is based, the paper doesn't include a single word of even informed speculation attempting to explain why some kids accessed GAM and others did not. Nor do the authors seem to notice that by the end of the study, the no-GAM group has dwindled to a grand total of *six* kids who reported mental health data, as compared to 57 in the group receiving treatment.

eTable 3. Prevalence of Outcomes Over Time by Exposure Group

Time Point:	Baseline		3 Months		6 Months		12 Month	
Exposure:	*PB/GAH*	*None*	*PB/GAH*	*None*	*PB/GAH*	*None*	*PB/GAH*	*None*
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Outcomes (no.,%)								
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To be clear, attrition in a study like this is normal. Inevitable. If you send out four waves of surveys, you're going to have far fewer responses at the end than you did at the beginning. A much bigger problem is a significant difference in the *rates* of attrition between two groups: when one group falls out of the study at a much higher rate than the other. This "undermines the assumption that the program and control groups have the same measured and unmeasured characteristics at baseline," as a helpful guide published by a pair of researchers at Mathematica, a top public policy analysis firm, puts it. "It can create an imbalance between the two groups if the characteristics of those who have follow-up data differ from those who do not." (There isn't a traditional "control" group in the JAMA Network Open paper, but the same logic about differential rates of attrition applies any time you're comparing two groups in a manner that rests on an "all else is more or less equal" premise. If all else is far from equal, your comparison is broken.)

The vast majority of kids who dropped out of this study didn't access GAM. By the end of the study, just 6/63 of the remaining kids who provided mental health data, or 9.5% of the study participants, were in the no-GAM group. Overall, according to the researchers' data, 12/69 (17.4%) of the kids who *were* treated left the study, while 28/35 (80%) of the kids who *weren't* treated left it[3]. This is a massive difference. (They're a small group, but the no-GAM kids who were still in contact with clinic at the 12-month mark also had sky-high rates of moderate to severe depression and self-harm or suicidal thoughts, which might suggest something unusual about them as compared to everyone else in the cohort.)

(Deleted 'Update' went here — see footnote[4].)

Because the researchers don't even mention this large difference in the two groups' rates of attrition, all we can do is speculate. But it's easy to see how it might affect their findings. Let's say that a handful of the kids whose characteristics were measured at baseline weren't particularly gender dysphoric, for example — maybe they were just going through a rough patch, or maybe their socially conservative parents took them to a gender clinic over "cross-gender" behavior but nothing was really "wrong" with them. It stands to reason these kids and their parents would lose touch with the clinic because they no longer required its services. If these kids did pretty well over the next year, that would mean you're taking a handful of kids who would have represented pretty healthy members of the comparison group and tossing them out into the ether, nudging that group in a less-healthy-seeming direction on average. So when the on-background researcher tells me that "depression and suicidality significantly worsened among youth who had not (yet) started PB/GAH at 3 and 6 months relative to baseline levels," it's important to remember that ~~every two out of the three~~ new waves of the study, significant numbers of kids are dropping out — and overall the vast majority of the dropouts are on the "no GAM" side. If the dropouts had fairly good mental health, that could give the false appearance of the group "worsening" on average, even if *individual members* of the group aren't actually worsening. (Imagine you have just two kids at the first wave, one suicidal and one not. If the non-suicidal kid drops out before the second wave and the suicidal kid remains suicidal and in the study, your group has "worsened" from 50% suicidal to 100% suicidal.) (**Correction:** I shouldn't have said there are dropouts "every new wave of the study," as I originally did. Between the second and third waves there aren't any dropouts, and in fact the sample size in eTable 3 seems to go up one, perhaps due to a prior nonresponder now responding. But in the shift from 3 Months to 6 Months, about 14 member of the no-GAM group appear to flow into the GAM group, so it's the same issue: When you say the no-GAM group has gotten worse, you're talking about a group that is shrinking in size, and it seems unlikely that the kids who leave the study or switch to the GAM group are doing so randomly. Anyway, the correct way to describe the dropout pattern is that there are significant numbers of dropouts between the first wave and the second, and between the third wave and the forth — see eTables 3 and 4. I'm leaving the sentence up with one word struck through and the new, now-correct language in bold.)

On the flip side, what accounts for the handful of kids who didn't go on medication, but who did stay in touch with the clinic for six months or a full year? Because, again, the researchers exhibit such incuriosity about the quirks of their own data, all we can do is speculate. One possibility is that these kids had severe or worsening mental health comorbidities that, in the eyes of the clinicians, needed to be brought under control before blockers or hormones could be administered. This is a fairly frequent occurrence in youth gender clinics.

Frequent enough, at least, that the proposed next version of the adolescent guidelines for the World Professsional Association of Transgender Health's Standards of Care includes this recommendation:

> [W]hen a TGD [transgender or gender-diverse] adolescent is experiencing acute suicidality, self-harm, eating disorders or other mental health crises that threaten physical health, safety must be prioritized. According to the local context and guidelines, appropriate care should seek to mitigate threat or crisis such that there is sufficient time and stabilization for thoughtful gender-related assessment and decision making. For example, an actively suicidal adolescent may not be emotionally able to make an informed decision regarding [*sic, since the sentence ends here — in context, I think what's missing here is something like "these treatments"*]. If indicated, safety-related interventions should not preclude starting gender affirming care.

If even a small handful of the kids in the Tordoff study needed "sufficient time and stabilization for thoughtful gender-related assessment and decision making," that could partially account for a cohort of kids experiencing mental health problems — maybe genuinely worsening ones, in some cases — and not receiving GAM. This would represent causality flowing in the exact opposite direction as what the researchers claim: Rather than it being the case that the kids' mental health was bad because they didn't access GAM, they didn't access GAM because their mental health was bad.

We Can't Check These Theories Because The Researchers Refuse To Share Their Data

I thought I'd at least be able to nibble around the edges of some of these questions based on my correspondence with Diana Tordoff. She's a PhD student in epidemiology at UW–Seattle, listed as the corresponding author for the paper, and the one who "takes responsibility for the integrity of the data and the accuracy of the data analysis." She's the one who went on *Science Friday* to tout the importance of this study — more on that in a bit.

In a March 6 email, Tordoff wrote, "Although we provided the raw data in the supplement for transparency, I advise caution in interpreting these data as is." Great, I thought; I could hand off the data to someone who is better at this stuff than I am and ask what they think. Except the data wasn't actually included in the supplementary material. I asked Tordoff where it was. Radio silence. I sent a polite follow-up email. Again, nothing.

So I reached out to the media contact listed in all that material UW–Seattle had sent out and asked her if the data would be available. "Jesse, contacted the team, and they have no further comment at this time," said the PR person. "They decided to let the methods section speak for itself."

The problem is, there isn't much of a methods section to speak of, so there are a lot of serious questions about the validity of this research — including whether the authors took the proper statistical approach at all.

The Researchers Might Not Have Used The Right Statistical Method

The authors of Tordoff et al. got their results using a method called generalized estimating equations. This is above my pay grade, stats-wise, so I reached out to a coauthor on what I believe is the single most-cited paper on this technique I could find, James Hanley. He's a professor of epidemiology and biostatistics at McGill University who has taught many methods courses, and he agreed to look at the Tordoff et al. study and tell me what he thought. He generously marked up a copy of the paper with a bunch of his feedback and treated me to a one-on-one Zoom-tutoring session explaining what he found.

At the most basic, eyeballing-the-data level, Hanley agreed with me that the results communicated in the supplemental materials were damning for the researchers. If the treatments "were that good, the later percentages would be a lot lower," he said of the percentages in the rightmost part of eTable 3. "Of course, the entire cohort was not surveyed at 12 months, so we cannot say how the entire group was faring at that timepoint, but of those that were questioned at the end, there is a substantial percentage that is reporting suicidal thoughts." If these treatments did successfully address suicidality and depression, one would expect the corresponding numbers to have dropped considerably, which they didn't.

But Hanley also said he simply thought the researcher chose a questionable technique for their analysis — one that obscures many potentially important features of their data, especially the dropout issues. He described generalized estimating equations as "quite a poor person's way of dealing with [this sort of data]." "Today very few data-analysts would do this for longitudinal data, where you have four measurements on the same person," he said. "There's fancier ways of handling such data today." Hanley thinks a so-called multilevel or hierarchical model would have been better. Also, "[I]nstead of dichotomizing the scores, leaving them as-is would have allowed us to see a curve for each participant." I'll explain this in more depth in the next section, but here Hanley means a curve showing each person's or group's mental health scores over time.

In this sort of analysis, said Hanley, "We would also see where the follow-up of each participant stopped, and where that person was at when they left. It might be that they left because they were feeling better, or because they felt that the treatment was not doing that much for them." This would allow the researchers to more specifically "count who went up and who went down," mental health–wise, he explained. "And you could probably even say, if they got treatment here, did they go down? So it's a lot more transparent to do things properly by these hierarchical models."

Another problem Hanley noted is that 17 individuals in the sample provided only baseline data, subsequently dropping out of the study — and yet this data was included in the final model. Here's where we risk getting slightly too in the weeds, and I don't want to get lost, because I think many of the critiques of the Tordoff et al. study don't rely on a particularly sophisticated understanding of statistics. But what Hanley is saying here is that the researchers' model, which for the stats geek is this…

$$\textbf{Model 2: } logit(Y_i) = \beta_0 + \beta_1 E_i + \beta_2 T_i + \beta_3 Y_0 + \sum \alpha_k X_{k0}$$

…draws significantly from these one-time observations. "That, to me, is major because any comparison they make now has a subtraction involving some people that aren't there anymore and can only contribute to the baseline prevalences." The researchers don't explain why they include this data in the model, but Hanley's point — that a bunch of people immediately drop out between waves one and two — is apparent from a glimpse at eTables 2 and 3. There are 20 immediate dropouts when it comes to the number of study participants who responded to the survey at all, and 17 when it comes to the number who provided responses on the mental health measures.

eTable 2. Prevalence of Exposure Over Time

	Baseline	3 months	6 months	12 months
N	104	84	84	65
Exposure (no.,%)				
PB/GAH	7 (7%)	44 (52%)	59 (71%)	57 (89%)
None	97(93%)	41 (48%)	24 (29%)	7 (11%)

eTable 3. Prevalence of Outcomes Over Time by Exposure Group

Time Point:	Baseline		3 Months		6 Months		12 Month	
Exposure	*PB/GAH*	*None*	*PB/GAH*	*None*	*PB/GAH*	*None*	*PB/GAH*	*None*
N	7	92	44	38	59	24	57	6
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Moderate to Severe Anxiety	4 (57%)	47 (51%)	23 (52%)	23 (61%)	28 (48%)	10 (42%)	29 (51%)	4 (67%)
Self-harm or Suicidal Thoughts	3 (43%)	41 (45%)	13 (30%)	21 (55%)	25 (42%)	11 (46%)	21 (37%)	5 (83%)

Overall, Hanley described generalized estimating equations as "a very crude way to deal with [this type of data], and kind of a naive way." The technique "gives them great power to kind of make any comparison they want, and then talk about change — well, it is change, but they don't talk about change properly."

The Problem With Variable Dichotomization

The dichotomization issue Hanley mentioned is extremely important.

As I noted above, Tordoff et al. suffers from a strange lack of concrete statistical information. Let's focus on the main instrument the researchers used to gauge depression and suicidality, the so-called Patient Health Questionnaire 9-item, or PHQ-9, which consists of nine items plus a final item that isn't factored into the score, and which is filled out as follows (or click here):

ID #: ______________________ DATE: ______________

Over the last 2 weeks, how often have you been bothered by any of the following problems? (use "✓" to indicate your answer)	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
	add columns	+	+	
(Healthcare professional: For interpretation of TOTAL, please refer to accompanying scoring card).	TOTAL:			

10. If you checked off *any* problems, how difficult have these problems made it for you to do your work, take care of things at home, or get

Not difficult at all ______

Somewhat difficult ______

Very difficult

Extremely difficult ______

The lowest possible score is zero (9 x 0), and the highest possible score is 27 (9 x 3). Rather than report on the average values participants in the study reported, the researchers *dichotomized* this data — they turned it into a variable that has only two values, yes or no (or 1 or 0, if you like). If you score 10 or higher, you're coded as a *yes*, meaning you have "moderate or severe depression." Lower than 10, you're coded as a *no*, meaning you do *not* have "moderate or severe depression." The researchers also dichotomized suicidality, which is covered by the ninth item — whether the respondent has experienced "Thoughts that you would be better off dead, or of hurting yourself" and which is scored from 0 to 3 based on how frequently the respondent said they felt that way in the last couple weeks. If they get a 1, a 2, or a 3, they're considered a *yes* regarding self-harm or suicidal ideation; if they get a 0, they're a *no*.

This strips out a lot of useful information. For example, in the Tordoff et al. study, someone who scores a 27 on the PHQ-9 — an almost unfathomable level of distress — is viewed as having the same mental health status as someone who scores a 10. If you read through the above items, it's easy to imagine that someone who scores a 10 is having a bit of a difficult time, but is still pretty functional. Not so for folks at the higher ranges. Most PHQ-9 scores, in this study, count as a *yes*, you have depression problems.

The researchers don't report on their participants' mental health in a careful, detailed way, save for one table that provides a breakdown of what percentage of participants were in each "bucket" of minimal, mild, moderate, moderately severe, and severe depression at baseline (which, again, includes 17 readings of kids who were subsequently lost to all follow-up, so it's unclear what we should do with them). You won't even find the average PHQ-9 score at baseline anywhere in the paper or in the supplementals, let alone the scores at various waves of data collection, or broken down by GAM/no-GAM. The reported odds ratios refer simply to the probability of someone in the study getting a 10 or higher on the PHQ-9, a 1 or higher on the suicide question, or a 10 or higher on an anxiety scale (I'm mostly ignoring that one because the researchers report a null finding there, anyway). Compare this lack of basic data to how a group of Dutch researchers reported their findings in an important 2014 study of youth medical transition. In that paper, the authors provided clear information about the average outcome scores at each wave of data collection. There's no mystery about exactly what the numbers are.

There are many downsides to the statistical bluntness and lack of transparency in the Tordoff et al. study. For example, by the study's method, a kid who scores a 24 on the PHQ-9 at baseline and a 15 three months later hasn't improved at all — he is "moderately or severely depressed" at both waves — whereas a kid who scores a 10 at baseline and a 9 three months later has graduated from "moderately or severely suppressed" to "not moderately or severely depressed." A one-point decrease can be much more important than a nine-point one. This is a nice advertisement for the limits of variable dichotomization.

To be sure, sometimes dichotomized variables are useful. Everywhere in medicine you have to establish cutoff points simply to determine, or help determine, who "officially" has a condition, is eligible for treatment, and so on. But to publish an entire paper based in part on a 27-point scale and offer no insights into how the treatment versus control groups fared, other than whether or not they scored a 10 or higher on that scale — I really think it suggests the researchers are hiding something, that they ran other analyses, didn't find what they wanted to find, and then chose a very crude method (to borrow Hanley's adjective) that allowed them to "show" that a treatment they favor "works."

One potential hint that this might be the case is that at no point do the authors show that they checked whether their findings are robust to different thresholds. As they note, the PHQ-9's 27-point scale has other cutoff points, such as 15 (moderately severe) and 20 (severe). If you're going to stick solely to dichotomized measures, why not at least report what happens when you apply those different cutoffs to the same model? I bet the answer is that usually, they got nothing — no evidence the GAM group did better than the no-GAM group.

It's definitely possible I'm being uncharitable here. A lot of this would be easy to check if the researchers would provide the data. But because they won't, and because they didn't even summarize it anywhere, we're forced to guess about why they made the choices they did.

One Of The Researchers Responds

We'll likely never know for sure, but I would wager that the mental health differences observed between the GAM and no-GAM groups were mostly caused by factors other than receipt of puberty blockers and hormones. I'm basing that theory on the fact that the groups appear to be quite different, given the massive difference in their respective dropout rates. Plus, the entire sample had data taken *at a gender clinic*, meaning that for the minors, their parents consented to bring them there and have them evaluated. They were in a pretty good position to get puberty blockers or hormones if they wanted them and if the doctors agreed it was the right move.

Someone made similar arguments in the online comment system on the JAMA website, and Tordoff responded (click "comments" if that link doesn't work). First, she writes that at Seattle Children's Gender Clinic, kids who wanted to go on GAM (and who had parental approval if they were minors) were generally put on it regardless of their mental health status:

> In practice, the only instances when it would have been appropriate to delay initiation of PB/GAH is if there was a concern that a patient did not have the capacity to provide informed consent (which is exceedingly rare in adolescence). Therefore, youth who reported moderate to severe depression, anxiety, or suicidal thoughts were not precluded access to PB/GAH, especially since initiating PB/GAH is known to improve or mitigate these symptoms.

These are somewhat tangential points, but it's interesting that Tordoff claims that "initiating PB/GAH is known to improve or mitigate these symptoms," when the whole point of her study was to investigate this question, and when she and her team found that these medicines *didn't* do that. I'm also genuinely curious what percentage of youth gender clinicians would agree with her that it is "exceedingly rare" an adolescent can't provide meaningful informed consent for GAM — a lot of the ones I've spoken with have said this comes up with some frequency, especially in cases involving serious mental health comorbidities. (Tordoff somewhat misconstrues the new World Professional Association for Transgender Health guidelines elsewhere in her comment, in my opinion, but I'll relegate that point to a footnote[5].)

Either way, Tordoff is saying that the clinic usually didn't view severe depression or suicidality as a reason to slow down the administration of hormones. Plus, she said, "we have empirical evidence that there were not significant differences in the prescription of PB/GAH by baseline mental health":

> We observed that a similar proportion of youth with poor mental health symptoms at baseline received PB/GAH during follow-up compared to youth who didn't report these symptoms. Specifically, there were no significant differences in receipt of PB/GAH during our study follow-up period among youth with and without moderate to severe depression (64% v. 76%, p-value = 0.234); with and without moderate to severe anxiety (67% v. 71%, p-value = 0.703); and with and without self-harm or suicidal thoughts (62% v. 75%, p-value = 0.185) at baseline. Although we observed that youth with poor mental health at baseline were slightly less likely to be prescribed PB/GAH during our study, these difference[s] were small in magnitude (4-13 percentage points) and were not statistically significant.

The researcher who wanted to stay on background also said youth with and without mental health problems had "similar retention in the study," meaning the differential rates of attrition shouldn't be of much concern, although they didn't provide any data backing up this claim. Assuming all this is true — that the clinic does readily administer blockers and hormones with little regard to the mental health status of its patients, and that there were no significant differences on the attrition front — it would at least dent my claim that mental health problems might be causing a lack of access to GAM in this study, rather than the reverse.

The problem is, the researchers offer no data in their study or supplementals showing any of this — and Tordoff's informal data point in the direction we'd expect if my theory were true, that the more mentally ill kids were less likely to go on treatment! The differences she cites are by no means tiny — 12 percentage points for depression and 13 percentage points for self-harm or suicidal thoughts (the smaller one, 4 percentage points, applies to anxiety, where the researchers aren't claiming to have found anything).

Tordoff points out that these differences aren't statistically significant, which is true, but all that means is they're above the arbitrary $p < .05$ threshold. A statistically insignificant effect doesn't mean no effect exists — rather, it means that one can't conclusively exclude the possibility that any apparent difference is the result of random chance. In this case, the textbook definition of a p-value should cause us to conclude that there's about a 23% chance we'd observe a difference at least as large as 12 percentage points in the rates of depression between kids who did and didn't go on hormones, and about a 19% chance we would observe a difference at least as large as 13 points between the suicidality rates of the kids who did and didn't go on GAM, if there were no genuine relationships between these variables. So this by no means debunks the theory of serious, unaccounted-for baseline differences between the two groups.

Even if we adopt an extremely charitable stance toward Tordoff's argument here and assume that there's *no* evidence in her data of a connection between mental health status and whether or not a patient accessed GAM, remember that she and her colleagues are using very blunt *yes*/*no* measures of depression and suicidality — for both measures, the majority of points on the scale in question is treated as a *yes* rather than a *no* (specifically, scores from 10 to 27 are treated as a *yes* on the 0-to-27 depression scale, and scores from 1 to 3 are treated as a *yes* on the 0-to-3 suicide item). So even if it's the case that the researchers didn't observe a statistically significant difference in the percentage of two groups that reached the Moderate threshold, that doesn't mean there weren't important differences between these groups. In fact, almost every methodological choice made by the researchers would have the effect of blurring any differences that did exist.

To drive this point home, let's imagine an intentionally extreme scenario involving just two very different kids in the study, both natal females:

Kid A, 12 years old, scores a 10 on the PHQ-9, doesn't have gender dysphoria, and was dragged to the clinic because she has socially conservative parents unhappy she cut her hair short and wants to wear "boy" jeans. Her parents, upon being told there's nothing "wrong" with their kid other than some (barely "moderate") depression — perhaps exacerbated by her parents' attempts to exert so much control over her attire and fashion — don't bring her back to the gender clinic.

Kid B, also 12 years old, scores a 22 on the PHQ-9, has severe, crippling gender dysphoria and has already socially transitioned — he is a trans boy. He is quickly given an "official" diagnosis of gender dysphoria and started on puberty blockers, and he and his parents stay in contact with the clinic for the next three waves of data collection.

By the researchers' own methods, these two kids would be seen as having "similar" levels of depression, and this dyad would contribute to the conclusion that there were no significant differences between kids who did and didn't go on hormones or blockers, and who did versus didn't drop out! But of course these are wildly different situations, and of course there are a lot of differences here being obscured by a model stuffed with *yeses* and *nos*, with 1s and 0s.

Again, I'm speculating. But my point is that if the researchers' method can't even differentiate between these two kids in a hypothetical, intentionally extreme scenario, of course it's possible that other, less profound differences are being obscured. At-least-moderately depressed kids in the study are 12 percentage points less likely to go on GAM as compared to kids who don't meet that threshold. What's the size of that difference if we bump that threshold up a few PHQ-9 points? More to the point, what is the difference in the *average PHQ-9 scores of these two groups*? It's an eminently reasonable question that anyone should be able to answer simply by reading the paper itself. "Are the two groups we're comparing actually similar?" is a first-two-weeks-of-Stats-101-level question. And yet the answer is nowhere to be found in this paper — it's missing, like so much other basic information[6].

Part Of The Problem Is That Even High-Quality Media Outlets Don't Fact-Check Studies Like This One

I've already written about the abysmal job that mainstream media is doing covering youth gender medicine and don't want to simply recite those points again, but it's a very bad sign that this study was touted on *Science Friday* in the way that it was:

> [Host] IRA FLATOW: Diana, can you walk me through what you found in this study about trans and nonbinary kids and teens?
>
> DIANA TORDOFF: Absolutely. Thank you for having us here today. Our study was conducted at Seattle Children's Hospital's Gender Clinic. And our goal was to prospectively follow youth during their first year of receiving care to better understand their experiences, their well-being, as well as barriers they faced in accessing care. So we enrolled 104 trans youth, who are aged 13 to 20. And we found that youth who received puberty blockers or gender-affirming hormones were 60% less likely to be depressed and 73% less likely to have suicidal thoughts, compared to youth who did not receive these medications.
>
> IRA FLATOW: That's a huge difference.
>
> DIANA TORDOFF: It's huge.
>
> …
>
> IRA FLATOW: And major medical associations support gender-affirming care, right?
>
> DIANA TORDOFF: Absolutely. These medications are both safe. And their use in adolescents is supported by a large number of medical and professional societies, including the American Academy of Pediatrics and the American Medical Association.

That's it. The study found a "huge difference." No follow-up questions, such as why the kids who went on blockers and hormones in Tordoff's sample didn't get better. I wouldn't be surprised if it turned out that no one at *Science Friday* even read the study in full.

Tordoff also describes blockers and hormones for youth as "safe," without any further elaboration or detail. This is an exaggeration of our present state of knowledge in this area. "Any potential benefits of gender-affirming hormones must be weighed against the largely unknown long-term safety profile of these treatments in children and adolescents with gender dysphoria," said the UK's National Institute for Health and Care Excellence in 2020, alongside a companion report on puberty blockers that found scant quality evidence of their safety and efficacy as well. The so-called Cass Review, another important UK effort geared at summarizing the data and steering the future course of youth gender treatment there, which was released just weeks ago in interim form, noted that "The important question now, as with any treatment, is whether the evidence for the use and safety of the medication is strong enough as judged by reasonable clinical standards." As in, it's still an open question. The report also notes that "Short-term reduction in bone density is a well-recognised side effect [of puberty blockers], but data is weak and inconclusive regarding the long-term musculoskeletal impact."

In Sweden and Finland, health authorities are sufficiently concerned about the lack of evidence that it's safe and effective to give puberty blockers and hormones to gender dysphoric minors that they have significantly scaled back the administration of these treatments. According to an unofficial translation of Finland's new guidelines, announced in 2020, "puberty suppression treatment may be initiated on a case-by-case basis after careful consideration and appropriate diagnostic examinations if the medical indications for the treatment are present and there are no contraindications." When Sweden followed suit, instituting new restrictions of its own just a month and a half ago, its National Board of Health and Welfare noted that "There are no definite conclusions about the effect and safety of the treatments," per Google Translate. Sweden's move was animated in part by an alarming alleged scandal — this public television documentary argues that doctors and administrators at a major hospital there appeared to cover up serious adverse effects, including a spinal injury and suicidality, among kids who had undergone these treatments (I interviewed the lead presenter here but it's paywalled).

There isn't a whiff of any of this in the JAMA Network Open paper, nor in the *Science Friday* coverage — you'd think there's simply no debate here whatsoever, that the science is settled, when in fact the controversy has grown so heated that major European healthcare systems have changed their policies on these treatments. Maybe they're wrong to have done so, but it's quite surprising to see an outlet like *Science Friday* completely ignore any of this, and to see clinicians so uninterested in the controversy and so willing to gloss over warning signs in their own data.

It's similarly surprising that JAMA Network Open would allow researchers to claim that a treatment was correlated with improvement over time in the mental health of a group of young people when it wasn't. I reached out to the media contact there, as well as the journal's top two editors, Frederick Rivara and Stephan Fihn, both of whom are at the University of Washington–Seattle, but I didn't hear back.

I think the political environment is exacerbating things, unfortunately. At the state level, Republicans are seeking out genuinely bad and harmful policies. In Texas, what Greg Abbott and Ken Paxton are trying to do can only be described as state-sanctioned child abduction. It's horrific. So part of what's going on is there's a race to prove just how wrong these politicians are, and to produce evidence showing the treatments work. As Tordoff and her colleagues put it at the end of their paper, "Our findings have important policy implications, suggesting that the recent wave of legislation restricting access to gender-affirming care may have significant negative outcomes in the well-being of TNB youths." This is, again, a paper that found that kids who went on blockers and hormones *did not improve*. The science has become completely intertwined with the politics.

But the question of whether the GOP is off the rails on this issue (absolutely) and whether its policies will hurt kids who *should* go on blockers and/or hormones (absolutely) is different from the question of whether we should maintain vigilance and call out half-baked science when it comes to the literature on youth gender medicine (again: absolutely). Adolescent mental health and suicide research, in particular, is a vitally crucial area of science, and we should hold it to high standards. If we can't agree that it's wrong and potentially harmful to distort research on these subjects, what can we agree on?

Questions? Comments? The raw data from Tordoff et al. (2022)? I'm at singalminded@gmail.com or on Twitter at @jessesingal. The daytime image of Seattle Children's Hospital is from here.

1 I guess technically with puberty blockers, "it's complicated." There's a lot of heated debate over the claim that they are administered to "buy time" for a kid and their family to figure out if hormones are the right choice. If that's the case, I don't think stable mental health, rather than improved mental health, would necessarily be a knock on them. But if that's true, no one should claim blockers ameliorate suicidality, which plenty of people do. It's sort of a non sequitur in the case of this study, anyway, since, as per Table 1, so many more of the kids went on hormones (61.5%) than blockers (18.2%), meaning the study serves as an evaluation of the former much more than the latter.

2 Let's say you want to test a new flu medication. You find 50 patients who have the flu and invite them into your medical clinic. There you get some baseline information about their symptoms, give them all the medication, and then check back a week later. Look at that — on average, they've improved significantly!

Unfortunately, that's really only the first step to proving a medical treatment works. It's necessary but not sufficient. There could be other reasons your patients improved. Flu symptoms often abate on their own in time, for one thing. For another, placebo effects can be powerful: Strange as it sounds, it wouldn't be unprecedented if simply walking into a medical clinic and being seen by a doctor itself exerted a mysterious, salutary effect on the patients' health.

To account for these other possibilities — that it wasn't the drug, or wasn't *just* the drug, that caused the improvement — you need a control group. The gold-standard version of such an experimental setup would be to find 100 people with the flu, and then divide them randomly into two groups of 50, each of them equally sick, on average. You treat them identically with the clinic visit, symptom measurement, and so on, with the only exception being half of them get the actual treatment and half of them get a sugar pill or some other sham treatment we wouldn't expect to have any impact on the flu.

If, after that much more onerous procedure is followed, you find a statistically significant difference in the flu symptoms between the treatment and sham groups, *then* you've taken a pretty major step toward proving your treatment works. Improvement alone doesn't cut it, at least as far as gold-standard science is concerned. But if you don't even detect improvement, that's a big problem!

3 Where I'm getting these numbers from:

> The vast majority of kids who dropped out of this study didn't access GAM. By the end of the study, just **6/63** of the remaining kids who provided mental health data, or 9.5% of the study participants, were in the no-GAM group. Overall, according to the researchers' data, **12/69** (17.4%) of the kids who *were* treated left the study, while **28/35** (80%) of the kids who *weren't* treated left it.

In order:

6: eTable 3, 12 Month / *None*

63: = 6 + 57, eTable 3, 12 Month / *PB/GAH + None*

12: = 69 - 57, see below for 69 and 57 is from eTable 2, 12 months / *PB/GAH*

69: - Page 1, "By the end of the study, 69 youths (66.3%) had received PBs, GAHs, or both interventions"

28: = 35 - 7, see below for 35 and 7 is from eTable 2, 12 months / *None*

35: Page 1, "while 35 youths had not received either intervention"

4 I originally put a slightly panicky "Update" here because I managed to convince myself there was a potential error in my analysis of the attrition rates. This turned out to be a false alarm — my numbers are correct. I didn't want to leave a paragraph-long update about what turned out to be a non-issue in the body of the piece, so I'll stick it below for transparency's sake, followed by just a bit more detail about the numbers in this section and Footnote 3 for the true obsessives.

The update's original language:

> (**Update, evening of 4/6/2022:** A couple people pointed out that I might be overestimating the magnitude of this difference by failing to account for kids who leave the "None" group not because they are dropping out of the study but because they switched to the "PB/GH" group. I spent a couple more hours banging my head against eTable3 to little avail this afternoon and evening — because the researchers provide so little concrete data, it's *very* hard to figure out exactly what's going on with regard to who is leaving versus crossing over to the other group. I'm asking a couple other people to check my work on this for me and once I hear back from them, if need be I'll update or correct the figures in this paragraph and the footnote. It would take something very strange in the data for this to substantively affect my argument about differential rates of attrition — basically, it would need to be the case that a surprising number of kids switched from the None group to the PB/GAH group between 6 months and 12 month, *and* that a large number of kids already on blockers or hormones dropped out of the study during that same span. I think a large difference in dropout rate is a much more likely explanation, but, again, I'll circle back when I've checked this more thoroughly. Just wanted to get an initial Update published for transparency's sake.)

I'm not sure how I managed to convince myself something was afoot here. Calculating the different rates of attrition is pretty easy. In the prior footnote, I just used eTable 2, specifically the 12-month data...

eTable 2. Prevalence of Exposure Over Time

	Baseline	3 months	6 months	12 months
N	104	84	84	65
Exposure (no.,%)				
PB/GAH	7 (7%)	44 (52%)	59 (71%)	57 (89%)
None	97(93%)	41 (48%)	24 (29%)	7 (11%)

...plus this language from the body of the article: "By the end of the study, 69 youths (66.3%) had received PBs or GAHs... while 35 youths had not received either PBs or GAHs (33.7%) (eTable 3 in the Supplement)."

At the final wave of data, we don't really need to worry much about who switched groups versus dropped out, because we're left with a simple calculation. The total number of kids who went on GAM — the kids still in the study at 12 months plus the ones who dropped out — has to add up to 69. The number still in the study is 57, so there are 12 dropouts. Similarly, the total number of kids who didn't go on GAM — the kids still in the study at 12 months plus the ones who dropped out — has to add up to 35. The number still in the study is 7, so there are 28 dropouts. These are the numbers I originally presented and I have no how I managed to freak myself out about this.

5 Tordoff writes of the clinic's policy of administering puberty blockers and hormones even to severely suicidal, severely depressed kids, since it is "exceedingly rare" these conditions pose major obstacles to a minor giving true informed consent:

> These practices are consistent with updated guidance from the draft WPATH SOC8 guidelines, which state that for youth experiencing acute suicidality, self-harm, or other mental health crises, "safety-related interventions should not preclude starting gender-affirming care" and that "while addressing mental health concerns is important, it does not mean that all mental health challenges can or should be resolve completely[.]"

I think she's selectively cropping from the guidelines, leaving out the fact that the SOC8 includes plenty of cautions about the importance of making sure mental health problems are well-managed prior to the administration of blockers or hormones. To repeat the paragraph I referenced further up in this piece:

> First, when a TGD [transgender or gender-diverse] adolescent is experiencing acute suicidality, self-harm, eating disorders or other mental health crises that threaten physical health, safety must be prioritized. According to the local context and guidelines, appropriate care should seek to mitigate threat or crisis such that there is sufficient time and stabilization for thoughtful gender-related assessment and decision making. For example, an actively suicidal adolescent may not be emotionally able to make an informed decision regarding [these treatments]. If indicated, safety-related interventions should not preclude starting gender affirming care.

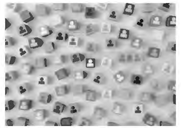
There's some hedging in the paragraph, but I don't know how anyone could read it and come away thinking that the SOC8 thinks that severe suicidality and depression *aren't* good reasons to potentially slow down major medical decisions, contrary to what Tordoff claims is going on at Seattle Children's Gender Clinic. (I do wonder whether the clinic's policies might have been more conservative in 2017 and 2018, when this group of kids came through, but we're already deep into Footnoteistan and there's no need to wander even further off-course...).

6 In one of her online comment responses, Tordoff writes that "our study design did not compare two cohorts.... Rather, we examined temporal trends within a single cohort of youth with a time-varying exposure variable." Okay, but at the end of the day, the results they published were generated by comparing the probability of one group versus another experiencing various outcomes, so I don't think there's anything wrong with harping on this question of whether those two groups were similar enough for any such comparisons to be meaningful.

If Democrats Get Destroyed By The "Critical Race Theory" Backlash, It'll Be Their Own Fault

You can't just keep robotically calling voters backwards bigots forever — not if you care about winning

Jesse Singal Nov 4, 2021 ♡ 90 💬 115



The Market Will Produce Endless Identities, Each More Boring Than The Last

You're not "radically" monogamous! You're not "radically" anything.

Jesse Singal Mar 23 ♡ 111 💬 105

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The mental health establishment is failing trans kids

Gender-exploratory therapy is a key step. Why aren't therapists providing it?

By Laura Edwards-Leeper
and
Erica Anderson

November 24, 2021 at 5:54 p.m. EST

By Laura Edwards-Leeper
and
Erica Anderson

November 24, 2021 at 5:54 p.m. EST

Daryn Ray for The Washington Post

correction

A previous version of this essay said that a quarter of study subjects who reversed their gender transitions did not report this change to their doctors. In fact, three-quarters did not share the information.

At 13, Patricia told her parents she was a transgender boy. She had never experienced any gender dysphoria — distress at a disconnect between gender identity and the sex assigned at birth — she said. But a year earlier, she'd been sexually assaulted by an older girl. Soon after this trauma, she met another older girl who used they/them pronouns and introduced her to drugs, violent poruography and the uotion of dissociation from her body. Her lingering psychic wounds, coinciding with a raft of new and unsettling ideas, plunged her into depression and anxiety. Patricia's parents took her to a therapist so she could talk through her shifting ideutity aud acute mood swings.

The job of a mental health provider here should have been clear: Perform an assessment, ask how long she'd experienced dysphoria and investigate how mental health issues and any other changes in her life might be contributing to it. Instead, on first meeting, the therapist simply affirmed her new identity, a step that can lead to hormonal and eventually surgical treatments. Was Patricia ready for these next steps — or, her parents wondered, was this a normal bout of teenage confusion stemming from a recent trauma? The therapist instructed them to "support"

their child's trans self-diagnosis and to socially transition her. If they didn't, Patricia might end her own life: 41 percent of unsupported children commit suicide, they were told. Would Patricia's parents rather have a dead child or a trans one?

They sought another therapist, one who was more curious and less certain, one who listened closely. After a year of exploring who she was, Patricia no longer felt she was a boy. She decided to stop binding her breasts and wearing boys' clothes.

We are both psychologists who have dedicated our careers to serving transgender patients with ethical, evidence-based treatment. But we see a surge of gender dysphoria cases like Patricia's — cases that are handled poorly. One of us was the founding psychologist in 2007 of the first pediatric gender clinic in the United States; the other is a transgender woman. We've held recent leadership positions in the World Professional Association for Transgender Health (WPATH), which writes the standards of care for transgender people worldwide. Together, across decades of doing this work, we've helped hundreds of people transition their genders. This is an era of ugly moral panic about bathrooms, woke indoctrination and identity politics in general. In response, we enthusiastically support the appropriate gender-affirming medical care for trans youth, and we are disgusted by the legislation trying to ban it.

Seeking a scientific explanation for trans identity could do more harm than good

But the number of adolescents requesting medical care is skyrocketing: Now 1.8 percent of people under 18 identify as transgender, double the figure from five years earlier, according to the Trevor Project. A flood of referrals to mental health providers and gender medical clinics, combined with a political climate that sees the treatment of each individual patient as a litmus test of social tolerance, is spurring many providers into sloppy, dangerous care. Often from a place of genuine concern, they are hastily dispensing medicine or recommending medical doctors prescribe it — without following the strict guidelines that govern this treatment. Canada, too, is following our lead: A study of 10 pediatric gender clinics there found that half do not require psychological assessment before initiating puberty blockers or hormones.

The standards of care recommend mental health support and comprehensive assessment for all dysphoric youth before starting medical interventions. The process, done conscientiously, can take a few months (when a young person's gender has been persistent and there are no simultaneous mental health issues) or up to several years in complicated cases. But few are trained to do it properly, and some clinicians don't even believe in it, contending without evidence that treating dysphoria medically will resolve other mental health issues. Providers and their behavior haven't been closely studied, but we find evidence every single day, from our peers across the country and concerned parents who reach out, that the field has moved from a more nuanced, individualized and developmentally appropriate assessment process to one where every problem looks like a medical one that can be solved quickly with medication or, ultimately, surgery. As a result, we may be harming some of the young people we strive to support — people who may not be prepared for the gender transitions they are being rushed into.

American opinions about transgender youth have shifted dramatically in the past 15 years. The pendulum has swung from a vile fear and skepticism around ever treating adolescents medically to what must be described, in some quarters, as an overcorrection. Now the treatment pushed by activists, recommended by some providers and taught in many training workshops is to affirm without question. "We don't actually have data on whether psychological assessments lower regret rates," Johanna Olson-Kennedy, a pediatrician at Children's Hospital in Los Angeles who is skeptical of therapy requirements and gives hormones to children as young as 12 (despite a lack of science supporting this practice, as well), told the Atlantic. "I don't send someone to a therapist when I'm going to start them on insulin." This perspective writes off questions about behavioral and mental health, seeing them as a delaying tactic or a dodge, a way of depriving desperate people of the urgent care they clearly need.

