Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

February 22-23, 2024

NVAC

February 22, 2024

OPENING REMARKS

Admiral Rachel L. Levine

Assistant Secretary for Health

NVAC

February 22, 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.

Public Comments

- Verbal comments are scheduled for 5:00 p.m., Eastern Time today and 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.

Meeting Highlights: February 22

- A 30-Fold Surge in Measles Cases in 2023: Protecting the Unvaccinated
- Innovation Insight: Analysis of the Pipeline and Industry Investment
- Innovation in Immunization Subcommittee Update
- Strong Supply Chains: Opportunities to Thwart Shortages
- A Cornerstone in Childhood Immunization: State Policies for School Entry
- Celebrating 30 Years of Saving Lives: The Vaccines for Children Program Now and in the Future
- Public Comment
- Adjourn 5:15 PM Eastern

Meeting Highlights: February 23

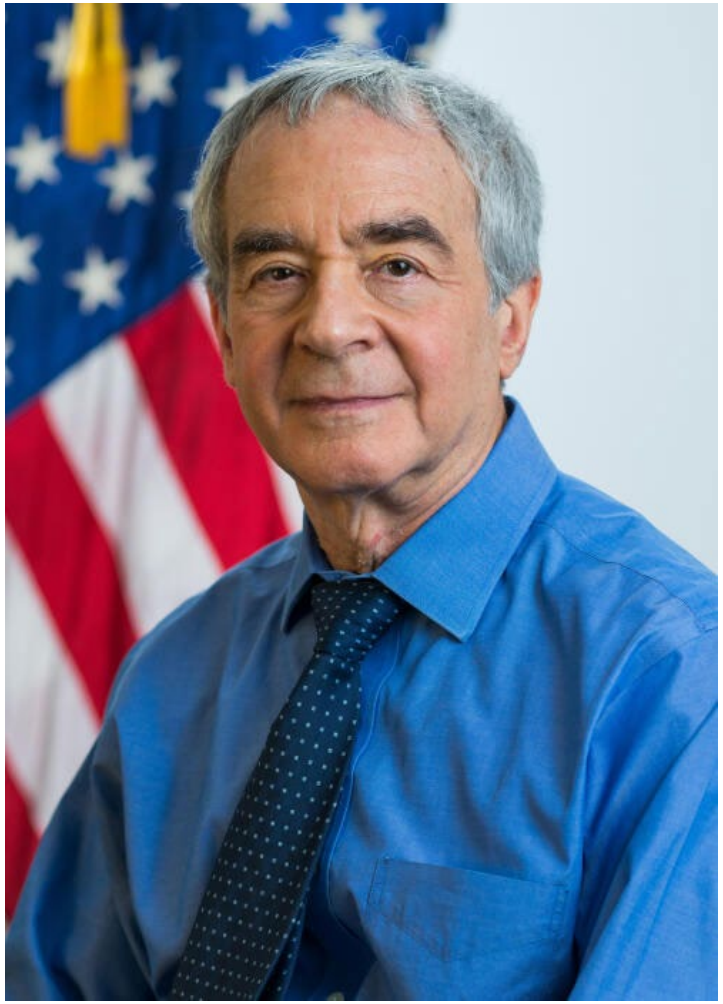
- Artificial Intelligence: Real Uses in Vaccine Development and Immunization Efforts
- Innovative Approaches to Improve Adult Immunization
- Immunization in Focus: Vaccinating Pregnant People
- Inclusion in Immunization: Special Practices for Special Needs
- Federal Agency and Liaison Member Updates
- Public Comments
- Adjourn 5:15 PM Eastern

Upcoming Meetings

- June 13-14, 2024
- September 12-13, 2024

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

In Memoriam: Jeff Kelman



- Chief Medical Officer at the Center for Medicare at the Centers for Medicare and Medicaid Services.
- NVAC Representative Member
- Provided Expertise to Advance
  - Adult Vaccination
  - Health Equity
  - Vaccine Safety and Effectiveness +

A 30-Fold Surge In Measles Cases in 2023: Protecting the Unvaccinated

Dr. Natasha Crowcroft
Dr. José Hagan
Dr. Joshua Sharfstein
Dr. Christine Hahn
Dr. Shara Epstein

NVAC

Global context

The importance of measles

Current trends in global measles epidemiology and vaccine coverage

Conclusions and action gaps

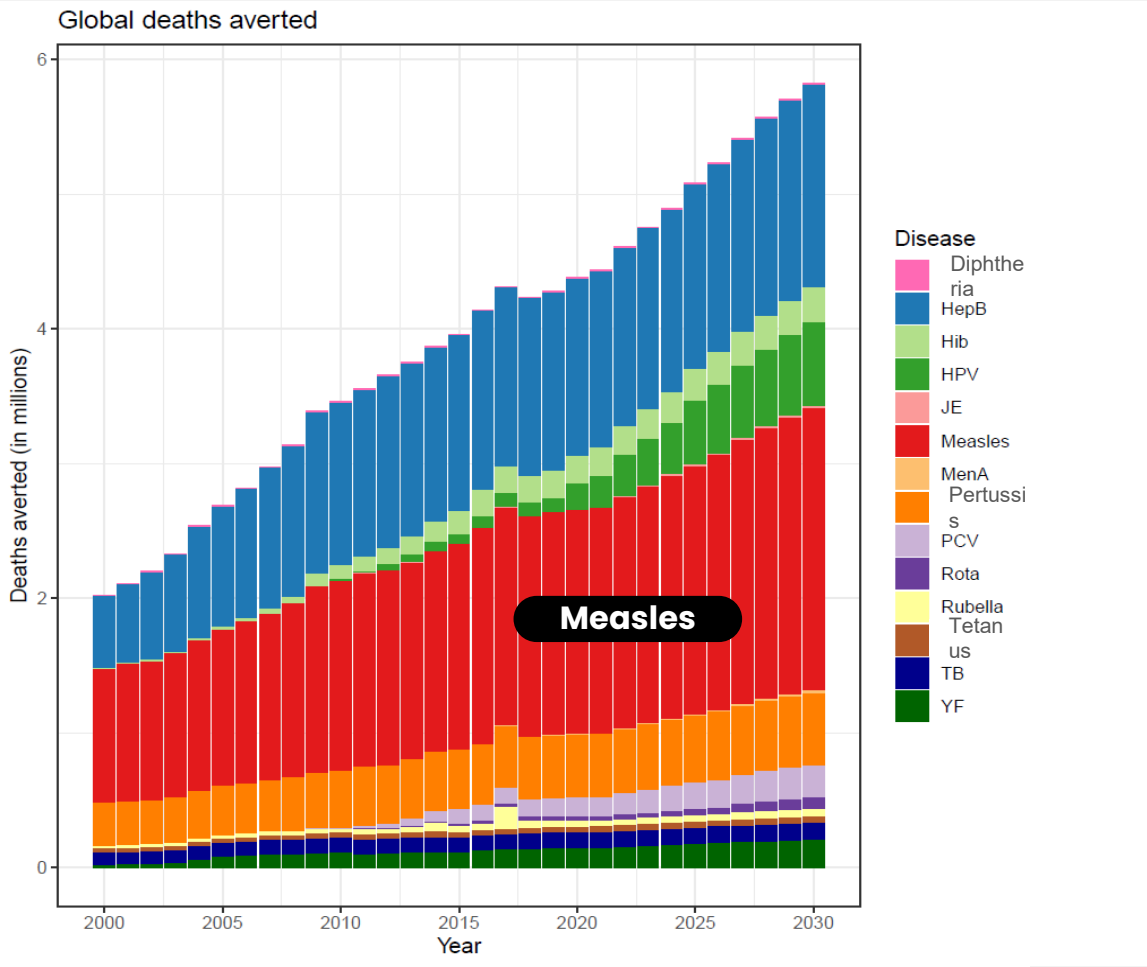
Dr. N.S. Crowcroft
Senior Technical Adviser Measles and Rubella
World Health Organization

Global goals won't be met without measles vaccine

Measles vaccine prevents more deaths than any other vaccine

Measles vaccine projected to prevent **37%** (18.8/51.5 million) deaths averted due to vaccinations administered in 2021-2030

Measles vaccine: **75% of economic benefits**, for 25% of costs



Carter A et al. Modeling the impact of vaccination for the immunization Agenda 2030: Deaths averted due to vaccination against 14 pathogens in 194 countries from 2021 to 2030. Vaccine. 2023 Aug 1:S0264-410X(23)00854-X.

12

“Measles as a tracer” in Immunization Agenda 2030

IA2030 Strategic priority 3: “Use **measles cases and outbreaks as a tracer** to identify weaknesses in immunization programmes, and to guide programmatic planning in identifying and addressing these weaknesses”[1]

IA2030 and coverage: **Target is second measles vaccine dose (MCV2) coverage ~90% by 2030**

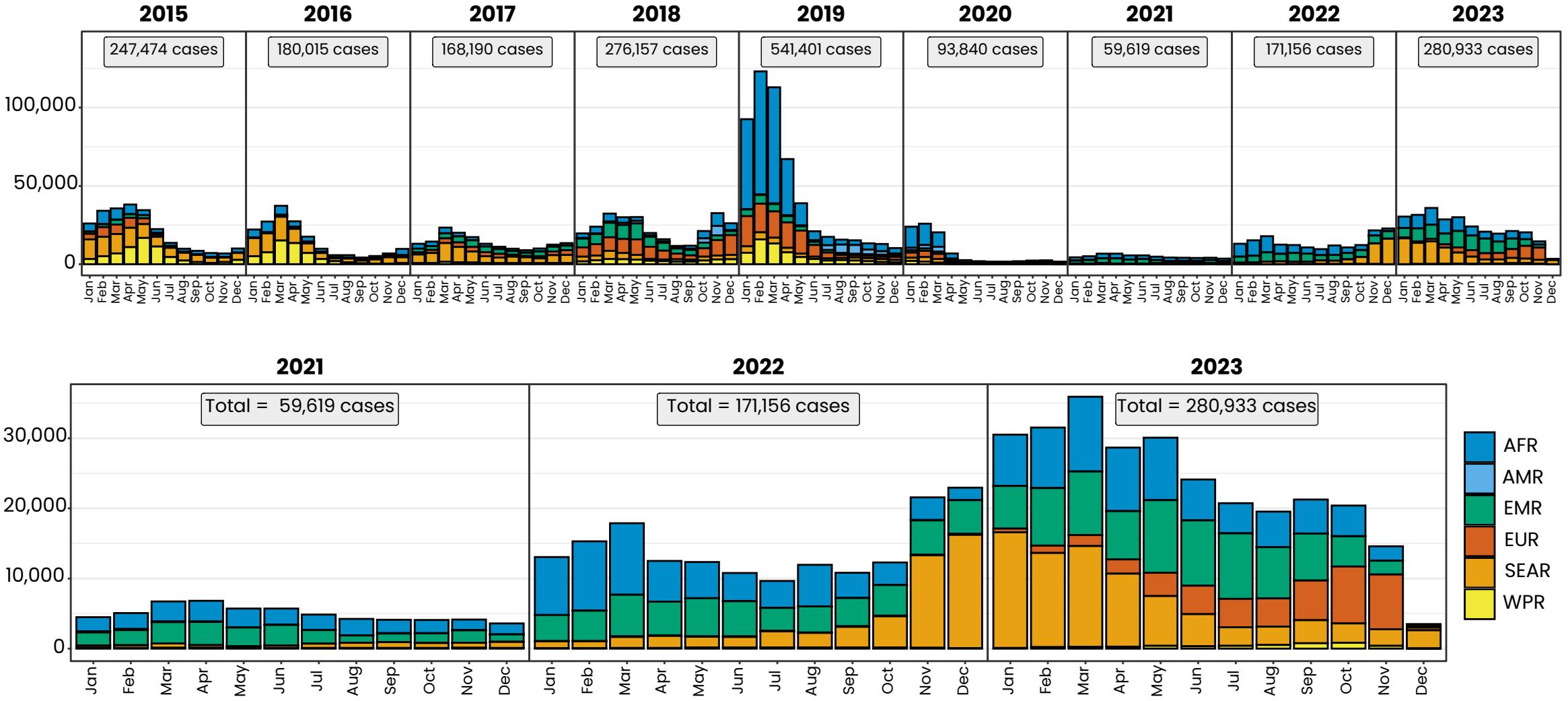
~90% of **Gavi-eligible countries** will require high quality measles campaigns for many years**.** Middle income countries are struggling without funding.

Sustainable Development Goals (SDGs): MCV2 coverage is an indicator of the **fully vaccinated child**

Measles makes inequity visible

1. ia2030-draft-4-wha_b8850379-1fce-4847-bfd1-5d2c9d9e32f8.pdf (who.int)

Measles case distribution by month and WHO Region (2015-2023)

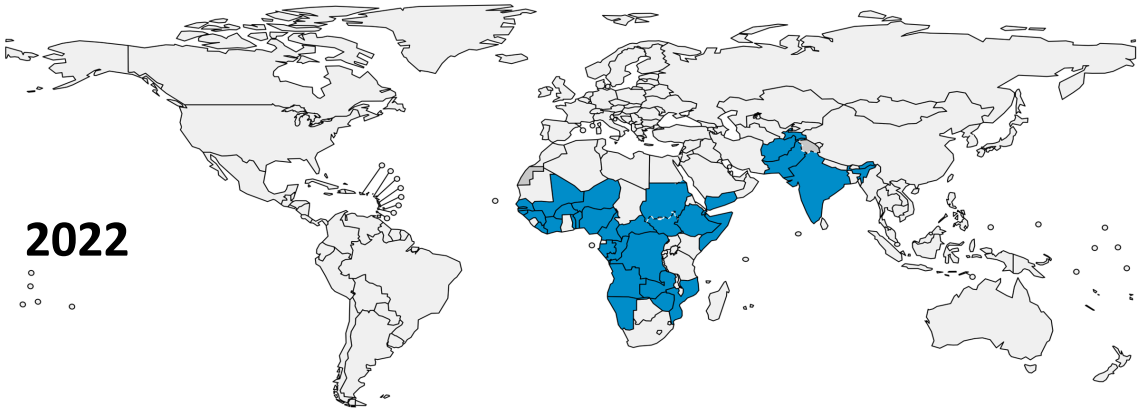


Notes: Based on data received 2024-01 - Data Source: IVB Database - This is surveillance data, hence for the last month(s), the data may be incomplete.

