Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

June 13-14, 2024

NVAC

June 13, 2024

OPENING REMARKS

Admiral Rachel L. Levine

Assistant Secretary for Health

NVAC

June 13, 2024

CHAIR'S WELCOME

Robert H. Hopkins, Jr., MD, MACP, FAAP
Chair, National Vaccine Advisory Committee

NVAC

Housekeeping and Meeting Minutes

- The meeting is recorded and streamed, so statements made are on the record and may be included in the meeting minutes.
  - **Webcast:** www.hhs.gov/live

- Before speaking, please ensure you are not muted and identify yourself.
- Please speak clearly and mute yourself when not speaking.
- For the members and speakers attending remotely, you are encouraged to be on camera when speaking. Please stop sharing video when not speaking.

Meeting Highlights: June 13

- Being Ready for a Rapid Response: A Proactive Discussion of Production Capabilities
- Pride, Equity, and Community: Mpox Vaccination in 2024
- Fall and Winter Respiratory Diseases: The Vaccination Season Ahead
- Outbreak Update: Measles Cases in Illinois
- Breast Cancer Vaccine Innovations in the Works
- Public Comment
- **Adjourn 4:30 PM Eastern**

Meeting Highlights: June 14

- Immunization Data: Innovations, Improvements, and Updates
- Saluting Global Immunization Efforts: 154+ Million Lives Saved
- Research Review: An Eye-Opening Study on Switching Arms Between COVID-19 Vaccine Doses
- Federal Agency and Liaison Member Updates
- Towards an Updated National Strategy: Progress and Priorities
- Public Comments
- **Adjourn 2:30 PM Eastern**

Public Comments

- Verbal comments are scheduled for 4:15 p.m., Eastern Time today and 2:15 p.m., Eastern tomorrow
  - Please limit all verbal comments to 3 minutes in length.
- Submit written comments to nvac@hhs.gov
  - You may submit written comments. Written comments should not exceed 3 pages in length.
  - Requests for public comment should be sent to NVAC@hhs.gov at least 5 days in advance of a scheduled public meeting.

Upcoming Meetings

- September 12-13, 2024

Learn more: www.hhs.gov/vaccines/nvac

Being Ready for a Rapid Response: A Proactive Discussion of Production Capabilities

Dr. Christine Oshansky
Dr. Lorna Meldrum
Julian Ritchey

NVAC

ASPR
ADMINISTRATION FOR STRATEGIC PREPAREDNESS AND RESPONSE

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
BARDA

Vaccines for Pandemic Influenza Preparedness and Response

Christine Oshansky, Ph.D.

Influenza and Emerging Infectious Diseases Division (**IEIDD**)

Biomedical Advanced Research and Development Authority (**BARDA**)

National Vaccine Advisory Committee Meeting

13 June 2024

ASPR's mission:
Assist the country in **preparing for**, **responding to**, and **recovering from** public health emergencies and disasters.

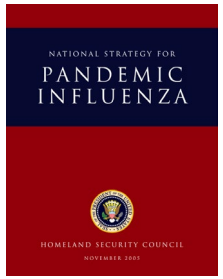
The BARDA Model

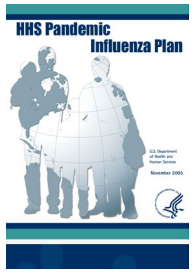
BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.

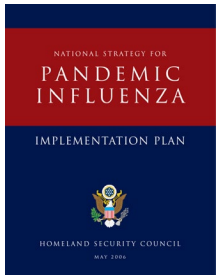
- Flexible, nimble authorities
- Multi-year funding
- Cutting edge expertise
- Facilitate partnerships
- Promote innovation

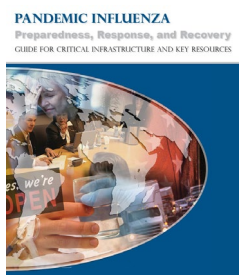
Pandemic Preparedness Policy

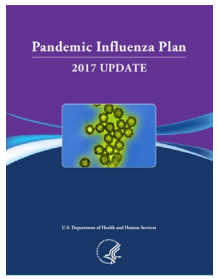
- USG has established several pandemic preparedness goals under plans, such as

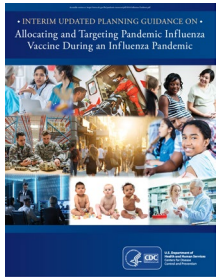


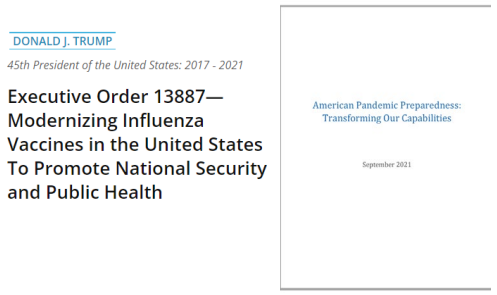


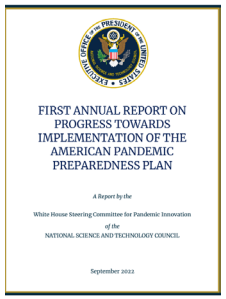


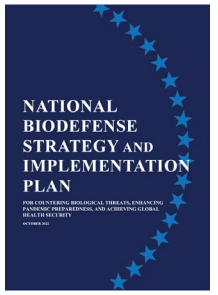


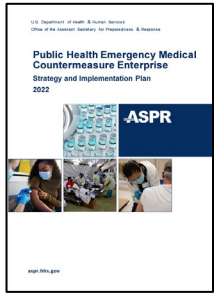












- These goals include:
  - Maintaining enough potentially pandemic influenza antigen and adjuvants to rapidly formulate and deploy vaccine to vaccinate 26 million persons in the highest priority population groups identified by CDC (Tier 1 group)
  - Delivery of first finished doses of pandemic vaccine within 3 months of a pandemic declaration
  - Having a sufficient supply to meet public demand within 4 months of a pandemic declaration
  - Manufacture, fill, finish, release, and deliver enough adjuvanted vaccine for the entire U.S. population within 6 months of PHE declaration (i.e., 660M doses) – two doses for every person

Goal 1: Preparedness: Rapidly develop safe, effective medical countermeasures accessible to all Americans

Goal 2: Response: Enhance and maintain a sustainable, mission-ready response posture

Goal 3: Partnerships Leverage Support Services Leverage mechanisms to foster flexible partnerships

U.S. Pandemic Influenza Vaccine Response Capabilities: Leveraging Success

	2005	2017-2019	2023-
Pandemic Preparedness Level	» No effective capability	» 1st dose (known virus): 2-3 mo » 1st dose (novel virus): 4-5 mo » 660M doses: ~7 mo » Full immunization (2-dose): 9 mo	**GOALS (for any new virus)** » <100 days to 1st dose (from date sequence is available) » 120 days to meet U.S. population needs » Faster distribution/administration » Increased/broader efficacy
U.S. Flu Vaccine Infrastructure	» Two U.S.-licensed seasonal » One U.S.-based manufacturer » One technology *(egg-based inactivated)* » One formulation *(15 ug/dose trivalent)* » No pandemic vaccine data	» Multiple licensed seasonal » 3 U.S.-based manufacturers » 3 technologies » Multiple seasonal formulations » FDA-licensed pandemic vx » Stockpiled pandemic vx components	**INITIATIVES**: » Fast vaccine platforms (e.g., RNA) » Alternative delivery technology » More temp-stable formulations » Single-dose formulation » Broadly priming vaccine (Pan Flu) » U.S.-based manufacturing capacity for new technologies

COVID-19

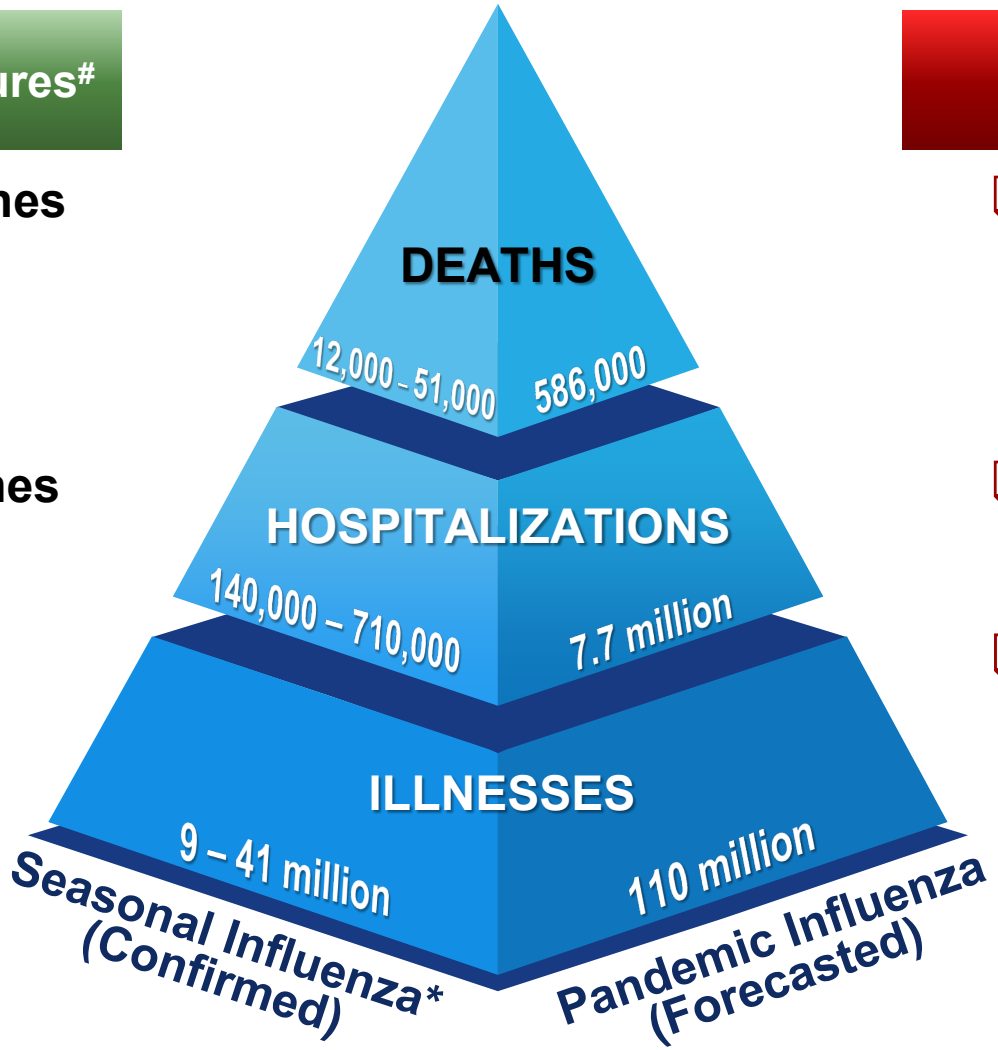
Influenza Readiness and Response Gaps

Available Medical Countermeasures#

☑ **Pandemic Influenza Vaccines**
- » CSL Seqirus AUDENZ
- » GSK H5N1 Vaccine
- » sanofi H5N1 Vaccine

☑ **Seasonal Influenza Vaccines**
- » Many licensed vaccines

☑ **Outpatient Treatment**
- » Oseltamivir
- » Baloxavir marboxil
- » Zanamivir
- » Peramivir



#FDA-licensed | *https://www.cdc.gov/flu/about/burden/index.html

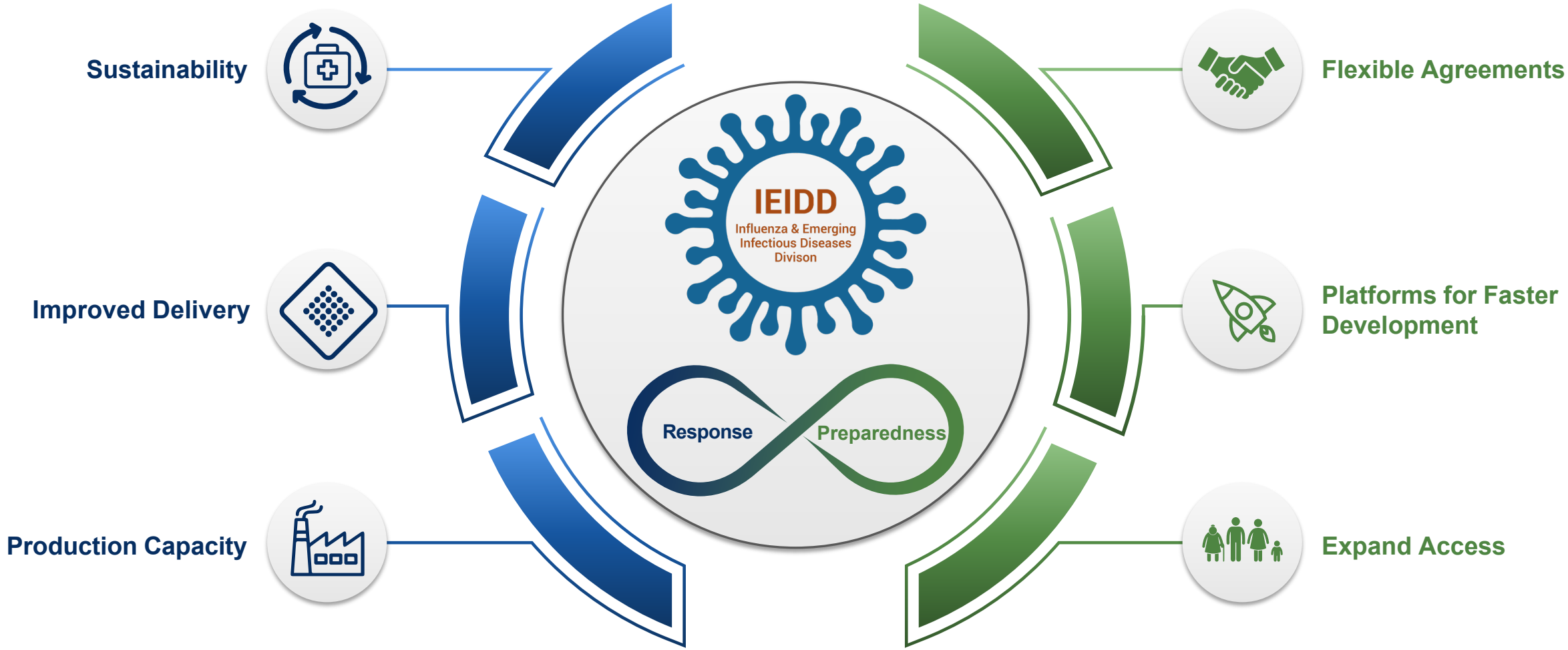
Gaps

❑ **Expanded vaccine licensures and manufacturing capacity**

❑ **Faster and better influenza vaccines**

❑ **Safety and immunogenicity data for influenza viruses with pandemic potential to reduce response timelines**

IEIDD Goal: Establish New & Leverage Existing Infrastructures & Capabilities to Support Response & Preparedness



Pandemic Vaccines and Adjuvants Program

ACCELERATING PANDEMIC RESPONSE TIMELINES

- Identify areas for improvements to U.S. licensed manufacturing processes, e.g., validated fill-finish capacity
- Manage the **U.S. National Pre-pandemic Influenza Vaccine Stockpile (NPIVS)** to vaccinate the CDC-defined Tier 1 population early
- Maintain a **robust library** of influenza virus vaccine seeds
- **Expedited procurement** of enough vaccine for the U.S. population within 6 months of a pandemic declaration

GOAL

To advance timely vaccination strategies to mitigate the next pandemic

BARDA – Biomedical Advanced Research and Development Authority

CSL Seqirus sanofi GSK

- Ensure **nimble vaccine implementation strategies**
- Expand **safety and immunogenicity datasets** for influenza vaccines targeted to diverse subtypes, i.e., H2Nx, H5Nx, H7Nx, H9Nx
- Generate data to **support administration,** e.g., physical and chemical compatibility, vial sterility assurance, extractable volume studies
- Proactive assessments to confirm that NPIVS antigen and adjuvant are **safe and immunogenic**

ENSURING CLINICAL AND ANALYTICAL DATA EXISTS TO SUPPORT VACCINE ADMINISTRATION

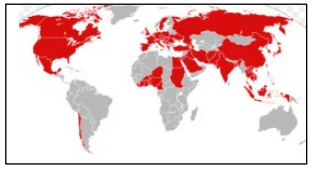
Making Decisions about Pre-Pandemic Influenza Vaccines

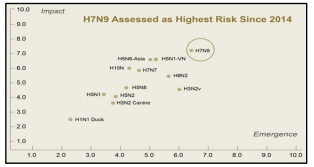
Interagency decision – making body

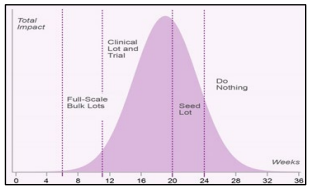
Surveillance – Epi data

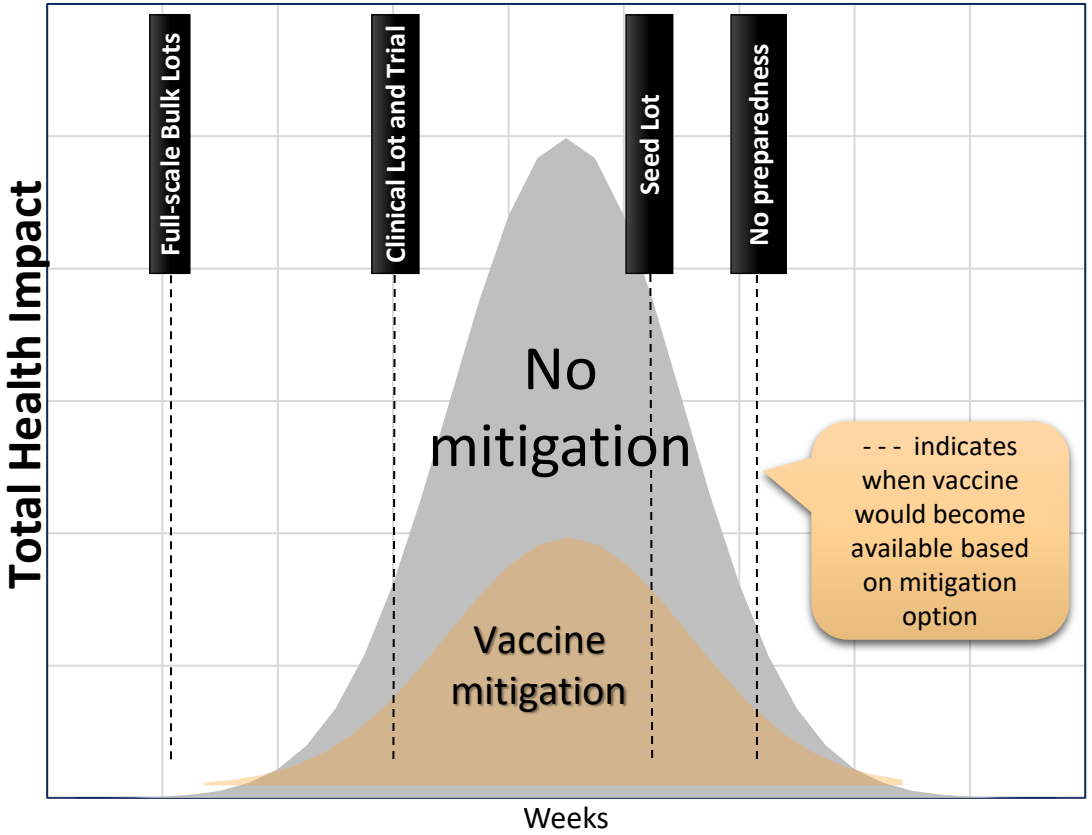
Decision using a metered response approach

Implementation



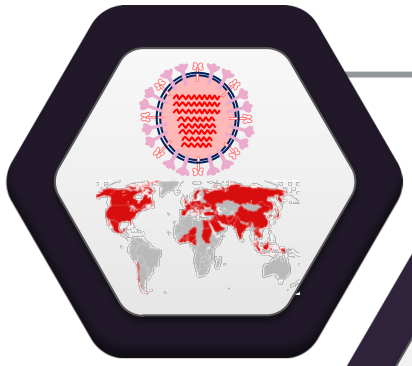




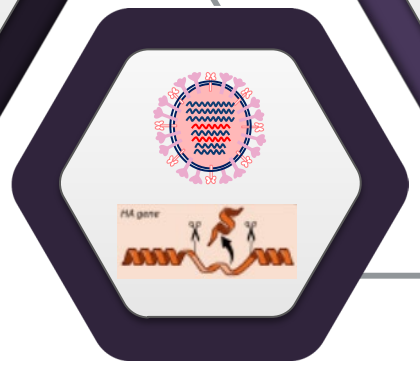


Overview:
Vaccines for Pandemic Influenza Response Program

CDC/Disease outbreak/ Surveillance/IRAT



WHO/ERL CVV development/ Potency reagents



Seed Development/Bulk production/ Final container

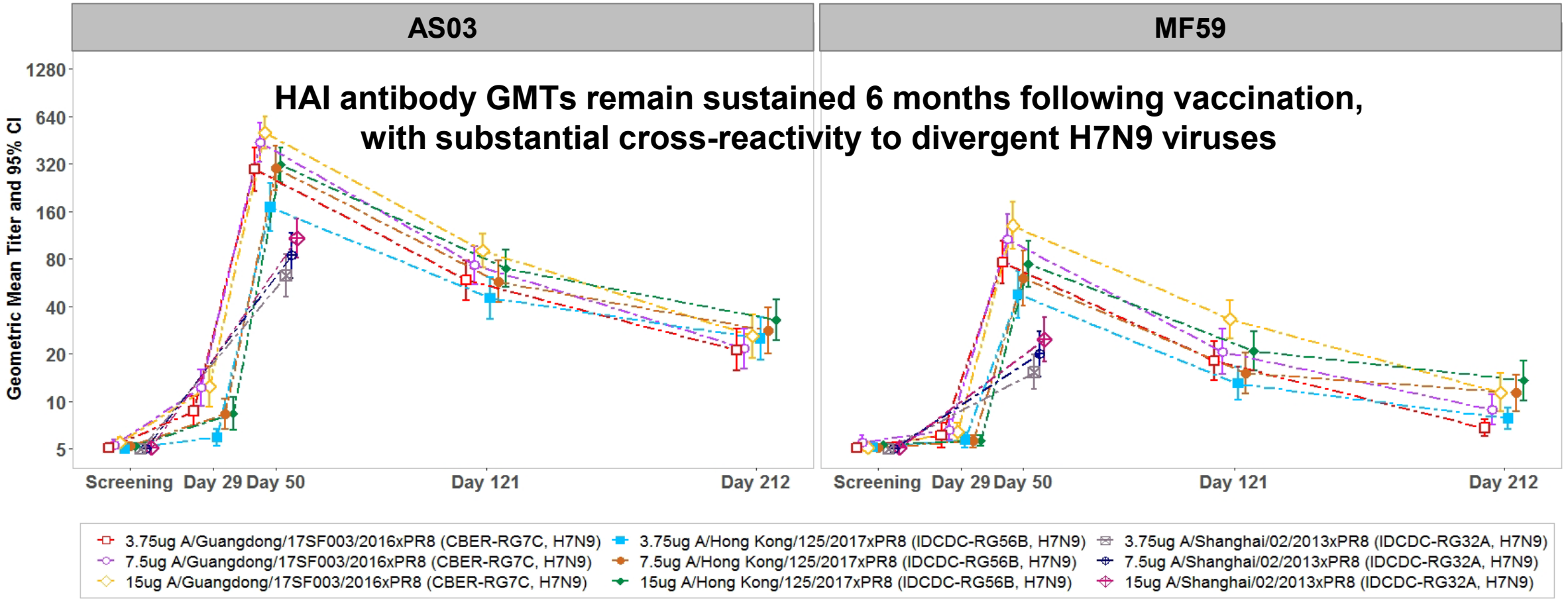
Vaccine/Adjuvant Stockpile and Stability Programs

Clinical trials

Pre-EUA living documents in place

Faster to first doses
Faster to 600M doses
Faster to full immunization

Pandemic Readiness: Panblok H7N9 Influenza Vaccine Clinical Trial



Vaccines. 2021 Mar 19;6(1):41.
ClinicalTrials.gov Identifier: NCT03283319

Pandemic Readiness: H7N9 Influenza Vaccine Clinical Trial

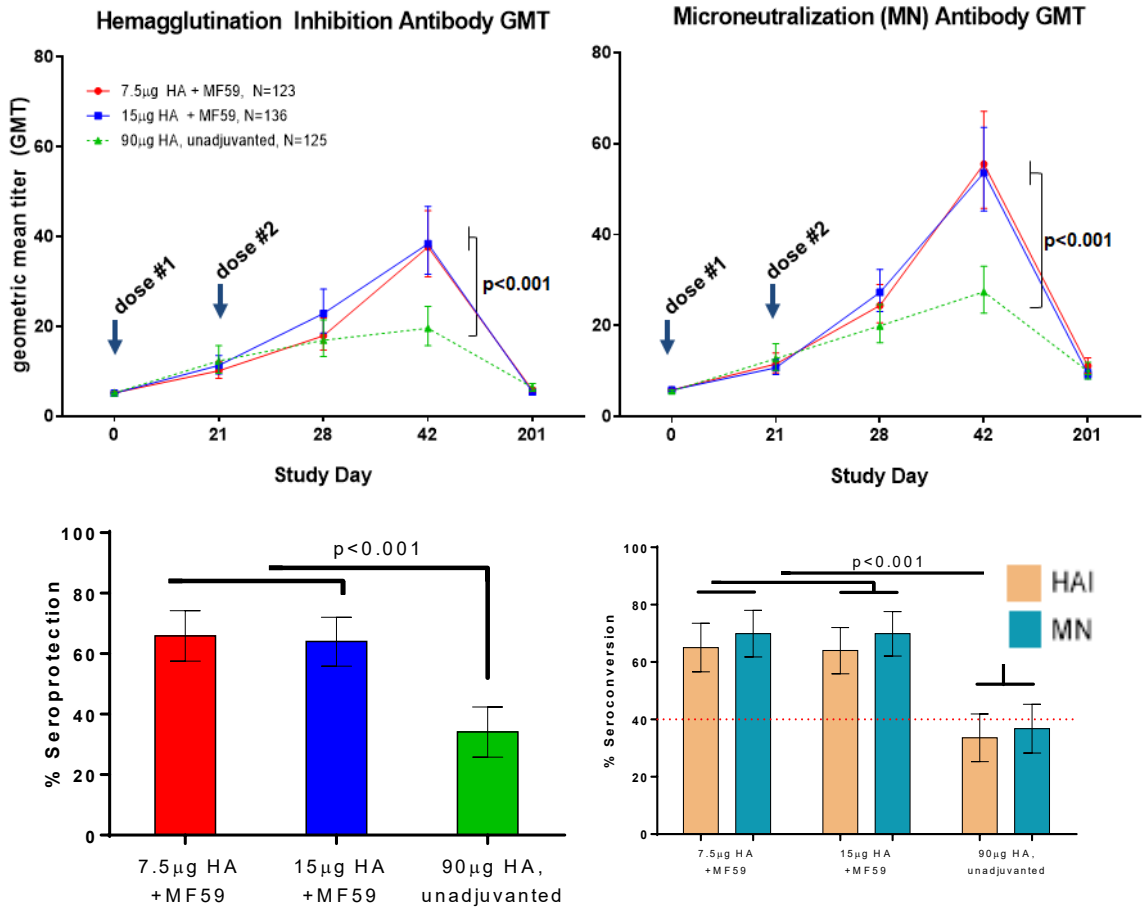
GSK-sponsored

- FluLaval™ process (split virion, egg): A/Hong Kong/125/2017 (H7N9)-like candidate
- Clinical design: safety and immunogenicity of varying doses of A/Hong Kong/125/2017 (H7N9) in combination with full or half doses of AS03 adjuvant.
- Study complete; NCT#: NCT04789577

SPR (95% CI)	1.9ug HA + AS03 half dose	1.9ug HA + AS03 full dose	3.75ug HA + AS03 half dose	3.75ug HA + AS03 full dose	7.5ug HA + AS03 half dose	7.5ug HA + AS03 full dose	Placebo
Adults 18-64y							
D1	0 (0.0, 7.5)	0 (0.0, 8.2)	0 (0.0, 7.4)	0 (0.0, 7.3)	0 (0.0, 7.5)	0 (0.0, 8.0)	0 (0.0, 7.4)
D22	14.9 (6.2, 28.3)	9.3 (2.6, 22.1)	12.5 (4.7, 25.2)	16.3 (7.3, 29.7)	19.1 (9.1, 33.3)	15.9 (6.6, 30.1)	0 (0.0, 7.4)
D43	71.7 (56.5, 84.0)	70.3 (53.0, 84.1)	65 (48.3, 79.4)	81.4 (66.6, 91.6)	60.5 (43.4, 76.0)	78.4 (61.8, 90.2)	0 (0.0, 9.0)
Adults 65y+							
D1	0 (0.0, 7.0)	4 (0.5, 13.7)	0 (0.0, 7.3)	0 (0.0, 7.9)	0 (0.0, 6.6)	0 (0.0, 7.1)	2.1 (0.1, 11.3)
D22	2 (0.0, 10.4)	8 (2.2, 19.2)	8.2 (2.3, 19.6)	8.9 (2.5, 21.2)	5.6 (1.2, 15.4)	16 (7.2, 29.1)	2.1 (0.1, 11.3)
D43	40 (26.4, 54.8)	58.7 (43.2, 73.0)	44.4 (29.6, 60.0)	62.5 (45.8, 77.3)	51 (36.6, 65.2)	55.3 (40.1, 69.8)	2.3 (0.1, 12.3)

BARDA Ready In Times of Emergency (BRITE) Clinical Trial

- A randomized, double-blinded, Phase 2 clinical trial to assess safety and immunogenicity of long-term stored A/Vietnam/1203/2004 (H5N1) vaccine administered with and without adjuvant
- A/Vietnam/1203/2004 (H5N1) vaccine appears to remain safe, tolerable, and immunogenic when administered as a two-dose vaccine regimen in healthy adults, despite extended storage of HA antigen or MF59 adjuvant within the NPIVS

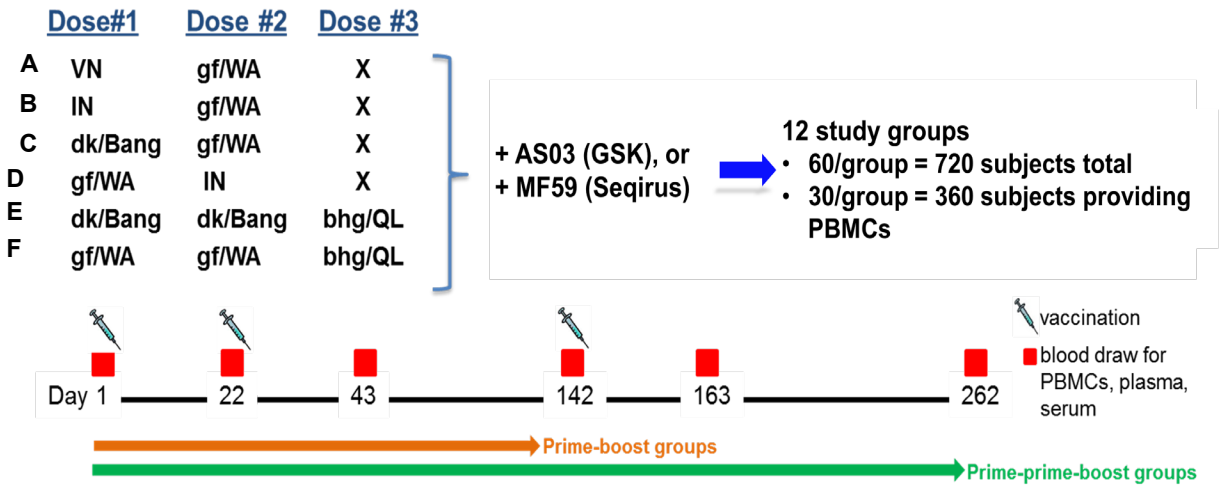


Vaccine. 2019 Jan 14;37(3):435-443.
ClinicalTrials.gov: NCT02680002.

BARDA-sponsored trial: A heterologous prime and boost vaccination strategy to induce cross-protective immunity against stockpiled A(H5) influenza virus vaccines

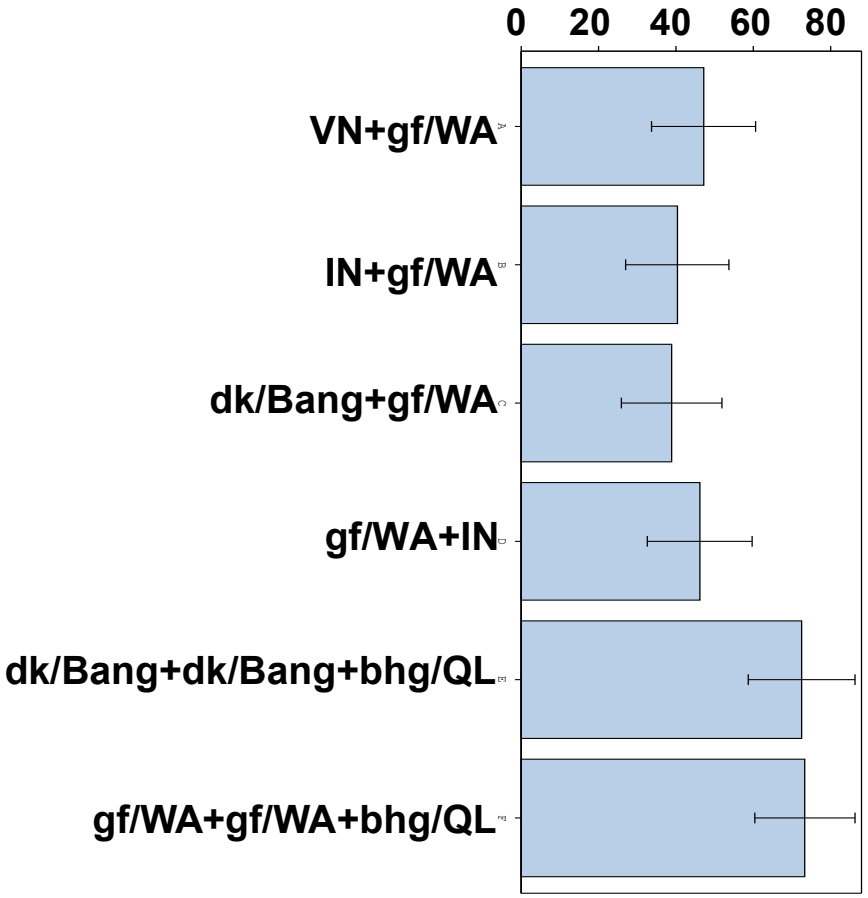
Potential vaccination strategy for induction of cross-protective immunity using stockpiled influenza H5 vaccines

Vaccine Strain		Clade	Manufacturing Process
VN	A/Viet Nam/1203/2004 (H5N1)-like	1	Sanofi Fluzone®
IN	A/Indonesia/05/2005 (H5N1)-like	2.1.3.2	Sanofi Fluzone®
dk/Bang	A/duck/Bangladesh/19097/2013 (H5N1)-like	2.3.2.1a	CSL Seqirus Flucelvax®
gf/WA	A/gyrfalcon/Washington/41088-6/2014 (H5N8)-like	2.3.4.4	CSL Seqirus Afluria®
bhg/QL	A/bar headed goose/Qinghai Lake/1A/2005 (H5N1)-like	2.2	Sanofi Fluzone®



BPI16005, NCT# NCT03497845

Seroprotection Rate (SPR) + 95% CI



Pandemic Readiness: H2Nx Influenza Vaccine Clinical Trial

CSL Seqirus-sponsored

- AUDENZ™ process (subunit, cell): A/chicken/Ohio/494832/2007 (H2N3)-like candidate
- As individuals born after 1968 have never been exposed to A/H2 viruses, the overall global immunity against A/H2N2 is decreasing. Therefore, introduction of a new A/H2 virus strain via reassortment of an avian or swine variant could cause another pandemic.
- Clinical design: safety and immunogenicity of varying doses of influenza A/chicken/Ohio/494832/2007 (H2N3) vaccine in combination with MF59 adjuvant
- Enrollment complete
- NCT#: NCT05875961

Study Group (2 doses 21 days apart)	Number of Subjects	
	Adults born after 1968	Adults born prior to 1968
3.75ug HA + MF59	50	50
7.5ug HA + MF59	50	50
15ug HA + MF59	50	50
15ug HA unadjuvanted	50	50
1.875ug HA + 2X MF59	50	50
3.75ug HA +2X MF59	50	50

Total N = 600

Pandemic Readiness: H5Nx Influenza Vaccine Clinical Trials

GSK-sponsored

- FluLaval™ process (split virion, egg): A/Astrakhan/3212/2020 (H5N8)-like candidate—CVV IDCDC-RG71A
- Clinical design: safety and immunogenicity of varying doses of influenza A/Astrakhan/3212/2020 (H5N8; clade 2.3.4.4b) vaccine in combination with full or half doses of AS03 adjuvant
- Enrollment complete
- NCT# NCT05975840

Study Group (2 doses 21 days apart)	Number of Subjects	
	18-64 years	>65 years
3.75ug HA + $AS03_B$	65	65
3.75ug HA + $AS03_A$	65	65
7.5ug HA + $AS03_B$	65	65
7.5ug HA + $AS03_A$	65	65

* Targeting up to 20% poultry workers

Total N = 520

CSL Seqirus-sponsored

- AUDENZ™ process (subunit, cell): A/Astrakhan/3212/2020 (H5N8)-like candidate
- Clinical design: heterologous prime and boost strategy using influenza A/Astrakhan/3212/2020 (H5N8; clade 2.3.4.4b) and A/Guangdong/18SF020/2018 (H5N6; clade 2.3.4.4h) vaccines
- Enrollment complete
- NCT#: NCT05874713

Arm	Study Group	Dose 1 (Day 1)	Dose 2 (Day 22)	Dose 3 (6months)	18-64* yrs	>65 yrs
1	7.5ug HA + MF59	H5N8	H5N8	H5N8	120	120
2	7.5ug HA + MF59	H5N8	H5N6	H5N8	60	60
3	7.5ug HA + MF59	H5N6	H5N8	H5N8	60	60

Targeting up to 50% poultry workers

Total N = 480

BARDA's Influenza and Emerging Infectious Diseases Division Advanced Vaccine Development

FASTER VACCINE PLATFORMS, NEXT GENERATION INFLUENZA VACCINES

Goal: Enable design, testing, and manufacture of safe and effective vaccines against novel influenza viruses within 100 days of recognition

GREATER EFFICACY, IMPROVED VACCINE PERFORMANCE

Goal: Achieve immunity in the population more quickly with a formulation that confers protection against a novel virus with a single dose of vaccine

Influenza Vaccines R&D Portfolio

ARCTURUS therapeutics
AstraZeneca
AAHI
janssen
vaxxas
sanofi
CSL Seqirus

FASTER VACCINE DELIVERY

Goal: Utilize delivery method that reduces need for cold chain and needles/syringes; may enable self-administration and/or improve efficacy and performance

MANUFACTURING CAPACITY

Goal: Enable production of enough vaccine for the United States population within 120 days after recognition of a novel pandemic Influenza virus

BARDA Website:
medicalcountermeasures.gov
Learn about BARDA's programs, our annual industry day, and funding opportunities!

Solicitations:
sam.gov/
See official announcements and info for government contract solicitations

ASPR Website:
aspr.hhs.gov/BARDA/
Check out ASPR's programs, news, and announcements

DRIVe Website:
drive.hhs.gov
Learn about DRIVe, including open EZ-BAA solicitations

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Pandemic Vaccines and Adjuvants Program
Influenza and Emerging Infectious Diseases Division (**IEIDD**)
Biomedical Advanced Research and Development Authority (**BARDA**)
Administration for Strategic Preparedness and Response (**ASPR**)
U.S. Department of Health and Human Services (**HHS**)
Christine.Oshansky@hhs.gov

CSL Seqirus

CSL Seqirus Preparedness Posture for Pandemic Influenza

Lorna Meldrum, VP, International Commercial & Pandemic

HHS National Vaccine Advisory Committee (NVAC) Meeting
June 13, 2024

CSL Seqirus - On the Front Line of Influenza

- Second largest producer of influenza vaccines in the world
- Pandemic influenza preparedness agreements with 30 governments
- Expansive global manufacturing network, with a 100-day pandemic track record (2009-10 H1N1 pandemic)
- 3 registered & industrialised pandemic influenza platforms
  - Cell-based technology adjuvanted with MF59 (Holly Springs NC)
  - Egg-based technology adjuvanted with MF59 (Liverpool UK)
  - Egg-based technology adjuvanted with Alum (Parkville Aus)
- COVID-19 pandemic vaccines: manufactured 50 million doses & delivered to 6 countries (recombinant)
- COVID-19 seasonal vaccine: next generation sa-mRNA, approved in Japan, seeking approvals in US, Europe and internationally
- R&D program in adjuvanted cell vaccine & sa-mRNA vaccine technology

CSL Seqirus & BARDA Partnership in Holly Springs

▪**Relationship history:** **17-year public-private partnership** began in 2006 with predecessor company Chiron (Liverpool UK), then Novartis (Liverpool UK, Holly Springs NC), now Seqirus (Liverpool UK, Holly Springs NC, Parkville AUS)

▪**Holly Springs objective:** Established to provide domestic cell-based vaccine and adjuvant manufacturing capacity to support delivery of 150 million doses of vaccine in the event of an influenza pandemic – culminated in being **certified "pandemic ready" by BARDA in May 2022**

▪7 contracts awarded to-date:

- **Clinical programs:** Flu cell culture (FCC) seasonal and pandemic licensure, H2N3 and H5N8 clinical development
- **Manufacturing infrastructure:** Established Holly Springs site and subsequently viral pilot plant (VPP) and small-scale filling (SSF) facilities
- **FCC 3.0 process implementation:** Yield improvement process
- **Antigen/Adjuvant stockpiles:** Annual pre-pandemic antigen lots, additional lots of antigen based on circulating strains concern (H7N9, H2N3, H5N8) and MF59 adjuvant

CSL Seqirus Pandemic Innovation

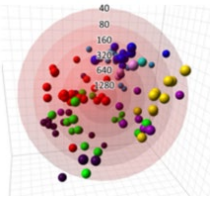
Proven partner to 30+ governments with a 100-day track record in pandemic influenza

Cell-Culture Technology

MF59 Adjuvant

sa-mRNA (future)

Global access for governments to MF59-adjuvanted, cell & egg-based APAs / pandemic vaccine for widespread coverage

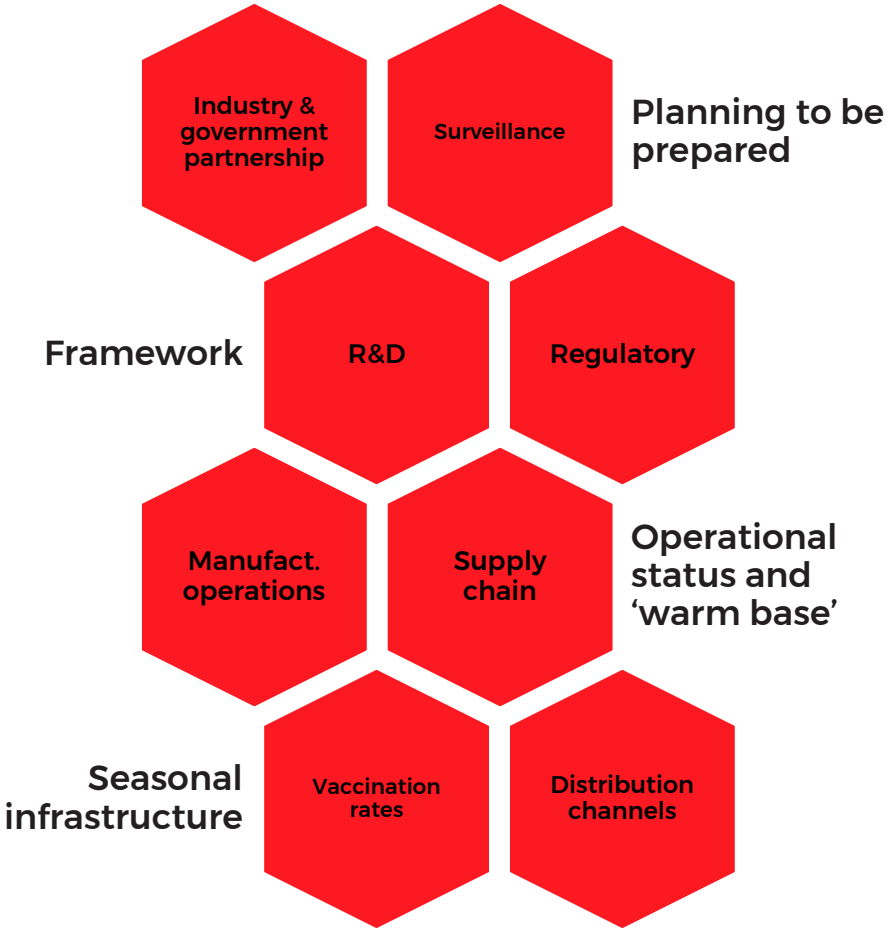


Pre-pandemic stockpiles for outbreak resilience

Selected technology partnerships
(MF59 & Investment in capacity, R&D)

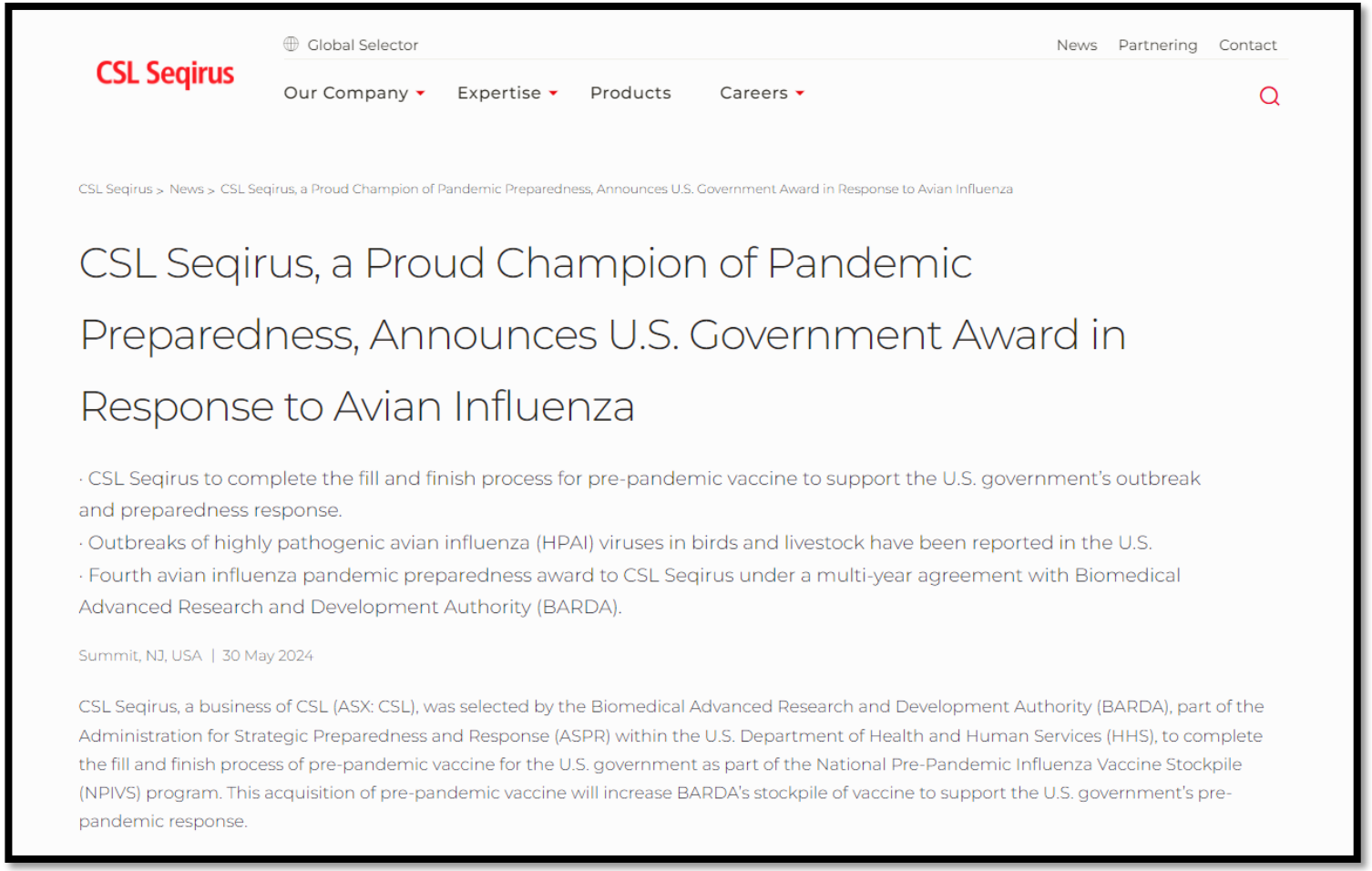
Robust Pandemic Preparedness is Built on Expertise

Public-private partnership is critical to pandemic readiness and resilience



Putting Preparedness into Action for H5 avian flu

CSL Seqirus recently awarded contract to complete fill-finish process for pre-pandemic vaccines developed under partnership with BARDA



CSL Seqirus

Global Selector | News | Partnering | Contact

Our Company | Expertise | Products | Careers

CSL Seqirus > News > CSL Seqirus, a Proud Champion of Pandemic Preparedness, Announces U.S. Government Award in Response to Avian Influenza

CSL Seqirus, a Proud Champion of Pandemic Preparedness, Announces U.S. Government Award in Response to Avian Influenza

· CSL Seqirus to complete the fill and finish process for pre-pandemic vaccine to support the U.S. government's outbreak and preparedness response.
· Outbreaks of highly pathogenic avian influenza (HPAI) viruses in birds and livestock have been reported in the U.S.
· Fourth avian influenza pandemic preparedness award to CSL Seqirus under a multi-year agreement with Biomedical Advanced Research and Development Authority (BARDA).