But comprehensive assessment and gender-exploratory therapy is the most critical part of the transition process. It helps a young person peel back the layers of their developing adolescent identity and examine the factors that contribute to their dysphoria. In this stage, patients reflect on the duration of the dysphoria they feel; the continuum of gender; the intersection with sexual orientation; what medical interventions might realistically entail; social media, Internet and peer influences; how other factors (e.g., autism, trauma, eating disorders/body image concerns, self-esteem, depression, anxiety) may help drive dysphoria, rather than assuming that they are always a result of dysphoria; family dynamics and social/peer relationships; and school/academic challenges. The messages that teens get from TikTok and other sources may not be very productive for understanding this constellation of issues.

The latest form of transphobia: Saying lesbians are going extinct

There are several reasons the process can move too quickly and hurtle toward medical treatment. For one, the stigma around mental health in general, along with the trauma caused to transgender adults by the health-care field in the past (yes, including conversion therapy), has made our peers extremely skeptical of becoming "gatekeepers" — experts who deny the needed help because they supposedly know best. Slowing down the process and encouraging deeper, thoughtful exploration is considered, many tell us, unnecessary and unaffirming. Providers may also be afraid of being cast as transphobic bigots by their local colleagues and referral sources if they engage in gender exploring therapy with patients, as some have equated this with conversion therapy. We've personally experienced this backlash at professional conferences.

All this means only that the purpose of assessment is improperly understood. The approach WPATH recommends is collaborative and aims to provide a developmentally appropriate process that involves the parents and takes the complexities of adolescence into consideration. (The constituency of agitated parents who feel excluded is also growing rapidly. These are not conservative evangelicals who don't believe trans people exist or deserve treatment. They're usually progressive, educated, loving people who all say, *If our kid is really trans, we'll fully support them. We just want to be as sure as possible, and we can't find a provider who will*

actually engage in gender exploring therapy. Instead, doctors and psychologists and social workers are ready to start hormones after one short visit.)

Another reason that teens can receive substandard mental health care is that gender clinics are disastrously overwhelmed. Most have a single social worker who completes a brief "intake," relying instead on other mental health clinicians in the community to assess patients and offer their conclusions. Frequently, those community clinicians, just like the parents, assume that a more comprehensive assessment will occur in the gender specialty clinic. But in our experience, and based on what our colleagues share, this is rarely the case. Most clinics appear to assume that a referral means a mental health provider in the community has diagnosed gender dysphoria and thereby given the green light for medical intervention.

When working in gender clinics, we've also both received letters from therapists who had "assessed" patients they were referring to us. An astonishing number of these were nothing but a paragraph that stated the youth identified as trans, had dysphoria and wanted hormones, so that course was recommended. There are nearly 200,000 members of the American Psychological Association and the American Psychiatric Association. Add to that the clinical social workers, marriage counselors and family therapists. The overwhelming majority of those well-intentioned professionals receive limited or no training in the assessment of gender-diverse youth. (We receive requests frequently from people eager for more comprehensive, nuanced trainings, which we both deliver.) In simple terms, the demand for competent care has outstripped the supply of competent providers.

In professional circles, we hear from pediatric endocrinologists and others who prescribe hormones for trans youth. Many openly discuss how they use the adult informed-consent model of care with their teen patients, which almost always means no mental health involvement and sometimes no parent input, either. "If you are trans, I believe you," says A.J. Eckert, the medical director of Anchor Health Initiative in Connecticut. Eckert is wary of psychologists who follow the guidelines by completing a comprehensive assessment before recommending medical intervention for youths. "Gender-affirming medicine," Eckert holds, means that "you are best equipped to make decisions about your own body," full stop. These providers do not always realize they've confessed to ignoring the standards of care. (Contacted by The Post for comment on this essay, Eckert said that "no medical or surgical interventions are provided to anyone who has not started puberty" but added that, as Anchor Health sees it, "Therapy is not a requirement in this approach because being trans is not a pathology.")

The battle over trans rights is about power, not science

Some providers may move quickly because they believe that an adolescent's clarity around their gender identity is no different than that of transgender adults, whose care is now typically based on simple informed consent. Some assume that a person with gender dysphoria who declares they are transgender is transgender and needs medical interventions immediately. Yet

we know this is not always true. In a recent study of 100 detransitioners, for instance, 38 percent reported that they believed their original dysphoria had been caused by "something specific, such as trauma, abuse, or a mental health condition." Fifty-five percent said they "did not receive an adequate evaluation from a doctor or mental health professional before starting transition."

A handful of studies supposedly showing the suicide risk of gender minority youth who are not supported are also not entirely conclusive. The term "support," for instance, is defined differently across studies, and it is never defined as "starting medical interventions." Supporting trans youth may include using the correct name/pronouns or allowing the young person to present in a way that aligns with their affirmed gender (e.g., clothing, hairstyle). These studies also show correlations between teen-transition hurdles and suicidality, but not causal relationships. Suicide is a horrifying outcome for too many gender-diverse youth, but its specter should not be used to push forward unrelated medical treatment without professional care or attention for each patient.

I was a straight woman whose spouse came out as trans. It didn't change a thing.

Longer-term longitudinal studies are needed to better understand the role of medical interventions on lifetime psychological health, particularly with the newer subset of adolescents presenting with no childhood dysphoria and significant mental health concerns. Research is needed to help determine whether quick medical treatment or a more cautious approach is best in these cases. Based on our experience with patients, we suspect that there will be variability based on age, when gender identity questions first emerged and other factors — which is why an individualized approach with careful assessment is so critical.

Trans youth, more than most patients in the health-care system, require an interdisciplinary approach: Their doctors rely on mental health colleagues for direction, and it is crucial that those therapists take the reins. Without proper assessment, many youths are being rushed toward the medical model, and we don't know if they will be liberated or restrained by it. National figures do not yet exist, but the rising number of detransitioners that clinicians report seeing (they are forming support groups online) indicates that this approach can backfire. This is not the most common outcome of a transition process, but it is hardly unheard of, either. These are typically youth who experienced gender dysphoria and other complex mental health issues, rushed to medicalize their bodies and regretted it later. Only a quarter of them told their doctors they had reversed their transitions, making this population especially hard to track.

Anti-trans legislation has never been about protecting children

Many trans activists want to silence detransitioners or deny their existence, because those cases do add fuel to the conservative agenda that is pushing to deny medical treatment to all transgender young people. (Those conservative views are unacceptable, and medically unsound.) Instead, we should be learning from them and returning to the empirically supported careful assessment model recommended by WPATH. And none of this means that we shouldn't

be listening to the views of gender-diverse teens; it only means that we should listen in the fullest and most probing way possible.

The pressure by activist medical and mental health providers, along with some national LGBT organizations to silence the voices of detransitioners and sabotage the discussion around what is occurring in the field is unconscionable. Not only is it harmful to detransitioned young people — to be made to feel as if their lived experiences are not valid, the very idea that the gender-transition treatment is meant to remedy — but it will undoubtedly raise questions regarding the objectivity of our field and our commitment to help trans people. The fact that some people detransition does not mean that transgender people should not receive the services they need.

The energy currently spent fighting this political battle would be much better directed toward improving care for all gender-diverse young people. They deserve nothing less.

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Evidence review: Gonadotrophin releasing hormone analogues for children and adolescents with gender dysphoria

This document will help inform Dr Hilary Cass' independent review into gender identity services for children and young people. It was commissioned by NHS England and Improvement who commissioned the Cass review. It aims to assess the evidence for the clinical effectiveness, safety and cost-effectiveness of gonadotrophin releasing hormone (GnRH) analogues for children and adolescents aged 18 years or under with gender dysphoria.

The document was prepared by NICE in October 2020.

The content of this evidence review was up to date on 14 October 2020. See summaries of product characteristics (SPCs), British National Formulary (BNF) or the Medicines and Healthcare products Regulatory Agency (MHRA) or NICE websites for up-to-date information.

Contents

1. Introduction

This review aims to assess the evidence for the clinical effectiveness, safety and cost-effectiveness of gonadotrophin releasing hormone (GnRH) analogues for children and adolescents aged 18 years or under with gender dysphoria. The review follows the NHS England Specialised Commissioning process and template and is based on the criteria outlined in the PICO framework (see appendix A). This document will help inform Dr Hilary Cass' independent review into gender identity services for children and young people.

Gender dysphoria in children, also known as gender identity disorder or gender incongruence of childhood (World Health Organisation 2020), refers to discomfort or distress that is caused by a discrepancy between a person's gender identity (how they see themselves[1] regarding their gender) and that person's sex assigned at birth and the associated gender role, and/or primary and secondary sex characteristics (Diagnostic and Statistical Manual of Mental Disorders 2013).

GnRH analogues suppress puberty by delaying the development of secondary sexual characteristics. The intention is to alleviate the distress associated with the development of secondary sex characteristics, thereby providing a time for on-going discussion and exploration of gender identity before deciding whether to take less reversible steps. In England, the GnRH analogue triptorelin (a synthetic decapeptide analogue of natural GnRH, which has marketing authorisations for the treatment of prostate cancer, endometriosis and precocious puberty [onset before 8 years in girls and 10 years in boys]) is used for this purpose. The use of triptorelin for children and adolescents with gender dysphoria is off-label.

For children and adolescents with gender dysphoria it is recommended that management plans are tailored to the needs of the individual, and aim to ameliorate the potentially negative impact of gender dysphoria on general developmental processes, support young people and their families in managing the uncertainties inherent in gender identity development and provide on-going opportunities for exploration of gender identity. The plans may also include psychological support and exploration and, for some individuals, the use of GnRH analogues in adolescence to suppress puberty; this may be followed later with gender-affirming hormones of the desired sex (NHS England 2013).

2. Executive summary of the review

Nine observational studies were included in the evidence review. Five studies were retrospective observational studies (Brik et al. 2020, Joseph et al. 2019, Khatchadourian et al. 2014, Klink et al. 2015, Vlot et al. 2017), 3 studies were prospective longitudinal observational studies (Costa et al. 2015, de Vries et al. 2011, Schagen et al. 2016) and 1 study was a cross-sectional study (Staphorsius et al. 2015). Two studies (Costa et al. 2015

[1] Gender refers to the roles, behaviours, activities, attributes and opportunities that any society considers appropriate for girls and boys, and women and men (World Health Organisation, Health Topics: Gender).

and Staphorsius et al. 2015) provided comparative evidence and the remaining 7 studies used within-person, before and after comparisons.

The terminology used in this topic area is continually evolving and is different depending on stakeholder perspectives. In this evidence review we have used the phrase 'people's assigned sex at birth' rather than natal or biological sex, gonadotrophin releasing hormone (GnRH) analogues rather than 'puberty blockers' and gender-affirming hormones rather than 'cross sex hormones'. The research studies included in this evidence review may use historical terms which are no longer considered appropriate.

In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?

Critical outcomes

The critical outcomes for decision making are the impact on gender dysphoria, mental health and quality of life. The quality of evidence for these outcomes was assessed as very low certainty using modified GRADE.

Impact on gender dysphoria

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that treatment with GnRH analogues before starting gender-affirming hormones does not affect gender dysphoria (measured using the Utrecht Gender Dysphoria Scale [UGDS]). The mean (±SD) gender dysphoria (UGDS) score was not statistically significantly different at baseline compared with follow-up (n=41, 53.20 [±7.91] versus 53.9 [±17.42], p=0.333).

Impact on mental health

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that treatment with GnRH analogues before starting gender-affirming hormones may reduce depression (measured using the Beck Depression Inventory-II [BDI-II]). The mean [±SD] BDI score was statistically significantly lower (improved) from baseline compared with follow-up (n=41, 8.31 [±7.12] versus 4.95 [±6.72], p=0.004).

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that treatment with GnRH analogues before starting gender-affirming hormones does not affect anger (measured using the Trait Anger Scale [TPI]). The mean [±SD] anger (TPI) score was not statistically significantly different at baseline compared with follow-up (n=41, 18.29 [±5.54] versus 17.88 [±5.24], p=0.503).

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that treatment with GnRH analogues before starting gender-affirming hormones does not affect anxiety (measured using the Trait Anxiety Scale [STAI]). The mean [±SD] anxiety (STAI) score was not statistically significantly different at baseline compared with follow-up (n=41, 39.43 [±10.07] versus 37.95 [±9.38], p=0.276).

Impact on quality of life

No evidence was identified.

Important outcomes

The important outcomes for decision making are impact on body image, psychosocial impact, engagement with health care services, impact on extent of and satisfaction with surgery and stopping treatment. The quality of evidence for all these outcomes was assessed as very low certainty using modified GRADE.

Impact on body image

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that treatment with GnRH analogues before starting gender-affirming hormones does not affect body image (measured using the Body Image Scale [BIS]). The mean [±SD] body image (BIS) scores were not statistically significantly different from baseline compared with follow-up for primary sexual characteristics (n=57, 4.10 [±0.56] versus 3.98 [±0.71], p=0.145), secondary sexual characteristics (n=57, 2.74 [±0.65] versus 2.82 [±0.68], p=0.569) or neutral body characteristics (n=57, 2.41 [±0.63] versus 2.47 [±0.56], p=0.620).

Psychosocial impact

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that treatment with GnRH analogues before starting gender-affirming hormones may improve psychosocial impact over time (measured using the Children's Global Assessment Scale [CGAS]). The mean [±SD] CGAS score was statistically significantly higher (improved) from baseline compared with follow-up (n=41, 70.24 [±10.12] versus 73.90 [±9.63], p=0.005).

This study also found that psychosocial functioning may improve over time (measured using the Child Behaviour Checklist [CBCL] and the self-administered Youth Self-Report [YSR]). The mean [±SD] CBCL scores were statistically significantly lower (improved) from baseline compared with follow-up for Total T score (n=54, 60.70 [±12.76] versus 54.46 [±11.23], p<0.001), internalising T score (n=54, 61.00 [±12.21] versus 52.17 [±9.81], p<0.001) and externalising T score (n=54, 58.04 [±12.99] versus 53.81 [±11.86], p=0.001). The mean [±SD] YSR scores were statistically significantly lower (improved) from baseline compared with follow-up for Total T score (n=54, 55.46 [±11.56] versus 50.00 [±10.56], p<0.001), internalising T score (n=54, 56.04 [±12.49] versus 49.78 [±11.63], p<0.001) and externalising T score (n=54, 53.30 [±11.87] versus 49.98 [±9.35], p=0.009). The proportion of adolescents scoring in the clinical range decreased from baseline to follow up on the CBCL total problem scale (44.4% versus 22.2%, p=0.001) and the internalising scale of the YSR (29.6% versus 11.1%, p=0.017).

The study by Costa et al. 2015 in 201 adolescents with gender dysphoria who had 6 months of psychological support followed by either GnRH analogues and continued psychological support or continued psychological support only, found that during treatment with GnRH analogues psychosocial impact in terms of global functioning may improve over time (measured using the CGAS). In the group receiving GnRH analogues, the mean [±SD] CGAS score was statistically significantly higher (improved) after 6 months (n=60, 64.70 [±13.34]) and 12 months (n=35, 67.40 [±13.39]) compared with baseline (n=101, 58.72 [±11.38], p=0.003 and p<0.001, respectively). However, there was no statistically significant difference in global functioning (CGAS scores) between the group receiving GnRH analogues plus psychological support and the group receiving psychological support only at any time point.

The study by Staphorsius et al. 2015 in 40 adolescents with gender dysphoria (20 of whom were receiving GnRH analogues) gave mean [±SD] CBCL scores for each group, but statistical analysis is unclear (transfemales receiving GnRH analogues 57.4 [±9.8], transfemales not receiving GnRH analogues 58.2 [±9.3], transmales receiving GnRH analogues 57.5 [±9.4], transmales not receiving GnRH analogues 63.9 [±10.5]).

Engagement with health care services

The study by Brik et al. 2018 in 143 children and adolescents with gender dysphoria receiving GnRH analogues found that 9 adolescents in the original sampling frame (9/214, 4.2%) were excluded from the study because they stopped attending appointments.

The study by Costa et al. 2015 in 201 adolescents with gender dysphoria who had 6 months of psychological support followed by either GnRH analogues and continued psychological support or continued psychological support only had a large loss to follow-up over time. The sample size at baseline and 6 months was 201, which dropped by 39.8% to 121 after 12 months and by 64.7% to 71 at 18 months follow-up. No explanation of the reasons for loss to follow-up are reported.

Impact on extent of and satisfaction with surgery

No evidence was identified.

Stopping treatment

The study by Brik et al. 2018 in 143 children and adolescents with gender dysphoria receiving GnRH analogues reported the reasons for stopping GnRH analogues. During the follow-up period 6.2% (9/143) of adolescents had stopped GnRH analogues after a median duration of 0.8 years (range 0.1 to 3.0). Five adolescents stopped treatment because they no longer wished to receive gender-affirming treatment for various reasons. In 4 adolescents (all transmales), GnRH analogues were stopped mainly because of adverse effects (such as mood and emotional lability), although they wanted to continue treatments for gender dysphoria.

The study by Khatchadourian et al. 2014 in 27 adolescents with gender dysphoria who started GnRH analogues reported the reasons for stopping them. Eleven out of 26 where data was available (42%) stopped GnRH analogues during follow up.

In children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?

Evidence was available for bone density, cognitive development or functioning, and other safety outcomes. The quality of evidence for all these outcomes was assessed as very low certainty using modified GRADE.

Bone density

The study by Joseph et al. 2019 in 70 adolescents with gender dysphoria found that GnRH analogues may reduce the expected increase in lumbar or femoral bone density (measured with the z-score). However, the z-scores were largely within 1 standard deviation of normal,

and actual lumbar or femoral bone density values were not statistically significantly different between baseline and follow-up:

- The mean z-score [±SD] for lumbar bone mineral apparent density (BMAD) was statistically significantly lower at 1 year compared with baseline in transfemales (baseline 0.859 [±0.154], 1 year −0.228 [±1.027], p=0.000) and transmales (baseline −0.186 [±1.230], 1 year −0.541 [±1.396], p=0.006).
- The mean z-score [±SD] for lumbar BMAD was statistically significantly lower after receiving GnRH analogues for 2 years compared with baseline in transfemales (baseline 0.486 [±0.809], 2 years −0.279 [±0.930], p=0.000) and transmales (baseline −0.361 [±1.439], 2 years −0.913 [±1.318], p=0.001).
- The mean z-score [±SD] for femoral neck bone mineral density (BMD) was statistically significantly lower after receiving GnRH analogues for 2 years compared with baseline in transfemales (baseline 0.0450 [±0.781], 2 years −0.600 [±1.059], p=0.002) and transmales (baseline −1.075 [±1.145], 2 years −1.779 [±0.816], p=0.001).

The study by Klink et al. 2015 in 34 adolescents with gender dysphoria found that GnRH analogues may reduce the expected increase in lumbar (transmales only), but not femoral bone density. However, the z-scores are largely within 1 standard deviation of normal. Actual lumbar or femoral bone density values were not statistically significantly different between baseline and follow-up (apart from BMD measurements in transmales):

- The mean z-score [±SD] for lumbar BMAD was not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales, but was statistically significantly lower when starting gender-affirming hormones in transmales (GnRH analogues 0.28 [±0.90], gender-affirming hormones −0.50 [±0.81], p=0.004).

The study by Vlot et al. 2017 in 70 adolescents with gender dysphoria found that GnRH analogues may reduce the expected increase in lumbar or femoral bone density. However, the z-scores were largely within 1 standard deviation of normal. Actual lumbar or femoral bone density values were not statistically significantly different between baseline and follow-up (apart from in transmales with a bone age ≥14 years). This study reported change in bone density from starting GnRH analogues to starting gender-affirming hormones by bone age:

- The median z-score [range] for lumbar BMAD in transfemales with a bone age of <15 years was statistically significantly lower at starting gender-affirming hormones than at starting GnRH analogues (GnRH analogues −0.20 [−1.82 to 1.18], gender-affirming hormones −1.52 [−2.36 to 0.42], p=0.001) but was not statistically significantly different in transfemales with a bone age ≥15 years.
- The median z-score [range] for lumbar BMAD in transmales with a bone age of <14 years was statistically significantly lower at starting gender-affirming hormones than at starting GnRH analogues (GnRH analogues −0.05 [−0.78 to 2.94], gender-affirming hormones −0.84 [−2.20 to 0.87], p=0.003) and in transmales with a bone age ≥14 years (GnRH analogues 0.27 [−1.60 to 1.80], gender-affirming hormones −0.29 [−2.28 to 0.90], p≤0.0001).

- The median z-score [range] for femoral neck BMAD in transfemales with a bone age of <15 years was not statistically significantly lower at starting gender-affirming hormones than at starting GnRH analogues (GnRH analogues −0.71 [−3.35 to 0.37], gender-affirming hormones −1.32 [−3.39 to 0.21], p≤0.1) or in transfemales with a bone age ≥15 years (GnRH analogues −0.44 [−1.37 to 0.93], gender-affirming hormones −0.36 [−1.50 to 0.46]).
- The z-score for femoral neck BMAD in transmales with a bone age of <14 years was not statistically significantly lower at starting gender-affirming hormones than at starting GnRH analogues (GnRH analogues −0.01 [−1.30 to 0.91], gender-affirming hormone −0.37 [−2.28 to 0.47]) but was statistically significantly lower in transmales with a bone age ≥14 years (GnRH analogues 0.27 [−1.39 to 1.32], gender-affirming hormones −0.27 [−1.91 to 1.29], p=0.002).

Cognitive development or functioning

The study by Staphorsius et al. 2015 in 40 adolescents with gender dysphoria (20 of whom were receiving GnRH analogues) measured cognitive development or functioning (using an IQ test, and reaction time and accuracy measured using the Tower of London task):

- The mean (±SD) IQ in transfemales receiving GnRH analogues was 94.0 (±10.3) and 109.4 (±21.2) in the control group. In transmales receiving GnRH analogues the mean (±SD) IQ was 95.8 (±15.6) and 98.5 (±15.9) in the control group.
- The mean (±SD) reaction time in transfemales receiving GnRH analogues was 10.9 (±4.1) and 9.9 (±3.1) in the control group. In transmales receiving GnRH analogue it was 9.9 (±3.1) and 10.0 (±2.0) in the control group.
- The mean (±SD) accuracy score in transfemales receiving GnRH analogues was 73.9 (±9.1) and 83.4 (±9.5) in the control group. In transmales receiving GnRH analogues it was 85.7 (±10.5) and 88.8 (±9.7) in the control group.

No statistical analyses or interpretation of the results was reported.

Other safety outcomes

The study by Schagen et al. 2016 in 116 adolescents with gender dysphoria found that GnRH analogues do not affect renal or liver function:

- There was no statistically significant difference between baseline and 1 year results for serum creatinine in transfemales, but there was a statistically significant decrease between baseline and 1 year in transmales (p=0.01).
- Glutamyl transferase, alanine aminotransferase (ALT), and aspartate aminotransferase (AST) levels did not significantly change from baseline to 12 months of treatment.

The study by Khatchadourian et al. 2014 in 27 adolescents with gender dysphoria who started GnRH analogues narratively reported adverse effects from GnRH analogues in 26 adolescents:

- 1 transmale developed sterile abscesses; they were switched from leuprolide acetate to triptorelin, and this was well tolerated
- 1 transmale developed leg pains and headaches, which eventually resolved
- 1 participant gained 19 kg within 9 months of starting GnRH analogues.

In children and adolescents with gender dysphoria, what is the cost-effectiveness of GnRH analogues compared to one or a combination of psychological support, social transitioning to the desired gender or no intervention?

No cost-effectiveness evidence was found for GnRH analogues in children and adolescents with gender dysphoria.

From the evidence selected, are there any subgroups of children and adolescents with gender dysphoria that may benefit from GnRH analogues more than the wider population of interest?

Some studies reported data separately for the following subgroups of children and adolescents with gender dysphoria: sex assigned at birth males (transfemales) and sex assigned at birth females (transmales). This included some direct comparisons of these subgroups, and differences were largely seen at baseline as well as follow up. No evidence was found for other specified subgroups.

Sex assigned at birth males (transfemales)

Impact on gender dysphoria

The study by Costa et al. 2015 in 201 adolescents with gender dysphoria who had 6 months of psychological support followed by either GnRH analogues and continued psychological support or continued psychological support only, found that gender dysphoria (measured using the UGDS) in sex assigned at birth males is lower than in sex assigned at birth females. Sex assigned at birth males had a statistically significantly lower (improved) mean [±SD] UGDS score of 51.6 [±9.7] compared with sex assigned at birth females (56.1 [±4.3], $p<0.001$), but it was not reported if this was at baseline or follow-up.

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that gender dysphoria (measured using the UGDS) in sex assigned at birth males is lower than in sex assigned at birth females at baseline and follow up. The mean [±SD] UGDS score was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at baseline (n=not reported, mean UGDS score: 47.95 [±9.70] versus 56.57 [±3.89]) and follow up (n=not reported, 49.67 [±9.47] versus 56.62 [±4.00]); between sex difference $p<0.001$).

Impact on mental health

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that the impact on mental health (depression, anger and anxiety) may be different in sex assigned at birth males compared with sex assigned at birth females. Over time there was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for depression, but sex assigned at birth males had statistically significantly lower levels of anger and anxiety than sex assigned at birth females at baseline and follow up.

- The mean [±SD] depression (BDI-II) score was not statistically significantly different in sex assigned at birth males compared with sex assigned at birth females at baseline (n=not reported, mean BDI score [±SD]: 5.71 [±4.31] versus 10.34 [±8.24]) and follow-up (n=not reported, 3.50 [±4.58] versus 6.09 [±7.93]), between sex difference $p=0.057$

- The mean [±SD] anger (TPI) score was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at baseline (n=not reported, mean TPI score [±SD]: 5.22 [±2.76] versus 6.43 [±2.78]) and follow-up (n=not reported, 5.00 [±3.07] versus 6.39 [±2.59]), between sex difference p=0.022
- The mean [±SD] anxiety (STAI) score was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at baseline (n=not reported, mean STAI score [±SD]: 4.33 [±2.68] versus 7.00 [±2.36]) and follow-up (n=not reported, 4.39 [±2.64] versus 6.17 [±2.69]), between sex difference p<0.001.

Impact on body image

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that the impact on body image may be different in sex assigned at birth males compared with sex assigned at birth females. Sex assigned at birth males are less dissatisfied with their primary and secondary sex characteristics than sex assigned at birth females at both baseline and follow up, but the satisfaction with neutral body characteristics is not different.

- The mean [±SD] BIS score for primary sex characteristics was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at baseline (n=not reported, mean BIS score [±SD]: 4.02 [±0.61] versus 4.16 [±0.52]) and follow up (n=not reported, 3.74 [±0.78] versus 4.17 [±0.58]) between sex difference p=0.047.
- The mean [±SD] BIS score for secondary sex was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at baseline (n=not reported, mean BIS score [±SD]: 2.66 [±0.50] versus 2.81 [±0.76]) and follow up (n=not reported, 2.39 [±0.69] versus 3.18 [±0.42]), between sex difference p=0.001.
- The mean [±SD] BIS score for neutral body characteristics was not statistically significantly different in sex assigned at birth males compared with sex assigned at birth females at baseline (n=not reported, 2.60 [±0.58] versus 2.24 [±0.62], between sex difference p=0.777).

Psychosocial impact

The study by Costa et al. 2015 in 201 adolescents with gender dysphoria who had 6 months of psychological support followed by either GnRH analogues and continued psychological support or continued psychological support only, found that sex assigned at birth males had statistically significant lower mean [±SD] CGAS scores at baseline compared with sex assigned at birth females (n=201, 55.4 [±12.7] versus 59.2 [±11.8], p=0.03), but no conclusions could be drawn.

The study by de Vries et al. 2011 in 70 adolescents with gender dysphoria found that psychosocial impact in terms of global functioning (CGAS) and psychosocial functioning (CBCL and YSR) may be different in sex assigned at birth males compared with sex assigned at birth females, but no conclusions could be drawn.

- There was no statistically significant difference between sex assigned at birth males and sex assigned at birth females (at baseline or follow up) for the CBCL Total T

score, the CBCL internalising T score, the YSR Total T score or the YSR internalising T score.

- Sex assigned at birth males had statistically higher mean [±SD] CGAS scores compared with sex assigned at birth females at baseline (n=54, 73.10 [±8.44] versus 67.25 [±11.06]) and follow up (n=54, 77.33 [±8.69] versus 70.30 [±9.44]), between sex difference p=0.021.
- Sex assigned at birth males had statistically lower mean [±SD] CBCL externalising T scores compared with sex assigned at birth females at baseline (n=54, 54.71 [±12.91] versus 60.70 [±12.64]) and follow up (n=54, 48.75 [±10.22] versus 57.87 [±11.66]), between sex difference p=0.015.
- Sex assigned at birth males had statistically lower mean [±SD] YSR externalising T scores compared with sex assigned at birth females at both baseline (n=54, 48.72 [±11.38] versus 57.24 [±10.59]) and follow up (n=54, 46.52 [±9.23] versus 52.97 [±8.51]), between sex difference p=0.004.

Bone density

The studies by Joseph et al. 2019, Klink et al. 2015 and Vlot et al. 2017 provided evidence on bone density in sex assigned at birth males (see above for details).

Cognitive development or functioning

The study by Staphorsius et al. 2015 provided evidence on cognitive development or functioning in sex assigned at birth males (see above for details).

Other safety outcomes

The study by Schagen et al. 2016 provided evidence on renal function in sex assigned at birth males (see above).

Sex assigned at birth females (transmales)

Impact on gender dysphoria

The studies by de Vries et al. 2011 and Costa et al. 2015 found that gender dysphoria (measured using the UGDS) in sex assigned at birth females is higher than in sex assigned at birth males at baseline and follow up (see above for details).

Impact on mental health

The study by de Vries et al. 2011 found that the impact on mental health (depression, anger and anxiety) may be different in sex assigned at birth females compared with sex assigned at birth males. Over time there was no statistically significant difference between sex assigned at birth females and sex assigned at birth males for depression, but sex assigned at birth females had statistically significantly greater levels of anger and anxiety than sex assigned at birth males at both baseline and follow up (see above for details).

Impact on body image

The study by de Vries et al. 2011 found that the impact on body image may be different in sex assigned at birth females compared with sex assigned at birth males. Sex assigned at birth females are more dissatisfied with their primary and secondary sex characteristics than sex assigned at birth males at both baseline and follow up, but the satisfaction with neutral body characteristics is not different (see above for details).

Psychosocial impact

The studies by de Vries et al. 2011 and Costa et al. 2015 found that psychosocial impact in terms of global functioning (CGAS) and psychosocial functioning (CBCL and YSR) may be different in sex assigned at birth females compared with sex assigned at birth males, but no conclusions could be drawn (see above for details).

Bone density

The studies by Joseph et al. 2019, Klink et al. 2015 and Vlot et al. 2017 provided evidence on bone density in sex assigned at birth females (see above for details).

Cognitive development or functioning

The study by Staphorsius et al. 2015 provided evidence on cognitive development or functioning in sex assigned at birth females (see above for details).

Other safety outcomes

The study by Schagen et al. 2016 provided evidence on renal function in sex assigned at birth females (see above for details).

From the evidence selected:

(a) what are the criteria used by the research studies to define gender dysphoria, gender identity disorder and gender incongruence of childhood?

(b) what were the ages at which participants commenced treatment with GnRH analogues?

(c) what was the duration of treatment with GnRH analogues?

All studies that reported diagnostic criteria for gender dysphoria (6/9 studies) used the version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria that was in use at the time. In 5 studies (Costa et al. 2015, Klink et al. 2015, Schagen et al. 2016, Staphorsius et al. 2015 and Vlot et al. 2017) the DSM-fourth edition, text revision (IV-TR) criteria were used. The study by Brik et al. 2020 used DSM-V criteria. It was not reported how gender dysphoria was defined in the remaining 3 studies.

The studies show variation in the age (11 to 18 years old) at which children and adolescents with gender dysphoria started GnRH analogues.

Most studies did not report the duration of treatment with GnRH analogues (Joseph et al. 2019, Khatchadourian et al. 2014, Vlot et al. 2017, Costa et al. 2015, de Vries et al. 2011, Schagen et al. 2016), but where this was reported (Brik et al. 2020, Klink et al. 2015, Staphorsius et al. 2015) there was a wide variation ranging from a few months to about 5 years.

Discussion

A key limitation to identifying the effectiveness and safety of GnRH analogues for children and adolescents with gender dysphoria is the lack of reliable comparative studies. The lack of clear, expected outcomes from treatment with a GnRH analogue (the purpose of which is to suppress secondary sexual characteristics which may cause distress from unwanted pubertal changes) also makes interpreting the evidence difficult.

The studies included in this evidence review are all small, uncontrolled observational studies, which are subject to bias and confounding, and all the results are of very low certainty using modified GRADE. They all reported physical and mental health comorbidities and concomitant treatments very poorly. All the studies are from a limited number of, mainly European, care facilities. They are described as either tertiary referral or expert services but the low number of services providing such care and publishing evidence may bias the results towards the outcomes in these services only and limit extrapolation.

Many of the studies did not report statistical significance or confidence intervals. Changes in outcome scores for clinical effectiveness and bone density were assessed with regards to statistical significance. However, there is relatively little interpretation of whether the changes in outcomes are clinically meaningful.

In the observational, retrospective studies providing evidence on bone density, participants acted as their own controls and change in bone density was determined between starting GnRH analogues and follow up. Observational studies such as these can only show an association with GnRH analogues and bone density; they cannot show that GnRH analogues caused any differences in bone density seen. Because there was no comparator group and participants acted as their own controls, it is not known whether the findings are associated with GnRH analogues or due to changes over time.

Conclusion

The results of the studies that reported impact on the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning), in children and adolescents with gender dysphoria are of very low certainty using modified GRADE. They suggest little change with GnRH analogues from baseline to follow-up.

Studies that found differences in outcomes could represent changes that are either of questionable clinical value, or the studies themselves are not reliable and changes could be due to confounding, bias or chance. It is plausible, however, that a lack of difference in scores from baseline to follow-up is the effect of GnRH analogues in children and adolescents with gender dysphoria, in whom the development of secondary sexual characteristics might be expected to be associated with an increased impact on gender dysphoria, depression, anxiety, anger and distress over time without treatment. The study by de Vries et al. 2011 reported statistically significant reductions in the Child Behaviour Checklist (CBCL) and Youth Self-Report (YSR) scores from baseline to follow up, which include measures of distress. As the aim of GnRH analogues is to reduce distress caused by the development of secondary sexual characteristics, this may be an important finding. However, as the studies all lack appropriate controls who were not receiving GnRH analogues, any positive changes could be a regression to mean.

The results of the studies that reported bone density outcomes suggest that GnRH analogues may reduce the expected increase in bone density (which is expected during puberty). However, as the studies themselves are not reliable, the results could be due to confounding, bias or chance. While controlled trials may not be possible, comparative studies are needed to understand this association and whether the effects of GnRH analogues on bone density are seen after they are stopped. All the studies that reported safety outcomes provided very low certainty evidence.

No cost-effectiveness evidence was found to determine whether or not GnRH analogues are cost-effective for children and adolescents with gender dysphoria.

The results of the studies that reported outcomes for subgroups of children and adolescents with gender dysphoria, suggest there may be differences between sex assigned at birth males (transfemales) and sex assigned at birth females (transmales).

3. Methodology

Review questions

The review question(s) for this evidence review are:

1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?
2. For children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?
3. For children and adolescents with gender dysphoria, what is the cost-effectiveness of GnRH analogues compared to one or a combination of psychological support, social transitioning to the desired gender or no intervention?
4. From the evidence selected, are there any subgroups of children and adolescents with gender dysphoria that may derive more (or less) advantage from treatment with GnRH analogues than the wider population of children and adolescents with gender dysphoria?
5. From the evidence selected,
    a) what are the criteria used by the research studies to define gender dysphoria, gender identity disorder and gender incongruence of childhood?
    b) what were the ages at which participants commenced treatment with GnRH analogues?
    c) what was the duration of treatment with GnRH analogues?

See appendix A for the full review protocol.

Review process

The methodology to undertake this review is specified by NHS England in their 'Guidance on conducting evidence reviews for Specialised Services Commissioning Products' (2020).

The searches for evidence were informed by the PICO document and were conducted on 23 July 2020.

See appendix B for details of the search strategy.

Results from the literature searches were screened using their titles and abstracts for relevance against the criteria in the PICO framework. Full text references of potentially

relevant evidence were obtained and reviewed to determine whether they met the inclusion criteria for this evidence review.

See appendix C for evidence selection details and appendix D for the list of studies excluded from the review and the reasons for their exclusion.

Relevant details and outcomes were extracted from the included studies and were critically appraised using a checklist appropriate to the study design. See appendices E and F for individual study and checklist details.

The available evidence was assessed by outcome for certainty using modified GRADE. See appendix G for GRADE Profiles.

4. Summary of included studies

Nine observational studies were identified for inclusion. Five studies were retrospective observational studies (Brik et al. 2020, Joseph et al. 2019, Khatchadourian et al. 2014, Klink et al. 2015, Vlot et al. 2017), 3 studies were prospective longitudinal observational studies (Costa et al. 2015, de Vries et al. 2011, Schagen et al. 2016) and 1 study was a cross-sectional study (Staphorsius et al. 2015).

The terminology used in this topic area is continually evolving and is different depending on stakeholder perspectives. In this evidence review we have used the phrase 'people's assigned sex at birth' rather than natal or biological sex, gonadotrophin releasing hormone (GnRH) analogues rather than 'puberty blockers' and gender-affirming hormones rather than 'cross sex hormones'. The research studies included in this evidence review may use historical terms which are no longer considered appropriate.

Table 1 provides a summary of these included studies and full details are given in appendix E.