Large or disruptive (LoD) measles outbreaks, 2022-2023

Definition: >=20 cases per million over 12 months – IA2030 Global impact indicator 1.3

- Number of countries reporting LoD outbreaks increased from **32 in 2022 to 51 in 2023**.
- Increase mainly observed in EURO (9) and EMRO (13)



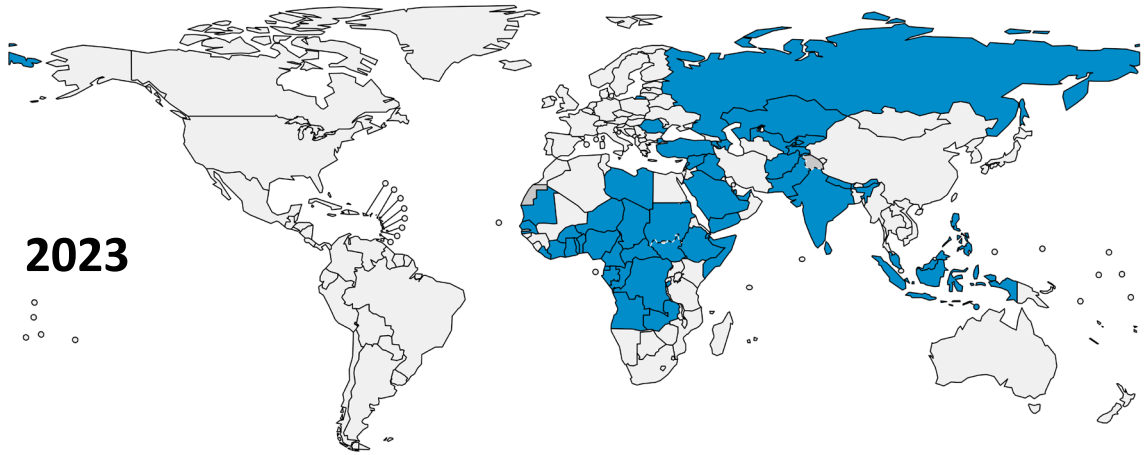
World Health Organization

Map production: World Health Organization, 2024. All rights reserved
Data source: IVB Database

Disclaimer: The boundaries and names shown and the designations used on this map do notimply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

0 875 1750 3500 Kilometers

Region	Cases	L&D Outbreaks
AFRO	62,671	24
EMRO	53,259	6
EURO	451	1
SEARO	43,578	1
Global	159,959	32



World Health Organization

Map production: World Health Organization, 2024. All rights reserved
Data source: IVB Database

Disclaimer: The boundaries and names shown and the designations used on this map do notimply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

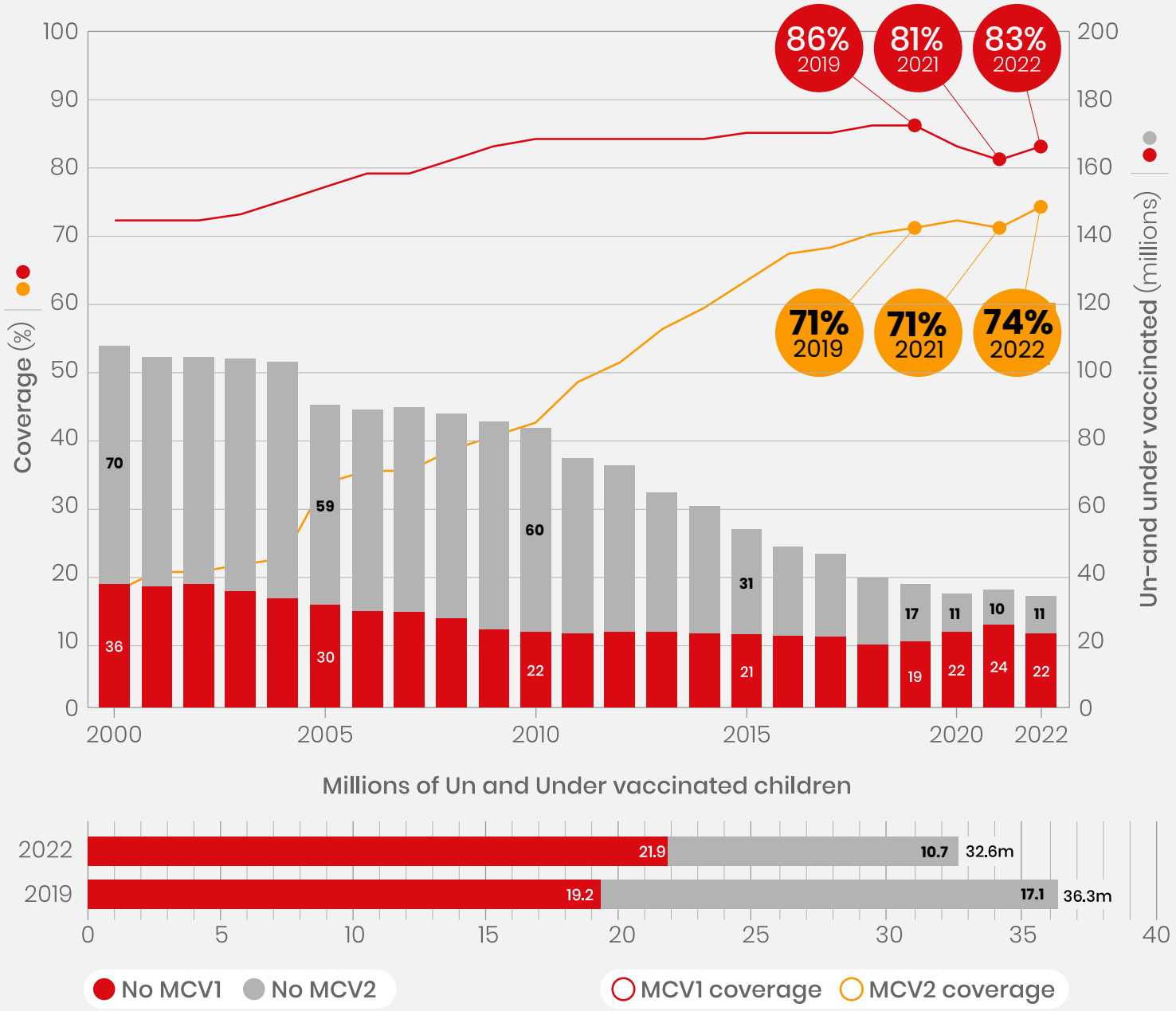
0 875 1750 3500 Kilometers

Region	Cases	L&D Outbreaks
AFRO	66,473	22
EMRO	79,147	13
EURO	41,568	9
SEARO	82,337	5
WPRO	3,635	2
Global	273,160	51

Measles vaccine coverage improved less than DTP in 2022

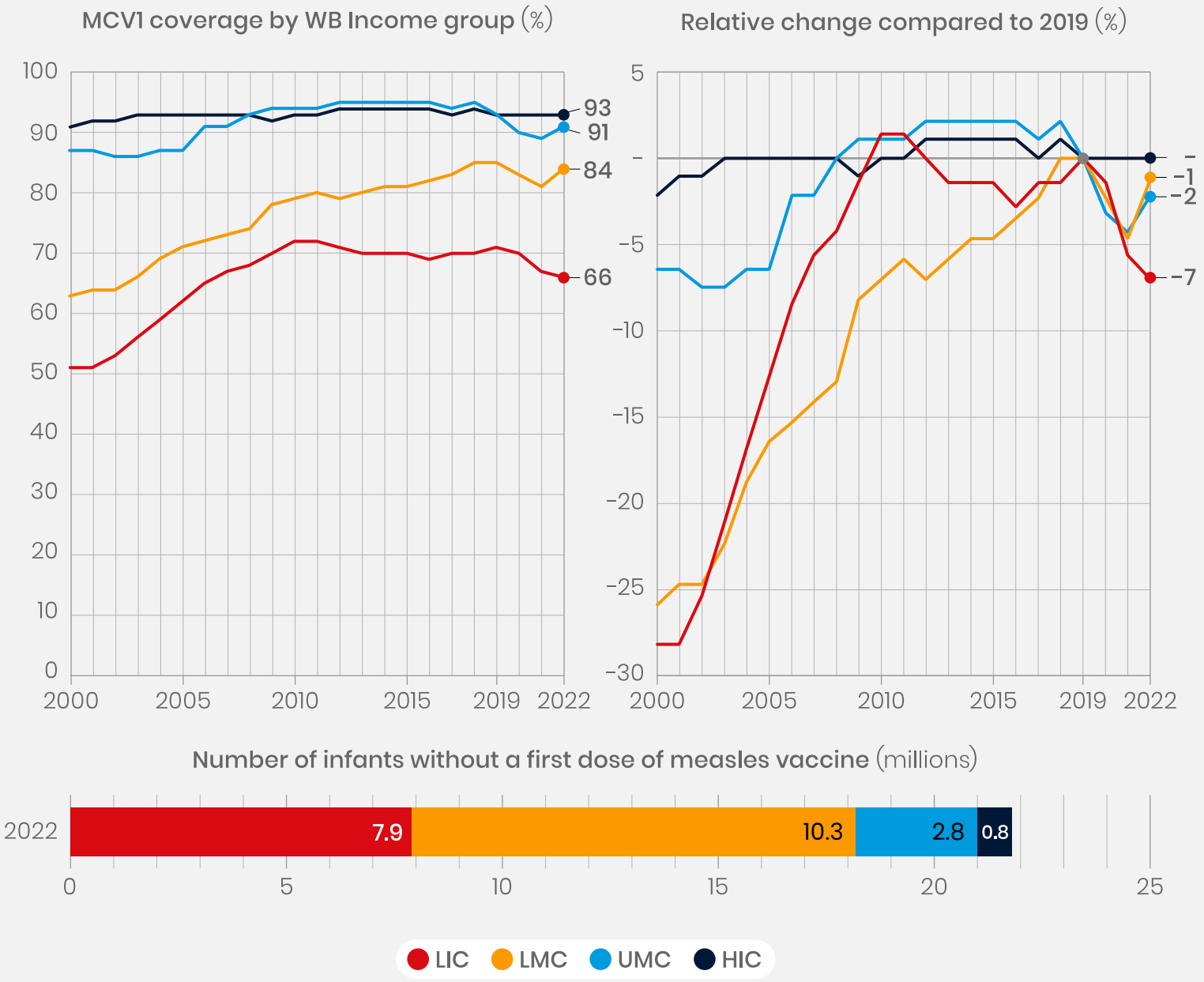
DTP coverage rose to within 1% of pre-pandemic levels

Measles MCV1 coverage **remained - 3% below the pre-pandemic peak of 86%**



Low-Income countries (LICs) are lagging in the recovery

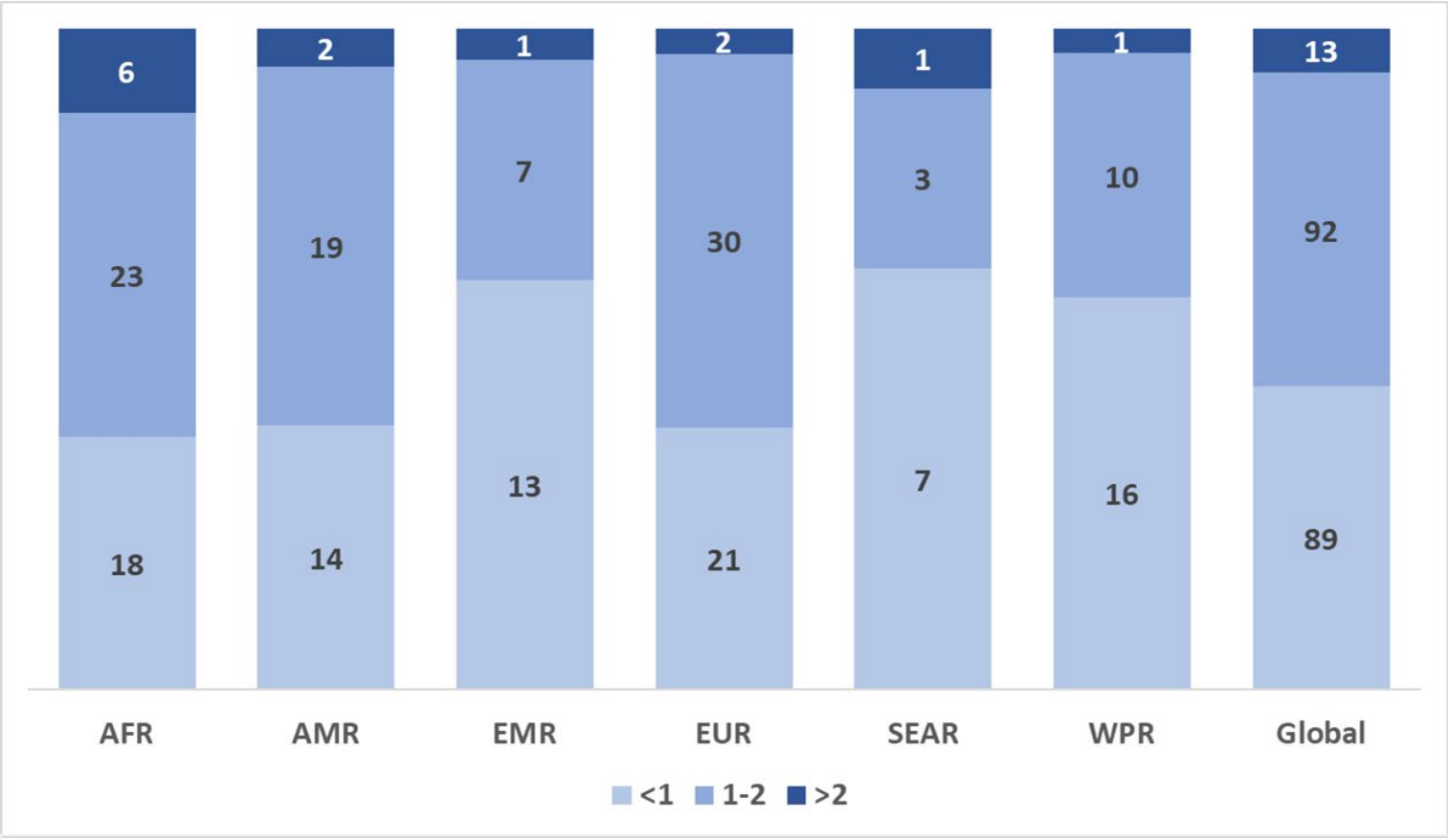
Low-income countries are showing no signs of recovery, but instead **falling another 1% compared to 2021**.



Over half of countries at high risk of measles outbreak: 48% of these are LMICs

142 million children <5y are susceptible to measles, 73% of these children living in LMICs and 62% living in settings at highest or high-risk of an outbreak by the end of 2024.