Summit, NJ, USA | 30 May 2024

CSL Seqirus, a business of CSL (ASX: CSL), was selected by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response (ASPR) within the U.S. Department of Health and Human Services (HHS), to complete the fill and finish process of pre-pandemic vaccine for the U.S. government as part of the National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS) program. This acquisition of pre-pandemic vaccine will increase BARDA's stockpile of vaccine to support the U.S. government's pre-pandemic response.

Link:
CSL Seqirus, a Proud Champion of Pandemic Preparedness, Announces U.S. Government Award in Response to Avian Influenza

sanofi

BEING READY FOR A RAPID RESPONSE: A PROACTIVE DISCUSSION OF PRODUCTION CAPABILITIES

Julian Ritchey, VP Public Affairs & Patient Advocacy, US Vaccines

Sanofi: Committed Influenza Market Leader and Pandemic Preparedness Partner

Long-standing global public health partner with the largest R&D and Industrial footprint for influenza vaccines for over 70 years

Demonstrated domestic end-to-end capability with 2009 H1N1 response in less than 100 days

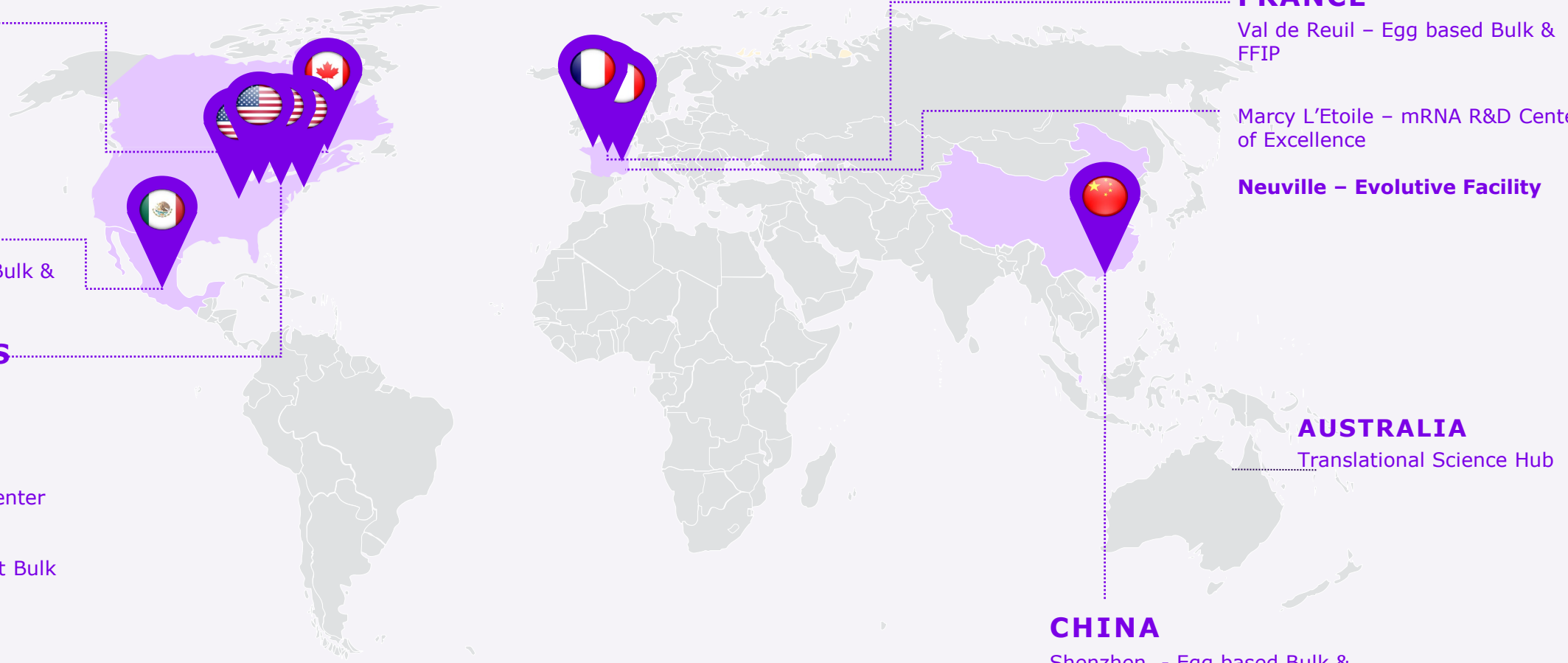
Committed to continuously exploring diverse technologies to better address future pandemic challenges (Egg, Recombinant, mRNA)

Employs a holistic approach to pandemic preparation from Innovation through Implementation

sanofi

Sanofi Is Continually Investing In Cutting Edge Influenza R&D And Production Sites

"End-to-End" Pandemic response capability for Egg and Recombinant plus mRNA
Center of Excellence provides domestic infrastructure



CANADA

Toronto –
Egg based Bulk
FFIP

MEXICO

Ocoyoacac – Egg based Bulk & FFIP

UNITED STATES

Swiftwater –
Egg based Bulk
Recombinant Bulk
FFIP

Waltham – mRNA R&D Center of Excellence

Pearl River - Recombinant Bulk

Ridgefield - FFIP

FRANCE

Val de Reuil – Egg based Bulk & FFIP

Marcy L'Etoile – mRNA R&D Center of Excellence

Neuville – Evolutive Facility

AUSTRALIA

Translational Science Hub

CHINA

Shenzhen - Egg based Bulk & FFIP

sanofi

Sanofi Supports PPP Pandemic/Epidemic Alert And Response Tools For Early Detection

Sanofi is a leader in influenza viral detection around the world and designing pandemic preparedness and response tools with global stakeholders (WHO, HERA,…) and collaborates with governments in developing a locally tailored solution

Global Influenza Hospital Surveillance Network

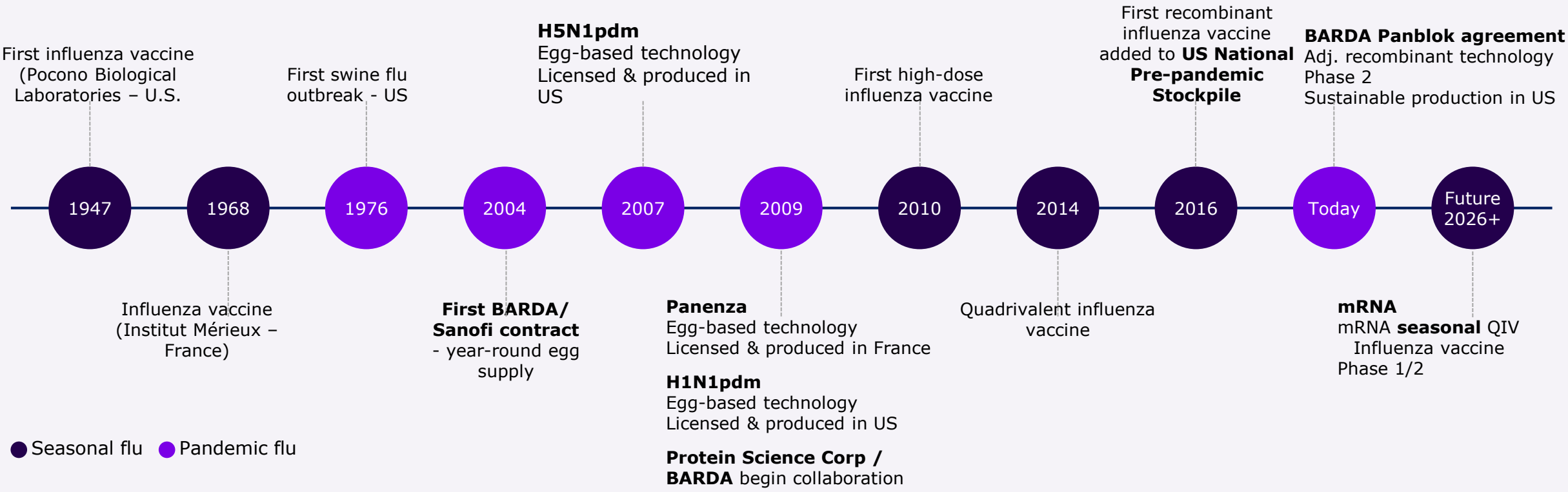
The Global Influenza Hospital Surveillance Network (www.gihsn.org) : an active acute respiratory disease surveillance covering 100 hospitals in 20 countries including the United States.

Aiolos

AIOLOS: A multi-sources data integration tool to detect outbreaks of respiratory viruses and to support data-driven decision making. The prototype funded by French and German governments (available in 2024) could be applicable to other countries.
https://aiolos-project.org

Sanofi Has Partnered With BARDA For Decades To Ensure Pandemic Preparedness In The US

Sanofi legacy and future steps in the field of influenza vaccines



More than 250M people able to be immunized with Sanofi influenza vaccines each year[1]

Involved in **various partnerships** (BARDA[1], EU[2] HERA[3]) **& collaborations** (GIHSN[4], DRIVE[5], …)

Sanofi influenza production sites **can be mobilized for switching from seasonal to pandemic production**

Note: 1 – BARDA; Biomedical Advanced Research and Development Authority; 2 – EU: European Union; 3 – HERA: Health Emergency Preparedness and Response Authority; GIHSN – Global Influenza Hospital Surveillance Network; DRIVE – Diabetes Research on Patient Stratification **Sources:** 1. Sanofi Internal data

Sanofi Offers Diversified Influenza Vaccine Platforms For Rapid And Reliable Pandemic Response

US PIV*
Egg-based

A/H5N1 unadjuvanted
A/H1N1 unadjuvanted

H5 licensed in US (2007)
H1 licensed in US (2009)
Produced in the US

EU PIV*
Egg-based

A/H1N1 unadjuvanted

Licensed in France (2009)
Supplied during H1N1 pandemic
Produced in France

Panblok
Recombinant

A/H5 adjuvanted

Clinical development ongoing
Production planned in US

mRNA

mRNA Influenza

Clinical development ongoing
mRNA Center of Excellence located in US

sanofi

*PIV: Pandemic Influenza Vaccine

Sanofi Evolutive Vaccine Facilities (EVF) Enable Rapid Pandemic Response Across Production Platforms

Modular production facilities, able to switch from one process/product to another, while respecting regulatory requirements **with process standardization**

Possibility to **produce multiple vaccines or biologics products in one EVF** vs. 1 dedicated in current vaccines industrial facilities, and **based on different technology platforms** (mRNA, insect cell mammalian cell, *E. Coli*, yeast, Enzymes, etc.) **for investigational** (Phase II/III), **launch and commercial** products

State-of-the-art Digital Ambition (Cobots, Artificial Intelligence…)

Single-Use processing (disposable fermenters, bioreactors…)

Flexible to easily expand to 3 ballrooms per EVF Facility

2 Facilities
Neuville – France
Tuas – Singapore

Sanofi Environmental Vision incorporated (neutral CO2 footprint, Low energy consumption, Zero landfill through maximal waste recycling)

Sanofi is committed to innovative manufacturing and technological solutions to address existing and emerging patient health needs

Thank you!

Being Ready for a Rapid Response: A Proactive Discussion of Production Capabilities

Discussion

NVAC

Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

June 13-14, 2024

Break

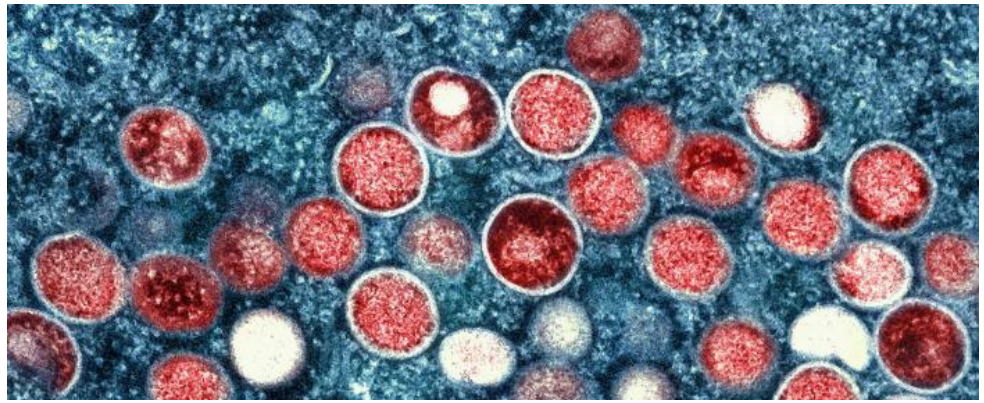
NVAC

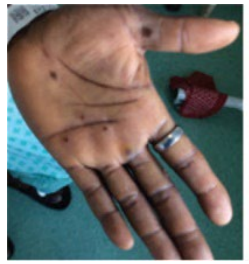
Pride, Equity, and Community: Mpox Vaccination in 2024

Dr. Jennifer McQuiston
Dr. Tevin Warren
Dr. David Holland
Emily Halden Brown
Japer Bowles
Dr. Agam Rao

NVAC

Clade II Mpox: An Ongoing Public Health Risk

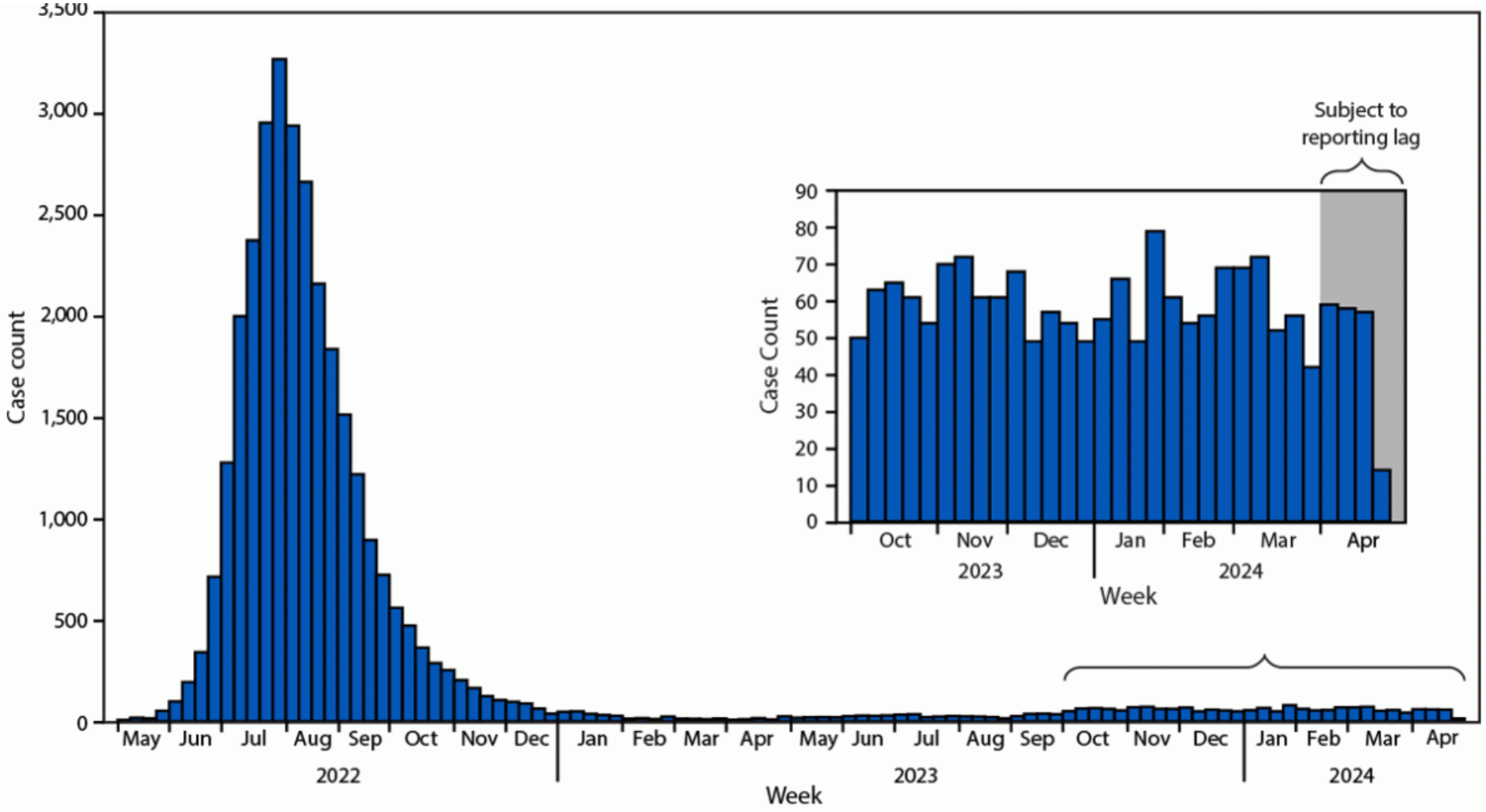




Division of High-Consequence Pathogens and Pathology
Centers for Disease Control and Prevention

NVAC
June 13, 2024

U.S. Mpox Cases, 2022-Present



Domestic Outbreak Response Mpox 2022-2023

Mpox Response By the Numbers

1.2 million
Vaccine doses administered

76 million
Page views of CDC mpox websites

147,000+
Specimen tests performed by LRN

1,400+
CDC responders deployed to the Mpox response

37,000+
Wastewater samples collected between July 2022 and July 2023

50+
Community engagement and listening sessions

2,600+
Web tickets submitted

13
Health Alert Network notices and COCA calls

423,000+
Mpox resources downloaded

856
Social media posts

41
MMWRs published

75+
Partners and community organizations mobilized

Key Milestones Clade II Mpox Response (2022)

- **Mid-May 2022:** First U.S. case diagnosed in Massachusetts Laboratory Response Network (LRN) laboratory, CDC launches emergency response
- **June 2022:** Outbreak escalates, 50K JYNNEOS doses distributed, communication to LGBTQ+ community underway
- **July 2022:** CDC expands testing to commercial labs; WHO declares a PHEIC and the U.S. government declares a PHE; White House Task force is created; 1 million doses of JYNNEOS distributed.
- **Aug 2022:** Cases begin to decline, survey showed protective behavioral changes being embraced
- **Sept 2022:** Health Equity initiatives launched to improve vaccine access and uptake among Black and Hispanic persons; vaccine performance estimates show excellent protection

Key Milestones Clade II Mpox Response (2023-Present)

- **Feb 2023:** ACIP votes to recommend the 2-dose JYNNEOS vaccine series for persons 18 years and older at risk for mpox during an mpox outbreak
- **April 2023:** CDC highlights risks for fatal outcomes and impact on Black and Hispanic persons
- **April-Sept 2023:** Cases reach low steady state
- **Oct 2023-April 2024:** Cases tick up slightly, but remain steady at ~59 cases per week
- **May 2024:** CDC highlights that most cases continue to be in persons who are unvaccinated or only received 1 dose

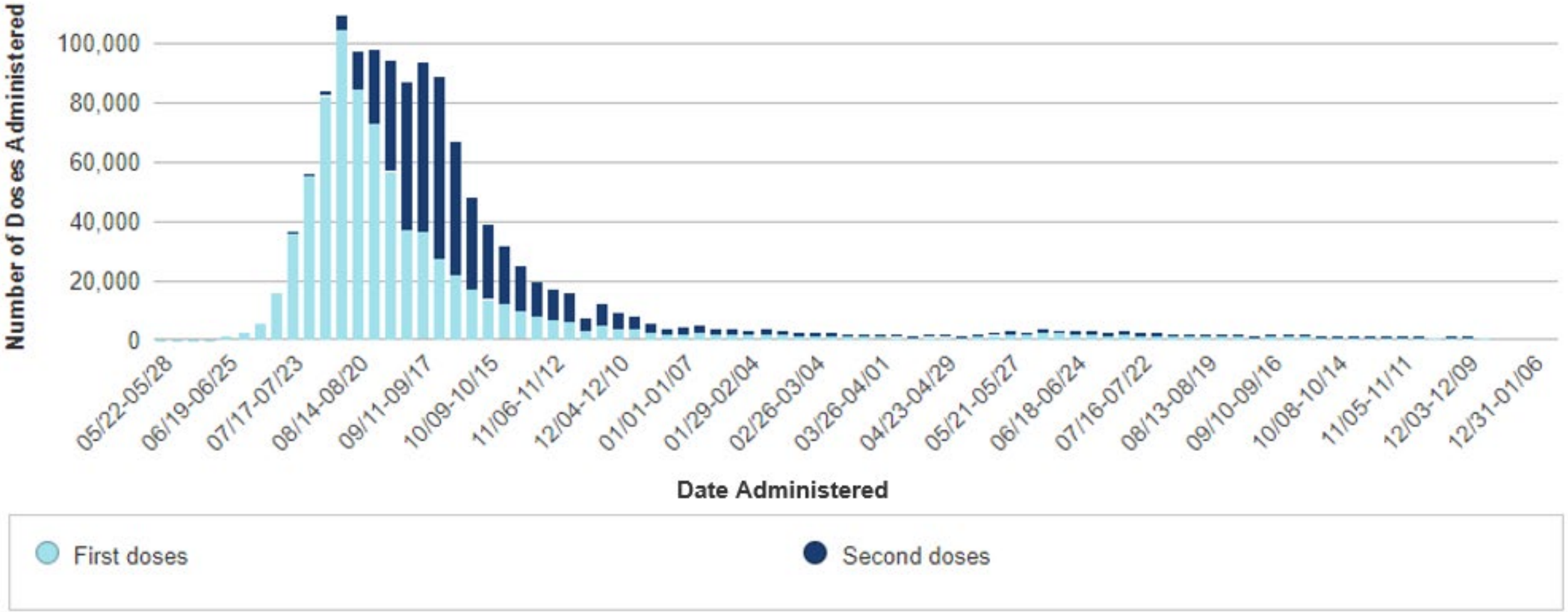
Lessons from the 2022 Mpox Response

- **Take an approach that deeply engages the community most affected**
  - Engaging, listening, and acting on suggestions from the GBMSM community
  - Strong coordination between partners (federal agencies, state and local, and private) to ensure timely, tailored information and seamless delivery
- **Keep public health responses flexible and responsive**
  - Rapid expansion of commercial testing
  - Evolving vaccine strategy based on increasing supplies, feedback (i.e. location of injection sites, removal of risk assessments)
- **Importance of flexible resources and investments**
  - Syndemic approach with other activities/mechanisms
- **Continue to invest in foundational research**
  - JYNNEOS was pre-approved for use because of decades of research, more is needed

Clade II Mpox is Not Over…

- U.S. mpox cases continue at ~59 cases per week, steady for >6 months
  - Mainly in cisgender men (94%), especially those identifying as gay or bisexual (90%)
  - Most cases continue to be in unvaccinated persons or those who have gotten only one dose
  - Severe immunocompromise remains a risk for fatal outcomes
  - Local/regional spread (most do not report international travel)
  - TPOXX-resistant cases (n>50) are being detected (including 18 new cases, multiple states)
- CDC recommends persons at risk for mpox exposure get 2 doses of JYNNEOS (no matter how long since 1st dose)
- JYNNEOS commercially available as of April 1, 2024
  - Phasing out SNS availability by August
  - May increase equitable access issues
- No booster recommended at this time – no epidemiologic signals of waning immunity; will continue to assess

U.S. JYNNEOS Vaccine Administration, 2022–2024*



[Mpox Vaccine Administration in the U.S. | Mpox | Poxvirus | CDC]

*Data reported to CDC between May 22, 2022 - January 6, 2024

CDC: Encouraging Vaccination

- CDC Foundation Partner campaign: Dashaun Wesley
- MMWR highlighting science
- Models indicate that outbreaks >100 cases did not occur when population-level immunity from vaccination or previous infection was >50% among MSM
- Calls with state, local, territorial partners highlighting science, funding opportunities
- Summer of Pride Partnership with OASH
- CDC awarded $46.2 million to 62 jurisdictions to support mpox response and vaccine administration

Clade I Mpox, Increasing in DRC

- >20,000 clade I mpox cases in the DRC since 2023.
  - Clade I is more severe with higher mortality.
- Sexual transmission reported - including among heterosexual partners and MSM
- No vaccine or therapeutics routinely being used in DRC (outside of special studies)
  - Working to change this
- U.S. preparedness: clade II mpox response IS clade I mpox preparedness
- We have a window to stop clade I mpox from becoming the next global outbreak

Mpox Caused by Human-to-Human Transmission of Monkeypox Virus with Geographic Spread in the Democratic Republic of the Congo

Print

HAN HEALTH ALERT NETWORK

NVH This is an official CDC HEALTH ADVISORY

QUESTIONS?

Summer of PRIDE: Mpox Equity Update

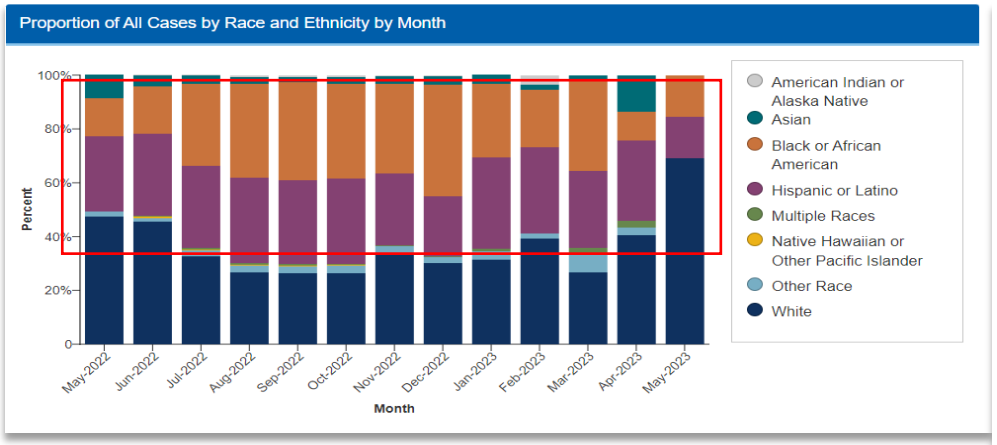
National Vaccine Advisory Committee Meeting

June 13, 2024

Tevin Warren, DrPH, MPH

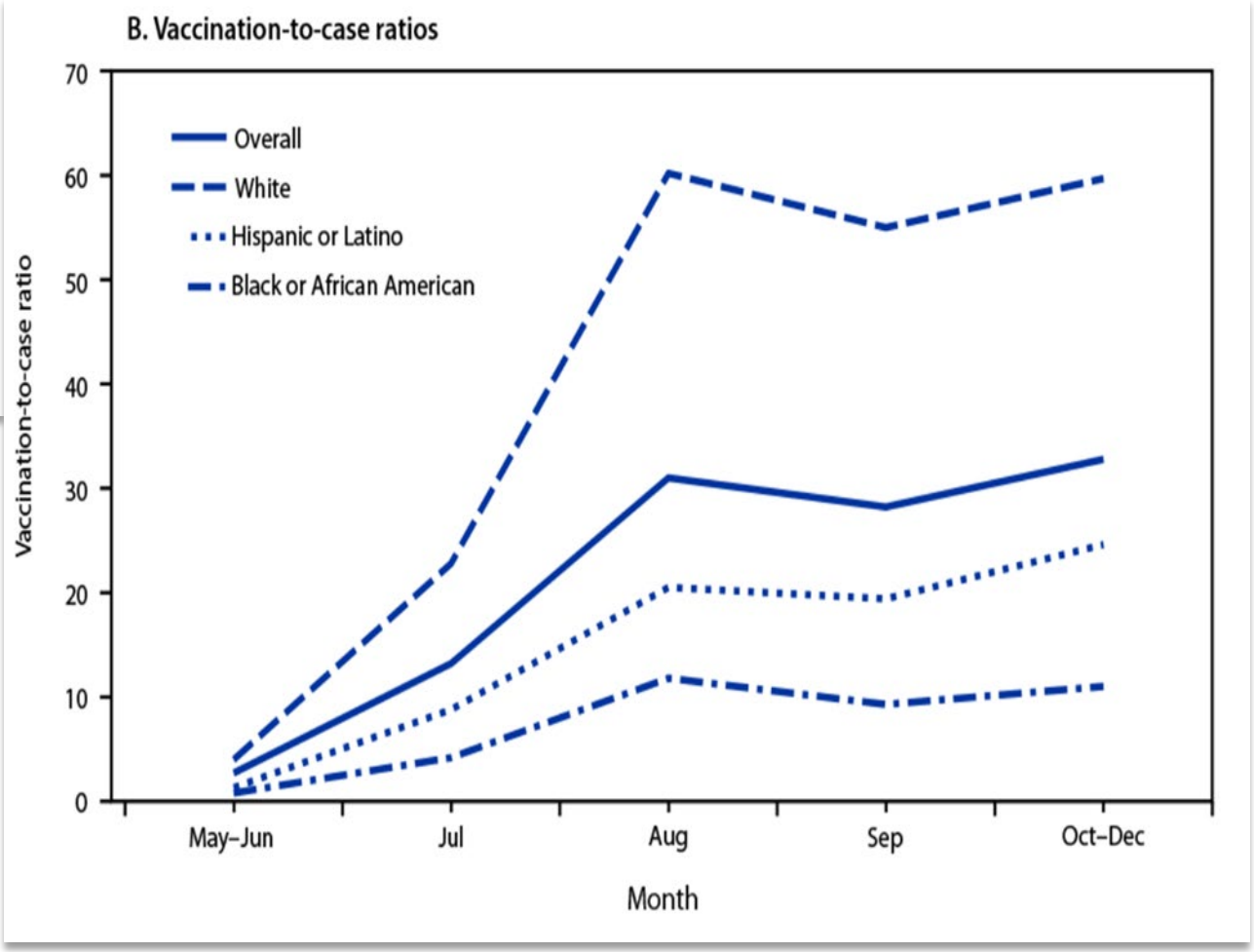
OASH | Office of the Assistant Secretary for Health

Mpox Disparities Created By Systemic Racism

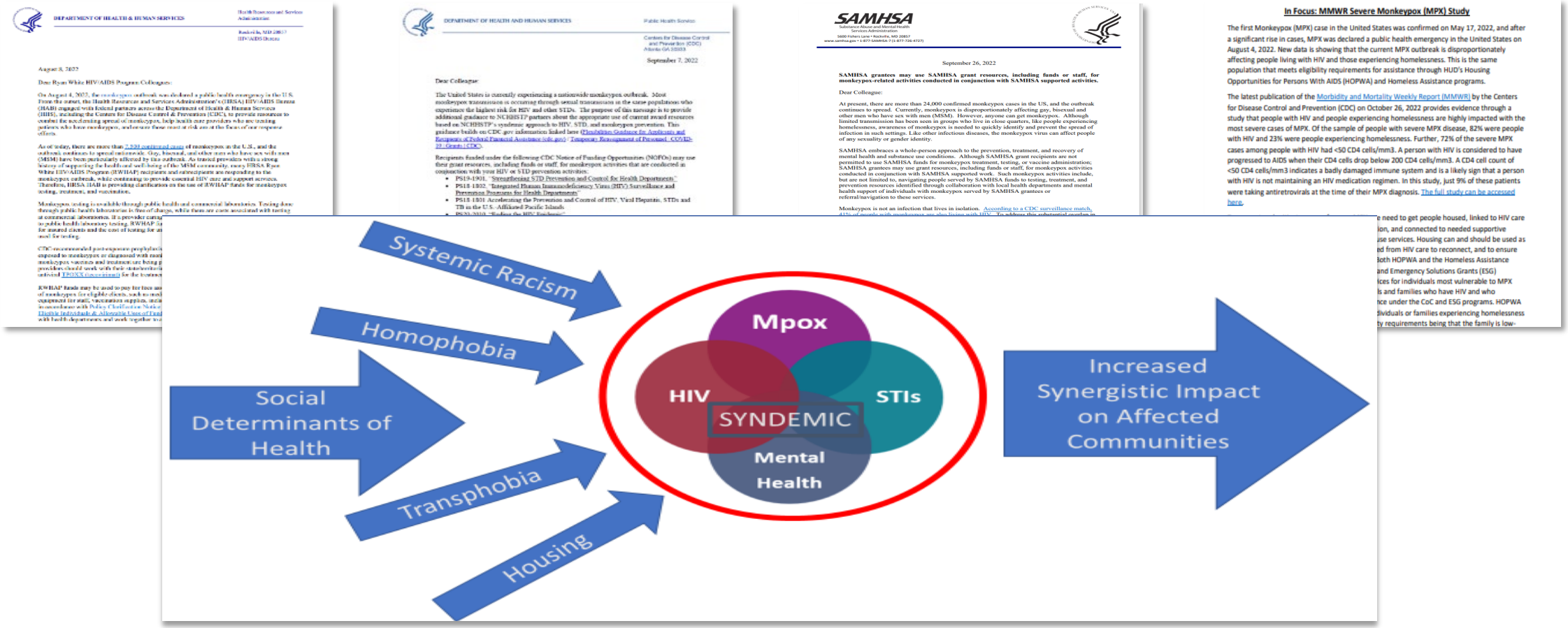


Deaths

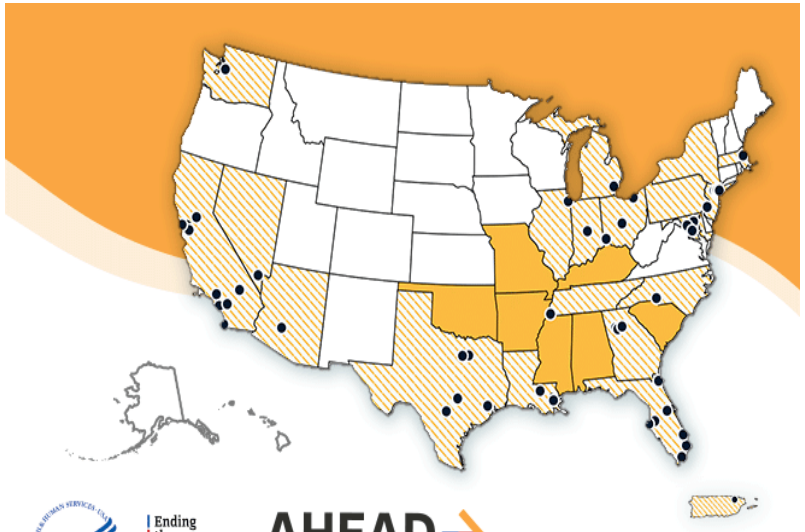
Race and ethnicity, total	28,233 (93.5)	38 (100.0)
American Indian or Alaska Native, non-Hispanic	115 (0.4)	0 (—)
Asian, non-Hispanic	786 (2.8)	0 (—)
Black or African American, non-Hispanic	9,295 (32.9)	33 (86.8)
Native Hawaiian or other Pacific Islander, non-Hispanic	68 (0.2)	0 (—)
White, non-Hispanic	8,277 (29.3)	3 (7.9)
Hispanic or Latino	8,849 (31.3)	2 (5.3)
Other race, non-Hispanic	668 (2.4)	0 (—)
Multiple races, non-Hispanic	175 (0.6)	0 (—)
Unknown	1,950	0



Syndemic Problems Require Syndemic Solutions



Ending The HIV Epidemic



Ending the HIV Epidemic
A PLAN FOR AMERICA

AHEAD
America's HIV Epidemic Analysis Dashboard

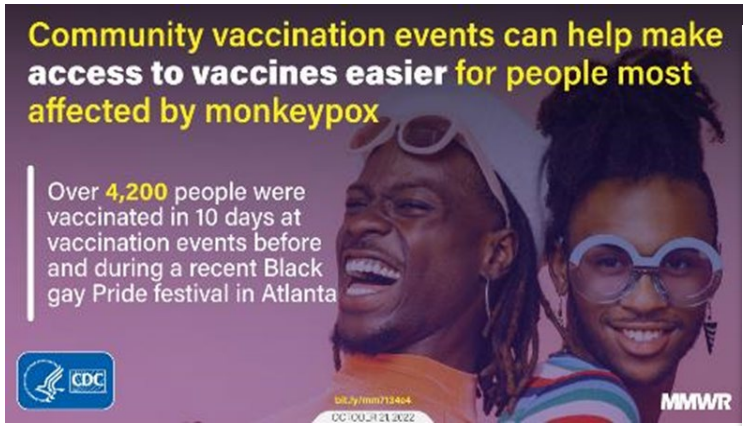
TABLE. Jurisdiction-specific estimates of immunity and inferred* risk and size of mpox recurrence — United States, 2023

Jurisdiction	Estimated immunity level, %†	Inferred* risk for recurrence, %	Inferred* cumulative *Monkeypox virus* infections vs. 2022§	Jurisdictional immunity grouping¶	MSM at increased risk for *Monkeypox virus* exposure**
Duval County, Florida	6	57	4.08	Low	12,425
Shelby County, Tennessee	10	55	3.77	Low	10,626
Hamilton County, Ohio	10	55	3.79	Low	9,970
Bexar County, Texas	11	54	3.67	Low	17,916
Dallas County, Texas	12	53	3.62	Low	45,264
Tarrant County, Texas	15	51	3.32	Low	15,909
Palm Beach County, Florida	15	52	3.36	Low	12,824
Hillsborough County, Florida	15	52	3.39	Low	17,802
Wayne County, Michigan	16	51	3.29	Low	14,705
Harris County, Texas	17	50	3.16	Low	60,769
San Bernardino County, California	18	49	3.07	Low	15,829
East Baton Rouge Parish, Louisiana	18	50	3.14	Low	3,735
Baltimore City, Maryland	19	49	3.04	Low	10,800
Pinellas County, Florida	20	48	2.96	Low	13,430
Gwinnett County, Georgia	21	48	2.89	Low	5,672
Marion County, Indiana	24	46	2.60	Low	12,681
Fulton County, Georgia	25	45	2.58	Low	27,831
Prince George's County, Maryland	26	44	2.03	Medium	9,007
Orange County, Florida	26	45	2.09	Medium	21,838
Dekalb County, Georgia	26	45	2.12	Medium	14,053
Cuyahoga County, Ohio	27	44	1.90	Medium	11,470
Cobb County, Georgia	27	44	1.96	Medium	5,980
Essex County, New Jersey	29	43	1.66	Medium	7,806
Franklin County, Ohio	31	42	1.41	Medium	15,752
Travis County, Texas	32	41	1.30	Medium	16,218
San Juan Municipio, Puerto Rico	32	41	1.30	Medium	3,773
Maricopa County, Arizona	32	41	1.33	Medium	33,513
Mecklenburg County, North Carolina	33	40	1.18	Medium	12,947
Montgomery County, Maryland	34	40	1.10	Medium	7,515
Clark County, Nevada	36	39	0.97	Medium	20,231
Bronx County, New York	36	39	0.98	Medium	19,723
Hudson County, New Jersey	37	38	0.86	Medium	8,009
Miami-Dade County, Florida	40	36	0.72	Medium	40,489
Orange County, California	45	33	0.48	Medium	17,090
Philadelphia County, Pennsylvania	47	32	0.42	Medium	18,771
Sacramento County, California	52	28	0.20	High	9,723
San Diego County, California	54	27	0.19	High	27,536
Riverside County, California	58	25	0.18	High	21,314
Broward County, Florida	59	24	0.18	High	33,886
Orleans Parish, Louisiana	61	23	0.18	High	8,057
Cook County, Illinois	63	22	0.17	High	60,444
Los Angeles County, California	63	22	0.17	High	117,361
Suffolk County, Massachusetts	64	21	0.17	High	10,356
King County, Washington	65	20	0.16	High	24,308
Alameda County, California	75	14	0.14	High	14,167
Queens County, New York	78	12	0.13	High	20,057
District of Columbia	98	<1	0.08	High	22,348
Kings County, New York	99	<1	0.07	High	30,540
New York County, New York	100	<1	0.07	High	37,900
San Francisco County, California	100	<1	0.07	High	23,577

Summer of PRIDE Mpox Equity Intervention

- Collaborate with umbrella organizations for Black Prides and House/Ballroom Community to identify 20-30 events.
- Connect local health departments and these events with the charge of developing syndemic-focused Sexual Health spaces that include mpox vaccine/education and related services.
- <u>USG role is coordination only.</u>

Are All Large LGBTQI+ Events Built The Same? NO!