Table 1 Summary of included studies

Study	Population	Intervention and comparison	Outcomes reported
Brik et al. 2020 Retrospective observational single-centre study Netherlands	The study was conducted at the Curium-Leiden University Medical Centre gender clinic in Leiden, the Netherlands and involved adolescents with gender dysphoria. The sample size was 143 adolescents (median age at start of treatment was 15.0 years, range 11.1 to 18.6 years in transfemales; 16.1 years, range 10.1 to 17.9 years in transmales) from a sampling frame of 269 children and adolescents registered at the clinic between November 2010 and January 2018.	**Intervention** 143 children and adolescents receiving GnRH analogues (no specific treatment, dose, route or frequency of administration reported). The median duration was 2.1 years (range 1.6–2.8 years). **Comparison** No comparator.	**Critical Outcomes** • No critical outcomes reported **Important outcomes** • Stopping treatment

Study	Population	Intervention and comparison	Outcomes reported
	Participants were included in the study if they were diagnosed with gender dysphoria according to the DSM-5 criteria, registered at the clinic, were prepubertal and within the appropriate age range, and had started GnRH analogues. No concomitant treatments were reported.		
Costa et al. 2015 Prospective longitudinal observational single centre cohort study United Kingdom	The study was conducted at the Gender Identity Development Service in London and involved adolescents with gender dysphoria. The sample size was 201 adolescents (mean [±SD] age 15.52±1.41 years, range 12 to 17 years) from a sampling frame of 436 consecutive adolescents referred to the service between 2010 and 2014. The mean [±SD] age at the start of GnRH analogues was 16.48 [±1.26] years, range 13 to 17 years. Participants were invited to participate following a 6-month diagnostic process using DSM-IV-TR criteria. No concomitant treatments were reported.	**Intervention** 101 adolescents assessed as being immediately eligible for GnRH analogues (no specific treatment, dose or route of administration reported) plus psychological support. The average duration of treatment was approximately 12 months (no exact figure given). **Comparison** 100 adolescents assessed as not immediately eligible for GnRH analogues (more time needed to make the decision to start GnRH analogues) who had psychological support only. None received GnRH analogues throughout the study.	**Critical Outcomes** • No critical outcomes reported **Important outcomes** • Psychosocial impact
de Vries et al. 2011 Prospective longitudinal observational single centre before and after study Netherlands	The study was conducted at the Amsterdam gender identity clinic of the VU University Medical Centre and involved adolescents who were defined as "transsexual". The sample size was 70 adolescents receiving GnRH analogues (mean age [±SD] at assessment 13.6±1.8 years) from a sampling frame of 196 consecutive adolescents referred to the service between 2000 and 2008. Participants were invited to participate if they subsequently started gender-affirming hormones between 2003 and 2009. No diagnostic criteria or concomitant treatments were reported.	**Intervention** 70 individuals assessed at baseline (T0) before the start of GnRH analogues (no specific treatment, dose or route of administration reported). **Comparison** No comparator.	**Critical Outcomes** • Gender dysphoria • Mental health (depression, anger and anxiety) **Important outcomes** • Body image • Psychosocial impact

Study	Population	Intervention and comparison	Outcomes reported
Joseph et al. 2019 Retrospective longitudinal observational single centre study United Kingdom	This study was conducted at the Early intervention clinic at University College London Hospital (all participants had been seen at the Gender Identity Development Service in London) and involved adolescents with gender dysphoria. The sample size was 70 adolescents with gender dysphoria (no diagnostic criteria described) all offered GnRH analogues. The mean age at the start of treatment was 13.2 years (SD ±1.4) for transfemales and 12.6 years (SD ±1.0) for transmales. Details of the sampling frame were not reported. Further details of how the sample was drawn are not reported. No concomitant treatments were reported.	**Intervention** GnRH analogues. No specific treatment, duration, dose or route of administration reported. **Comparison** No comparator.	**Critical Outcomes** • No critical outcomes reported **Important outcomes** • Safety: bone density
Khatchadourian et al. 2014 Retrospective observational chart review single centre study Canada	This study was conducted at the Endocrinology and Diabetes Unit at British Columbia Children's Hospital, Canada and involved youths with gender dysphoria. The sample size was 27 young people with gender dysphoria who started GnRH analogues (at mean age 14.7 [SD ±1.9] years) out of 84 young people seen at the unit between 1998 and 2011. Diagnostic criteria and concomitant treatments were not reported.	**Intervention** 84 young people with gender dysphoria. For GnRH analogues no specific treatment, duration, dose or route of administration reported. **Comparison** No comparator.	**Critical Outcomes** • No critical outcomes reported **Important outcomes** • Stopping treatment • Safety: adverse effects
Klink et al. 2015 Retrospective longitudinal observational single centre study Netherlands	This study was conducted in the Netherlands at a tertiary referral centre. It is unclear which centre this was. The sample size was 34 adolescents (mean age 14.9 [SD ±1.9] years for transfemales and 15.0 [SD ±2.0] years for transmales at start of GnRH analogues). Details of the sampling frame are not reported. Participants were included if they met DSM-IV-TR criteria for gender identity disorder of adolescence and had been treated with GnRH analogues and gender-affirming hormones during their pubertal years. No concomitant treatments were reported.	**Intervention** The intervention was GnRH analogue monotherapy (triptorelin 3.75 mg subcutaneously every 4 weeks) followed by gender-affirming hormones with discontinuation of GnRH analogues after gonadectomy. Duration of GnRH analogues was 1.3 years (range 0.5 to 3.8 years) in transfemales and 1.5 years (0.25 to 5.2 years in transmales. **Comparison** No comparator.	**Critical Outcomes** • No critical outcomes reported **Important outcomes** • Safety: bone density

Study	Population	Intervention and comparison	Outcomes reported
Schagen et al. 2016 Prospective longitudinal study Netherlands	This study was conducted at the Centre of Expertise on Gender Dysphoria at the VU University Medical Centre (Amsterdam, Netherlands) and involved adolescents with gender dysphoria. The sample size was 116 adolescents (median age [range] 13.6 years [11.6 to 17.9] in transfemales and 14.2 years [11.1 to 18.6] in transmales during first year of GnRH analogues) out of 128 adolescents who started GnRH analogues. Participants were included if they met DSM-IV-TR criteria for gender dysphoria, had lifelong extreme gender dysphoria, were psychologically stable and were living in a supportive environment. No concomitant treatments were reported.	**Intervention** The intervention was GnRH analogue monotherapy (triptorelin 3.75 mg at 0, 2 and 4 weeks followed by intramuscular injections every 4 weeks, for at least 3 months). **Comparison** No comparator.	**Critical Outcomes** • No critical outcomes reported **Important outcomes** • Safety: liver and renal function.
Staphorsius et al. 2015 Cross-sectional (single time point) assessment single centre study Netherlands	This study was conducted at the VU University Medical Centre (Amsterdam, Netherlands) and involved adolescents with gender dysphoria. The sample size was 85, of whom 40 were adolescents with gender dysphoria (20 of whom were being treated with GnRH analogues) and 45 were controls without gender dysphoria (not further reported here). Mean (±SD) age 15.1 (±2.4) years in transfemales and 15.8 (±1.9) years in transmales. Details of the sampling frame are not reported. Participants were included if they were diagnosed with Gender Identity Disorder according to the DSM-IV-TR and at least 12 years old and Tanner stage of at least B2 or G2 to G3 with measurable oestradiol and testosterone levels in girls and boys, respectively. No concomitant treatments were reported.	**Intervention** The intervention was a GnRH analogue (triptorelin 3.75 mg every 4 weeks subcutaneously or intramuscularly). The mean duration of treatment was 1.6 years (SD ±1.0). **Comparison** Adolescents with gender dysphoria not treated with GnRH analogues.	**Critical Outcomes** • No critical outcomes reported **Important outcomes** • Psychosocial impact • Safety: cognitive functioning
Vlot et al. 2017 Retrospective observational data analysis study	This study was conducted at the VU University Medical Centre (Amsterdam, Netherlands) and involved adolescents with gender dysphoria. The sample size was 70 adolescents (median age [range] 15.1 years [11.7 to 18.6] for	**Intervention** The intervention was a GnRH analogue (triptorelin 3.75 mg every 4 weeks subcutaneously). **Comparison** No comparator.	**Critical Outcomes** • No critical outcomes reported **Important outcomes**

Study	Population	Intervention and comparison	Outcomes reported
Netherlands	transmales and 13.5 years [11.5 to 18.3] for transfemales at start of GnRH analogues). Details of the sampling frame are not reported. Participants were included if they had a diagnosis of gender dysphoria according to DSM-IV-TR criteria who were receiving GnRH analogues and then gender-affirming hormones. No concomitant treatments were reported.		• Safety: bone density
Abbreviations: DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, fourth edition, text revision; GnRH, Gonadotrophin releasing hormone; SD, Standard deviation.			

5. Results

In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?

Outcome	Evidence statement
Clinical Effectiveness	
Critical outcomes	
Impact on gender dysphoria **Certainty of evidence: very low**	This is a critical outcome because gender dysphoria in children and adolescents is associated with significant distress and problems with functioning. One uncontrolled, prospective observational longitudinal study (de Vries et al. 2011) provided evidence relating to the impact on gender dysphoria in adolescents, measured using the Utrecht Gender Dysphoria Scale (UGDS). The UGDS is a validated screening tool for both adolescents and adults to assess gender dysphoria. It consists of 12 items, to be answered on a 1- to 5-point scale, resulting in a sum score between 12 and 60. The higher the UGDS score the greater the gender dysphoria. The study measured the impact on gender dysphoria at 2 time points: • before starting a GnRH analogue (mean [±SD] age: 14.75 [±1.92] years), and • shortly before starting gender-affirming hormones (mean [±SD] age: 16.64 [±1.90] years). The mean (±SD) UGDS score was not statistically significantly different at baseline compared with follow-up (n=41, 53.20 [±7.91] versus 53.9 [±17.42], p=0.333) **(VERY LOW)**.

	This study provides very low certainty evidence that treatment with GnRH analogues, before starting gender-affirming hormones, does not affect gender dysphoria.
Impact on mental health: depression **Certainty of evidence: very low**	This is a critical outcome because self-harm and thoughts of suicide have the potential to result in significant physical harm and, for completed suicides, the death of the young person. One uncontrolled, prospective observational longitudinal study (de Vries et al. 2011) provided evidence relating to the impact on depression in children and adolescents with gender dysphoria. Depression was measured using the Beck Depression Inventory-II (BDI-II). The BDI-II is a valid, reliable, and widely used tool for assessing depressive symptoms. There are no specific scores to categorise depression severity, but it is suggested that 0 to 13 is minimal symptoms, 14 to 19 is mild depression, 20 to 28 is moderate depression, and severe depression is 29 to 63. The study provided evidence for depression measured at 2 time points: • before starting a GnRH analogue (mean [±SD] age: 14.75 [±1.92] years), and • shortly before starting gender-affirming hormones (mean [±SD] age: 16.64 [±1.90] years). The mean (±SD) depression (BDI) score was statistically significantly lower (improved) from baseline compared with follow-up (n=41, 8.31 [±7.12] versus 4.95 [±6.72], p=0.004) **(VERY LOW)**. **This study provides very low certainty evidence that treatment with GnRH analogues, before starting gender-affirming hormones, may reduce depression.**
Impact on mental health: anger **Certainty of evidence: very low**	This is a critical outcome because self-harm and thoughts of suicide have the potential to result in significant physical harm and, for completed suicides, the death of the young person. One uncontrolled, prospective observational longitudinal study (de Vries et al. 2011) provided evidence relating to the impact on anger in children and adolescents with gender dysphoria. Anger was measured using the Trait Anger Scale of the State-Trait Personality Inventory (TPI). This is a validated 20-item inventory tool which measures the intensity of anger as the disposition to experience angry feelings as a personality trait. Higher scores indicate greater anger. The study provided evidence for anger measured at 2 time points: • before starting a GnRH analogue (mean [±SD] age: 14.75 [±1.92] years), and • shortly before starting gender-affirming hormones (mean [±SD] age: 16.64 [±1.90] years). The mean (±SD) anger (TPI) score was not statistically significantly different at baseline compared with follow-up (n=41, 18.29 [±5.54] versus 17.88 [±5.24], p=0.503) **(VERY LOW)**. **This study provides very low certainty evidence that treatment with GnRH analogues, before starting gender-affirming hormones, does not affect anger.**

Impact on mental health: anxiety **Certainty of evidence: very low**	This is a critical outcome because self-harm and thoughts of suicide have the potential to result in significant physical harm and, for completed suicides, the death of the young person. One uncontrolled, prospective observational longitudinal study (de Vries et al. 2011) provided evidence relating to the impact on anxiety in children and adolescents with gender dysphoria. Anxiety was measured using the Trait Anxiety Scale of the State-Trait Personality Inventory (STAI). This is a validated and commonly used measure of trait and state anxiety. It has 20 items and can be used in clinical settings to diagnose anxiety and to distinguish it from depressive illness. Higher scores indicate greater anxiety. The study provided evidence for anxiety at 2 time points: • before starting a GnRH analogue (mean [±SD] age: 14.75 [±1.92] years), and • shortly before starting gender-affirming hormones (mean [±SD] age: 16.64 [±1.90] years). The mean (±SD) anxiety (STAI) score was not statistically significantly different at baseline compared with follow-up (n=41, 39.43 [±10.07] versus 37.95 [±9.38], p=0.276) (**VERY LOW**). **This study provides very low certainty evidence that treatment with GnRH analogues, before starting gender-affirming hormones, does not affect levels of anxiety.**
Quality of life	This is a critical outcome because gender dysphoria in children and adolescents may be associated with a significant reduction in health-related quality of life. No evidence was identified.
Important outcomes	
Impact on body image **Certainty of evidence: very low**	This is an important outcome because some children and adolescents with gender dysphoria may want to take steps to suppress features of their physical appearance associated with their sex assigned at birth or accentuate physical features of their desired gender. One uncontrolled, prospective observational longitudinal study provided evidence relating to the impact on body image (de Vries et al. 2011). Body image was measured using the Body Image Scale (BIS) which is a validated 30-item scale covering 3 aspects: primary, secondary and neutral body characteristics. Higher scores represent a higher degree of body dissatisfaction. The study (de Vries et al. 2011) provided evidence for body image measured at 2 time points: • before starting a GnRH analogue (mean [±SD] age: 14.75 [±1.92] years), and • shortly before starting gender-affirming hormones (mean [±SD] age: 16.64 [±1.90] years). The mean (±SD) body image (BIS) scores for were not statistically significantly different from baseline compared with follow-up for:

	• primary sexual characteristics (n=57, 4.10 [±0.56] versus 3.98 [±0.71], p=0.145) • secondary sexual characteristics (n=57, 2.74 [±0.65] versus 2.82 [±0.68], p=0.569) • neutral body characteristics (n=57, 2.41 [±0.63] versus 2.47 [±0.56], p=0.620) **(VERY LOW)**. **This study provides very low certainty evidence that treatment with GnRH analogues, before starting gender affirming hormones, does not affect body image.**
Psychosocial impact: global functioning **Certainty of evidence: very low**	This is an important outcome because gender dysphoria in children and adolescents is associated with internalising and externalising behaviours, and emotional and behavioural problems which may impact on social and occupational functioning. One uncontrolled, observational, prospective cohort study (de Vries et al 2011) and one prospective cross-sectional cohort study (Costa et al. 2015) provided evidence relating to psychosocial impact in terms of global functioning. Global functioning was measured using the Children's Global Assessment Scale (CGAS). The CGAS tool is a validated measure of global functioning on a single rating scale from 1 to 100. Lower scores indicate poorer functioning. One study (de Vries et al. 2011) provided evidence for global functioning (CGAS) at 2 time points: • before starting a GnRH analogue (mean [±SD] age: 14.75 [±1.92] years), and • shortly before starting gender-affirming hormones (mean [±SD] age: 16.64 [±1.90] years). The mean (±SD) CGAS score was statistically significantly higher (improved) from baseline compared with follow-up (n=41, 70.24 [±10.12] versus 73.90 [±9.63], p=0.005) **(VERY LOW)**. One study (Costa et al. 2015) in adolescents with gender dysphoria who had 6 months of psychological support followed by either GnRH analogues and continued psychological support (the immediately eligible group) or continued psychological support only (the delayed eligible group who did not receive GnRH analogues) provided evidence for global functioning (CGAS) measured at 4 time points: • at baseline (T0) in both groups, • after 6 months of psychological support in both groups (T1), • after 6 months of GnRH analogues and 12 months of psychological support in the immediately eligible group and 12 months of psychological support only in the delayed eligible group (T2), and • after 18 months of psychological support and 12 months of GnRH analogues in the immediately eligible group and after 18 months of psychological support only in the delayed eligible group (T3). The mean [±SD] CGAS score was statistically significantly higher (improved) for all adolescents (including those not receiving GnRH analogues) at T1, T2 or T3 compared with baseline (T0).

	For the immediately eligible group (who received GnRH analogues) versus the delayed eligible group (who did not receive GnRH analogues) there were no statistically significant differences in CGAS scores between the 2 groups at baseline T0 (n=201, p=0.23), T1 (n=201, p=0.73), T2 (n=121, p=0.49) or T3 (n=71, p=0.14) time points. For the immediately eligible group (who received GnRH analogues), the mean (±SD) CGAS score was not statistically significantly different at: • T1 compared with T0 • T2 compared with T1 • T3 compared with T2. The mean (±SD) CGAS score was statistically significantly higher (improved) at: • T2 compared with T0 (n=60, 64.70 [±13.34] versus n=101, 58.72 [±11.38], p=0.003) • T3 compared with T0 (n=35, 67.40 [±13.39] versus n=101, 58.72 [±11.38], p<0.001) • T3 compared with T1 (n=35, 67.40 [±13.93] versus n=101, 60.89 [±12.17], p<0.001) **(VERY LOW)**. **These studies provide very low certainty evidence that during treatment with GnRH analogues, global functioning may improve over time. However, there was no statistically significant difference in global functioning between GnRH analogues plus psychological support compared with psychological support only at any time point.**
Psychosocial impact: psychosocial functioning **Certainty of evidence: very low**	This is an important outcome because gender dysphoria in children and adolescents is associated with internalising and externalising behaviours, and emotional and behavioural problems which may impact on social and occupational functioning. Two studies provided evidence for this outcome. One uncontrolled, observational, prospective cohort study (de Vries et al, 2011) and 1 cross-sectional observational study (Staphorsius et al. 2015) assessed psychosocial functioning using the Child Behaviour Checklist (CBCL) and the self-administered Youth Self-Report (YSR). The CBCL is a checklist parents complete to detect emotional and behavioural problems in children and adolescents. YSR is similar but is self-completed by the child or adolescent. The scales consist of a Total problems score, which is the sum of the scores of all the problem items. An internalising problem scale sums the anxious/depressed, withdrawn-depressed, and somatic complaints scores while the externalising problem scale combines rule-breaking and aggressive behaviour. The standard scores are scaled so that 50 is average for the child or adolescent's age and gender, with a SD of 10 points. Higher scores indicate greater problems, with a T-score above 63 considered to be in the clinical range. One study (de Vries et al. 2011) provided evidence for psychosocial functioning (CBCL and YSR scores) at 2 time points: • before starting a GnRH analogue (mean [±SD] age: 14.75 [±1.92] years), and

	• shortly before starting gender-affirming hormones (mean [±SD] age: 16.64 [±1.90] years). At follow up, the mean (±SD) CBCL scores were statistically significantly lower (improved) compared with baseline for: • Total T score (n=54, 60.70 [±12.76] versus 54.46 [±11.23], p<0.001 • Internalising T score (n=54, 61.00 [±12.21] versus 52.17 [±9.81], p<0.001) • Externalising T score (n=54, 58.04 [±12.99] versus 53.81 [±11.86], p=0.001). At follow up, the mean (±SD) YSR scores were statistically significantly lower (improved) compared with baseline for: • Total T score (n=54, 55.46 [±11.56] versus 50.00 [±10.56], p<0.001) • Internalising T score (n=54, 56.04 [±12.49] versus 49.78 [±11.63], p<0.001) • Externalising T score (n=54, 53.30 [±11.87] versus 49.98 [±9.35], p=0.009). The proportion of adolescents scoring in the clinical range decreased from baseline to follow up on the CBCL total problem scale (44.4% versus 22.2%, p=0.001) and the internalising scale of the YSR (29.6% versus 11.1%, p=0.017) **(VERY LOW)**. One study (Staphorsius et al. 2015) assessed CBCL in a cohort of adolescents with gender dysphoria (transfemale: n=18, mean [±SD] age 15.1 [±2.4] years and transmale: n=22, mean [±SD] age 15.8 [±1.9] years) either receiving GnRH analogues (transfemale, n=8 and transmale, n=12), or not receiving GnRH analogues (transfemale, n=10 and transmale, n=10). The mean (±SD) CBCL scores for each group were (statistical analysis unclear): • transfemales (total) 57.8 [±9.2] • transfemales receiving GnRH analogues 57.4 [±9.8] • transfemales not receiving GnRH analogues 58.2 [±9.3] • transmales (total) 60.4 [±10.2] • transmales receiving GnRH analogues 57.5 [±9.4] • transmales not receiving GnRH analogues 63.9 [±10.5] **(VERY LOW)**. **These studies provide very low certainty evidence that during treatment with GnRH analogues psychosocial functioning may improve, with the proportion of adolescents in the clinical range for some CBCL and YSR scores decreasing over time.**
Engagement with health care services **Certainty of evidence: very low**	This is an important outcome because patient engagement with health care services will impact on their clinical outcomes. Two uncontrolled observational cohort studies provided evidence relating to loss to follow up, which could be a marker of engagement with health care services (Brik et al. 2018 and Costa et al. 2015).

	In one retrospective study (Brik et al. 2018), 9 adolescents (9/214, 4.2%) who had stopped attending appointments were excluded from the study between November 2010 and July 2019 **(VERY LOW)**. One prospective study (Costa et al. 2015) had evidence for a large loss to follow-up over time. The sample size at baseline (T0) and 6 months (T1) was 201, which dropped by 39.8% to 121 after 12 months (T2) and by 64.7% to 71 at 18 months follow-up (T3). No explanation of the reasons for loss to follow-up are reported **(VERY LOW)**. Due to their design there was no reported loss to follow-up in the other 3 effectiveness studies (de Vries et al 2011; Khatchadourian et al. 2014; Staphorsius et al. 2015). **These studies provide very low certainty evidence about loss to follow up, which could be a marker of engagement with health care services, during treatment with GnRH analogues. Due to the large variation in rates between studies no conclusions could be drawn.**
Impact on extent of and satisfaction with surgery	This is an important outcome because some children and adolescents with gender dysphoria may proceed to transitioning surgery. No evidence was identified.

Stopping treatment
 	
Certainty of evidence: very low
	This is an important outcome because there is uncertainty about the short- and long-term safety and adverse effects of GnRH analogues in children and adolescents with gender dysphoria.
	
	Two uncontrolled, retrospective, observational cohort studies provided evidence relating to stopping GnRH analogues. One study had complete reporting of the cohort (Brik et al. 2018), the other (Khatchadourian et al. 2014) had incomplete reporting of its cohort, particularly for transfemales where outcomes for only 4/11 were reported.
	
	Brik et al. 2018 narratively reported the reasons for stopping GnRH analogues in a cohort of 143 adolescents (38 transfemales and 105 transmales). Median age at the start of GnRH analogues was 15.0 years (range, 11.1–18.6 years) in transfemales and 16.1 years (range, 10.1–17.9 years) in transmales. Of these adolescents, 125 (87%, 36 transfemales, 89 transmales) subsequently started gender-affirming hormones after 1.0 (0.5–3.8) and 0.8 (0.3–3.7) years of GnRH analogues. At the time of data collection, the median duration of GnRH analogue use was 2.1 years (1.6–2.8).
	
	During the follow-up period 6.3% (9/143) of adolescents had discontinued GnRH analogues after a median duration of 0.8 years (range 0.1 to 3.0). The percentages and reasons for stopping were:
	• 2.8% (4/143) stopped GnRH analogues although they wanted to continue endocrine treatments for gender dysphoria:
	  ○ 1 transmale stopped due to increase in mood problems, suicidal thoughts and confusion attributed to GnRH analogues
	  ○ 1 transmale had hot flushes, increased migraines, fear of injections, stress at school and unrelated medical issues, and temporarily stopped treatment (after 4 months) and restarted 5 months later.

	○ 1 transmale had mood swings 4 months after starting GnRH analogues. After 2.2 years had unexplained severe nausea and rapid weight loss and discontinued GnRH analogues after 2.4 years ○ 1 transmale stopped GnRH analogues because of inability to regularly collect medication and attend appointments for injections. • 3.5% (5/143) stopped treatment because they no longer wished to receive gender-affirming treatment for various reasons **(VERY LOW)**. Khatchadourian et al. 2014 narratively reported the reasons for stopping GnRH analogues in a cohort of 26 adolescents (15 transmales and 11 transfemales), 42% (11/26) discontinued GnRH analogues during follow-up between 1998 and 2011. Of 15 transmales receiving GnRH analogues, 14 received testosterone during the observation period, of which: • 7 continued GnRH analogues after starting testosterone • 7 stopped GnRH analogues after a median of 3.0 years (range 0.2 to 9.2 years), of which: ○ 5 stopped after hysterectomy and salpingo-oophorectomy ○ 1 stopped after 2.2 years (transitioned to gender-affirming hormones) ○ 1 stopped after <2 months due to mood and emotional lability **(VERY LOW)**. Of 11 transfemales receiving GnRH analogues, 5 received oestrogen during the observation period, of which: • 4 continued GnRH analogues after starting oestrogen • 1 stopped GnRH analogues when taking oestrogen (no reason reported) **(VERY LOW)**. Of the remaining 6 transfemales taking GnRH analogues: • 1 stopped GnRH analogues after a few months due to emotional lability • 1 stopped GnRH analogues before taking oestrogen (the following year delayed due to heavy smoking) • 1 stopped GnRH analogues after 13 months due not to pursuing transition **(VERY LOW)**. **These studies provide very low certainty evidence for the number of adolescents who stop GnRH analogues and the reasons for this.**

Abbreviations: GnRH, gonadotrophin releasing hormone; SD, standard deviation.

In children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?

Outcome	Evidence statement

Safety	
Change in bone density: lumbar **Certainty of evidence: very low**	This is an important outcome because puberty is an important time for bone development and puberty suppression may affect bone development, as shown by changes in lumbar bone density. Three uncontrolled, observational, retrospective studies provided evidence relating to the effect of GnRH analogues on bone density (based on lumbar BMAD) between starting with a GnRH analogue and at 1 and 2 year intervals (Joseph et al. 2019), and between starting GnRH analogues and starting gender-affirming hormones (Klink et al. 2015 and Vlot et al. 2017). All outcomes were reported separately for transfemales and transmales; also see subgroups table below. BMAD is a size adjusted value of BMD incorporating body size measurements using UK norms in growing adolescents. It was reported as g/cm^3 and as z-scores. Z-scores report how many standard deviations from the mean a measurement sits. A z-score of 0 is equal to the mean, a z-score of −1 is equal to 1 standard deviation below the mean, and a z-score of +1 is equal to 1 standard deviation above the mean. One retrospective observational study (Joseph et al. 2019, n=70) provided non-comparative evidence on change in lumbar BMAD increase using z-scores. • The z-score for lumbar BMAD was statistically significantly lower at 2 years compared with baseline in transfemales (z-score [±SD]: baseline 0.486 [0.809], 2 years −0.279 [0.930], p=0.000) and transmales (baseline −0.361 [1.439], 2 years −0.913 [1.318], p=0.001) **(VERY LOW)**. • The z-score for lumbar BMAD was statistically significantly lower at 1 year compared with baseline in transfemales (baseline 0.859 [0.154], 1 year −0.228 [1.027], p=0.000) and transmales (baseline −0.186 [1.230], 1 year −0.541 [1.396], p=0.006) **(VERY LOW)**. • Actual lumbar BMAD values in g/cm^3 were not statistically significantly different between baseline and 1 or 2 years in transfemales or transmales **(VERY LOW)**. Two retrospective observational studies (Klink et al. 2015 and Vlot et al. 2017, n=104 in total) provided non-comparative evidence on change in lumbar BMAD between starting GnRH analogues and starting gender-affirming hormones. All outcomes were reported separately for transfemales and transmales; also see subgroups table below. In Klink et al. 2015 the z-score for lumbar BMAD was not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales but was statistically significantly lower when starting gender-affirming hormones in transmales (z-score mean [±SD]: GnRH analogue 0.28 [±0.90], gender-affirming hormone −0.50 [±0.81], p=0.004). Actual lumbar BMAD values in g/cm^3 were not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales or transmales **(VERY LOW)**.

	Vlot et al. 2017 reported change from starting GnRH analogues to starting gender-affirming hormones in lumbar BMAD by bone age. • The z-score for lumbar BMAD in transfemales with a bone age of <15 years was statistically significantly lower at starting gender-affirming hormone treatment than at starting GnRH analogues (z-score median [range]: GnRH analogue −0.20 [−1.82 to 1.18], gender-affirming hormone −1.52 [−2.36 to 0.42], p=0.001) but was not statistically significantly different in transfemales with a bone age ≥15 years **(VERY LOW)**. • The z-score for lumbar BMAD in transmales with a bone age of <14 years was statistically significantly lower at starting gender-affirming hormone treatment than at starting GnRH analogues (z-score median [range]: GnRH analogue −0.05 [−0.78 to 2.94], gender-affirming hormone −0.84 [−2.20 to 0.87], p=0.003) and in transmales with a bone age ≥14 years (GnRH analogue 0.27 [−1.60 to 1.80], gender-affirming hormone −0.29 [−2.28 to 0.90], p≤0.0001) **(VERY LOW)**. • Actual lumbar BMAD values in g/cm^3 were not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales or transmales with young or old bone age **(VERY LOW)**. Two uncontrolled, observational, retrospective studies provided evidence for the effect of GnRH analogues on bone density (based on lumbar BMD) between starting GnRH analogues and either at 1 or 2 year intervals (Joseph et al. 2019), or starting gender-affirming hormones (Klink et al. 2015). All outcomes were reported separately for transfemales and transmales; also see subgroups table below. One retrospective observational study (Joseph et al. 2019, n=70) provided non-comparative evidence on change in lumbar BMD increase using z-scores. • The z-score for lumbar BMD was statistically significantly lower at 2 years compared with baseline in transfemales (z-score mean [±SD]: baseline 0.130 [0.972], 2 years −0.890 [±1.075], p=0.000) and transmales (baseline −0.715 [±1.406], 2 years −2.000 [1.384], p=0.000) **(VERY LOW)**. • The z-score for lumbar BMD was statistically significantly lower at 1 year compared with baseline in transfemales (z-score mean [±SD]: baseline −0.016 [±1.106], 1 year −0.461 [±1.121], p=0.003) and transmales (baseline −0.395 [±1.428], 1 year −1.276 [±1.410], p=0.000) **(VERY LOW)**. • With the exception of transmales, where lumbar BMD in kg/m^2 increased between baseline and 1 year (mean [±SD]: baseline 0.694 [±0.149], 1 year 0.718 [±0.124], p=0.006), actual lumbar BMD values were not statistically significantly different between baseline and 1 or 2 years in transfemales or between 0 and 2 years in transmales **(VERY LOW)**. One retrospective observational study (Klink et al. 2015, n=34) provided non-comparative evidence on change in lumbar BMD between starting GnRH analogues and starting gender-affirming hormones. • The z-score for lumbar BMD was not statistically significantly different between starting GnRH analogue and starting gender-affirming hormone treatment in transfemales, but was

	statistically significantly lower when starting gender-affirming hormones in transmales (z-score mean [±SD]: GnRH analogue 0.17 [±1.18], gender-affirming hormone −0.72 [±0.99], p<0.001) **(VERY LOW)**. • Actual lumbar BMD in g/cm^2 was not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales but was statistically significantly lower when starting gender-affirming hormones in transmales (mean [±SD]: GnRH analogues 0.95 [±0.12], gender-affirming hormones 0.91 [±0.10], p=0.006) **(VERY LOW)**. **These studies provide very low certainty evidence that GnRH analogues reduce the expected increase in lumbar bone density (BMAD or BMD) compared with baseline (although some findings were not statistically significant). These studies also show that GnRH analogues do not statistically significantly decrease actual lumbar bone density (BMAD or BMD).**
Change in bone density: femoral **Certainty of evidence: very low**	This is an important outcome because puberty is an important time for bone development and puberty suppression may affect bone development, as shown by changes in femoral bone density. Two uncontrolled, observational, retrospective studies provided evidence relating to the effect of GnRH analogues on bone density (based on femoral BMAD) between starting treatment with a GnRH analogue and starting gender-affirming hormones (Klink et al. 2015 and Vlot et al. 2017). All outcomes were reported separately for transfemales and transmales; also see subgroups table below. One retrospective observational study (Klink et al. 2015, n=34) provided non-comparative evidence on change in femoral area BMAD between starting GnRH analogues and starting gender-affirming hormones. All outcomes were reported separately for transfemales and transmales. • The z-score for femoral area BMAD was not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales or transmales **(VERY LOW)**. • Actual femoral area BMAD values were not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transmales or transfemales **(VERY LOW)**. One retrospective observational study (Vlot et al. 2017, n=70) provided non-comparative evidence on change in femoral neck (hip) BMAD between starting GnRH analogues and starting gender-affirming hormones. All outcomes were reported separately for transfemales and transmales; also see subgroups table below. • The z-score for femoral neck BMAD in transfemales with a bone age of <15 years was not statistically significantly lower at starting gender-affirming hormones than at starting GnRH analogues (z-score median [range]: GnRH analogue −0.71 [−3.35 to 0.37], gender-affirming hormone −1.32 [−3.39 to 0.21], p≤0.1) or in transfemales with a bone age ≥15 years (GnRH analogue −0.44 [−1.37 to 0.93], gender-affirming hormone −0.36 [−1.50 to 0.46]) **(VERY LOW)**.

	• The z-score for femoral neck BMAD in transmales with a bone age of <14 years was not statistically significantly lower at starting gender-affirming hormones than at starting GnRH analogues (z-score median [range]: GnRH analogue −0.01 [−1.30 to 0.91], gender-affirming hormone −0.37 [−2.28 to 0.47]) but was statistically significantly lower in transmales with a bone age ≥14 years (GnRH analogue 0.27 [−1.39 to 1.32], gender-affirming hormone −0.27 [−1.91 to 1.29], p=0.002) **(VERY LOW)**. • Actual femoral neck BMAD values were not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales or in transmales with a young bone age, but were statistically significantly lower in transmales with a bone age ≥14 years (GnRH analogue 0.33 [0.25 to 0.39), gender-affirming hormone 0.30 [0.23 to 0.41], p≤0.01) **(VERY LOW)**. Two uncontrolled, observational, retrospective studies provided evidence for the effect of GnRH analogues on bone density (based on femoral BMD) between starting GnRH analogues and either at 1 or 2 year intervals (Joseph et al. 2019), or starting gender-affirming hormones (Klink et al. 2015). All outcomes were reported separately for transfemales and transmales; also see subgroups table below. One retrospective observational study (Joseph et al. 2019, n=70) provided non-comparative evidence on change in femoral neck BMD increase using z-scores. All outcomes were reported separately for transfemales and transmales. • The z-score for femoral neck BMD was statistically significantly lower at 2 years compared with baseline in transfemales (z-score mean [±SD]: baseline 0.0450 [±0.781], 2 years −0.600 [±1.059], p=0.002) and transmales (baseline −1.075 [±1.145], 2 years −1.779 [±0.816], p=0.001) **(VERY LOW)**. • The z-score for femoral neck BMD was statistically significantly lower at 1 year compared with baseline in transfemales (z-score mean [±SD]: baseline 0.157 [±0.905], 1 year −0.340 [±0.816], p=0.002) and transmales (baseline −0.863 [±1.215], 1 year −1.440 [±1.075], p=0.000) **(VERY LOW)**. • Actual femoral neck BMD values in kg/m^2 were not statistically significantly different between baseline and 1 or 2 years in transmales or transfemales **(VERY LOW)**. One retrospective observational study (Klink et al. 2015, n=34) provided non-comparative evidence on change in femoral area BMD between starting GnRH analogues and starting gender-affirming hormones. All outcomes were reported separately for transfemales and transmales. • The z-score for femoral area BMD was not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales, but was statistically significantly lower in transmales (z-score mean [±SD]: GnRH analogue 0.36 [±0.88], gender-affirming hormone −0.35 [±0.79], p=0.001) **(VERY LOW)**. • Actual femoral area BMD values were not statistically significantly different between starting GnRH analogues and starting gender-affirming hormones in transfemales, but were

	statistically significantly lower in transmales (mean [±SD] GnRH analogue 0.92 [±0.10], gender-affirming hormone 0.88 [±0.09], p=0.005) **(VERY LOW)**. **These studies provide very low certainty evidence that GnRH analogues may reduce the expected increase in femoral bone density (femoral neck or area BMAD or BMD) compared with baseline (although some findings were not statistically significant). These studies also show that GnRH analogues do not statistically significantly decrease actual femoral bone density (femoral area BMAD or femoral neck BMD), apart from actual femoral area BMD in transmales.**
Cognitive development or functioning **Certainty of evidence: very low**	This is an important outcome because puberty is an important time for cognitive development and puberty suppression may affect cognitive development or functioning. One cross-sectional observational study (Staphorsius et al. 2015, n=70) provided comparative evidence on cognitive development or functioning in adolescents with gender dysphoria on GnRH analogues compared with adolescents with gender dysphoria not on GnRH analogues. Cognitive functioning was measured using an IQ test. Reaction time (in seconds) and accuracy (percentage of correct trials) were measured using the Tower of London (ToL) task. All outcomes were reported separately for transfemales and transmales; also see subgroups table below. No statistical analyses or interpretation of the results in these groups were reported: • IQ in transfemales (mean [±SD] GnRH analogue 94.0 [±10.3], control 109.4 [±21.2]). IQ transmales (GnRH analogue 95.8 [±15.6], control 98.5 [±15.9]. • Reaction time in transfemales (mean [±SD] GnRH analogue 10.9 [±4.1], control: 9.9 [±3.1]). Reaction time transmales (GnRH analogue 9.9 [±3.1], control 10.0 [±2.0]). • Accuracy score in transfemales (GnRH analogue 73.9 [±9.1], control 83.4 [±9.5]. Accuracy score in transmales (GnRH analogue 85.7 [±10.5], control 88.8 [±9.7]. **This study provides very low certainty evidence (with no statistical analysis) on the effects of GnRH analogues on cognitive development or functioning. No conclusions could be drawn.**
Other safety outcomes: kidney function **Certainty of evidence: very low**	This is an important outcome because if renal damage (raised serum creatinine is a marker of this) is suspected, GnRH analogues may need to be stopped. One prospective observational study (Schagen et al. 2016, n=116) provided non-comparative evidence on change in serum creatinine between starting GnRH analogues and at 1 year. All outcomes were reported separately for transfemales and transmales; also see subgroups table below. • There was no statistically significant difference between baseline and 1 year for serum creatinine in transfemales (mean [±SD] baseline 70 [±12], 1 year 66 [±13], p=0.20). • There was a statistically significant decrease between baseline and 1 year for serum creatinine in transmales (baseline 73 [±8], 1 year 68 [±13], p=0.01).

	This study provides very low certainty evidence that GnRH analogues do not affect renal function.
Other safety outcomes: liver function **Certainty of evidence: very low**	This is an important outcome because if treatment-induced liver injury (raised liver enzymes are a marker of this) is suspected, GnRH analogues may need to be stopped. One prospective observational study (Schagen et al. 2016, n=116) provided non-comparative evidence on elevated liver enzymes between starting GnRH analogues and during use. No comparative values or statistical analyses were reported. • Glutamyl transferase was not elevated at baseline or during use in any person. • Mild elevations of AST and ALT above the reference range were present at baseline but were not more prevalent during use than at baseline. • Glutamyl transferase, AST, and ALT levels did not significantly change from baseline to 12 months of use. **This study provides very low certainty evidence (with no statistical analysis) that GnRH analogues do not affect liver function.**
Other safety outcomes: adverse effects **Certainty of evidence: very low**	This is an important outcome because if there are adverse effects, GnRH analogues may need to be stopped. One uncontrolled, retrospective, observational cohort study (Khatchadourian et al. 2014) provided evidence relating to adverse effects from GnRH analogues. It had incomplete reporting of its cohort, particularly for transfemales where outcomes for only 4/11 were reported. Khatchadourian et al. 2014 reported adverse effects in a cohort of 26 adolescents (15 transmales and 11 transfemales) receiving GnRH analogues. Of these: • 1 transmale developed sterile abscesses; they were switched from leuprolide acetate to triptorelin, and this was well tolerated. • 1 transmale developed leg pains and headaches, which eventually resolved • 1 participant gained 19 kg within 9 months of starting GnRH analogues. **This study provides very low certainty evidence about potential adverse effects of GnRH analogues. No conclusions could be drawn.**

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BMAD, bone mineral apparent density; BMD, bone mineral density; GnRH, gonadotrophin releasing hormone; IQ, intelligence quotient; NS, not significant; SD, standard deviation.

In children and adolescents with gender dysphoria, what is the cost-effectiveness of GnRH analogues compared to one or a combination of psychological support, social transitioning to the desired gender or no intervention?

Outcome	Evidence statement

Cost-effectiveness	No studies were identified to assess the cost-effectiveness of GnRH analogues for children and adolescents with gender dysphoria.

From the evidence selected, are there any subgroups of children and adolescents with gender dysphoria that may benefit from GnRH analogues more than the wider population of interest?