Number of countries at risk of measles outbreak* by end 2024, by WHO Region



Countries risk status

13/194 = 7% (highest-risk)

92/194 = 47% (high-risk)

89/194 = 46% (lower-risk)

**Risk assessed by ratio of <5 years old susceptible to the size of one birth cohort*

Source: US CDC

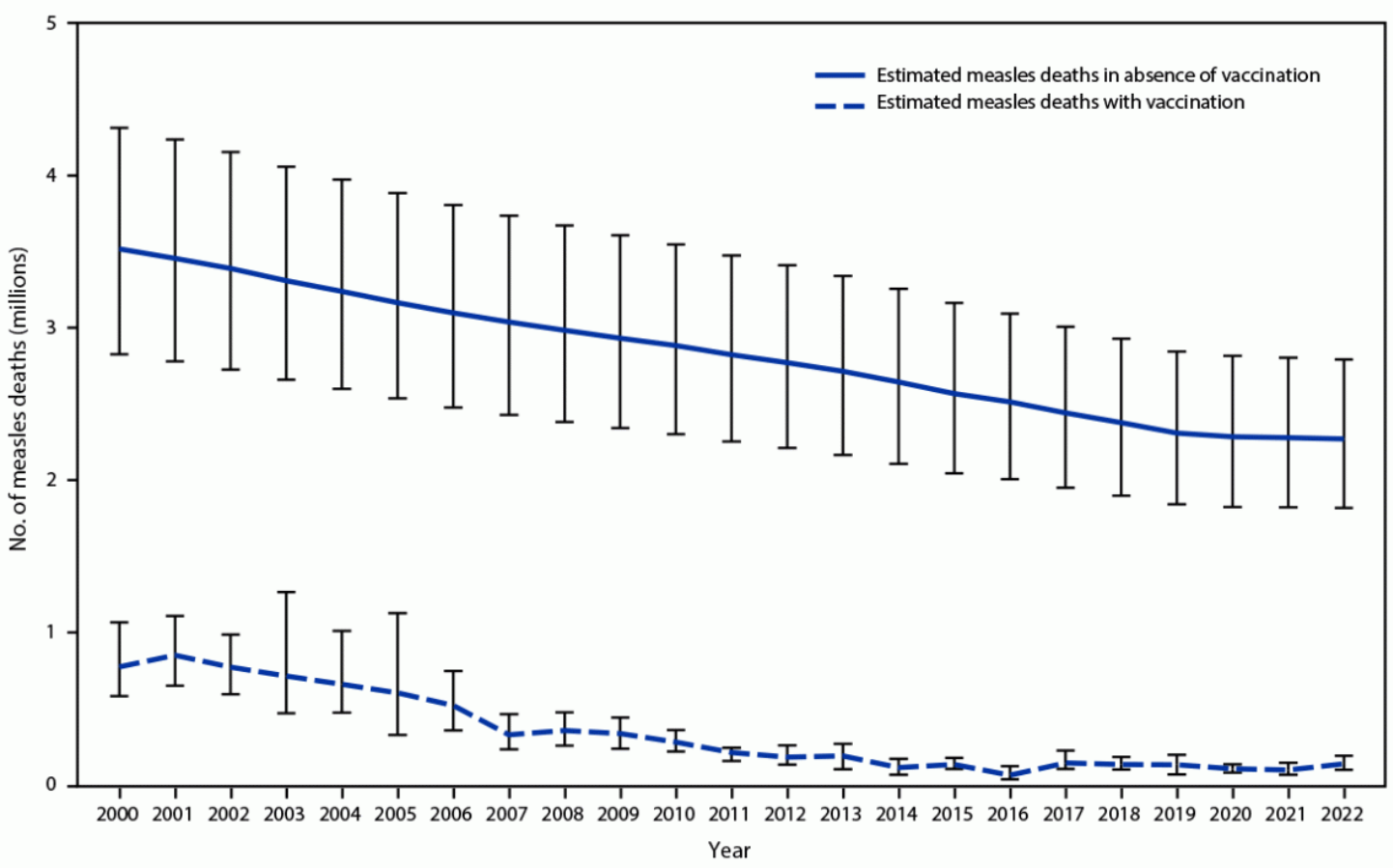
Number of deaths globally and by region in 2022

Region	Number of Countries	Estimated measles cases	Estimated deaths	Percentage of deaths	Percentage of population
African	47	5,138,698	85,417	62.7	14.7
Americas	35	825	1†	0	13.0
Eastern Mediterranean	21	1,193,257	39,656	29.1	9.7
European	53	63,707	70	0	11.8
South East Asian	11	1,896,917	9,542	7.0	26.0
Western Pacific	27	938,883	1,531	1.1	24.4
Global	**194**	**9,232,288**	**136,216**	**100**	**100**

91.8% deaths occur in 24% of the world's population.
75.2% of the world's population have only 8.1% deaths
24.8% population has close to no deaths from measles

† Estimated measles mortality rounded to 1

During 2000–2022, Measles vaccination prevented an estimated 57 million deaths worldwide



Source: WHO AFR

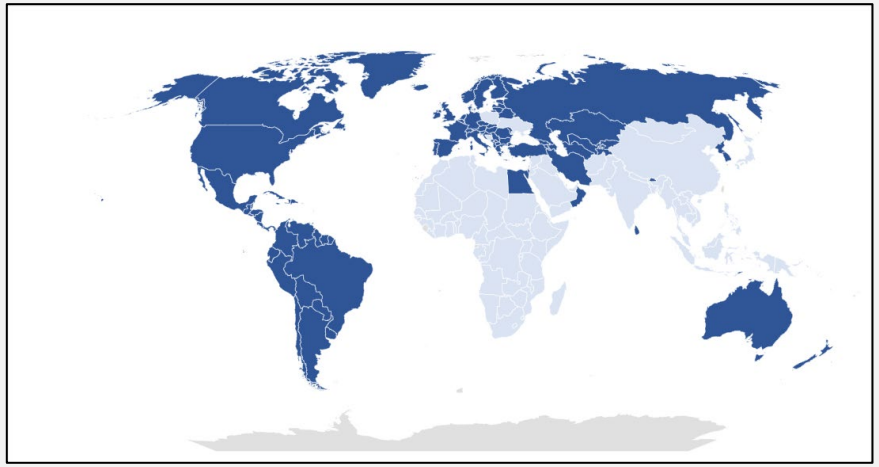
* With 95% CIs indicated by error bars.
† Deaths prevented by vaccination are estimated by the area between estimated deaths with vaccination and those without vaccination. A cumulative total of 57 million deaths were estimated to have been prevented by vaccination during 2000–2022.

Rubella elimination is pathway towards measles elimination

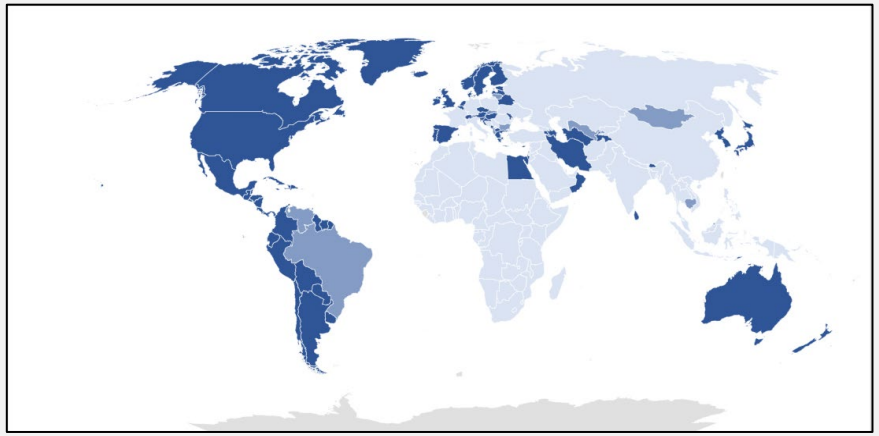
Countries verified for elimination

WHO Region	Rubella Achieved (Gavi-eligible)	Measles Achieved (Gavi-eligible)
AFR	0	0
AMR	35 (1)	33 (1)
EMR	4 (0)	4 (0)
EUR	50 (2)	35 (1)
SEAR	5 (1)	5 (1)
WPR	5 (0)	6 (0)
Total	**99 (4)**	**83 (3)**

99 (51%) countries verified for rubella elimination



83 (43%) countries verified for measles elimination

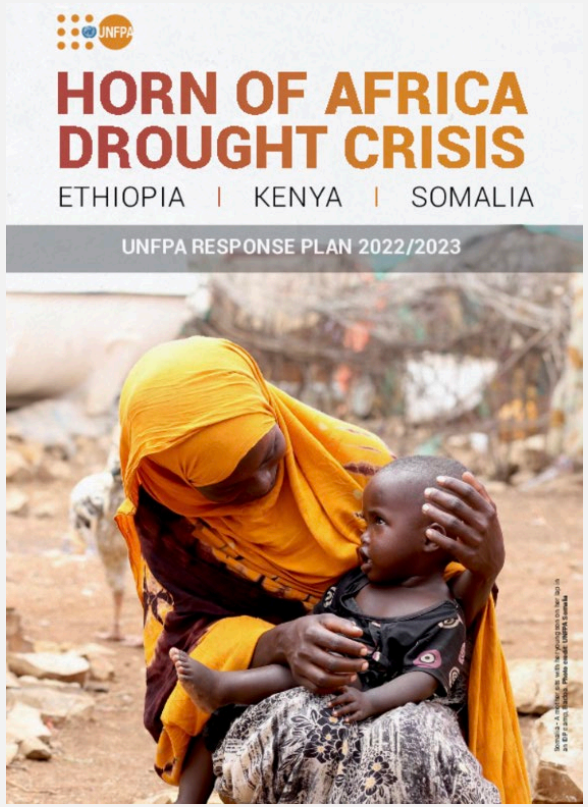


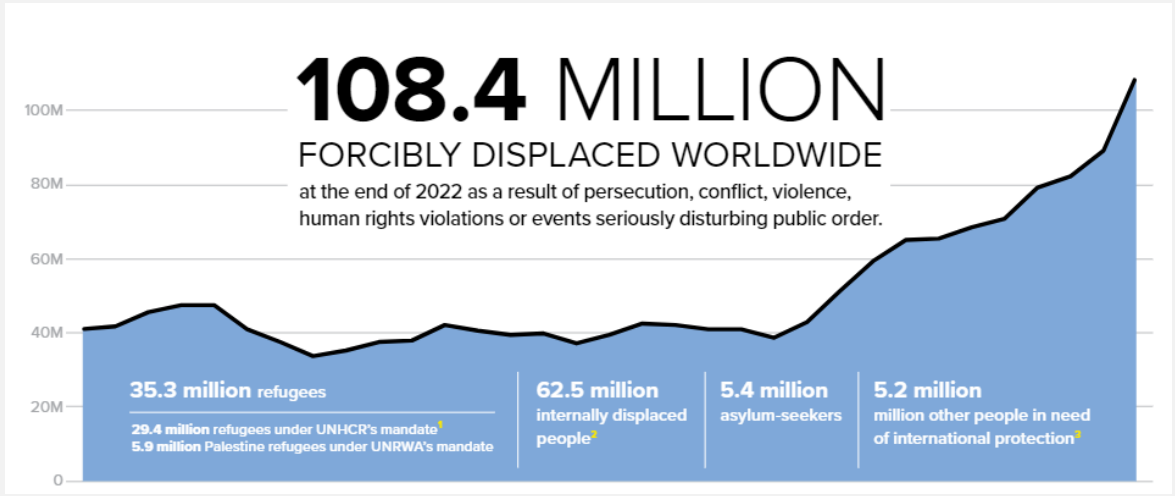
Maps are not WHO endorsed borders. The evaluation of progress towards measles and/or rubella elimination is based on the most recent report submitted by the National Verification Committee (NVC) and evaluated by the Regional Verification Commission (RVC).

Conclusions: Measles is a crisis among many crises

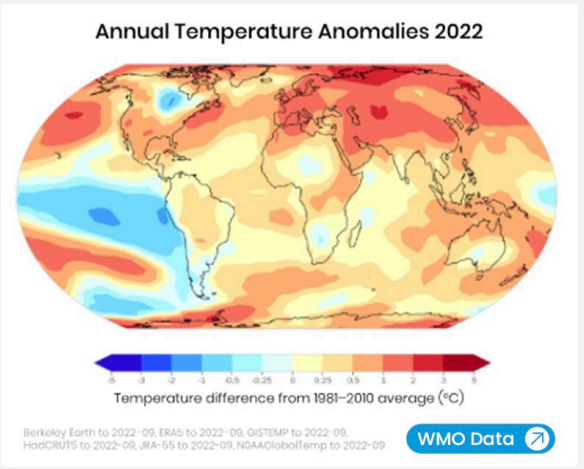
Food, energy, war, economic, climate, natural, humanitarian

~45% of measles outbreaks are in conflict and fragile affected countries, making measles prevention and response more challenging





https://www.unhcr.org/global-trends-report-2022



Measles resurgence in the European Region

Jose Hagan, M.D., M.S.