Ethnicity*			
Hispanic or Latino	**328 (7.7)**	224 (7.8)	104 (7.4)
Non-Hispanic or Latino	**3,872 (90.4)**	2,585 (89.9)	1,287 (91.4)
Unknown	**82 (1.9)**	65 (2.3)	17 (1.2)
Race*			
Asian	**132 (3.1)**	89 (3.1)	43 (3.1)
Black or African American	**2,069 (48.3)**	1,322 (46.0)	747 (53.1)
White	**1,625 (37.9)**	1,144 (39.8)	481 (34.2)
Other	**396 (9.2)**	276 (9.6)	120 (8.5)
Unknown	**60 (1.4)**	43 (1.5)	17 (1.2)

Black prides offer a unique opportunity to reach people with access issues related to stigma or insurance. These prides are regional and national magnets for black MSM and transgender people.

Race and ethnicity**				
Black or African American, NH	929 (25.6)	516 (21.6)	**1,445 (24.0)**	116 (13.9)
White, NH	2,051 (56.5)	1,218 (51.1)	**3,269 (54.3)**	438 (52.3)
Other, NH	327 (9.0)	278 (11.7)	**605 (10.1)**	84 (10.0)
Hispanic or Latino	245 (6.7)	157 (6.6)	**402 (6.7)**	86 (10.3)
Unknown	81 (2.2)	215 (9.0)	**296 (4.9)**	113 (13.5)

Summer of PRIDE 2024 List of Events

May 18-19: Long Beach Pride

May 24-27: DC Black Pride

May 31- Jun 8: DC Capital Pride

Jun 1-2: Philadelphia Pride

Jun 8-9: LA Pride

Jun 16-18: Dallas Southern Black Pride

Jun 17: Baltimore Pride

Jun 17: Da Bronx Pride Festival

Jun 22-23: Chicago Pride Festival

June 24: PG County Pride

Jun 23-24: Puerto Rico Gay Pride

Jun 29: Baton Rouge Pride

Jun 29: Pride San Antonio

Jun 29: Charlotte Black Pride

July 4-7: Black Pride LA

July 14-16: Hotter Than July

Aug 1-4: Jacksonville Black Pride

Aug 3: Indiana Pride of Color

Aug 10: Austin Pride

Aug 14-18: NYC Black Pride

Aug 28-Sep 2: Atlanta Black Pride Weekend

Sep 7-8: Oakland Pride

Sep 16: Texas Latino Pride Festival

Sep 29- Oct 8: Jacksonville FL River City Pride

Oct 1: Atlanta Pride

Oct 3-9: Baltimore Black Pride

Oct 4-6: OUR FEST

Oct 6-7: Las Vegas Pride,

Oct 19-20: Phoenix Pride

Oct 25-29: Black Pride Vegas

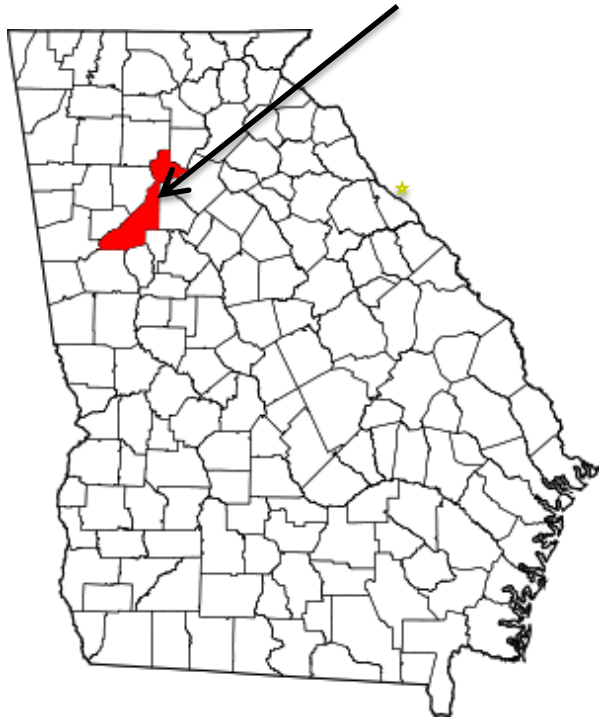
OASH | Office of the Assistant Secretary for Health

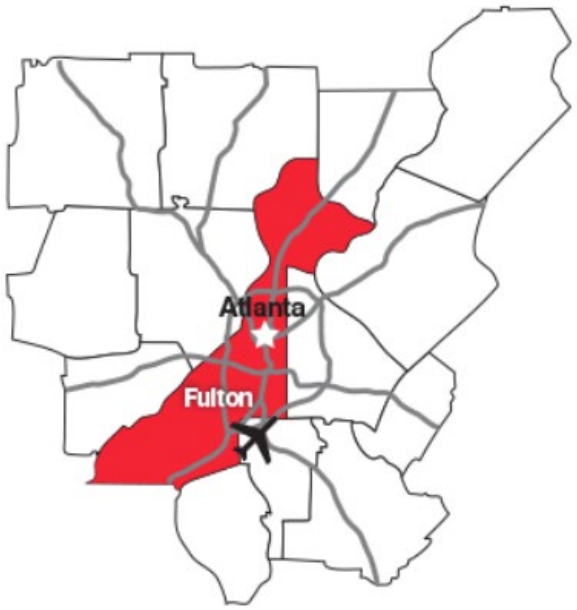
Thank you!

Mpox response in Fulton County, Georgia: Reversing inequity in vaccine distribution

David P. Holland, MD, MHS
Chief Medical Officer
Associate Professor (adjunct)
Emory University

FULTON COUNTY
BOARD OF HEALTH





Contains about 90% of City of Atlanta (most of the rest is in DeKalb)

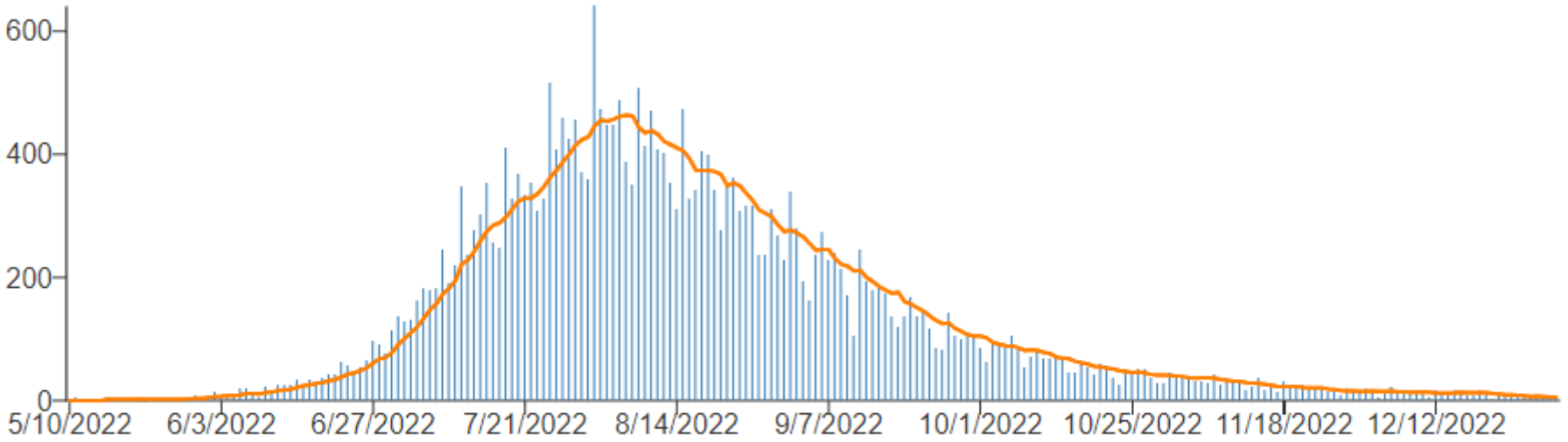
Fulton County, Georgia

- Population ~1,000,000
- 90% of Atlanta inside Fulton
  - Atlanta's population is only 500,000
- Demographics
  - 46% White
  - 44% Black
  - 7.5% Hispanic

Other counties of note

- DeKalb (the capital “K” is important – they’re sensitive)
- Gwinnett
- Cobb
- Clayton

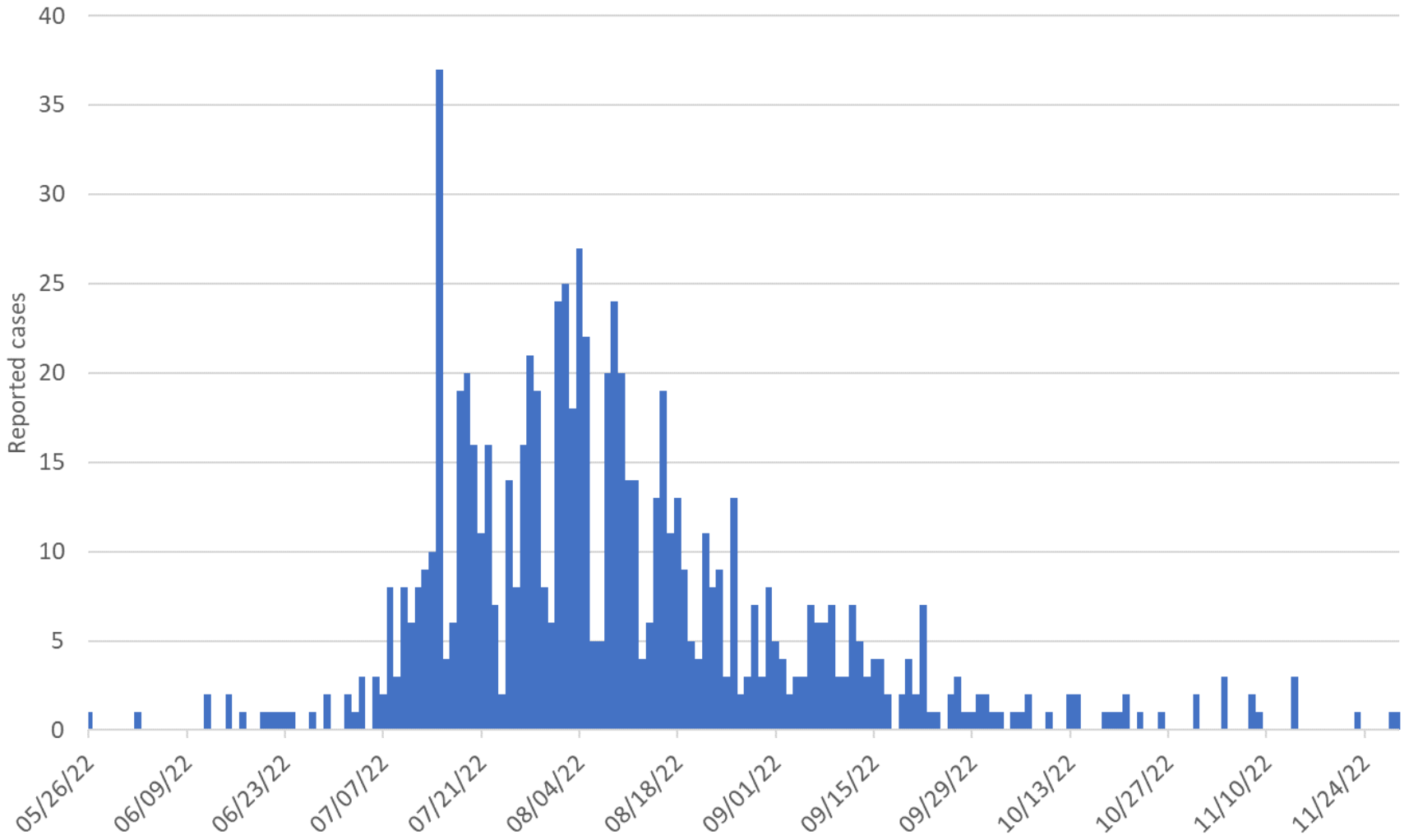
2022 – The summer of mpox



United States

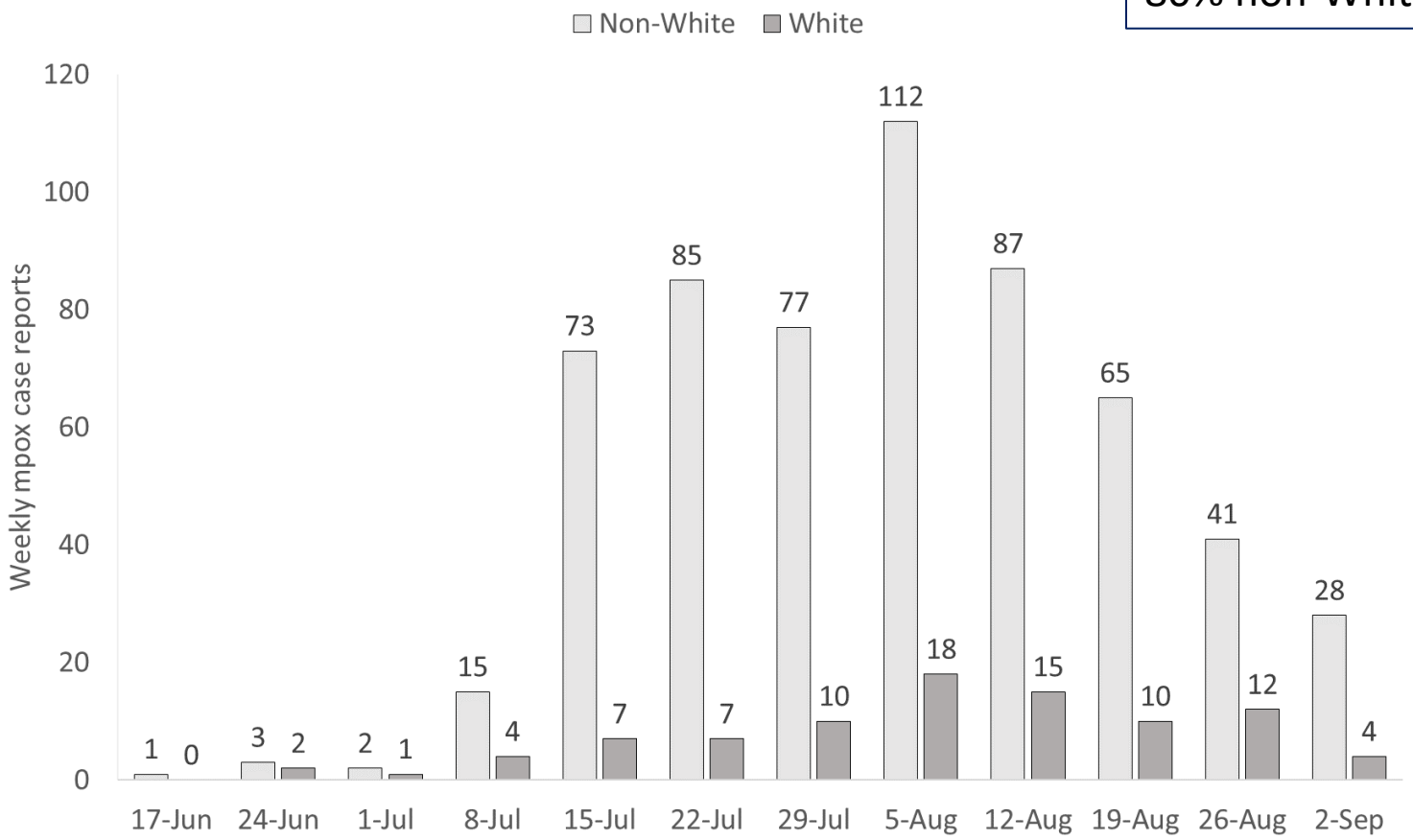
https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html

Fulton County



Fulton County

Approximately
80% non-White



This should have been easy

- Limited segment of the population
  - One with much less vaccine hesitancy
  - 2021 COVID vaccine hesitancy survey:
    - 85% for LGBTQ+ vs 74% for heterosexuals
    - Higher than baseline for all racial groups in men

      McNaghten AD et al., MMWR February 4, 2022 / 71(5);171–176
- Vaccines were ready to go
- We had literally just finished with a national mass-vax campaign

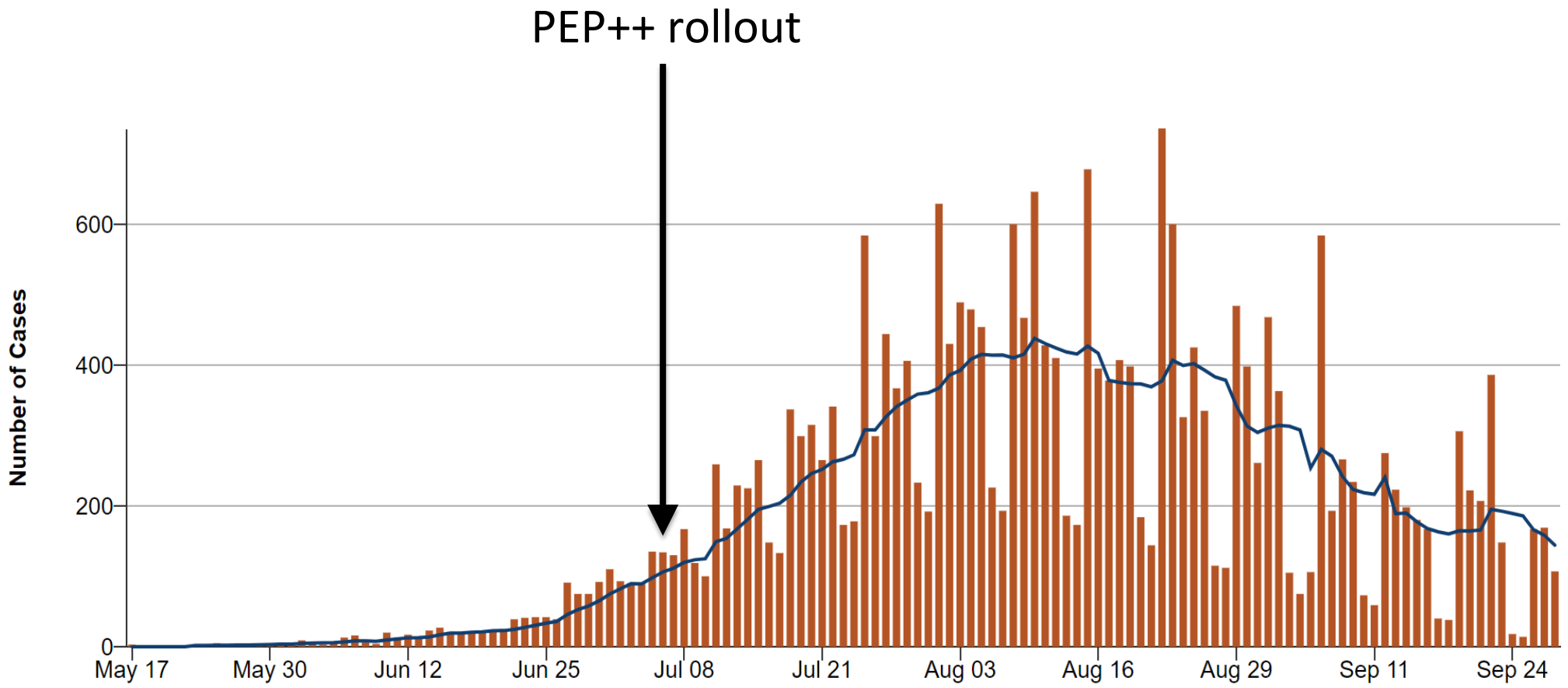
What is PEP++?

- Hint: It’s not the pro version of PEP

- Complicated, but boils down to:
  - Known contact to mpox, or
  - MSM and trans women who have sex with men with multiple sex partners in the past 14 days

- Lots of issues:
  - Required trans women to disclose gender identity
  - Required everyone to claim multiple sex partners

What constitutes a “public health emergency?”



It’s impossible to do equity with scarcity

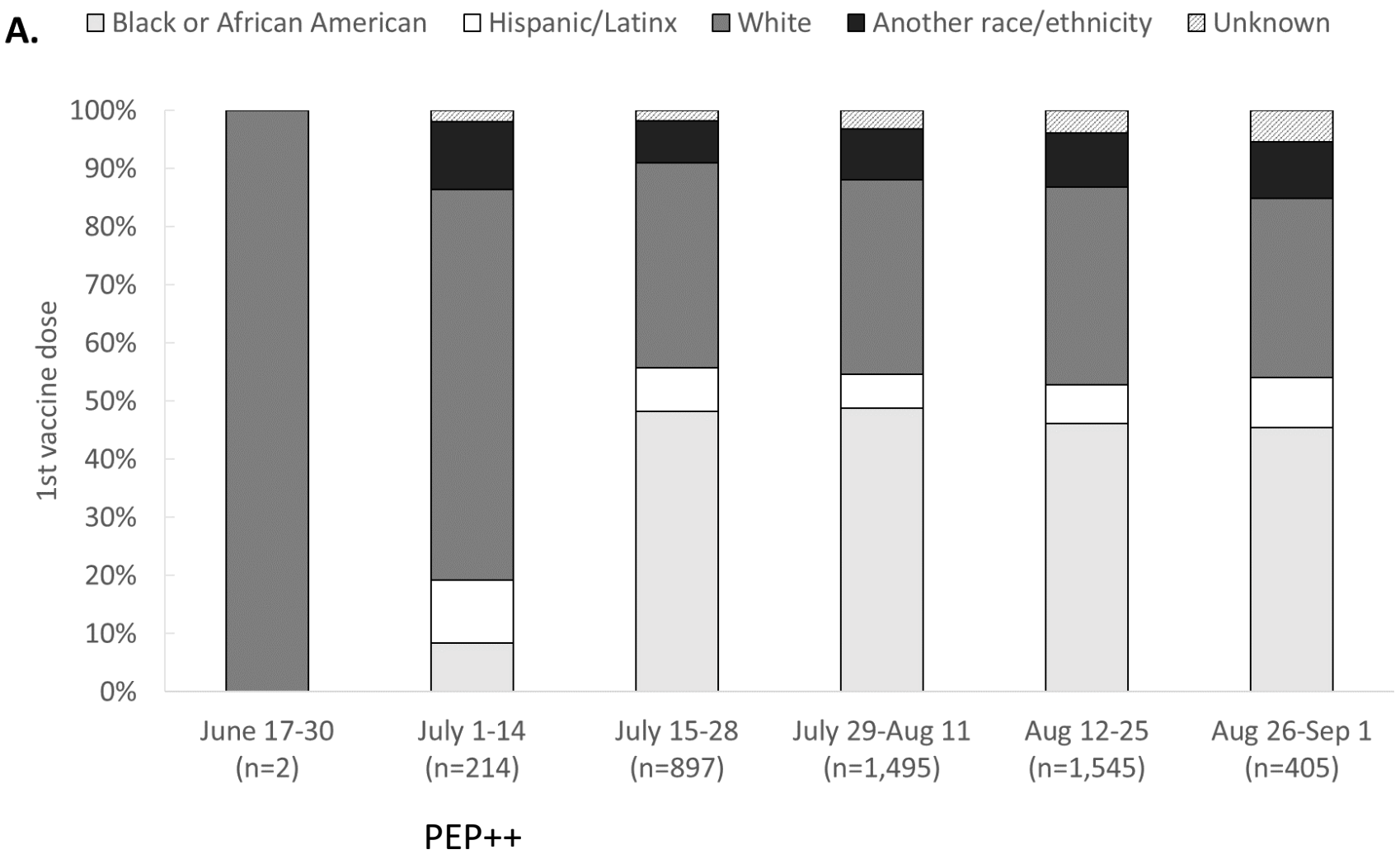
- Vaccines came out in an inconsistent dribble
  - Impossible to plan more than a few days before events
  - Created *Hunger Games* approach to vaccine appointments
  - Those with more access to social media and other outlets were more likely to get appointments

- First vaccine event: >90% of recipients were White

Interventions

- Reached out to CBOs we partner with on HIV
  - Asked them to create a list of people they serve
- Second event:
  - Gave the CBOs 2-hour head start
  - Actually it was only 25 minutes because it went so fast
- Ongoing events:
  - Reserved Friday for CBOs
  - No appointments, no “proof of eligibility”
  - Also, standard appointments had a “heads up” and came out after work

Vaccine distribution by race/ethnicity



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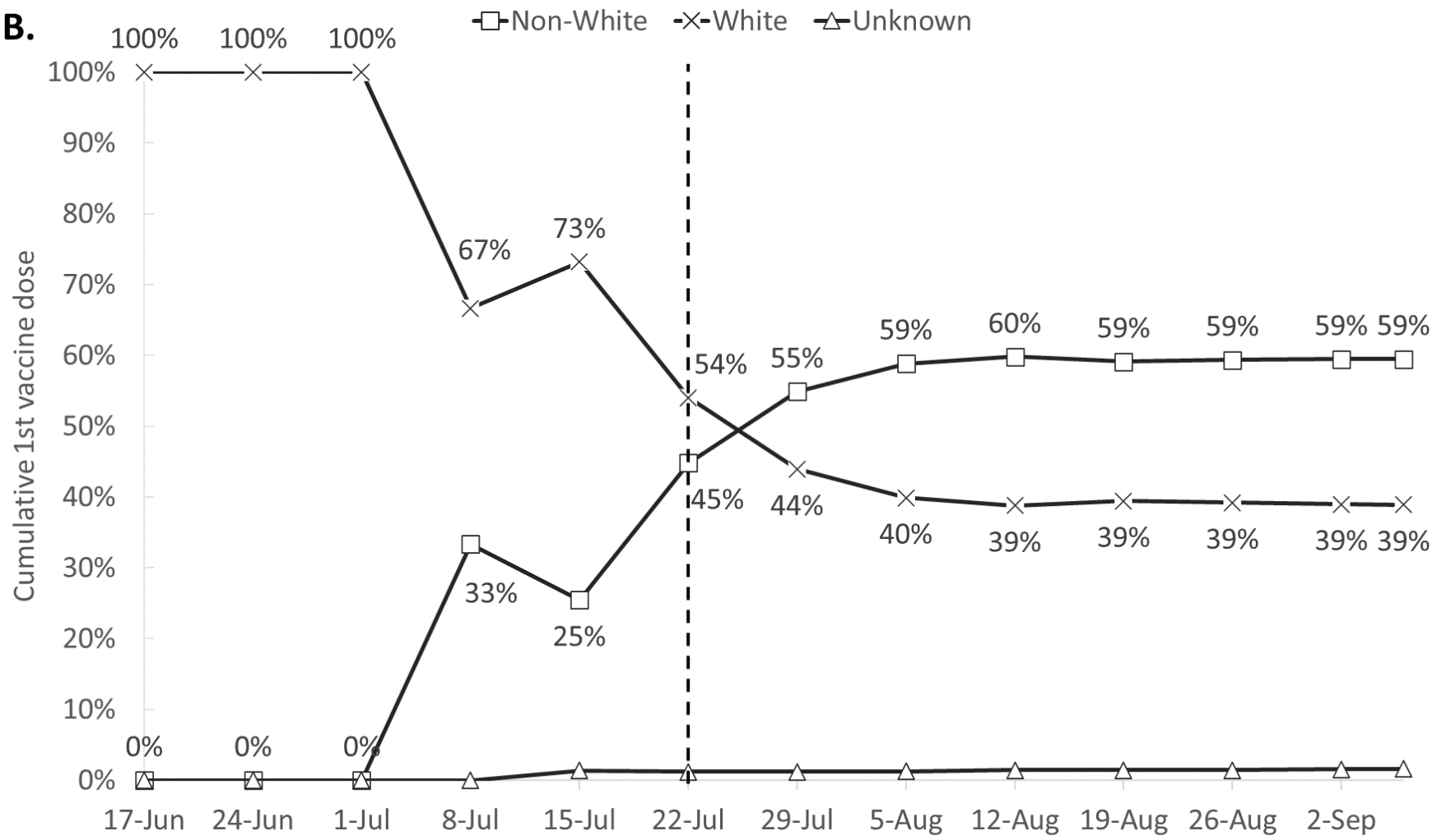
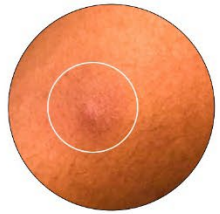


Cumulative 1st dose vaccine administration by race

Overall 59% went to non-White participants (vs 12% nationwide)

MONKEYPOX VACCINATIONS IN PEOPLE WITH DARKER SKIN

Vaccinations are a very important way for sexually-active individuals to protect themselves from monkeypox. However, **Black** and **Brown** individuals, and some others with **darker skin**, may develop a dark patch **HYPERPIGMENTATION** at the site of an intradermal injection. This is a normal reaction to the vaccine, but it may be unappealing to some.



IF YOU NOTICE A DARK SPOT

- Taking ibuprofen and/or an antihistamine daily for 5-7 days after vaccination may reduce inflammation and therefore reduce the darkening, though not completely.
- Protect the site from the sun using either clothing or sunscreen
- It will fade over time, but it could take several months for some people.
- Other things to try (may help spots resolve faster but will not be immediate):
  - Topical retinoids (Differin® gel available over the counter, Retin-A® available with a prescription)
  - Vitamin C solutions (look for 20% or greater vitamin C)
  - There are also other dark spot removers available by prescription

YOU CAN ALSO ASK TO RECEIVE THE VACCINE IN ALTERNATIVE INJECTION SITES, INCLUDING:

- Upper chest under the collarbone
- Back of the arm (triceps)
- Upper back over or just below the scapula
- The shoulder (deltoid)

Vaccinations will not be less likely to cause hyperpigmentation at these sites, but it may be less noticeable. Also, these sites are usually covered by clothing, protecting them from the sun so that they may resolve more quickly.

DON'T FORGET

When making these choices, it is also important to remember that monkeypox disease can cause permanent scars on any part of the body, so everyone should consider their own personal risks when making such a decision.

FULTON COUNTY
BOARD OF HEALTH

At the end(?)

- **75% of non-White recipients received their 2nd dose**
- Approximately cases reported in Fulton in 2023

Mpox Vaccination in Montgomery County, MD

Emily Halden Brown
Ending the HIV Epidemic Program Manager
Montgomery County Department of Health & Human Services
Sexual Health & Wellness Services

MONTGOMERY COUNTY PRIDE

Montgomery County, MD

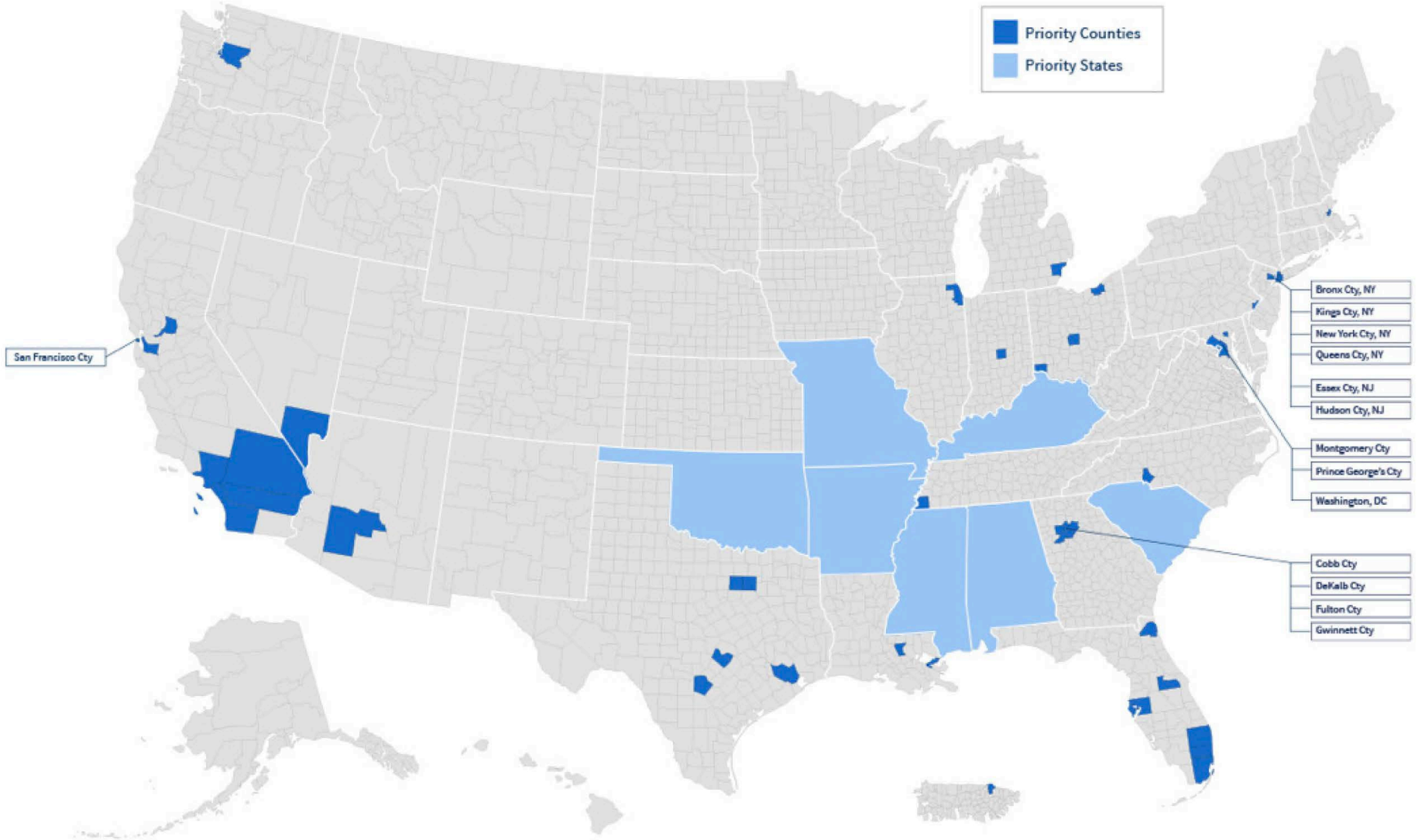
- ~1.1 Million residents
- Among most diverse counties in the U.S.[1]
- Wealthy & healthy [2]
- Low unemployment and high health insurance rates
- Pockets of poverty & growing lower-income sector[3]
- MC-DHHS has provided safety net HIV & STI testing, treatment & prevention services to residents since 1988.

Montgomery County was named a Phase I *Ending the HIV Epidemic* priority jurisdiction in 2019.

GOAL

75% reduction in new HIV infections by **2025**
and at least **90%** reduction by **2030**.

Ending the HIV Epidemic: Priority Jurisdictions

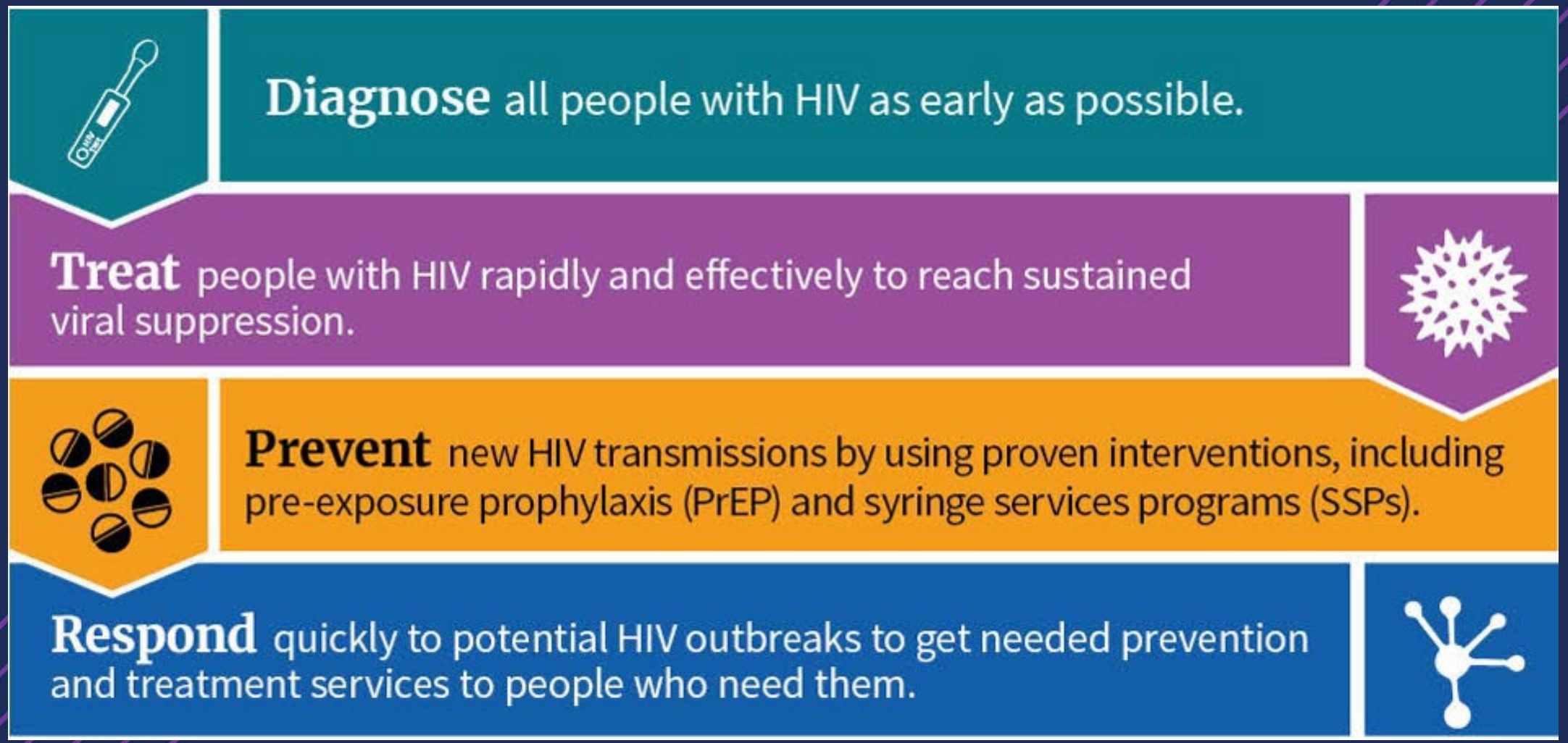


Maryland

- Baltimore City
- Montgomery County
- Prince George's County

Washington, DC

Ending the HIV Epidemic: 4 Pillars



The impact of EHE on our sexual health services

Expansion: Montgomery County Sexual Health & Wellness Services

Dennis Avenue Health Center

- Ryan White HIV Services (Medical Care, Medical & Non-Medical Case Management)
- STI testing & treatment services
- PrEP Clinic
- Partner Services

Upcounty Regional Services Center

- STI testing & treatment services
- Partner Services
- Linkage-to-Care to Dennis Avenue

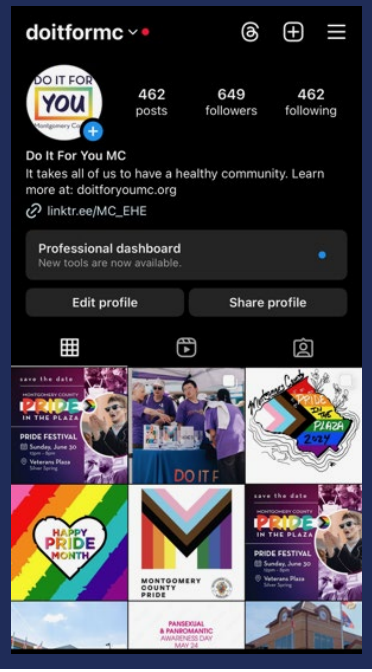
Community Outreach

- HIV and limited POC STI testing
- Linkage-to-Care
- Linkage-to-PrEP
- Resource referrals
- Health Education

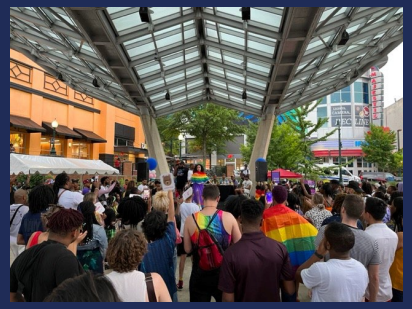
LGBTQ+ - Inclusive Sexual Health Campaign & Intentional Community Outreach

DO IT FOR YOU
Montgomery County

HAZLO POR TI
Montgomery County



2021



PRIDE IN THE PLAZA YEAR 1

- Partner:
  - Capitol Ballroom Council (Pride in the Plaza Mini Ball)
- 42 tabling partners
- ~35 tests

2022

PRIDE IN THE PLAZA YEAR 2

- Partners:
  - Capitol Ballroom Council
  - Live in Your Truth Programs
- 72 tabling partners
- 77 tests (HBI)

2023

PRIDE IN THE PLAZA YEAR 3

- Key partner:
  - Live in Your Truth Programs
  - Capitol Ballroom Council
- 97 tabling partners
- 120 tests
- 11 Mpox vax

The Impact of EHE on our Mpox Response

Montgomery County's Mpox Response

JUNE 2022

Initial Mpox response plan created at Montgomery County HHS

JULY 2022

County receives limited quantity of vaccine

PEP-only protocol

MID- AUGUST 2022

Team used pre-registration form to prioritize those at highest risk for appointments.

SEPTEMBER 2022

Spanish-language Mpox Virtual Townhall hosted in collaboration with Latino Health Initiative and other partners

VACCINATION CONTNUES IN STI/HIV CLINICS

JUNE 25, 2023

Mpox vaccine offered at Pride in the Plaza for $15 gift card.
11 doses administered; some were 2nd doses

Mpox screening questions incorporated into outreach testing

MAY 2022

CDC HAN alert released

Increasing media coverage of Mpox

HAN
HEALTH ALERT NETWORK

JUNE 27, 2022

County hosts 2nd annual **Pride in the Plaza** festival

Provides basic Mpox info from Maryland Health Department

EARLY AUGUST 2022

Vaccine pre-registration system opens

Over 1,000 responses in first week

HIV/STI clinics inundated with calls

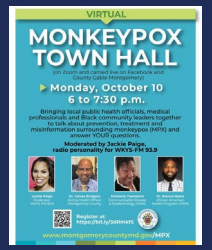
Public email developed

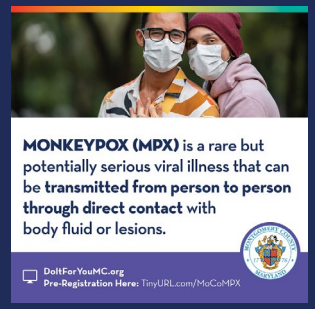
LATE AUGUST 2022

LGBTQ+ Mpox Virtual Townhall hosted in collaboration with key community partners and Montgomery County Council

OCTOBER 2022

Mpox Virtual Townhall with focus on Black/African-American communities hosted in collaboration with African-American Health Program





JUNE 2024

Mpox vaccine will be offered at Pride in the Plaza 2024

The Community and Mpox

National Vaccine Advisory Committee and Office of Infectious Disease and HIV/AIDS Policy Presentation:

Thursday, June 13th

Japer Bowles

Director

The Mayor's Office of LGBTQ Affairs

MAYOR'S OFFICE OF LGBTQ AFFAIRS

WE ARE WASHINGTON DC

GOVERNMENT OF THE DISTRICT OF COLUMBIA

MURIEL BOWSER, MAYOR

Agenda

1. Who we serve and how
2. Events - Health centered
3. Programs - Health centered
4. Q&A

Mission

The mission of the MOLGBTQA is to address the important concerns of the District's lesbian, gay, bisexual, transgender, and questioning residents through empowering young LGBTQ+ community leaders, removing barriers for LGBTQ+ business owners, building a cohesive LGBTQ+ community across all eight wards, and providing resources for the at-risk LGBTQ+ population

DC Government Structure

Mayor's Office on Community Affairs Agencies

What We Do

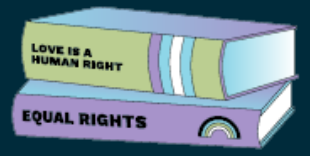
Navigating DC Government

Employment Services

Healthcare

Grant Program

Cultural Competency



Housing Voucher Program

Signature Events

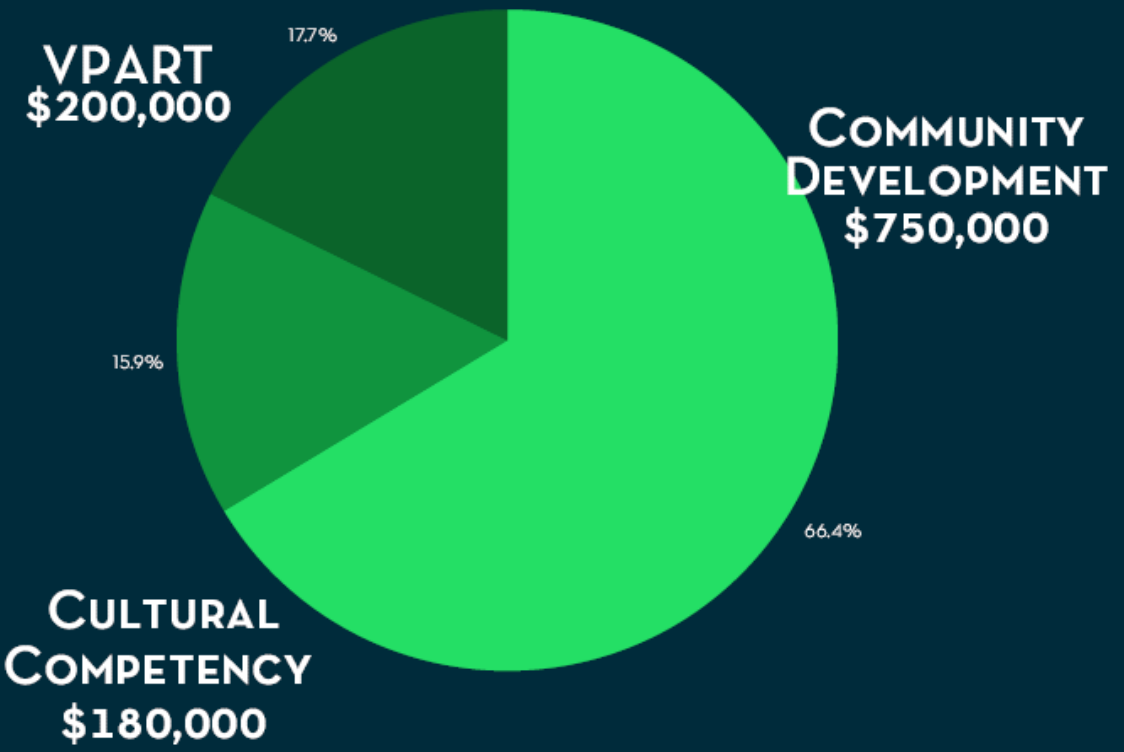
Mayor's Office of LGBTQ Affairs Grants

FY24 MOLGBTQA GRANTS

LGBTQIA+ Community Development Grant

Cultural Competency Grant

Violence Prevention and Response Team



Mayor's Office of Community Affairs
Reach. Connect. Engage. Inspire

We Are Washington DC
Government of the District of Columbia
Muriel Bowser, Mayor

Signature Events

Pride Parade/Festival

District of Pride Showcase

17th Street High Heel Race

LGBTQIA+ Flag Raising

Health at every event

Being IN community is core to the success of this community affairs office. knowing the health disparities of our community, is crucial:

- to provide direct connection to services;
- to be creditable messengers; and
- to collaborate with partners

LGBTQIA+ Dedicated Events

The MOLGBGTQA co-hosts numerous events throughout the year dedicated to our LGBTQIA+ community. We take Pride, that whenever possible, we partner to provide health services at our events.