Subgroup	Evidence statement
Sex assigned at birth males (transfemales) **Certainty of evidence: Very low**	Some studies reported data separately for sex assigned at birth males (transfemales). This included some direct comparisons with sex assigned at birth females (transmales). **Impact on gender dysphoria** One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) provided evidence for gender dysphoria in sex assigned at birth males. See the clinical effectiveness results table above for a full description of the study. The mean (±SD) UGDS score was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at both baseline (T0) (n=not reported, mean UGDS score [±SD]: 47.95 [±9.70] versus 56.57 [±3.89]) and T1 (n=not reported, 49.67 [±9.47] versus 56.62 [±4.00]); between sex difference p<0.001 **(VERY LOW)**. One further prospective observational longitudinal study (Costa et al. 2015) provided evidence for the impact on gender dysphoria in sex assigned at birth males. See the clinical effectiveness results table above for a full description of the study. Sex assigned at birth males had a statistically significantly lower (improved) mean (±SD) UGDS score of 51.6 [±9.7] compared with sex assigned at birth females (56.1 [±4.3], p<0.001). However, it was not reported if this was baseline or follow-up **(VERY LOW)**. **These studies provide very low certainty evidence that in sex assigned at birth males (transfemales), gender dysphoria is lower than in sex assigned at birth females (transmales).** **Impact on mental health** One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) provided evidence for the impact on mental health (depression, anger and anxiety) in sex assigned at birth males. See the clinical effectiveness results table above for a full description of the study. • The mean (±SD) depression (BDI-II) score was not statistically significantly different in sex assigned at birth males compared with sex assigned at birth females at both baseline (T0) (n=not reported, mean BDI score [±SD]: 5.71 [±4.31] versus 10.34 [±8.24]) and T1 (n=not reported, 3.50 [±4.58] versus 6.09 [±7.93]), between sex difference p=0.057 • The mean (±SD) anger (TPI) score was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at both baseline (T0) (n=not reported, mean TPI score [±SD]: 5.22 [±2.76]

versus 6.43 [±2.78]) and T1 (n=not reported, 5.00 [±3.07] versus 6.39 [±2.59]), between sex difference p=0.022
- The mean (±SD) anxiety (STAI) score was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at both baseline (T0) (n=not reported, mean STAI score [±SD]: 4.33 [±2.68] versus 7.00 [±2.36]) and T1 (n=not reported, 4.39 [±2.64] versus 6.17 [±2.69]), between sex difference p<0.001 **(VERY LOW)**.

This study provides very low certainty evidence that the impact on mental health (depression, anger and anxiety) may be different in sex assigned at birth males (transfemales) compared with sex assigned at birth females (transmales). Over time there was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for depression. However, sex assigned at birth males had statistically significantly lower levels of anger and anxiety than sex assigned at birth females at both baseline and follow up.

Impact on body image

One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) provided evidence relating to the impact on body image in sex assigned at birth males.

- The mean (±SD) BIS score for primary sex characteristics was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at both baseline (T0) (n=not reported, mean BIS score [±SD]: 4.02 [±0.61] versus 4.16 [±0.52]) and T1 (n=not reported, 3.74 [±0.78] versus 4.17 [±0.58]), between sex difference p=0.047
- The mean (±SD) BIS score for secondary sex was statistically significantly lower (improved) in sex assigned at birth males compared with sex assigned at birth females at both baseline (T0) (n=not reported, mean BIS score [±SD]: 2.66 [±0.50] versus 2.81 [±0.76]) and T1 (n=not reported, 2.39 [±0.69] versus 3.18 [±0.42]), between sex difference p=0.001
- The mean (±SD) BIS score for neutral body characteristics was not statistically significantly different in sex assigned at birth males compared with sex assigned at birth females at both baseline (T0) (n=not reported, mean BIS score [±SD]: 2.60 [±0.58] versus 2.24 [±0.62]) and T1 (n=not reported, 2.32 [±0.59] versus 2.61 [±0.50]), between sex difference p=0.777 **(VERY LOW)**.

This study provides very low certainty evidence that the impact on body image may be different in sex assigned at birth males (transfemales) compared with sex assigned at birth females (transmales). Sex assigned at birth males are less dissatisfied with their primary and secondary sex characteristics than sex assigned at birth females at both baseline and follow up, but the satisfaction with neutral body characteristics is not different.

Psychosocial impact

One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) provided evidence for psychosocial impact in terms

	of global functioning (CGAS) and psychosocial functioning (CBCL and YSR) in sex assigned at birth males. • Sex assigned at birth males had statistically higher mean (±SD) CGAS scores compared with sex assigned at birth females at both baseline (T0) (n=54, 73.10 [±8.44] versus 67.25 [±11.06]) and T1 (n=54, 77.33 [±8.69] versus 70.30 [±9.44]), between sex difference p=0.021 • There was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for the CBCL Total T score at T0 or T1 (n=54, p=0.110) • There was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for the CBCL internalising T score at T0 or T1 (n=54, p=0.286) • Sex assigned at birth males had statistically lower mean (±SD) CBCL externalising T scores compared with sex assigned at birth females at both T0 (n=54, 54.71 [±12.91] versus 60.70 [±12.64]) and T1 (n=54, 48.75 [±10.22] versus 57.87 [±11.66]), between sex difference p=0.015 • There was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for the YSR Total T score at T0 or T1 (n=54, p=0.164) • There was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for the YSR internalising T score at T0 or T1 (n=54, p=0.825) • Sex assigned at birth males had statistically lower mean (±SD) YSR externalising T scores compared with sex assigned at birth females at both T0 (n=54, 48.72 [±11.38] versus 57.24 [±10.59]) and T1 (n=54, 46.52 [±9.23] versus 52.97 [±8.51]), between sex difference p=0.004 **(VERY LOW)**. One uncontrolled, observational, prospective cohort study (Costa et al. 2015) provided evidence for psychosocial impact in terms of global functioning (CGAS) in sex assigned at birth males. • Sex assigned at birth males had statistically significant lower mean (±SD CGAS scores at baseline) compared with sex assigned at birth females (n=201, 55.4 [±12.7] versus 59.2 [±11.8], p=0.03) **(VERY LOW)**. **These studies provide very low certainty evidence that psychosocial impact may be different in sex assigned at birth males (transfemales) compared with sex assigned at birth females (transmales). However, no conclusions could be drawn.** **Change in bone density: lumbar** Three uncontrolled, observational, retrospective studies provided evidence relating to the effect of GnRH analogues on lumbar bone density in sex assigned at birth males (Joseph et al. 2019, Klink et al. 2015 and Vlot et al. 2017). See the safety results table above for a full description of the results. **These studies provide very low certainty evidence that GnRH analogues reduce the expected increase in lumbar bone density (BMAD or BMD) in sex assigned at birth males (transfemales; although some findings were not statistically significant). These studies also show that GnRH analogues do not statistically**

	significantly decrease actual lumbar bone density (BMAD or BMD) in sex assigned at birth males (transfemales). **Change in bone density: femoral** Three uncontrolled, observational, retrospective studies provided evidence for the effect of GnRH analogues on femoral bone density in sex assigned at birth males (Joseph et al. 2019, Klink et al. 2015 and Vlot et al. 2017). See the safety results table above for a full description of the results. **These studies provide very low certainty evidence that GnRH analogues may reduce the expected increase in femoral bone density (femoral neck or area BMAD or BMD) in sex assigned at birth males (transfemales; although some findings were not statistically significant). These studies also show that GnRH analogues do not statistically significantly decrease actual femoral bone density (femoral area BMAD or femoral neck BMD) in sex assigned at birth males (transfemales).** **Cognitive development or functioning** One cross-sectional observational study (Staphorsius et al. 2015) provided comparative evidence on cognitive development or functioning in sex assigned at birth males. See the safety results table above for a full description of the results. **This study provides very low certainty evidence (with no statistical analysis) on the effects of GnRH analogues on cognitive development or functioning in sex assigned at birth males (transfemales). No conclusions could be drawn.** **Other safety outcomes: kidney function** One prospective observational study (Schagen et al. 2016) provided non-comparative evidence on change in serum creatinine in sex assigned at birth males. See the safety results table above for a full description of the results. **This study provides very low certainty evidence that GnRH analogues do not affect renal function in sex assigned at birth males (transfemales).**
Sex assigned at birth females (transmales) **Certainty of evidence: Very low**	Some studies reported data separately for sex assigned at birth females (transmales). This included some direct comparisons with sex assigned at birth males (transfemales). **Impact on gender dysphoria** One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) and one prospective observational longitudinal study (Costa et al. 2015) provided evidence for gender dysphoria in sex assigned at birth females. See the sex assigned at birth males (transfemales) row above for a full description of the results. **These studies provide very low certainty evidence that in sex assigned at birth females (transmales), gender dysphoria is higher than in sex assigned at birth males (transfemales) at both baseline and follow up.**

	Impact on mental health One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) provided evidence relating to the impact on mental health (depression, anger and anxiety) in sex assigned at birth females. See the sex assigned at birth males (transfemales) row above for a full description of the results. **This study provides very low certainty evidence that the impact on mental health (depression, anger and anxiety) may be different in sex assigned at birth females (transmales) compared with sex assigned at birth males (transfemales). Over time there was no statistically significant difference between sex assigned at birth females and sex assigned at birth males for depression. However, sex assigned at birth females had statistically significantly greater levels of anger and anxiety than sex assigned at birth males at baseline and follow up.** **Impact on body image** One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) provided evidence relating to the impact on body image in sex assigned at birth females. See the sex assigned at birth males (transfemales) row above for a full description of the results. **This study provides very low certainty evidence that the impact on body image may be different in sex assigned at birth females (transmales) compared with sex assigned at birth males (transfemales). Sex assigned at birth females are more dissatisfied with their primary and secondary sex characteristics than sex assigned at birth males at both baseline and follow up, but the satisfaction with neutral body characteristics is not different.** **Psychosocial impact** One uncontrolled prospective observational longitudinal study (de Vries et al. 2011) provided evidence for psychosocial impact in terms of global functioning (CGAS) and psychosocial functioning (CBCL and YSR) in sex assigned at birth females. One uncontrolled, observational, prospective cohort study (Costa et al. 2015) provided evidence for psychosocial impact in terms of global functioning (CGAS) in sex assigned at birth females. See the sex assigned at birth males (transfemales) row above for a full description of the results. **These studies provide very low certainty evidence that psychosocial impact may be different in sex assigned at birth females (transmales) compared with sex assigned at birth males (transfemales). However, no conclusions could be drawn.** **Change in bone density: lumbar** Three uncontrolled, observational, retrospective studies provided evidence relating to the effect of GnRH analogues on lumbar bone density in sex assigned at birth females (Joseph et al. 2019, Klink et al. 2015 and Vlot et al. 2017). See the safety results table above for a full description of the results.

	These studies provide very low certainty evidence that GnRH analogues reduce the expected increase in lumbar bone density (BMAD or BMD) in sex assigned at birth females (transmales; although some findings were not statistically significant). These studies also show that GnRH analogues do not statistically significantly decrease actual lumbar bone density (BMAD or BMD) in sex assigned at birth females (transmales). **Change in bone density: femoral** Three uncontrolled, observational, retrospective studies provided evidence relating to the effect of GnRH analogues on femoral bone density in sex assigned at birth females (Joseph et al. 2019, Klink et al. 2015 and Vlot et al. 2017). See the safety results table above for a full description of the results. **These studies provide very low certainty evidence that GnRH analogues may reduce the expected increase in femoral bone density (femoral neck or area BMAD or BMD) in sex assigned at birth females (transmales; although some findings were not statistically significant). These studies also show that GnRH analogues do not statistically significantly decrease actual femoral bone density (femoral area BMAD or femoral neck BMD) in sex assigned at birth females (transmales), apart from actual femoral area.** **Cognitive development or functioning** One cross-sectional observational study (Staphorsius et al. 2015) provided comparative evidence on cognitive development or functioning in sex assigned at birth females. See the safety results table above for a full description of the results. **This study provides very low certainty evidence (with no statistical analysis) on the effects of GnRH analogues on cognitive development or functioning in sex assigned at birth females (transmales). No conclusions could be drawn.** **Other safety outcomes: kidney function** One prospective observational study (Schagen et al. 2016) provided non-comparative evidence on change in serum creatinine in sex assigned at birth females (transmales). See the safety results table above for a full description of the results. **This study provides very low certainty evidence that GnRH analogues do not affect renal function in sex assigned at birth females (transmales).**
Duration of gender dysphoria	No evidence was identified.
Age at onset of gender dysphoria	No evidence was identified.
Age at which GnRH analogue started	No evidence was identified.
Age at onset of puberty	No evidence was identified.

Tanner stage at which GnRH analogue started	No evidence was identified.
Diagnosis of autistic spectrum disorder	No evidence was identified.
Diagnosis of mental health condition	No evidence was identified.

Abbreviations: BDI-II, Beck Depression Inventory-II; BIS, Body Image Scale; CBCL, Child Behaviour Checklist; CGAS, Children's Global Assessment Scale; SD, standard deviation; STAI, Trait Anxiety Scale of the State-Trait Personality Inventory; TPI, Trait Anger Scale of the State-Trait Personality Inventory; UGDS, Utrecht Gender Dysphoria Scale; YSR, Youth Self-Report

From the evidence selected,

(a) what are the criteria used by the research studies to define gender dysphoria, gender identity disorder and gender incongruence of childhood?

(b) what were the ages at which participants commenced treatment with GnRH analogues?

(c) what was the duration of treatment with GnRH analogues?

Outcome	Evidence statement
Diagnostic criteria	In 5 studies (Costa et al. 2015, Klink et al. 2015, Schagen et al. 2016, Staphorsius et al. 2015 and Vlot et al. 2017) the DSM-IV-TR criteria of gender identity disorder was used. The study by Brik et al. 2020 used DSM-V criteria. The DSM-V has one overarching definition of gender dysphoria with separate specific criteria for children and for adolescents and adults. The general definition describes a conflict associated with significant distress and/or problems functioning associated with this conflict between the way they feel and the way they think of themselves which must have lasted at least 6 months. It was not reported how gender dysphoria was defined in the remaining 3 studies **(VERY LOW)**. **From the evidence selected, all studies that reported diagnostic criteria for gender dysphoria (6/9 studies) used the DSM criteria in use at the time the study was conducted.**
Age when GnRH analogues started	8/9 studies reported the age at which participants started GnRH analogues, either as the mean age (with SD) or median age (with the range): **Study** / **Mean age (±SD)** Costa et al. 2015 — 16.5 years (±1.3) de Vries et al. 2011 — 13.6 years (±1.8) Joseph et al. 2019 — 13.2 years (±1.4) in transfemales; 12.6 years (±1.0) in transmales Khatchadourian et al. 2014 — 14.7 years (±1.9)

	<table><tr><td>Klink et al. 2015</td><td>14.9 years (±1.9) in transfemales 15.0 years (±2.0) in transmales</td></tr></table> <table><tr><th>Study</th><th>Median age (range)</th></tr><tr><td>Brik et al. 2020</td><td>15.5 years (11.1–18.6) in transfemales 16.1 years (10.1–17.9) in transmales</td></tr><tr><td>Schagen et al. 2016</td><td>13.6 years (11.6–17.9) in transfemales 14.2 years (11.1–18.6) in transmales</td></tr><tr><td>Vlot et al. 2017</td><td>13.5 years (11.5–18.3) in transfemales 15.1 years (11.7–18.6) in transmales</td></tr></table> Age at the start of GnRH analogues was not reported in Staphorsius et al. 2015, but participants were required to be at least 12 years **(VERY LOW)**. **The evidence included showed wide variation in the age (11 to 18 years old) at which children and adolescents with gender dysphoria started GnRH analogues.**
Duration of treatment	The duration of treatment with GnRH analogues was reported in 3/9 studies. The median duration was: • 2.1 years (range 1.6–2.8) in Brik et al. 2020. • 1.3 years (range 0.5–3.8) in transfemales and 1.5 years (range 0.25–5.2) in transmales in Klink et al. 2015. In Staphorsius et al. 2015, the mean duration was 1.6 years (SD ±1.0). In de Vries et al. 2011, the mean duration of time between starting GnRH analogues and gender-affirming hormones was 1.88 years (SD ±1.05). **The evidence included showed wide variation in the duration of treatment with GnRH analogues, but most studies did not report this information. Treatment duration ranged from a few months up to about 5 years.**

Abbreviations: DSM, Diagnostic and Statistical Manual of Mental Disorders criteria; SD, standard deviation.

6. Discussion

A key limitation to identifying the effectiveness and safety of GnRH analogues for children and adolescents with gender dysphoria is the lack of reliable comparative studies. The lack of clear, expected outcomes from treatment with a GnRH analogue (the purpose of which is to suppress secondary sexual characteristics which may cause distress from unwanted pubertal changes) also makes interpreting the evidence difficult. The size of the population with gender dysphoria means conducting a prospective trial may be unrealistic, at least on a single centre basis. There may also be ethical issues with a 'no treatment arm' in comparative trials of GnRH analogues, where there may be poor mental health outcomes if treatment is withheld. However, the use of an active comparator such as close psychological support may reduce ethical concerns in future trials.

The studies included in this evidence review are all small, uncontrolled observational studies, which are subject to bias and confounding, and are of very low certainty as

assessed using modified GRADE. All the included studies reported physical and mental health comorbidities and concomitant treatments very poorly. For example, very little data are reported on how many children and adolescents needed additional mental health support, and for what reasons, or whether additional interventions, and what form and duration (for example drug treatment or counselling) that took. This is a possible confounder for the treatment outcomes in the studies because changes in critical and important outcomes may be attributable to external care rather than the psychological support or GnRH analogues used in the studies.

The studies that reported diagnostic criteria for gender dysphoria (6/9 studies) used the Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria in use at the time the study was conducted (either DSM-IV-TR or DSM-V). The definition was unclear in the remaining studies. There was wide variation in the ages at which participants started a GnRH analogue, typically ranging from about 11 to 18 years. Similarly, there was a wide variation in the duration of use, but few studies reported this.

Changes in outcome scores for clinical effectiveness were assessed for statistical significance in the 3 studies reporting these outcomes (Costa et al. 2015; de Vries et al. 2011; Staphorsius et al. 2015). However, there is relatively little interpretation of whether the changes in outcome scores seen in these studies are clinically meaningful.

For some outcomes there was no statistically significant difference from before starting GnRH analogues until just before starting gender-affirming hormones. These were the Utrecht Gender Dysphoria Scale (UGDS) (which was assessed in 1 study de Vries et al. 2011), the Trait Anger (TPI) and Trait Anxiety (STAI) Scales (which were assessed in 1 study de Vries et al. 2011), and Body Image Scale (BIS) which was assessed in 1 study (de Vries et al. 2011).

The Beck Depression Inventory (BDI-II) was used in 1 study (de Vries et al. 2011) to assess change in depression from before starting GnRH analogues to just before starting gender-affirming hormones. The result is statistically significant, with the mean (±SD) BDI-II score decreasing from 8.31 (±7.12) at baseline to 4.95 (±6.27) at follow up (p=0.004). However, both scores fall into the minimal range using the general guidelines for interpretation of BDI-II (0 to 13 minimal, 14 to 19 mild depression, 20 to 28 moderate depression and 29 to 63 severe depression), suggesting that while statistically significant, it is unclear if this is a clinically meaningful change.

Psychosocial outcomes were assessed in 3 studies (Costa et al. 2015; de Vries et al. 2011; Staphorsius et al. 2015) using the Children's Global Assessment Scale (CGAS) and Child Behavior Checklist/Youth Self-Report (CBCL/YSR). The CGAS score was assessed in 2 studies (Costa et al. 2015; de Vries et al. 2011). In de Vries et al. 2011 the mean (±SD) CGAS score statistically significantly increased over time from 70.24 [±10.12] at baseline to 73.90 [±9.63] at follow up. CGAS scores are clinically categorised into 10 categories (10 to 1, 20 to 11 and so on until 100 to 91) and both scores reported were in a single category (71 to 80, no more than slight impairment) suggesting that while statistically significant, it is unclear if this is a clinically meaningful change. The Costa et al. 2015 study does highlight a larger change in CGAS scores from baseline to follow-up (mean [±SD] 58.72 [±11.38] compared with 67.40 [±13.39]), but whether this is clinically meaningful is unclear. The average score moved from the clinical category of 60 to 51 (variable functioning with sporadic difficulties) at baseline to 70 to 61 (some difficulty in a single area, but generally

functioning pretty well) at follow up, but the large standard deviations suggest clinically significant overlaps between the scores from baseline to follow-up.

Psychosocial functioning using the CBCL/YSR was assessed in 2 studies (de Vries et al. 2011; Staphorsius et al. 2015). In de Vries et al. 2011 there was a statistically significant reduction in both CBCL and YSR scores from before starting GnRH analogues to just before starting gender-affirming hormones. The study interpreted the CBCL/YSR with a proportion of adolescents who scored in the clinical range (a T-score above 63), which allows changes in clinically meaningful scores to be assessed, and proportions of adolescents in the clinical range for some CBCL and YSR scores decreased over time. One cross-sectional study (Staphorsius et al. 2015) assessed CBCL scores only, but it was unclear if this was the Total T score, or whether subscales of internalising or externalising scores were also assessed, and whether the results were statistically significant.

The 2 prospective observational studies (Costa et al. 2015; de Vries et al. 2011) are confounded by a number of common factors. Firstly, the single assessment of scores at baseline means it is unclear if scores were stable, already improving or declining before starting treatment. Secondly, in an uncontrolled study any changes in scores from baseline to follow-up could be attributed to a regression-to-mean, for example getting older has been positively associated with maturity and wellbeing. The studies use mean and standard deviations in the descriptive statistics and analyses; however, they do not report testing the normality of data which would support the use of parametric measures. The study by de Vries et al. 2011 used general linear models (regression) to examine between and within group variances (changes in outcomes). In using such models, the data is assumed to be balanced (measured at regular intervals and without missing data), but the large ranges in ages at which participants were assessed and started on various interventions suggests that ascertainment of outcome was unlikely to be regular and missing data was likely. Missing data was handled through listwise deletion (omits those cases with the missing data and analyses the remaining data) which is acceptable if data loss is completely random but for some outcomes where there was incomplete data for individual items this was not random (items were introduced by the authors after the first eligible adolescents had started GnRH analogues). The study provided no detail on whether these assumptions for the modeling were met, they also provided no adequate assessment of whether any regression diagnostics (analysis that seek to assess the validity of a model) or model fit (how much of the variance in outcome is explained by the between and within group variance) were undertaken.

The 2 retrospective observational studies (Brik et al. 2020; Khatchadourian et al. 2014) both only report absolute numbers for each trajectory along with reasons for stopping GnRH analogues. It is difficult to assess outcomes from such single centre studies because there is little comparative data for outcomes from other such services. A lack of any critical or other important outcomes also means the success of the treatment across all the participants is difficult to judge.

Three uncontrolled, observational, retrospective studies provided evidence relating to the effect of GnRH analogues on bone density (Joseph et al. 2019; Klink et al. 2015; Vlot et al. 2017). In all 3 studies, the participants acted as their own controls and change in bone density was determined between starting GnRH analogues and either after 1 and 2 year follow-up timepoints (Joseph et al. 2019) or when gender-affirming hormones were started

(Klink et al. 2015 and Vlot et al. 2017). Observational studies such as these can only show an association with GnRH analogues and bone density; they cannot show that GnRH analogues caused any differences in bone density seen. Because there was no comparator group and participants acted as their own controls, it is unclear whether the findings are associated with GnRH analogues or due to changes over time. The authors reported z-scores which allows for comparison with the expected increase in bone density in the general population. However, because no concomitant treatments or comorbidities were reported it is possible that the findings may not be because of GnRH analogues and there is another way in which the study population differs from the general population.

All the studies are from a limited number of, mainly European, care facilities. They are described as either tertiary referral or expert services but the low number of services providing such care and publishing evidence may bias the results towards the outcomes in these services only and limit extrapolation.

The first study (Brik et al. 2020) was an uncontrolled, retrospective, observational study that assessed the outcome trajectories of adolescents receiving GnRH analogues for gender dysphoria. This study followed-up 143 individuals who had received GnRH analogues (38 transfemales and 105 transmales) using clinical records to show outcomes for up to 9 years (continuing use of GnRH analogues, reasons for stopping GnRH analogues and onward care such as gender-affirming hormone use). The methods and results are well reported, but no analysis of data was undertaken. The views of adolescents and their parents are particularly difficult to interpret because no data on how many responded to each question and in what ways are reported.

The second study (Costa et al. 2015) was an uncontrolled, prospective observational study which assessed global functioning in adolescents with gender dysphoria using CGAS every 6 months, including during the first 6 months where statistically significant improvements were seen without GnRH analogues. The study is confounded by significant unexplained loss to follow-up (64.7%: from n=201 adolescents to n=71 after 18 months). Missing data for those lost to follow-up maybe more than sufficient to change the direction of effects seen in the study if the reasons for loss to follow-up are systematic (such as deriving little or no benefit from treatment). The study uses clustered data in its analysis, a single outcome (CGAS) measured in clusters (at different visits), and the analysis does not take account of the correlation of scores (data at different time points are not independent) as a significant change in scores early in the study means the successive changes measured against baseline were also significant. The study relies on multiple (>20) pairwise independent *t*-tests to examine change in CGAS between the 4 time points, increasing the possibility of type-I error (a false positive which occurs when a researcher incorrectly rejects a true null hypothesis) because the more tests performed the more likely a statistically significant result will be observed by chance alone.

The Costa et al. 2015 study compares immediately eligible and delayed eligible cohorts, however, it is highly likely that they are non-comparable groups because the immediately eligible group were those able to start GnRH analogues straight away whilst those in the delayed eligible group were either not ready to make a decision about starting treatment (no age comparison was made between the 2 groups so it is unclear if they were a younger cohort than the immediately eligible group) or had comorbid mental health or psychological difficulties. The authors report that those with concomitant problems (such as mental health

problems, substantial problems with peers, or conflicts with parents or siblings) were referred to local mental health services but no details are provided.

The third study (de Vries et al. 2011) was an uncontrolled, prospective observational study which assessed gender dysphoria and psychological functioning before and after puberty suppression in adolescents with gender dysphoria. Although the study mentions the DSM-IV-TR there is no explicit discussion of this, or any other criteria, being used as the diagnostic criteria for study entry. There are no details reported for how the outcomes in the study were assessed, and by whom. The length of follow-up for the outcomes in the model are questionable in relation to whether there was sufficient time for GnRH analogues to have a measurable effect. The time points used are start of GnRH analogues and start of gender-affirming hormones. Overall, the mean time between starting GnRH analogues and gender-affirming hormones was 1.88 (±1.05) years, but the range is as low as just 5 months between the 2 time points, which may be insufficient for any difference in outcome to have occurred in some individuals.

The fourth study (Joseph et al. 2019) was a retrospective, longitudinal observational single centre study which assessed bone mineral density in adolescents with gender dysphoria in the UK. For inclusion in the study, participants had to have been assessed by the Gender Identity Development Service multi-disciplinary psychosocial health team for at least 4 assessments over a minimum of 6 months. No other diagnostic criteria, such as the DSM-IV-TR, are discussed. Bone density was assessed using dual energy X-ray absorptiometry (DAXA) scan of the lumbar spine (L1-L4) and the femoral neck at baseline (n=70), 1 year (n=70) and 2 years after starting GnRH analogues (n=39). The results suggest a possible association between GnRH analogues and bone mineral apparent density. However, the evidence is of poor quality, and the results could be due to bias or chance. No concomitant treatments or comorbidities were reported.

The fifth study (Khatchadourian et al. 2014) was an uncontrolled retrospective observational study which describes patient characteristics at presentation, treatment, and response to treatment in 84 adolescents with gender dysphoria, of whom 27 received GnRH analogues. The study used clinical records to show outcomes for up to 13 years (continuing use of GnRH analogues, reasons for stopping GnRH analogues and onward care such as gender-affirming hormone use). The methods are well reported but the results for those taking GnRH analogues are poorly and incompletely reported, particularly for transfemales, and no analysis of data was undertaken. It is difficult to assess the results for stopping GnRH analogues due to incomplete reporting of this outcome.

The sixth study (Klink et al. 2015) was a retrospective longitudinal observational single centre study which assessed bone mineral density in adolescents with gender dysphoria, diagnosed with the DSM-IV-TR criteria. Bone density was assessed when starting GnRH analogues and then when starting gender-affirming hormones. Results are reported for transmales and transfemales separately and no results for the whole cohort are given. Statistical analyses were reported for all outcomes of interest but, because there was no comparator group and participants acted as their own controls, it is not known whether the findings are associated with GnRH analogues or due to changes over time. The authors reported z-scores which allows for comparison with the expected increase in bone density in the general population. However, because no concomitant treatments or comorbidities were

reported it is possible that the findings may not be because of GnRH analogues and there is another way in which the study population differs from the general population.

The seventh study (Schagen et al. 2016) was a prospective observational study of 116 adolescents which provided very low certainty non-comparative evidence on change in serum creatinine between starting GnRH analogues and 1 year, and liver function during treatment. Statistical analyses were reported for changes in serum creatinine but not for liver function. Because there was no comparator group and participants acted as their own controls, it is not known whether the findings are associated with GnRH analogues or due to changes over time, or concomitant treatments.

The eighth study (Staphorsius et al. 2015) was a cross-sectional study of 85 adolescents, 40 with gender dysphoria (of whom 20 were receiving GnRH analogues) and 45 matched controls (not further reported in this evidence review). The study includes 1 outcome of interest for clinical effectiveness (CBCL) and 1 outcome of interest for safety (cognitive development or functioning). The mean (±SD) CBCL, IQ test, reaction time and accuracy scores were given for each group, but the statistical analysis is unclear. It is not reported what analysis was used or which of the groups were compared, therefore it is difficult to interpret the results.

The ninth study (Vlot et al. 2017) was a retrospective observational study which assessed bone mineral apparent density in adolescents with DSM-IV-TR gender dysphoria. Measurements were taken at the start of GnRH analogues and at the start of gender-affirming hormones. Results are reported for young bone age and old bone age in transmales and transfemales separately, and no results for the whole cohort are given. Statistical analyses were reported for all outcomes of interest but, because there was no comparator group and participants acted as their own controls, it is not known whether the findings are associated with GnRH analogues or due to changes over time. The authors reported z-scores which allows for comparison with the expected increase in bone density in the general population. However, because no concomitant treatments or comorbidities were reported it is possible that the findings may not be because of GnRH analogues and there is another way in which the study population differs from the general population.

7. Conclusion

The results of the studies that reported impact on the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning) in children and adolescents with gender dysphoria are of very low certainty using modified GRADE. They suggest little change with GnRH analogues from baseline to follow-up.

Studies that found differences in outcomes could represent changes that are either of questionable clinical value, or the studies themselves are not reliable and changes could be due to confounding, bias or chance. It is plausible, however, that a lack of difference in scores from baseline to follow-up is the effect of GnRH analogues in children and adolescents with gender dysphoria, in whom the development of secondary sexual characteristics might be expected to be associated with an increased impact on gender dysphoria, depression, anxiety, anger and distress over time without treatment. One study reported statistically significant reductions in the Child Behaviour Checklist/Youth Self-Report (CBCL/YSR) scores from

baseline to follow up, and given that the purpose of GnRH analogues is to reduce distress caused by the development of secondary sexual characteristics and the CBCL/YSR in part measures distress, this could be an important finding. However, as the studies all lack reasonable controls not receiving GnRH analogues, the natural history of the outcomes measured in the studies is not known and any positive changes could be a regression to mean.

The results of the studies that reported bone density outcomes suggest that GnRH analogues may reduce the increase in bone density which is expected during puberty. However, as the studies themselves are not reliable, the results could be due to confounding, bias or chance. While controlled trials may not be possible, comparative studies are needed to understand this association and whether the effects of GnRH analogues on bone density are seen after treatment is stopped. All the studies that reported safety outcomes provided very low certainty evidence.

No cost-effectiveness evidence was found to determine whether or not GnRH analogues are cost-effective for children and adolescents with gender dysphoria.

The results of the studies that reported outcomes for subgroups of children and adolescents with gender dysphoria, suggest there may be differences between sex assigned at birth males (transfemales) and sex assigned at birth females (transmales).

Appendix A PICO document

The review questions for this evidence review are:

1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?
2. For children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention?
3. For children and adolescents with gender dysphoria, what is the cost-effectiveness of GnRH analogues compared to one or a combination of psychological support, social transitioning to the desired gender or no intervention?
4. From the evidence selected, are there any subgroups of children and adolescents with gender dysphoria that may derive more (or less) advantage from treatment with GnRH analogues than the wider population of children and adolescents with gender dysphoria?
5. From the evidence selected,
   a) what are the criteria used by the research studies to define gender dysphoria, gender identity disorder and gender incongruence of childhood?
   b) what were the ages at which participants commenced treatment with GnRH analogues?
   c) what was the duration of treatment with GnRH analogues?

PICO table

P – Population and Indication	Children and adolescents aged 18 years or less who have gender dysphoria, gender identity disorder or gender incongruence of childhood as defined by study: The following subgroups of children and adolescents with gender dysphoria, gender identity disorder or gender incongruence of childhood need to be considered: • Sex assigned at birth males. • Sex assigned at birth females. • The duration of gender dysphoria: less than 6 months, 6-24 months, and more than 24 months. • The age of onset of gender dysphoria. • The age at which treatment was initiated. • The age of onset of puberty. • Tanner stage at which treatment was initiated. • Children and adolescents with gender dysphoria who have a pre-existing diagnosis of autistic spectrum disorder. • Children and adolescents with gender dysphoria who had a significant mental health symptom load at diagnosis including anxiety, depression (with or without a history of self-harm and suicidality), suicide attempts, psychosis, personality disorder, Attention Deficit Hyperactivity Disorder and eating disorders.
I – Intervention	Any GnRH analogue including: triptorelin*; buserelin; histrelin; goserelin (Zoladex); leuprorelin/leuprolide (Prostap); nafarelin.

	* Triptorelin (brand names Gonapeptyl and Decapeptyl) are used in Leeds Hospital, England. The search should include brand names as well as generic names.
C – Comparator(s)	One or a combination of: • Psychological support. • Social transitioning to the gender with which the individual identifies. • No intervention.
O – Outcomes	There are no known minimal clinically important differences and there are no preferred timepoints for the outcome measures selected. **All outcomes should be stratified by:** • The age at which treatment with GnRH analogues was initiated. • The length of treatment with GnRH analogues where possible. **A: Clinical Effectiveness** *Critical to decision making* • **Impact on Gender Dysphoria** This outcome is critical because gender dysphoria in adolescents and children is associated with significant distress and problems functioning. Impact on gender dysphoria may be measured by the Utrecht Gender Dysphoria Scale. Other measures as reported in studies may be used as an alternative to the stated measure. • **Impact on mental health** Examples of mental health problems include self-harm, thoughts of suicide, suicide attempts, eating disorders, depression/low mood and anxiety. These outcomes are critical because self-harm and thoughts of suicide have the potential to result in significant physical harm and for completed suicides the death of the young person. Disordered eating habits may cause significant morbidity in young people. Depression and anxiety are also critical outcomes because they may impact on social, occupational, or other areas of functioning of children and adolescents. The Child and Adolescent Psychiatric Assessment (CAPA) may be used to measure depression and anxiety. The impact on self-harm and suicidality (ideation and behaviour) may be measured using the Suicide Ideation Questionnaire Junior. Other measures may be used as an alternative to the stated measures. • **Impact on Quality of Life** This outcome is critical because gender dysphoria in children and adolescents may be associated with a significant reduction in health-related quality of life. Quality of Life may be measured by the KINDL questionnaire, Kidscreen 52. Other measures as reported in studies may be used as an alternative to the stated measure. *Important to decision making* • **Impact on body Image** This outcome is important because some transgender young people may desire to take steps to suppress features of their physical appearance associated with their sex assigned at birth or accentuate physical features of their desired gender. The Body Image Scale could be used as a measure. Other measures

	as reported in studies may also be used as an alternative to the stated measure. • **Psychosocial Impact** Examples of psychosocial impact are: coping mechanisms which may impact on substance misuse; family relationships; peer relationships. This outcome is important because gender dysphoria in adolescents and children is associated with internalising and externalising behaviours and emotional and behavioural problems which may impact on social and occupational functioning. The child behavioural check list (CBCL) may be used to measure the impact on psychosocial functioning. Other measures as reported in studies may be used as an alternative to the stated measure. • **Engagement with health care services** This outcome is important because patient engagement with healthcare services will impact on their clinical outcomes. Engagement with health care services may be measured using the Youth Health Care measure-satisfaction, utilization, and needs (YHC-SUN) questionnaire. Loss to follow up should also be ascertained as part of this outcome. Alternative measures to the YHC-SUN questionnaire may be used as reported in studies. • **Transitioning surgery – Impact on extent of and satisfaction with surgery** This outcome is important because some children and adolescents with gender dysphoria may proceed to transitioning surgery. Stated measures of the extent of transitioning surgery and satisfaction with surgery in studies may be reported. • **Stopping treatment** The proportion of patients who stop treatment with GnRH analogues and the reasons why. This outcome is important to patients because there is uncertainty about the short- and long-term safety and adverse effects of GnRH analogues in children and adolescents being treated for gender dysphoria. **B: Safety** • Short and long-term safety and adverse effects of taking GnRH analogues are important because GnRH analogues are not licensed for the treatment of adolescents and children with gender dysphoria. Aspects to be reported on should include: o Impact of the drug use such as its impact on bone density, arterial hypertension, cognitive development/functioning o Impact of withdrawing the drug such as, slipped upper femoral epiphysis, reversibility on the reproductive system, and any others as reported. **C: Cost effectiveness** Cost effectiveness studies should be reported.
Inclusion criteria	
Study design	Systematic reviews, randomised controlled trials, controlled clinical trials, cohort studies. If no higher level quality evidence is found, case series can be considered.

Language	English only
Patients	Human studies only
Age	18 years or less
Date limits	2000-2020
Exclusion criteria	
Publication type	Conference abstracts, non-systematic reviews, narrative reviews, commentaries, letters, editorials, guidelines and pre-publication prints
Study design	Case reports, resource utilisation studies

Appendix B Search strategy

Medline, Embase, the Cochrane Library, HTA and APA PsycInfo were searched on 23 July 2020, limiting the search to papers published in English language in the last 20 years. Conference abstracts and letters were excluded.