Team Leader, Disease Control and Elimination

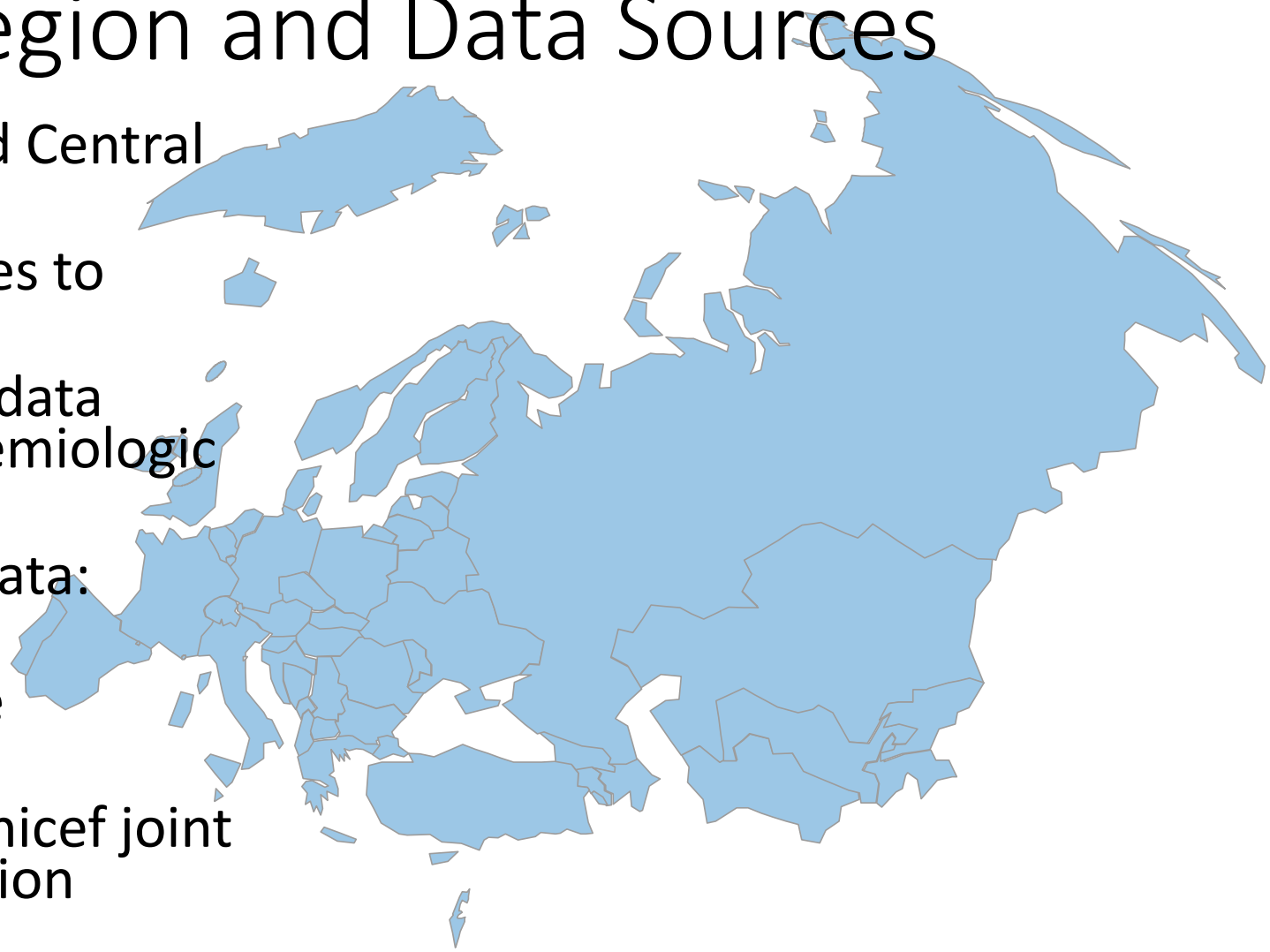
Vaccine-preventable Diseases and Immunization Unit

World Health Organization

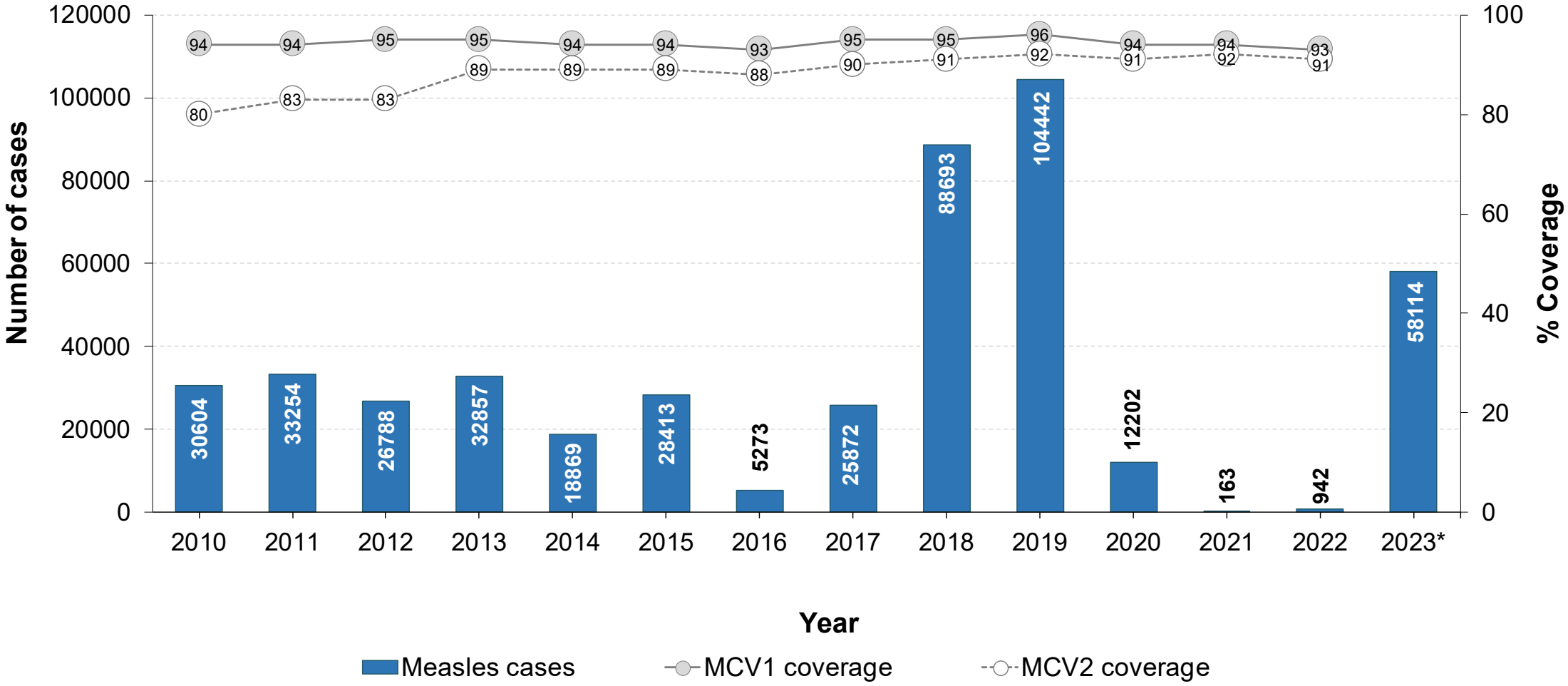
European Region

WHO European Region and Data Sources

- 53 Member States in Europe and Central Asia
- Countries submit data on measles to WHO/Europe monthly
- 51 countries submit case-based data allowing for more detailed epidemiologic analysis (or report zero cases)
- 2 countries submit aggregated data: Belgium and Kazakhstan
- Presented regional case data are submitted as of Feb 9th
- Coverage data are from WHO-Unicef joint estimates of national immunization coverage



Measles cases, MCV1 and MCV2 coverage by year—WHO European Region, 2010–December 2023

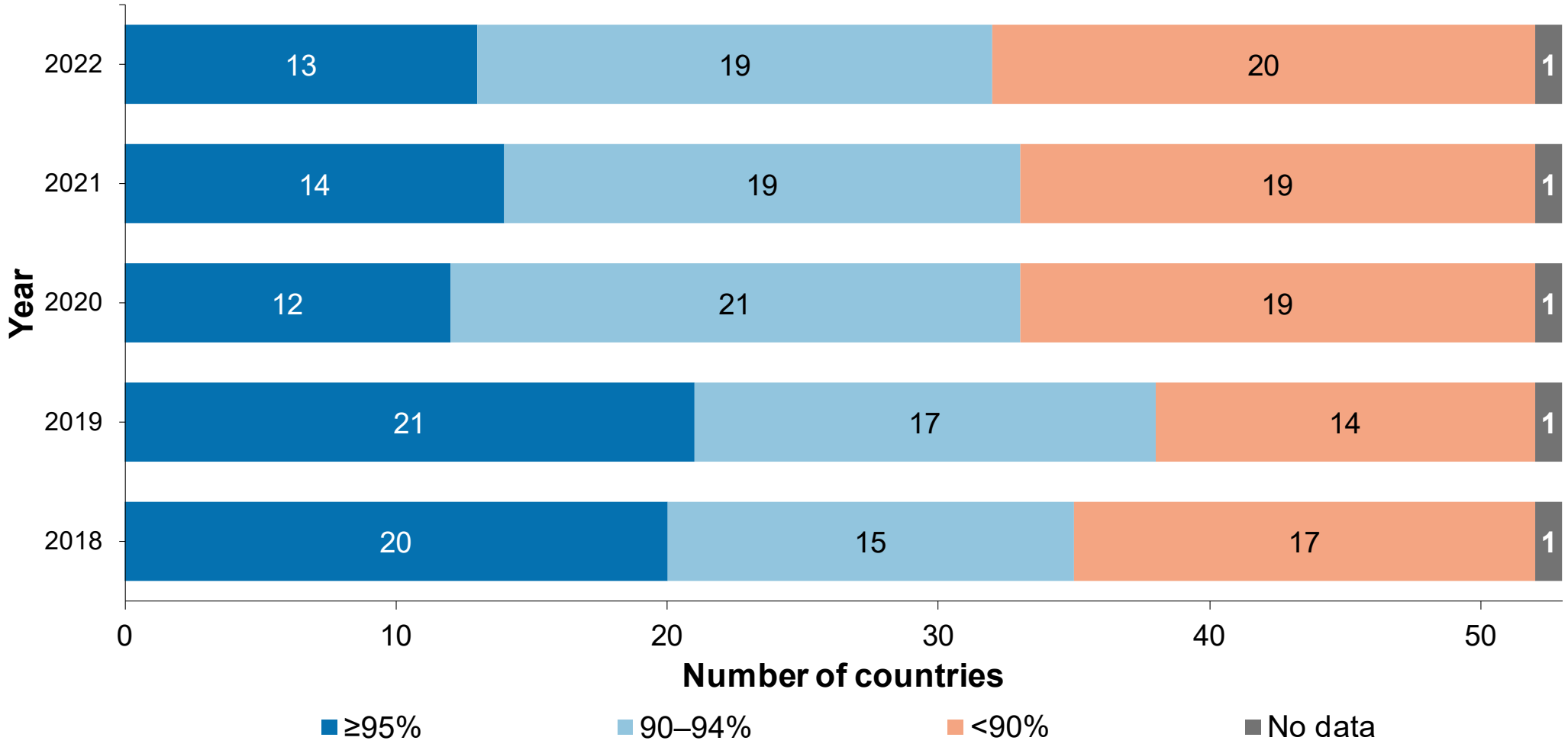


MCV1: first dose of measles-containing vaccine
MCV2: second dose of measles-containing vaccine

*January –December 2023

Data source: 1) Measles cases – monthly aggregated and case-based data reported by Member States to WHO/Europe or via ECDC/TESSy as of 09 February 2024.
2) MCV1 and MCV2 coverage - WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) as of 26 June 2023.

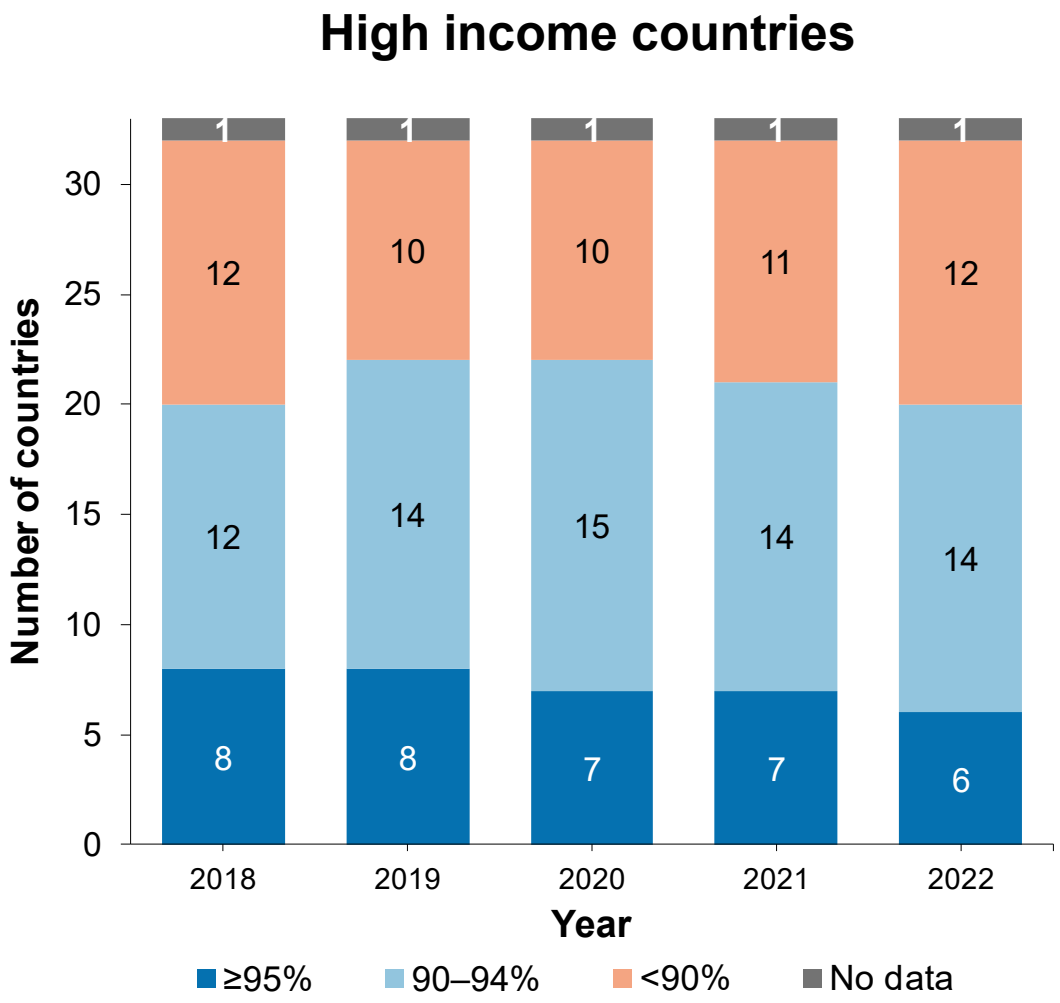
Number of countries categorized by national MCV2 coverage estimate—WHO European Region, 2018–2022