Examples:

- 17th street high heel race provided rapid testing
- "Know Your Status" Kiki Ball for Trans Pride
- National HIV Testing Day for District of Pride Showcase

Health Dedicated Events

The MOLGBGTQA co-hosts numerous events throughout the year dedicated to supporting better health. We ensure that these events aren't just inclusive of our community, but community-centered.

Examples:

- National Youth HIV/AIDS Awareness Day - Instagram LIVE! w/ LGBTQIA youth
- National Black HIV/AIDS Awareness Day - DC Health Event

Health Programs

LGBTQIA+ Health Coordinator

The MOLGBTQA is proudly staffed with a DC Health Liaison that coordinates health care services (MPOX, PrEP, HIV and STI testing, etc.), partnerships and collaborations with the LGBTQIA+ community

Results:

- Provide another direct connection to health care services
- Impactful partnership events
- Expanded Naloxone Training and Administration
- Expanded condom distribution

LGBTQIA+ Community Development Grants

The MOLGBTQA provided funding to community based organizations that led the charge to educate the community and provide services to prevent and treat MPOX.

Results:

- 55 DC residents tested for Mpox;
- 4 DC residents treated for Mpox;
- 133 DC vaccinated against Mpox with the Jynneos vaccine

World Pride 2025

2025 marks the 50th Anniversary of Pride celebrations in Washington, DC! In celebration of this momentous occasion and through years of advocacy and bidding through InterPride, the Capital Pride Alliance (CPA), in partnership with the DC Government, Team DC, and the Center for Black Equity are proudly hosting WorldPride 2025 from May 23 – June 8, 2025. WorldPride is one of the largest biennial international LGBTQIA+ festivals and the DC region is expected to host 3 million visitors, 3 to 4 times the size of 2023's historic turnout of 750,000 over the Pride weekend (June 9th -11th). WorldPride attendees will have an opportunity to celebrate in the nation's capital at the WorldPride Festival, Parade, Opening and Closing Concert, contribute to an International LGBTQIA+ Human Rights Conference, cheer and/or participate in a Sports Festival, and enjoy DC's impressive collection of public art and museums, food and nightlife, and cultural events that celebrate our DCValues.

GOALS: Healthiest and Safest LGBTQIA+ Event:

- Comprehensive Health Services: Provide accessible healthcare services, including testing, vaccinations, and informational resources, to prioritize the well-being of attendees.
- Community Outreach: Conduct outreach and educational campaigns on health and safety practices within the LGBTQIA+ community, fostering a sense of responsibility and care among attendees.

Mayor's Office of Community Affairs
Reach. Connect. Engage. Inspire

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Government of the District of Columbia
Muriel Bowser, Mayor

Q&A

THANK YOU!

Follow -US-

@DCLGBTQ

MAYOR'S OFFICE OF COMMUNITY AFFAIRS
Reach. Connect. Engage. Inspire

GOVERNMENT OF THE DISTRICT OF COLUMBIA
MURIEL BOWSER, MAYOR

Pride, Equity, and Community: Mpox Vaccination in 2024

Discussion

NVAC

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

June 13-14, 2024

Lunch

Resume at 1:30 PM ET

NVAC

Fall and Winter Respiratory Diseases: The Vaccination Season Ahead

Dr. Emily Brunson
Molly Howell
Dr. Bob Hopkins
Dr. Brendan Jackson

NVAC

Promoting Uptake of Respiratory Virus Vaccines

Emily K. Brunson
June 13, 2024

The National Academies of SCIENCES ENGINEERING MEDICINE

Respiratory Vaccine Uptake

- Uptake can mitigate morbidity, mortality, and other social impacts
- Uptake isn’t guaranteed:
  - 2023 uptake (October 2023 – April 2024)
    - Flu:: 47.7% of all adults
    - COVID-19: 22.0% of all adults
    - RSV: 23.1% age 65+
- General strategies to increase uptake exist, there are also distinct characteristics of the vaccines that warrant some variation in emphasis

The Issue of Access

- Access plays a significant role in vaccine uptake
- Access can include literal access to vaccines
- It can also include:
  - Ability to pay for vaccines
  - Ability to take time off work
  - Access to childcare, eldercare
  - Ability to access vaccines in places that feel “safe”
  - Ability to access information

Strategies to Improve Access

1. Ensure equity in accessibility
   - Address structural barriers
     - Example: Provide vaccines in non-health care settings/mobile clinics
   - Provide low- or no-cost vaccines
2. Increase community demand
   - Develop culturally sensitive, community-based campaigns
   - Utilize trusted community leaders
3. Improve provider- and system-based demand

The Issue of Choice

- Choice also plays a role in vaccine uptake
- People do not make their choices in a vacuum – social networks are key
- Aspects of choice to consider:
  - Public awareness and understanding of the different vaccines – especially important for “new” COVID-19 and RSV vaccines
  - Individuals’ motivation to get vaccinated

General Communication Strategies

1. Communicate with transparency and openness
   - Safety and efficacy, including negative results
   - What is known and what is not
   - Adapt to different groups as needed
2. Use updated data to highlight susceptibility to infection
3. Use trusted messengers

Addressing mis- and dis-information

- Social media use and the recent COVID-19 pandemic have amplified mis- and dis-information about vaccines
- To address mis- and dis-information, public messaging should:
  - Provide accurate information and acknowledge uncertainty
  - Present information from reliable sources such as the CDC
  - Ensure new information is provided quickly and widely
  - Offer consistent, unified messages
  - Optimize communication content for internet searches

Vaccine specific recommendations

Flu

- Specific emphasis is needed for at-risk groups. Communication should also address how the vaccine matches with circulating flu strains

COVID-19

- Concern about COVID-19 has waned. Communication should address why vaccines are needed given the current conditions of the virus mutations

RSV

- The newness of this vaccine is key. Communication should emphasize who the vaccine is for and what it can do, relying on information from last year's vaccination campaign

Respiratory Virus Season Vaccines Implementation

Molly Howell, MPH
Immunization Director, North Dakota
Department of Health and Human Services

June 13, 2024

AIM Association of Immunization Managers

About AIM

- **Who:** Representatives from the 64 federally-funded awardees (50 states, 6 major cities, 8 territories/federated states)
- **What:** A non-profit, tax-exempt organization
- **When:** Established in 1999
- **Why:** To enable immunization program managers to work together

Vision:
A nation free of vaccine-preventable diseases across the lifespan.

Mission:
Through national leadership, advocacy, collaboration, and a collective voice, AIM represents and supports immunization programs in the development and implementation of effective immunization policies, programs and practices.

Immunization Program Basics: Who are AIM members and what do they do?

Immunization Program Manager: Routine Activities

- Strategies to increase coverage rates
- Data collection and analysis (IIS)
- Immunization education, promotion, communication
- Immunization Quality Improvement for Providers (IQIP)
- Outbreak control
- Partnerships with traditional/nontraditional partners
- Reaching underserved populations
- Vaccines for Children (VFC) Program

Implementing a New Vaccine/Product

- Add product to IIS (work with vendor on coding, etc)
- Add product to VFC (inform providers, plan for supply)
- Educate partners, providers and public
- Work with insurers, including Medicaid – is there coverage for patients, payment for providers?
- Create plan to ensure access and equity

2023-24 Season Experience: Flu Season + + +

- Annual flu vaccination
- COVID-19 Vaccine Bridge Access Program implementation
- Transition to commercialization of COVID-19 vaccine
- RSV vaccines for adults 60+ (shared clinical decision making)
- RSV vaccine for pregnant people (protection for the infant)
- RSV immunization (nirsevimab) for infants and young children

Nirsevimab: 2023-24 Challenges

- **VFC**: Uncertainty about VFC inclusion led to limited planning
  - Low enrollment of birthing hospitals in VFC
  - Providers unsure about what to expect
  - Providers unable or unwilling to order and stock nirsevimab
- **Supply**: Assumption of sufficient supply led to unequal distribution and inconsistency across jurisdictions
- **IIS/EMR:** Adding a monoclonal antibody, recording birth dose for yet-to-be named newborns, giving 2 100mg doses to some babies/children
- **Insurance coverage**
  - Insurers have up to one year to ACIP recommended "vaccines"
  - Birth dose payment included in "bundle", negotiated annually
  - Coverage and admins fee challenging for major insurers and Medicaid

2023-24 Implementation Challenges: Older Adults, Maternal Populations

- Collecting data on specific populations
- Ensuring access and equity
- Focusing on LTCF (insurance coverage and data collection)
- Educating providers and public about severity of RSV and COVID, especially in older adults

2023-24 Respiratory Vaccine Uptake Rates

CHILDREN

COVID
14.4%

Flu
53.9%

Nirsevimab
41.3%*

PREGNANT PERSONS

COVID
13.3%

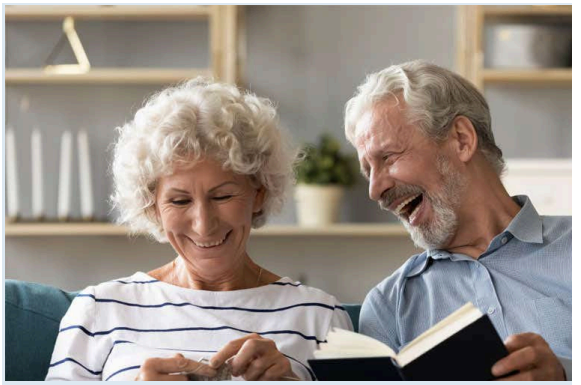
Flu
38.1%

RSV Maternal
17.8%

ADULTS

COVID
22.5%

Flu
48.5%



OLDER ADULTS

COVID
41.5% adults 75+

Flu
78.4% adults 75+

RSV
24.4% adults 60+

*As of March 2024, 41.3% of females with an infant <8 months reported that their infant receivednirsevimab (Source: CDC RSVVaxView)

Nirsevimab: 2024-25 Season Preparations

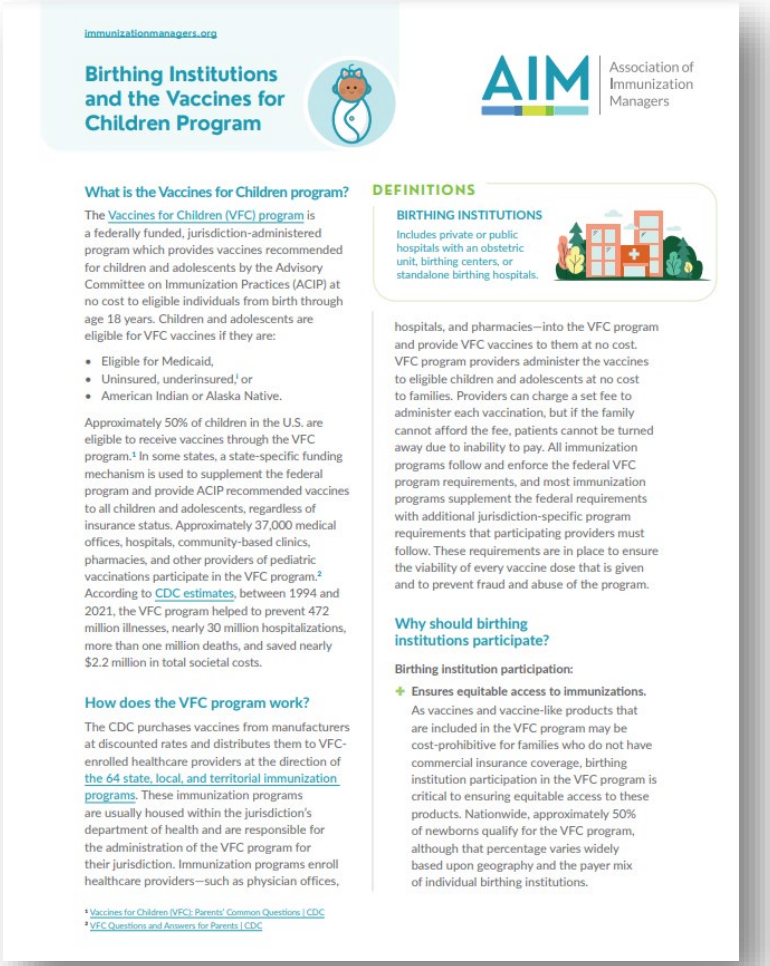
Efforts to Increase Birthing Institution Enrollment in VFC

Immunization Program Activity

- Outreach and recruitment
- Partnerships with Medicaid, state hospital associations, prenatal groups, health systems, etc.
- VFC policy updates
  - Virtual enrollment site visits
  - Borrowing and replacement models

AIM Activity

- Partnership with American Hospital Association (AHA)
  - Fact Sheet: birthing institutions and VFC
  - Pilot project with a multi-jurisdiction hospital systems
- Peer sharing program (webinars, hub of peer resources)



immunizationmanagers.org

Birthing Institutions and the Vaccines for Children Program

AIM Association of Immunization Managers

What is the Vaccines for Children program?

The Vaccines for Children (VFC) program is a federally funded, jurisdiction-administered program which provides vaccines recommended for children and adolescents by the Advisory Committee on Immunization Practices (ACIP) at no cost to eligible individuals from birth through age 18 years. Children and adolescents are eligible for VFC vaccines if they are:

- Eligible for Medicaid,
- Uninsured, underinsured,[1] or
- American Indian or Alaska Native.

Approximately 50% of children in the U.S. are eligible to receive vaccines through the VFC program.[1] In some states, a state-specific funding mechanism is used to supplement the federal program and provide ACIP recommended vaccines to all children and adolescents, regardless of insurance status. Approximately 37,000 medical offices, hospitals, community-based clinics, pharmacies, and other providers of pediatric vaccinations participate in the VFC program.[2] According to CDC estimates, between 1994 and 2021, the VFC program helped to prevent 472 million illnesses, nearly 30 million hospitalizations, more than one million deaths, and saved nearly $2.2 million in total societal costs.

How does the VFC program work?

The CDC purchases vaccines from manufacturers at discounted rates and distributes them to VFC-enrolled healthcare providers at the direction of the 64 state, local, and territorial immunization programs. These immunization programs are usually housed within the jurisdiction's department of health and are responsible for the administration of the VFC program for their jurisdiction. Immunization programs enroll healthcare providers—such as physician offices,

DEFINITIONS

BIRTHING INSTITUTIONS

Includes private or public hospitals with an obstetric unit, birthing centers, or standalone birthing hospitals.

hospitals, and pharmacies—into the VFC program and provide VFC vaccines to them at no cost. VFC program providers administer the vaccines to eligible children and adolescents at no cost to families. Providers can charge a set fee to administer each vaccination, but if the family cannot afford the fee, patients cannot be turned away due to inability to pay. All immunization programs follow and enforce the federal VFC program requirements, and most immunization programs supplement the federal requirements with additional jurisdiction-specific program requirements that participating providers must follow. These requirements are in place to ensure the viability of every vaccine dose that is given and to prevent fraud and abuse of the program.

Why should birthing institutions participate?

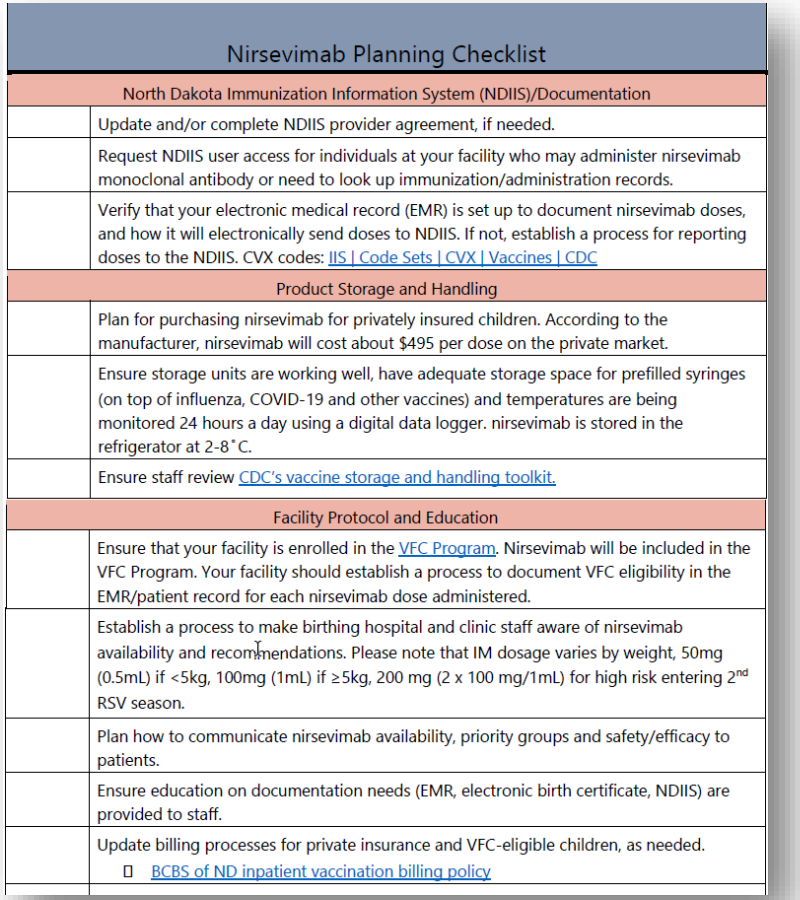
Birthing institution participation:

+ **Ensures equitable access to immunizations.** As vaccines and vaccine-like products that are included in the VFC program may be cost-prohibitive for families who do not have commercial insurance coverage, birthing institution participation in the VFC program is critical to ensuring equitable access to these products. Nationwide, approximately 50% of newborns qualify for the VFC program, although that percentage varies widely based upon geography and the payer mix of individual birthing institutions.

[1] Vaccines for Children (VFC): Parents' Common Questions | CDC
[2] VFC Questions and Answers for Parents | CDC

Nirsevimab:
North Dakota Experience: Plans for Next Season

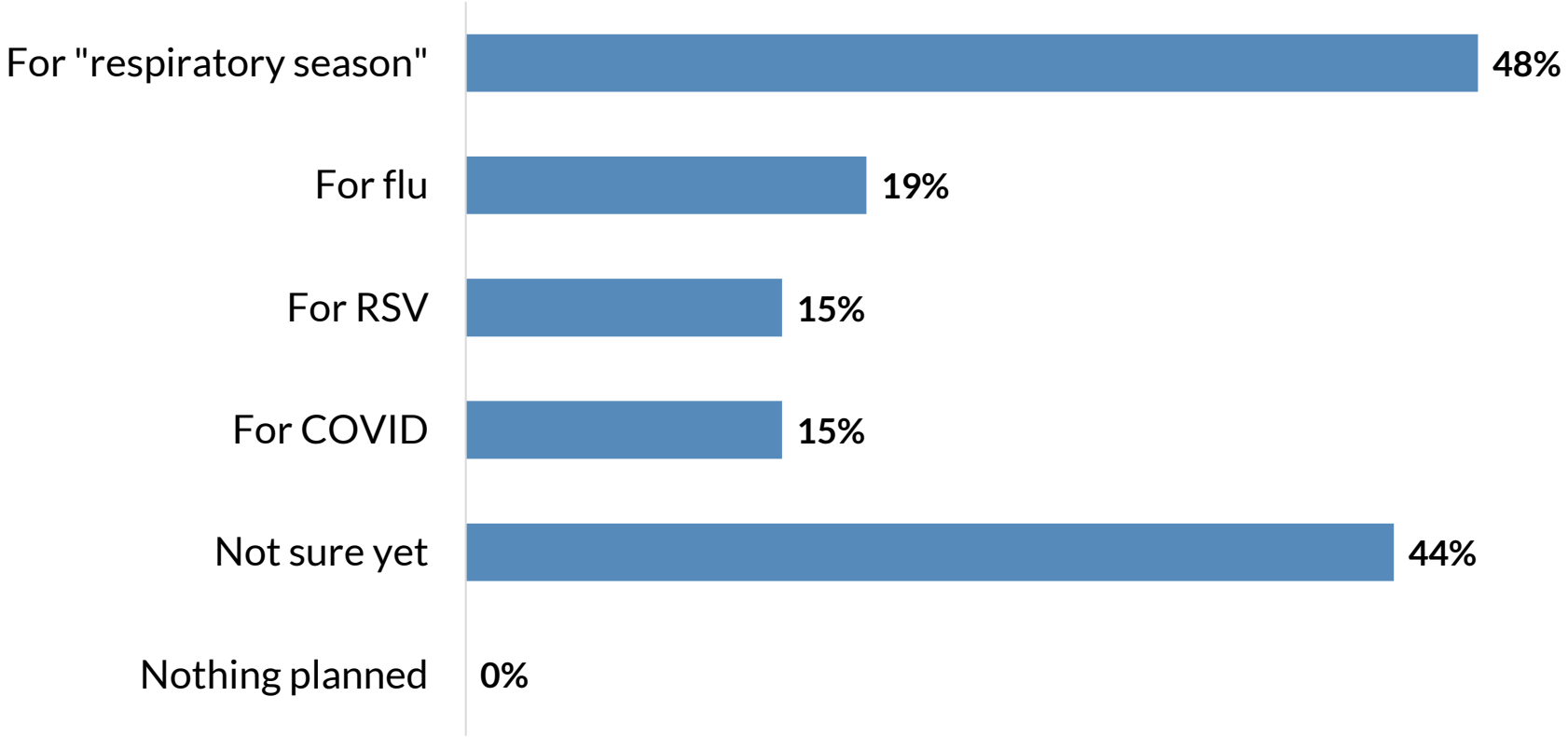
- Developing a tip sheet to assist providers in estimating nirsevimab need for next season
- Education of birthing hospitals regarding nirsevimab and participation in VFC Program
- Most birthing hospitals enrolled in VFC in ND
- Reminder/recall functionality to IIS for nirsevimab
- Planning for allocations of supply
- Equity (public vs. private stock)
- Dashboard for "respiratory season"



Nirsevimab Planning Checklist	
North Dakota Immunization Information System (NDIIS)/Documentation	
	Update and/or complete NDIIS provider agreement, if needed.
	Request NDIIS user access for individuals at your facility who may administer nirsevimab monoclonal antibody or need to look up immunization/administration records.
	Verify that your electronic medical record (EMR) is set up to document nirsevimab doses, and how it will electronically send doses to NDIIS. If not, establish a process for reporting doses to the NDIIS. CVX codes: IIS | Code Sets | CVX | Vaccines | CDC
Product Storage and Handling	
	Plan for purchasing nirsevimab for privately insured children. According to the manufacturer, nirsevimab will cost about $495 per dose on the private market.
	Ensure storage units are working well, have adequate storage space for prefilled syringes (on top of influenza, COVID-19 and other vaccines) and temperatures are being monitored 24 hours a day using a digital data logger. nirsevimab is stored in the refrigerator at 2-8˚C.
	Ensure staff review CDC's vaccine storage and handling toolkit.
Facility Protocol and Education	
	Ensure that your facility is enrolled in the VFC Program. Nirsevimab will be included in the VFC Program. Your facility should establish a process to document VFC eligibility in the EMR/patient record for each nirsevimab dose administered.
	Establish a process to make birthing hospital and clinic staff aware of nirsevimab availability and recommendations. Please note that IM dosage varies by weight, 50mg (0.5mL) if <5kg, 100mg (1mL) if ≥5kg, 200 mg (2 x 100 mg/1mL) for high risk entering 2nd RSV season.
	Plan how to communicate nirsevimab availability, priority groups and safety/efficacy to patients.
	Ensure education on documentation needs (EMR, electronic birth certificate, NDIIS) are provided to staff.
	Update billing processes for private insurance and VFC-eligible children, as needed. ☐ BCBS of ND inpatient vaccination billing policy

2024-25 Respiratory Season Campaigns

Is your jurisdiction preparing an educational or media campaign for fall vaccinations? (Check all that apply) *n=27*



*Poll data from AIM General Membership Webinar 5/23/2024

Promoting Respiratory Illness Vaccination 2023–2024 Toolkit for Health Care Providers

Wisconsin Department of Health Services | Division of Public Health
Bureau of Communicable Diseases | Immunization Section

P-02781 (10/2023)

WISCONSIN DEPARTMENT of HEALTH SERVICES

Respiratory Syncytial Virus (RSV) Vaccine & Pregnancy: What You Need to Know

Why should you consider RSV vaccine during pregnancy?

RSV usually causes only mild upper respiratory infections for most people, including pregnant women. However, it can lead to severe disease in babies and some young children. RSV is the No. 1 cause of infant hospitalizations in the United States, with four out of five of these hospitalizations in otherwise healthy infants with no underlying medical conditions. Infant RSV hospitalization rates are even higher in American Indian infants, at 4-10 times greater than the general population. Pregnant women who get the RSV vaccine, Abrysvo™, pass antibodies to the baby, helping prevent RSV lower respiratory

What are the maternal RSV vaccin

The Advisory Committee on Immunization Practic
when these criteria are met:

- Pregnant women during 32-36 weeks ges
- During the months of September through

is the maternal RSV
gestational weeks 32 and 3
enting severe medically atte
rom 0-90 days and 76% effe
y differ somewhat from the
vaccination for best materna
s who are born at least two
rth through the first RSV se

North Dakota Health
600 E Boulevard Ave, Dept 325 • Bismarck, ND 58505
701.328.2310 • Toll-free 800.427.2622 • 711 (TTY) • www.hhs.nd.gov

YES! Get your COVID-19 and flu vaccines.

2023-2024 COVID-19/Flu Media Campaign

DEPARTMENT OF HEALTH

health.state.mn.us

As

Thank you!

immunizationmanagers.org

@AIMimmunization

Association of Immunization Managers

AIM

Association of Immunization Managers

Lessons Learned from Prior Seasons: Flu, COVID-19, and RSV

Robert (Bob) H. Hopkins, Jr., MD
NFID Medical Director

National Foundation for Infectious Diseases®

About NFID

Founded in 1973, the National Foundation for Infectious Diseases (NFID) is a non-profit 501(c)(3) organization

Vision:
Healthier lives for all through the effective prevention and treatment of infectious diseases

Mission:
Educate and engage the public, communities, and healthcare professionals about infectious diseases across the lifespan

Core Values:
- Collaboration
- Diversity, Equity, Inclusion
- Evidence-Based
- Integrity
- Transparency

National Foundation for Infectious Diseases®

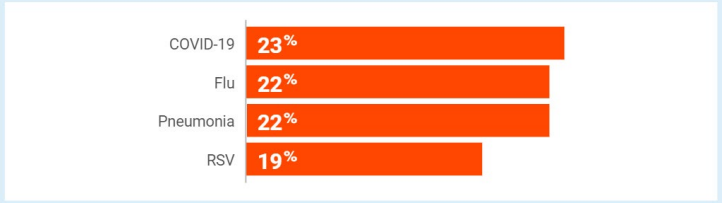
www.nfid.org

NFID National Survey Results: 2019-2023 (www.nfid.org/flusurveys)

2023 Attitudes about Influenza, COVID-19, Respiratory Syncytial Virus, and Pneumococcal Disease

NFID survey of US adults revealed insights around beliefs about influenza (flu), COVID-19, respiratory syncytial virus (RSV), and pneumococcal disease, as well as attitudes and practices around vaccination

CONCERNS ABOUT GETTING INFECTED WITH:



Fewer than **1 in 4** US adults are concerned about themselves or someone in their family getting infected this fall and winter

Perceptions on Influenza, Pneumococcal Disease, and COVID-19 — 2022

NFID survey conducted among US adults revealed insights about knowledge, attitudes, and behaviors related to influenza (flu), pneumococcal disease, and COVID-19

FLU

of US adults agree flu vaccination is the best way to prevent flu-related hospitalizations and deaths

but only **49%** plan to get vaccinated **against flu** during the 2022-2023 flu season

Perceptions on Influenza, Pneumococcal Disease, and COVID-19 — 2021

NFID survey conducted among US adults uncovered insights about knowledge, attitudes, and behaviors related to influenza (flu), pneumococcal disease, and COVID-19

FLU

agree flu vaccination is the best way to prevent flu-related hospitalizations and deaths

but **44%** are unsure or do not plan to get vaccinated **against flu** during the 2021–2022 flu season

Perceptions on Influenza, Pneumococcal Disease, and COVID-19 — 2020

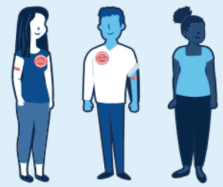
NFID survey conducted among US adults uncovered insights about influenza (flu) and pneumococcal disease awareness, as well as attitudes and behaviors around vaccination during the COVID-19 pandemic

FLU

agree flu vaccination is the best preventive measure against flu-related deaths and hospitalizations

but only **59%** plan to get vaccinated **against flu** during the 2020–2021 flu season

59% of White adults and **65%** of Hispanic adults plan to get vaccinated against flu for the 2020–2021 season,



but **62%** of Black adults are not sure or do not plan to get vaccinated

Attitudes about Influenza and Pneumococcal Disease Prevention — 2019

A National Foundation for Infectious Diseases (NFID) survey[1] conducted among US adults uncovered insights about influenza (flu) and pneumococcal disease knowledge, as well as attitudes and behaviors around vaccination

FLU

60%

agree the flu vaccine is the best preventive measure against flu-related deaths and hospitalizations

Top reasons for NOT getting a flu vaccine[2]

51% don't think flu vaccines work very well

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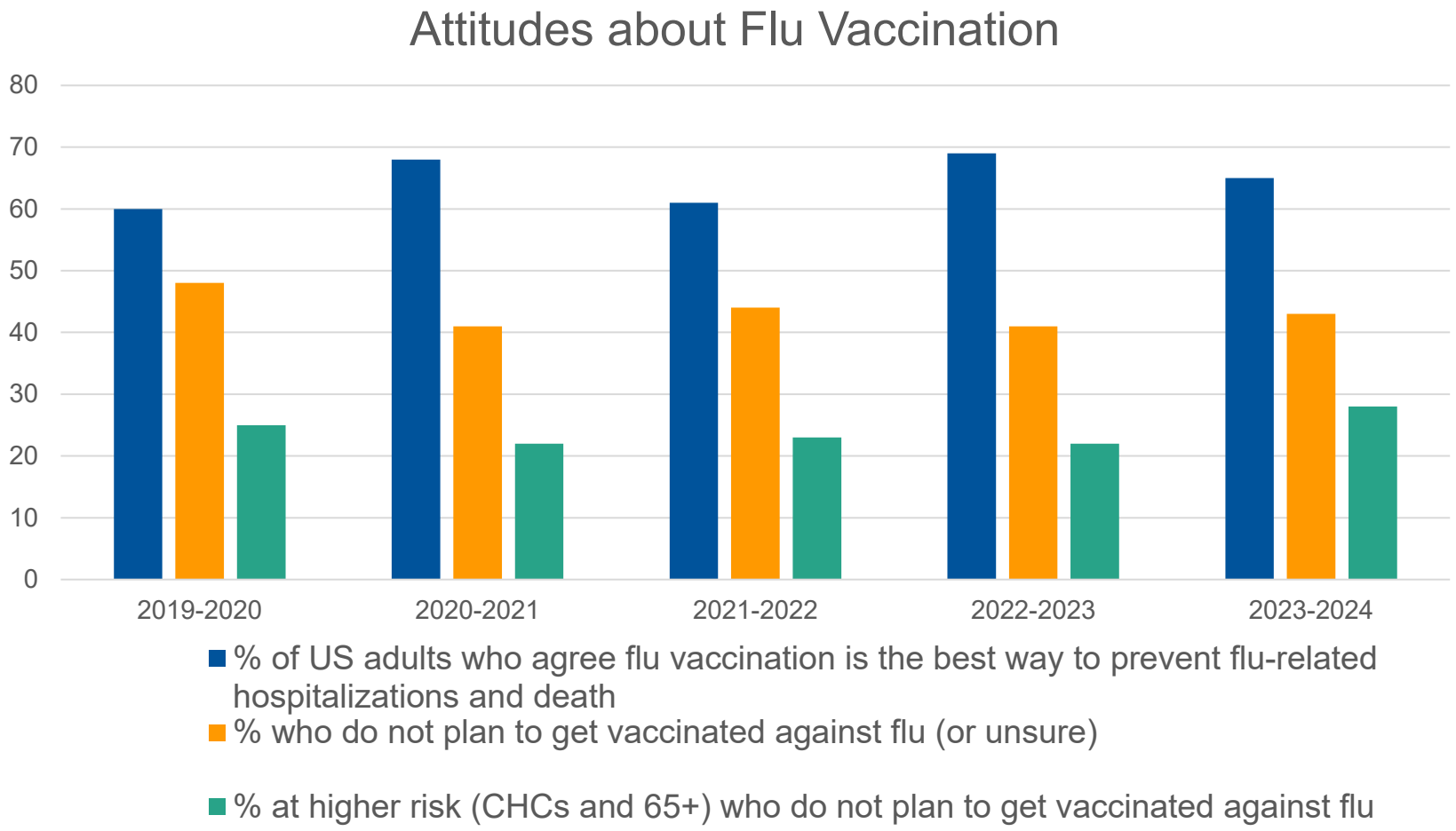
Intention to Get Vaccinated



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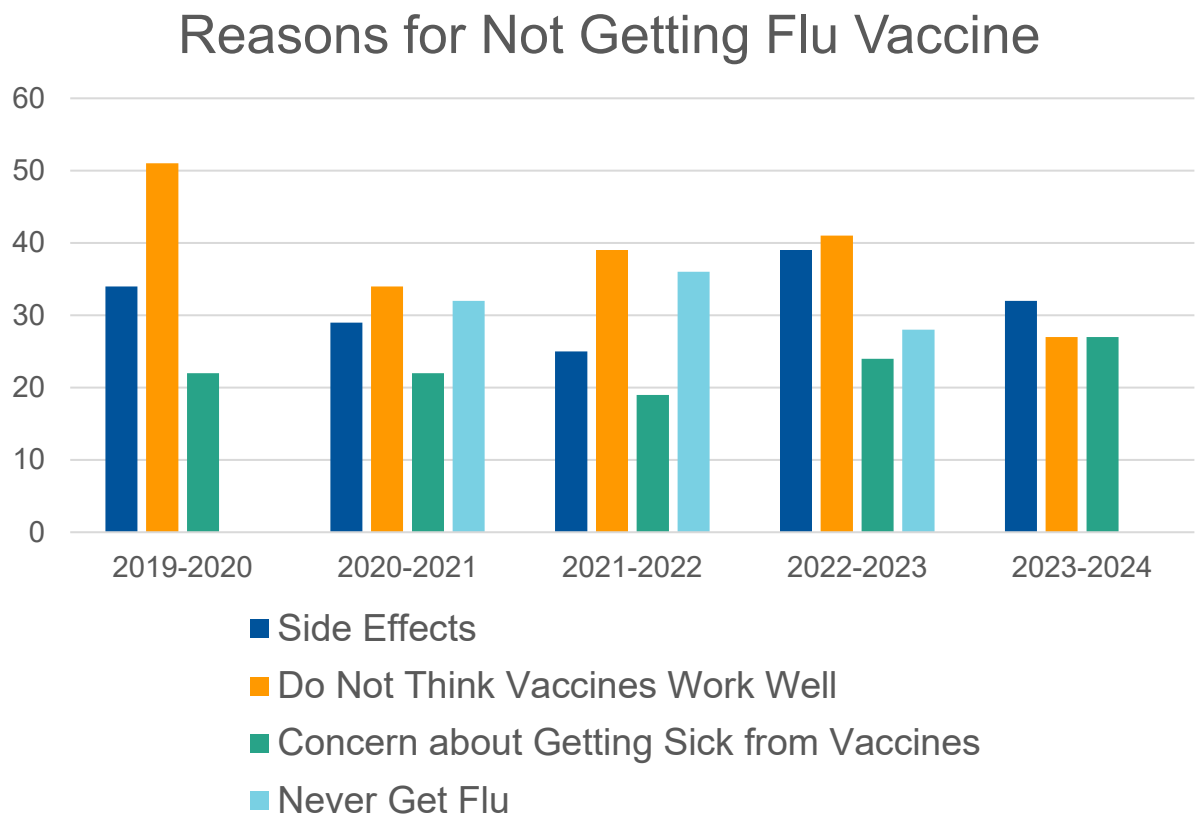
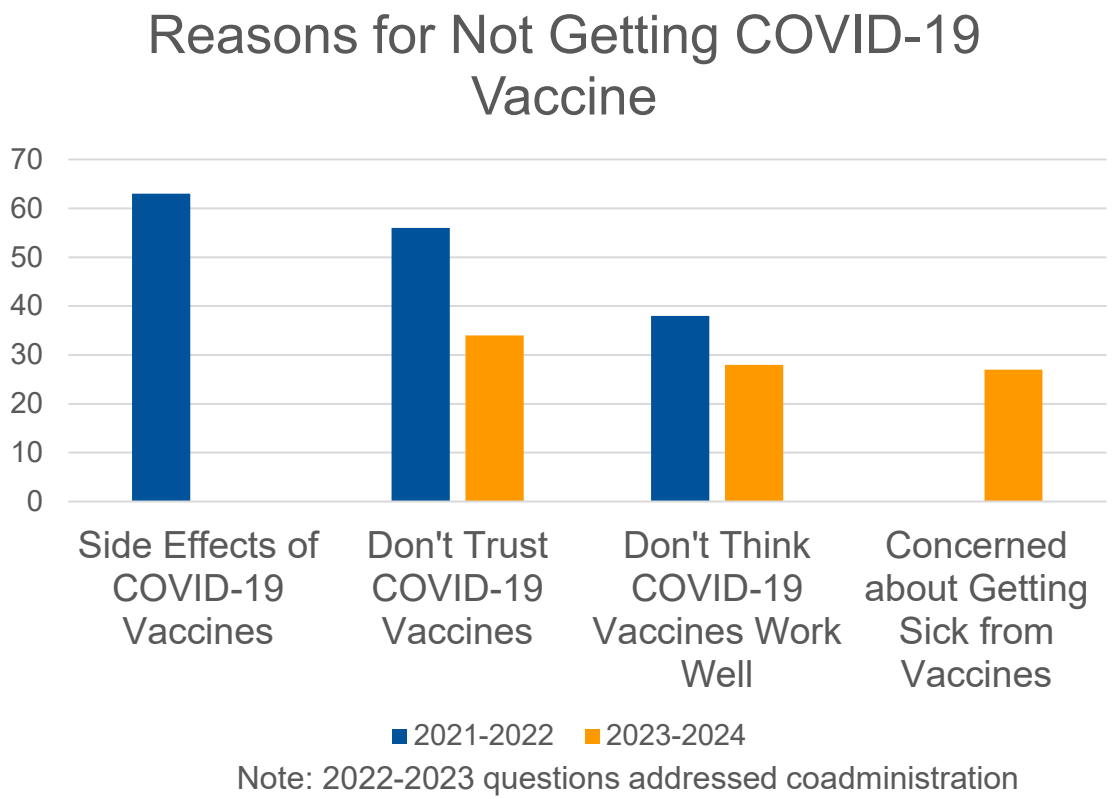
*People at higher risk for complications from flu as defined in the surveys include those age 65 years and older, adults whocurrently or ever smoked tobacco, and those who have or ever have had diabetes, asthma, chronic obstructive pulmonary disease (COPD), heart disease, stroke, or kidney disease.