Database: Medline
Platform: Ovid
Version: Ovid MEDLINE(R) <1946 to July 21, 2020>
Search date: 23/7/2020
Number of results retrieved: 144
Search strategy:

1 Gender Dysphoria/ (485)
2 Gender Identity/ (18452)
3 "Sexual and Gender Disorders"/ (75)
4 Transsexualism/ (3758)
5 Transgender Persons/ (3143)
6 Health Services for Transgender Persons/ (136)
7 exp Sex Reassignment Procedures/ (836)
8 (gender* adj3 (dysphori* or affirm* or incongruen* or identi* or disorder* or confus* or minorit* or queer*)).tw. (7435)
9 (transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*).tw. (12678)
10 (trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*).tw. (102343)
11 ((sex or gender*) adj3 (reassign* or chang* or transform* or transition*)).tw. (6974)
12 (male-to-female or m2f or female-to-male or f2m).tw. (114841)
13 or/1-12 (252702)
14 exp Infant/ or Infant Health/ or Infant Welfare/ (1137479)
15 (prematur* or pre-matur* or preterm* or pre-term* or infan* or newborn* or new-born* or perinat* or peri-nat* or neonat* or neo-nat* or baby* or babies or toddler*).ti,ab,in,jn. (852400)
16 exp Child/ or exp Child Behavior/ or Child Health/ or Child Welfare/ (1913257)

17 Minors/ (2574)
18 (child* or minor or minors or boy* or girl* or kid or kids or young*).ti,ab,in,jn. (2361686)
19 exp pediatrics/ (58118)
20 (pediatric* or paediatric* or peadiatric*).ti,ab,in,jn. (836269)
21 Adolescent/ or Adolescent Behavior/ or Adolescent Health/ (2024207)
22 Puberty/ (13278)
23 (adolescen* or pubescen* or prepubescen* or pre-pubescen* or pubert* or prepubert* or pre-pubert* or teen* or preteen* or pre-teen* or juvenil* or youth* or under*age*).ti,ab,in,jn. (424246)
24 Schools/ (38104)
25 Child Day Care Centers/ or exp Nurseries/ or Schools, Nursery/ (7199)
26 (pre-school* or preschool* or kindergar* or daycare or day-care or nurser* or school* or pupil* or student*).ti,ab,jn. (468992)
27 (("eight" or "nine" or "ten" or "eleven" or "twelve" or "thirteen" or "fourteen" or "fifteen" or "sixteen" or "seventeen" or "eighteen" or "nineteen") adj2 (year or years or age or ages or aged)).ti,ab. (89353)
28 (("8" or "9" or "10" or "11" or "12" or "13" or "14" or "15" or "16" or "17" or "18" or "19") adj2 (year or years or age or ages or aged)).ti,ab. (887838)
29 or/14-28 (5534171)
30 13 and 29 (79263)
31 (transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*).tw. (7)
32 30 or 31 (79263)
33 Gonadotropin-Releasing Hormone/ (27588)
34 (pubert* adj3 block*).ti,ab. (78)
35 ((gonadotrophin or gonadotropin) and releasing).ti,ab. (17299)
36 (GnRH adj2 analog*).ti,ab. (2541)
37 GnRH*.ti,ab. (20991)
38 "GnRH agonist*".ti,ab. (4040)
39 Triptorelin Pamoate/ (1906)
40 triptorelin.ti,ab. (677)
41 arvekap.ti,ab. (1)
42 ("AY 25650" or AY25650).ti,ab. (1)
43 ("BIM 21003" or BIM21003).ti,ab. (0)
44 ("BN 52014" or BN52014).ti,ab. (0)
45 ("CL 118532" or CL118532).ti,ab. (0)
46 Debio.ti,ab. (83)
47 diphereline.ti,ab. (17)
48 moapar.ti,ab. (0)
49 pamorelin.ti,ab. (0)
50 trelstar.ti,ab. (3)
51 triptodur.ti,ab. (1)
52 ("WY 42422" or WY42422).ti,ab. (0)
53 ("WY 42462" or WY42462).ti,ab. (0)
54 gonapeptyl.ti,ab. (0)
55 decapeptyl.ti,ab. (210)
56 salvacyl.ti,ab. (0)
57 Buserelin/ (2119)
58 buserelin.ti,ab. (1304)

59 bigonist.ti,ab. (0)
60 ("hoe 766" or hoe-766 or hoe766).ti,ab. (69)
61 profact.ti,ab. (2)
62 receptal.ti,ab. (30)
63 suprecur.ti,ab. (4)
64 suprefact.ti,ab. (22)
65 tiloryth.ti,ab. (0)
66 histrelin.ti,ab. (55)
67 "LHRH-hydrogel implant".ti,ab. (1)
68 ("RL 0903" or RL0903).ti,ab. (1)
69 ("SPD 424" or SPD424).ti,ab. (1)
70 goserelin.ti,ab. (875)
71 Goserelin/ (1612)
72 ("ici 118630" or ici118630).ti,ab. (51)
73 ("ZD-9393" or ZD9393).ti,ab. (0)
74 zoladex.ti,ab. (379)
75 leuprorelin.ti,ab. (413)
76 carcinil.ti,ab. (0)
77 enanton*.ti,ab. (23)
78 ginecrin.ti,ab. (0)
79 leuplin.ti,ab. (13)
80 Leuprolide/ (2900)
81 leuprolide.ti,ab. (1743)
82 lucrin.ti,ab. (11)
83 lupron.ti,ab. (162)
84 provren.ti,ab. (0)
85 procrin.ti,ab. (3)
86 ("tap 144" or tap144).ti,ab. (40)
87 (a-43818 or a43818).ti,ab. (3)
88 Trenantone.ti,ab. (1)
89 staladex.ti,ab. (0)
90 prostap.ti,ab. (6)
91 Nafarelin/ (327)
92 nafarelin.ti,ab. (251)
93 ("76932-56-4" or "76932564").ti,ab. (0)
94 ("76932-60-0" or "76932600").ti,ab. (0)
95 ("86220-42-0" or "86220420").ti,ab. (0)
96 ("rs 94991 298" or rs94991298).ti,ab. (0)
97 synarel.ti,ab. (12)
98 deslorelin.ti,ab. (263)
99 gonadorelin.ti,ab. (201)
100 ("33515-09-2" or "33515092").ti,ab. (0)
101 ("51952-41-1" or "51952411").ti,ab. (0)
102 ("52699-48-6" or "52699486").ti,ab. (0)
103 cetrorelix.ti,ab. (463)
104 cetrotide.ti,ab. (41)
105 ("NS 75A" or NS75A).ti,ab. (0)
106 ("NS 75B" or NS75B).ti,ab. (0)

107 ("SB 075" or SB075).ti,ab. (0)
108 ("SB 75" or SB75).ti,ab. (63)
109 gonadoliberin.ti,ab. (143)
110 kryptocur.ti,ab. (6)
111 cetrorelix.ti,ab. (463)
112 cetrotide.ti,ab. (41)
113 antagon.ti,ab. (17)
114 ganirelix.ti,ab. (138)
115 ("ORG 37462" or ORG37462).ti,ab. (3)
116 orgalutran.ti,ab. (20)
117 ("RS 26306" or RS26306).ti,ab. (5)
118 ("AY 24031" or AY24031).ti,ab. (0)
119 factrel.ti,ab. (11)
120 fertagyl.ti,ab. (11)
121 lutrelef.ti,ab. (5)
122 lutrepulse.ti,ab. (3)
123 relefact.ti,ab. (10)
124 fertiral.ti,ab. (0)
125 (hoe471 or "hoe 471").ti,ab. (6)
126 relisorm.ti,ab. (4)
127 cystorelin.ti,ab. (18)
128 dirigestran.ti,ab. (5)
129 or/33-128 (42216)
130 32 and 129 (416)
131 limit 130 to english language (393)
132 limit 131 to (letter or historical article or comment or editorial or news or case reports) (36)
133 131 not 132 (357)
134 animals/ not humans/ (4686361)
135 133 not 134 (181)
136 limit 135 to yr="2000 -Current" (144)

Database: Medline in-process
Platform: Ovid
Version: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations <1946 to July 21, 2020>
Search date: 23/7/2020
Number of results retrieved:
Search strategy: 42

1 Gender Dysphoria/ (0)
2 Gender Identity/ (0)
3 "Sexual and Gender Disorders"/ (0)
4 Transsexualism/ (0)
5 Transgender Persons/ (0)
6 Health Services for Transgender Persons/ (0)
7 exp Sex Reassignment Procedures/ (0)

8 (gender* adj3 (dysphori* or affirm* or incongruen* or identi* or disorder* or confus* or minorit* or queer*)).tw. (1645)
9 (transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*).tw. (2333)
10 (trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*).tw. (20884)
11 ((sex or gender*) adj3 (reassign* or chang* or transform* or transition*)).tw. (968)
12 (male-to-female or m2f or female-to-male or f2m).tw. (15513)
13 or/1-12 (39905)
14 exp Infant/ or Infant Health/ or Infant Welfare/ (0)
15 (prematur* or pre-matur* or preterm* or pre-term* or infan* or newborn* or new-born* or perinat* or peri-nat* or neonat* or neo-nat* or baby* or babies or toddler*).ti,ab,in,jn. (80723)
16 exp Child/ or exp Child Behavior/ or Child Health/ or Child Welfare/ (0)
17 Minors/ (0)
18 (child* or minor or minors or boy* or girl* or kid or kids or young*).ti,ab,in,jn. (321871)
19 exp pediatrics/ (0)
20 (pediatric* or paediatric* or peadiatric*).ti,ab,in,jn. (119783)
21 Adolescent/ or Adolescent Behavior/ or Adolescent Health/ (0)
22 Puberty/ (0)
23 (adolescen* or pubescen* or prepubescen* or pre-pubescen* or pubert* or prepubert* or pre-pubert* or teen* or preteen* or pre-teen* or juvenil* or youth* or under*age*).ti,ab,in,jn. (60264)
24 Schools/ (0)
25 Child Day Care Centers/ or exp Nurseries/ or Schools, Nursery/ (0)
26 (pre-school* or preschool* or kindergar* or daycare or day-care or nurser* or school* or pupil* or student*).ti,ab,jn. (69233)
27 (("eight" or "nine" or "ten" or "eleven" or "twelve" or "thirteen" or "fourteen" or "fifteen" or "sixteen" or "seventeen" or "eighteen" or "nineteen") adj2 (year or years or age or ages or aged)).ti,ab. (10319)
28 (("8" or "9" or "10" or "11" or "12" or "13" or "14" or "15" or "16" or "17" or "18" or "19") adj2 (year or years or age or ages or aged)).ti,ab. (112800)
29 or/14-28 (525529)
30 13 and 29 (9196)
31 (transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*).tw. (3)
32 30 or 31 (9197)
33 Gonadotropin-Releasing Hormone/ (0)
34 (pubert* adj3 block*).ti,ab. (19)
35 ((gonadotrophin or gonadotropin) and releasing).ti,ab. (1425)
36 (GnRH adj2 analog*).ti,ab. (183)
37 GnRH*.ti,ab. (1695)
38 "GnRH agonist*".ti,ab. (379)
39 Triptorelin Pamoate/ (0)
40 triptorelin.ti,ab. (72)
41 arvekap.ti,ab. (0)
42 ("AY 25650" or AY25650).ti,ab. (0)
43 ("BIM 21003" or BIM21003).ti,ab. (0)
44 ("BN 52014" or BN52014).ti,ab. (0)
45 ("CL 118532" or CL118532).ti,ab. (0)

46 Debio.ti,ab. (11)
47 diphereline.ti,ab. (6)
48 moapar.ti,ab. (0)
49 pamorelin.ti,ab. (0)
50 trelstar.ti,ab. (0)
51 triptodur.ti,ab. (0)
52 ("WY 42422" or WY42422).ti,ab. (0)
53 ("WY 42462" or WY42462).ti,ab. (0)
54 gonapeptyl.ti,ab. (0)
55 decapeptyl.ti,ab. (8)
56 salvacyl.ti,ab. (0)
57 Buserelin/ (0)
58 buserelin.ti,ab. (59)
59 bigonist.ti,ab. (0)
60 ("hoe 766" or hoe-766 or hoe766).ti,ab. (3)
61 profact.ti,ab. (0)
62 receptal.ti,ab. (0)
63 suprecur.ti,ab. (1)
64 suprefact.ti,ab. (2)
65 tiloryth.ti,ab. (0)
66 histrelin.ti,ab. (9)
67 "LHRH-hydrogel implant".ti,ab. (0)
68 ("RL 0903" or RL0903).ti,ab. (0)
69 ("SPD 424" or SPD424).ti,ab. (0)
70 goserelin.ti,ab. (68)
71 Goserelin/ (0)
72 ("ici 118630" or ici118630).ti,ab. (0)
73 ("ZD-9393" or ZD9393).ti,ab. (0)
74 zoladex.ti,ab. (6)
75 leuprorelin.ti,ab. (47)
76 carcinil.ti,ab. (0)
77 enanton*.ti,ab. (1)
78 ginecrin.ti,ab. (0)
79 leuplin.ti,ab. (1)
80 Leuprolide/ (0)
81 leuprolide.ti,ab. (121)
82 lucrin.ti,ab. (4)
83 lupron.ti,ab. (10)
84 provren.ti,ab. (0)
85 procrin.ti,ab. (0)
86 ("tap 144" or tap144).ti,ab. (0)
87 (a-43818 or a43818).ti,ab. (0)
88 Trenantone.ti,ab. (1)
89 staladex.ti,ab. (0)
90 prostap.ti,ab. (0)
91 Nafarelin/ (0)
92 nafarelin.ti,ab. (5)
93 ("76932-56-4" or "76932564").ti,ab. (0)

94 ("76932-60-0" or "76932600").ti,ab. (0)
95 ("86220-42-0" or "86220420").ti,ab. (0)
96 ("rs 94991 298" or rs94991298).ti,ab. (0)
97 synarel.ti,ab. (0)
98 deslorelin.ti,ab. (14)
99 gonadorelin.ti,ab. (13)
100 ("33515-09-2" or "33515092").ti,ab. (0)
101 ("51952-41-1" or "51952411").ti,ab. (0)
102 ("52699-48-6" or "52699486").ti,ab. (0)
103 cetrorelix.ti,ab. (31)
104 cetrotide.ti,ab. (5)
105 ("NS 75A" or NS75A).ti,ab. (0)
106 ("NS 75B" or NS75B).ti,ab. (0)
107 ("SB 075" or SB075).ti,ab. (0)
108 ("SB 75" or SB75).ti,ab. (2)
109 gonadoliberin.ti,ab. (4)
110 kryptocur.ti,ab. (1)
111 cetrorelix.ti,ab. (31)
112 cetrotide.ti,ab. (5)
113 antagon.ti,ab. (0)
114 ganirelix.ti,ab. (8)
115 ("ORG 37462" or ORG37462).ti,ab. (0)
116 orgalutran.ti,ab. (3)
117 ("RS 26306" or RS26306).ti,ab. (0)
118 ("AY 24031" or AY24031).ti,ab. (0)
119 factrel.ti,ab. (2)
120 fertagyl.ti,ab. (1)
121 lutrelef.ti,ab. (0)
122 lutrepulse.ti,ab. (0)
123 relefact.ti,ab. (0)
124 fertiral.ti,ab. (0)
125 (hoe471 or "hoe 471").ti,ab. (0)
126 relisorm.ti,ab. (0)
127 cystorelin.ti,ab. (1)
128 dirigestran.ti,ab. (0)
129 or/33-128 (2332)
130 32 and 129 (45)
131 limit 130 to english language (45)
132 limit 131 to yr="2000 -Current" (42)

Database: Medline epubs ahead of print
Platform: Ovid
Version: Ovid MEDLINE(R) Epub Ahead of Print <July 21, 2020>
Search date: 23/7/2020
Number of results retrieved: 8
Search strategy:

1 Gender Dysphoria/ (0)

2 Gender Identity/ (0)
3 "Sexual and Gender Disorders"/ (0)
4 Transsexualism/ (0)
5 Transgender Persons/ (0)
6 Health Services for Transgender Persons/ (0)
7 exp Sex Reassignment Procedures/ (0)
8 (gender* adj3 (dysphori* or affirm* or incongruen* or identi* or disorder* or confus* or minorit* or queer*)).tw. (486)
9 (transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*).tw. (640)
10 (trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*).tw. (1505)
11 ((sex or gender*) adj3 (reassign* or chang* or transform* or transition*)).tw. (178)
12 (male-to-female or m2f or female-to-male or f2m).tw. (2480)
13 or/1-12 (4929)
14 exp Infant/ or Infant Health/ or Infant Welfare/ (0)
15 (prematur* or pre-matur* or preterm* or pre-term* or infan* or newborn* or new-born* or perinat* or peri-nat* or neonat* or neo-nat* or baby* or babies or toddler*).ti,ab,in,jn. (15496)
16 exp Child/ or exp Child Behavior/ or Child Health/ or Child Welfare/ (0)
17 Minors/ (0)
18 (child* or minor or minors or boy* or girl* or kid or kids or young*).ti,ab,in,jn. (53563)
19 exp pediatrics/ (0)
20 (pediatric* or paediatric* or peadiatric*).ti,ab,in,jn. (22796)
21 Adolescent/ or Adolescent Behavior/ or Adolescent Health/ (0)
22 Puberty/ (0)
23 (adolescen* or pubescen* or prepubescen* or pre-pubescen* or pubert* or prepubert* or pre-pubert* or teen* or preteen* or pre-teen* or juvenil* or youth* or under*age*).ti,ab,in,jn. (13087)
24 Schools/ (0)
25 Child Day Care Centers/ or exp Nurseries/ or Schools, Nursery/ (0)
26 (pre-school* or preschool* or kindergar* or daycare or day-care or nurser* or school* or pupil* or student*).ti,ab,jn. (12443)
27 (("eight" or "nine" or "ten" or "eleven" or "twelve" or "thirteen" or "fourteen" or "fifteen" or "sixteen" or "seventeen" or "eighteen" or "nineteen") adj2 (year or years or age or ages or aged)).ti,ab. (1416)
28 (("8" or "9" or "10" or "11" or "12" or "13" or "14" or "15" or "16" or "17" or "18" or "19") adj2 (year or years or age or ages or aged)).ti,ab. (20166)
29 or/14-28 (88366)
30 13 and 29 (1638)
31 (transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*).tw. (1)
32 30 or 31 (1638)
33 Gonadotropin-Releasing Hormone/ (0)
34 (pubert* adj3 block*).ti,ab. (2)
35 ((gonadotrophin or gonadotropin) and releasing).ti,ab. (176)
36 (GnRH adj2 analog*).ti,ab. (30)
37 GnRH*.ti,ab. (223)
38 "GnRH agonist*".ti,ab. (49)
39 Triptorelin Pamoate/ (0)

40 triptorelin.ti,ab. (12)
41 arvekap.ti,ab. (0)
42 ("AY 25650" or AY25650).ti,ab. (0)
43 ("BIM 21003" or BIM21003).ti,ab. (0)
44 ("BN 52014" or BN52014).ti,ab. (0)
45 ("CL 118532" or CL118532).ti,ab. (0)
46 Debio.ti,ab. (2)
47 diphereline.ti,ab. (1)
48 moapar.ti,ab. (0)
49 pamorelin.ti,ab. (0)
50 trelstar.ti,ab. (0)
51 triptodur.ti,ab. (0)
52 ("WY 42422" or WY42422).ti,ab. (0)
53 ("WY 42462" or WY42462).ti,ab. (0)
54 gonapeptyl.ti,ab. (0)
55 decapeptyl.ti,ab. (0)
56 salvacyl.ti,ab. (0)
57 Buserelin/ (0)
58 buserelin.ti,ab. (7)
59 bigonist.ti,ab. (0)
60 ("hoe 766" or hoe-766 or hoe766).ti,ab. (0)
61 profact.ti,ab. (0)
62 receptal.ti,ab. (0)
63 suprecur.ti,ab. (0)
64 suprefact.ti,ab. (1)
65 tiloryth.ti,ab. (0)
66 histrelin.ti,ab. (2)
67 "LHRH-hydrogel implant".ti,ab. (0)
68 ("RL 0903" or RL0903).ti,ab. (0)
69 ("SPD 424" or SPD424).ti,ab. (0)
70 goserelin.ti,ab. (11)
71 Goserelin/ (0)
72 ("ici 118630" or ici118630).ti,ab. (0)
73 ("ZD-9393" or ZD9393).ti,ab. (0)
74 zoladex.ti,ab. (1)
75 leuprorelin.ti,ab. (13)
76 carcinil.ti,ab. (0)
77 enanton*.ti,ab. (1)
78 ginecrin.ti,ab. (0)
79 leuplin.ti,ab. (0)
80 Leuprolide/ (0)
81 leuprolide.ti,ab. (22)
82 lucrin.ti,ab. (0)
83 lupron.ti,ab. (2)
84 provren.ti,ab. (0)
85 procrin.ti,ab. (0)
86 ("tap 144" or tap144).ti,ab. (1)
87 (a-43818 or a43818).ti,ab. (0)

88 Trenantone.ti,ab. (0)
89 staladex.ti,ab. (0)
90 prostap.ti,ab. (0)
91 Nafarelin/ (0)
92 nafarelin.ti,ab. (4)
93 ("76932-56-4" or "76932564").ti,ab. (0)
94 ("76932-60-0" or "76932600").ti,ab. (0)
95 ("86220-42-0" or "86220420").ti,ab. (0)
96 ("rs 94991 298" or rs94991298).ti,ab. (0)
97 synarel.ti,ab. (0)
98 deslorelin.ti,ab. (3)
99 gonadorelin.ti,ab. (3)
100 ("33515-09-2" or "33515092").ti,ab. (0)
101 ("51952-41-1" or "51952411").ti,ab. (0)
102 ("52699-48-6" or "52699486").ti,ab. (0)
103 cetrorelix.ti,ab. (6)
104 cetrotide.ti,ab. (2)
105 ("NS 75A" or NS75A).ti,ab. (0)
106 ("NS 75B" or NS75B).ti,ab. (0)
107 ("SB 075" or SB075).ti,ab. (0)
108 ("SB 75" or SB75).ti,ab. (0)
109 gonadoliberin.ti,ab. (0)
110 kryptocur.ti,ab. (0)
111 cetrorelix.ti,ab. (6)
112 cetrotide.ti,ab. (2)
113 antagon.ti,ab. (1)
114 ganirelix.ti,ab. (1)
115 ("ORG 37462" or ORG37462).ti,ab. (0)
116 orgalutran.ti,ab. (0)
117 ("RS 26306" or RS26306).ti,ab. (0)
118 ("AY 24031" or AY24031).ti,ab. (0)
119 factrel.ti,ab. (0)
120 fertagyl.ti,ab. (0)
121 lutrelef.ti,ab. (0)
122 lutrepulse.ti,ab. (0)
123 relefact.ti,ab. (0)
124 fertiral.ti,ab. (0)
125 (hoe471 or "hoe 471").ti,ab. (0)
126 relisorm.ti,ab. (0)
127 cystorelin.ti,ab. (0)
128 dirigestran.ti,ab. (0)
129 or/33-128 (310)
130 32 and 129 (8)
131 limit 130 to english language (8)
132 limit 131 to yr="2000 -Current" (8)

Database: Medline daily update
Platform: Ovid

Version: Ovid MEDLINE(R) Daily Update <July 21, 2020>
Search date: 23/7/2020
Number of results retrieved: 1
Search strategy

1 Gender Dysphoria/ (4)
2 Gender Identity/ (38)
3 "Sexual and Gender Disorders"/ (0)
4 Transsexualism/ (2)
5 Transgender Persons/ (26)
6 Health Services for Transgender Persons/ (1)
7 exp Sex Reassignment Procedures/ (3)
8 (gender* adj3 (dysphori* or affirm* or incongruen* or identi* or disorder* or confus* or minorit* or queer*)).tw. (24)
9 (transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*).tw. (39)
10 (trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*).tw. (87)
11 ((sex or gender*) adj3 (reassign* or chang* or transform* or transition*)).tw. (15)
12 (male-to-female or m2f or female-to-male or f2m).tw. (181)
13 or/1-12 (358)
14 exp Infant/ or Infant Health/ or Infant Welfare/ (932)
15 (prematur* or pre-matur* or preterm* or pre-term* or infan* or newborn* or new-born* or perinat* or peri-nat* or neonat* or neo-nat* or baby* or babies or toddler*).ti,ab,in,jn. (981)
16 exp Child/ or exp Child Behavior/ or Child Health/ or Child Welfare/ (1756)
17 Minors/ (3)
18 (child* or minor or minors or boy* or girl* or kid or kids or young*).ti,ab,in,jn. (3672)
19 exp pediatrics/ (75)
20 (pediatric* or paediatric* or peadiatric*).ti,ab,in,jn. (1658)
21 Adolescent/ or Adolescent Behavior/ or Adolescent Health/ (2006)
22 Puberty/ (8)
23 (adolescen* or pubescen* or prepubescen* or pre-pubescen* or pubert* or prepubert* or pre-pubert* or teen* or preteen* or pre-teen* or juvenil* or youth* or under*age*).ti,ab,in,jn. (732)
24 Schools/ (56)
25 Child Day Care Centers/ or exp Nurseries/ or Schools, Nursery/ (5)
26 (pre-school* or preschool* or kindergar* or daycare or day-care or nurser* or school* or pupil* or student*).ti,ab,jn. (622)
27 (("eight" or "nine" or "ten" or "eleven" or "twelve" or "thirteen" or "fourteen" or "fifteen" or "sixteen" or "seventeen" or "eighteen" or "nineteen") adj2 (year or years or age or ages or aged)).ti,ab. (98)
28 (("8" or "9" or "10" or "11" or "12" or "13" or "14" or "15" or "16" or "17" or "18" or "19") adj2 (year or years or age or ages or aged)).ti,ab. (1301)
29 or/14-28 (6705)
30 13 and 29 (130)
31 (transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*).tw. (0)
32 30 or 31 (130)
33 Gonadotropin-Releasing Hormone/ (11)

34 (pubert* adj3 block*).ti,ab. (0)
35 ((gonadotrophin or gonadotropin) and releasing).ti,ab. (10)
36 (GnRH adj2 analog*).ti,ab. (2)
37 GnRH*.ti,ab. (14)
38 "GnRH agonist*".ti,ab. (4)
39 Triptorelin Pamoate/ (1)
40 triptorelin.ti,ab. (1)
41 arvekap.ti,ab. (0)
42 ("AY 25650" or AY25650).ti,ab. (0)
43 ("BIM 21003" or BIM21003).ti,ab. (0)
44 ("BN 52014" or BN52014).ti,ab. (0)
45 ("CL 118532" or CL118532).ti,ab. (0)
46 Debio.ti,ab. (1)
47 diphereline.ti,ab. (0)
48 moapar.ti,ab. (0)
49 pamorelin.ti,ab. (0)
50 trelstar.ti,ab. (0)
51 triptodur.ti,ab. (0)
52 ("WY 42422" or WY42422).ti,ab. (0)
53 ("WY 42462" or WY42462).ti,ab. (0)
54 gonapeptyl.ti,ab. (0)
55 decapeptyl.ti,ab. (0)
56 salvacyl.ti,ab. (0)
57 Buserelin/ (0)
58 buserelin.ti,ab. (0)
59 bigonist.ti,ab. (0)
60 ("hoe 766" or hoe-766 or hoe766).ti,ab. (0)
61 profact.ti,ab. (0)
62 receptal.ti,ab. (0)
63 suprecur.ti,ab. (0)
64 suprefact.ti,ab. (0)
65 tiloryth.ti,ab. (0)
66 histrelin.ti,ab. (0)
67 "LHRH-hydrogel implant".ti,ab. (0)
68 ("RL 0903" or RL0903).ti,ab. (0)
69 ("SPD 424" or SPD424).ti,ab. (0)
70 goserelin.ti,ab. (1)
71 Goserelin/ (2)
72 ("ici 118630" or ici118630).ti,ab. (0)
73 ("ZD-9393" or ZD9393).ti,ab. (0)
74 zoladex.ti,ab. (0)
75 leuprorelin.ti,ab. (0)
76 carcinil.ti,ab. (0)
77 enanton*.ti,ab. (0)
78 ginecrin.ti,ab. (0)
79 leuplin.ti,ab. (0)
80 Leuprolide/ (0)
81 leuprolide.ti,ab. (0)

82 lucrin.ti,ab. (0)
83 lupron.ti,ab. (0)
84 provren.ti,ab. (0)
85 procrin.ti,ab. (0)
86 ("tap 144" or tap144).ti,ab. (0)
87 (a-43818 or a43818).ti,ab. (0)
88 Trenantone.ti,ab. (0)
89 staladex.ti,ab. (0)
90 prostap.ti,ab. (0)
91 Nafarelin/ (0)
92 nafarelin.ti,ab. (0)
93 ("76932-56-4" or "76932564").ti,ab. (0)
94 ("76932-60-0" or "76932600").ti,ab. (0)
95 ("86220-42-0" or "86220420").ti,ab. (0)
96 ("rs 94991 298" or rs94991298).ti,ab. (0)
97 synarel.ti,ab. (0)
98 deslorelin.ti,ab. (0)
99 gonadorelin.ti,ab. (0)
100 ("33515-09-2" or "33515092").ti,ab. (0)
101 ("51952-41-1" or "51952411").ti,ab. (0)
102 ("52699-48-6" or "52699486").ti,ab. (0)
103 cetrorelix.ti,ab. (0)
104 cetrotide.ti,ab. (0)
105 ("NS 75A" or NS75A).ti,ab. (0)
106 ("NS 75B" or NS75B).ti,ab. (0)
107 ("SB 075" or SB075).ti,ab. (0)
108 ("SB 75" or SB75).ti,ab. (0)
109 gonadoliberin.ti,ab. (0)
110 kryptocur.ti,ab. (0)
111 cetrorelix.ti,ab. (0)
112 cetrotide.ti,ab. (0)
113 antagon.ti,ab. (0)
114 ganirelix.ti,ab. (0)
115 ("ORG 37462" or ORG37462).ti,ab. (0)
116 orgalutran.ti,ab. (0)
117 ("RS 26306" or RS26306).ti,ab. (0)
118 ("AY 24031" or AY24031).ti,ab. (0)
119 factrel.ti,ab. (0)
120 fertagyl.ti,ab. (0)
121 lutrelef.ti,ab. (0)
122 lutrepulse.ti,ab. (0)
123 relefact.ti,ab. (0)
124 fertiral.ti,ab. (0)
125 (hoe471 or "hoe 471").ti,ab. (0)
126 relisorm.ti,ab. (0)
127 cystorelin.ti,ab. (0)
128 dirigestran.ti,ab. (0)
129 or/33-128 (23)

130 32 and 129 (1)
131 limit 130 to english language (1)
132 limit 131 to yr="2000 -Current" (1)

Database: Embase
Platform: Ovid
Version: Embase <1974 to 2020 July 22>
Search date: 23/7/2020
Number of results retrieved: 367
Search strategy:

1 exp Gender Dysphoria/ (5399)
2 Gender Identity/ (16820)
3 "Sexual and Gender Disorders"/ (24689)
4 Transsexualism/ (3869)
5 exp Transgender/ (6597)
6 Health Services for Transgender Persons/ (158848)
7 exp Sex Reassignment Procedures/ or sex transformation/ (3058)
8 (gender* adj3 (dysphori* or affirm* or incongru* or identi* or disorder* or confus* or minorit* or queer*)).tw. (13005)
9 (transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*).tw. (22509)
10 (trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*).tw. (154446)
11 ((sex or gender*) adj3 (reassign* or chang* or transform* or transition*)).tw. (10327)
12 (male-to-female or m2f or female-to-male or f2m).tw. (200166)
13 or/1-12 (582812)
14 exp juvenile/ or Child Behavior/ or Child Welfare/ or Child Health/ or infant welfare/ or "minor (person)"/ or elementary student/ (3437324)
15 (prematur* or pre-matur* or preterm* or pre-term* or infan* or newborn* or new-born* or perinat* or peri-nat* or neonat* or neo-nat* or baby* or babies or toddler*).ti,ab,in,jn. (1186161)
16 (child* or minor or minors or boy* or girl* or kid or kids or young*).ti,ab,in,jn. (3586795)
17 exp pediatrics/ (106214)
18 (pediatric* or paediatric* or peadiatric*).ti,ab,in,jn. (1491597)
19 exp adolescence/ or exp adolescent behavior/ or adolescent health/ or high school student/ or middle school student/ (105108)
20 (adolescen* or pubescen* or prepubescen* or pre-pubescen* or pubert* or prepubert* or pre-pubert* or teen* or preteen* or pre-teen* or juvenil* or youth* or under*age*).ti,ab,in,jn. (641660)
21 school/ or high school/ or kindergarten/ or middle school/ or primary school/ or nursery school/ or day care/ (103791)
22 (pre-school* or preschool* or kindergar* or daycare or day-care or nurser* or school* or pupil* or student*).ti,ab,jn. (687437)
23 (("eight" or "nine" or "ten" or "eleven" or "twelve" or "thirteen" or "fourteen" or "fifteen" or "sixteen" or "seventeen" or "eighteen" or "nineteen") adj2 (year or years or age or ages or aged)).ti,ab. (138908)
24 (("8" or "9" or "10" or "11" or "12" or "13" or "14" or "15" or "16" or "17" or "18" or "19") adj2 (year or years or age or ages or aged)).ti,ab. (1562903)

25 or/14-24 (7130881)
26 13 and 25 (182161)
27 (transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*).tw.
(17)
28 26 or 27 (182161)
29 gonadorelin/ (37580)
30 (pubert* adj3 block*).ti,ab. (142)
31 ((gonadotrophin or gonadotropin) and releasing).ti,ab. (21450)
32 (GnRH adj2 analog*).ti,ab. (4013)
33 GnRH*.ti,ab. (29862)
34 "GnRH agonist*".ti,ab. (6719)
35 exp gonadorelin agonist/ or gonadorelin derivative/ or gonadorelin acetate/ (23304)
36 Triptorelin/ (5427)
37 triptorelin.ti,ab. (1182)
38 arvekap.ti,ab. (3)
39 ("AY 25650" or AY25650).ti,ab. (1)
40 ("BIM 21003" or BIM21003).ti,ab. (0)
41 ("BN 52014" or BN52014).ti,ab. (0)
42 ("CL 118532" or CL118532).ti,ab. (0)
43 Debio.ti,ab. (185)
44 diphereline.ti,ab. (51)
45 moapar.ti,ab. (0)
46 pamorelin.ti,ab. (0)
47 trelstar.ti,ab. (5)
48 triptodur.ti,ab. (1)
49 ("WY 42422" or WY42422).ti,ab. (0)
50 ("WY 42462" or WY42462).ti,ab. (0)
51 gonapeptyl.ti,ab. (10)
52 decapeptyl.ti,ab. (307)
53 salvacyl.ti,ab. (1)
54 buserelin acetate/ or buserelin/ (5164)
55 buserelin.ti,ab. (1604)
56 bigonist.ti,ab. (1)
57 ("hoe 766" or hoe-766 or hoe766).ti,ab. (89)
58 profact.ti,ab. (4)
59 receptal.ti,ab. (37)
60 suprecur.ti,ab. (8)
61 suprefact.ti,ab. (30)
62 tiloryth.ti,ab. (0)
63 histrelin/ (446)
64 histrelin.ti,ab. (107)
65 "LHRH-hydrogel implant".ti,ab. (1)
66 ("RL 0903" or RL0903).ti,ab. (1)
67 ("SPD 424" or SPD424).ti,ab. (1)
68 goserelin.ti,ab. (1487)
69 Goserelin/ (7128)
70 ("ici 118630" or ici118630).ti,ab. (49)
71 ("ZD-9393" or ZD9393).ti,ab. (0)

72 zoladex.ti,ab. (501)
73 leuprorelin/ (11312)
74 leuprorelin.ti,ab. (727)
75 carcinil.ti,ab. (0)
76 enanton*.ti,ab. (38)
77 ginecrin.ti,ab. (1)
78 leuplin.ti,ab. (26)
79 leuprolide.ti,ab. (2788)
80 lucrin.ti,ab. (47)
81 lupron.ti,ab. (361)
82 provren.ti,ab. (0)
83 procrin.ti,ab. (11)
84 ("tap 144" or tap144).ti,ab. (63)
85 (a-43818 or a43818).ti,ab. (3)
86 Trenantone.ti,ab. (7)
87 staladex.ti,ab. (0)
88 prostap.ti,ab. (11)
89 nafarelin acetate/ or nafarelin/ (1441)
90 nafarelin.ti,ab. (324)
91 ("76932-56-4" or "76932564").ti,ab. (0)
92 ("76932-60-0" or "76932600").ti,ab. (0)
93 ("86220-42-0" or "86220420").ti,ab. (0)
94 ("rs 94991 298" or rs94991298).ti,ab. (0)
95 synarel.ti,ab. (28)
96 deslorelin/ (452)
97 deslorelin.ti,ab. (324)
98 gonadorelin.ti,ab. (338)
99 ("33515-09-2" or "33515092").ti,ab. (0)
100 ("51952-41-1" or "51952411").ti,ab. (0)
101 ("52699-48-6" or "52699486").ti,ab. (0)
102 cetrorelix/ (2278)
103 cetrorelix.ti,ab. (717)
104 cetrotide.ti,ab. (113)
105 ("NS 75A" or NS75A).ti,ab. (0)
106 ("NS 75B" or NS75B).ti,ab. (0)
107 ("SB 075" or SB075).ti,ab. (1)
108 ("SB 75" or SB75).ti,ab. (76)
109 gonadoliberin.ti,ab. (152)
110 kryptocur.ti,ab. (6)
111 cetrorelix.ti,ab. (717)
112 cetrotide.ti,ab. (113)
113 antagon.ti,ab. (32)
114 ganirelix/ (1284)
115 ganirelix.ti,ab. (293)
116 ("ORG 37462" or ORG37462).ti,ab. (4)
117 orgalutran/ (1284)
118 orgalutran.ti,ab. (68)
119 ("RS 26306" or RS26306).ti,ab. (6)

120 ("AY 24031" or AY24031).ti,ab. (0)
121 factrel.ti,ab. (14)
122 fertagyl.ti,ab. (20)
123 lutrelef.ti,ab. (7)
124 lutrepulse.ti,ab. (6)
125 relefact.ti,ab. (10)
126 fertiral.ti,ab. (0)
127 (hoe471 or "hoe 471").ti,ab. (4)
128 relisorm.ti,ab. (6)
129 cystorelin.ti,ab. (26)
130 dirigestran.ti,ab. (5)
131 or/29-130 (80790)
132 28 and 131 (988)
133 limit 132 to english language (940)
134 133 not (letter or editorial).pt. (924)
135 134 not (conference abstract or conference paper or conference proceeding or "conference review").pt. (683)
136 nonhuman/ not (human/ and nonhuman/) (4649157)
137 135 not 136 (506)
138 limit 137 to yr="2000 -Current" (420)
139 elsevier.cr. (25912990)
140 138 and 139 (372)
141 remove duplicates from 140 (367)

Database: Cochrane Library – incorporating Cochrane Database of Systematic Reviews (CDSR); CENTRAL
Platform: Wiley
Version:
CDSR – Issue 7 of 12, July 2020
CENTRAL – Issue 7 of 12, July 2020
Search date: 23/7/2020
Number of results retrieved: CDSR – 1; CENTRAL - 8.