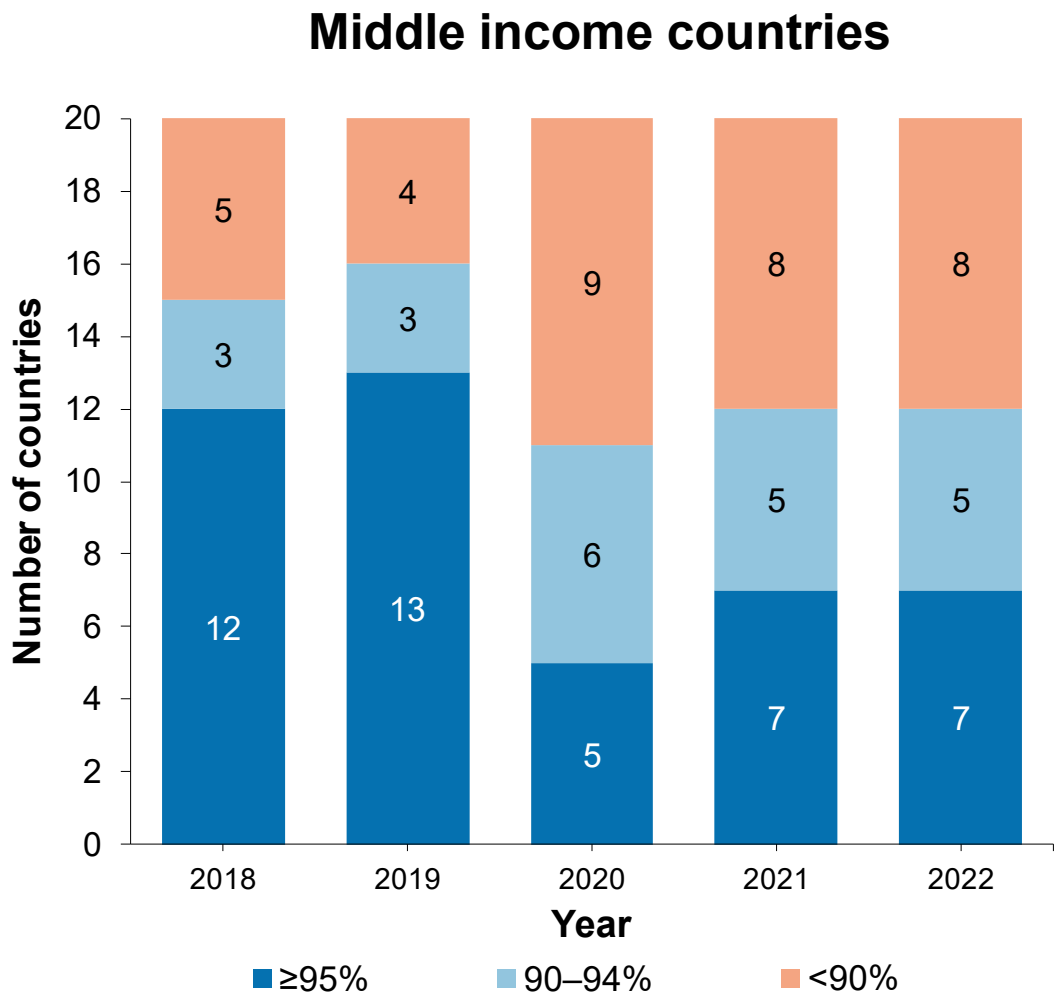


MCV2: measles-containing vaccine, second dose
N (total # of countries in the Region) = 53

Data source: WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) as of 26 June 2023

Number of countries categorized by national MCV2 coverage estimate and income level—WHO European Region, 2018–2022





MCV2: measles-containing vaccine, second dose

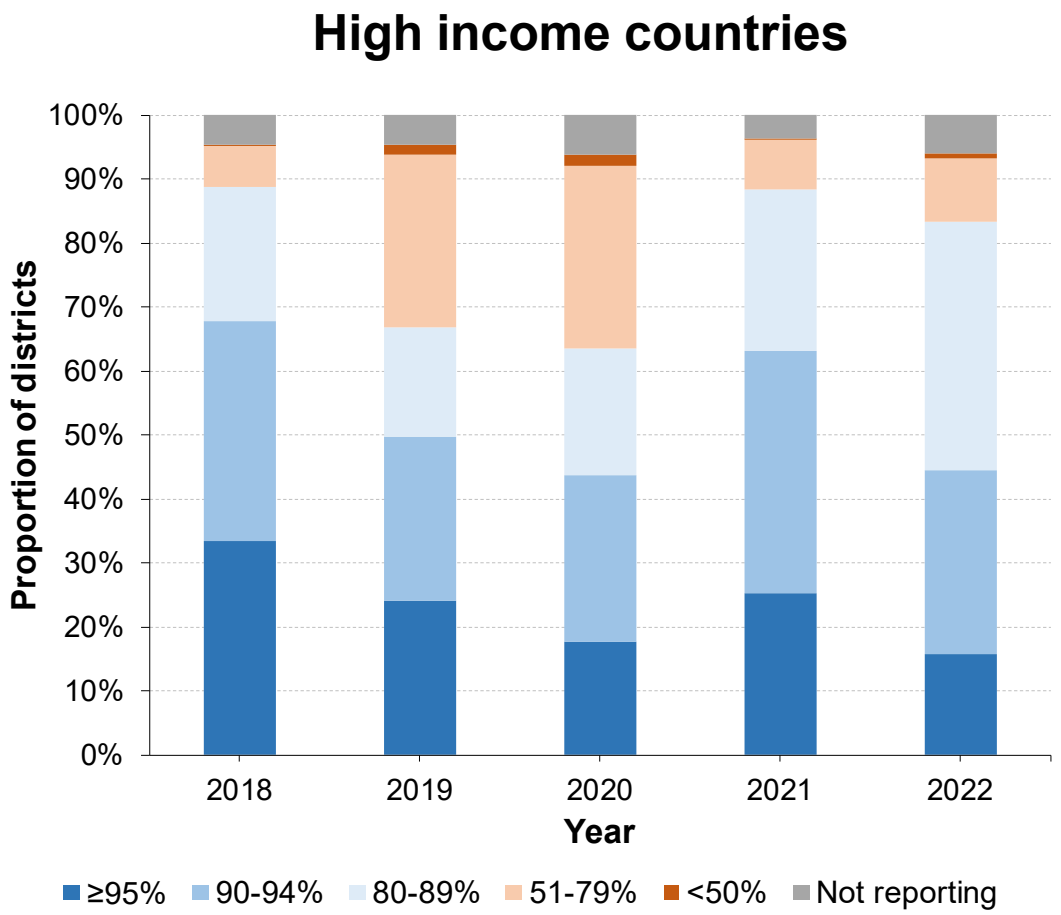
N (total # of high-income countries in the Region) = 33

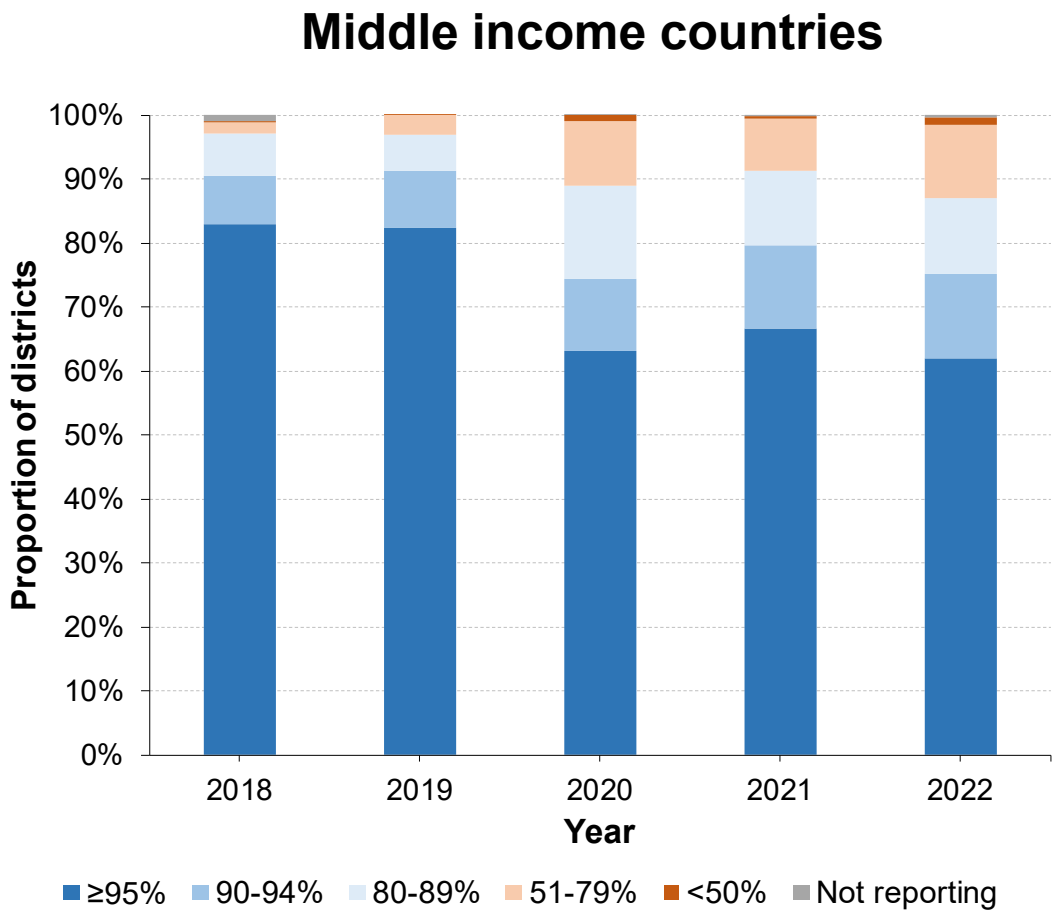
N (total # of middle-income countries in the Region) = 20

World Bank Country and Lending Groups: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

Data source: WHO/UNICEF Estimates of National Immunization Coverage (WUENIC) as of 26 June 2023

Proportion of districts by different categories of MCV2 reported coverage by countries income level—WHO European Region, 2018–2022





Number of high-income countries reporting district MCV2 coverage by category were 22 in 2018, 18 in 2019, 17 in 2020 and 2021, and 12 in 2022

Number of middle-income countries reporting district MCV2 coverage by category were 19 in 2018, 18 in 2019 and 2020, 20 in 2021and 19 in 2022

MCV2: measles-containing vaccine, second dose

N (total # of high-income countries in the Region) = 33

N (total # of countries in the Region with more than one administrative level) = 29

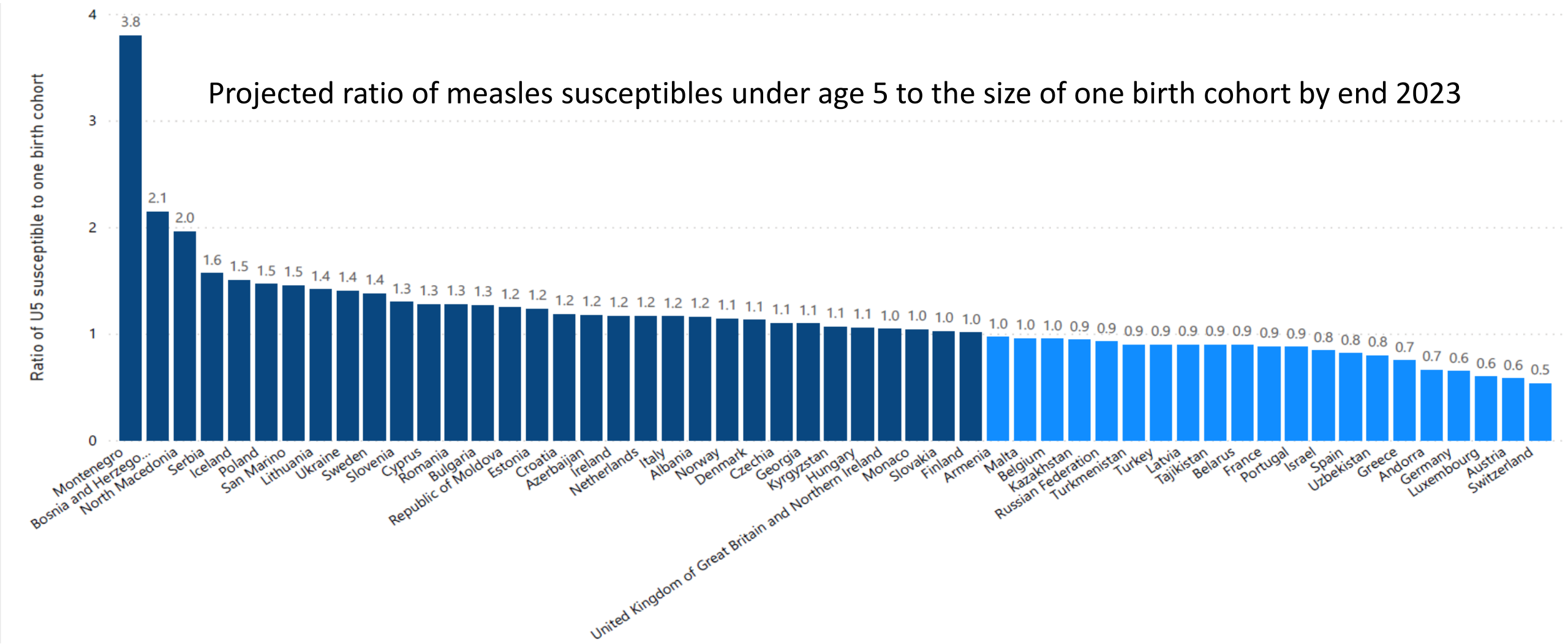
N (total # of middle-income countries in the Region) = 20

N (total # of countries in the Region with more than one administrative level) = 20

World Bank Country and Lending Groups: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

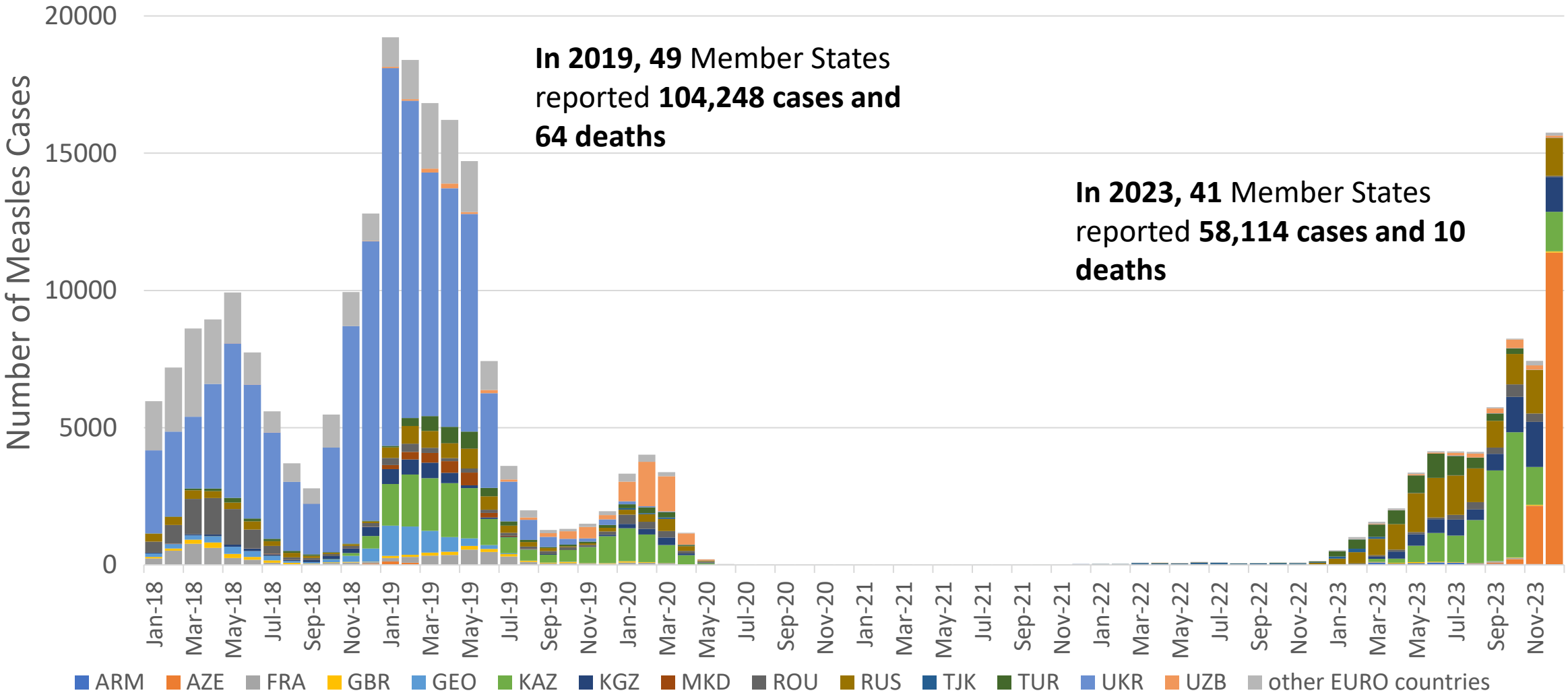
Data source: WHO/UNICEF Joint Reporting Form on immunization (JRF) as of 28 July 2023