Reasons for Not Getting Vaccinated



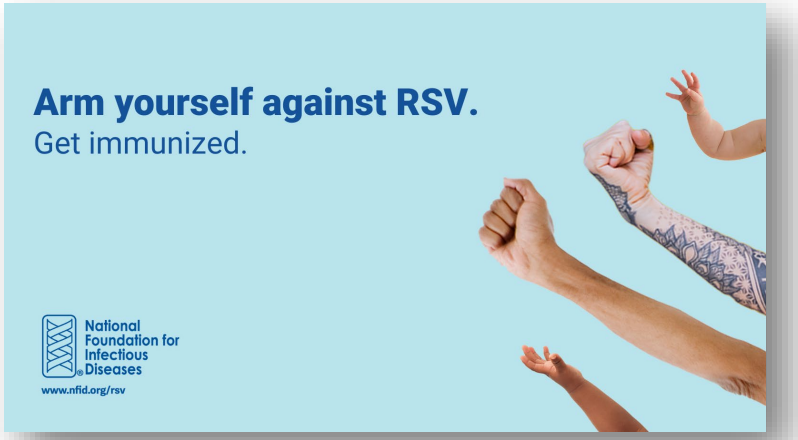


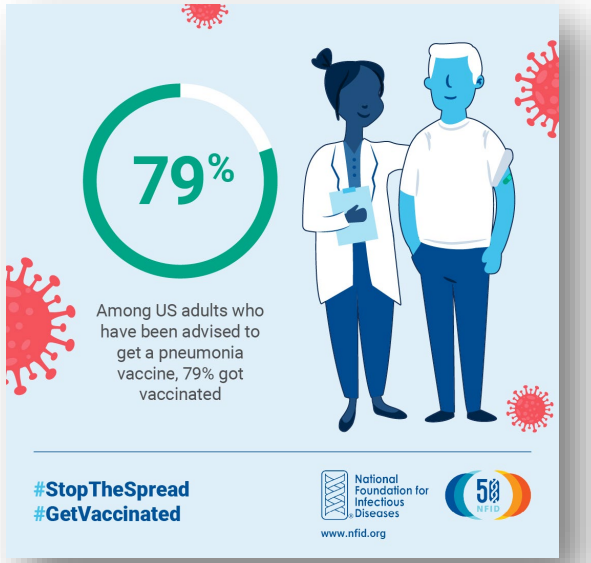
Note: 2022-2023 questions addressed coadministration

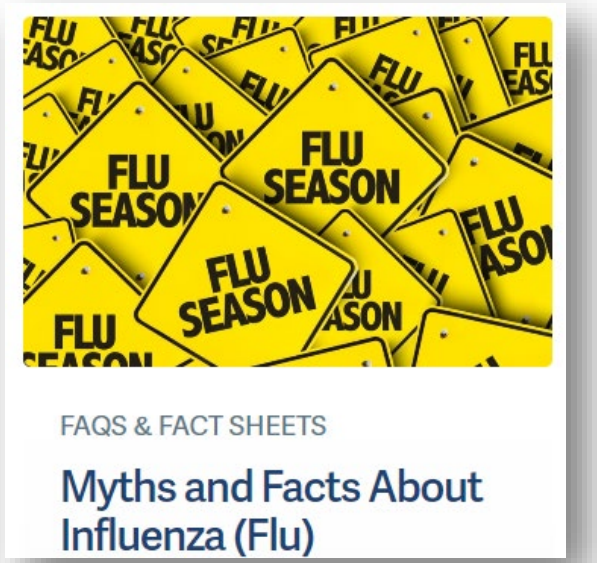
National Foundation for Infectious Diseases®

Key Survey Takeaways

- Importance of strong healthcare professional (HCP) recommendation
- Emphasize role of vaccination in preventing hospitalization and death (partial protection vs. complete prevention)
- Address misconceptions about vaccines and the diseases they protect against



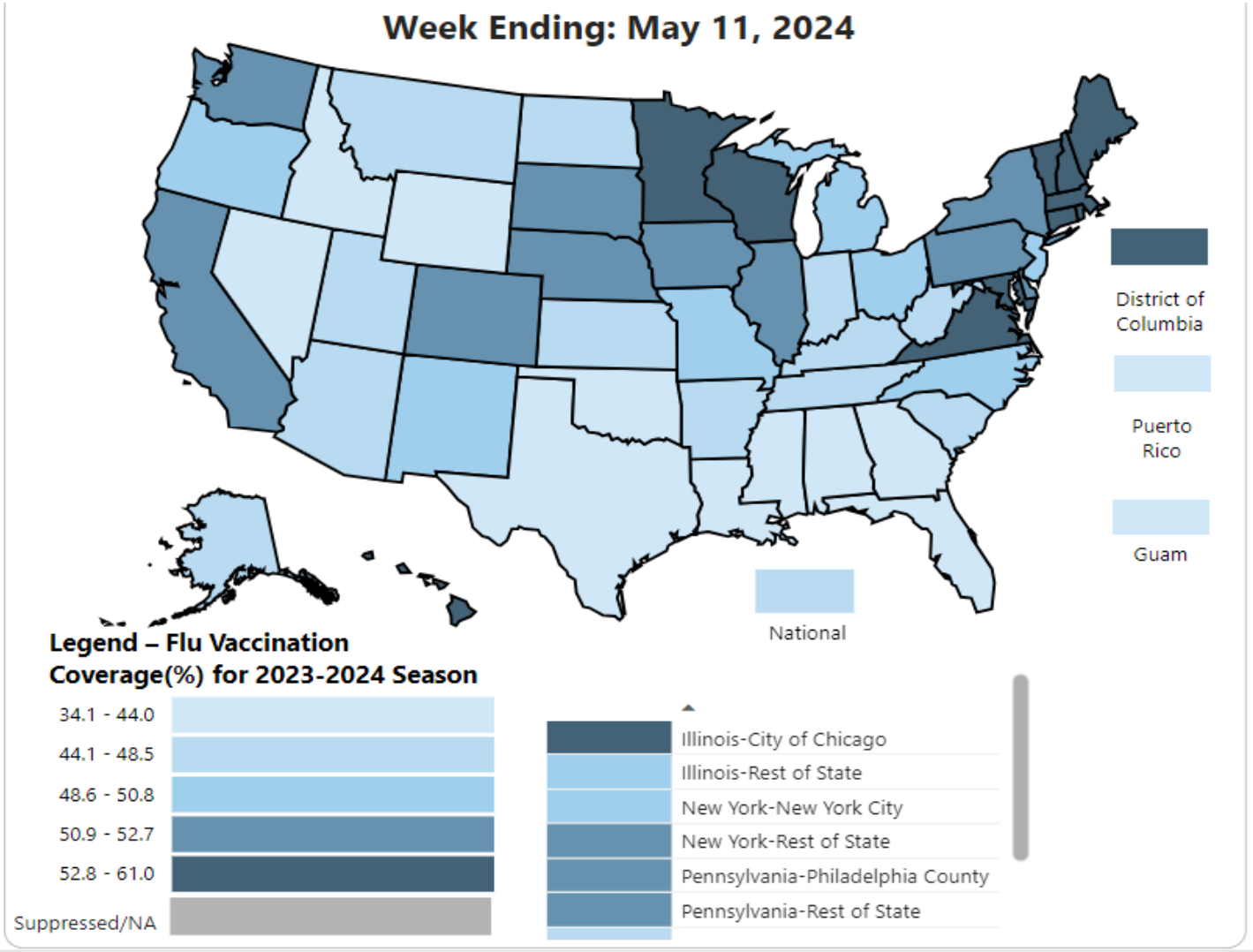




National Foundation for Infectious Diseases

www.nfid.org/resources

2023-2024 Season Flu Vaccination Coverage (Adults 18+)

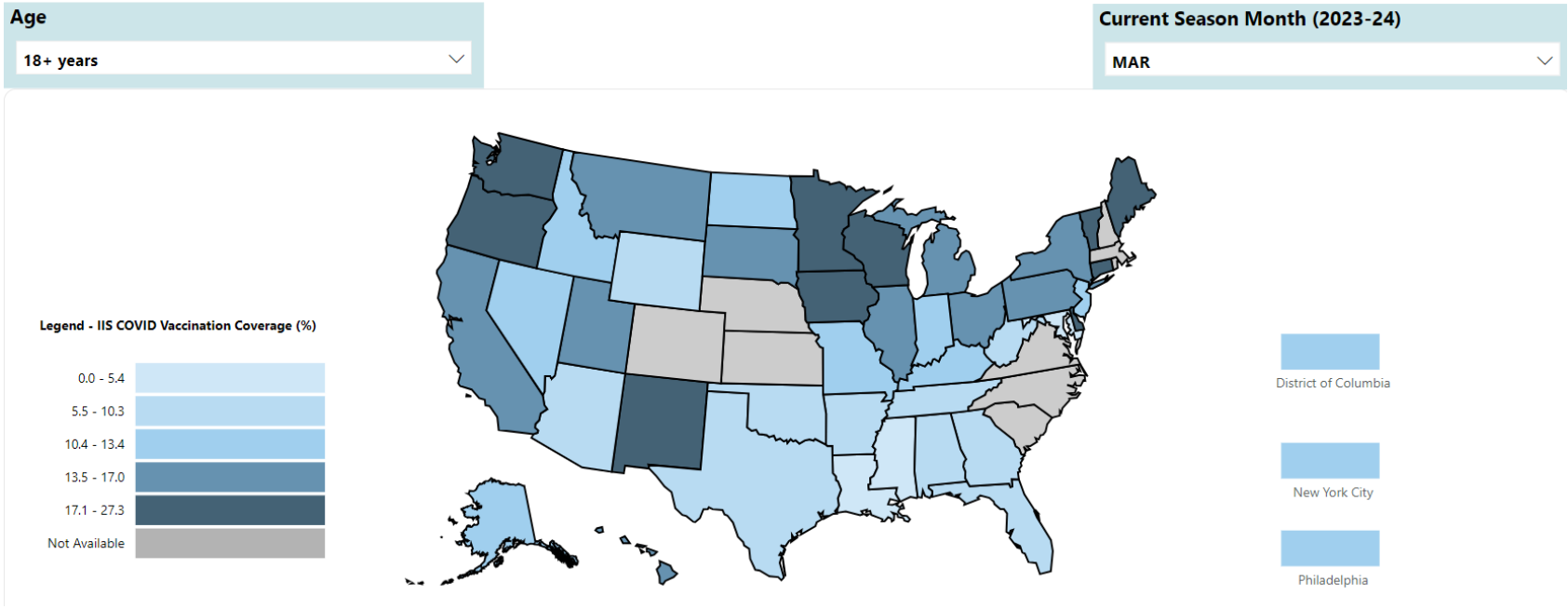


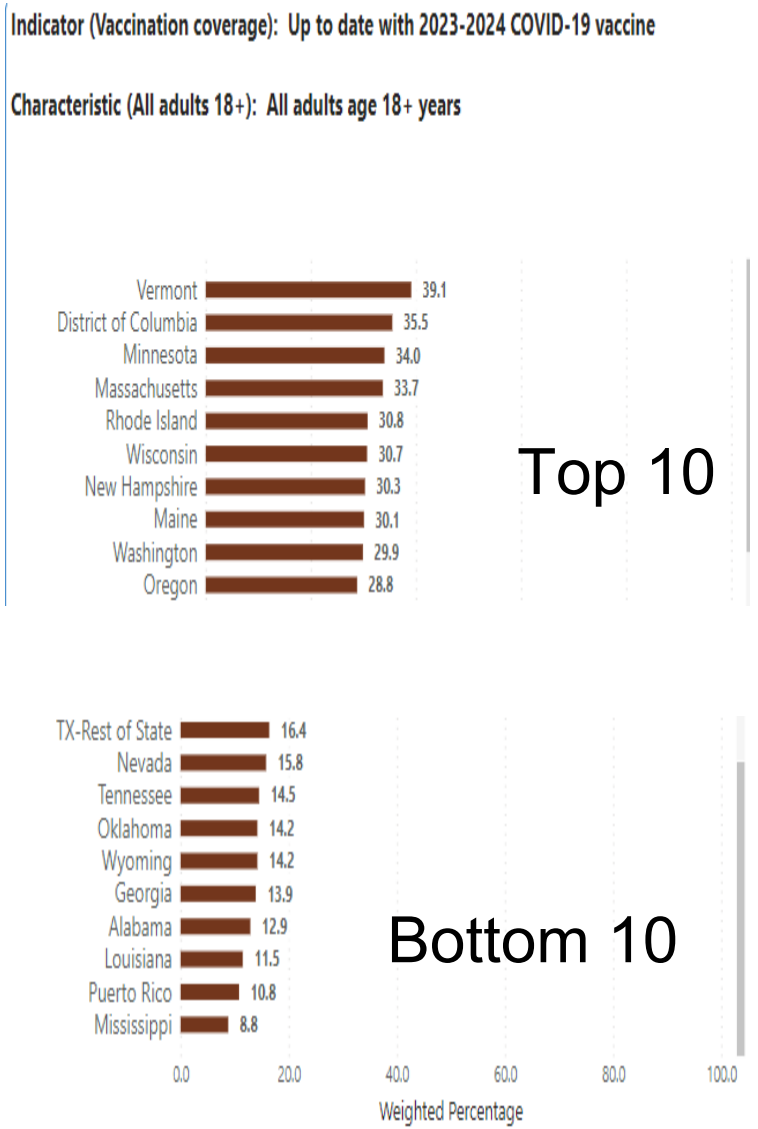
National Foundation for Infectious Diseases

www.cdc.gov/flu/fluvaxview/dashboard/vaccination-adult-coverage.html

COVID-19 Vaccination, 2023-2024 (Adults 18+)

Figure 4D. Monthly Cumulative Number and Percent of Adults 18 Years and Older Who Received 1+ updated 2023-24 COVID-19 Vaccination Doses*,† by Age Group and Jurisdiction, United States
Data Source: Jurisdictional Immunization Information Systems (IIS)
Data are current through March 31, 2024





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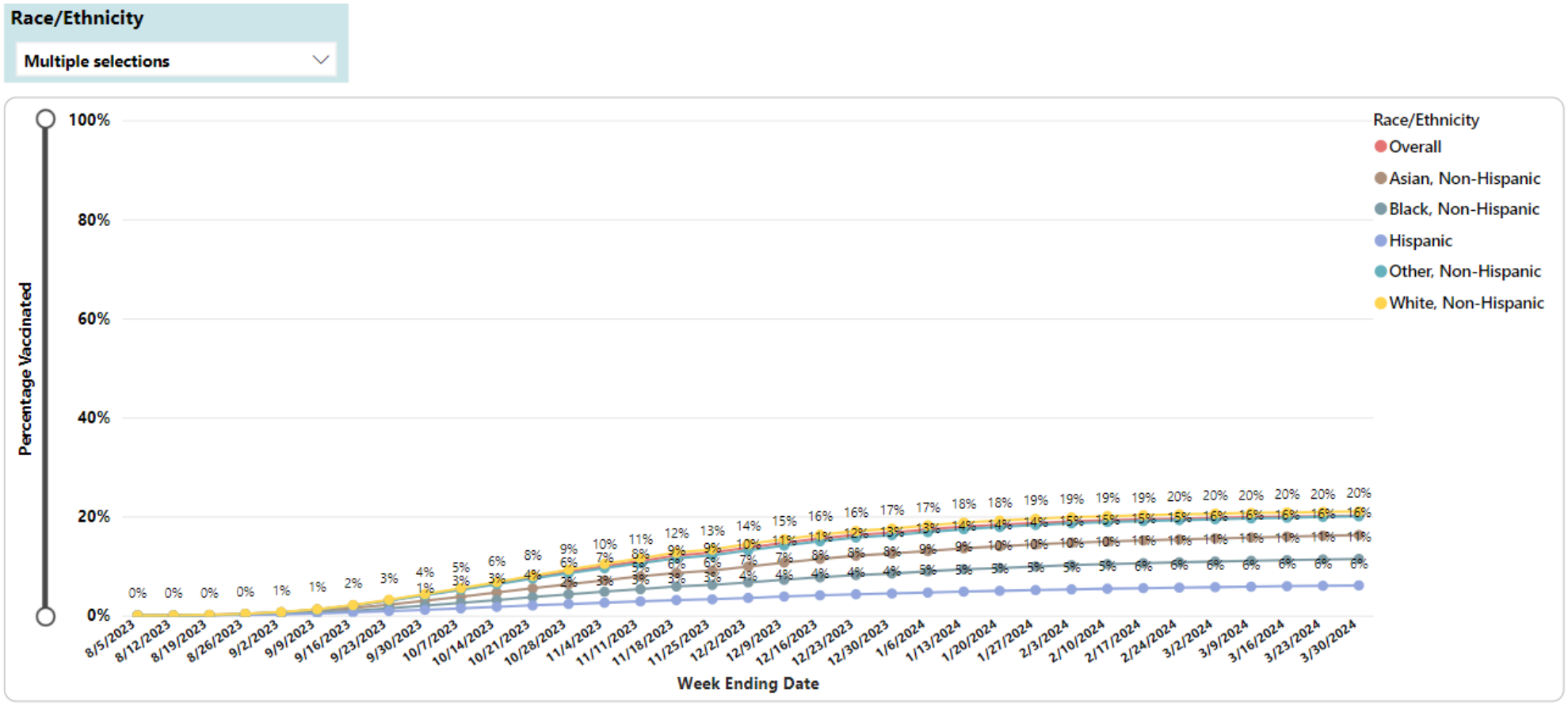
www.cdc.gov/vaccines/imz-managers/coverage/covidvaxview/interactive/adults.html

RSV Vaccination, 2023-2024 (Older Adults 65+)

Figure 3. Weekly Cumulative RSV Vaccination Coverage*, by Race and Ethnicity, Medicare Fee-For-Service Beneficiaries aged ≥65 years and enrolled in a Part D plan, United States
Data Source: Centers for Medicare & Medicaid Services Chronic Conditions Warehouse



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Where Do We Go from Here? Address '3 Cs'

- **Confidence/Complacency/Convenience**
- **Strong HCP recommendation** remains strongest motivator for vaccine receipt

- **HCP Confidence** is critical for strong recommendation
  - Some data suggests slip in this component during COVID-19 pandemic
  - Systematic approach to assess concerns
  - Additional regularly updated online resources from trusted sources may help to improve HCP confidence

www.nature.com/articles/s41541-024-00826-y
www.mdpi.com/2076-393x/11/3/516

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Where Do We Go from Here? Confidence

- Improve vaccine literacy among the public
  - Start early
  - Educate about organisms, diseases, vaccines
  - Outbreaks unfortunate but do provide context
  - Must be in language which reaches target audiences
- Positive social media messaging re: vaccine value and benefits
  - Mixed data on refuting antivaccine messages
- Recognize effect of pandemic on level of anxiety in individuals and communities
  - RISK becomes a prime decision driver in this context
- Mandates can have positive and negative impacts …

www.mdpi.com/2076-393x/11/3/516

Where Do We Go from Here? Complacency

- Providing information about disease and risk while not ‘fear mongering’ can be a delicate balance
- Outbreaks of vaccine-preventable diseases [measles, polio, etc.] can help put a face on importance and value of vaccines—reduce complacency

www.mdpi.com/2076-393x/11/3/516

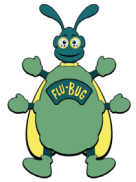
Where Do We Go from Here? Convenience

- Minimize direct and indirect costs of vaccination
  - Enhance VFC
  - Enact VFA to close gaps in out-of-pocket costs
  - Assure reimbursement covers all associated costs of vaccination
- Access at multiple points of contact
  - Pandemic successes in community not currently replicated widely
  - Requires collaboration throughout the Immunization Neighborhood
- Coadministration: Opportunity to minimize indirect cost to patients/families
- **No missed vaccine, no missed location, no missed opportunity**

Building Awareness and Sustaining Strong Momentum throughout 2024-2025 Respiratory Season

Chronic Health Conditions Partner Outreach

National Immunization Awareness Month



Annual News Conference and Flu Vaccine Clinic

Healthy Lung Month

National Influenza Vaccination Week (12/2-12/6)

August | September | October | November | December | January | February | March

Flu Awareness Night (9/12)

KAP Consumer Survey

World Heart Day (9/29)

Media Outreach on News Conference + Survey

American Diabetes Month

World Pneumonia Day (11/12)

'Are You That Person?' PSAs (English and Spanish)

Paid Social Campaign

American Heart Month

National Kidney Awareness Month

Disparities-Focused Outreach

Collecting/Sharing Patient Stories and Partner Outreach and Engagement

Ongoing Media Outreach

National Foundation for Infectious Diseases®

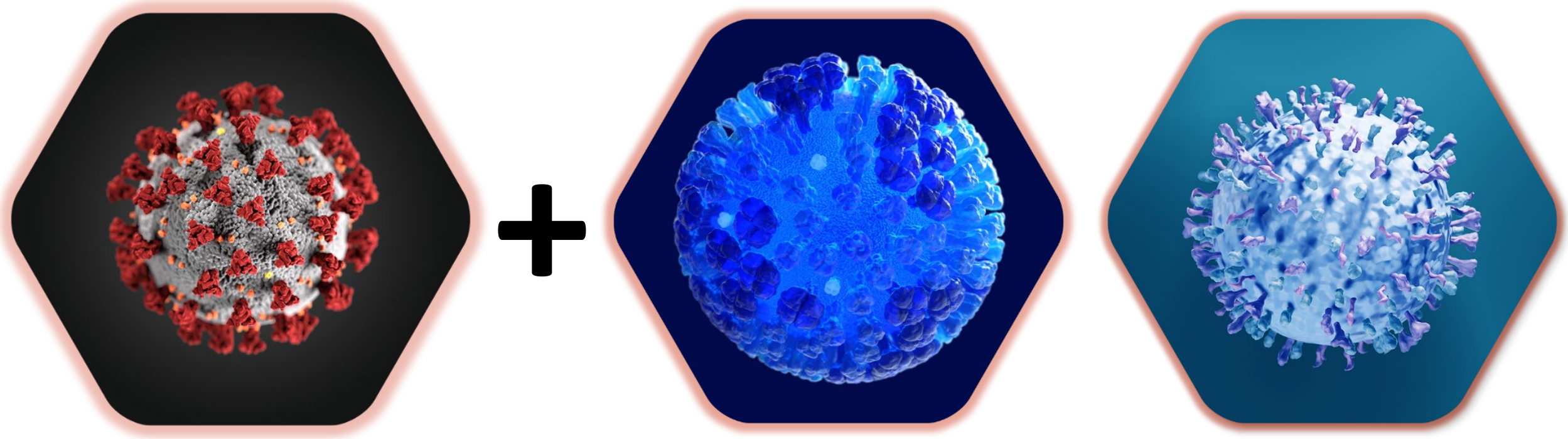
National Foundation for Infectious Diseases®

National Vaccine Advisory Committee: Planning for Fall/Winter Virus Season

Brendan Jackson, MD, MPH (CDR, USPHS)
Senior Advisor for Readiness and Response
National Center for Immunization and Respiratory Diseases

June 2024

Fall and winter respiratory virus season: not what it used to be



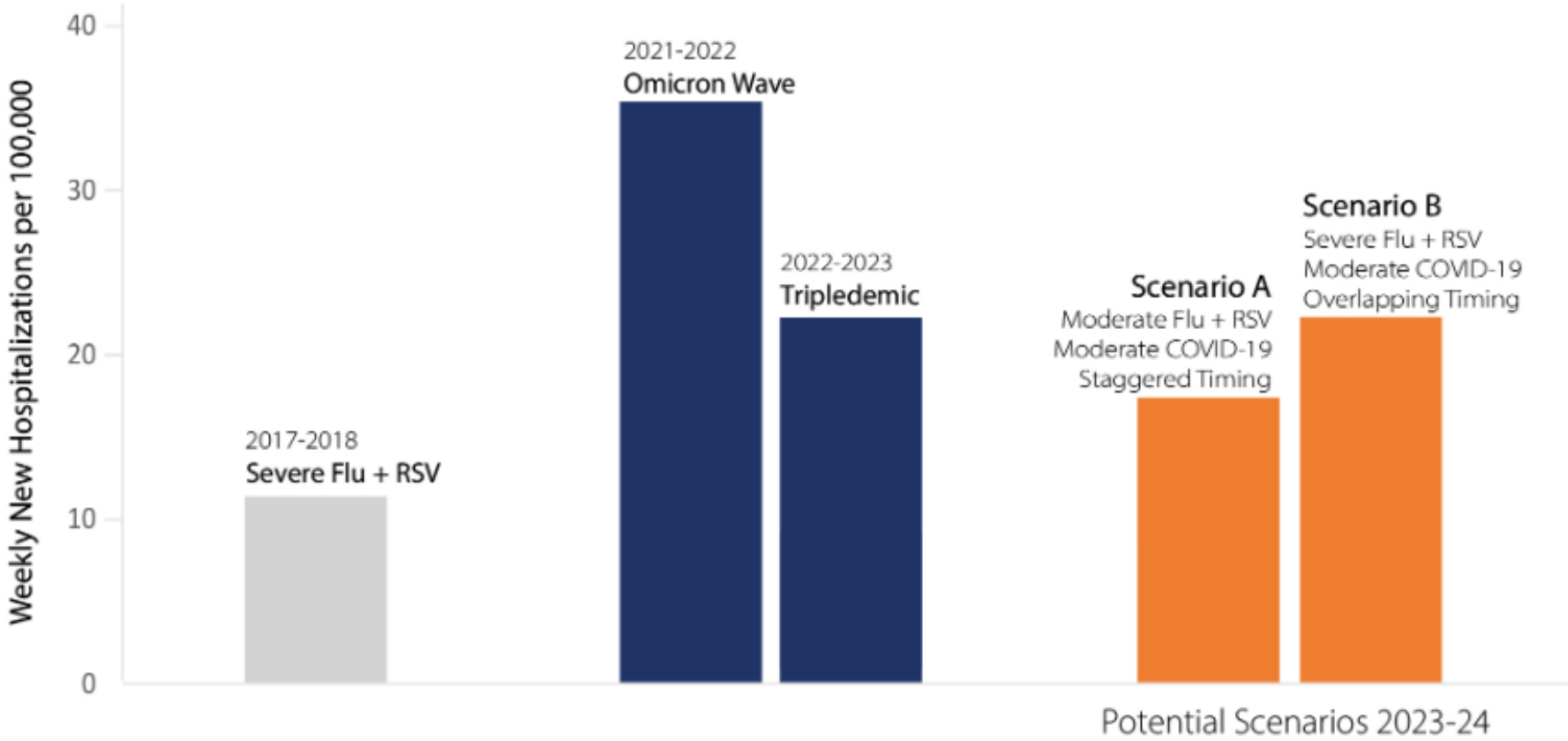
COVID-19 lower than previous years but still many hospitalizations

Influenza and **RSV** back to pre-pandemic levels

CDC Respiratory Disease Season Outlook

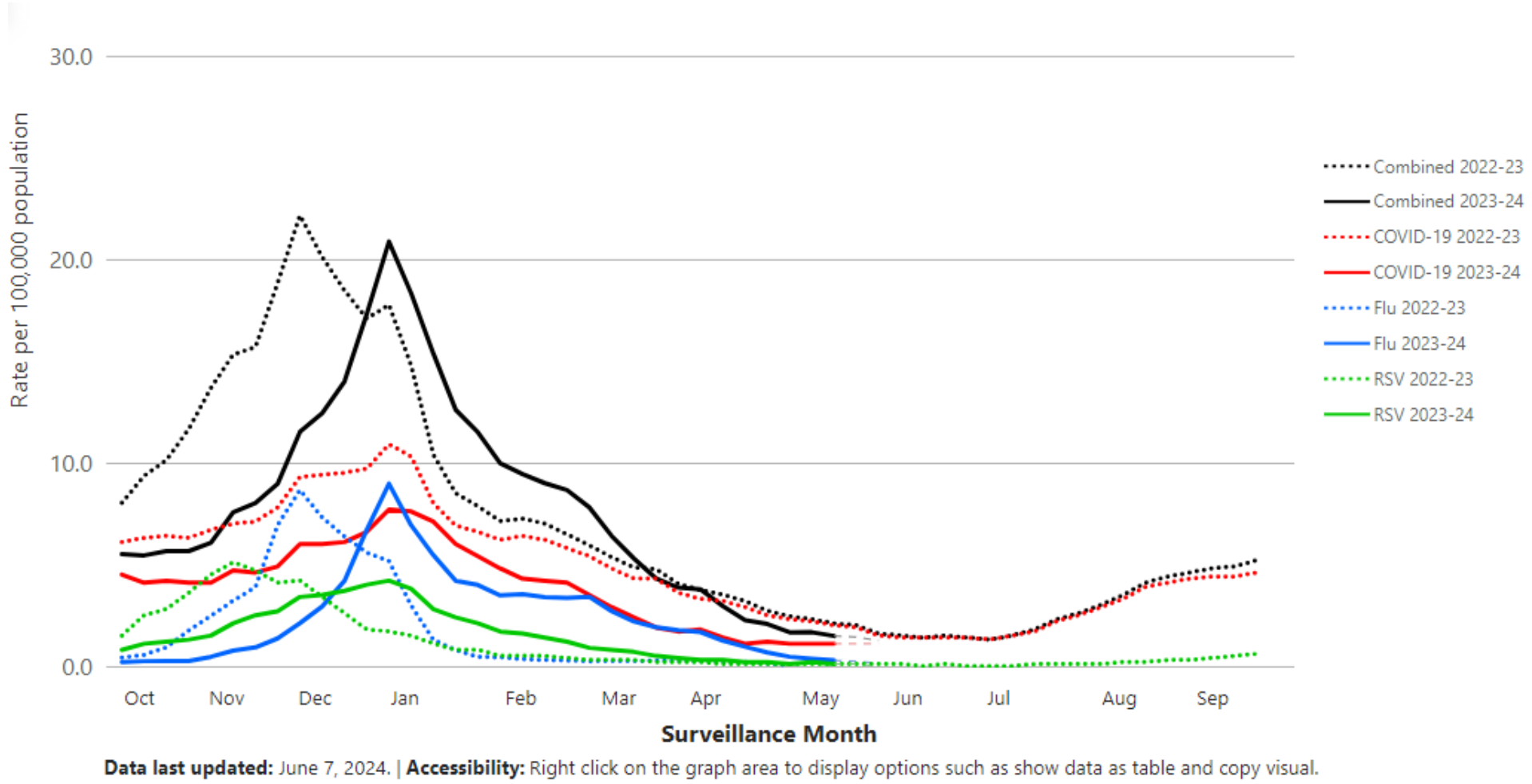
Combined Peak Burden of COVID-19, Influenza, and RSV

Even moderate COVID-19 + Flu + RSV waves this season could cause more hospitalizations than a severe pre-pandemic season



https://www.cdc.gov/forecast-outbreak-analytics/about/season-outlook.html

Last season's hospitalization rates were similar to those from the year before



Data last updated: June 7, 2024. | **Accessibility:** Right click on the graph area to display options such as show data as table and copy visual.

https://www.cdc.gov/resp-net/dashboard/

Immunizations to Protect Against Flu, COVID-19 and RSV

Disease	What Products are Available?	Who Should Use These Products?	What Are the Benefits?	Where Can You Access?	More Information
Flu	Updated flu vaccines for 2023-2024 are available, including flu shots and a nasal spray flu vaccine	Everyone six months and older should get an updated flu vaccine. People 65 and older should get a high-dose or adjuvanted flu vaccine, if available.	Flu vaccines reduce the risk of flu illness, severe illness, hospitalization, and death.	Visit https://www.vaccines.gov/ to find a vaccine.	https://www.cdc.gov/flu/prevent/index.html
COVID-19	Updated 2023-24 COVID-19 vaccines are available for 2023-2024	Everyone six months and older should get an updated vaccine. Some groups may need additional doses to stay up to date.	COVID-19 vaccines are effective at protecting people from serious illness, hospitalization, death from COVID-19; they also reduce the risk of Long COVID.	Visit www.vaccines.gov. There, you can also find providers that are participating in the Bridge Access Program, which provides no-cost COVID-19 vaccines to adults without health insurance and adults whose insurance does not cover all COVID-19 vaccine costs. The Vaccines for Children Program provides vaccines at no cost for eligible children.	https://www.cdc.gov/coronavirus/2019-ncov/index.html
RSV	RSV vaccines	Adults aged 60 and older	Vaccination against RSV can help prevent severe RSV illness, hospitalization, and death.	Talk to your healthcare provider to see if RSV vaccine is right for you.	https://www.cdc.gov/rsv/about/prevention.html Some children aged 8 through 19 months who are at increased risk for severe RSV may benefit from an additional RSV immunization product.
	RSV vaccine	People who are 32 through 36 weeks pregnant during RSV season	Vaccination against RSV while pregnant can help protect babies from severe RSV illness, hospitalization, and death.	Pregnant people should talk to their doctor about which option may be best.	
	OR				
	RSV immunization	Infants entering or born during RSV season	Immunization against RSV from monoclonal antibodies can help prevent severe RSV illness,hospitalization, and death.	Parents and expecting parents should talk to their doctor about which option may be best.	

Immunization rates are suboptimal

Children

COVID
14.1%

RSV
41.3%†

Flu
53.3%

Pregnant Persons

COVID
13.3%

RSV ‡
17.8%

Flu
38.1%

Adults ≥18 years

COVID
22.5%

Flu
48.4%

Older Adults§

COVID
41.0%

RSV
24.1%

Flu
73.4%

*Children and adult estimates are from the National Immunization Survey (NIS); pregnant person estimates are from the Vaccine Safety Datalink (VSD).
† Through March 31, 2024
‡ Through January 31, 2024
§ Defined as ≥65 years for COVID and flu and ≥60 years for RSV

https://www.cdc.gov/vaccines/imz-managers/coverage/respvaxview/index.html

Centers for Disease Control and Prevention

Search

Respiratory Illness

- Respiratory Guidance +
- **Respiratory Virus Data Channel Snapshot**
- Activity Levels
- Illness Severity
- Groups Most Impacted +
- Vaccination Trends +
- Resources to Prepare +

Respiratory Virus Data Channel Weekly Snapshot

Provides a summary of the key viral respiratory illness findings for COVID-19, influenza, and RSV from the past week and access to additional information and figures.

Español

Note: data summaries are based on CDC subject matter expert interpretation of publicly available findings across multiple data systems, some of which are not included in the data visualizations on these web pages.

The amount of respiratory illness (fever plus cough or sore throat) causing people to seek healthcare is low nationally. This week, no jurisdictions experienced moderate, high, or very high activity.

Reported on Friday, June 7th, 2024.

https://www.cdc.gov/respiratory-viruses/data-research/dashboard/snapshot.html

RespVaxView

This page provides access to the weekly COVID-19, flu, and RSV vaccination dashboards. These dashboards provide in-depth vaccination data from a variety of data sources including surveys, healthcare claims, electronic medical records, and immunization information systems data. Select from the options below for the vaccine of interest. Please visit VaxView Vaccination Coverage | CDC for data on routine vaccinations.

Vaccination coverage is the estimated percentage of people who have received specific vaccines. Vaccination coverage information is used to identify areas and groups with lower vaccination coverage so public health departments, healthcare partners, and schools can take action to help improve vaccination coverage and protect everyone from vaccine-preventable diseases. During the COVID-19 Public Health Emergency (PHE), CDC tracked nearly all COVID-19 vaccines administered. However, the end of the PHE limits the completeness of COVID-19 vaccine administration data CDC receives. As a result, survey data are now the primary source for tracking vaccination coverage for COVID-19, RSV, and flu. Other available data sources will be used to provide additional insight into the vaccination landscape.

COVIDVaxView

Weekly COVID-19 Vaccination Dashboard ›

FluVaxView

Weekly Flu Vaccination Dashboard ›

RSVVaxView

Weekly RSV Vaccination Dashboard ›

https://www.cdc.gov/vaccines/imz-managers/coverage/respvaxview/index.html

Learning from last season

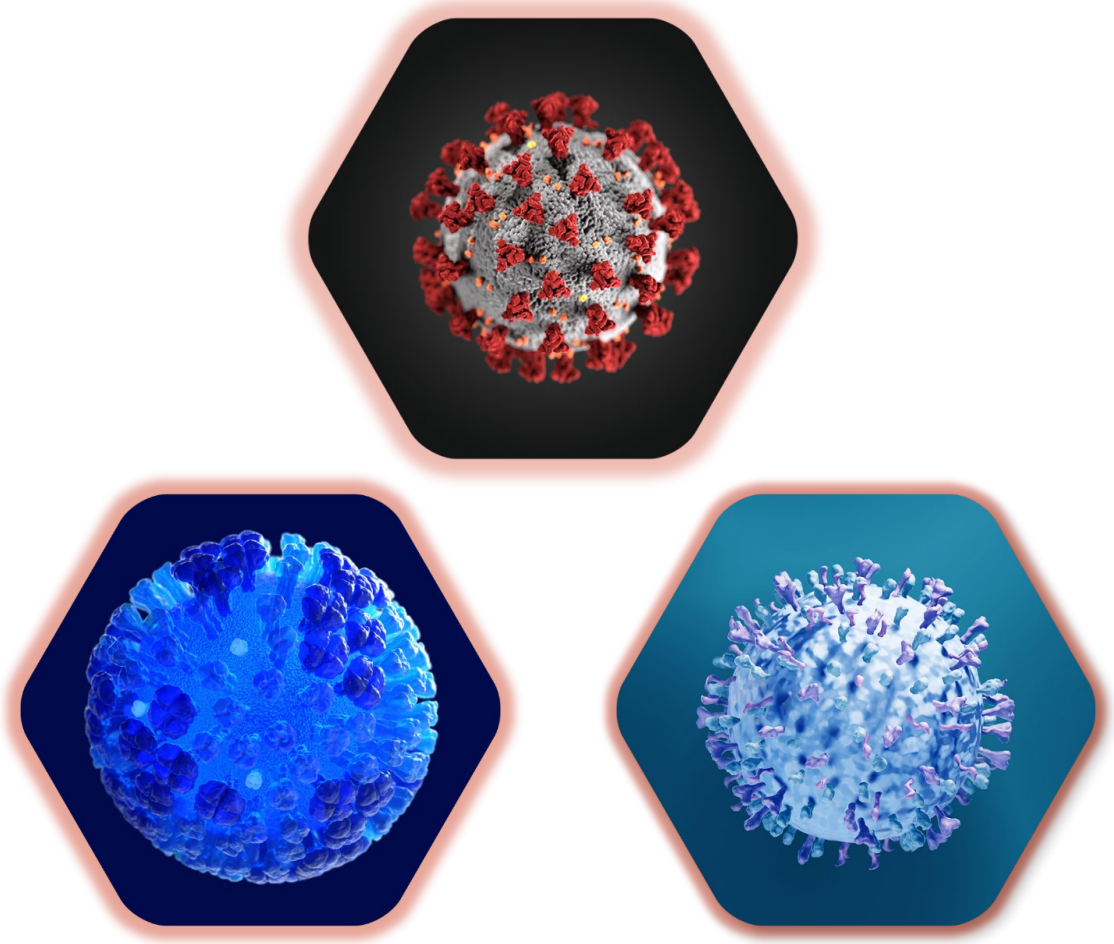
Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from Respiratory Syncytial Virus (RSV) during the 2023–2024 Respiratory Virus Season

Print

Distributed via the CDC Health Alert Network
October 23, 2023, 3:30 PM ET
CDCHAN-00499

Preparing for 2024–2025 Season

- Vaccine Planning and Operations
- Data
- Communications
- Community and Partner Engagement
- Provider Engagement
- Long-Term Care
- Testing and Treatment



FDA U.S. FOOD & DRUG ADMINISTRATION

Updated COVID-19 Vaccines for Use in the United States Beginning in Fall 2024

FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met on June 5, 2024, to discuss and make recommendations on the selection of the 2024-2025 Formula for COVID-19 vaccines for use in the United States beginning in the fall of 2024.

...

Based on the totality of the evidence, FDA has advised the manufacturers of the licensed and authorized COVID-19 vaccines that the COVID-19 vaccines for use in the United States beginning in fall 2024 should be monovalent JN.1 vaccines to more closely match currently circulating SARS-CoV-2 viruses.

https://www.fda.gov/vaccines-blood-biologics/updated-covid-19-vaccines-use-united-states-beginning-fall-2024

United States is transitioning from quadrivalent to trivalent influenza vaccines

Why is the United States transitioning from quadrivalent to trivalent flu vaccines?

The influenza B/Yamagata vaccine component in flu vaccines is being removed because influenza B/Yamagata viruses have not been detected after March 2020, using global surveillance for actively circulating influenza viruses.

https://www.cdc.gov/flu/prevent/trivalent.htm

Upcoming Advisory Committee on Immunization Practices (ACIP) meeting – June 26-28

- Updates on immunizations for COVID-19, influenza, and RSV followed by votes on recommendations

- Particular focus on adult RSV vaccines:
  - Data on safety, efficacy, effectiveness, and economic analysis
  - Update to benefits and risks discussion
  - Data on revaccination at 24-month interval
  - Coadministration data

https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2024-06-26-28-508.pdf

WHAT YOU SHOULD KNOW IN 2023–2024

Respiratory viruses are expected to surge this fall and winter, causing illnesses like **flu, COVID-19, and respiratory syncytial virus (RSV)**.

Respiratory viruses can be very serious, especially among people who are at higher risk for severe illness. This includes **older adults, infants and young children, pregnant people, people who have a weakened immune system, and people with certain underlying or chronic health conditions.**


A FLU VACCINE CAN TAKE FLU FROM
WILD
TO
mild
#FIGHT FLU
CDC

Vaccines.gov

Home | Find COVID-19 Vaccines | Español

Need help finding a COVID-19 vaccine in the U.S.? Call 1-800-232-0233 (TTY 1-888-720-7489)

Find a COVID-19 vaccine near you

Use Vaccines.gov to find a location near you, then call or visit their website to make an appointment.

Find COVID-19 Vaccines

Powered by **VaccineFinder**

Healthcare Provider Toolkit: Preparing Your Patients for the Fall and Winter Virus Season

Español Print

On This Page

https://www.cdc.gov/respiratory-viruses/tools-resources/health-care-providers.html

Updating healthcare provider outreach

Clinicians are Saying	Solutions
"Shorter Information is Better"	Streamline Information
"Give me what I need, when I need it"	Strategic Outreach
"Put information in the tools I'm already using"	Integrate Public Health Practice into Healthcare

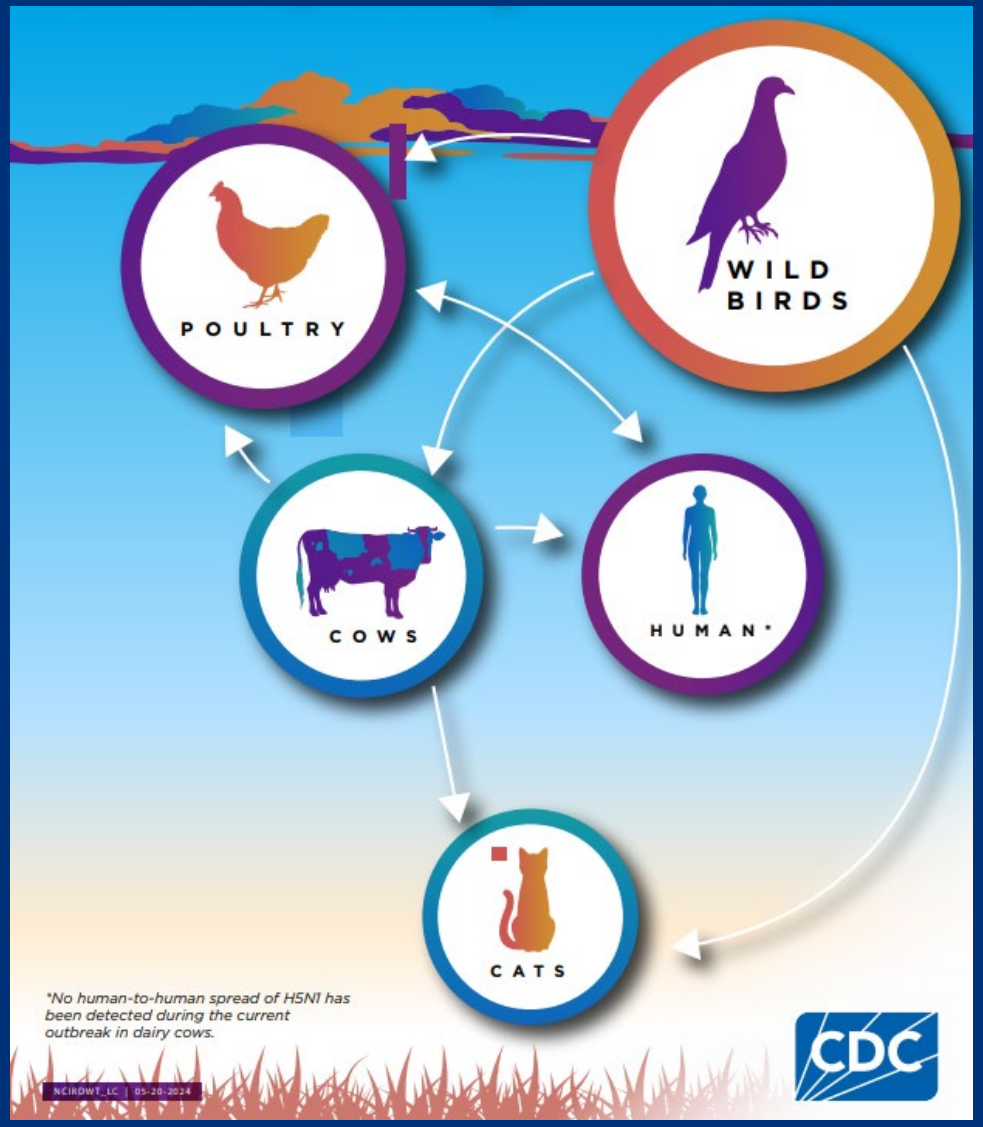
CDC's Bridge Access Program

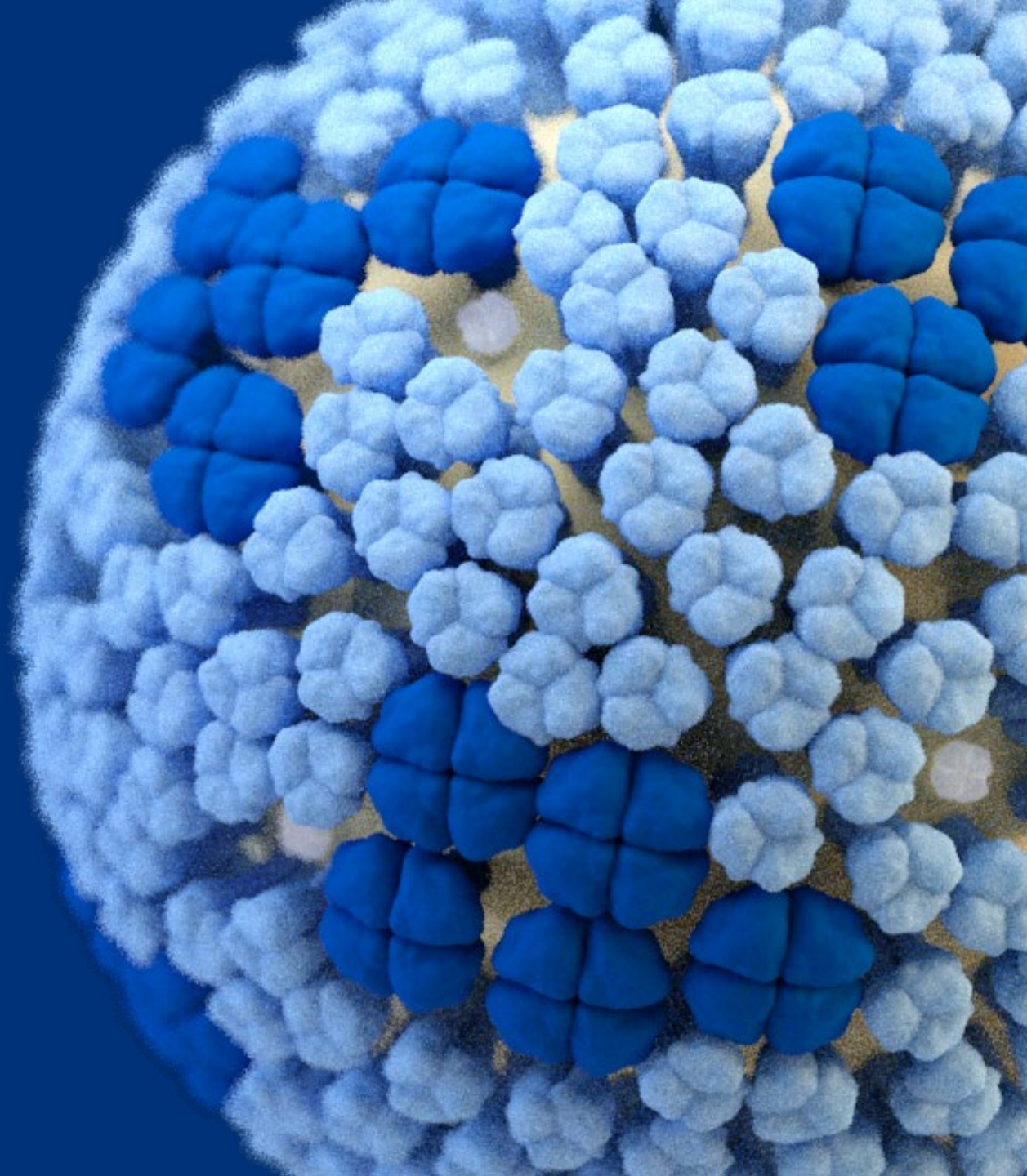
What You Need to Know

CDC's Bridge Access Program provides free COVID-19 vaccines to adults without health insurance and adults whose insurance does not cover all COVID-19 vaccine costs. This program will end in August 2024. Use these resources to promote the program and expand equitable access for COVID-19 vaccination.

https://www.cdc.gov/vaccines/programs/bridge/index.html

Influenza A/H5N1





Thank you for the ongoing partnerships

Please feel free to contact us at NCIRDResponseOperations@cdc.gov

Long-Term Care Quick Start Guide: Preparing for Respiratory Virus Season

Español Print

When respiratory viruses are spreading in the community, the risk for spread in long-term care (LTC) settings, including nursing homes, increases as well. Existing infection prevention and control measures can help prevent and slow the spread of flu, RSV, and COVID-19 to protect residents and staff. Preparing and responding to respiratory viruses in LTC settings requires a comprehensive approach that includes infection prevention, testing, vaccination, and treatment.