#1 [mh ^"Gender Dysphoria"] 3
#2 [mh ^"gender identity"] 227
#3 [mh ^"sexual and gender disorders"] 2
#4 [mh ^transsexualism] 27
#5 [mh ^"transgender persons"] 36
#6 [mh ^"health services for transgender persons"] 0
#7 [mh "sex reassignment procedures"] 4
#8 (gender* NEAR/3 (dysphori* or affirm* or incongruen* or identi* or disorder* or confus* or minorit* or queer*)):ti,ab 308
#9 (transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*):ti,ab 929
#10 (trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*):ti,ab 3915
#11 ((sex or gender*) NEAR/3 (reassign* or chang* or transform* or transition*)):ti,ab 493
#12 (male-to-female or m2f or female-to-male or f2m):ti,ab 489

#13 {or #1-#12} 6142
#14 [mh infant] or [mh ^"infant health"] or [mh ^"infant welfare"] 27769
#15 (prematur* or pre-matur* or preterm* or pre-term* or infan* or newborn* or new-born* or perinat* or peri-nat* or neonat* or neo-nat* or baby* or babies or toddler*):ti,ab 69476
#16 [mh child] or [mh "child behavior"] or [mh ^"child health"] or [mh ^"child welfare"] 42703
#17 [mh ^minors] 8
#18 (child* or minor or minors or boy* or girl* or kid or kids or young*):ti,ab 175826
#19 [mh pediatrics]661
#20 (pediatric* or paediatric* or peadiatric*):ti,ab 30663
#21 [mh ^adolescent] or [mh ^"adolescent behavior"] or [mh ^"adolescent health"] 102154
#22 [mh ^puberty] 295
#23 (adolescen* or pubescen* or prepubescen* or pre-pubescen* or pubert* or prepubert* or pre-pubert* or teen* or preteen* or pre-teen* or juvenil* or youth* or under*age*):ti,ab 34139
#24 [mh ^schools] 1914
#25 [mh ^"Child Day Care Centers"] or [mh nurseries] or [mh ^"schools, nursery"] 277
#26 (pre-school* or preschool* or kindergar* or daycare or day-care or nurser* or school* or pupil* or student*):ti,ab 54723
#27 (("eight" or "nine" or "ten" or "eleven" or "twelve" or "thirteen" or "fourteen" or "fifteen" or "sixteen" or "seventeen" or "eighteen" or "nineteen") NEAR/2 (year or years or age or ages or aged)):ti,ab 6710
#28 (("8" or "9" or "10" or "11" or "12" or "13" or "14" or "15" or "16" or "17" or "18" or "19") NEAR/2 (year or years or age or ages or aged)):ti,ab 196881
#29 {or #14-#28} 469351
#30 #13 and #29 2146
#31 (transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*):ti,ab 0
#32 #30 or #31 2146
#33 [mh ^"Gonadotropin-Releasing Hormone"] 1311
#34 (pubert* NEAR/3 block*):ti,ab 1
#35 ((gonadotrophin or gonadotropin) and releasing):ti,ab 2095
#36 (GnRH NEAR/2 analog*):ti,ab 493
#37 GnRH*:ti,ab 3764
#38 "GnRH agonist*":ti,ab 1399
#39 [mh ^"Triptorelin Pamoate"] 451
#40 triptorelin:ti,ab 451
#41 arvekap:ti,ab 4
#42 ("AY 25650" or AY25650):ti,ab 0
#43 ("BIM 21003" or BIM21003):ti,ab 0
#44 ("BN 52014" or BN52014):ti,ab 0
#45 ("CL 118532" or CL118532):ti,ab 0
#46 Debio:ti,ab 301
#47 diphereline:ti,ab 25
#48 moapar:ti,ab 0
#49 pamorelin:ti,ab 5
#50 trelstar:ti,ab 3

#51 triptodur:ti,ab 0
#52 ("WY 42422" or WY42422):ti,ab 0
#53 ("WY 42462" or WY42462):ti,ab 0
#54 gonapeptyl:ti,ab 11
#55 decapeptyl:ti,ab 135
#56 salvacyl:ti,ab 0
#57 [mh ^Buserelin] 290
#58 Buserelin:ti,ab 339
#59 bigonist:ti,ab 0
#60 ("hoe 766" or hoe-766 or hoe766):ti,ab 11
#61 profact:ti,ab 1
#62 receptal:ti,ab 4
#63 suprecur:ti,ab 0
#64 suprefact:ti,ab 28
#65 tiloryth:ti,ab 0
#66 histrelin:ti,ab 5
#67 "LHRH-hydrogel implant":ti,ab 0
#68 ("RL 0903" or RL0903):ti,ab 0
#69 ("SPD 424" or SPD424):ti,ab 0
#70 goserelin:ti,ab 761
#71 [mh ^goserelin] 568
#72 ("ici 118630" or ici118630):ti,ab 7
#73 ("ZD-9393" or ZD9393):ti,ab 1
#74 zoladex:ti,ab 318
#75 leuprorelin:ti,ab 248
#76 carcinil:ti,ab 0
#77 enanton*:ti,ab 21
#78 ginecrin:ti,ab 1
#79 leuplin:ti,ab 7
#80 [mh ^Leuprolide] 686
#81 leuprolide:ti,ab696
#82 lucrin:ti,ab 21
#83 lupron:ti,ab 77
#84 provren:ti,ab 0
#85 procrin:ti,ab 2
#86 ("tap 144" or tap144):ti,ab 24
#87 (a-43818 or a43818):ti,ab 0
#88 Trenantone:ti,ab 3
#89 staladex:ti,ab 0
#90 prostap:ti,ab 9
#91 [mh ^Nafarelin] 77
#92 nafarelin:ti,ab 114
#93 ("76932-56-4" or "76932564"):ti,ab 0
#94 ("76932-60-0" or "76932600"):ti,ab 2
#95 ("86220-42-0" or "86220420"):ti,ab 0
#96 ("rs 94991 298" or rs94991298):ti,ab 0
#97 synarel:ti,ab 10
#98 deslorelin:ti,ab16

#99 gonadorelin:ti,ab 11
#100 ("33515-09-2" or "33515092"):ti,ab 0
#101 ("51952-41-1" or "51952411"):ti,ab 0
#102 ("52699-48-6" or "52699486"):ti,ab 0
#103 cetrorelix:ti,ab 221
#104 cetrotide:ti,ab 111
#105 ("NS 75A" or NS75A):ti,ab 0
#106 ("NS 75B" or NS75B):ti,ab 0
#107 ("SB 075" or SB075):ti,ab 0
#108 ("SB 75" or SB75):ti,ab 10
#109 gonadoliberin:ti,ab 5
#110 kryptocur:ti,ab 0
#111 cetrorelix:ti,ab 221
#112 cetrotide:ti,ab 111
#113 antagon:ti,ab 12
#114 ganirelix:ti,ab 142
#115 ("ORG 37462" or ORG37462):ti,ab 4
#116 orgalutran:ti,ab 45
#117 ("RS 26306" or RS26306):ti,ab 0
#118 ("AY 24031" or AY24031):ti,ab 0
#119 factrel:ti,ab 1
#120 fertagyl:ti,ab 0
#121 lutrelef:ti,ab 0
#122 lutrepulse:ti,ab 1
#123 relefact:ti,ab 1
#124 fertiral:ti,ab 0
#125 (hoe471 or "hoe 471"):ti,ab 3
#126 relisorm:ti,ab 0
#127 cystorelin:ti,ab 0
#128 dirigestran:ti,ab 0
#129 {or #33-#128} 6844
#130 #32 and #129 27
#131 #130 with Cochrane Library publication date Between Jan 2000 and Jul 2020, in Cochrane Reviews 1
#132 #130 27
#133 "conference":pt or (clinicaltrials or trialsearch):so 492465
#134 #132 not #133 9
#135 #134 with Publication Year from 2000 to 2020, in Trials 8

Database: HTA
Platform: CRD
Version: HTA
Search date: 23/7/2020
Number of results retrieved: 26
Search strategy:

1 MeSH DESCRIPTOR Gender Dysphoria EXPLODE ALL TREES 0
2 MeSH DESCRIPTOR Gender Identity EXPLODE ALL TREES 14

3 MeSH DESCRIPTOR Sexual and Gender Disorders EXPLODE ALL TREES 2

4 MeSH DESCRIPTOR Transsexualism EXPLODE ALL TREES 12
5 MeSH DESCRIPTOR Transgender Persons EXPLODE ALL TREES 3
6 MeSH DESCRIPTOR Health Services for Transgender Persons EXPLODE ALL TREES 0
7 MeSH DESCRIPTOR Sex Reassignment Procedures EXPLODE ALL TREES 1

8 ((gender* adj3 (dysphori* or affirm* or incongruen* or identi* or disorder* or confus* or minorit* or queer*))) 28
9 ((transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*)) 76
10 ((trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*)) 83
11 (((sex or gender*) adj3 (reassign* or chang* or transform* or transition*))) 24
12 (male-to-female or m2f or female-to-male or f2m) 86
13 ((transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*)) 0
14 #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 262
15 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13) IN HTA 30

*26 results are from 200 onwards. Downloaded as a set to sift for drug terms rather than continuing with search strategy.

Database: APA PsycInfo
Search date: July 2020 (Week 2)
Search Strategy:
---
1 Gender Dysphoria/ (936)
2 Gender Identity/ (8648)
3 Transsexualism/ (2825)
4 Transgender/ (5257)
5 exp Gender Reassignment/ (568)
6 (gender* adj3 (dysphori* or affirm* or incongruen* or identi* or disorder* or confus* or minorit* or queer*)).tw. (15471)
7 (transgend* or transex* or transsex* or transfem* or transwom* or transma* or transmen* or transperson* or transpeopl*).tw. (13028)
8 (trans or crossgender* or cross-gender* or crossex* or cross-sex* or genderqueer*).tw. (7679)
9 ((sex or gender*) adj3 (reassign* or chang* or transform* or transition*)).tw. (5796)
10 (male-to-female or m2f or female-to-male or f2m).tw. (63688)
11 or/1-10 (99560)
12 exp Infant Development/ (21841)
13 (prematur* or pre-matur* or preterm* or pre-term* or infan* or newborn* or new-born* or perinat* or peri-nat* or neonat* or neo-nat* or baby* or babies or toddler*).ti,ab,in,jn. (150219)

14 Child Characteristics/ or exp Child Behavior/ or Child Psychology/ or exp Child Welfare/ or Child Psychiatry/ (23423)
15 (child* or minor or minors or boy* or girl* or kid or kids or young*).ti,ab,in,jn. (984230)
16 (pediatric* or paediatric* or peadiatric*).ti,ab,in,jn. (78962)
17 Adolescent Psychiatry/ or Adolescent Behavior/ or Adolescent Development/ or Adolescent Psychology/ or Adolescent Characteristics/ or Adolescent Health/ (62142)
18 Puberty/ (2753)
19 (adolescen* or pubescen* or prepubescen* or pre-pubescen* or pubert* or prepubert* or pre-pubert* or teen* or preteen* or pre-teen* or juvenil* or youth* or under*age*).ti,ab,in,jn. (347604)
20 Schools/ or exp elementary school students/ or high school students/ or junior high school students/ or middle school students/ (113053)
21 Child Day Care/ or Nursery Schools/ (2836)
22 (pre-school* or preschool* or kindergar* or daycare or day-care or nurser* or school* or pupil* or student*).ti,ab,jn. (772814)
23 (("eight" or "nine" or "ten" or "eleven" or "twelve" or "thirteen" or "fourteen" or "fifteen" or "sixteen" or "seventeen" or "eighteen" or "nineteen") adj2 (year or years or age or ages or aged)).ti,ab. (21475)
24 (("8" or "9" or "10" or "11" or "12" or "13" or "14" or "15" or "16" or "17" or "18" or "19") adj2 (year or years or age or ages or aged)).ti,ab. (285697)
25 or/12-24 (1772959)
26 11 and 25 (49612)
27 (transchild* or transyouth* or transteen* or transadoles* or transgirl* or transboy*).tw. (14)
28 26 or 27 (49613)
29 exp Gonadotropic Hormones/ (4226)
30 (pubert* adj3 block*).ti,ab. (29)
31 ((gonadotrophin or gonadotropin) and releasing).ti,ab. (1060)
32 (GnRH adj2 analog*).ti,ab. (49)
33 GnRH*.ti,ab. (998)
34 "GnRH agonist*".ti,ab. (72)
35 triptorelin.ti,ab. (25)
36 arvekap.ti,ab. (0)
37 ("AY 25650" or AY25650).ti,ab. (0)
38 ("BIM 21003" or BIM21003).ti,ab. (0)
39 ("BN 52014" or BN52014).ti,ab. (0)
40 ("CL 118532" or CL118532).ti,ab. (0)
41 Debio.ti,ab. (7)
42 diphereline.ti,ab. (0)
43 moapar.ti,ab. (0)
44 pamorelin.ti,ab. (0)
45 trelstar.ti,ab. (0)
46 triptodur.ti,ab. (0)
47 ("WY 42422" or WY42422).ti,ab. (0)
48 ("WY 42462" or WY42462).ti,ab. (0)
49 gonapeptyl.ti,ab. (0)
50 decapeptyl.ti,ab. (3)
51 salvacyl.ti,ab. (1)

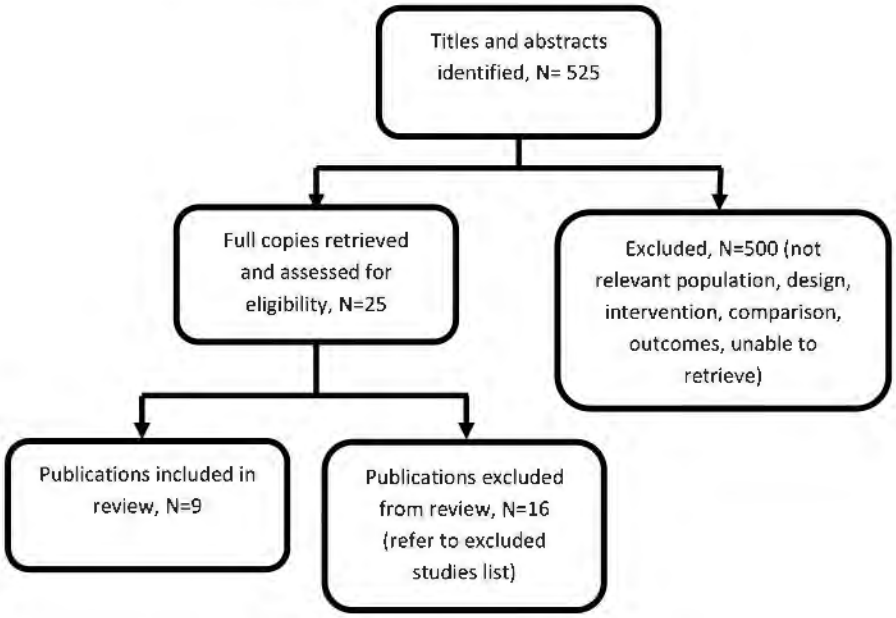
52 buserelin.ti,ab. (6)
53 bigonist.ti,ab. (0)
54 ("hoe 766" or hoe-766 or hoe766).ti,ab. (0)
55 profact.ti,ab. (0)
56 receptal.ti,ab. (0)
57 suprecur.ti,ab. (0)
58 suprefact.ti,ab. (0)
59 tiloryth.ti,ab. (0)
60 histrelin.ti,ab. (1)
61 "LHRH-hydrogel implant".ti,ab. (0)
62 ("RL 0903" or RL0903).ti,ab. (0)
63 ("SPD 424" or SPD424).ti,ab. (0)
64 goserelin.ti,ab. (30)
65 ("ici 118630" or ici118630).ti,ab. (0)
66 ("ZD-9393" or ZD9393).ti,ab. (0)
67 zoladex.ti,ab. (3)
68 leuprorelin.ti,ab. (12)
69 carcinil.ti,ab. (0)
70 enanton*.ti,ab. (1)
71 ginecrin.ti,ab. (0)
72 leuplin.ti,ab. (0)
73 leuprolide.ti,ab. (79)
74 lucrin.ti,ab. (1)
75 lupron.ti,ab. (18)
76 provren.ti,ab. (0)
77 procrin.ti,ab. (0)
78 ("tap 144" or tap144).ti,ab. (1)
79 (a-43818 or a43818).ti,ab. (0)
80 Trenantone.ti,ab. (0)
81 staladex.ti,ab. (0)
82 prostap.ti,ab. (0)
83 nafarelin.ti,ab. (1)
84 ("76932-56-4" or "76932564").ti,ab. (0)
85 ("76932-60-0" or "76932600").ti,ab. (0)
86 ("86220-42-0" or "86220420").ti,ab. (0)
87 ("rs 94991 298" or rs94991298).ti,ab. (0)
88 synarel.ti,ab. (0)
89 deslorelin.ti,ab. (8)
90 gonadorelin.ti,ab. (3)
91 ("33515-09-2" or "33515092").ti,ab. (0)
92 ("51952-41-1" or "51952411").ti,ab. (0)
93 ("52699-48-6" or "52699486").ti,ab. (0)
94 cetrorelix.ti,ab. (9)
95 cetrotide.ti,ab. (0)
96 ("NS 75A" or NS75A).ti,ab. (0)
97 ("NS 75B" or NS75B).ti,ab. (0)
98 ("SB 075" or SB075).ti,ab. (0)
99 ("SB 75" or SB75).ti,ab. (1)

100 gonadoliberin.ti,ab. (1)
101 kryptocur.ti,ab. (0)
102 cetrorelix.ti,ab. (9)
103 cetrotide.ti,ab. (0)
104 antagon.ti,ab. (0)
105 ganirelix.ti,ab. (0)
106 ("ORG 37462" or ORG37462).ti,ab. (0)
107 orgalutran.ti,ab. (0)
108 ("RS 26306" or RS26306).ti,ab. (0)
109 ("AY 24031" or AY24031).ti,ab. (0)
110 factrel.ti,ab. (0)
111 fertagyl.ti,ab. (0)
112 lutrelef.ti,ab. (0)
113 lutrepulse.ti,ab. (0)
114 relefact.ti,ab. (0)
115 fertiral.ti,ab. (0)
116 (hoe471 or "hoe 471").ti,ab. (0)
117 relisorm.ti,ab. (0)
118 cystorelin.ti,ab. (0)
119 dirigestran.ti,ab. (0)
120 or/29-119 (4869)
121 28 and 120 (130)
122 limit 121 to english language (120)
123 limit 122 to yr="2000 -Current" (93)

Appendix C Evidence selection

The literature searches identified 525 references. These were screened using their titles and abstracts and 25 references were obtained and assessed for relevance. Of these, 9 references are included in the evidence review. The remaining 16 references were excluded and are listed in appendix D.

Figure 1 – Study selection flow diagram



References submitted with Preliminary Policy Proposal

There is no preliminary policy proposal for this policy.

Appendix D Excluded studies table

Study reference	Reason for exclusion
Achille, C., Taggart, T., Eaton, N.R. et al. (2020) Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: Preliminary results. International Journal of Pediatric Endocrinology 2020(1): 8	Intervention – data for GnRH analogues not reported separately from other interventions
Bechard, Melanie, Vanderlaan, Doug P, Wood, Hayley et al. (2017) Psychosocial and Psychological Vulnerability in Adolescents with Gender Dysphoria: A "Proof of Principle" Study. Journal of sex & marital therapy 43(7): 678-688	Population – no GnRH analogues at time of study
Chew, Denise, Anderson, Jemma, Williams, Katrina et al. (2018) Hormonal Treatment in Young People With Gender Dysphoria: A Systematic Review. Pediatrics 141(4)	All primary studies included apart from 1 conference abstract
de Vries, Annelou L C, McGuire, Jenifer K et al. (2014) Young adult psychological outcome after puberty suppression and gender reassignment. Pediatrics 134(4): 696-704	Population – relevant population included in de Vries et al. 2011
Ghelani, Rahul, Lim, Cheryl, Brain, Caroline et al. (2020) Sudden sex hormone withdrawal and the effects on body composition in late pubertal adolescents with gender dysphoria. Journal of pediatric endocrinology & metabolism: JPEM 33(1): 107-112	Outcomes – not in the PICO

Study reference	Reason for exclusion
Giovanardi, G, Morales, P, Mirabella, M et al. (2019) Transition memories: experiences of trans adult women with hormone therapy and their beliefs on the usage of hormone blockers to suppress puberty. Journal of endocrinological investigation 42(10): 1231-1240	Population – adults only
Hewitt, Jacqueline K, Paul, Campbell, Kasiannan, Porpavai et al. (2012) Hormone treatment of gender identity disorder in a cohort of children and adolescents. The Medical journal of Australia 196(9): 578-81	Outcomes – no data reported for relevant outcomes
Jensen, R.K., Jensen, J.K., Simons, L.K. et al. (2019) Effect of Concurrent Gonadotropin-Releasing Hormone Agonist Treatment on Dose and Side Effects of Gender-Affirming Hormone Therapy in Adolescent Transgender Patients. Transgender Health 4(1): 300-303	Outcomes – not in the PICO
Klaver, Maartje, de Mutsert, Renee, Wiepjes, Chantal M et al. (2018) Early Hormonal Treatment Affects Body Composition and Body Shape in Young Transgender Adolescents. The journal of sexual medicine 15(2): 251-260	Outcomes – not in the PICO
Klaver, Maartje, de Mutsert, Renee van der Loos, Maria A T C et al. (2020) Hormonal Treatment and Cardiovascular Risk Profile in Transgender Adolescents. Pediatrics 145(3)	Outcomes – not in the PICO
Lopez, Carla Marisa, Solomon, Daniel, Boulware, Susan D et al. (2018) Trends in the use of puberty blockers among transgender children in the United States. Journal of pediatric endocrinology & metabolism : JPEM 31(6): 665-670	Outcomes – not in the PICO
Schagen, Sebastian E E, Lustenhouwer, Paul, Cohen-Kettenis, Peggy T et al. (2018) Changes in Adrenal Androgens During Puberty Suppression and Gender-Affirming Hormone Treatment in Adolescents With Gender Dysphoria. The journal of sexual medicine 15(9): 1357-1363	Outcomes – not in the PICO
Swendiman, Robert A, Vogiatzi, Maria G, Alter, Craig A et al. (2019) Histrelin implantation in the pediatric population: A 10-year institutional experience. Journal of pediatric surgery 54(7): 1457-1461	Population – less than 10% of participants had gender dysphoria; data not reported separately
Turban, Jack L, King, Dana, Carswell, Jeremi M et al. (2020) Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. Pediatrics 145(2)	Intervention – data for GnRH analogues not reported separately from other interventions
Vrouenraets, Lieke Josephina Jeanne Johanna, Fredriks, A Miranda, Hannema, Sabine E et al. (2016) Perceptions of Sex, Gender, and Puberty Suppression: A Qualitative Analysis of Transgender Youth. Archives of sexual behavior 45(7): 1697-703	Outcomes – not in the PICO
Zucker, Kenneth J, Bradley, Susan J, Owen-Anderson, Allison et al. (2010) Puberty-blocking hormonal therapy for adolescents with gender identity disorder: A descriptive clinical study. Journal of Gay & Lesbian Mental Health 15(1): 58-82	Intervention – data for GnRH analogues not reported separately from other interventions

Appendix E Evidence tables

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Brik T, Vrouenraets L, de Vries M, et al. (2020) Trajectories of adolescents treated with gonadotropin-releasing hormone analogues for gender dysphoria. Archives of Sexual Behaviour https://doi.org/10.1007/s10508-020-01660-8 Netherlands Retrospective observational single-centre study To document trajectories after the initiation of GnRH analogue and explore reasons for extended use and discontinuation of GnRH analogues. Includes participants seen between November 2010 and January 1, 2018.	Inclusion criteria were adolescents with gender dysphoria, according to the DSM-5 criteria, seen at the single centre and treated with GnRH analogues between November 2010 and January 1, 2018. The study excluded adolescents without a diagnosis of gender dysphoria, those who had coexisting problems that interfered with the diagnostic process and/or might interfere with successful treatment (not further defined), those adolescents not wanting hormones, those with ongoing diagnostic evaluation and those who did not attend appointments. The sample consisted of 143 adolescents meeting the inclusion/exclusion criteria, 38 transfemales, 105 transmales, with median ages of 15.0 years (range 11.1 to 18.6 years) and 16.1 years	The study only reports that GnRH analogues were given, no specific drug, dose, route, or frequency of administration are reported. No comparator cohort was used in the study. Follow-up was at (up to) 9 years (last follow-up July 2019).	**Critical outcomes** No critical outcomes assessed. **Important outcomes** ***Psychosocial impact*** Not assessed. ***Engagement with health care services*** Not formally assessed but the study reported that out of 214 age and developmentally appropriate adolescents for potential inclusion in the study, 9 were excluded as they stopped attending appointments (4.2%). ***Stopping treatment*** Of the 143 adolescents, 9 (6.2%, 1 transfemale and 8 transmales) stopped taking GnRH analogues after a median duration of 0.8 years (range 0.1 to 3.0). Four adolescents (2.8%) discontinued GnRH analogues although they wanted to continue endocrine treatments for gender dysphoria: • 1 transmale stopped due to increase in mood problems, suicidal thoughts and confusion attributed to GnRH analogues (later had gender-affirming hormones at an adult gender clinic)[1] • 1 transmale experienced hot flushes, increased migraines, had a fear of injections, stress at school and unrelated medical issues, and	This study was appraised using the Newcastle-Ottawa tool for cohort studies. **Domain 1: Selection** 1. somewhat representative 2. no-non exposed cohort 3. secure record 4. yes **Domain 2: Comparability** 1. no comparator **Domain 3: Outcome** 1. record linkage 2. yes 3. complete follow-up **Overall quality is assessed as poor.** Other comments: Physical and psychological comorbidity was poorly reported, concomitant use of other medicines was not reported. Source of funding: not reported.

	(range 10.1 to 17.9 years), respectively at commencement of GnRH analogues. Of the 143 adolescents in the study, 125 (87%, 36 transfemales and 89 transmales) subsequently started treatment with gender-affirming hormones after median 1.0 (range 0.5 to 3.8) years and 0.8 (0.3 to 3.7) years, respectively. Median age at the start of gender-affirming hormones was 16.2 years (range 14.5 to 18.6 years) in transfemales and 17.1 years (range 14.9 to 18.8 years) in transmales. Five adolescents who used GnRH analogues had not started gender-affirming hormones at the time of data collection as they were not yet eligible for this treatment due to age. At the time of data collection, they had used GnRH analogues for a median duration of 2.1 years (range 1.6 to 2.8). Tanner stage was not reported. Six adolescents had been referred to a gender clinic elsewhere for further		temporarily discontinued treatment (after 4 months)[2] • 1 transmale experienced mood swings 4 months after commencing GnRH analogues. After 2.2 years he developed unexplained severe nausea and rapid weight loss and due to his general condition discontinued GnRH analogues after 2.4 years[3] • 1 transmale stopped GnRH analogues as his parents were unable to regularly collect medication from the pharmacy and take him to appointments for the injections[4] Five adolescents (3.5%) stopped treatment as they no longer wished to continue with gender-affirming treatment. • 1 adolescent had been very distressed about breast development at the start of GnRH analogues and later thought that she might want to live as a woman without breasts. She did not want to live as a boy and discontinued GnRH analogues, although dreaded breast development and menstruation. • 1 adolescent experienced concurrent psychosocial problems interfering with the exploration of gender identity and did not currently want treatment.[5] • 1 adolescent felt more in between male and female and therefore did not want to continue with GnRH analogues.[6] • 1 adolescent made a social transition while using GnRH	

	treatment, including 1 who had prolonged use.		analogues and shortly after decided to discontinue treatment.[7] • 1 adolescent discontinued after using GnRH analogues as the treatment allowed them to feel who they were.[8]	

[1] The adolescent later indicated "I was already fully matured when I started GnRH analogues, menstruations were already suppressed by contraceptives. For me, it had no added value" (transmale, age 19 years).
[2] The adolescent restarted endocrine treatment (testosterone) 5 months later.
[3] The adolescent recovered over the next 2 years and subsequently started lynestrenol and testosterone treatment.
[4] The adolescent subsequently started lynestrenol to suppress menses, he was not yet eligible for testosterone treatment.
[5] The adolescent later reflected that "The decision to stop GnRH analogues to my mind was made by the gender team, because they did not think gender dysphoria was the right diagnosis. I do still feel like a man, but for me it is okay to be just me instead of a he or a she, so for now I do not want any further treatment" (adolescent assigned female sex at birth, age 16 years).
[6] The adolescent stated "At the moment, I feel more like 'I am' instead of 'I am a woman' or 'I am a man'" (adolescent assigned female sex at birth, age 16 years).
[7] The adolescent stated that "he had fallen in love with a girl and had never had such feelings, which made him question his gender identity. At subsequent visits, he indicated that he was happy living as a man.
[8] The adolescent stated "After using GnRH analogues for the first time, I could feel who I was without the female hormones, this gave me peace of mind to think about my future. It was an inner feeling that said I am a woman" (adolescent assigned female sex at birth, age 18 years).

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Costa R, Dunsford M, Skagerberg E, et al. (2015) Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. Journal of Sexual Medicine 12(11):2206-14. United Kingdom Prospective longitudinal observational single centre cohort study Includes participants referred to the service between 2010 and 2014.	Adolescents with gender dysphoria who completed a 6-month diagnostic process using DSM-IV-TR criteria for gender dysphoria (comprising the gender dysphoria assessment and psychological interventions) either immediately eligible for treatment with GnRH analogues or delayed eligible for treatment with GnRH analogues (received psychological support without any physical intervention). No exclusion criteria were reported. The sample consisted of 201 adolescents (sex assigned at birth male to female ratio 1:1.6)	**Intervention** 101 individuals were assessed as being immediately eligible for use of GnRH analogues (no specific treatment, dose or route, or frequency of administration reported but all received psychological support). **Comparison** The analyses were between the immediately eligible	**Critical outcomes** ***Impact on gender dysphoria*** The Utrecht gender dysphoria scale (UGDS) was used to assess adolescents' gender dysphoria related discomfort. The Cronbach's alpha (α) for the study was reported as 0.76 to 0.88, suggesting good internal consistency. UGDS was only reported once, for 160 adolescents (50 sex assigned at birth males and 110 sex assigned at birth females). The assessment time point is not reported (baseline or follow-up) and the comparison for gender related discomfort was between sex assigned at birth males and sex assigned at birth females. Sex assigned at birth males had a mean (±SD) UGDS score of 51.6 [±9.7] versus sex assigned at birth	This study was appraised using the Newcastle-Ottawa tool for cohort studies. **Domain 1: Selection** 1. somewhat representative 2. drawn from the same community as the exposed cohort. 3. secure record 4. no **Domain 2: Comparability** 1. partial comparator **Domain 3: Outcome** 1. independent assessment (unclear if blinded) 2. yes 3. incomplete follow-up

	mean (±SD) age 15.52±1.41 years) from a sampling frame of 436 consecutive adolescents referred to the service between 2010 and 2014. The mean (±SD) age (n=201) at the start of GnRH analogues was 16.48 [±1.26], range 13 to 17 years. The interval from the start of the diagnostic procedure to the start of puberty suppression took approximately 1.5 years [±0.63] from baseline. None of the delayed eligible individuals received puberty suppression at the time of this study. Tanner stage was not reported.	and delayed eligible (n=100) adolescents, Baseline assessment (following diagnostic procedure) was followed by follow-up at 6 months from baseline (T1), 12 months from baseline (T2) and 18 months from baseline (T3).	females score of 56.1 [±4.3], *t*-test 4.07; p<0.001. ***Impact on mental health*** Not assessed. ***Impact on quality of life*** Not assessed. **Important outcomes** ***Psychosocial impact*** The Children's Global Assessment Scale (CGAS) was used to assess adolescents' psychosocial functioning. The CGAS was administered by psychologists, psychotherapists, and psychiatrists (intra-class correlation assessment was 0.76 ≤ Cronbach's α ≤0.94). At baseline, CGAS scores were not associated with any demographic variable, in both sex assigned at birth males and sex assigned at birth females (all p>0.1). In comparison with sex assigned at birth females, sex assigned at birth males had statistically significantly lower mean (±SD) baseline CGAS scores (55.4 [±12.7] versus 59.2 [11.8]; *t*-test 2.15; p=0.03). There was no statistically significant difference in mean (±SD) CGAS scores at baseline (T0) between immediately eligible adolescents and delayed eligible adolescents (n=201, 58.72 [±11.38] versus 56.63 [±13.14]; *t*-test 1.21; p=0.23). **Immediately eligible compared with delayed eligible participants** At follow-up, there was no statistically significant difference in mean (±SD)	**Overall quality is assessed as poor.** Other comments: Physical and psychological comorbidity was poorly reported, concomitant use of other medicines was not reported. Large unexplained loss to follow-up (64.7%) at T3. Source of funding: not reported.

			CGAS scores at any follow-up time point (T1, T2 or T3) between immediately eligible adolescents and delayed eligible adolescents: • T1, n=201, 60.89 [±12.17] versus 60.29 [±12.81]; *t*-test 0.34; p=0.73 • T2, n=121, 64.70 [±13.34] versus 62.97 [±14.10]; *t*-test 0.69; p=0.49 • T3, n=71, 67.40 [±13.93] versus 62.53 [±13.54]; *t*-test 1.49; p=0.14. **All participants** There was a statistically significant increase in mean (±SD) CGAS scores at any follow-up time point (T1, T2 or T3) compared with baseline (T0) for the all adolescents group: • T0 (n=201) versus T1 (n=201), 57.73 [±12.27] versus 60.68 [±12.47]; *t*-test 4.87; p<0.001 • T0 (n=201) versus T2 (n=121), 57.73 [±12.27] versus 63.31 [±14.41]; *t*-test 3.70; p<0.001 • T0 (n=201) versus T3 (n=71), 57.73 [±12.27] versus 64.93 [±13.85]; *t*-test 4.11; p<0.001 There was a statistically significant increase in mean (±SD) CGAS scores when comparing the follow-up period T1 to T3 but not for the periods T1 to T2 and T2 to T3, for all adolescents: • T1 (n=201) versus T2 (n=121), 60.68 [±12.47] versus 63.31 [±14.41]; *t*-test 1.73; p<0.08 • T1 (n=201) versus T3 (n=71), 60.68 [±12.47] versus 64.93 [±13.85], *t*-test 2.40; p<0.02 • T2 (n=121) versus T3 (n=71), 63.31 [±14.41] versus 64.93 [±13.85], *t*-test 0.76; p=0.45	

			There were no statistically significant differences in CGAS scores between sex assigned at birth males and sex assigned at birth females with gender dysphoria in all the follow-up evaluations (all p>0.1). Delayed eligible and immediately eligible adolescents with gender dysphoria were not statistically significantly different for demographic variables (all p>0.1). **Immediately eligible participants** There was a statistically significant increase in mean (±SD) CGAS scores at follow-up times T2 and T3 compared with baseline (T0) but not for T0 versus T1, for the immediately eligible adolescents: • T0 (n=101) versus T1 (n=101), 58.72 [±11.38] versus 60.89 [±12.17]; *t*-test 1.31; p=0.19 • T0 (n=101) versus T2 (n=60), 58.72 [±11.38] versus 64.70 [±13.34]; *t*-test 3.02; p=0.003 • T0 (n=101) versus T3 (n=35), 58.72 [±11.38] versus 67.40 [±13.93]; *t*-test 3.66; p<0.001 There was a statistically significant increase in mean (±SD) CGAS scores when comparing the follow-up period T1 to T3 with each other but not for the periods T1 to T2 and T2 to T3, for the immediately eligible adolescents: • T1 (n=101) versus T2 (n=60), 60.89 [±12.17] versus 64.70 [±13.34]; *t*-test 1.85; p=0.07 • T1 (n=101) versus T3 (n=35), 60.89 [±12.17] versus 67.40 [±13.93], *t*-test 2.63; p<0.001	

			• T2 (n=60) versus T3 (n=35), 64.70 [±13.34] versus 67.40 [±13.93], *t*-test 0.94; p=0.35 The immediately eligible adolescents had a CGAS score which was not statistically significantly different compared to the sample of children/ adolescents without observed psychological /psychiatric symptoms after 12 months of puberty suppression (T3, *t*=0.01, *p*=0.99).	

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
de Vries A, Steensma T, Doreleijers T, et al. (2011) Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. The Journal of Sexual Medicine 8 (8):2276-83. Netherlands Prospective longitudinal observational single centre before and after study.	The sample size was 70 adolescents receiving GnRH analogues (mean age [±SD] at assessment 13.6±1.8 years) from a sampling frame of 196 consecutive adolescents referred to the service between 2000 and 2008. Inclusion criteria were if they subsequently started gender-affirming hormones between 2003 and 2009 (mean [±SD] age at start of GnRH analogues was 14.75 [±1.92] years)[1]. No specific exclusion criteria were described. No diagnostic criteria or concomitant treatments were reported. Tanner stage of the included adolescents was not reported.	**Intervention** 70 adolescents were assessed at baseline (T0) before the start of GnRH analogues (no specific treatment, dose or route of administration reported). **Comparison** The same 70 adolescents were assessed again at follow-up (T1), shortly before starting gender-affirming hormones. Not all adolescents completed all assessments for all items[2].	**Critical outcomes** ***Impact on gender dysphoria*** Impact on gender dysphoria was assessed using the Utrecht Gender Dysphoria Scale (UGDS). • There was no statistically significant difference in UGDS scores between T0 and T1 (n=41). There was a statistically significant difference between sex assigned at birth males and sex assigned at birth females, with sex assigned at birth females reporting more gender dysphoria, *F* (*df, errdf*), *P*: 15.98 (1,39), p<0.001. ***Impact on mental health*** Depressive symptoms were assessed using the Beck Depression Inventory (BDI-II). • There was a statistically significant reduction in BDI score between T0 and T1, n=41, 8.31 [±7.12] versus 4.95 [±6.72], *F* (*df, errdf*), *P*: 9.28 (1,39), p=0.004. • There was no statistically significant difference between sex assigned at	This study was appraised using the Newcastle-Ottawa tool for cohort studies. **Domain 1: Selection** 1. somewhat representative of children and adolescents who have gender dysphoria 2. no non-exposed cohort 3. no description 4. no **Domain 2: Comparability** 1. study controls for age, age at start of treatment, IQ, and parental factors **Domain 3: Outcome** 1. no description 2. no/unclear 3. complete **Overall quality is assessed as poor**. Other comments: Physical and psychological comorbidity was not reported, concomitant use of

			birth males and sex assigned at birth females, *F* (*df, errdf*), *P*: 3.85 (1,39), p=0.057. Anger and anxiety were assessed using Trait Anger and Anxiety (TPI and STAI, respectively) Scales of the State-Trait Personality Inventory. • There was no statistically significant difference in anger (TPI) scale scores between T0 and T1 (n=41). There was a statistically significant difference between sex assigned at birth males and sex assigned at birth females, with sex assigned at birth females reporting increased anger compared with sex assigned at birth males, *F* (*df, errdf*), *P*: 5.70 (1,39), p=0.022. • Similarly, there was no statistically significant difference in anxiety (STAI) scale scores between T0 and T1 (n=41). There was a statistically significant difference between sex assigned at birth males and sex assigned at birth females, with sex assigned at birth females reporting increased anxiety compared with sex assigned at birth males, *F* (*df, errdf*), *P*: 16.07 (1,39), p<0.001. ***Impact on quality of life*** Not assessed. **Important outcomes** ***Impact on body image*** Impact on body image was assessed using the Body Image Scale to measure body satisfaction (BIS).	other medicines was not reported. Source of funding: This study was supported by a personal grant awarded to the first author by the Netherlands Organization for Health Research and Development.

			There was no statistically significant difference between T0 and T1 for any of the 3 BIS scores (primary sex characteristics, secondary sex characteristics or neutral characteristics, n=57). There were statistically significant differences between sex assigned at birth males and sex assigned at birth females, with sex assigned at birth females reporting more dissatisfaction, for: • primary sexual characteristics, *F* (*df, errdf*), *P*: 4.11 (1,55), p=0.047. • secondary sexual characteristics, *F* (*df, errdf*), *P*: 11.57 (1,55), p=0.001. But no statistically significant difference between sex assigned at birth males and sex assigned at birth females was found for neutral characteristics. However, there was a significant interaction effect between sex assigned at birth sex and the changes of gender dysphoria between T0 and T1; sex assigned at birth females became more dissatisfied with their secondary sex characteristics compared with sex assigned at birth males, *F* (*df, errdf*), *P*: 14.59 (1,55), p<0.001) and neutral characteristics, *F* (*df, errdf*), *P*: 15.26 (1,55), p<0.001). ***Psychosocial impact*** Psychosocial impact was assessed using both the Child Behaviour Checklist (CBCL) and the Youth Self-Report (YSR) to parents and adolescents, respectively. The Children's Global Assessment Scale was also reported. There was a statistically significant decrease in mean (±SD) total, internalising, and externalising[3] parental	

			CBCL scores between T0 and T1[4] for all adolescents (n=54): • Total score (T0 – T1) 60.70 [±12.76] versus 54.46 [±11.23], *F* (*df, errdf*), *P*: 26.17 (1,52), p<0.001. • Internalising score (T0 – T1) 61.00 [±12.21] versus 54.56 [±10.22], *F* (*df, errdf*), *P*: 22.93 (1,52), p<0.001. • Externalising score (T0 – T1) 58.04 [±12.99] versus 53.81 [±11.86], *F* (*df, errdf*), *P*: 12.04 (1,52), p=0.001. There was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for total and internalising CBCL score but there was a significant difference for the externalising score: • Externalising score, *F* (*df, errdf*), *P*: 6.29 (1,52), p=0.015. There was a statistically significant decrease in mean (±SD) total, internalising, and externalising[3] YSR scores between T0 and T1 for all adolescents (n=54): • Total score (T0 – T1) 55.46 [±11.56] versus 50.00 [±10.56], *F* (*df, errdf*), *P*: 16.24 (1,52), p<0.001. • Internalising score (T0 – T1) 56.04 [±12.49] versus 49.78 [±11.63], *F* (*df, errdf*), *P*: 15.05 (1,52), p<0.001. • Externalising score (T0 – T1) 53.30 [±11.87] versus 49.98 [±9.35], *F* (*df, errdf*), *P*: 7.26 (1,52), p=0.009. There was no statistically significant difference between sex assigned at birth males and sex assigned at birth females for total and internalising YSR score but there was a significant difference for the externalising score:	

			• Externalising score, *F* (*df, errdf*), *P*: 9.14 (1,52), p=0.004. There was a statistically significant increase in CGAS mean (±SD) score between T0 and T1 (n=41), 70.24 [±10.12] versus 73.90 [±9.63], *F* (*df, errdf*), *P*: 8.76 (1,39), p=0.005. There was a statistically significant difference between sex assigned at birth males and sex assigned at birth females, with sex assigned at birth females reporting lower score for global functioning compared with sex assigned at birth males, *F* (*df, errdf*), *P*: 5.77 (1,52), p=0.021. The proportion of adolescents scoring in the clinical range significantly decreased between T0 and T1, on the CBCL total problem scale (44.4% versus 22.2%, X^2[1] = 6.00, p=0.001), and the internalising scale (29.6% versus 11.1%, X^2[1] = 5.71, p=0.017) of the YSR.	