Accumulation of children under 5y susceptible to measles



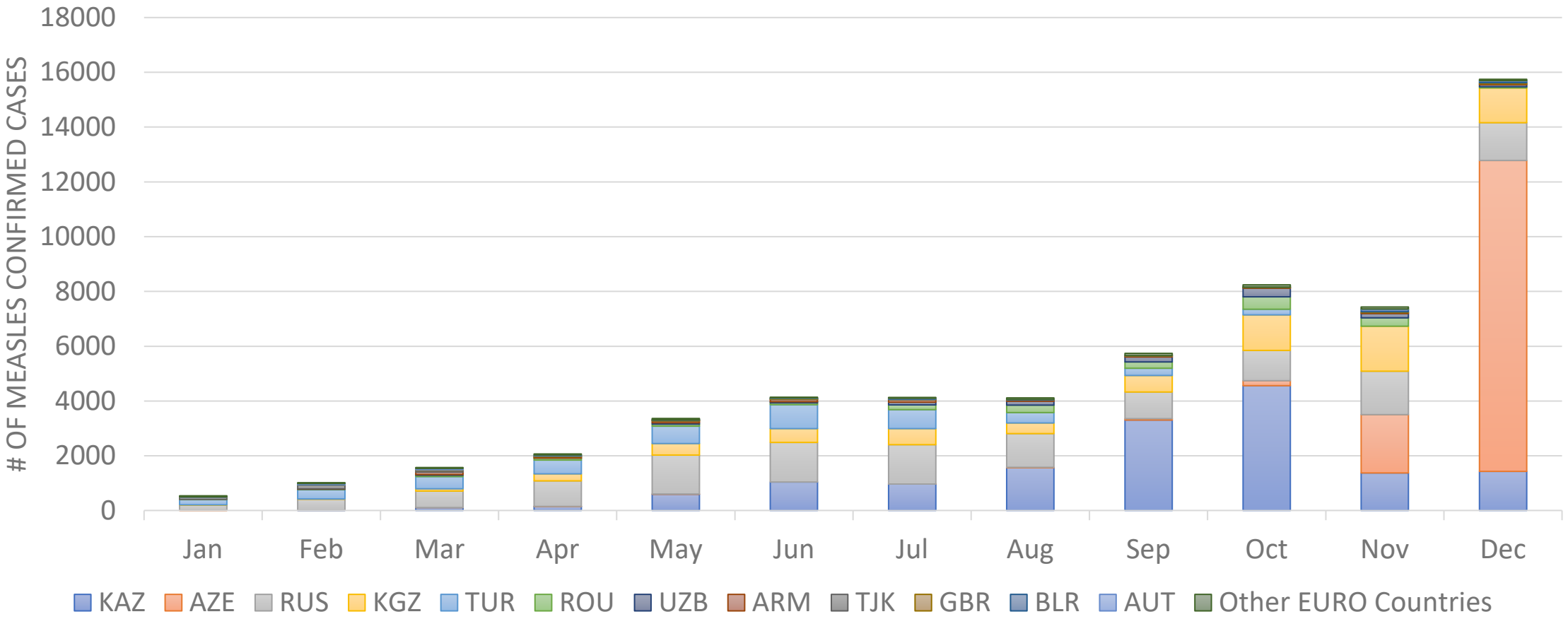
US CDC measles immunity profile. Data source: WHO-Unicef joint estimates of national immunization coverage (WUENIC), and WHO estimates of national and sub-national supplemental immunization activity coverage

Measles cases by month of onset, WHO European Region, 2018—2023



Data source: monthly aggregated and case-based data reported by Member States to WHO/Europe or via ECDC/TESSy as of 09 February 2024.

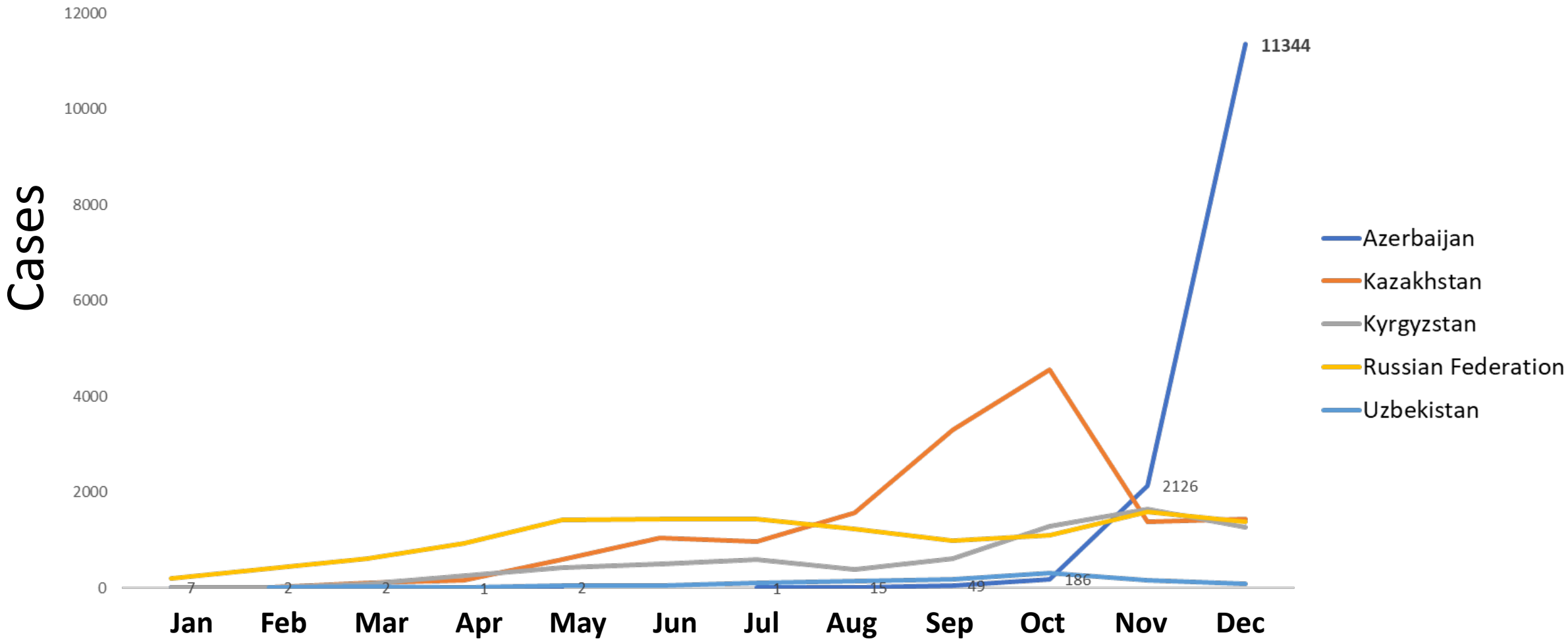
Measles cases by month of onset, WHO European Region, 2023



Major outbreak response immunization activities, Jun—Dec 2023

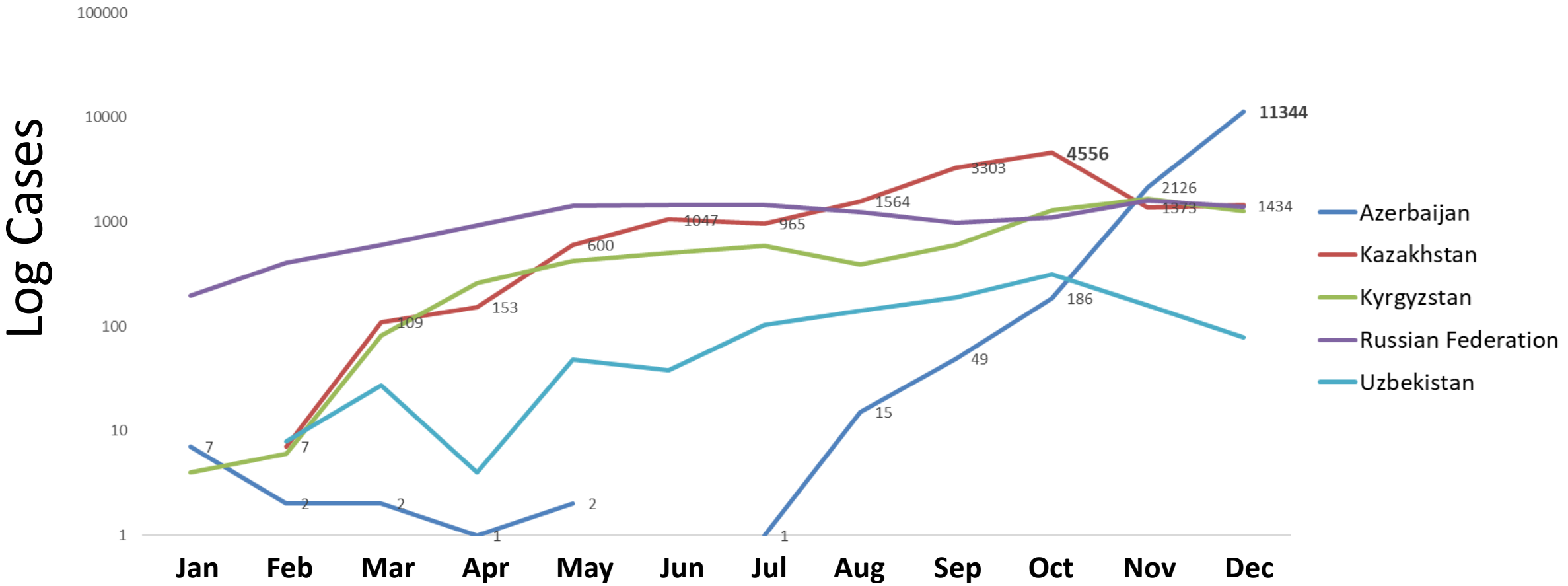
Data source: monthly aggregated and case-based data reported by Member States to WHO/Europe or via ECDC/TESSy as of 09 February 2024.

Measles cases by month of onset, 5 most-affected countries of WHO European Region in Dec 2023. N=47920 (86% of 58112 total cases)



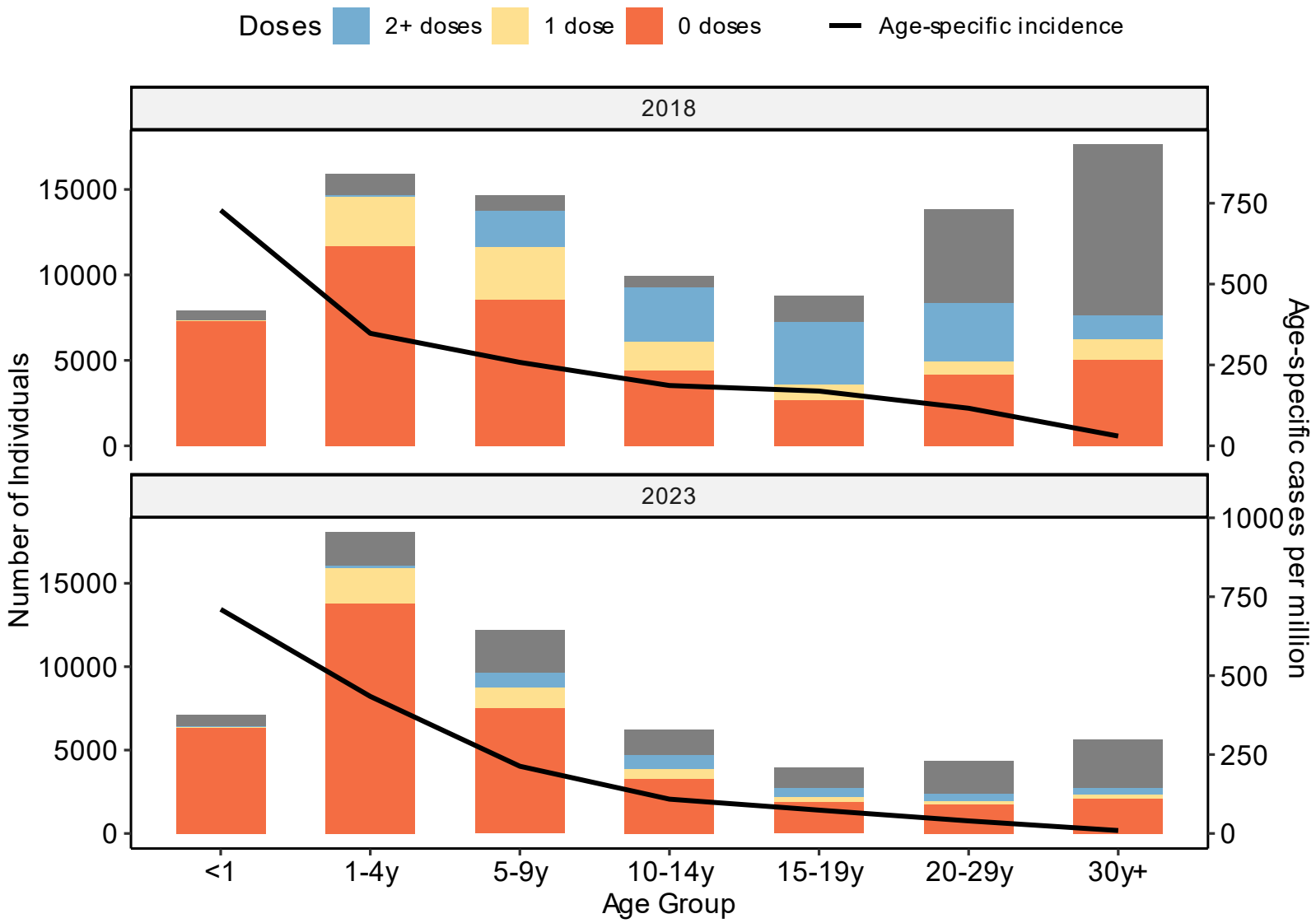
Data source: monthly aggregated and case-based data reported by Member States to WHO/Europe or via ECDC/TESSy as of 09 February 2024.