Below are some helpful CDC links to bookmark for the respiratory virus season.

https://www.cdc.gov/respiratory-viruses/tools-resources/long-term-care.html

Routine Immunizations on Schedule for Everyone (RISE)

Initiative to get all Americans back on-schedule with their routine immunizations

Understand the size, scope and cause of declines in routine vaccinations resulting from COVID-19 pandemic

Devise an evidence-based strategy and operational plan to better direct CDC routine vaccination catch-up activities

Equip partners with evidence-based strategies and resources to get vaccination back on schedule

Share data and insights on trends in routine vaccination rates to find and protect communities that have fallen behind on vaccinations

https://www.cdc.gov/vaccines/partners/routine-immunizations-lets-rise.html

Healthcare provider outreach strategies

S1

Strengthen and Build Partnerships

Prioritizing clinical partners with deep reach into populations at highest risk

S2

Streamline Materials

Co-create short, timely messaging and materials that help clinicians protect their patients

S3

Build Engagements into Clinical Workflows

Embed key information into systems and platforms that clinicians routinely use

S4

Routinize Partner Communications

Regular cadence of communications from CDC to providers

Fall and Winter Respiratory Diseases: The Vaccination Season Ahead

Discussion

NVAC

Outbreak Update: Measles Cases in Illinois

Commissioner Olusibmo Ige
Dr. Frank Belmonte

NVAC

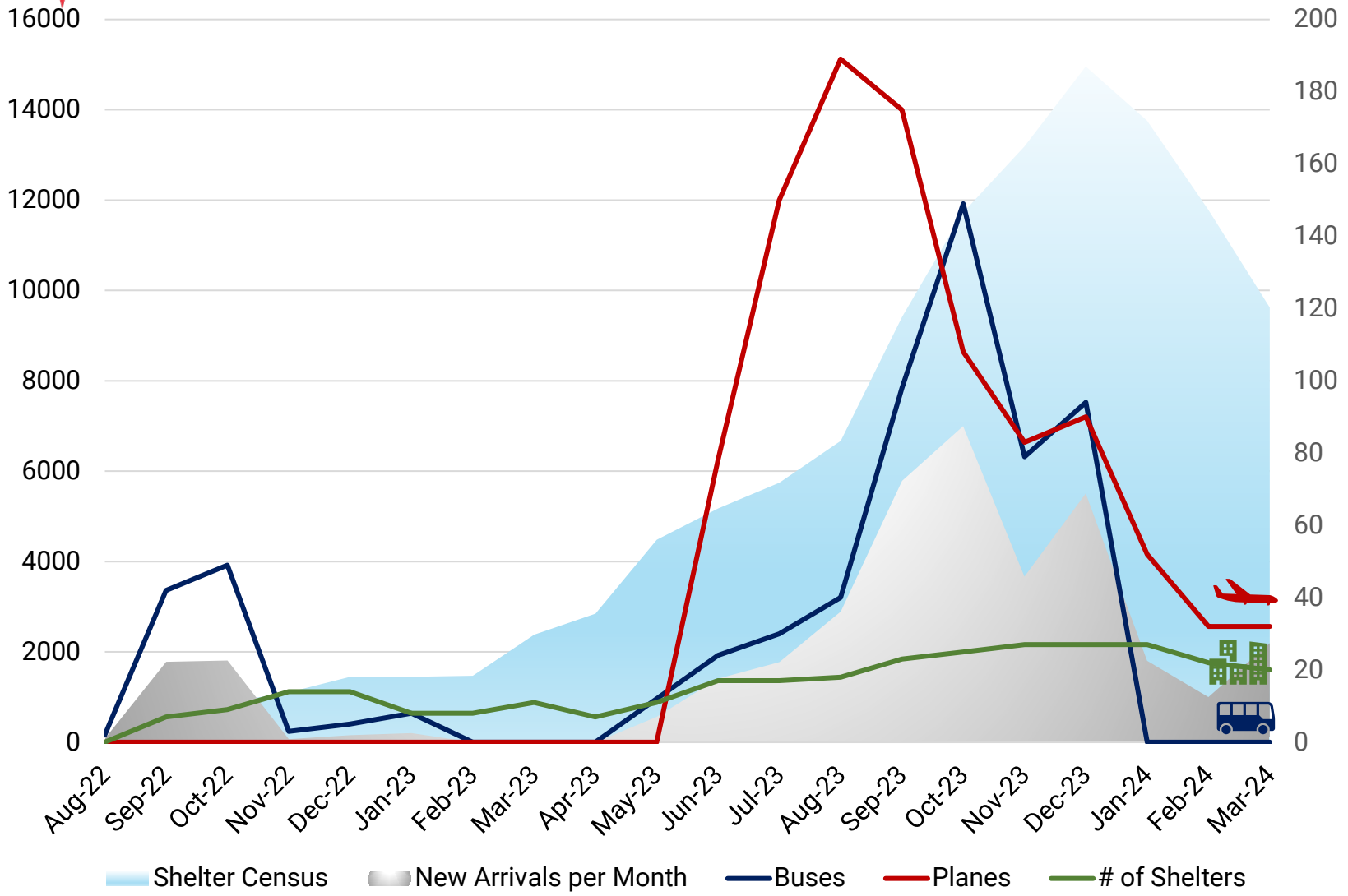
CDPH
Chicago Department of Public Health

CDPH Measles Response

June 13, 2024

Olusimbo Ige, PhD, MS, MPH
Commissioner, Chicago Department of Public Health

Context: Unvaccinated People in Close Quarters



By the numbers

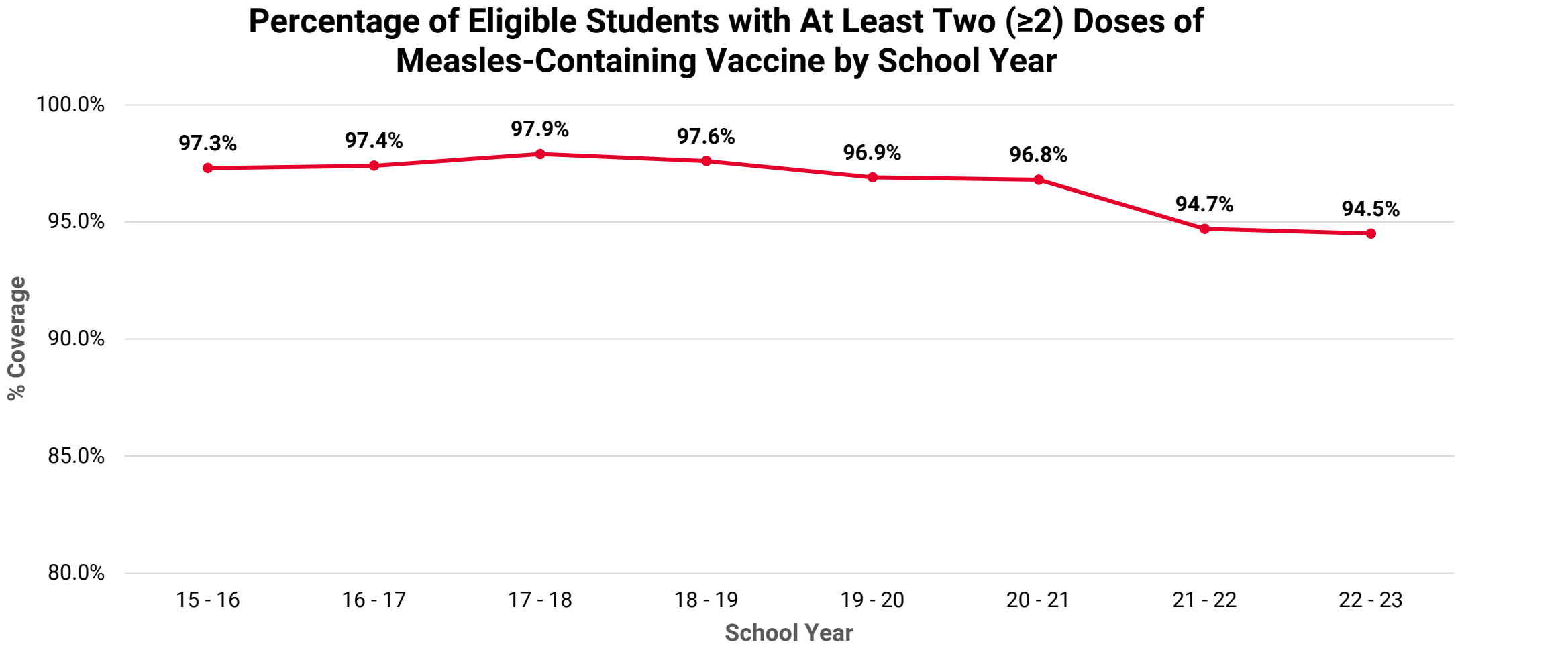
> 40,**000 new arrivals** have arrived since August 2022

# of arrivals exceeds the population of all but 50 of Illinois' municipalities

At its peak, the City operated **27 shelters**

At its peak, City sheltered **>14,900 residents**

Context: Lower MMR Coverage among Chicago Students

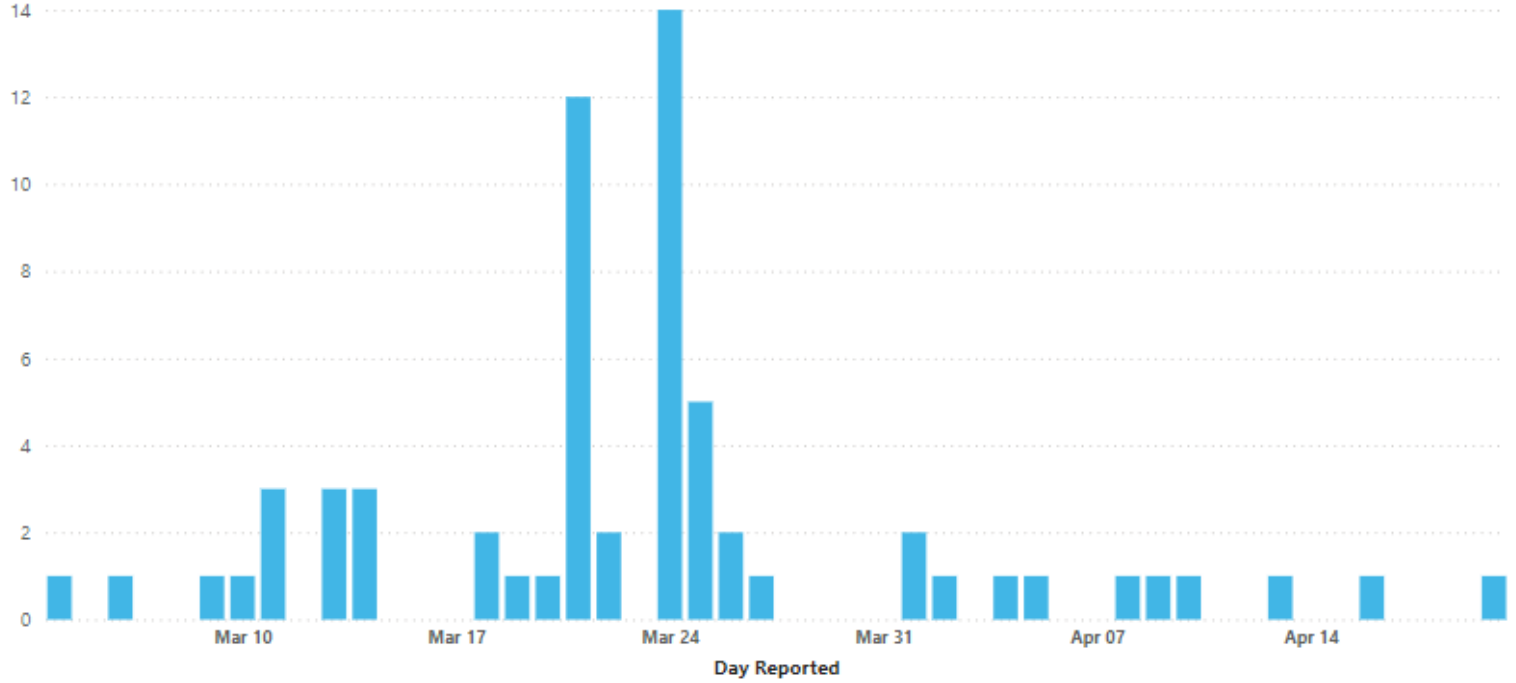


Chicago Measles Outbreak 2024

Cases This Year
64

Cases This Week: 06/02 - 06/08
0

Cases by Date Reported

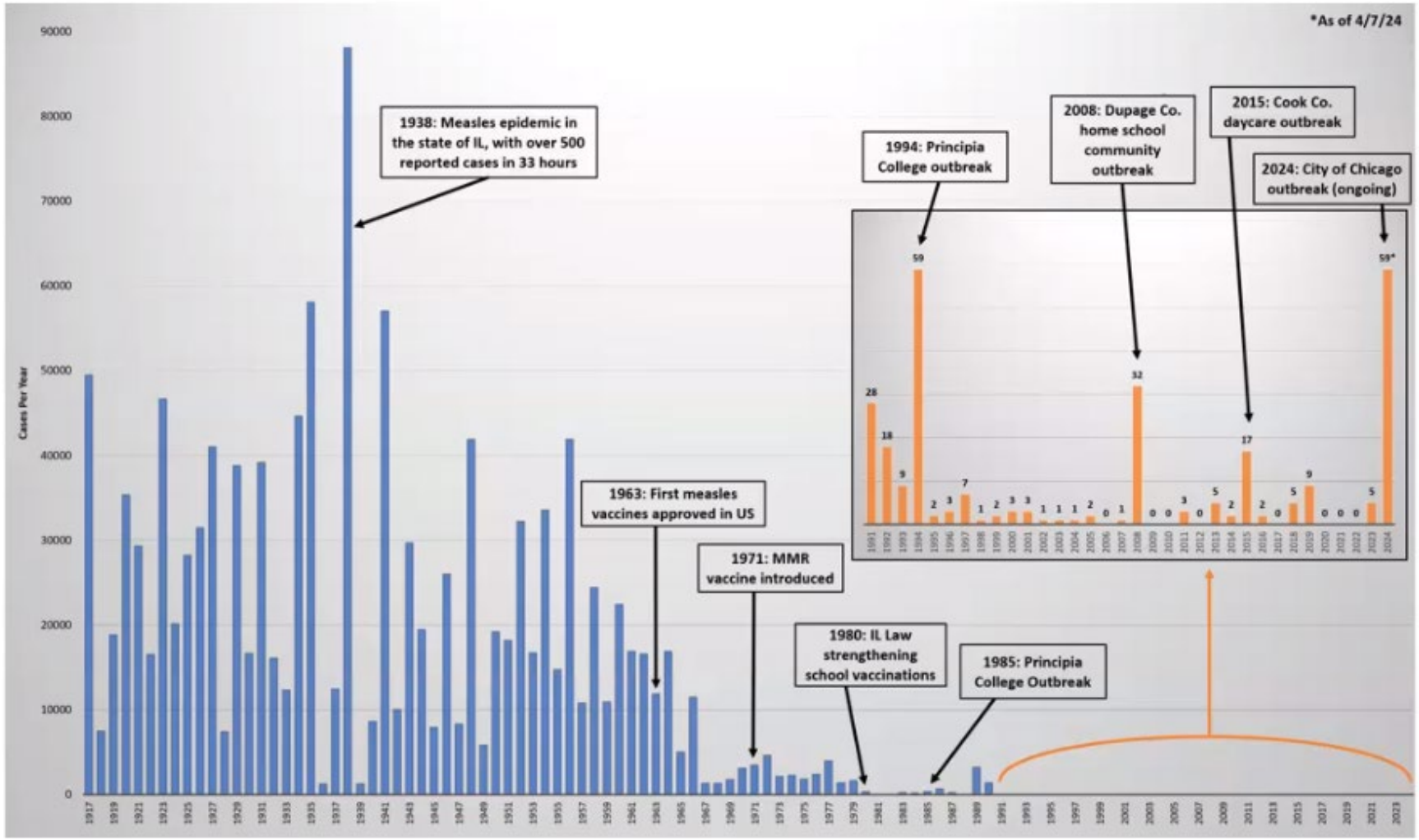


Cases by Age Group

Age Group	Count	%
0 - 4 years	33	52%
5 - 17 years	9	14%
18 - 49 years	18	28%
50+ years	4	6%

Largest Outbreak in Illinois since 1980

Measles Cases in Illinois 1917-2024*



Source: Illinois Department of Public Health, 2024

Largest Measles Outbreak in the Country

Measles Cases Nationwide 2024

As of May 30, 2024

Challenges

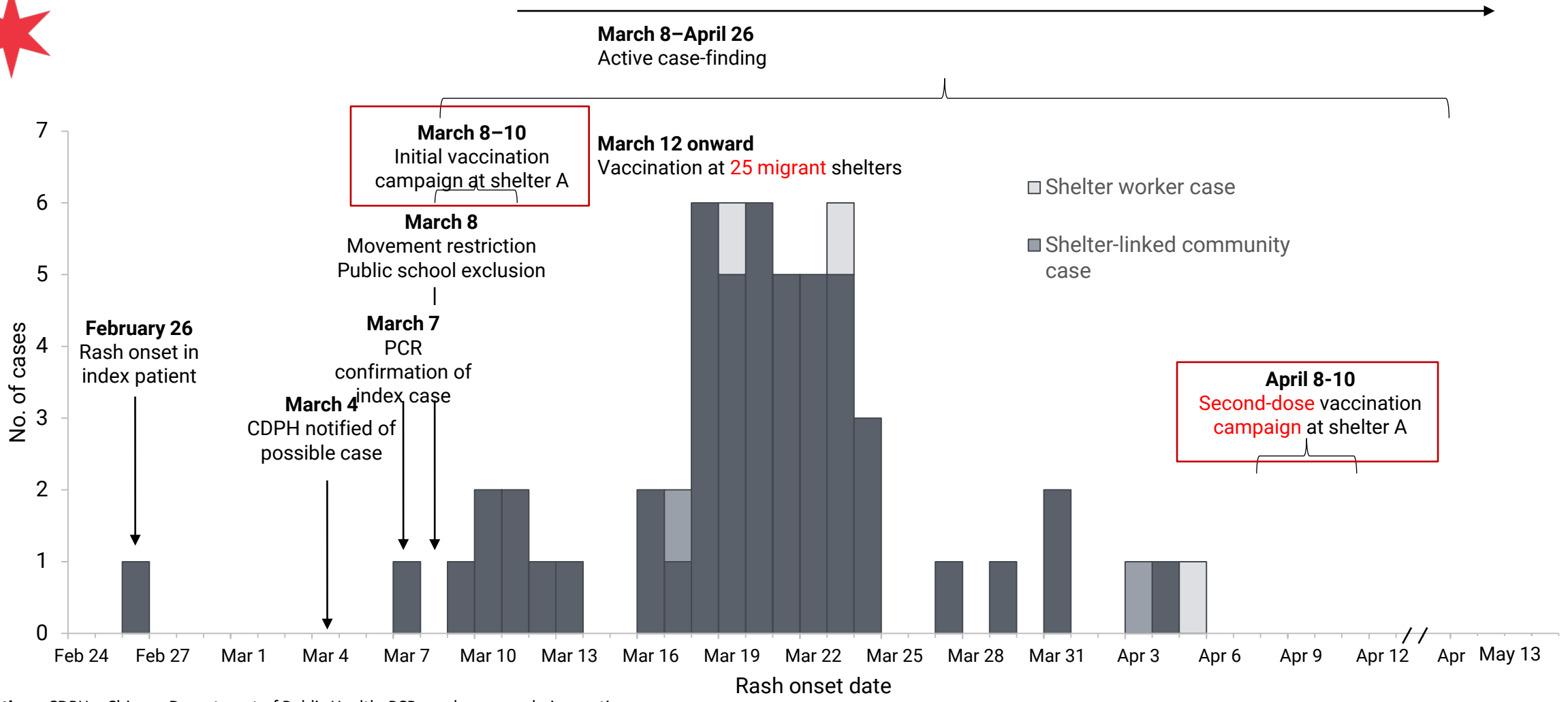
Environment

- Politically charged climate
- Resource constraints
  - Funding
  - Staffing
  - Vaccine supply
- No vaccination policy
  - Lacking infrastructure

Residents' Concerns

- Ability to work
- Access to schooling
- Culturally appropriate food

Measles Outbreak and Response: February 26–May 13, 2024



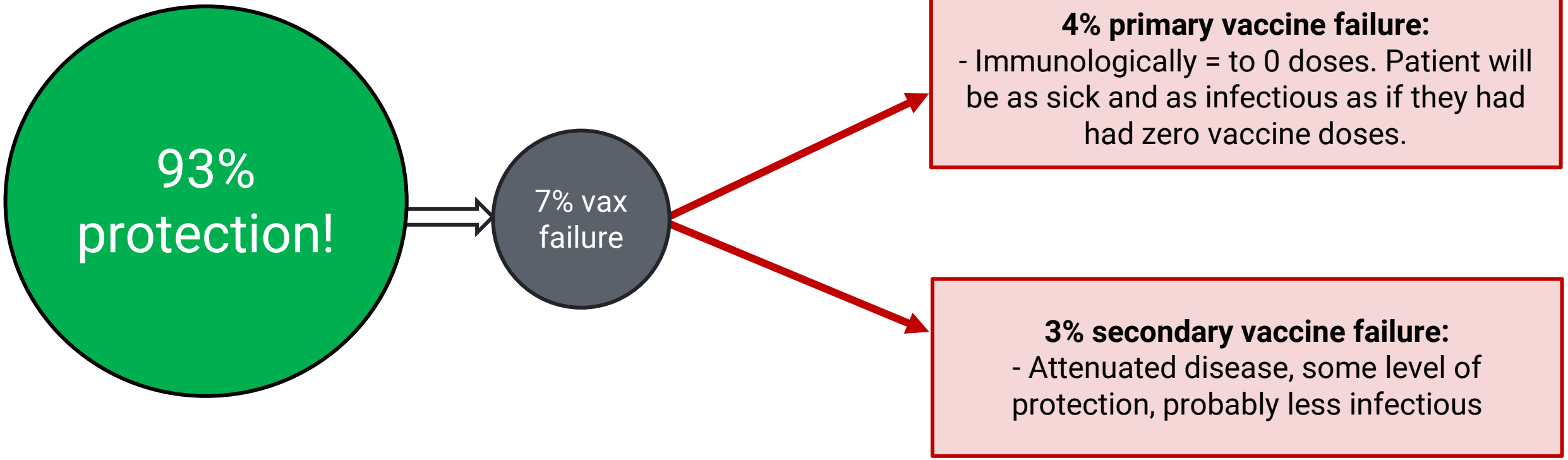
Abbreviations: CDPH = Chicago Department of Public Health; PCR = polymerase chain reaction.

* Shelter A resident cases were defined as those in persons exposed while residing at Shelter A. Shelter-linked community cases were defined as those in persons exposed outside of shelter A and epidemiologically linked to a case in a shelter A resident. Shelter worker cases were defined as those in persons exposed while working at shelter A

† Two persons with unknown or no rash onset were included by symptom onset date.

§ Interventions included active case-finding, vaccination events, and movement restricion

Congregate Settings: Breakthrough Cases



Anticipated

~430 ppl in Halsted with 1 historical dose:

→ 4% of 430 = 17 cases

→ 3% of 430 = 13 cases

Actual

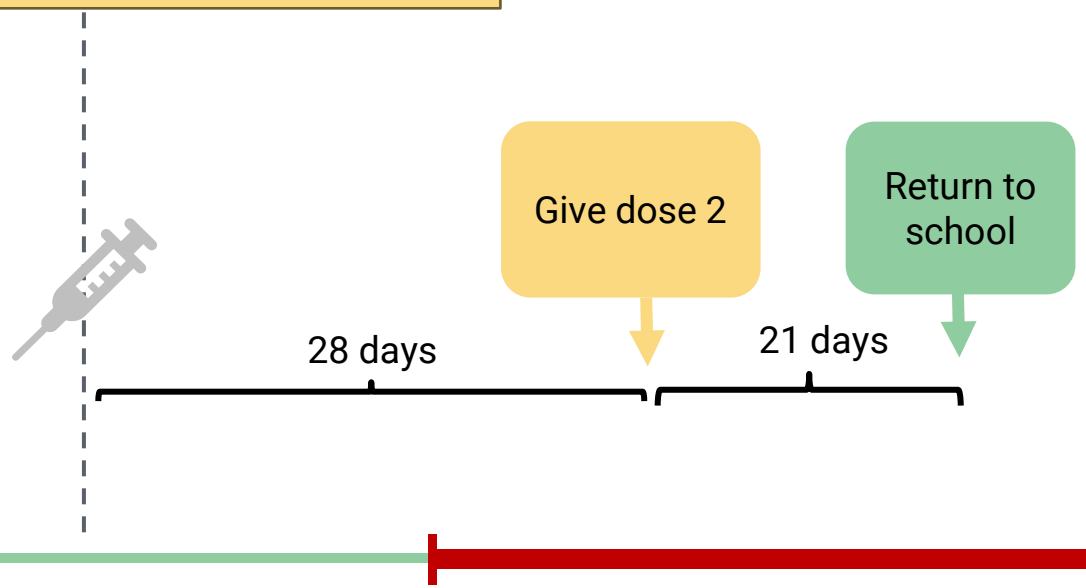
→ 13 cases after dose

→ 4 cases after 2 doses

Response to Breakthrough Cases

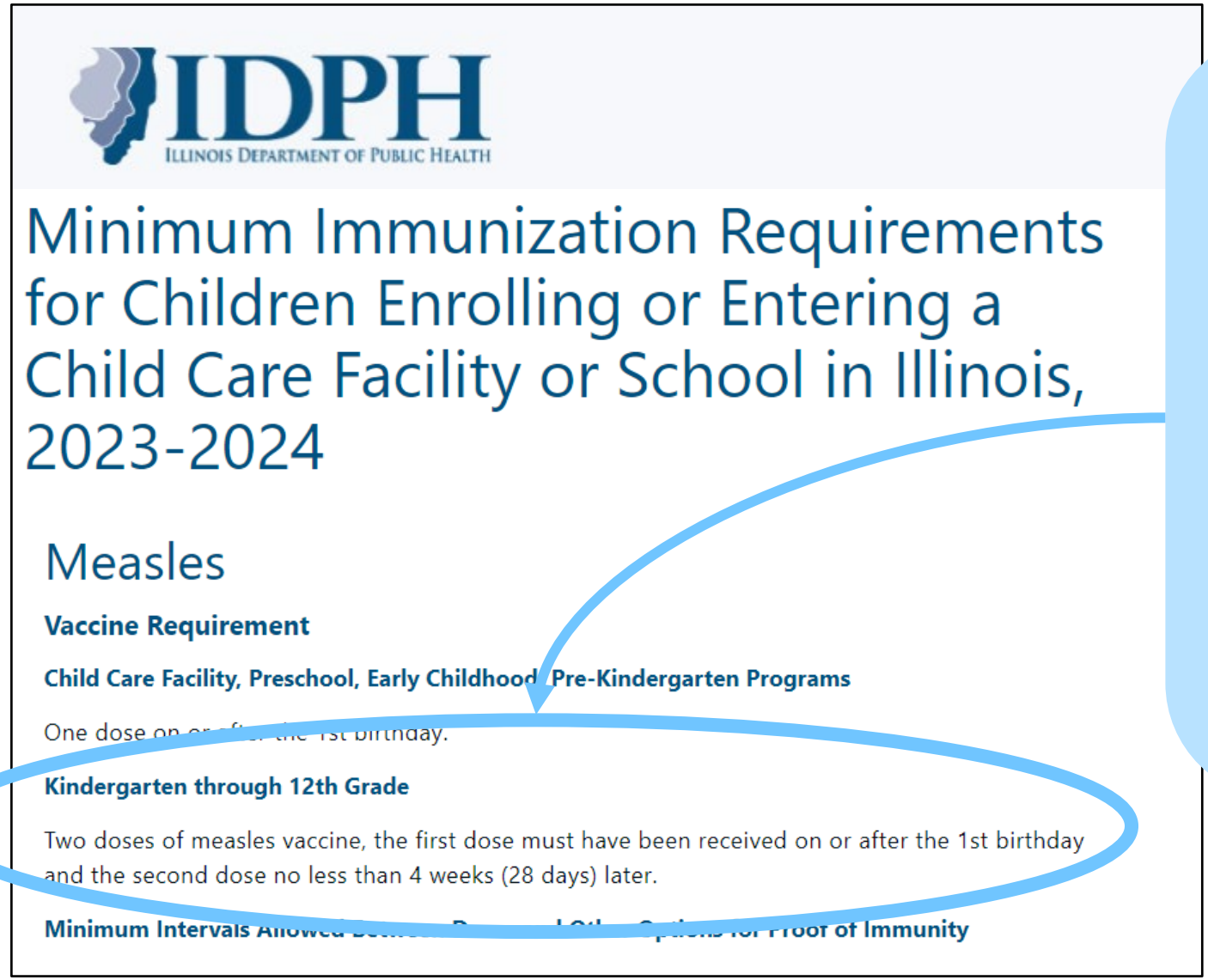
Cohort 2:

- Children ≥12m who had 1 dose 3/8/24 to 3/11/24



- Action Steps
- Give 2nd dose after 28 days
- Exclude from preschool or daycare
- Return to school 21 days after 2nd dose

Proposed Immunization Requirements



IDPH
Illinois Department of Public Health

Minimum Immunization Requirements for Children Enrolling or Entering a Child Care Facility or School in Illinois, 2023-2024

Measles

Vaccine Requirement

Child Care Facility, Preschool, Early Childhood, Pre-Kindergarten Programs

One dose on or after the 1st birthday.

Kindergarten through 12th Grade

Two doses of measles vaccine, the first dose must have been received on or after the 1st birthday and the second dose no less than 4 weeks (28 days) later.

Minimum Intervals Allowed Between Doses and Other Options for Proof of Immunity

Our proposal:

1. **Enforce** this requirement (2 doses required for K–12 grade)

and

2. **Apply it to younger children** (pre-K, early childhood, preschool, and child care settings)

Source: https://dph.illinois.gov/topics-services/prevention-wellness/immunization/minimum-immunization-requirements.html#table2

Innovative Solutions

Robust partnership engagement

- IDPH
- Cook County Health
- Mutual Aid
- Chicago Alders
- Healthcare system
- Mayor's Office of Immigrant, Migrant, and Refugee Rights
- CBOs
- FBOs

Address SDOHs to combat concerns

- Provision of resources to increase trust and comfortability

CDPH New Arrival Shelters Vaccination Response

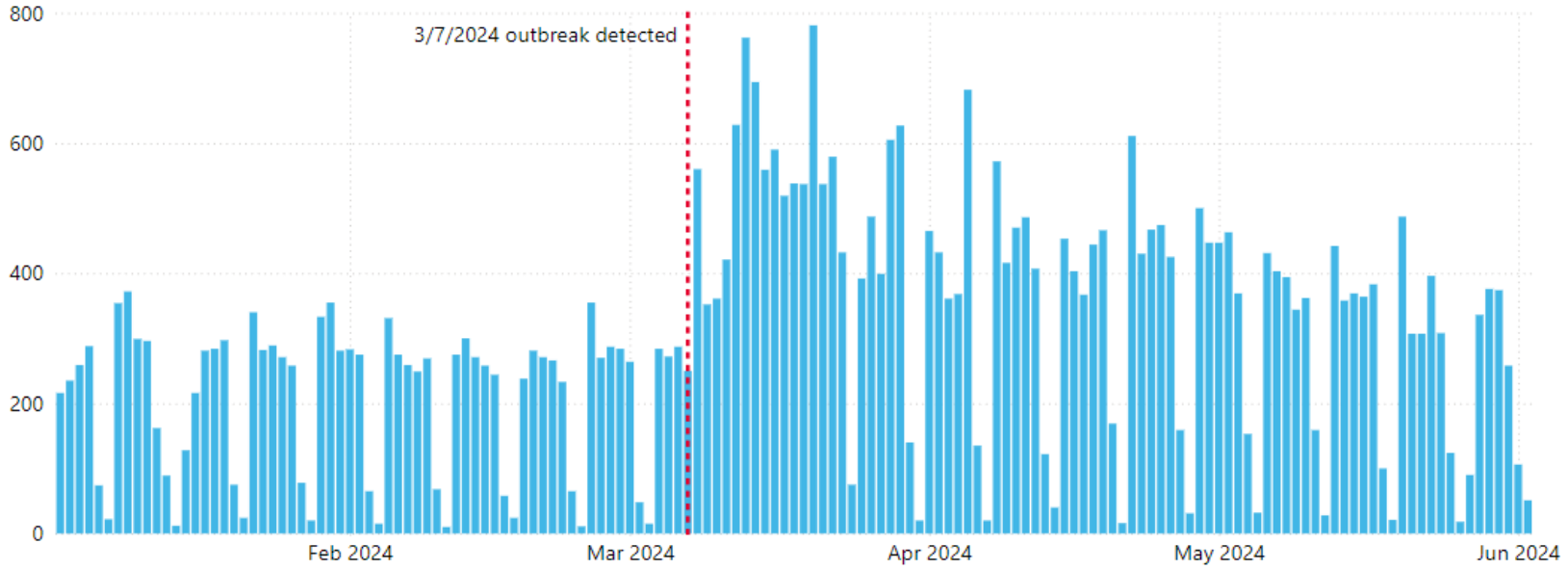
Data last updated 6/4/2024. Counts include vaccinations administered through 6/2/2024 to account for reporting lags.
Data are updated Tuesdays at 1 p.m. All data are provisional and subject to change.

Measles-Containing Vaccines Administered to Chicago Residents

Click here to view vaccines administered in 2023 compared to 2024

Doses Administered since 3/7/2024	Doses Administered Last Week (5/26/2024 - 6/1/2024)
31,843	1,558

Vaccinations Administered by Day



- **Proactive Vaccination**
  - 226 total vax clinics since Nov 1, 2023
- **Vaccination Locations**
  - 31 shelters and the Landing Zone
- **Vaccination Policy**
  - New Arrival vax policy
- **Broaden Population**
  - 20,000 vaccinations outside of shelters
- **Result**
  - NO FATALITIES

Messaging Context

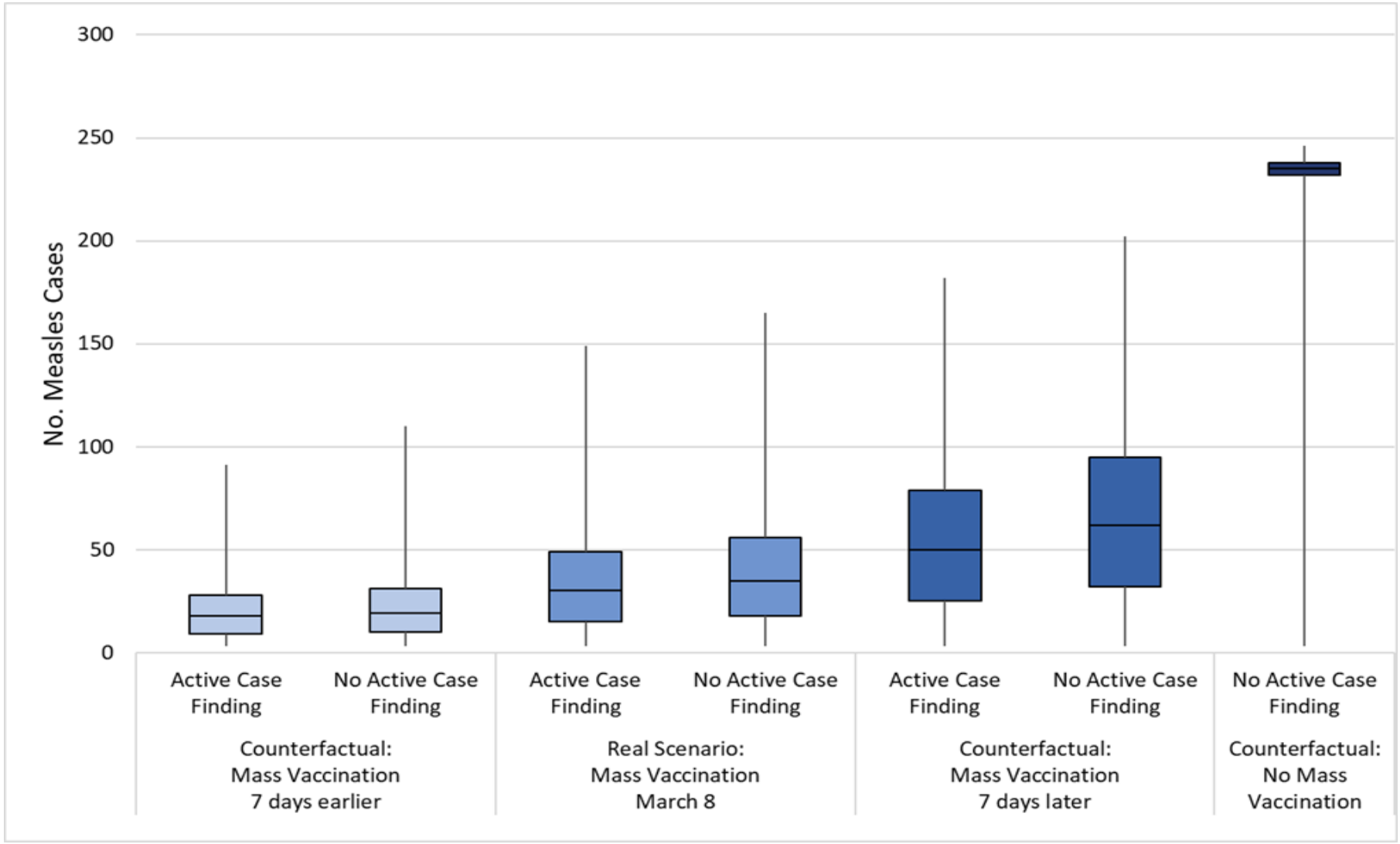
Anti-migrant commentary (12.6K interactions) dominated the discourse, accounting for **22% of all online interactions**

News of **possible exposures in public spaces** (4.2K interactions)

Shelter evictions (4.7K interactions) were the secondary driver of discourse. Many expressed concern for migrants facing their shelter stay limit and fear about the spread of measles.

Posts about the City's vaccination efforts garnered **limited visibility** (1.5K interactions), even with the City's new vaccine policy

Counterfactual Analysis



Data for Action

CDPH
Chicago Department of Public Health

Chicago.gov/Health

HealthyChicago@cityofchicago.org

@ChicagoPublicHealth

@ChiPublicHealth

Advocate Children's Hospital®

Now part of ADVOCATEHEALTH

A Case of Measles Exposure

Lessons Learned in Chicago

Frank Belmonte, D.O., MPH

Chief Medical Officer and Chair of Pediatrics
Advocate Children's Hospital

Case

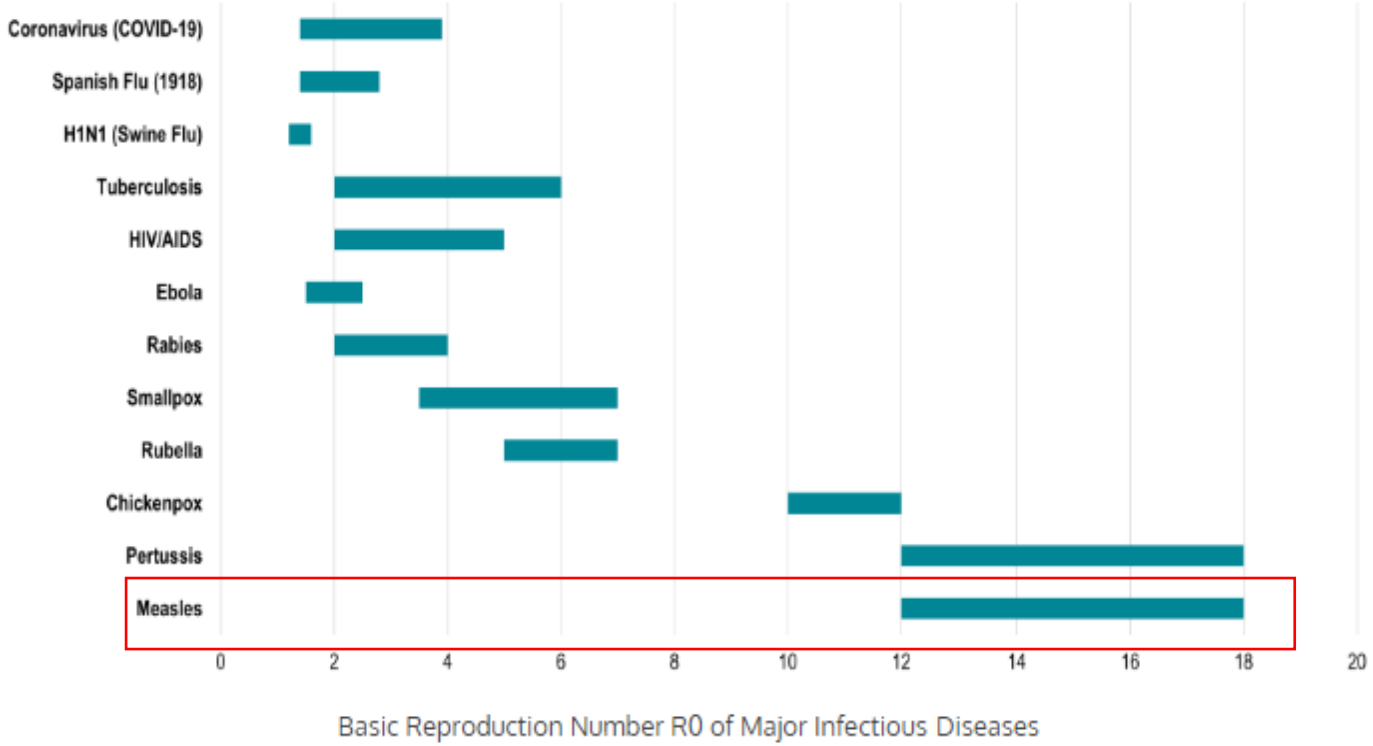
- 3/8/24: 3 year-old child presented to the Pediatric Emergency Department with upper respiratory tract symptoms. No rash at that time.
- Tested positive for Adenovirus and was sent home with supportive care
- Returned to the ED on 3/11/24 with a rash and increased lethargy. Vaccine records revealed that he received his first MMR vaccine at age 15 months. No known exposures. Admitted to a negative pressure room.
- 3/13/24 Measles PCR returns positive

Measles: Typical Course

- Rash begins at the hairline and spreads outward from face
- Rash typically lasts 6-7 days
- Fever, cough, coryza, conjunctivitis typically resolve around day 3 of rash
- Pharyngitis, vomiting, diarrhea, and acute otitis media can also occur

From CDC/PHIL

Measles Is Extremely Contagious



Basic Reproduction Number R0 of Major Infectious Diseases

- Spread by airborne particles that linger
- Exposure: In a shared airspace or an airspace occupied within the prior 2 hours

Source: CDC and WHO.

Three Part Intervention

Step 1: Determine who has been exposed

Step 2: Who needs post exposure prophylaxis (PEP)?

Step 3: Limit future exposures

Step 1: Determine Who Has Been Exposed

- Commenced Incident Command structure
- Determine patients/teammates exposed to infected patient or airspace within 2-hour window.
- 2 potential exposure times:
  ED trip 3/8/24
  Admission 3/11/24 (prior to negative pressure room)

Measles Typical Timeline

Quarantine Period for Susceptible Patients:
Until Day 21 from Exposure

Infectious Period: 4 days before and after onset of rash

Day 0: Exposure

Day 5: Earliest Onset of Symptoms

Day 10: Median Onset of Prodrome

Day 14: Median Onset of Rash

Day 18

Day 21: Latest Onset of Symptoms

Step 2: Who Needs Post-Exposure Prophylaxis (PEP)?

Age	Requirement
< 6 months old	Immunoglobulin within 6 days of exposure
6-12 months old	MMR within first 72 hours post exposure. Immunoglobulin after 72 hours and up to 6 days post exposure
>12 months	If not vaccinated, or partially vaccinated, same recommendations as above.