[1] There were statistically significant mean age [±SD] differences between sex assigned at birth males and sex assigned at birth females for age at assessment (13.14 [±1.55] versus 14.10 [±1.99] years, p=0.028), age at start of GnRH analogues (14.25 [±1.79] versus 15.21 [±1.95] years, p=0.036) and age at the start of gender-affirming hormones (16.24 [±1.21] versus 16.99 [±1.09] years, p=0.008). No statistically significant differences were seen for other baseline characteristics, time between GnRH analogue and gender-affirming hormones, full scale IQ, parental marital status, education, and sexual attraction to own, other or both sexes.

[2] Independent t-tests between mean scores on the CBCL, YSR, BDI, TPI, STAI, CGAS, UGS, and BIS of adolescents who completed both assessments and mean scores of adolescents who completed only one of the assessments revealed no significant differences on all used measures, at neither T0 or at T1.

[3] The CBCL/YSR has 2 components: Internalising score which sums the anxious/depressed, withdrawn-depressed, and somatic complaints scores; externalising score which sums rule-breaking and aggressive behaviour. The total problems score is the sum of the scores of all the problem items. The YSR is a child self-report version of the CBCL.

[4] A repeated measures ANOVA (analysis of variance) was used.

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Joseph T, Ting J, Butler G. (2019) The effect of GnRH analogue treatment on bone mineral density in young adolescents with gender dysphoria: findings from a large national cohort. Journal of pediatric endocrinology & metabolism 32(10): 1077-1081	Adolescents (12 to 14 years) with gender dysphoria (no diagnostic criteria described), n=70, including 31 transfemales and 39 transmales.	Treatment with a GnRH analogue for at least 1 year or ongoing until they reached 16 years. No specific treatment, dose or route of	**Critical outcomes** No critical outcomes assessed. **Important outcomes** ***Bone density: lumbar[1]*** **Lumbar spine bone mineral apparent density (BMAD)[2] 0 to 1 year** Transfemales (mean [±SD]):	This study was appraised using the Newcastle-Ottawa quality assessment checklist for cohort studies. **Domain 1: Selection**

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
United Kingdom Retrospective longitudinal observational single centre study To investigate whether there is any significant loss of bone mineral density (BMD) and bone mineral apparent density (BMAD) for up to 3 years of GnRH analogues. To investigate whether there was a significant drop after 1 year of treatment following abrupt withdrawal. 2011 to 2016	All had been seen and assessed by a Gender Identity Development Service multi-disciplinary psychosocial health team for at least 4 assessments over a minimum of 6 months. All participants had entered puberty and all but 2 of the transmales were postmenarchal. 57% of the transfemales were in early puberty (G2–3 and testicular volume >4 mL) and 43% were in late puberty (G4–5). Details of the sampling frame were not reported. Further details of how the sample was drawn are not reported.	administration reported. No concomitant treatments were reported. No comparator.	0.235 (0.030) g/cm3 at baseline, 0.233 g/cm3 (0.029) at 1 year (p=0.459); z-score 0.859 (0.154) at baseline, −0.228 (1.027) at 1 year (p=0.000) Transmales (mean [±SD]): 0.196 (0.035) g/cm3 at baseline, 0.201 (0.033) g/cm3 at 1 year (p=0.074); z-score −0.186 (1.230) at baseline, −0.541 (1.396) at 1 year (p=0.006) **Lumbar spine BMAD 0 to 2 years** Transfemales (mean [±SD]): 0.240 (0.027) g/cm3 at baseline, 0.240 (0.030) g/cm3 at 2 years (p=0.865); z-score 0.486 (0.809) at baseline, −0.279 (0.930) at 2 years (p=0.000) Transmales (mean [±SD]): 0.195 (0.058) g/cm3 at baseline, 0.198 (0.055) at 2 years (p=0.433); z-score −0.361 (1.439) at baseline, −0.913 (1.318) at 2 years (p=0.001) **Lumbar spine bone mineral density (BMD) 0 to 1 year** Transfemales (mean [±SD]): 0.860 (0.154) kg/m2 at baseline, 0.859 (0.129) kg/m2 at 1 year (p=0.962); z-score −0.016 (1.106) at baseline, −0.461 (1.121) at 1 year (p=0.003) Transmales (mean [±SD]): 0.694 (0.149) kg/m2 at baseline, 0.718 (0.124) kg/m2 at 1 year (p=0.006); z-score −0.395 (1.428) at baseline, −1.276 (1.410) at 1 year (p=0.000) **Lumbar spine BMD 0 to 2 years** Transfemales (mean [±SD]): 0.867 (0.141) kg/m2 at baseline, 0.878 (0.130) kg/m2 at 2 years (p=0.395); z-score 0.130 (0.972) at baseline, −0.890 (1.075) at 2 years (p=0.000) Transmales (mean [±SD]):	1. Somewhat representative of children and adolescents who have gender dysphoria 2. Not applicable 3. Via routine clinical records 4. No **Domain 2: Comparability** 1. No control group **Domain 3: Outcome** 1. Via routine clinical records 2. Yes 3. No statement **Overall quality is assessed as poor**. Other comments: although the evidence is of poor quality, the results suggest a possible association between GnRH analogues and BMAD. However, the results are not reliable and could be due to bias or chance. Further details of how the sample was drawn are not reported. No concomitant treatments were reported. Source of funding: None disclosed

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
			0.695 (0.220) kg/m2 at baseline, 0.731 (0.209) kg/m2 at 2 years (p=0.058); z-score −0.715 (1.406) at baseline, −2.000 (1.384) at 2 years (p=0.000) ***Bone density: femoral*** **Femoral neck (hip) BMD 0 to 1 year** Transfemales (mean [±SD]): 0.894 (0.118) kg/m2 at baseline, 0.905 (0.104) kg/m2 at 1 year (p=0.571); z-score 0.157 (0.905) at baseline, −0.340 (0.816) at 1 year (p=0.002) Transmales (mean [±SD]): 0.772 (0.137) kg/m2 at baseline, 0.785 (0.120) kg/m2 at 1 year (p=0.797); z-score −0.863 (1.215) at baseline, −1.440 (1.075) at 1 year (p=0.000) **Femoral neck (hip) BMD 0 to 2 years** Transfemales (mean [±SD]): 0.920 (0.116) kg/m2 at baseline, 0.910 (0.125) kg/m2 at 2 years (p=0.402); z-score 0.450 (0.781) at baseline, −0.600 (1.059) at 2 years (p=0.002) Transmales (mean [±SD]): 0.766 (0.215) kg/m2 at baseline, 0.773 (0.197) at 2 years (p=0.604); z-score −1.075 (1.145) at baseline, −1.779 (0.816) at 2 years (p=0.001)	

[1] Lumbar spine (L1-L4) BMD was measured by yearly dual energy X-ray absorptiometry (DXA) scans at baseline (n=70), 1 year (n=70), and 2 years (n=31).
[2] BMAD is a size adjusted value of BMD incorporating body size measurements using UK norms in growing adolescents. Reported as g/cm3 and z-scores. Hip BMAD z-scores were not calculated as there were no available reference ranges.

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Khatchadourian K, Shazhan A, Metzger D. (2014) Clinical management of youth with gender dysphoria in	27 young people with gender dysphoria who started GnRH analogues (at mean age [±SD] 14.7±1.9 years) out of 84 young	**Intervention** 84 young people with gender dysphoria were included. For GnRH analogues no	**Critical Outcomes** No critical outcomes assessed. **Important outcomes** ***Stopping treatment***	This study was appraised using the Newcastle-Ottawa tool for cohort studies. **Domain 1: Selection**

Vancouver. The Journal of Pediatrics 164 (4): 906-11. Canada Retrospective observational chart review single centre study	people seen at the unit between 1998 and 2011. Note: the transmale and transfemale subgroups reported in the paper is discrepant, 15 transmales and 11 transfemales (n=26) reported in the outcomes section rather than the n=27 stated in the paper; complete outcome reporting is also incomplete for the transfemale group. Inclusion criteria were at least Tanner stage 2 pubertal development, previous assessment by a mental health professional and a confirmed diagnosis of gender dysphoria (diagnostic criteria not specified). No exclusion criteria are specified.	specific treatment, dose or route of administration reported. **Comparison** No comparator.	The authors report that of 15 transmales taking GnRH analogues: • 14 transitioned to testosterone treatment during the observation period • 7 continued taking GnRH analogues after starting testosterone • 7 discontinued GnRH analogues after a median of 3.0 years (range 0.2 to 9.2 years), of which: o 5 discontinued after hysterectomy and salpingo-oophorectomy o 1 discontinued after 2.2 years (transitioned to gender-affirming hormone) o 1 discontinued after <2 months due to mood and emotional lability The authors report that of 11 transfemales taking GnRH analogues: • 5 received oestrogen treatment during the observation period • 4 continued taking GnRH analogues during oestrogen treatment • 1 discontinued GnRH analogues during oestrogen treatment (no reason reported) • 1 stopped GnRH analogues after a few months due to emotional lability • 1 stopped GnRH analogues before oestrogen treatment (the following year delayed due to heavy smoking) • 1 discontinued GnRH analogues after 13 months due to choosing not to pursue transition ***Safety*** Of the 27 patients treated with GnRH analogues:	1. not reported 2. no non-exposed cohort 3. secure record 4. no **Domain 2: Comparability** 1. not applicable **Domain 3: Outcome** 1. record linkage 2. yes 3. in complete missing data **Overall quality is assessed as poor.** Other comments: mental health comorbidity was reported for all participants but not for the GnRH analogue cohort separately. Concomitant use of other medicines was not reported. Source of funding: No source of funding identified.

			• 1 transmale participant developed sterile abscesses; they were switched from leuprolide acetate to triptorelin, and this was well tolerated. • 1 transmale participant developed leg pains and headaches on GnRH analogues, which eventually resolved without treatment. • 1 participant gained 19 kg within 9 months of initiating GnRH analogues, although their body mass index was >85 percentile before GnRH analogues.	

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Klink D, Caris M, Heijboer A et al. (2015) Bone mass in young adulthood following gonadotropin-releasing hormone analog treatment and cross-sex hormone treatment in adolescents with gender dysphoria. The Journal of clinical endocrinology and metabolism 100(2): e270-5 Netherlands Retrospective longitudinal observational single centre study To assess BMD development during GnRH analogues and at age 22 years in adolescents with gender dysphoria who started treatment for gender dysphoria during adolescence.	34 adolescents (mean age ±SD 14.9±1.9 for transfemales and 15.0±2.0 for transmales at start of GnRH analogues). Participants were included if they met DSM-IV-TR criteria for gender identity disorder of adolescence and had been treated with GnRH analogues and gender-affirming hormones during their pubertal years. No concomitant treatments were reported.	The intervention was GnRH analogue monotherapy (triptorelin pamoate 3.75 mg subcutaneously every 4 weeks) followed by gender-affirming hormones from 16 years with discontinuation of GnRH analogue after gonadectomy. Median duration of GnRH analogue monotherapy in transfemales was 1.3 years (range, 0.5 to 3.8 years), and in transmales was 1.5 years	**Critical outcomes** No critical outcomes assessed. **Important outcomes** ***Bone density: lumbar*** **Lumbar spine bone mineral apparent density (BMAD)[1]** Change from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales (mean [±SD]): GnRH analogue: 0.22 (0.03) g/cm3, gender-affirming hormones: 0.22 (0.02) g/cm3 (NS); z-score GnRH analogue: −0.44 (1.10), gender-affirming hormones: −0.90 (0.80) (p=NS) Change from starting GnRH analogue (mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales (mean [±SD]: GnRH analogue: 0.25 (0.03) g/cm3, gender-affirming hormones: 0.24 (0.02) g/cm3 (NS);	This study was appraised using the Newcastle-Ottawa quality assessment checklist for cohort studies. **Domain 1: Selection** 1. somewhat representative of children and adolescents who have gender dysphoria 2. not applicable 3. via routine clinical records 4. no **Domain 2: Comparability** 1. no control group **Domain 3: Outcome** 1. via routine clinical records 2. yes 3. follow-up rate variable across timepoints and no description of those lost **Overall quality is assessed as poor**.

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
1998 to 2012		(range, 0.25 to 5.2 years).	z-score GnRH analogue: 0.28 (0.90), gender-affirming hormones: −0.50 (0.81) (p=0.004) **Lumbar spine bone mineral density (BMD)[1]** Change from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales (mean [±SD]): GnRH analogue: 0.84 (0.13) g/m2, gender-affirming hormones: 0.84 (0.11) g/m2 (NS); z-score GnRH analogue: −0.77 (0.89), gender-affirming hormones: −1.01 (0.98) (NS) Change from starting GnRH analogue (mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales (mean [±SD]): GnRH analogue: 0.95 (0.12) g/m2, gender-affirming hormones: 0.91 (0.10) g/m2 (p=0.006); z-score GnRH analogue: 0.17 (1.18), gender-affirming hormones: −0.72 (0.99) (p<0.001) ***Bone density; femoral*** **Femoral area BMAD[1]** Change from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales (mean [±SD]), GnRH analogue: 0.28 (0.04) g/cm3, gender-affirming hormones: 0.26 (0.04) g/cm3 (NS); z-score GnRH analogue: −0.93 (1.22), gender-affirming hormones: −1.57 (1.74) (p=NS) Change from starting GnRH analogue	Other comments: Within person comparison. Small numbers of participants in each subgroup. No concomitant treatments or comorbidities were reported. Source of funding: None disclosed

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
			(mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales (mean [±SD]), GnRH analogue: 0.32 (0.04) g/cm3, gender-affirming hormones: 0.31 (0.04) (NS); z-score GnRH analogue: 0.01 (0.70), gender-affirming hormones: −0.28 (0.74) (NS) **Femoral area BMD[1]** Change from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales (mean [±SD]), GnRH analogue: 0.88 (0.12) g/m2, gender-affirming hormones: 0.87 (0.08) (NS); z-score GnRH analogue: −0.66 (0.77), gender-affirming hormones: −0.95 (0.63) (NS) Change from starting GnRH analogue (mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales (mean [±SD]), GnRH analogue: 0.92 (0.10) g/m2, gender-affirming hormones: 0.88 (0.09) (p=0.005); z-score GnRH analogue: 0.36 (0.88), gender-affirming hormones: −0.35 (0.79) (p=0.001)	

[1] BMD and BMAD of the lumbar spine and femoral region (nondominant side) measured by DXA scans at start of GnRH analogues, (n=32), start of gender-affirming hormones (n=34), and at 22 years (n=34).

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Schagen SEE, Cohen-Kettenis PT, Delemarre-van de Waal HA et al. (2016)	Adolescents with gender dysphoria (n=116), median age (range) 13.6 years (11.6 to 17.9) in transfemales and 14.2 years (11.1 to	GnRH analogue monotherapy (triptorelin pamoate 3.75 mg at 0, 2 and 4	**Critical outcomes** No critical outcomes assessed. **Important outcomes**	This study was appraised using the Newcastle-Ottawa quality assessment checklist for cohort studies.

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Efficacy and Safety of Gonadotropin-Releasing Hormone Agonist Treatment to Suppress Puberty in Gender Dysphoric Adolescents. The journal of sexual medicine 13(7): 1125-32 Netherlands Prospective longitudinal study To describe the changes in Tanner stage, testicular volume, gonadotropins, and sex steroids during GnRH analogues of adolescents with gender dysphoria to evaluate the efficacy. To report on liver enzymes, renal function and changes in body composition. 1998 to 2009	18.6) in transmales during first year of GnRH analogues. Participants were included if they met DSM-IV-TR criteria for gender dysphoria, had lifelong extreme gender dysphoria, were psychologically stable and were living in a supportive environment. No concomitant treatments were reported.	weeks followed by injections every 4 weeks, route of administration not described) for at least 3 months.	***Other safety outcomes: liver function*** Glutamyl transferase was not elevated at baseline or during treatment in any subject. Mild elevations of aspartate aminotransferase (AST) and alanine aminotransferase (ALT) above the reference range were present at baseline but were not more prevalent during treatment than at baseline. Glutamyl transferase, AST, and ALT levels did not significantly change from baseline to 12 months of treatment. No values or statistical analyses were reported. ***Other safety outcomes: kidney function*** **Change in serum creatinine between 0 and 1 year** Transfemales (mean [±SD]): 70 (12) micromol/l at baseline, 66 (13) micromol/l at 1 year (p=0.20) Transmales (mean [±SD]): 73 (8) micromol/l at baseline, 68 (13) micromol/l at 1 year (p=0.01)	**Domain 1: Selection** 1. somewhat representative of children and adolescents who have gender dysphoria 2. not applicable 3. via routine clinical records 4. no **Domain 2: Comparability** 1. no control group **Domain 3: Outcome** 1. via routine clinical records 2. yes 3. no statement **Overall quality is assessed as poor**. Other comments: Within person comparison. No concomitant treatments or comorbidities were reported. Source of funding: Ferring pharmaceuticals (triptorelin manufacturer)

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Staphorsius A, Baudewijntje P, Kreukels P, et al. (2015) Puberty suppression and executive functioning: an fMRI-study	The inclusion criteria were diagnosed with Gender Identity Disorder according to the DSM-IV-TR and at least 12 years old and Tanner stage of at least B2 or G2 to G3 with	**Intervention** GnRH analogues (triptorelin pamoate 3.75 mg every 4 weeks	**Critical Outcomes** No critical outcomes assessed. **Important outcomes** ***Psychosocial impact***	This study was appraised using the Newcastle-Ottawa tool for cohort studies. **Domain 1: Selection domain**

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
in adolescents with gender dysphoria. Psychoneuroendocrinology 565:190-9. Netherlands Cross-sectional (single time point) assessment single centre study	measurable oestradiol and testosterone levels in girls and boys, respectively. For all group's exclusion criteria were an insufficient command of the Dutch language (how assessed not reported), unadjusted endocrine disorders, neurological or psychiatric disorders that could lead to deviant test results (details not reported) use of psychotropic medication, and contraindications for an MRI scan. Additionally, adolescents receiving puberty delaying medication or any form of hormones besides oral contraceptives were excluded as controls. The sample size was 85 of whom 41 were adolescents (the numbers are discrepant with the number for whom outcomes are reported n=40) with gender dysphoria (20 of whom were being treated with GnRH analogues); 24 girls and 21 boys without gender dysphoria acted as controls (not further reported here). Details of the sampling frame are not reported. The ages at which GnRH analogues were started was not reported. The mean duration of treatment was 1.6 years (SD 1.0) Mean (±SD) Tanner stage for each group was reported: • Transfemales 3.9 [±1.1] • Transfemales on GnRH analogues 4.1 [±1.0]	subcutaneously or intramuscularly). **Comparison** The comparison was between adolescents with gender dysphoria receiving GnRH analogues and those without GnRH analogues.	The Child Behaviour Checklist (CBCL) was used to assess psychosocial impact. The CBCL was administered once during the study. The reported outcomes for each group were (n, mean [±SD]): • Transfemales (all, n=18) 57.8 [±9.2] • Transfemales on GnRH analogues (n=8) 57.4 [±9.8] • Transfemales without GnRH analogues (n=10) 58.2 [±9.3] • Transmales (all, n=22) 60.4 [±10.2] • Transmales on GnRH analogues (n=12) 57.5 [±9.4] • Transmales without GnRH analogues (n=10) 63.9 [±10.5] The analysis of the CBCL data is not discussed, and statistical analysis is unclear. ***Cognitive development or functioning*** **IQ**[1] • Transfemales (mean [±SD]) on GnRH analogues: 94.0 (10.3) • Transfemales (mean [±SD]) without GnRH analogues: 109.4 (21.2) • Transmales (mean [±SD]) on GnRH analogues: 95.8 (15.6) • Transmales (mean [±SD]) without GnRH analogues: 98.5 (15.9) **Reaction time**[2] • Transfemales (mean [±SD]) on GnRH analogues: 10.9 (4.1) • Transfemales (mean [±SD]) without GnRH analogues: 9.9 (3.1)	1. somewhat representative of children and adolescents who have gender dysphoria 2. drawn from the same community as the exposed cohort 3. via routine clinical records 4. no **Domain 2: Comparability** 1. study controls for age and diagnosis **Domain 3: Outcome** 1. via clinical assessment 2. yes 3. unclear **Overall quality is assessed as poor.** Other comments: Physical and psychological comorbidity was not reported, concomitant use of other medicines was not reported. Source of funding: This work was supported by an educational grant from the pharmaceutical firm Ferring BV, and by a VICI grant (453-08-003) from the Dutch Science Foundation. The authors state that funding sources did not play a role in any component of this study.

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
	• Transfemales without GnRH analogues 3.8 [±1.1] • Transmales 4.5 [±0.9] • Transmales on GnRH analogues 4.1 [±1.1] Transmales without GnRH analogues 4.9 [±0.3]		• Transmales (mean [±SD]) on GnRH analogues: 9.9 (3.1) • Transmales (mean [±SD]) without GnRH analogues: 10.0 (2.0) **Accuracy[3]** • Transfemales (mean [±SD]) on GnRH analogues: 73.9 (9.1) • Transfemales (mean [±SD]) without GnRH analogues: 83.4 (9.5) • Transmales (mean [±SD]) on GnRH analogues: 85.7 (10.5) • Transmales (mean [±SD]) without GnRH analogues: 88.8 (9.7)	

[1] Estimated with 4 subscales (arithmetic, vocabulary, picture arrangement, and block design) of the Wechsler Intelligence Scale for Children, third edition (WISC-III®, Wechsler 1991) or the Wechsler Adult Intelligence Scale, third edition (WAIS-III®, Wechsler 1997), depending on the participant's age.
[2] Reaction time in seconds in the Tower of London task
[3] Percentage of correct trials in the Tower of London task

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
Vlot, Mariska C, Klink, Daniel T, den Heijer, Martin et al. (2017) Effect of pubertal suppression and cross-sex hormone therapy on bone turnover markers and bone mineral apparent density (BMAD) in transgender adolescents. Bone 95: 11-19 Netherlands Retrospective observational data analysis study	Adolescents with gender dysphoria, n=70. Median age (range) 15.1 years (11.7 to 18.6) for transmales and 13.5 years (11.5 to 18.3) for transfemales at start of GnRH analogues. Participants were included if they had a diagnosis of gender dysphoria according to DSM-IV-TR criteria who were treated with GnRH analogues and then gender-affirming hormones. No concomitant treatments were reported. The study categorised	GnRH analogues (triptorelin pamoate 3.75 mg every 4 weeks subcutaneously).	**Critical outcomes** No critical outcomes reported **Important outcomes** ***Bone density: lumbar*** **Lumbar spine bone mineral apparent density (BMAD)** Change from starting GnRH analogue to starting gender-affirming hormones in transfemales (bone age of <15 years; median [range]), GnRH analogue: 0.21 (0.17 to 0.25) g/cm3, gender-affirming hormones: 0.20 (0.18 to 0.24) g/cm3 (NS); z-score GnRH analogue: −0.20 (−1.82 to 1.18), gender-affirming hormones: −1.52 (−2.36 to 0.42) (p=0.001)	This study was appraised using the Newcastle-Ottawa quality assessment checklist for cohort studies. **Domain 1: Selection** 1. Somewhat representative of children and adolescents who have gender dysphoria 2. Not applicable 3. Via routine clinical records 4. No **Domain 2: Comparability** 1. No control group **Domain 3: Outcome** 1. Via routine clinical records 2. Yes

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
To investigate the course of 3 bone turnover markers in relation to bonemineral density, in adolescents with gender dysphoria during GnRH analogue and gender-affirming hormones. 2001 to 2011	participants into a young and old pubertal group, based on their bone age. The young transmales had a bone age of <14 years and the old transmales had a bone age of ≥14 years. The young transfemales group had a bone age of <15 years and the old transfemales group ≥15 years.		Change from starting GnRH analogue to starting gender-affirming hormones in transfemales (bone age of ≥15; median [range]), GnRH analogue: 0.22 (0.18 to 0.25) g/cm3, gender-affirming hormones: 0.22 (0.19 to 0.24) g/cm3 (NS); z-score GnRH analogue: −1.18 (−1.78 to 1.09), gender-affirming hormones: −1.15 (−2.21 to 0.08) (p≤0.1) Change from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of <15 years; median [range]), GnRH analogue: 0.23 (0.20 to 0.29) g/cm3, gender-affirming hormones: 0.23 (0.19 to 0.28) g/cm3 (NS); z-score GnRH analogue: −0.05 (−0.78 to 2.94), gender-affirming hormones: −0.84 (−2.20 to 0.87) (p=0.003) Change from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of ≥15; median [range]), GnRH analogue: 0.26 (0.21 to 0.29) g/cm3, gender-affirming hormones: 0.24 (0.20 to 0.28) g/cm3 (p≤0.01); z-score GnRH analogue: 0.27 (−1.60 to 1.80), gender-affirming hormones: −0.29 (−2.28 to 0.90) (p≤ 0.0001) ***Bone density; femoral*** **Femoral neck BMAD** Change from starting GnRH analogue to starting gender-affirming hormones in transfemales (bone age of <15 years; median [range]), GnRH analogue: 0.29 (0.20 to 0.33) g/cm3, gender-affirming hormones: 0.27 (0.20 to 0.33) g/cm3 (p≤0.1); z-score GnRH analogue: −0.71 (−3.35 to	3. Follow-up rate variable across outcomes and no description of those lost **Overall quality is assessed as poor**. Other comments: Within person comparison. No concomitant treatments were reported. Source of funding: grant from Abbott diagnostics

Study details	Population	Interventions	Study outcomes	Appraisal and Funding
			0.37), gender-affirming hormones: −1.32 (−3.39 to 0.21) (p≤0.1) Change from starting GnRH analogue to starting gender-affirming hormones in transfemales (bone age of ≥15; median [range]), GnRH analogue: 0.30 (0.26 to 0.36) g/cm3, gender-affirming hormones: 0.30 (0.26 to 0.34) g/cm3 (NS); z-score GnRH analogue: −0.44 (−1.37 to 0.93), gender-affirming hormones: −0.36 (−1.50 to 0.46) (NS) Change from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of <15 years; median [range]), GnRH analogue: 0.31 (0.26 to 0.36) g/cm3, gender-affirming hormones: 0.30 (0.22 to 0.35) g/cm3 (NS); z-score GnRH analogue: −0.01 (−1.30 to 0.91), gender-affirming hormones: −0.37 (−2.28 to 0.47) (NS) Change from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of ≥15; median [range]), GnRH analogue: 0.33 (0.25 to 0.39) g/cm3, gender-affirming hormones: 0.30 (0.23 to 0.41) g/cm3 (p≤0.01); z-score GnRH analogue: 0.27 (−1.39 to 1.32), gender-affirming hormones: −0.27 (−1.91 to 1.29) (p=0.002)	

Appendix F Quality appraisal checklists

Newcastle-Ottawa tool for cohort studies

Question	
Domain: Selection	
1. Representativeness of the exposed cohort	Truly representative of the average [describe] in the community Somewhat representative of the average [describe] in the community Selected group of users e.g. nurses, volunteers No description of the derivation of the cohort
2. Selection of the non-exposed cohort	Drawn from the same community as the exposed cohort Drawn from a different source No description of the derivation of the non-exposed cohort
3. Ascertainment of exposure	Secure record (e.g. surgical records) Structured interview Written self-report No description
4. Demonstration that outcome of interest was not present at start of study	Yes / No
Domain: Comparability	
1. Comparability of cohorts on the basis of the design or analysis	Study controls for [select most important factor] Study controls for any additional factor [this criteria could be modified to indicate specific control for a second important factor]
Domain: Outcome	
1. Assessment of outcome	Independent blind assessment Record linkage Self-report No description
2. Was follow-up long enough for outcomes to occur	Yes [select and adequate follow up period for outcome of interest] No
3. Adequacy of follow up of cohorts	Complete follow up (all subjects accounted for) Subjects lost to follow up unlikely to introduce bias (small number lost to follow up [select an adequate %] follow up or description provided of those lost) Follow up rate [select an adequate %] and no description of those lost No statement

Appendix G Grade profiles

Table 2: Question 1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – gender dysphoria

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Impact on gender dysphoria									
Mean±SD Utrecht Gender Dysphoria Scale[1] (version(s) not reported), time point at baseline (before GnRH analogues) versus follow-up (before gender-affirming hormones, higher scores indicate more gender dysphoria)									
1 cohort study de Vries et al 2011	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=41	None	Baseline: 53.20±7.91 GnRH analogue: 53.9±17.42 *P*=0.333	Critical	VERY LOW

Abbreviations: GnRH, gonadotrophin releasing hormone; *P*, P-value; SD, Standard deviation.

1 The UGDS is a validated screening tool for both adolescents and adults to assess gender dysphoria. It consists of 12 items, to be answered on a 1- to 5-point scale, resulting in a sum score between 12 and 60. The higher the UGDS score the greater the gender dysphoria.
2 Downgraded 1 level - the cohort study by de Vries et al. (2011) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

Table 3: Question 1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – mental health

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Impact on mental health									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Mean±SD Beck Depression Inventory-II, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones). (Lower scores indicate benefit)									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=41	None	Baseline: 8.31±7.12 GnRH analogue: 4.95±6.72 *P*=0.004	Critical	VERY LOW
Mean±SD Trait Anger (TPI), time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit)									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=41	None	Baseline: 18.29±5.54 GnRH analogue: 17.88±5.24 *P*=0.503	Critical	VERY LOW
Mean±SD Trait Anxiety (STAI), time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit)									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=41	None	Baseline: 39.43±10.07 GnRH analogue: 37.95±9.38 *P*=0.276	Critical	VERY LOW

Abbreviations: GnRH, gonadotrophin releasing hormone; *P*, P-value; SD, Standard deviation.

1 Downgraded 1 level - the cohort study by de Vries et al. (2011) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

Table 4: Question 1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – body image

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Impact on body image									
Mean±SD Body Image Scale (primary sexual characteristics), time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit)									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=57	None	Baseline: 4.10±0.56 GnRH analogue: 3.98±0.71 *P*=0.145	Important	VERY LOW
Mean±SD Body Image Scale (secondary sexual characteristics), time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit)									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=57	None	Baseline: 2.74±0.65 GnRH analogue: 2.82±0.68 *P*=0.569	Important	VERY LOW
Mean±SD Body Image Scale (neutral characteristics), time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit)									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=57	None	Baseline: 2.41±0.63 GnRH analogue: 2.47±0.56 *P*=0.620	Important	VERY LOW

Abbreviations: GnRH, gonadotrophin releasing hormone; *P*, P-value; SD, Standard deviation.

1 Downgraded 1 level - the cohort study by de Vries et al. (2011) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

Table 5: Question 1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – psychosocial impact

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Psychosocial impact									
Mean [±SD] Children's Global Assessment Scale score, at baseline, higher scores indicate benefit)									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	n=101 58.72 [±11.38]	n=100 56.63 [±13.14]	*P*=0.23	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, at 6 months[2] (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	n=101 60.89 [±12.17]	n=100 60.29 [±12.81]	*P*=0.73	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, at 12 months[3] (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	n=60 64.70 [±13.34]	n=61 62.97 [±14.10]	*P*=0.49	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, at 18 months[4] (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	n=35 67.40 [±13.93]	n=36 62.53 [±13.54]	*P*=0.14	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, participants at 6 months compared to baseline (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=101 N=101	None	Baseline: 58.72±11.38 6 months: 60.89±12.17 *P*=0.19	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, participants at 12 months compared to baseline (higher scores indicate benefit).									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=101 N=60	None	Baseline: 58.72±11.38 12 months: 64.70±13.34 *P*=0.003	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, participants at 18 months compared to baseline (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=101 N=35	None	Baseline: 58.72±11.38 18 months: 67.40±13.93 *P*<0.001	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, participants at 12 months compared to 6 months (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=101 N=60	None	6 months: 60.89±12.17 12 months: 64.70±13.34 *P*=0.07	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, participants at 18 months compared to 6 months (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=101 N=35	None	6 months: 60.89±12.17 18 months: 67.40±13.93 *P*<0.001	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, participants at 18 months compared to 12 months (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=60 N=35	None	12 months: 64.70±13.34 18 months: 67.40±13.93 *P*=0.35	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, in all participants (including those not treated with GnRH analogues) at 6 months[2] compared to baseline (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=201	None	Baseline: 57.73±12.27 6 months: 60.68±12.47 *P*<0.001	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, in all participants (including those not treated with GnRH analogues) at 12 months[3] compared to baseline (higher scores indicate benefit).									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=201 N=121	None	Baseline: 57.73±12.27 12 months: 63.31±14.41 *P*<0.001	Important	VERY LOW
Mean±SD Children's Global Assessment Scale score, in all participants (including those not treated with GnRH analogues) at 18 months[4] compared to baseline (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=201 N=71	None	Baseline: 57.73±12.27 18 months: 64.93±13.85 *P*<0.001	Important	VERY LOW
Mean±SD Children's Global Assessment Scale score, in all participants (including those not treated with GnRH analogues) at 12 months compared to 6 months (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=201 N=121	None	6 months: 60.68±12.47 12 months: 63.31±14.41 *P*<0.08	Important	VERY LOW
Mean±SD Children's Global Assessment Scale score, in all participants (including those not treated with GnRH analogues) at 18 months compared to 6 months (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=201 N=71	None	6 months: 60.68±12.47 18 months: 64.93±13.85 *P*<0.02	Important	VERY LOW
Mean±SD Children's Global Assessment Scale score, in all participants (including those not treated with GnRH analogues) at 18 months compared to 12 months (higher scores indicate benefit).									
1 cohort study Costa et al 2015	Serious limitations[1]	No serious indirectness	No serious inconsistency	Not calculable	N=121 N=71	None	12 months: 63.31±14.41 18 months: 64.93±13.85 *P*<0.45	Important	VERY LOW
Mean±SD Children's Global Assessment Scale score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, higher scores indicate benefit).									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=41	None	Baseline: 70.24±10.12 GnRH analogue: 73.90±9.63 *P*=0.005	Important	VERY LOW
Mean±SD Child Behaviour Checklist (total T) score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit).									
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 60.70±12.76 GnRH analogue: 54.46±11.23 *P*<0.001	Important	VERY LOW
Mean±SD Child Behaviour Checklist (internalising T) score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit).									
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 61.00±12.21 GnRH analogue: 52.1±9.81 *P*<0.001	Important	VERY LOW
Mean±SD Child Behaviour Checklist (externalising T) score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit).									
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 58.04±12.99 GnRH analogue: 53.81±11.86 *P*=0.001	Important	VERY LOW
Proportion of adolescents scoring in the clinical range Child Behaviour Checklist total problem scale, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit).									
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 44.4% GnRH analogue: 22,2% *P*=0.001	Important	VERY LOW
Mean±SD Youth Self-Report (total T) score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormone, lower scores indicate benefit).									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 55.46±11.56 GnRH analogue: 50.00±10.56 *P*<0.001	Important	VERY LOW
Mean±SD Youth Self-Report (internalising T) score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit).									
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 56.04±12.49 GnRH analogue: 49.78±11.63 *P*<0.001	Important	VERY LOW
Mean±SD Youth Self-Report (externalising T) score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit).									
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 53.30±11.87 GnRH analogue: 49.98±9.35 *P*=0.009	Important	VERY LOW
Proportion of adolescents scoring in the clinical range Youth Self-Report (internalising T) score, time point at baseline (before GnRH analogues) versus follow-up (just before gender-affirming hormones, lower scores indicate benefit).									
1 cohort study de Vries et al 2011	Serious limitations[5]	No serious indirectness	Not applicable	Not calculable	N=54	None	Baseline: 29.6% GnRH analogue: 11.1% *P*=0.017	Important	VERY LOW
Mean±SD Child Behaviour Checklist score, transfemales (lower scores indicate benefit									
1 cross-sectional study Staphorsius et al 2015	Serious limitations[6]	No serious indirectness	Not applicable	Not calculable	N=8	N=10	GnRH analogue: 57.4 [±9.8] No GnRH analogue: 58.2 [±9.3]	Important	VERY LOW
Mean±SD Child Behaviour Checklist score, transmales (lower scores indicate benefit)									
1 cross-sectional study	Serious limitations[6]	No serious indirectness	Not applicable	Not calculable	N=12	N=10	GnRH analogues: 57.5 [±9.4] No GnRH analogue: 63.9 [±10.5]	Important	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Staphorsius et al 2015									

Abbreviations: GnRH, gonadotrophin releasing hormone; *P*, P-value; SD, Standard deviation.

1 Downgraded 1 level - the cohort study by Costa et al. (2015) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).
2 6 months from baseline (after 6 months of psychological support – both groups).
3 12 months from baseline (delayed eligible gender dysphoria [GD] adolescents, after 12 months of psychological support; immediately eligible GD adolescents, after 12 months of psychological support + 6 months of puberty suppression).
4 18 months from baseline (delayed eligible gender dysphoria [GD] adolescents, after 12 months of psychological support; immediately eligible GD adolescents, after 12 months of psychological support + 6 months of puberty suppression).
5 Downgraded 1 level - the cohort study by de Vries et al. (2011) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).
6 Downgraded 1 level - the cohort study by Staphorsius et al. (2015) was assessed as at high risk of bias (poor quality overall; lack of blinding and no randomisation).

Table 6: Question 1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – engagement with healthcare services

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Engagement with healthcare services									
Number (proportion) failing to engage with health care services (did not attend clinic), at (up to) 9 years follow-up									
1 cohort study Brik et al 2018	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	9/214 (4.2%)	None	9 adolescents out of 214 failed to attend clinic and were excluded from the study (4.2%)	Important	VERY LOW
Loss to follow-up									
1 cohort study	Serious limitations[2]	No serious indirectness	Not applicable		201	None	The sample size at baseline and 6 months was 201, which dropped by 39.8% to 121 after	Important	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Costa et al 2015				Not calculable			12 months and by 64.7% to 71 at 18 months follow-up. No explanation of the reasons for loss to follow-up are reported.		

Abbreviations: GnRH, gonadotrophin releasing hormone.

1 Downgraded 1 level - the cohort study by Brik et al. (2018) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).
2 Downgraded 1 level - the cohort study by Costa et al. (2015) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

Table 7: Question 1. For children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – stopping treatment

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Stopping treatment									
Number (proportion) stopping GnRH analogues, at (up to) 9 years follow-up									
1 cohort study Brik et al 2018	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	9/143 (6.2%)	None	9/143 adolescents stopped GnRH analogues (6.2%)[2]	Important	VERY LOW
Number (proportion) stopping from GnRH analogues, at (up to) 13 years follow-up									
1 cohort study Khatchadourian et al 2014	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	11/27 (42%)	None	11/26 stopped GnRH analogues (42%)[4]	Important	VERY LOW
Number (proportion) stopping GnRH analogues but who wished to continue endocrine treatment, at (up to) 9 years follow-up									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 cohort study Brik et al 2018	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	4/143 (2.8%)	None	4/143 adolescents stopped GnRH analogues but wished to continue treatment (2.8%)	Important	VERY LOW
Number (proportion) stopping GnRH analogues who no longer wished gender-affirming treatment, at (up to) 9 years follow-up									
1 cohort study Brik et al 2018	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	5/143 (3.5%)	None	5/143 adolescents stopped GnRH analogues and no longer wished to continue gender-affirming treatment (3.5%)	Important	VERY LOW

Abbreviations: GnRH, gonadotrophin releasing hormone.