Measles cases by month of onset, 5 most-affected countries of WHO European Region in Dec 2023. N=47920 (86% of 58112 total cases)



Data source: monthly aggregated and case-based data reported by Member States to WHO/Europe or via ECDC/TESSy as of 09 February 2024.

Measles cases by age group and immunization status, WHO European Region



- Outbreaks during the 2018—2019 resurgence affected a wide age range reflecting residual immunity gaps across multiple birth cohorts
- Outbreaks in 2023 predominantly reflect accumulation of susceptibles due to the impact of the Covid-19 pandemic on routine immunization for children under 5

Data source: monthly aggregated and case-based data reported by Member States to WHO/Europe or via ECDC/TESSy as of 09 February 2024.

Discussion points

- Outbreaks are ongoing in multiple countries and continue into 2024
- Transmission in most affected countries is plateauing; new large outbreak in Azerbaijan
- Countries with large outbreaks in 2023 have responded with ORI or intensified routine - not all outbreak response and catchup data available with WHO yet
- WHO is supporting countries to fill immunity gaps to reach and maintain high MCV coverage at the subnational level, strengthen surveillance and outbreak preparedness, and address inequities in vaccination strategy and service delivery

Thank you

World Health Organization

European Region

Back to the Future?

The Threat of Measles in the United States

Joshua M. Sharfstein, M.D.
Johns Hopkins Bloomberg School of Public Health

February 2024

TWIN CITIES NEWS ›

Health officials confirm 2 measles cases in Twin Cities

Here's what those states are reporting:

- **California** - one confirmed case in Los Angeles County
- **Georgia** - one case in the Atlanta Metro area
- **Missouri** - one case in Clay County
- **New Jersey** - One confirmed case in Camden County
- **Pennsylvania** - Nine confirmed cases, eight in Philadelphia and one outside
- **Washington** - Three cases in Clark and Wahkiakum Counties
- **Ohio** - One case in Montgomery County
- **Maryland** - One case in Montgomery County

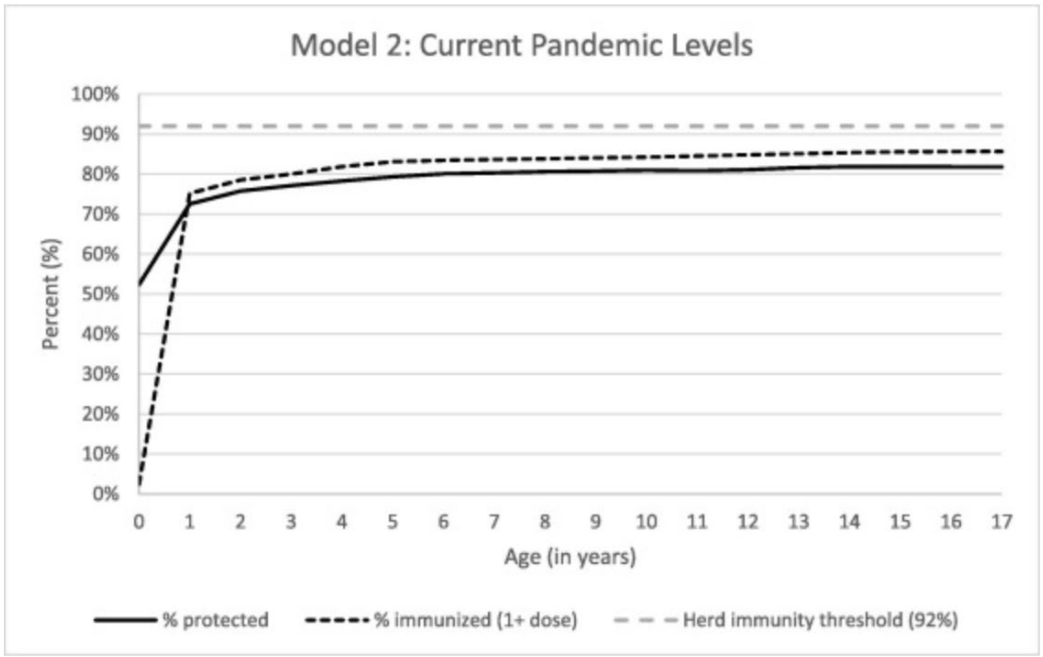
Measles outbreak involving cases at a Philadelphia day care center expands, health officials say

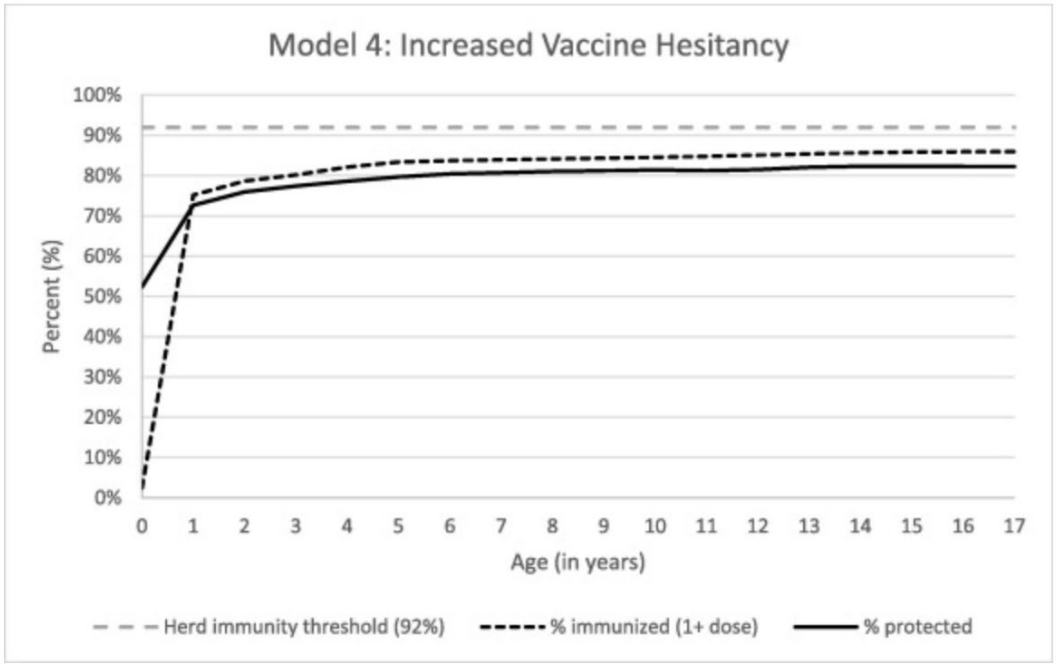
Virginia health officials warn travelers out of Dulles and Reagan airports of potential measles exposure

Sources: WCCO, USA Today, CNN, CBS

Estimating the number of US children susceptible to measles resulting from COVID-19-related vaccination coverage declines

Ashley Gambrell [a], Maria Sundaram [b], Robert A. Bednarczyk [a,c,d,*]





Source: Vaccine 7/30/22

Americans' Largely Positive Views of Childhood Vaccines Hold Steady

Americans remain steadfast in their belief in the overall value of childhood vaccines, with no change over the last four years in the large majority who say the benefits of childhood vaccines for measles, mumps and rubella (MMR) outweigh the risks, according to a new Pew Research Center survey.

Still, the survey finds that alongside broad support for childhood vaccines there are signs of some concern – especially among those closest to the decision-making process of vaccinating children. Parents see the risks of MMR vaccines as a bit higher than other Americans, and about half of those with a young child ages 0 to 4 say the statement "I worry that not all of the childhood vaccines are necessary" describes their views at least somewhat well. Concerns tend to be higher among mothers than fathers: Roughly half of mothers with a child under 18 rate the risk of side effects from MMR vaccines as medium or high – 15 percentage points higher than the share of fathers who say this.

Source: Pew Charitable Trusts 5/23

How the anti-vaccine movement is downplaying the danger of measles

Wellness influencers and anti-vaccine activists have reacted to measles outbreaks by spreading misinformation about the disease.

Measles and Misinformation Are Two Huge Public-Health Threats

Source: NBC, Time Magazine

Implications for Fighting Measles and Protecting Children

- More than vaccine campaigns
- Critical to remind public of value of protection against measles outbreaks

JAMA Forum

Of Mouse and Measles

Joshua M. Sharfstein, MD

Article Information

"Mickey Mouse Gets the Measles," reported one **website**. "Space Mountain with a Side of Measles," proclaimed a news **blog**, which could not resist adding that Measles was "not the name of an eighth 'Snow White' dwarf."

Countering Misinformation

- Broad coalitions
- Networks of trusted messengers
- Training clinicians
- Information immunization: warning people about scams
- Rapid responses to spreading falsehoods

There's a Psychological 'Vaccine' against Misinformation

Source: Scientific American

Announcing the Lancet Commission on Vaccine Refusal, Acceptance, and Demand in the USA