72 potential exposures on 3/11/24: 8 children requiring MMR vaccine
1 requiring IMIG (<6months)

All patients required notification by certified letter.

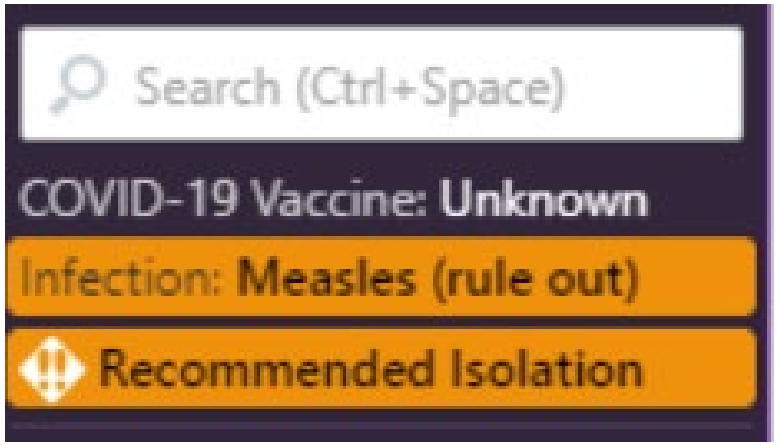
Measles PEP with Immunoglobulin

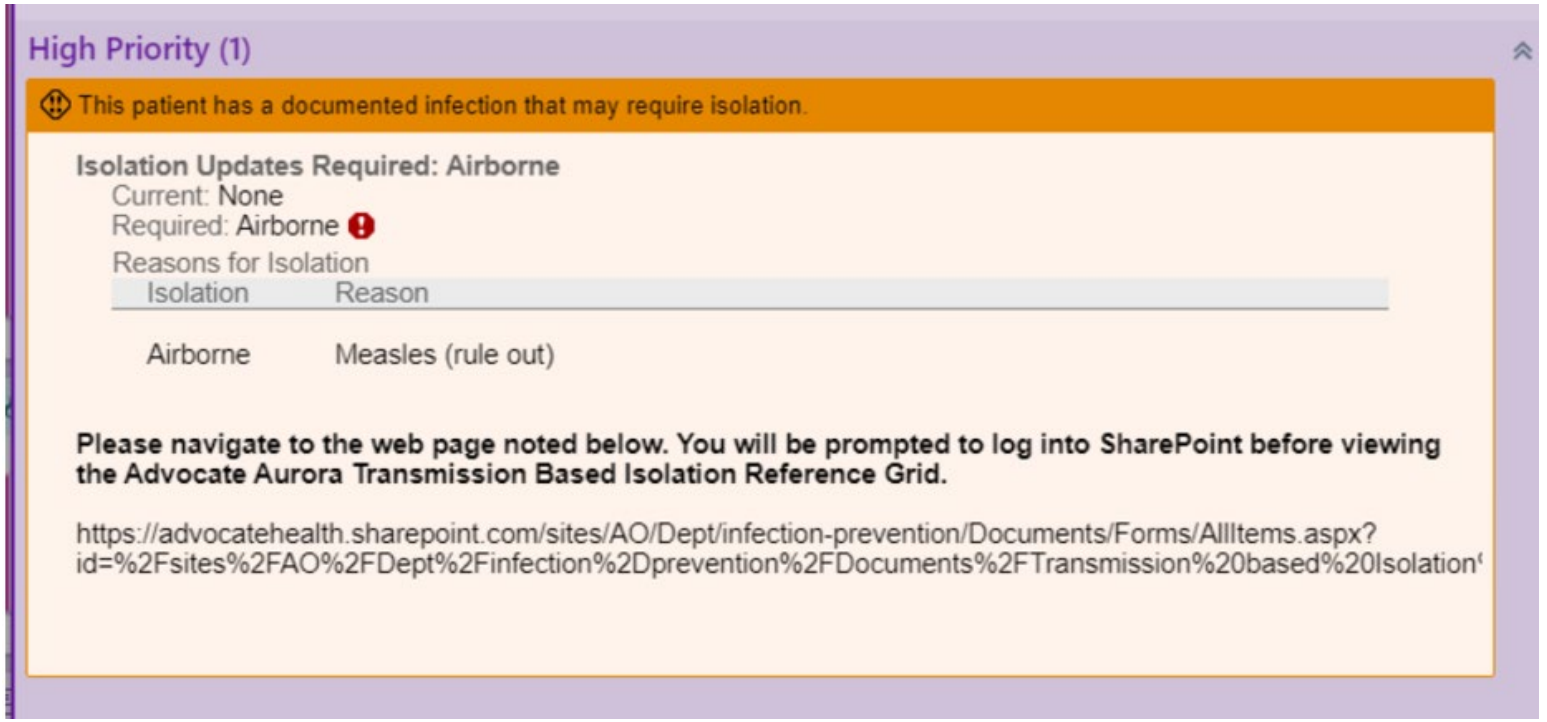
- Intramuscular (IM) IG is preferred for kids < 12 months old
- Intravenous (IV) IG is preferred for individuals > 12 months old
- IMIG may not be available – check with pharmacy!
- If IG is administered, quarantine time needs to be extended to 28 days

Step 3: Limit Future Exposures

- Activate Incident Command Structure – unlikely stakeholders include lab, pharmacy and public affairs
- Develop and disseminate educational tools to front line clinicians immediately! (webinar, written materials, online repository)
    - Recognition of Measles
    - Exposure guidelines and prophylaxis
    - Testing guidelines
- Email to patients eligible for MMR vaccine (ages 1 to 5)
- Flag in Epic EMR – to alert outpatient and ED clinicians on exposed patients.

Measles Exposure Flagging in EMR





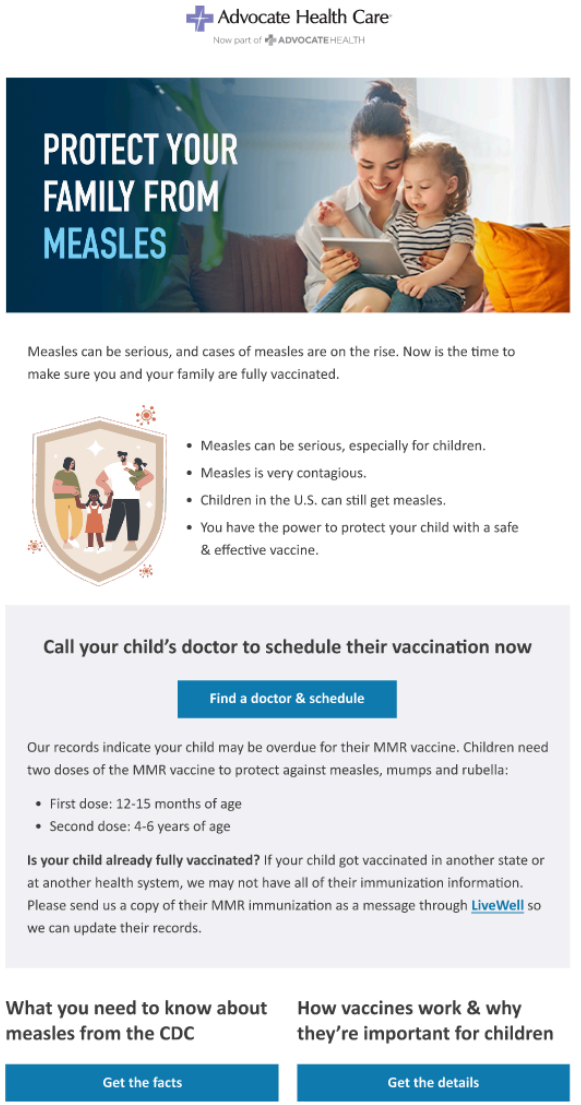
Potentially exposed to positive measles patient on 10/10/23. Upon arrival, mask patient immediately and place in negative pressure room with airborne isolation precautions. If negative pressure room not available place patient in room, close door keeping patient masked with airborne isolation precautions. Patient received IVIG for measles on 10/12/23. Isolation end date 11/7/23.

Proactive Patient Outreach

Targeted Email Campaign for MMR Vaccination

Initiated a targeted email campaign to nearly 16,000 families

- **Goal:** Increase awareness of local measles outbreak, boost MMR vaccination rates and curb measles spread in the community
- **Audience:** Parents of medical group patients potentially overdue for their first or second MMR dose
- **Content:** Educational information about measles, vaccination benefits and a call-to-action to schedule a vaccination appointment



Advocate Children's Hospital
Now part of ADVOCATEHEALTH

Promote Vaccination!!

- Provided 246 MMR vaccines to migrant children during the Chicago outbreak.
- O'Hare Airport and Migrant Shelters.
- Reviewed hundreds of vaccine records and entered previous vaccines into the Illinois vaccine registry Icare.

Advocate Children's Hospital
Now part of ADVOCATEHEALTH

This is a team sport!!!!

- The pandemic taught us the importance of working with our local and State public health authorities.

- Collaboration leads to a more comprehensive response!

Parent Perspective

Advocate Children's Hospital
Now part of ADVOCATEHEALTH

Questions?

Outbreak Update: Measles Cases in Illinois

Discussion

NVAC

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

June 13-14, 2024

Break

NVAC

Breast Cancer Vaccine Innovations in the Works

Dr. Nora Disis
Dr. Kiran Dhillon
Kristen Dahlgren

NVAC

Vaccines to treat and prevent cancer

Nora Disis, MD

Helen B. Slonaker Endowed Professor for Cancer Research

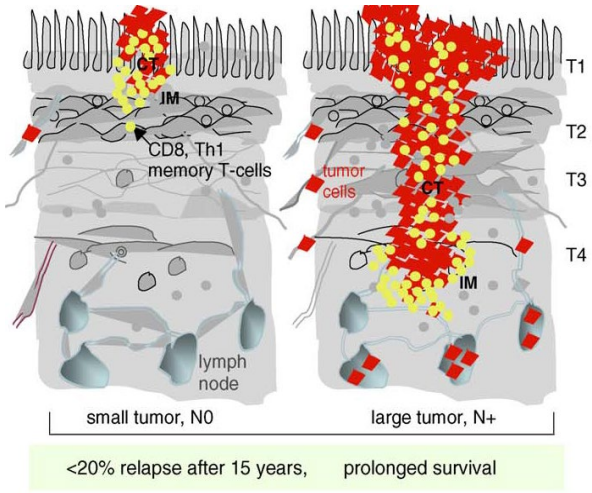
Professor, Medicine University of Washington, Member, Fred Hutch Cancer Center

Director, UW Medicine Cancer Vaccine Institute

CANCER VACCINE INSTITUTE
UW Medicine

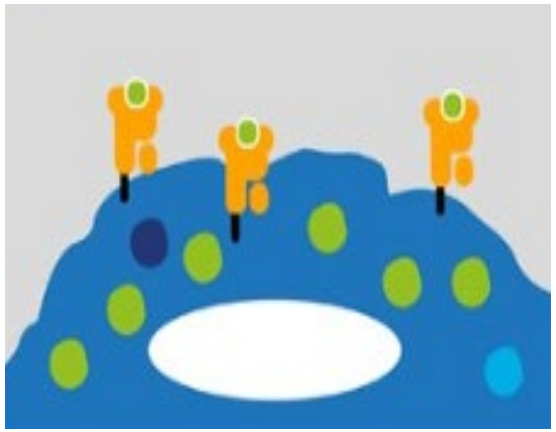
Tipping point for cancer vaccines

Type I T-cells are needed for cancer eradication

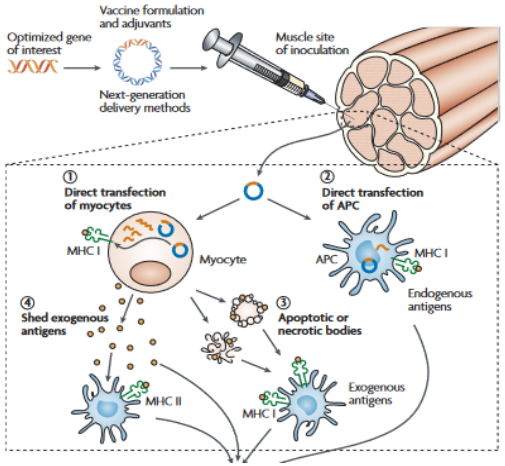


Bindea et al, Curr Opin Immunol, 2010

Hundreds of tumor antigens have been identified



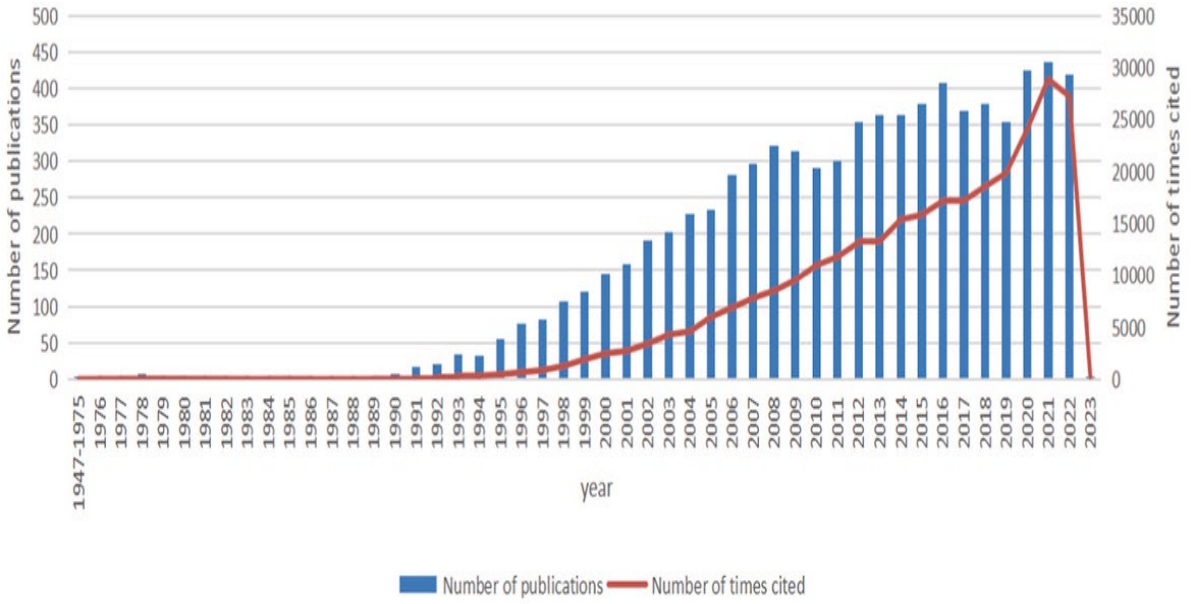
Safe and effective vaccine delivery



Kutzler et al, Nat Rev Genetics, 2008

Appropriate patient populations

USA leading the explosion of cancer vaccine research



The top 10 productive countries with publications.

Rank	Country	Article count	Percentage(n/7807)	H-index	TLS	Total citations	Average citation per article
1	USA	3769	48.28	182	29045	183964	48.81
2	CHINA	1011	12.95	59	7151	20999	20.77
3	JAPAN	698	8.94	62	4771	18913	27.1
4	GERMANY	588	7.53	83	7400	25698	43.7
5	ITALY	426	5.46	62	5475	16502	38.74
6	ENGLAND	401	5.14	74	5710	19564	48.79
7	FRANCE	341	4.37	77	6323	21903	64.23
8	NETHERLANDS	330	4.23	78	5981	19612	59.43
9	CANADA	277	3.55	63	4662	15846	57.21
10	BELGIUM	210	2.69	61	4837	12837	61.13

Yu et al, Heliyon, 2024

The UK Cancer Vaccine Initiative

UK NEWS WEBSITE OF THE YEAR

The Telegraph

Dozens of NHS hospitals to offer pioneer cancer vaccines in next three months

Health chiefs sign deal with BioNTech as part of cutting-edge clinical trials

By Joe Pinkstone, SCIENCE CORRESPONDENT

8 July 2023 · 2:33pm

BBC NEWS

Covid vaccine research now helping cancer patients

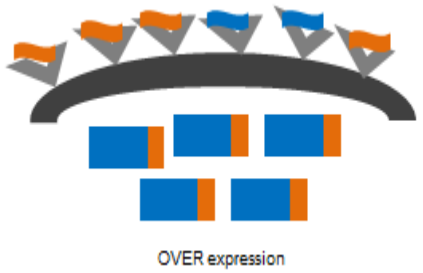
INDEPENDENT

Up to 10,000 Britons could take part in cancer vaccine trials

- Enroll 10,000 cancer patients
- mRNA personalized vaccines
- Treatment for existing cancer

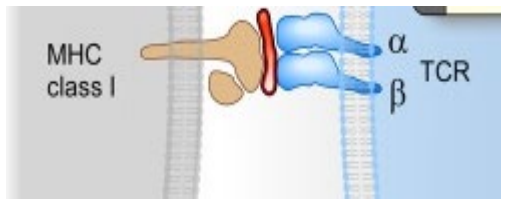
Types of immunogenic proteins

Aberrantly expressed

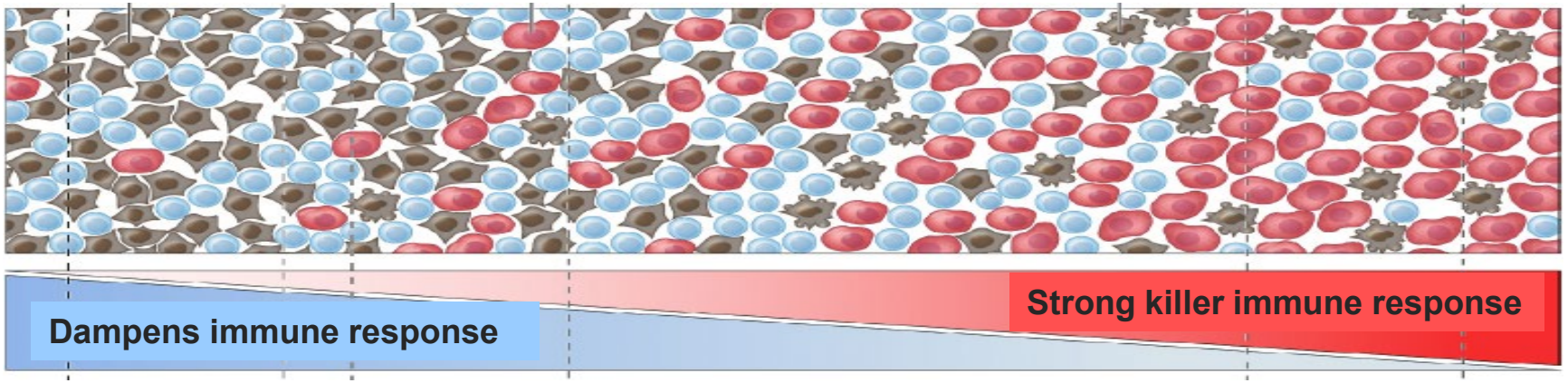


Self signal

Virus, mutation



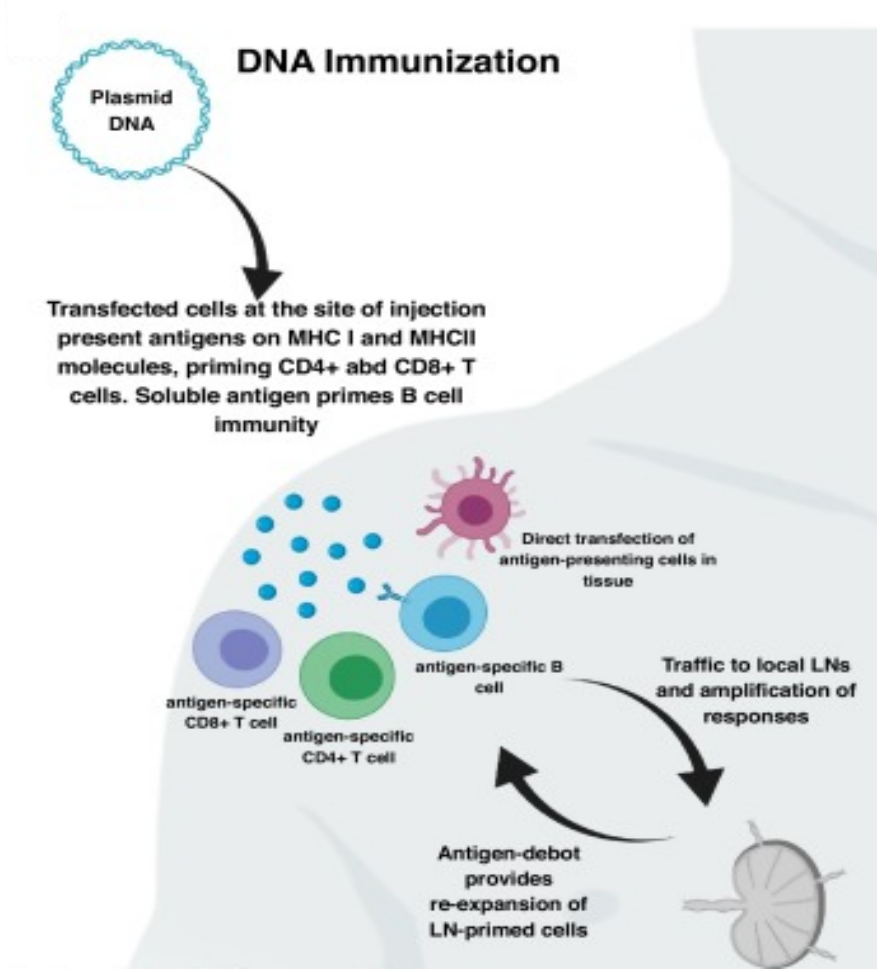
Danger signal



MOST CANCER PATIENTS

A FEW CANCER PATIENTS

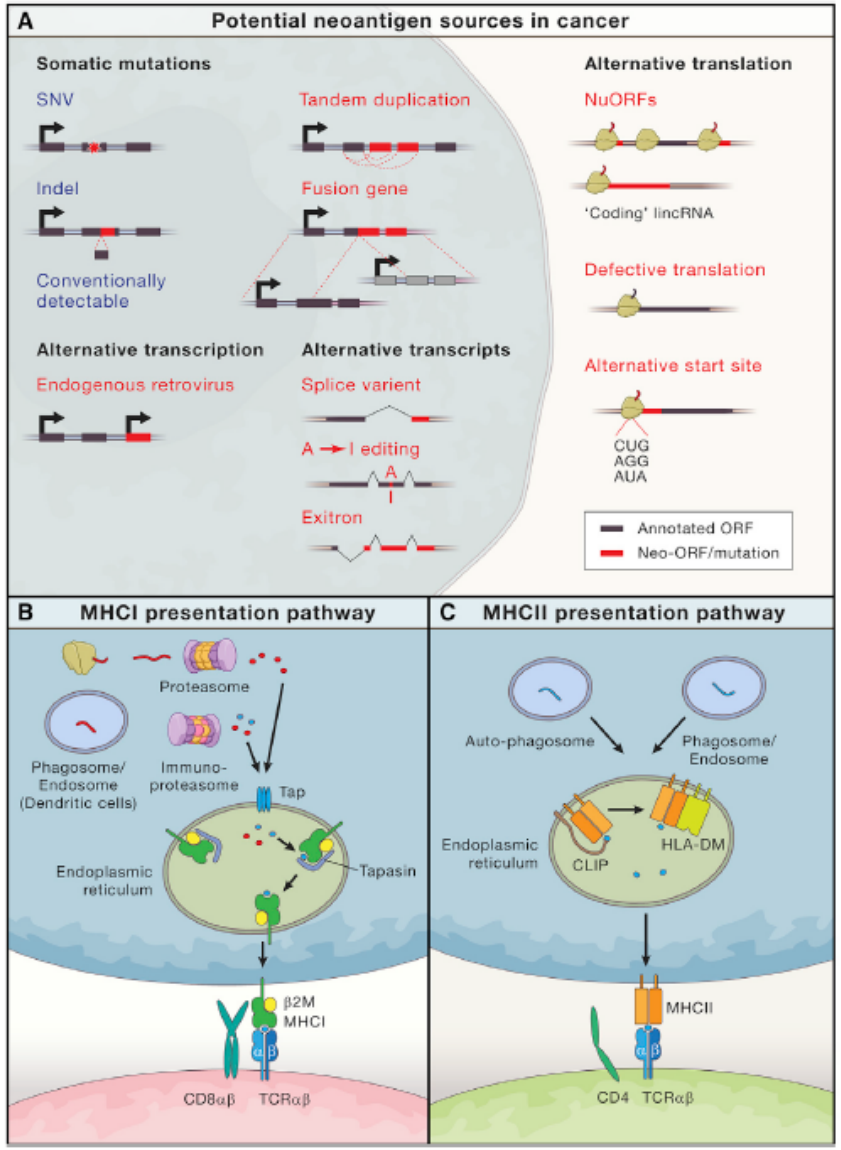
Nucleic acid vaccines are safe & effective

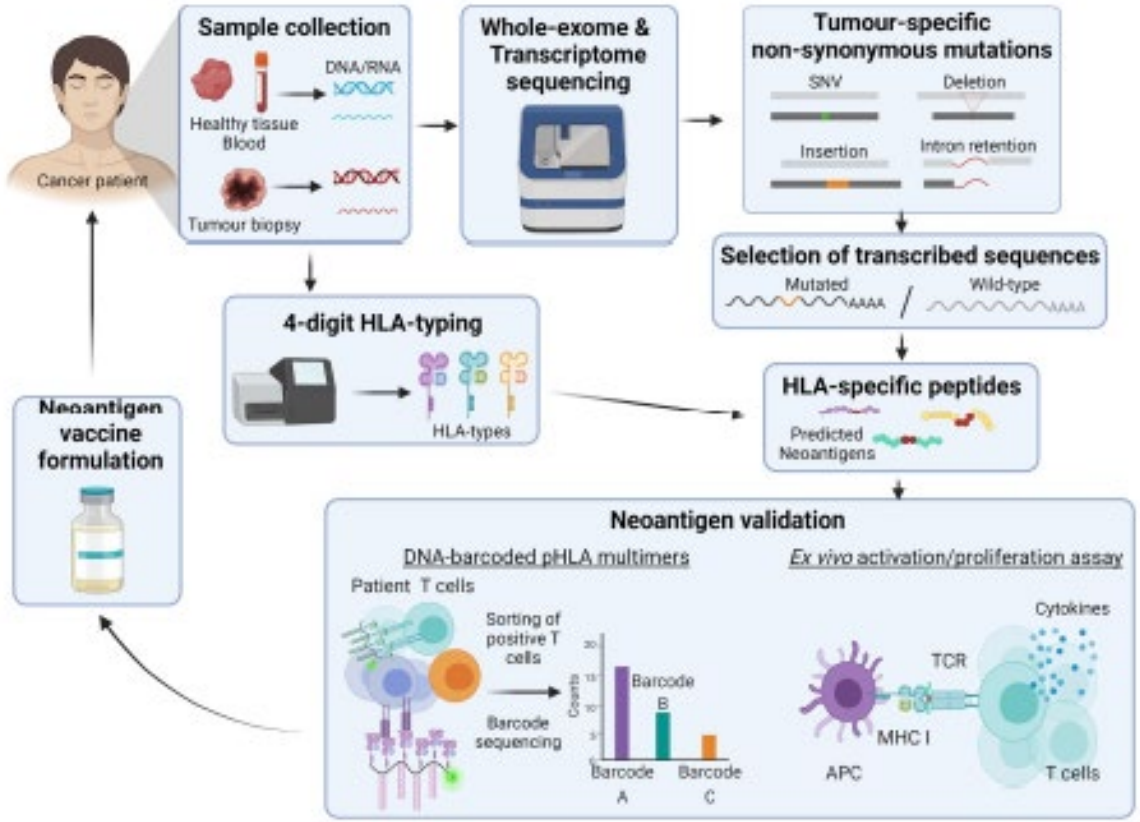


Gary et al, Current Opinions in Immunology, 2020

- Adaptable to multiple antigens
- Superior in the generation of cytotoxic T-cells
- Stable over time and at higher temps
- Persist at injection site
- Low cost
- Rapid manufacture

Mutation based personalized vaccines

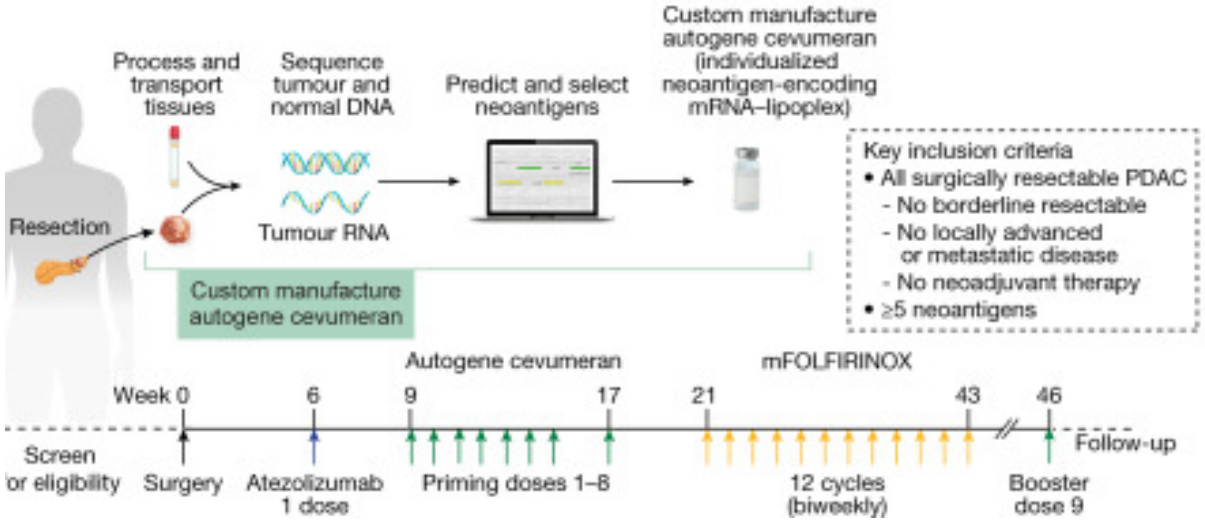




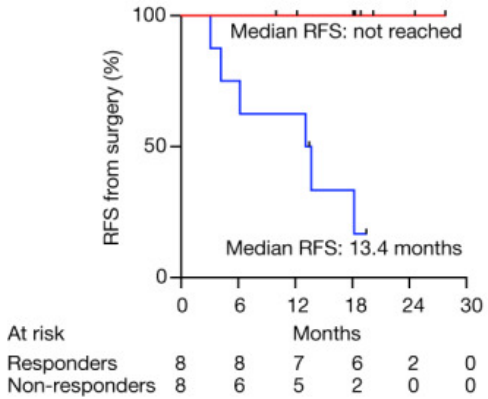
Tay et al, Vaccines, 2021

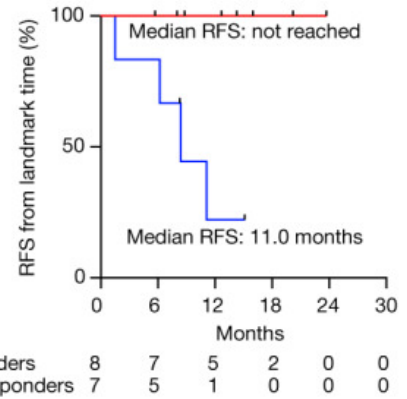
Sellars et al, Cell, 2022

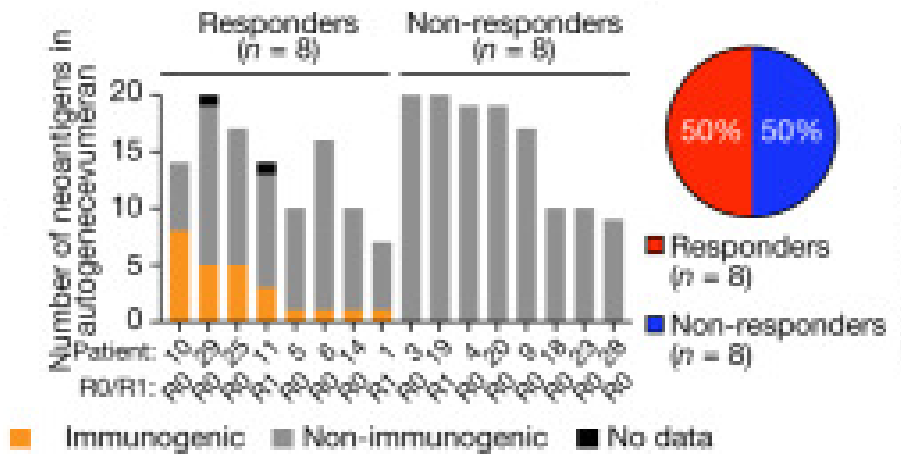
Personalized vaccine for pancreatic cancer



Rojas, LA et al Nature, 2023

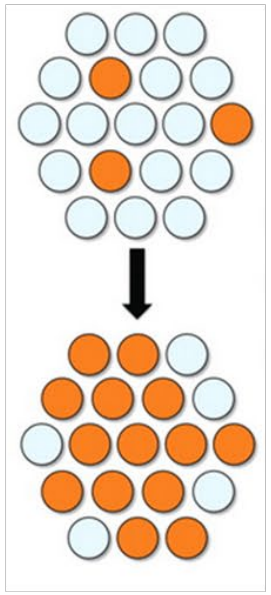




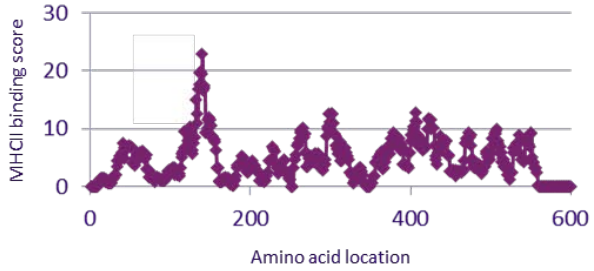


Epitope editing for non-mutated cancer vaccines

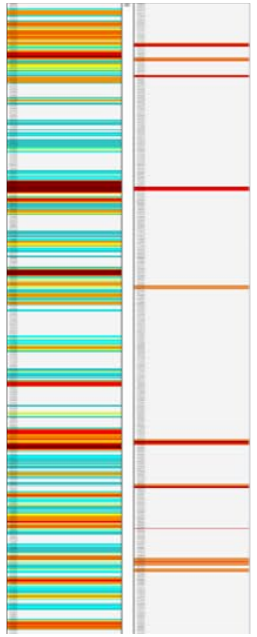
Proteins that are cancer “drivers”



Predicting which protein segments will have the right response



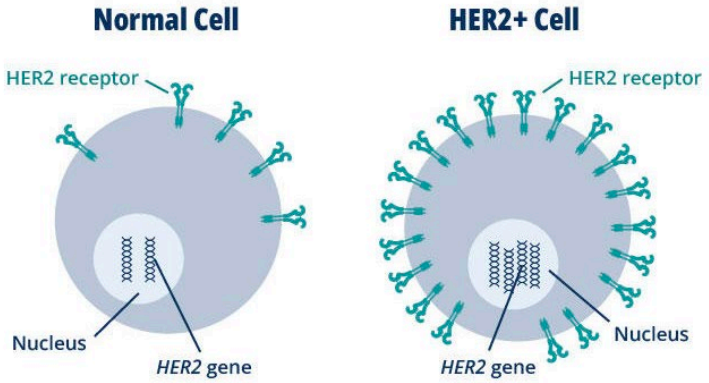
Barcode for effective cancer vaccine

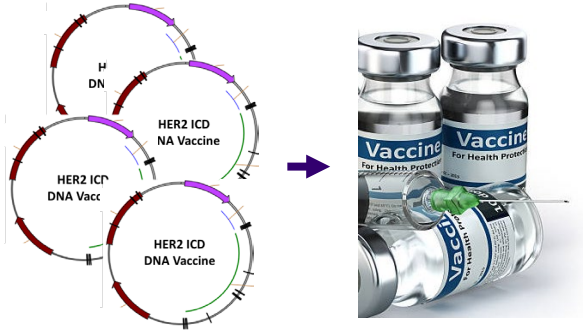


Multi-antigen cancer prevention & treatment vaccine

Vaccine to prevent breast cancer recurrence

30% of breast cancers caused by high expression of HER2 protein



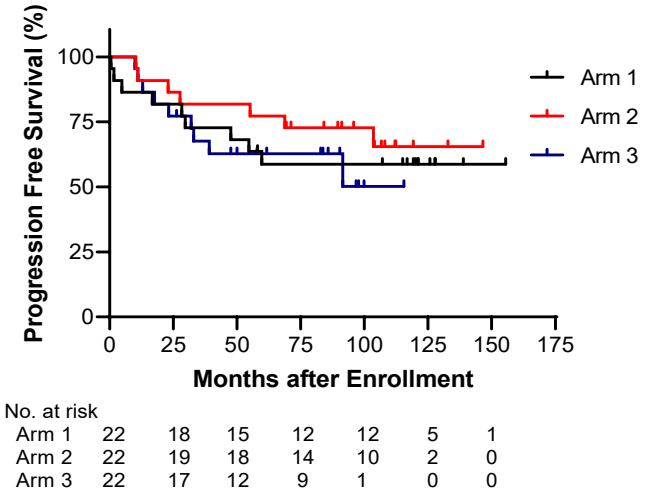


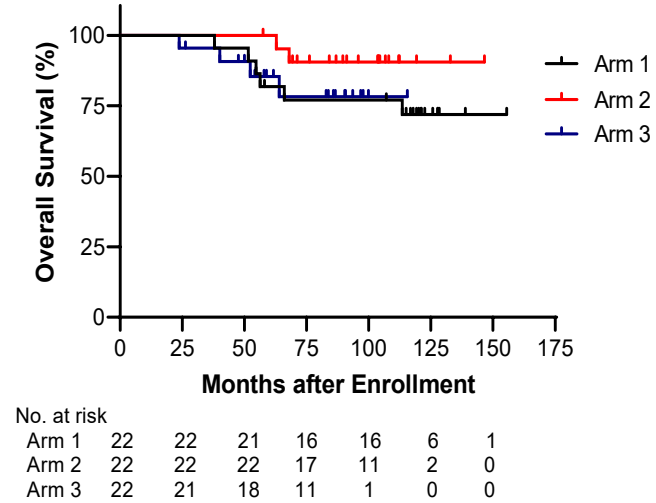
HER2 ICD DNA vaccine

Phase I Clinical Trial

- Stage III and IV HER2+ breast cancer patients
- Enrolled 66 patients with no evidence of disease or bone only disease
- Received one of three doses (10, 100, & 500 mcg), intradermally once a month for three months
- Safety, immune response, clinical response

Immunogenicity and clinical outcomes

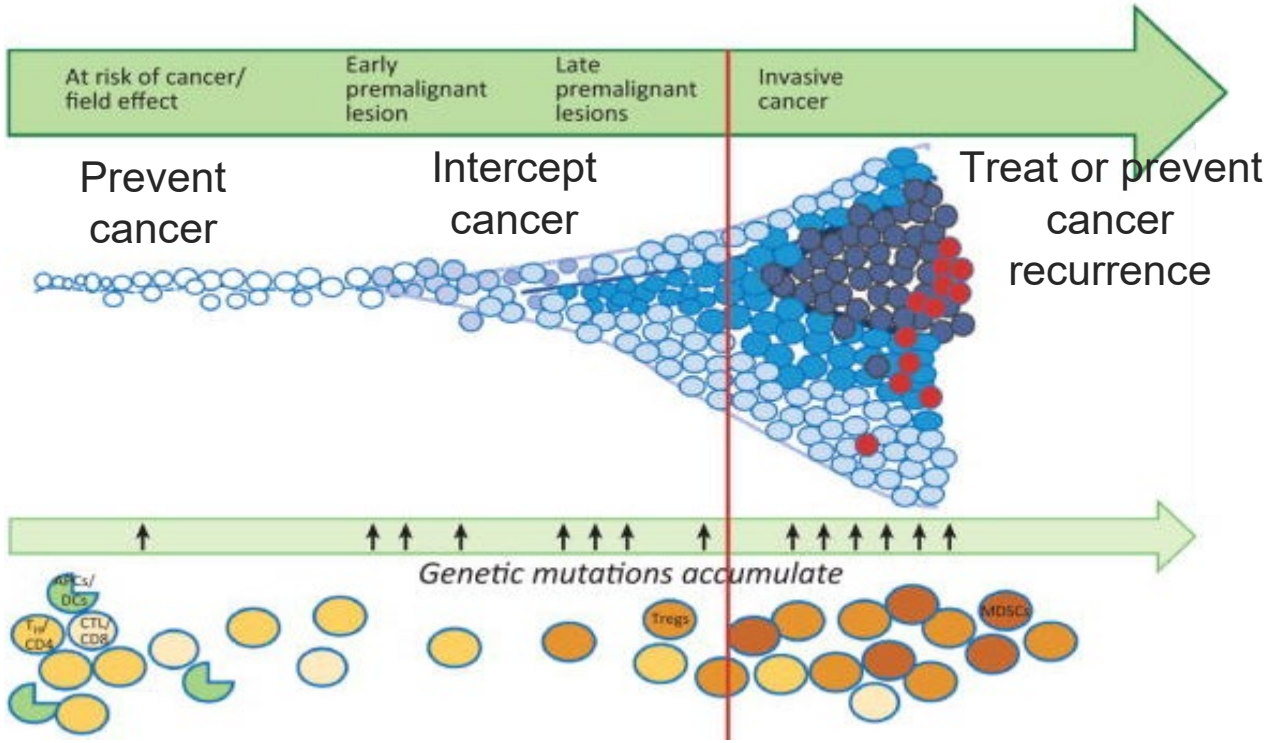




- All 3 doses elicited an immune response
- ~50% of patients have not had a relapse
- ~75-85% of patients alive 10 years after vaccination
- Licensed by a commercial partner
- Basket trial for different types of HER2+ cancers (uterine, gastric, lung, etc)

Disis et al, JAMA Oncology 2022

Cancer vaccines are moving forward in multiple clinical scenarios



Adapted from Dunn et al, Trends Cancer, 2016


Lung


Breast


Colon


Prostate


Ovary


Bladder

Clinical application of cancer vaccines

Kiran Dhillon, PhD
Executive Director

Cancer Vaccine Institute
University of Washington

CANCER VACCINE INSTITUTE
UW Medicine

Clinical application of cancer vaccines

Prevent cancer recurrence

Treat cancer

Prevent or intercept cancer

Vaccines to prevent cancer recurrence

Vaccinating patients who had been successfully treated to no evidence of disease or in some cases bone-only disease

JAMA Oncology | Original Investigation

Safety and Outcomes of a Plasmid DNA Vaccine Encoding the ERBB2 Intracellular Domain in Patients With Advanced-Stage ERBB2-Positive Breast Cancer
A Phase 1 Nonrandomized Clinical Trial

Mary L. (Nora) Disis, MD; Katherine A. Guthrie, PhD; Ying Liu, PhD; Andrew L. Coveler, MD; Doreen M. Higgins, BSN; Jennifer S. Childs, MPH; Yushe Dang, PhD; Lupe G. Salazar, MD

CLINICAL CANCER RESEARCH | CLINICAL TRIALS: IMMUNOTHERAPY

Immunization with a Plasmid DNA Vaccine Encoding the N-Terminus of Insulin-like Growth Factor Binding Protein-2 in Advanced Ovarian Cancer Leads to High-level Type I Immune Responses

Denise L. Cecil, John B. Liao, Yushe Dang, Andrew L. Coveler, Angela Kask, Yi Yang, Jennifer S. Childs, Doreen M. Higgins, and Mary L. Disis