1 Downgraded 1 level - the cohort study by Brik et al. (2018) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

2 Median duration of 0.8 years (range 0.1 to 3.0). Five adolescents stopped treatment because they no longer wished to receive gender-affirming treatment for various reasons. In 4 adolescents (all transmales), although they wanted to continue treatments for gender dysphoria, GnRH analogues were stopped mainly because of adverse effects (such as mood and emotional lability).

3 Downgraded 1 level - the cohort study by Khatchadourian et al. (2014) was assessed as at high risk of bias (poor quality overall; lack of blinding, no control group and high number of participants lost to follow-up).

4 Because of transitioning to gender-affirming hormones or gender-affirming surgery, adverse effects (such as mood and emotional lability) or no longer wishing to pursue transition.

Table 8. Question 2. For children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – bone density

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Bone density: change in lumbar BMAD									
Change in lumbar spine BMAD from baseline to 1 year in transfemales									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=31	None	Mean (SD), g/cm^3 Baseline: 0.235 (0.030) 1 year: 0.233 (0.029) p=0.459 z-score Baseline: 0.859 (0.154) 1 year: −0.228 (1.027) p=0.000	IMPORTANT	VERY LOW
Change in lumbar spine BMAD from baseline to 1 year in transmales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=39	None	Mean (SD), g/cm^3 Baseline: 0.196 (0.035) 1 year: 0.201 (0.033) p=0.074 z-score Baseline: −0.186 (1.230) 1 year: −0.541 (1.396) p=0.006	IMPORTANT	VERY LOW
Change in lumbar spine BMAD from baseline to 2 years in transfemales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=10	None	Mean (SD), g/cm^3 Baseline: 0.240 (0.027) 2 years: 0.240 (0.030) p=0.865 z-score Baseline: 0.486 (0.809) 2 years: −0.279 (0.930) p=0.000	IMPORTANT	VERY LOW
Change in lumbar spine BMAD from baseline to 2 years in transmales									
1 observational study	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=21	None	Mean (SD), g/cm^3 Baseline: 0.195 (0.058) 2 years: 0.198 (0.055) p=0.433	IMPORTANT	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Joseph et al. (2019)							z-score Baseline: −0.361 (1.439) 2 years: −0.913 (1.318) p=0.001		
Change in lumbar BMAD from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales									
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=11 N=12	None	Mean (SD), g/cm^3 GnRH analogue: 0.22 (0.03) Gender-affirming hormones: 0.22 (0.02) NS z-score GnRH analogue: −0.44 (1.10) Gender-affirming hormones: −0.90 (0.80) p-value: NS	IMPORTANT	VERY LOW
Change in lumbar BMAD from starting GnRH analogue (mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales									
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=18	None	Mean (SD), g/cm^3 GnRH analogue: 0.25 (0.03) Gender-affirming hormones: 0.24 (0.02) NS z-score GnRH analogue: 0.28 (0.90) Gender-affirming hormones: −0.50 (0.81) p-value: 0.004	IMPORTANT	VERY LOW
Change in lumbar BMAD from starting GnRH analogue to starting gender-affirming hormones in transfemales (bone age of <15 years)									
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=15	None	Median (range), g/cm^3 GnRH analogue: 0.21 (0.17 to 0.25) Gender-affirming hormones: 0.20 (0.18 to 0.24)	IMPORTANT	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
							NS z-score GnRH analogue: −0.20 (−1.82 to 1.18) Gender-affirming hormones: −1.52 (−2.36 to 0.42) p-value: <0.01		
Change in lumbar BMAD from starting GnRH analogue to starting gender-affirming hormones in transfemales (bone age of ≥15)									
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=5	None	Median (range), g/cm^3 GnRH analogue: 0.22 (0.18 to 0.25) Gender-affirming hormones: 0.22 (0.19 to 0.24) NS z-score GnRH analogue: −1.18 (−1.78 to 1.09) Gender-affirming hormones: −1.15 (−2.21 to 0.08) p-value: p≤0.1	IMPORTANT	VERY LOW
Change in lumbar BMAD from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of <14 years)									
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=11	None	Median (range), g/cm^3 GnRH analogue: 0.23 (0.20 to 0.29) Gender-affirming hormones: 0.23 (0.19 to 0.28) NS z-score GnRH analogue: −0.05 (−0.78 to 2.94) Gender-affirming hormones: −0.84 (−2.20 to 0.87) p-value: ≤0.01	IMPORTANT	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Change in lumbar BMAD from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of ≥14)									
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=23	None	Median (range), g/cm3 GnRH analogue: 0.26 (0.21 to 0.29) Gender-affirming hormones: 0.24 (0.20 to 0.28) p≤0.01 z-score GnRH analogue: 0.27 (−1.60 to 1.80) Gender-affirming hormones: −0.29 (−2.28 to 0.90) p-value: p ≤ 0.01)	IMPORTANT	VERY LOW
Bone density: change in lumbar BMD									
Change in lumbar spine BMD from baseline to 1 year in transfemales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=31	None	Mean (SD), kg/m2 Baseline: 0.860 (0.154) 1 year: 0.859 (0.129) p=0.962 z-score Baseline: −0.016 (1.106) 1 year: −0.461 (1.121) p=0.003	IMPORTANT	VERY LOW
Change in lumbar spine BMD from baseline to 1 year in transmales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=39	None	Mean (SD), kg/m2 Baseline: 0.694 (0.149) 1 year: 0.718 (0.124) p=0.006 z-score Baseline: −0.395 (1.428) 1 year: −1.276 (1.410) p=0.000	IMPORTANT	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Change in lumbar spine BMD from baseline to 2 years in transfemales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=10	None	Mean (SD), kg/m2 Baseline: 0.867 (0.141) 2 years: 0.878 (0.130) p=0.395 z-score Baseline: 0.130 (0.972) 2 years: −0.890 (1.075) p=0.000	IMPORTANT	VERY LOW
Change in lumbar spine BMD from baseline to 2 years in transmales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=21	None	Mean (SD), kg/m2 Baseline: 0.695 (0.220) 2 years: 0.731 (0.209) p=0.058 z-score Baseline: −0.715 (1.406) 2 years: −2.000 (1.384) p=0.000	IMPORTANT	VERY LOW
Change in lumbar BMD from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales									
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=12 N=11	None	Mean (SD), g/m2 GnRH analogue: 0.84 (0.13) Gender-affirming hormones: 0.84 (0.11) NS z-score GnRH analogue: −0.77 (0.89) Gender-affirming hormones: −1.01 (0.98) NS	IMPORTANT	VERY LOW
Change in lumbar BMD from starting GnRH analogue (mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=18	None	Mean (SD), g/m2 GnRH analogue: 0.95 (0.12) Gender-affirming hormones: 0.91 (0.10) p-value: 0.006 z-score GnRH analogue: 0.17 (1.18) Gender-affirming hormones: −0.72 (0.99) p-value: <0.001	IMPORTANT	VERY LOW
Bone density: change in femoral neck (hip) BMD									
Change in femoral neck BMD from baseline to 1 year in transfemales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=31	None	Mean (SD), kg/m2 Baseline: 0.894 (0.118) 1 year: 0.905 (0.104) p=0.571 z-score Baseline: 0.157 (0.905) 1 year: −0.340 (0.816) p=0.002	IMPORTANT	VERY LOW
Change from baseline to 1 year in femoral neck BMD in transmales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=39	None	Mean (SD), kg/m2 Baseline: 0.772 (0.137) 1 year: 0.785 (0.120) p=0.797 z-score Baseline: −0.863 (1.215) 1 year: −1.440 (1.075) p=0.000	IMPORTANT	VERY LOW
Change from baseline to 2 years in femoral neck BMD in transfemales									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=10	None	Mean (SD), kg/m2 Baseline: 0.920 (0.116) 2 years: 0.910 (0.125) p=0.402 z-score Baseline: 0.450 (0.781) 2 years: −0.600 (1.059) p=0.002	IMPORTANT	VERY LOW
Change from baseline to 2 years in femoral neck BMD in transmales									
1 observational study Joseph et al. (2019)	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=21	None	Mean (SD), kg/m2 Baseline: 0.766 (0.215) 2 years: 0.773 (0.197) p=0.604 z-score Baseline: −1.075 (1.145) 2 years: −1.779 (0.816) p=0.001	IMPORTANT	VERY LOW
Bone density: change in femoral neck (hip) BMAD									
Change from starting GnRH analogue to starting gender-affirming hormones in femoral neck BMAD in transfemales (bone age of <15 years)									
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=16	None	Median (range), g/cm3 GnRH analogue: 0.29 (0.20 to 0.33) Gender-affirming hormones: 0.27 (0.20 to 0.33) p≤0.1 z-score GnRH analogue: −0.71 (−3.35 to 0.37) Gender-affirming hormones: −1.32 (−3.39 to 0.21) p≤0.1	IMPORTANT	VERY LOW
Change in femoral neck BMAD from starting GnRH analogue to starting gender-affirming hormones in transfemales (bone age of ≥15)									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=6	None	Median (range), g/cm3 GnRH analogue: 0.30 (0.26 to 0.36) Gender-affirming hormones: 0.30 (0.26 to 0.34) NS z-score GnRH analogue: −0.44 (−1.37 to 0.93) Gender-affirming hormones: −0.36 (−1.50 to 0.46) NS	IMPORTANT	VERY LOW
Change in femoral neck BMAD from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of <14 years)									
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=10	None	Median (range), g/cm3 GnRH analogue: 0.31 (0.26 to 0.36) Gender-affirming hormones: 0.30 (0.22 to 0.35) NS z-score GnRH analogue: −0.01 (−1.30 to 0.91) Gender-affirming hormones: −0.37 (−2.28 to 0.47) NS	IMPORTANT	VERY LOW
Change in femoral neck BMAD from starting GnRH analogue to starting gender-affirming hormones in transmales (bone age of ≥14)									
1 observational study Vlot et al. 2017	Serious limitations[3]	No serious indirectness	Not applicable	Not calculable	N=23	None	Median (range), g/cm3 GnRH analogue: 0.33 (0.25 to 0.39) Gender-affirming hormones: 0.30 (0.23 to 0.41) p-value: ≤0.01 z-score	IMPORTANT	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
							GnRH analogue: 0.27 (−1.39 to 1.32) Gender-affirming hormones: −0.27 (−1.91 to 1.29) p-value: ≤0.01		
Bone density: change in femoral area BMD									
Change in femoral BMD from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales									
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=14 N=6	None	Mean (SD), g/m2 GnRH analogue: 0.88 (0.12) Gender-affirming hormones: 0.87 (0.08) NS z-score GnRH analogue: −0.66 (0.77) Gender-affirming hormones: −0.95 (0.63) NS	IMPORTANT	VERY LOW
Change in femoral BMD from starting GnRH analogue (mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales									
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=18 N=13	None	Mean (SD), g/m2 GnRH analogue: 0.92 (0.10) Gender-affirming hormones: 0.88 (0.09) p-value: 0.005 z-score GnRH analogue: 0.36 (0.88) Gender-affirming hormones: −0.35 (0.79) p-value: 0.001	IMPORTANT	VERY LOW
Bone density: change in femoral area BMAD									
Change in femoral BMAD from starting GnRH analogue (mean age 14.9±1.9) to starting gender-affirming hormones (mean age 16.6±1.4) in transfemales									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=12 N=10	None	Mean (SD), g/cm3 GnRH analogue: 0.28 (0.04) Gender-affirming hormones: 0.26 (0.04) NS z-score GnRH analogue: −0.93 (1.22) Gender-affirming hormones: −1.57 (1.74) p-value: NS	IMPORTANT	VERY LOW
Change in femoral BMAD from starting GnRH analogue (mean age 15.0±2.0) to starting gender-affirming hormones (mean age 16.4±2.3) in transmales									
1 observational study Klink et al. 2015	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable	N=18 N=18	None	Mean (SD), g/cm3 GnRH analogue: 0.32 (0.04) Gender-affirming hormones: 0.31 (0.04) NS z-score GnRH analogue: 0.01 (0.70) Gender-affirming hormones: −0.28 (0.74) NS	IMPORTANT	VERY LOW

Abbreviations: BMAD, bone mineral apparent density; BMD, bone mineral density; GnRH, gonadotrophin releasing hormone; NS, not significant; SD, standard deviation.

1 Downgraded 1 level - the cohort study by Joseph et al. (2019) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

2 Downgraded 1 level - the cohort study by Klink et al. (2015) was assessed as at high risk of bias (poor quality overall; lack of blinding, no randomisation, no control group and high number of participants lost to follow-up).

3 Downgraded 1 level - the cohort study by Vlot et al. (2017) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control).

Table 9 Question 2: For children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – cognitive development or functioning

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Cognitive development or functioning (1 cross-sectional study)									
IQ (4 subscales: arithmetic, vocabulary, picture arrangement, and block design) at a single time point between GnRH analogue treated and untreated transfemales									
1 Cross-sectional study Staphorsius et al. 2015	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=8 Mean (SD) 94.0 (10.3)	N=10 Mean (SD) 109.4 (21.2)	NR	IMPORTANT	VERY LOW
IQ (4 subscales: arithmetic, vocabulary, picture arrangement, and block design) at a single time point between GnRH analogue treated and untreated transmales									
1 Cross-sectional study Staphorsius et al. 2015	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=12 Mean (SD) 95.8 (15.6)	N=10 Mean (SD) 98.5 (15.9)	NR	IMPORTANT	VERY LOW
Reaction time at a single time point between GnRH analogue treated and untreated transfemales									
1 Cross-sectional study Staphorsius et al. 2015	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=8 Mean (SD) 10.9 (4.1)	N=10 Mean (SD) 9.9 (3.1)	NR	IMPORTANT	VERY LOW
Reaction time at a single time point between GnRH analogue treated and untreated transmales									
1 Cross-sectional study	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=12 Mean (SD) 9.9 (3.1)	N=10 Mean (SD) 10.0 (2.0)	NR	IMPORTANT	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Staphorsius et al. 2015									
Accuracy at a single time point between GnRH analogue treated and untreated transfemales									
1 cohort study Staphorsius et al. 2015	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=8 Mean (SD) 73.9 (9.1)	N=10 Mean (SD) 83.4 (9.5)	NR	IMPORTANT	VERY LOW
Accuracy at a single time point between GnRH analogue treated and untreated transmales									
1 cohort study Staphorsius et al. 2015	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=12 Mean (SD) 85.7 (10.5)	N=10 Mean (SD) 88.8 (9.7)	NR	IMPORTANT	VERY LOW

Abbreviations: GnRH, gonadotrophin releasing hormone; NR, not reported; *P*, P-value; SD, Standard deviation.

1 Downgraded 1 level - the cohort study by Staphorsius et al. (2015) was assessed as at high risk of bias (poor quality overall; lack of blinding and no randomisation).

Table 10: Question 2: In children and adolescents with gender dysphoria, what is the short-term and long-term safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? – other safety outcomes

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
Other safety outcomes: change in serum creatinine									
Change in serum creatinine (micromol/l) between baseline and 1 year in transfemales									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients% (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Intervention	Comparator	Result		
1 observational study Schagen et al. 2016	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=28	None	Mean (SD) Baseline: 70 (12) 1 year: 66 (13) p-value: 0.20	IMPORTANT	VERY LOW
Change in serum creatinine (µmol/l) between baseline and 1 year in transmales									
1 observational study Schagen et al. 2016	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	N=29	None	Mean (SD) Baseline: 73 (8) 1 year: 68 (13) p-value: 0.01	IMPORTANT	VERY LOW
Other safety outcomes: liver enzymes									
Presence of elevated liver enzymes (AST, ALT, and glutamyl transferase) between baseline and during treatment									
1 observational study Schagen et al. 2016	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	39	None	Glutamyl transferase was not elevated at baseline or during treatment in any subject. Mild elevations of AST and ALT above the reference range were present at baseline but were not more prevalent during treatment than at baseline. Glutamyl transferase, AST, and ALT levels did not significantly change from baseline to 12 months of treatment.	IMPORTANT	VERY LOW
Other safety outcomes: adverse effects									
Proportion of patients reporting adverse effects									
1 cohort study Khatchadourian et al 2014	Serious limitations[2]	No serious indirectness	Not applicable	Not calculable[2]	27	None	3/27 adolescents[3]	Important	VERY LOW

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; GnRH, gonadotrophin releasing hormone; P, P-value; SD, standard deviation.

1 Downgraded 1 level - the cohort study by Schagen et al. (2016) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control).

2 Downgraded 1 level - the cohort study by Khatchadourian et al. (2014) was assessed as at high risk of bias (poor quality overall; lack of blinding, no control group and high number of participants lost to follow-up).

3 1 transmale developed sterile abscesses; they were switched from leuprolide acetate to triptorelin, and this was well tolerated. 1 transmale developed leg pains and headaches, which eventually resolved without treatment. 1 participant gained 19 kg within 9 months of initiating GnRH analogues.

Table 11: Question 4. From the evidence selected, are there any subgroups of children and adolescents with gender dysphoria that may derive more (or less) advantage from treatment with GnRH analogues than the wider population of children and adolescents with gender dysphoria? – critical outcomes

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Sex assigned at birth males	Sex assigned at birth females	Result		
Subgroups: sex assigned at birth males compared with sex assigned at birth females									
Impact on gender dysphoria									
Mean [±SD] Utrecht Gender Dysphoria Scale (version(s) not reported), time point at baseline (before GnRHa) versus follow-up (just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[2] score at T0 47.95 [±9.70] score at T1 49.67 [±9.47]	n-NR[2] score at T0 56.57 [±3.89] score at T1 56.62 [±4.0]	*F*-ratio 15.98 (*df, errdf*: 1,39), *P*<0.001	Critical	VERY LOW
Impact on mental health									
Mean [±SD] Beck Depression Inventory-II, time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Sex assigned at birth males	Sex assigned at birth females	Result		
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[2] score at T0 5.71 [±4.31] score at T1 3.50 [±4.58]	n-NR[2] score at T0 10.34 [±8.24] score at T1 6.09 [±7.93]	*F*-ratio 3.85 (*df, errdf*: 1,39), *P*=0.057	Critical	VERY LOW
Mean [±SD] Trait Anger (TPI), time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[2] score at T0 5.22 [±2.76] score at T1 5.00 [±3.07]	n-NR[2] score at T0 6.43 [±2.78] score at T1 6.39 [±2.59]	*F*-ratio 5.70 (*df, errdf*: 1,39), *P*=0.022	Critical	VERY LOW
Mean [±SD] Trait Anxiety (STAI), time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[2] score at T0 4.33 [±2.68] score at T1 4.39 [±2.64]	n-NR[2] score at T0 7.00 [±2.36] score at T1 6.17 [±2.69]	*F*-ratio 16.07 (*df, errdf*: 1,39), *P*<0.001	Critical	VERY LOW

Abbreviations: GnRH, gonadotrophin releasing hormone; NR, not reported; *P*, P-value; SD, Standard deviation.

1 Downgraded 1 level - the cohort study by de Vries et al. (2011) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

2 The overall sample size completing the outcome at both time points was 41.

Table 11: Question: 4. From the evidence selected, are there any subgroups of children and adolescents with gender dysphoria that may derive more (or less) advantage from treatment with GnRH analogues than the wider population of children and adolescents with gender dysphoria? – important outcomes

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Sex assigned at birth males	Sex assigned at birth females	Result		
Subgroups: sex assigned at birth males compared with sex assigned at birth females									
Impact on body image									
Mean [±SD] Body Image Scale (primary sexual characteristics), time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[2] score at T0 4.02 [±0.16] score at T1 3.74 [±0.78]	n-NR[2] score at T0 4.16 [±0.52] score at T1 4.17 [±0.58]	*F*-ratio 4.11 (*df, errdf*: 1,55), *P*=0.047	Important	VERY LOW
Mean [±SD] Body Image Scale (secondary sexual characteristics), time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[2] score at T0 2.66 [±0.50] score at T1 2.39 [±0.69]	n-NR[2] score at T0 2.81 [±0.76] score at T1 3.18 [±0.42]	*F*-ratio 11.57 (*df, errdf*: 1,55), *P*=0.001[3]	Important	VERY LOW
Mean [±SD] Body Image Scale (neutral characteristics), time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Sex assigned at birth males	Sex assigned at birth females	Result		
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[2] score at T0 2.60 [±0.58] score at T1 2.32 [±0.59]	n-NR[2] score at T0 2.24 [±0.62] score at T1 2.61 [±0.50]	*F*-ratio 0.081 (*df, errdf*: 1,55), *P*=0.777[3]	Important	VERY LOW
Psychosocial impact									
Mean [±SD] Children's Global Assessment Scale score, at baseline.									
1 cohort study Costa et al 2015	Serious limitations[4]	No serious indirectness	No serious inconsistency	Not calculable	n=not reported 55.4 [±12.7]	n=not reported 59.2 [±11.8]	*t*-test 2.15; *P*=0.03[5]	Important	VERY LOW
Mean [±SD] Children's Global Assessment Scale score, time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[6] score at T0 73.10 [±8.84] score at T1 77.33 [±8.69]	n-NR[6] score at T0 67.25 [±11.06] score at T1 70.30 [±9.44]	*F*-ratio 5.77 (*df, errdf*: 1,39), *P*=0.021	Important	VERY LOW
Mean [±SD] Child Behaviour Checklist (total T) score, time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[7] score at T0 59.42 [±11.78] score at T1 50.38	n-NR[7] score at T0 61.73 [±13.60]	*F*-ratio 2.64 (*df, errdf*: 1,52), *P=0.110*	Important	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Sex assigned at birth males	Sex assigned at birth females	Result		
					[±10.57]	score at T1 57.73 [±10.82]			
Mean [±SD] Child Behaviour Checklist (internalising T) score, time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[7] score at T0 60.00 [±9.51] score at T1 52.17 [±9.81]	n-NR[7] score at T0 61.80 [±14.12] score at T1 56.30 [±10.33]	*F*-ratio 1.16 (*df, errdf*: 1,52), *P*=0.286	Important	VERY LOW
Mean [±SD] Child Behaviour Checklist (externalising T) score, time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[7] score at T0 54.71 [±12.91] score at T1 48.75 [±10.22]	n-NR[7] score at T0 60.70 [±12.64] score at T1 57.87 [±11.66]	*F*-ratio 6.29 (*df, errdf*: 1,52), *P*=0.015	Important	VERY LOW
Mean [±SD] Youth Self-Report (total T) score, time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[7] score at T0 53.56 [±12.26] score at T1 47.84 [±10.86]	n-NR[7] score at T0 57.10 [±10.87] score at T1 51.86 [±10.11]	*F*-ratio 1.99 (*df, errdf*: 1,52), *P*=0.164	Important	VERY LOW

QUALITY					Summary of findings			IMPORTANCE	CERTAINTY
					No of events/No of patients (n/N%)		Effect		
Study	Risk of bias	Indirectness	Inconsistency	Imprecision	Sex assigned at birth males	Sex assigned at birth females	Result		
Mean [±SD] Youth Self-Report (internalising T) score, time point at baseline (T0 before GnRH analogues) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[7] score at T0 55.88 [±11.81] score at T1 49.24 [±12.24]	n-NR[7] score at T0 56.17 [±13.25] score at T1 50.24 [±11.28]	*F*-ratio 0.049 (*df, errdf*: 1,52), *P*=0.825	Important	VERY LOW
Mean [±SD] Youth Self-Report (externalising T) score, time point at baseline (T0 before GnRHa) versus follow-up (T1 just before gender-affirming hormones).									
1 cohort study de Vries et al 2011	Serious limitations[1]	No serious indirectness	Not applicable	Not calculable	n-NR[7] score at T0 48.72 [±11.83] score at T1 46.52 [±9.23]	n-NR[7] score at T0 57.24 [±10.59] score at T1 52.97 [±8.51]	*F*-ratio 9.14 (*df, errdf*: 1,52), *P*=0.004	Important	VERY LOW

Abbreviations: GnRH, gonadotrophin releasing hormone; NR, not reported; *P*, P-value; SD, Standard deviation.

1 Downgraded 1 level - the cohort study by de Vries et al. (2011) was assessed as at high risk of bias (poor quality overall; lack of blinding and no control group).

2 The overall sample size completing the outcome at both time points was 57.

3 There was a significant interaction effect between sex assigned at birth and BDI between T0 and T1; sex assigned at birth females became more dissatisfied with their secondary F (df, errdf), P: 14.59 (1,55), P<0.001) and neutral F (df, errdf), P: 15.26 (1,55), P<0.001) sex characteristics compared with sex assigned at birth males.

4 Serious limitations – the cohort study by Costa et al. 2015 was assessed as at high risk of bias (poor quality).

5 At baseline, CGAS scores were not associated with any demographic variable, in both sex assigned at birth males and females. There were no statistically significant differences in CGAS scores between gender dysphoric sex assigned at birth males and females in all follow-up evaluations (P>0.1; full data not reported).

6 The overall sample size completing the outcome at both time points was 41

7 The overall sample size completing the outcome at both time points was 54.

Glossary

Beck Depression Inventory-II (BDI-II)	The BDI-II is a tool for assessing depressive symptoms. There are no specific scores to categorise depression severity, but it is suggested that 0 to 13 is minimal symptoms, 14 to 19 is mild depression, 20 to 28 is moderate depression, and severe depression is 29 to 63.
Body Image Scale (BIS)	The BIS is used to measure body satisfaction. The scale consists of 30 body features, which the person rates on a 5-point scale. Each of the 30 items falls into one of 3 basic groups based on its relative importance as a gender-defining body feature: primary sex characteristics, secondary sex characteristics, and neutral body characteristics. A higher score indicates more dissatisfaction.
Bone mineral apparent density (BMAD)	BMAD is a size adjusted value of bone mineral density (BMD) incorporating body size measurements using UK norms in growing adolescents.
Child Behaviour Checklist (CBCL)	CBCL is a checklist parents complete to detect emotional and behavioural problems in children and adolescents.
Children's Global Assessment Scale (CGAS)	The CGAS tool is a validated measure of global functioning on a single rating scale from 1 to 100. Lower scores indicate poorer functioning.
Gender	The roles, behaviours, activities, attributes, and opportunities that any society considers appropriate for girls and boys, and women and men.
Gender dysphoria	Discomfort or distress that is caused by a discrepancy between a person's gender identity (how they see themselves regarding their gender) and that person's sex assigned at birth (and the associated gender role, and/or primary and secondary sex characteristics).
Gonadotrophin releasing hormone (GnRH) analogues	GnRH analogues competitively block GnRH receptors to prevent the spontaneous release of 2 gonadotropin hormones, Follicular Stimulating Hormone (FSH) and Luteinising Hormone (LH) from the pituitary gland. The reduction in FSH and LH secretion reduces oestradiol secretion from the ovaries in those whose sex assigned at birth was female and testosterone secretion from the testes in those whose sex assigned at birth was male.
Sex assigned at birth	Sex assigned at birth (male or female) is a biological term and is based on genes and how external and internal sex and reproductive organs work and respond to hormones. Sex is the label that is recorded when a baby's birth is registered.
Tanner stage	Tanner staging is a scale of physical development.
Trait Anger Spielberger scales of the State-Trait Personality Inventory (TPI)	The TPI is a validated 20-item inventory tool which measures the intensity of anger as the disposition to experience angry feelings as a personality trait. Higher scores indicate greater anger.
Transgender (including transmale and transfemale)	Transgender is a term for someone whose gender identity is not congruent with their birth-registered sex. A transmale is a person who identifies as male and a transfemale is a person who identifies as female.

Utrecht Gender Dysphoria Scale (UGDS)	The UGDS is a validated screening tool for both adolescents and adults to assess gender dysphoria. It consists of 12 items, to be answered on a 1- to 5-point scale, resulting in a sum score between 12 and 60. The higher the UGDS score the greater the impact on gender dysphoria.
Youth Self-Report (YSR)	The self-administered YSR is a checklist to detect emotional and behavioural problems in children and adolescents. It is self-completed by the child or adolescent. The scales consist of a Total problems score, which is the sum of the scores of all the problem items. An internalising problem scale sums the anxious/depressed, withdrawn-depressed, and somatic complaints scores while the externalising problem scale combines rule-breaking and aggressive behaviour.

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To: (b)(6) (b)(6) (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (b)(6) (b)(6) (b)(6)

Subject: RE: NEED YOUR INPUT (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Date: 2022/11/21 10:08:00

Priority: Normal

Type: Note

Fascinating – your recommendation sounds good.

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Senior Advisor to the Director
Phone: (b)(6) (b)(6)
Email: (b)(6)

From: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Thursday, November 17, 2022 7:14 PM
To: (b) (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: NEED YOUR INPUT: (b)(6); (b)(7)(C) (b)(6); (b)(7)(C)

Hi (b)(6)

(b)(6); (b)(7)(C)

- • Case Summary:

(b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

Thanks, (b)(6)

From: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Sent: Thursday, November 17, 2022 6:46 PM
To: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: (b)(6); (b)(7)(C)

(b)(6); (b)(7)(C)

ALLEGATION:

(b)(6); (b)(7)(C)

From: Cameron, Emily (OS/OCR) <Emily.Cameron@hhs.gov>
Sent: Wednesday, November 16, 2022 5:29 PM
To: (b)(6) (b)(6) (HHS/OCR) (b)(6)
Subject: (b)(6); (b)(7)(C)

Hello,

(b)(6); (b)(7)(C)

Thanks for your help!

Emily Cameron, JD
She/Her
Supervisory Equal Opportunity Specialist
U.S. Department of Health &Human Services
Office for Civil Rights
Southwest Region • 1301 Young Street
Suite 106 - 1130 • Dallas, TX 75202
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Recipient:	(b)(6) (b)(6 (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (b)(6) (b)(6) (b)(6)
Sent Date:	2022/11/21 10:08:24
Delivered Date:	2022/11/21 10:08:00

From: (b)(6) (b)(6) (HHS/OCR) </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0BDEC12AD0974EACABABE032F2B37C91-(b)(6)

To: Seeger, Rachel (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3090ef9b170d45969add4ff475a95583-Rachel Seeg <Rachel.Seeger@hhs.gov>

Subject: RE: Texas Transgender 'Abuse' Policy Portends Biden Investigation [Bloomberg Law, 03/10/2022]

Date: 2022/03/10 09:41:00

Priority: Normal

Type: Note

Thank you!

(b)(6) (b)(6) (b) (b)(6) Esq., MSW (she/her)
Phone: (b)(6) (b)(6)
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From: Seeger, Rachel (HHS/OCR) <Rachel.Seeger@hhs.gov>
Sent: Thursday, March 10, 2022 9:13 AM
To: Rainer, Melanie Fontes (OS/IOS) <Melanie.Rainer@hhs.gov>; (b) (b)(6) (b)(6) (HHS/OCR) (b)(6) Schuham, Aaron (HHS/OGC) <Aaron.Schuham@hhs.gov>; Rodriguez, Paul (HHS/OGC) <PaulR.Rodriguez@hhs.gov>; Greenberg, Mark H (HHS/OGC) <MarkH.Greenberg@hhs.gov>
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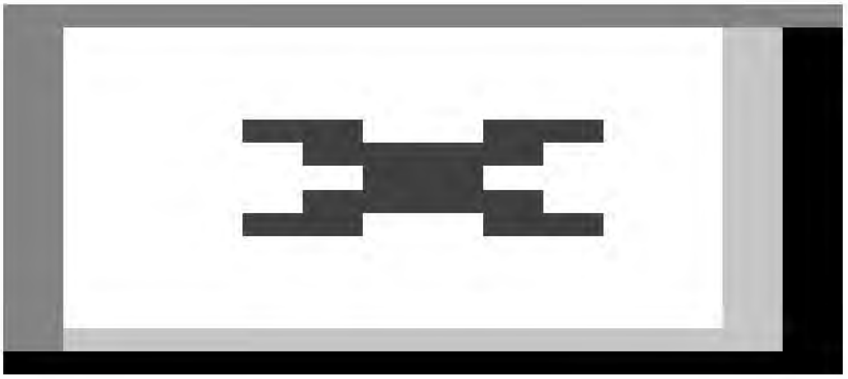
Subject: Texas Transgender 'Abuse' Policy Portends Biden Investigation [Bloomberg Law, 03/10/2022]

Texas Transgender 'Abuse' Policy Portends Biden Investigation: [Bloomberg Law (Shira Stein), 03/10/2022]



A person takes a picture of an Inclusive Pride flag and a rainbow flag at the Stonewall National Monument, the first US national monument dedicated to LGBTQ history and rights, marking the birthplace of the modern lesbian, gay, bisexual, transgender, and queer civil rights movement, on June 1, 2020 in New York City. ANGELA WEISS/AFP via Getty Images

Texas Transgender 'Abuse' Policy Portends Biden Investigation

March 10, 2022, 5:40 AM

- Biden administration says state policy violates federal law
- Options for HHS response are limited, but DOJ could intervene

The administration has just two options to stop Texas from investigating families for child abuse if they are suspected of seeking gender-affirming care for transgender children—pulling federal health funding or suing the state.

Attorneys say both options are likely being discussed at the Departments of Justice and Health and Human Services, especially in light of strong statements and guidance opposing the state's actions by President Joe Biden and his agencies March 2.

A Texas judge last week issued an injunction against the state's child protective services agency temporarily blocking it from investigating the parents of a transgender teen for alleged child abuse.

Opponents of the Texas policy are waiting for more federal actions. New York Attorney General Letitia James called on the DOJ Wednesday to investigate Texas Gov. Greg Abbott's policy.

Advocates and former HHS officials said the likely road for the administration is an HHS or DOJ investigation and possible DOJ involvement in the ongoing litigation. Withdrawal of federal health funds for an entire state agency is possible, but it would be a "nuclear option," said Leon Rodriguez, who ran the HHS's Office of Civil Rights (OCR) under President Barack Obama. He's now a partner as Seyfarth Shaw LLP.

The OCR enforces Section 1557 of the Affordable Care Act, which "prohibits discrimination on the basis of race, color, national origin, sex, age, and disability in covered health programs or activities." It typically handles complaints about actions of individual health providers or hospitals. It rarely uses its enforcement power against an entire state's policy.

"Short of litigating or initiating funding removal or withdrawal proceedings, there's not a whole lot in their toolkit said Joseph Wardenski, a former DOJ civil rights attorney.

A supporter of Texas's authority says the Biden administration is going too far by including transgender issues in the ACA's nondiscrimination clause. "I see no basis for them to be able to enforce Section 1557 against any state by reinterpreting sex to cover something that is not in the statute, which is what it sounds like they're trying to," said Roger Severino, former Trump administration OCR director. "They're on thin ice in their announcement suggesting they have an authority that is actually blocked by court injunctions."

But, other observers like Katie Keith, director of the health policy and the law initiative at Georgetown Law's O'Neill Institute, pointed out that the injunctions are fairly narrow and only applied to specific plaintiffs.

"I suspect the Administration is carefully weighing what else they can do and how quickly they can do it, looking for the widest positive impact while not creating challenges in other lawsuits," Laura Durso, who was OCR chief of staff until earlier this year, said in an email.

The HHS actions thus far "made crystal clear that any enforcement of this policy violates multiple federal laws. In addition, HHS also mobilized its own law enforcement

arm and invited parents who are targeted by this policy to bring individual complaints to HHS," said Shannon Minter, legal director for the National Center for Lesbian Rights.

Gender-affirming care for children with gender dysphoria often includes puberty blocking drugs, which are reversible. Sex hormone treatment isn't recommended until around the age of 16, when a minor has the mental capacity to give informed consent, under the Endocrine Society's medical guidelines. And genital surgeries aren't recommended, and typically aren't available, until a patient has reached the age of 18.

Call for Complaints

HHS Secretary Xavier Becerra put out a rare call March 2 asking people in Texas to file complaints if they believe they were "being targeted by a child welfare investigation because of this discriminatory gubernatorial order."
This is the "clearest invitation I've ever seen to a marginalized population to file complaints," said Matthew Cortland, a senior resident fellow at Data for Progress working on disability and health care.

Getting these complaints would not only help the agency investigate allegations of federal law violations, but it could also help the agency as it prepares to come out with a new 1557 regulation.

Severino said a new regulation is the OCR's only option. "The only way I see for HHS to do anything in enforcement on gender identity is to pass a new regulation that would have to be upheld in court."

Regulations from both the Obama administration and Trump administration implementing Section 1557 are still tied up in court. Those court cases found that the word "sex" could not be interpreted to include gender identity in the regulations. However, the Biden administration announcedin May 2021 that it would interpret "sex" in the statute itself to include gender identity in light of the Supreme Court's finding in Bostock v. Clayton County.
Complaint data "would give OCR more of a record to come out more strongly in rulemaking if they got a bunch of complaints," said Keith. That could lead to policies that "more directly combat" the actions by Texas and others like it.

Once the agency receives a complaint, it can investigate. If the OCR finds a civil rights violation occurred, it can file a complaint with an HHS administrative law judge. If the

judge finds a violation, the HHS then has the authority to order various streams of federal funding be withheld, said Rodriguez.

The option to remove federal funds has "almost never been used. We only used it once during the time that I was director," and that was against an individual, he said

What "makes it a really brutal penalty is that it's everything. So there's no sliding scale here, there's no sentencing guidelines. This is a 100% withhold if it is implemented," Rodriguez said.

Lawsuit Involvement

The Biden administration could get involved in one other major way—a lawsuit.

The DOJ is probably waiting to see what happens in the Texas courts before getting involved. The existing case, backed by the ACLU and Lambda Legal, is going well so far for the plaintiffs, Wardenski said.

"Part of why the guidance OCR released is so powerful is that every move they make on this issue is heavily scrutinized and will brought up in court," Durso said.

The DOJ could also file a statement of interest in this case, like it did in Arkansas when the state passed a law prohibiting gender-affirming care for transgender children, Keith said
The ACLU will be able to use the HHS guidance in its case, Cortland said. "HHS clearly staked out a position that providing supportive medical care to trans children is not abuse."

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To contact the editor responsible for this story: Fawn Johnson
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Other coverage from the Bulletin:

Texas Loses Appeal Over Investigation Of Family Of Transgender Teen, Files Lawsuit Against HHS.

The AP (3/9, DeMillo) reports, "A Texas court on Wednesday tossed out the state's appeal of an order preventing child welfare officials from investigating the parents of a

transgender teenager over gender-confirming care the youth received." The court "dismissed Republican Attorney General Ken Paxton's appeal of the temporary order a judge issued last week halting the investigation by the Department of Family and Protective Services into the parents of the 16-year-old girl." Meanwhile, "Paxton on Wednesday also filed a challenge in federal court to guidance that President Joe Biden's administration issued in response to the Texas governor's directive."

CNN (3/9, Rose, Maxouris, 89.21M) reports, "On March 2, the US Department of Health and Human Services released guidance saying healthcare providers who report families seeking gender-affirming care or refuse to provide treatment may be violating federal law," with HHS Secretary Xavier Becerra adding in a statement, "HHS will take immediate action if needed." However, "in its federal court filing Wednesday, Texas argued federal protections over care for transgender youth are an 'erroneous interpretation of federal law' and said the guidance threatens state agencies with losing funding if they don't abide by the 'HHS's misinterpretation of their obligations' under the law."

The Hill (3/9, Dress, 5.69M) and the Texas Tribune (3/9, Park, 258K) also report.

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Recipient: Seeger, Rachel (HHS/OCR) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3090ef9b170d45969add4ff475a95583-Rachel Seeg <Rachel.Seeger@hhs.gov>

Sent Date: 2022/03/10 09:41:33

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