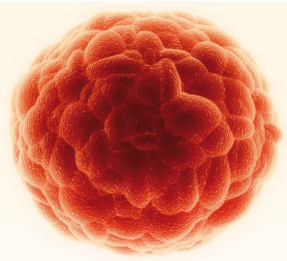
ONGOING STUDIES

Phase I:
NCT02157051
NCT02780401

Phase II:
NCT05455658
NCT03384914

STEMVAC – Vaccination to treat cancer

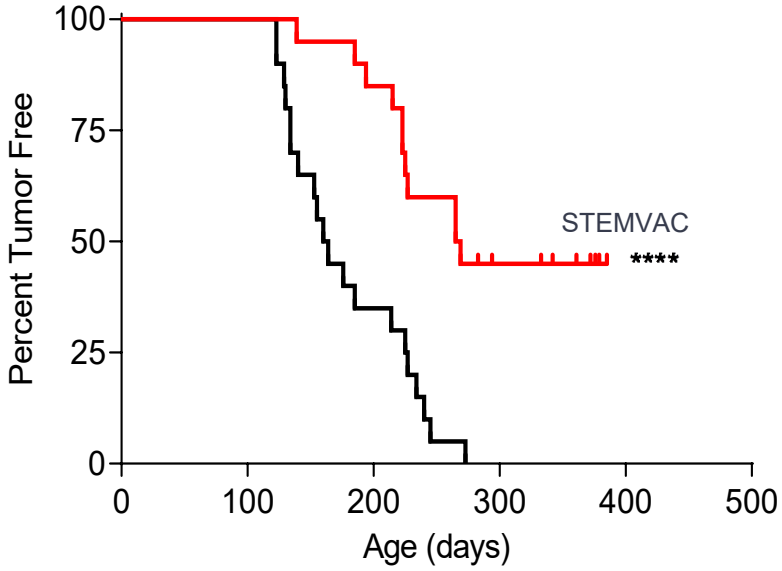
Cancer Stem Cell



Resistance to therapy
Recurrence
Metastasis

STEMVAC DNA vaccine
Targets 5 stem cell proteins

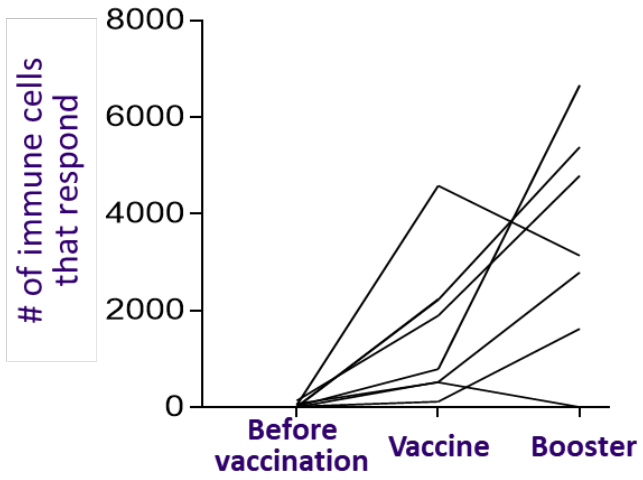
CD105, Yb-1, SOX2, CDH3, MDM2

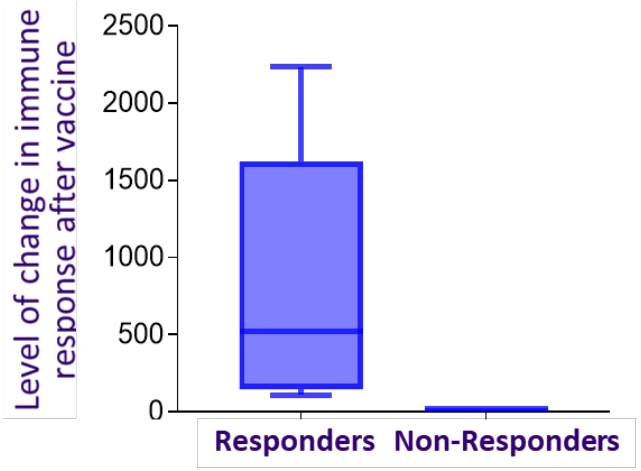


Effective in preventing
mammary cancer in mice

STEMVAC generated strong immune responses in a Phase I clinical trial

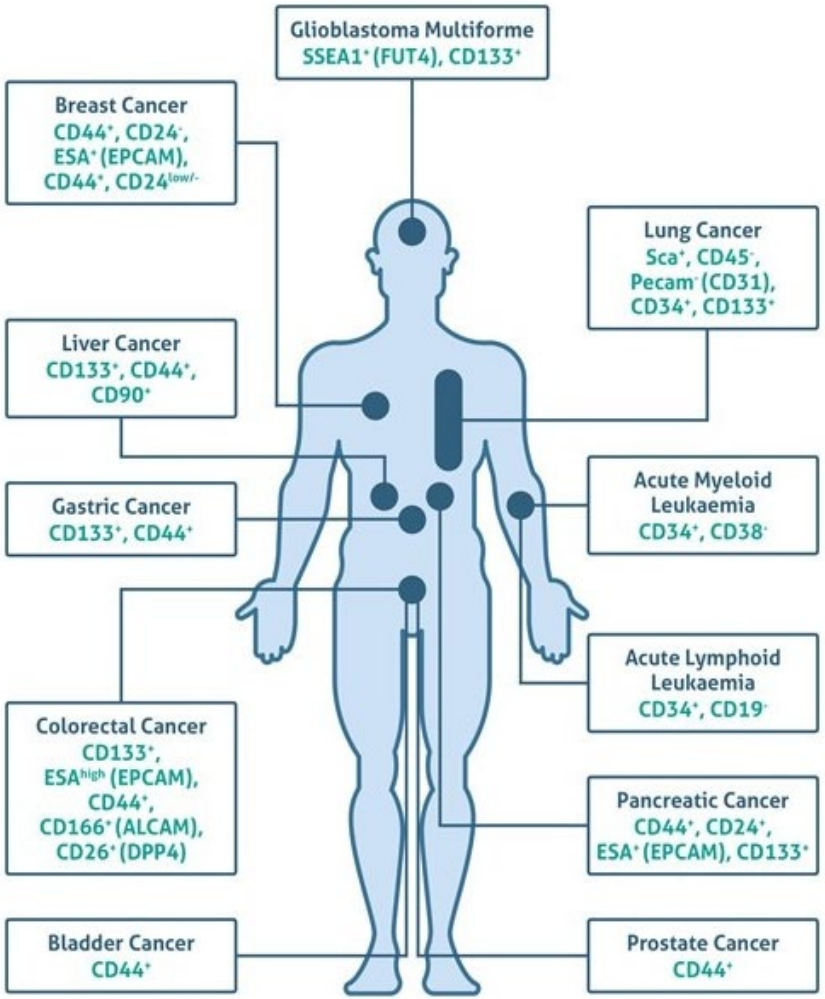
Clinical Trial
Phase I, dose escalation
3 doses of vaccine
Stage III/IV Breast Cancer Hormone receptor positive or Triple Negative
30 patients (10 per dose)
3 vaccines 1 month apart, id
Boosters at 3 and 9 months





- ✓ We detected an immune response to all 5 stem cell proteins
- ✓ Boosters increase level of response
- ✓ Very high levels of STEMVAC-specific immunity

STEMVAC may be effective for many cancers



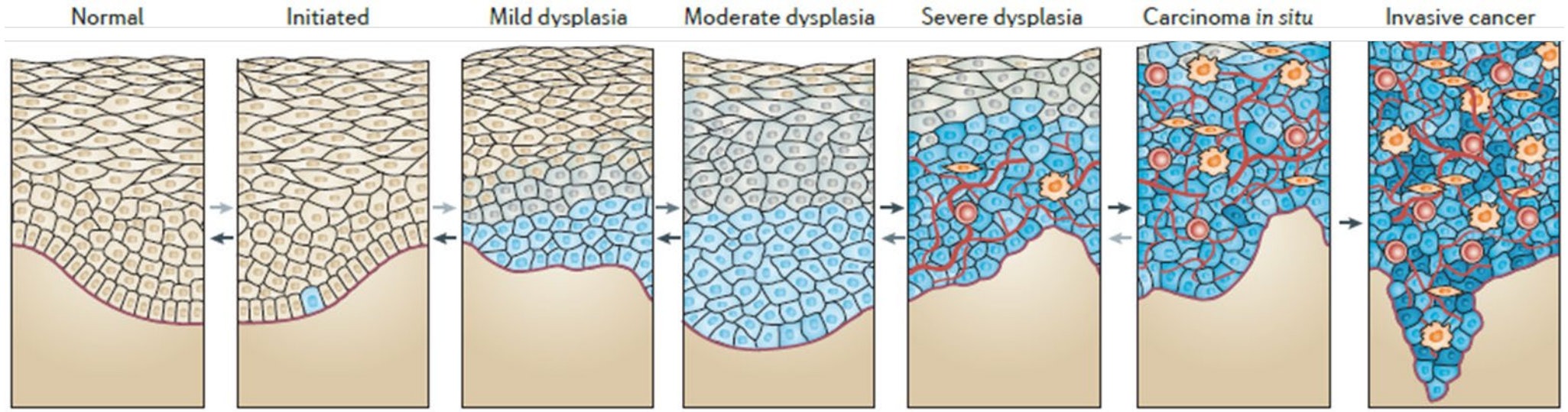
Ongoing clinical trials:

- NCT05455658 - Phase II non-metastatic triple negative breast cancer
- NCT05242965 – Phase II randomized in non-small cell lung cancer

Under development:

- Metastatic triple negative breast cancer
- Metastatic hormone receptor positive breast cancer

Vaccines to intercept or prevent cancer



Multi-antigen vaccines in development

Prostate: Intraepithelial neoplasia

Colon: Adenomatous polyps

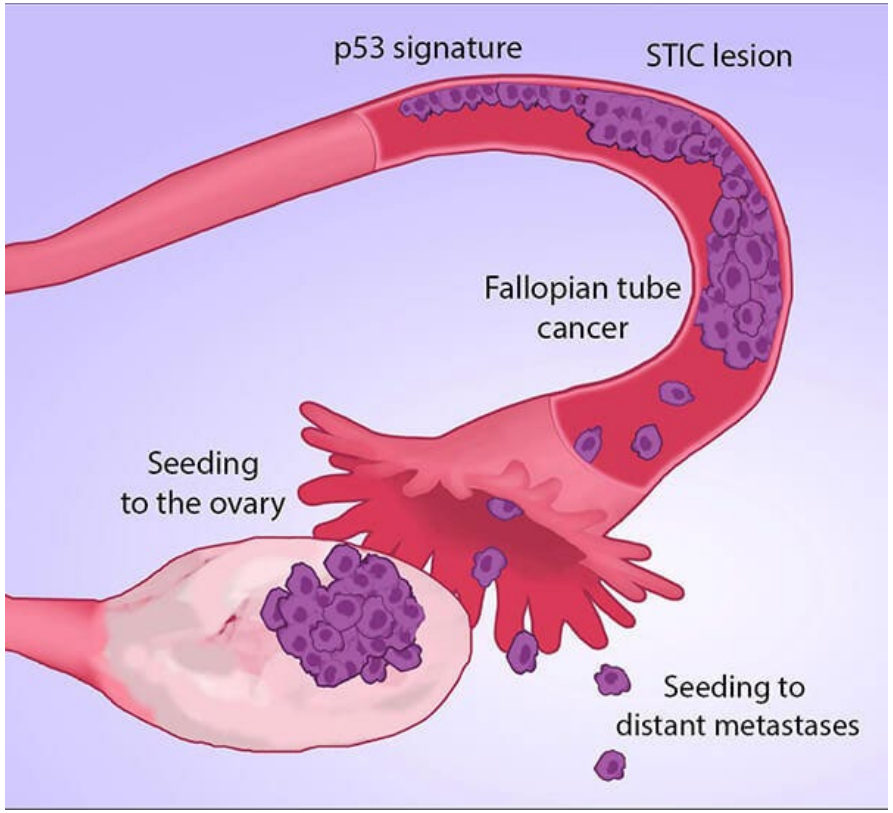
Ovary: Serous tubal intraepithelial carcinoma

Breast: Ductal carcinoma in situ

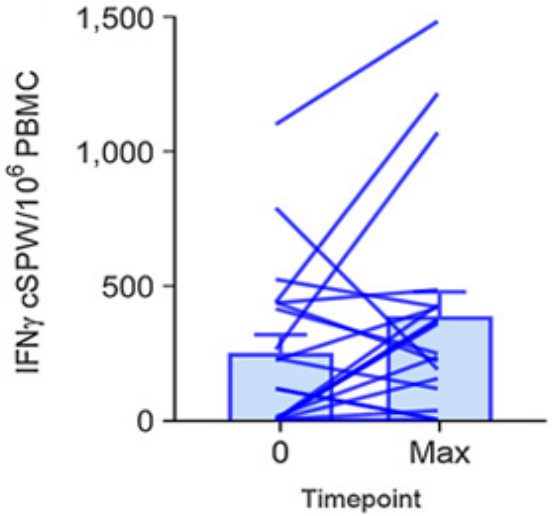
Bladder: Carcinoma in situ

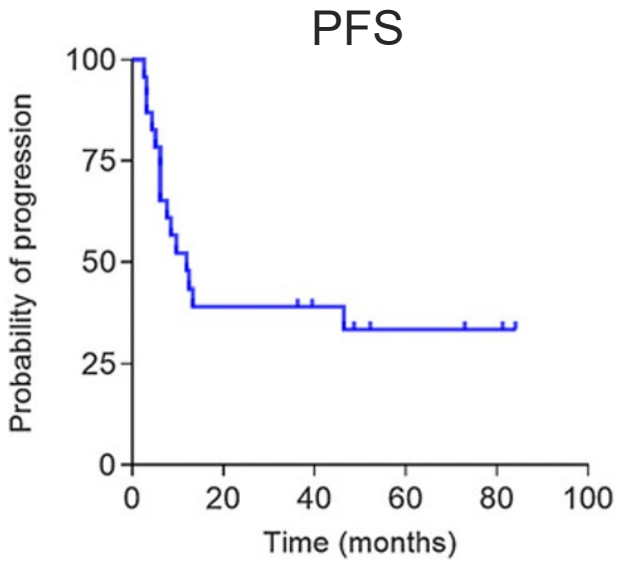
Preventing ovarian cancer, the ‘silent killer’

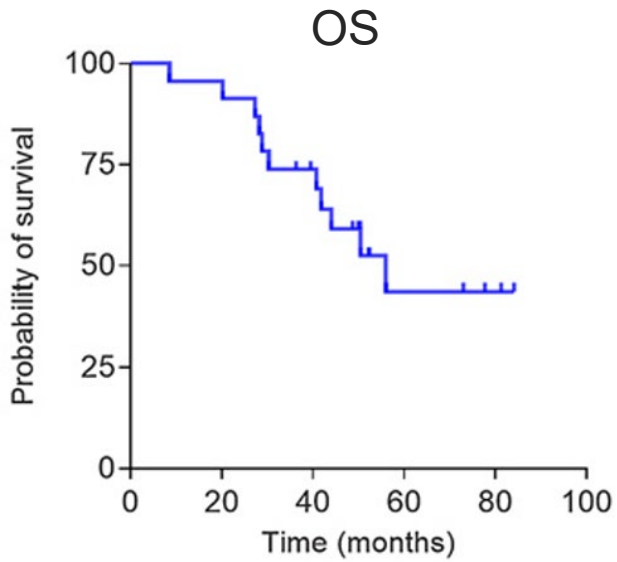
- Serous tubal intraepithelial carcinoma (STIC) – precancerous lesion thought to be origin for most high grade serous ovarian cancers (HGSOC)
- Prophylactic removal of ovaries and fallopian tubes in patients at high risk reduces risk by 80% but does not eliminate it completely
- STIC found in patients with genetic high risk and found incidentally after hysterectomy in patients at normal risk
- Can a vaccine of STIC-associated antigens prevent ovarian and peritoneal cancer?



IGFBP-2 vaccine induced immune responses in patients with advanced stage ovarian cancer







Median survival (without vaccine) is 18 months
in similar patient populations

Currently developing a multi-antigenic STIC vaccine, including IGFBP-2 epitopes

Interception of vulvar intraepitheilial neoplasia (VIN)

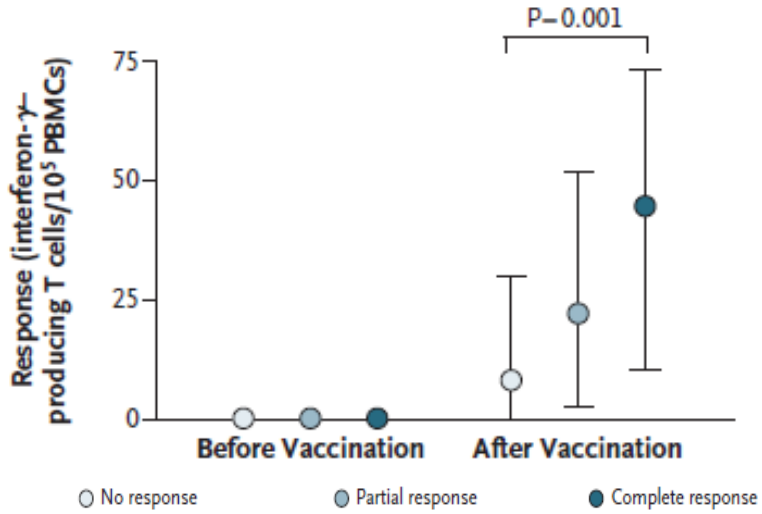
Table 3. Clinical Results at 3, 12, and 24 Months after the Last Vaccination.*

Patient No.	No. of Vaccinations	At 3 Months				At 12 Mo		At 24 Mo
		Symptoms	Lesion Response	Histologic Findings	Type of HPV Infection	Symptoms	Lesion Response	Lesion Response
1	4	Mild to moderate	Partial	VIN 2	16	Mild to moderate	Partial	Partial†
2	4	Severe	None	VIN 3	16		Carcinoma	
3	4	Severe	None	VIN 3	16	None	Partial	Partial‡
6	4	None	Complete	Normal	16	None	Complete	Complete
7	4	None	Complete	Normal	None	None	Complete	Complete
8	4	Mild to moderate	Complete	Normal	6b	None	Complete§	Complete
9	3	None	Complete	Normal	None	None	Complete	Complete
10	4	None	Partial	VIN 3	16	Lost to follow-up¶		
11	4	None	None	VIN 3	16	None	Complete	Complete
12	4	Mild to moderate	None	VIN 3	16	Mild to moderate	Partial	None‖
13	4	Mild to moderate	Partial	VIN 3	16	Mild to moderate	Partial	Partial
16	4	Mild to moderate	Partial	VIN 1	16	Mild to moderate	Complete	Complete
18	4	Severe	None	VIN 3	16	Severe	None	None
22	4	Mild to moderate	None	VIN 3	16	Severe	Partial	Partial
23	4	Mild to moderate	Partial	VIN 2	16	None	Partial	Microinvasive carcinoma**
26	4	None	None	VIN 3	16	None	None	None
27	3	None	Partial	VIN 3	16	None	Complete	Complete
28	4	None	None	VIN 3	16	None	None	None
29	4	None	Complete	Normal	None	None	Complete	Complete
30	4	Mild to moderate	Partial	VIN 2	16	None	Complete	Complete

Pre-Vaccine

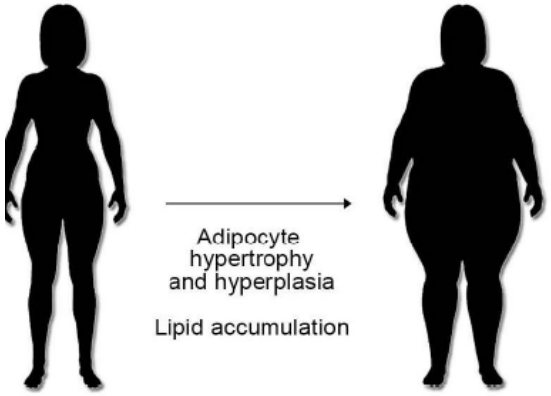
Post-Vaccine

- 79% had clinical responses at 12 months
- 47% had complete responses which were maintained at 24mo
- All patients had vaccine induced T-cell responses



Extended peptide vaccines HPV oncoproteins: E6, E7; 3 vaccines, sq monthly

Can we prevent breast cancer by targeting a risk factor – obesity?

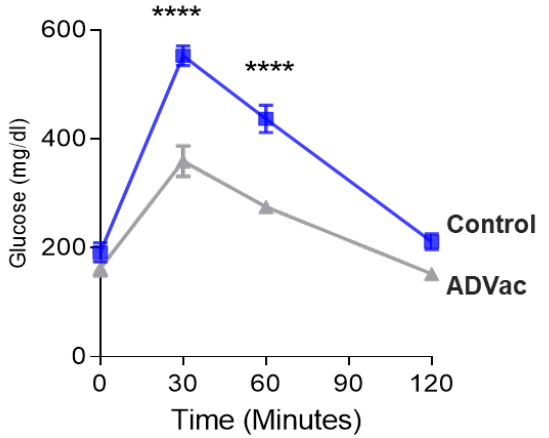


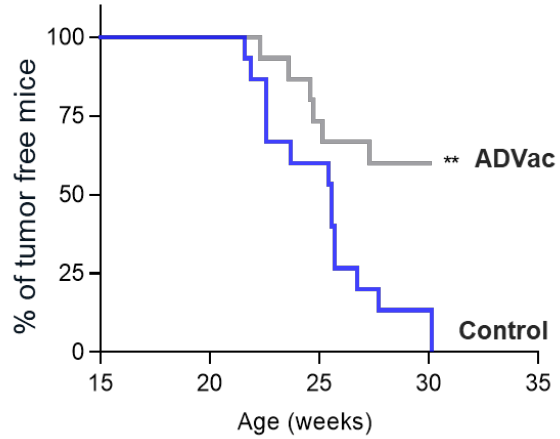
Metabolic dysfunction in inflammatory fat can lead to metabolic syndrome & increased risk for many cancers in individuals with obesity

ADVac DNA vaccine

Targets proteins associated with inflammation from adipocytes

Reversal of diabetes & breast cancer prevention in obese mice?





Vision for a cancer-free future

Intermediate Risk
Chronic inflammation

Vaccines to target risk factors to prevent cancer

High Risk
Genetic mutations or precancerous lesions

Vaccines to intercept or prevent cancer

Very High Risk
Cancer diagnosed

Vaccines to treat cancer & prevent recurrence

Our Team

Director
Nora Disis, MD

Clinical Team
Jennifer Childs
Andrew Coveler, MD
Will Gwin, MD
Katelyn Jones
Kris Kauno
John Liao, MD/PhD
Marcy Paxtian
Shaveta Vinayak, MD

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David Johnson, PhD
Nicole Kretzer, MD/PhD
Ying Liu, PhD
Kevin Potts
Xuanyu Xu

Mouse Modeling Core
Lauren Corulli
June Rambousek
Erin Rodmaker
Danielle Rodriguez

Immune Monitoring Laboratory
Adam Prince
Huiyun Shen
Yi Yang

More info:

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CANCER
VACCINE
COALITION
MOVING SCIENCE FORWARD... FASTER

KRISTEN DAHLGREN

FOUNDER & CEO

Award winning News Correspondent for NBC News including Today Show and NBC Nightly News for more than 2 decades. Breast Cancer Survivor.

Stage 2 IDC w/lobular features

8 rounds of ACT chemo

Double mastectomy

25 Rounds of radiation

6 surgeries including LVA, Diep Flap, revision, flap removal w implants, more revisions

Today:

- no feeling in chest, abdomen, part of my lower leg
- Limited shoulder mobility
- Lung Fibrosis from radiation
- chemically induced menopause

2019

BREAST CANCER HAS BEEN NORMALIZED IN SPITE OF THE FACTS:

2 MINUTES

how often someone in the US is diagnosed with Breast Cancer

1 IN 40

how great a woman's chance is of dying from breast cancer, in the US

1 IN 8

how many women in the US have a chance of developing breast cancer in her lifetime

1 IN 3

how many new female cancers in the US will be from breast cancer, each year

Cancer.org

Why did we put more weight on lives lost during COVID-19 than we are now?

--Noubar Afeyan, Founder & Chairman, Moderna

Can we accelerate the process?

A COVID style push to :

- Move scientists out of silos
- Engage the public
- Involve Industry
- Streamline the pipeline
- **BRING IN GOVERNMENT**

Dr. Nora Disis, UW Cancer Vaccine Institute

Move Scientists out of Silos: ☑

Dr. Nora Disis:
UW/CVI Director American Cancer Society Clinical Research Professor. Editor-in-Chief for JAMA Oncology Pioneering investigator and expert in breast and ovarian cancer immunology.

Dr. Larry Norton:
Medical Director, Evelyn H. Lauder Breast Center at Memorial Sloan Kettering Renowned as a leader in the development of drug treatments for breast cancer. Founding Scientific Director, BCRF.

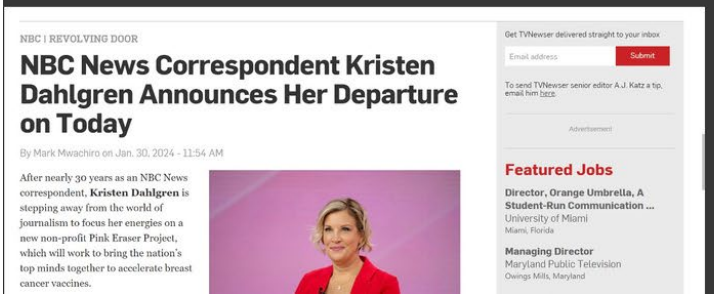
Dr Beth Mittendorf:
Brigham and Women's Hospital Vice Chair for Research, Co-Leader, Breast Program, Dana-Farber/Harvard Cancer Center. Director, Breast Immuno-Oncology program. Co-Leader, Parker Institute for Cancer Immunotherapy, Dana-Farber Cancer Institute

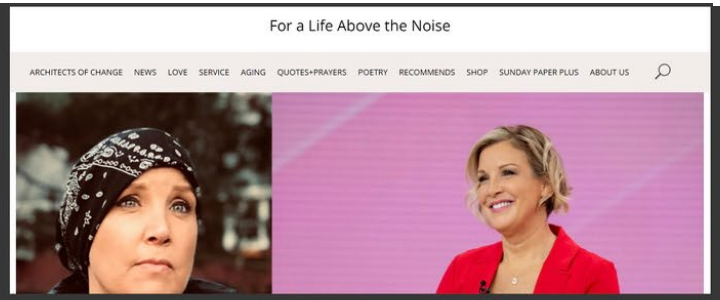
Dr.Powel Brown
MD Andersen Dept of Clinical Cancer Prevention. Currently focused on developing molecularly targeted therapy for the prevention of ER- breast cancer. Principal Investigator of the N01 Contract that support multi-center Phase I and II early phase chemoprevention trials.

Dr. G. Thomas Budd
Cleveland Clinic. Recently presented positive data from Phase I Trial of alpha-lactalbumin vaccine in high-risk operable triple negative breast cancer (TNBC) and patients at high genetic risk for TNBC

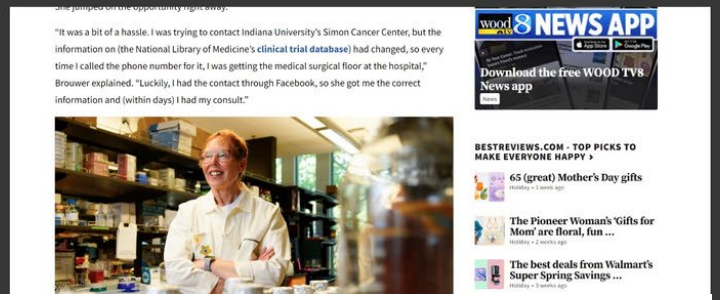
Engage the public: ☑

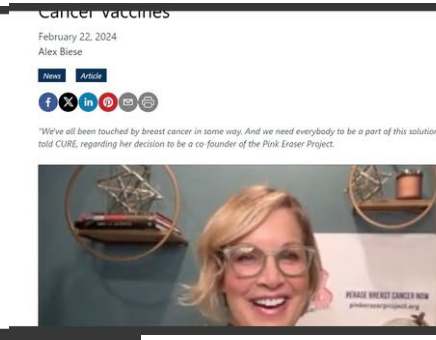
01-2024
People



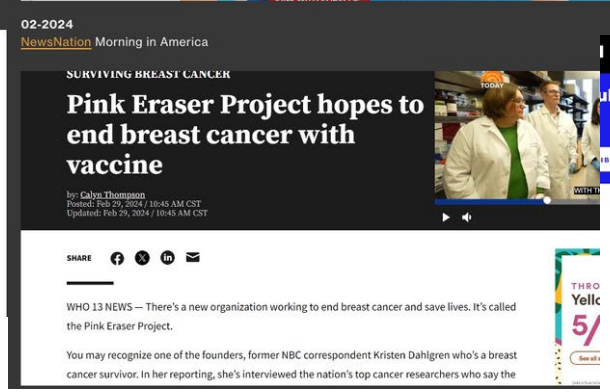


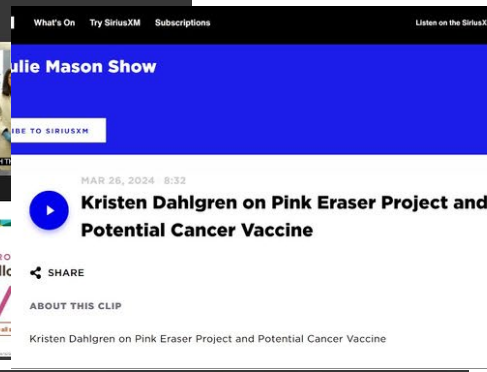
02-2024
SUNDAY PAPER

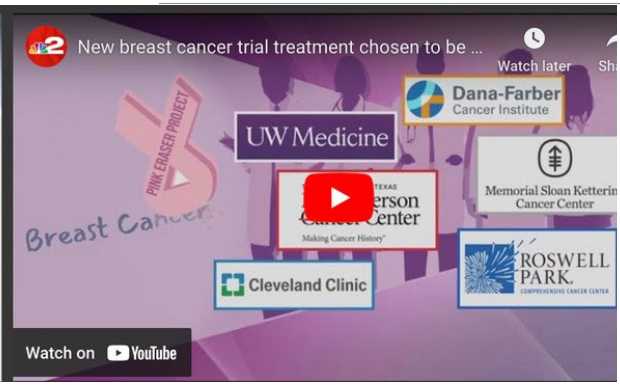




02-2024
NewsNation Morning in America







Involve industry : ☑

- Moderna
- BioNtech
- Johnson & Johnson
- Genentech
- GSK
- Pfizer
- Anixa Biosciences
- Epithany/ Aston
- Immunolight

Among others....

Streamline the pipeline & Engaging Government :

- Accelerate established concepts
- Quickly enroll studies and design clinical trials to yield swift “go-no-go” decisions for advancement.
- Work with FDA to provide roadmap for approval a la Covid

Together we can do this

The UK Cancer Vaccine Launchpad

The foundations and the Frontiers of Cancer therapy

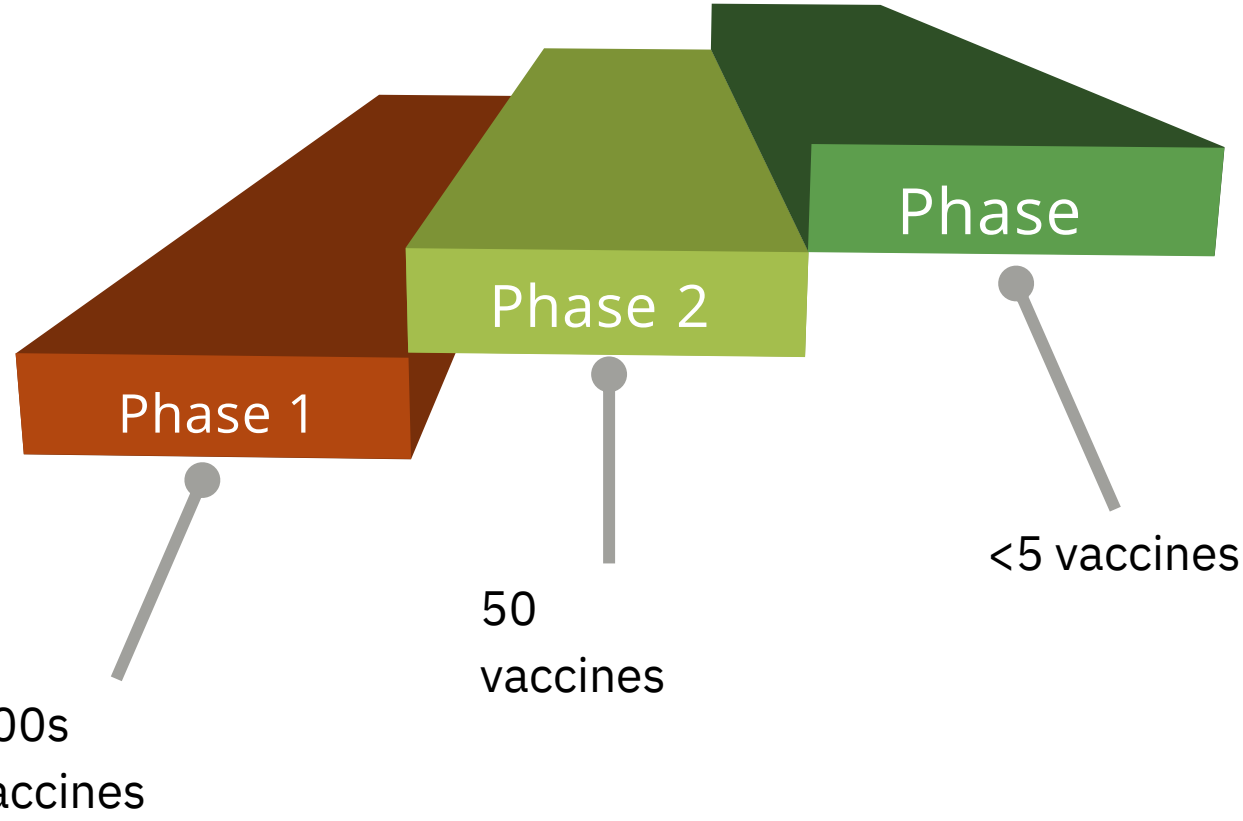
Dr. Lennard Lee

Associate Professor | University of Oxford

Honorary consultant in Medical Oncology | Oxford University Hospitals NHS Foundation Trust

Senior National clinical advisor | NHSE & Office for Life Sciences (DHSC)

A global vaccine technology race is underway



National Cancer Vaccine Advance

BBC NEWS

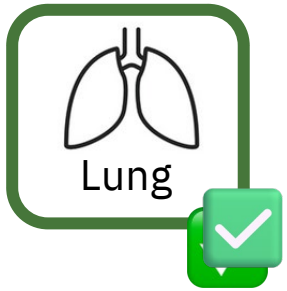
UK plan for national mRNA cancer vaccine advance

4 hours ago

By Michelle Roberts
Digital health editor

16 active cancer vaccine sites

500+ patients consented to trials in year 1




Renal


Bladde
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Gastric


Endometria
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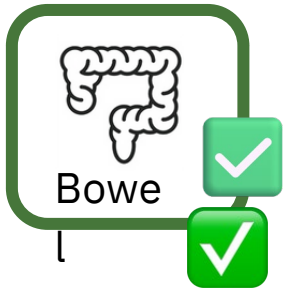


Breas
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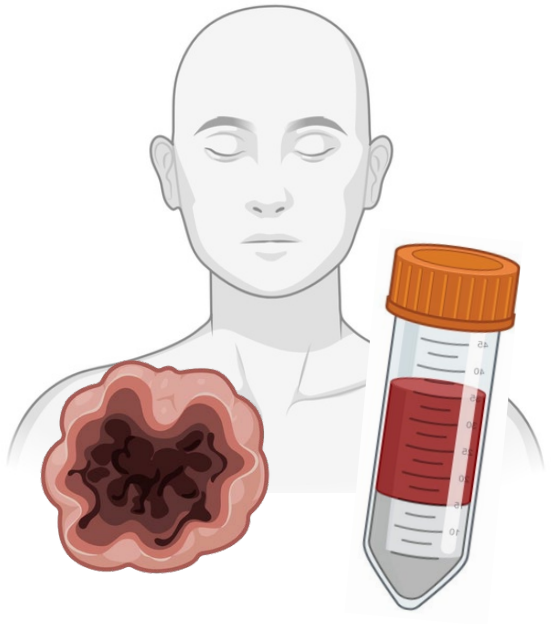
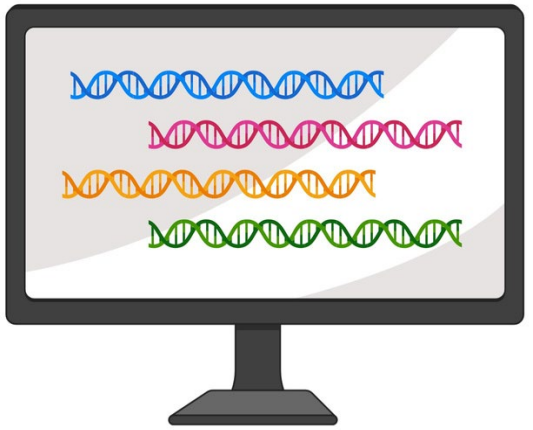
CNS

Genomics underpinning cancer vaccines



Tissue acquisition

Genomic sequencing



Target identification and prioritisation

Vaccine manufacturing

UK NEWS WEBSITE OF THE YEAR

The Telegraph

Dozens of NHS hospitals to offer pioneer cancer vaccines in next three months

Health chiefs sign deal with BioNTech as part of cutting-edge clinical trials

By Joe Pinkstone, SCIENCE CORRESPONDENT

8 July 2023 • 2:33pm

118

INDEPENDENT

NEWS › HEALTH

Up to 10,000 Britons could take part in cancer vaccine trials

Participants could receive groundbreaking treatment after the Government signed an agreement with a leading pharmaceutical company.

NHS
University Hospitals Birmingham
NHS Foundation Trust

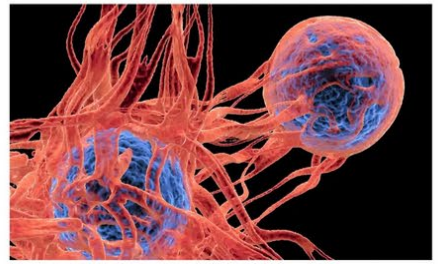
UHB first to start mRNA cancer vaccine trial for colorectal cancer

University Hospitals Birmingham NHS Foundation Trust (UHB) is the first site in the UK to launch the BioNTech Messenger RNA (mRNA) cancer vaccines trial which will aim to recruit 10,000 people across the UK.

The Guardian
Newspaper of the year

'A silver lining': how Covid ushered in a vaccines golden era

Pandemic accelerated advances in vaccine technology, opening up possibilities for combating array of diseases



CNBC

HEALTH AND SCIENCE

BioNTech says it will start cancer vaccine trials in the UK from September

PUBLISHED FRI, JAN 6 2023-8:27 AM EST | UPDATED FRI, JAN 6 2023-8:54 AM EST

Jenni Reid

SHARE

THE TIMES

Britain jabs its way to centre stage in the mRNA revolution

sky news

Pioneering cancer vaccine trials could start in UK by September

The prospect of a cancer vaccine takes a step forward as German pharmaceutical firm BioNTech announces a partnership with the UK government for plans to deliver personalised treatments to 10,000 patients by 2030 through a new research and development hub in Cambridge.

By Adam Solomons, news reporter

Forbes

BREAKING

Cancer Vaccine Trials—Using Same mRNA Tech Behind Covid Shots—Could Launch In U.K. This September

Robert Hart Forbes Staff
I cover breaking news.

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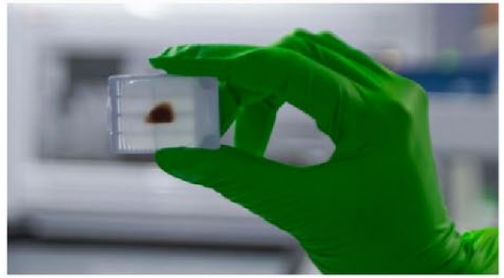


BBC NEWS

Covid vaccine research now helping cancer patients

By Gill Dummigan
Health Correspondent, BBC North West

Ten months ago, Adrian Taylor was told he had incurable cancer and there were few treatment options left.

Operation Cancer Vaccine

The UK will initiate a global advance of vaccines for cancer for immunity against cancer

Transformative benefit will be achieved across multiple cancer subtypes, for early and late stage cancers

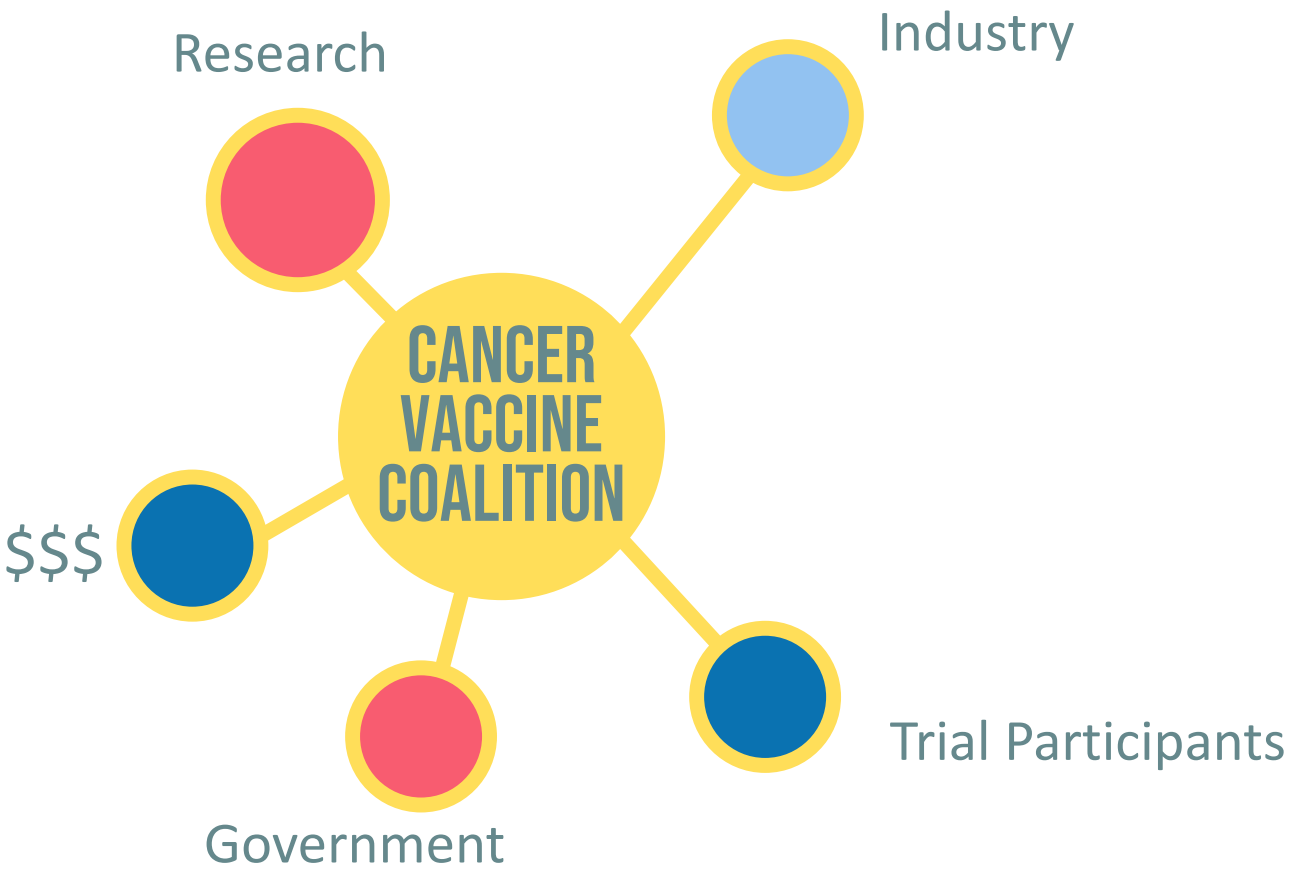
To place 10,000 people through clinical trials by 2030

No NHS??

- American Ingenuity
- National pride
- Philanthropy
- Strong Industry
- History of sucess from space race to Manhattan Project.

CANCER VACCINE COALITION

MOVING SCIENCE FORWARD... FASTER



CVC is the hub

Bringing together stakeholders to create an ecosystem where breast cancer clinical trials can move forward quickly.

- We connect researchers to collaborate on ideas and inspire eachother to innovate and find collective solutions to problems.
- We connect industry partners to manufacture and develop vaccines.
- We connect government stakeholders to streamline the approval pipeline.
- We connect philanthropic donors and investors to fund trials.
- We connect patients to enroll trials quickly.

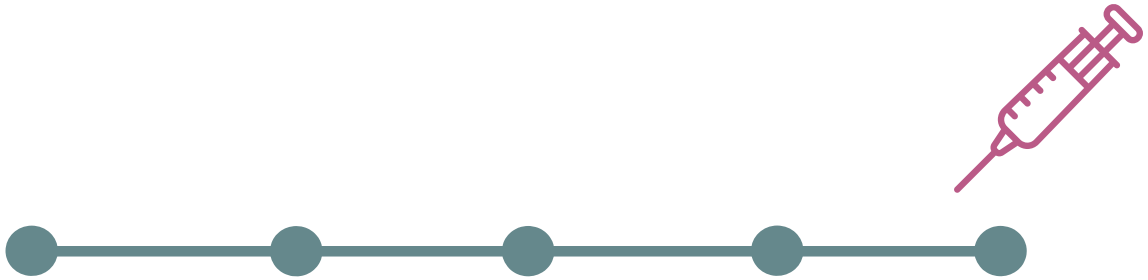
MISSION

TO SPEED THE DEVELOPMENT OF VACCINES AND END BREAST CANCER AS A FATAL DISEASE. (WITH OTHER VACCINES TO FOLLOW)

VISION

CVC aims to revolutionize cancer research by bringing together the world's best scientists and thought leaders, supporting and funding vaccine development, while building a social movement and structure to rapidly enroll clinical trials with the goal of a breast cancer vaccine to market in 5-10 years.


2024
2050


2024
2030

860,000 LIVES SAVED IN U.S. ALONE

- We spend over $26 BILLION on breast cancer care alone annually
- It is estimated that for less than $2 Billion we could have safe, effective, breast cancer vaccines to market

- WHY WOULDN'T WE INVEST NOW IN THE BEST R-O-I imaginable:

An end to cancer as a fatal disease

- Success in Breast cancer vaccines = success in other solid tumor vaccines.

We can build a better world for the next generation

Thank you!

Breast Cancer Vaccine Innovations in the Works

Discussion

NVAC

Public Comment

NVAC

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

June 13-14, 2024

NVAC