Idaho Measles Outbreak 2023

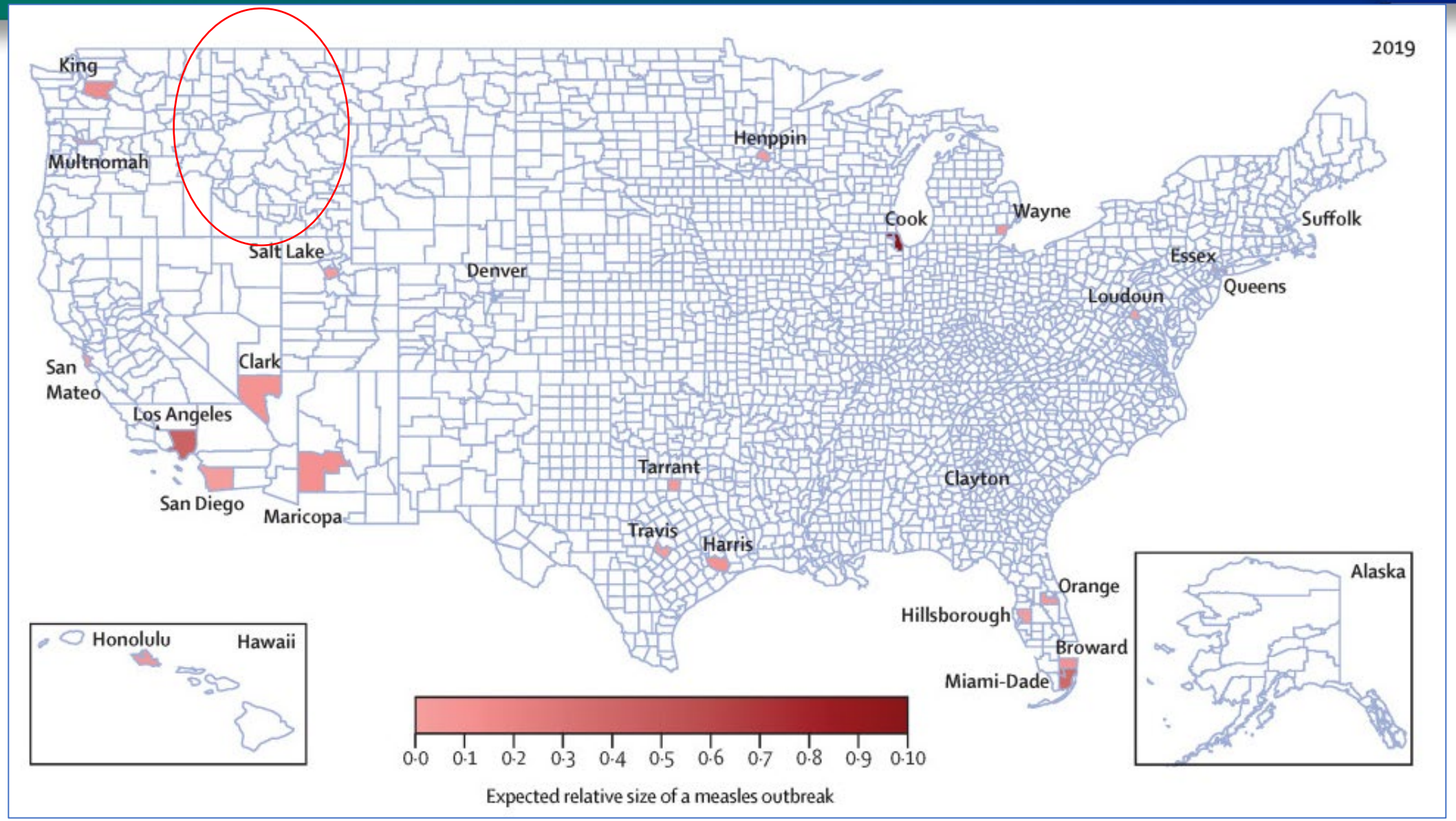
Christine Hahn, MD

Idaho Division of Public Health

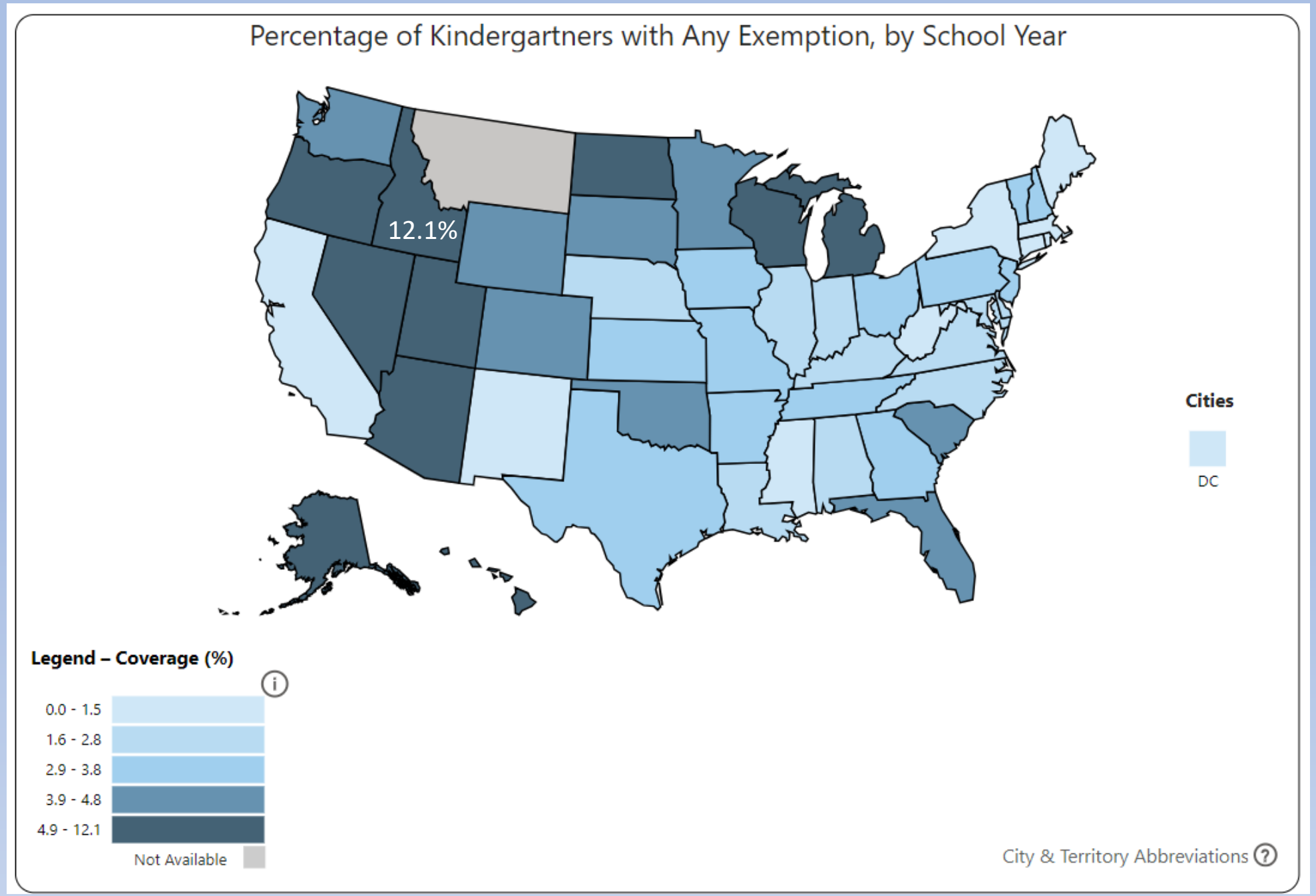
NVAC 2/22/2024

IDAHO DEPARTMENT OF HEALTH & WELFARE

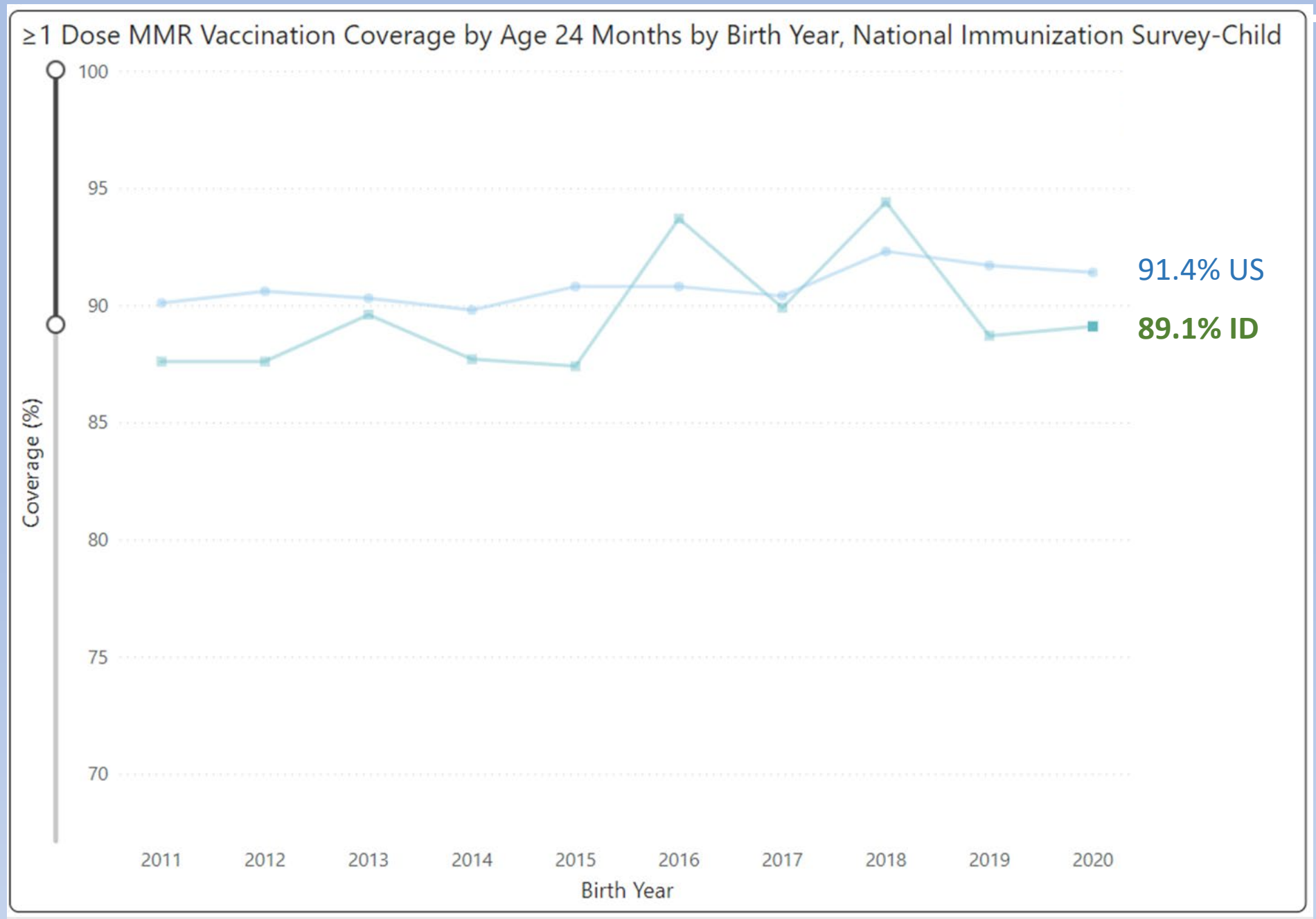
Top 25 US counties predicted to be at the highest risk of measles in 2019

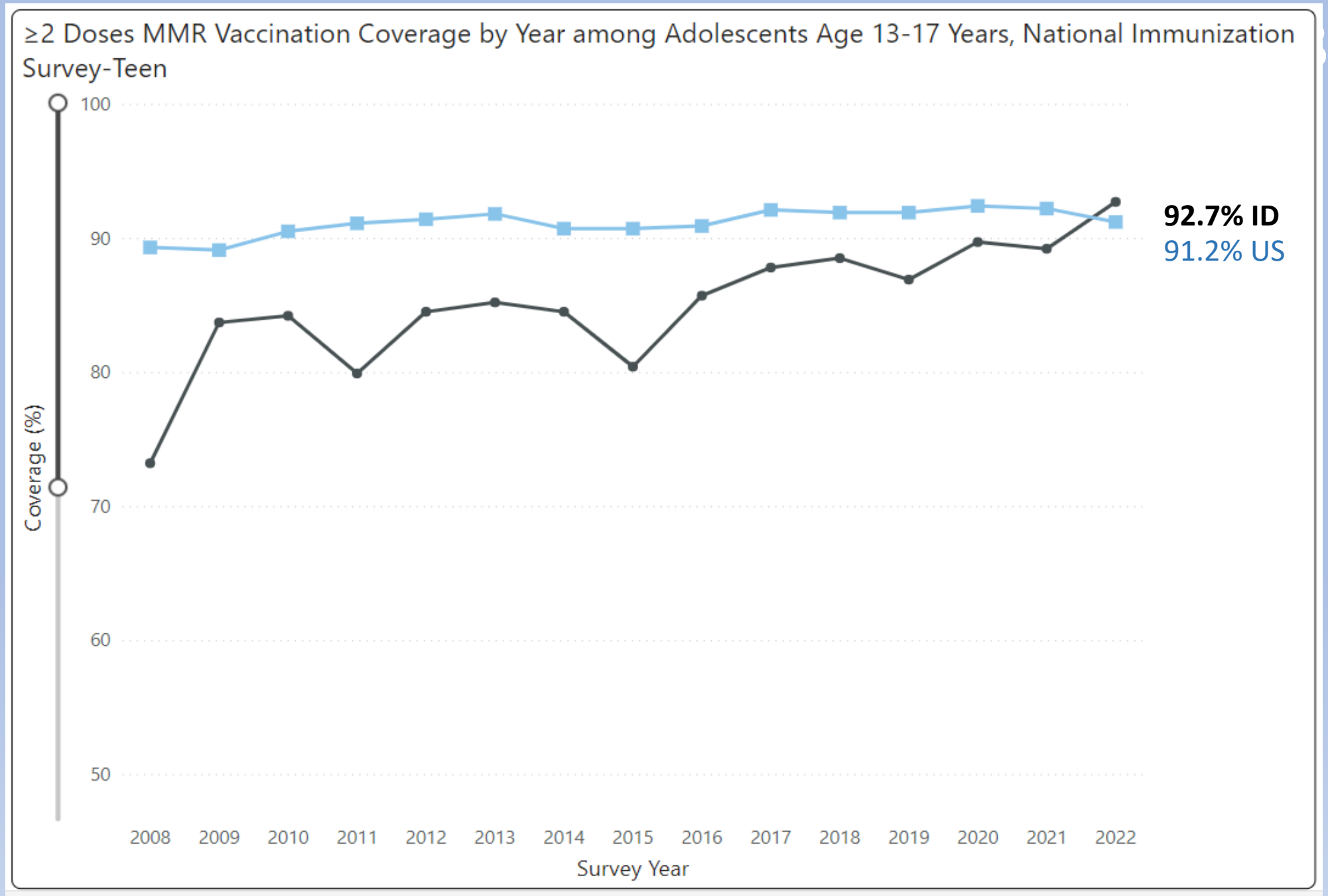


Source: https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(19)30231-2/fulltext



Source: https://www.cdc.gov/vaccines/imz-managers/coverage/schoolvaxview/data-reports/index.html


≥1 Dose MMR Vaccination Coverage by Age 24 Months by Birth Year, National Immunization Survey-Child
100
95
90
85
80
75
70
Coverage (%)
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
Birth Year
91.4% US
89.1% ID


≥2 Doses MMR Vaccination Coverage by Year among Adolescents Age 13-17 Years, National Immunization Survey-Teen
100
90
80
70
60
50
Coverage (%)
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019
2020
2021
2022
Survey Year
92.7% ID
91.2% US

Measles, Idaho, Sep 2023

- 9/13 young adult male returned to Idaho Sep 13 after international travel
- 9/15 hospitalized after presenting to ED with rash, fever, cough
- 9/17 public health notified of suspected case of measles
- 9/19 state public health laboratory reported positive PCR

IDAHO DEPARTMENT OF HEALTH & WELFARE

Services & Programs | Health & Wellness | News & Notices

Home | Newsroom Articles | Additional measles reported in Southwest Idaho; public health officials continue to recommend immunization

Additional measles reported in Southwest Idaho; public health officials continue to recommend immunization

, 2023

mmunications

ur people have been confirmed to have measles in Nampa, Idaho. All are children that were unvaccinated and were exposed in f the initial measles patient announced by public health officials Sept. 20.

ned to see this spread, but not surprised," said Dr. Christine Hahn, Idaho state epidemiologist and medical director for the ic Health at the Department of Health and Welfare. "Measles is very infectious. We are hopeful that this disease does not dely in the community

xposed to measles, yo

oms include fever, run
ous complications can
mptoms of measles sh
t calling ahead so the

eminding everyone th

IDAHO DEPARTMENT OF HEALTH & WELFARE

Services & Programs | Health & Wellness | News & Notices

Home | Newsroom Articles | Measles reported in Idaho resident; public health officials remind Idahoans to protect themselves from highly contagious illness by getting immunized

Measles reported in Idaho resident; public health officials remind Idahoans to protect themselves from highly contagious illness by getting immunized

September 20, 2023

Author: DHW Communications

An adult male with confirmed measles has been reported in southwest Idaho. He was unvaccinated and was exposed during recent international travel. He was hospitalized, and is now recovering at home.

During their infectious period, the

Investigation is ongoing, and peop
districts. However, it is possible th

Vaccination is highly protective ag

"Measles is an acute, highly contag
and medical director for the Divisi
through coughing and sneezing, bu

HEALTH ALERT NETWORK

HEALTH DISTRICT 4

ADVISORY FOR HEALTHCARE PROVIDERS

MEASLES REPORTED IN IDAHO

September 19, 2023

A patient with confirmed measles has been reported in an unvaccinated adult resident of southwest Idaho who was exposed during recent international travel.

This person with measles spent time at the Boise airport on September 13 during their infectious period, and in the Nampa area on September 14-15.

Investigation is ongoing, and possibly exposed people are being notified by the local public health district; however, it is possible that some people who were exposed would not have been identified by public health officials; vigilance for this highly infectious disease is critical.

Providers are reminded to:

- Consider measles infection in exposed patients with compatible symptoms, including:
  - Prodrome of fever, cough, coryza, and conjunctivitis for 2-4 days
  - Generalized maculopapular rash that usually begins on the face at the hairline and then spreads to the neck, trunk, and extremities
  - Koplik spots may appear on buccal mucosa 1-2 days prior to rash
- Be prepared for the possibility of patients with measles at your facility. Infection prevention and control specialists with the Idaho Division of Public Health, Healthcare Associated Infections Program are available at 208-334-5871.

In urgent/emergency healthcare settings:

- Patients with suspected measles should wear a mask covering the nose and mouth and be triaged immediately away from waiting rooms, in airborne isolation if available.

In outpatient clinic settings:

- Schedule suspected measles patients to be seen at end of day, if possible, and keep them out of waiting rooms
  - Use standard and airborne infection control precautions
  - Only staff with documented immunity to measles should enter patient's room
  - After the suspect patient is discharged, do not have additional patients or staff enter the room for 2 hours.

All healthcare settings:

IDAHO DEPARTMENT OF HEALTH & WELFARE

Services & Programs | Health & Wellness | News & Notices

Home | DHW Voice | Measles is back in Idaho

Measles is back in Idaho

October 6, 2023 | BY: Dr. Christine Hahn, Division of Public Health

beola" or "red measles"), with 10 cases reported to ted States in 2000. Only two cases of measles were

ease that doesn't last long?

ns

t

e

ve

but are more likely in:

leukemia or HIV infection

IDAHO DEPARTMENT OF HEALTH & WELFARE

DHWVoice

Promoting and protecting the health and safety of Idahoans

DHWVoice | DHWBLOG.COM

Share This Post

More DHW Voice Posts You May Like

DECEMBER 13, 2022

Ohio outbreak a good reminder to protect your family from measles

Read the full article

AUGUST 8, 2023

National Immunization Month is an opportunity to review your vaccines

Read the full article

AUGUST 2, 2022

National Immunization Awareness Month is a chance to review your vaccinations

Read the full article

Public health investigation

- Airline investigation– fellow travelers exposed from multiple states and countries on two flights

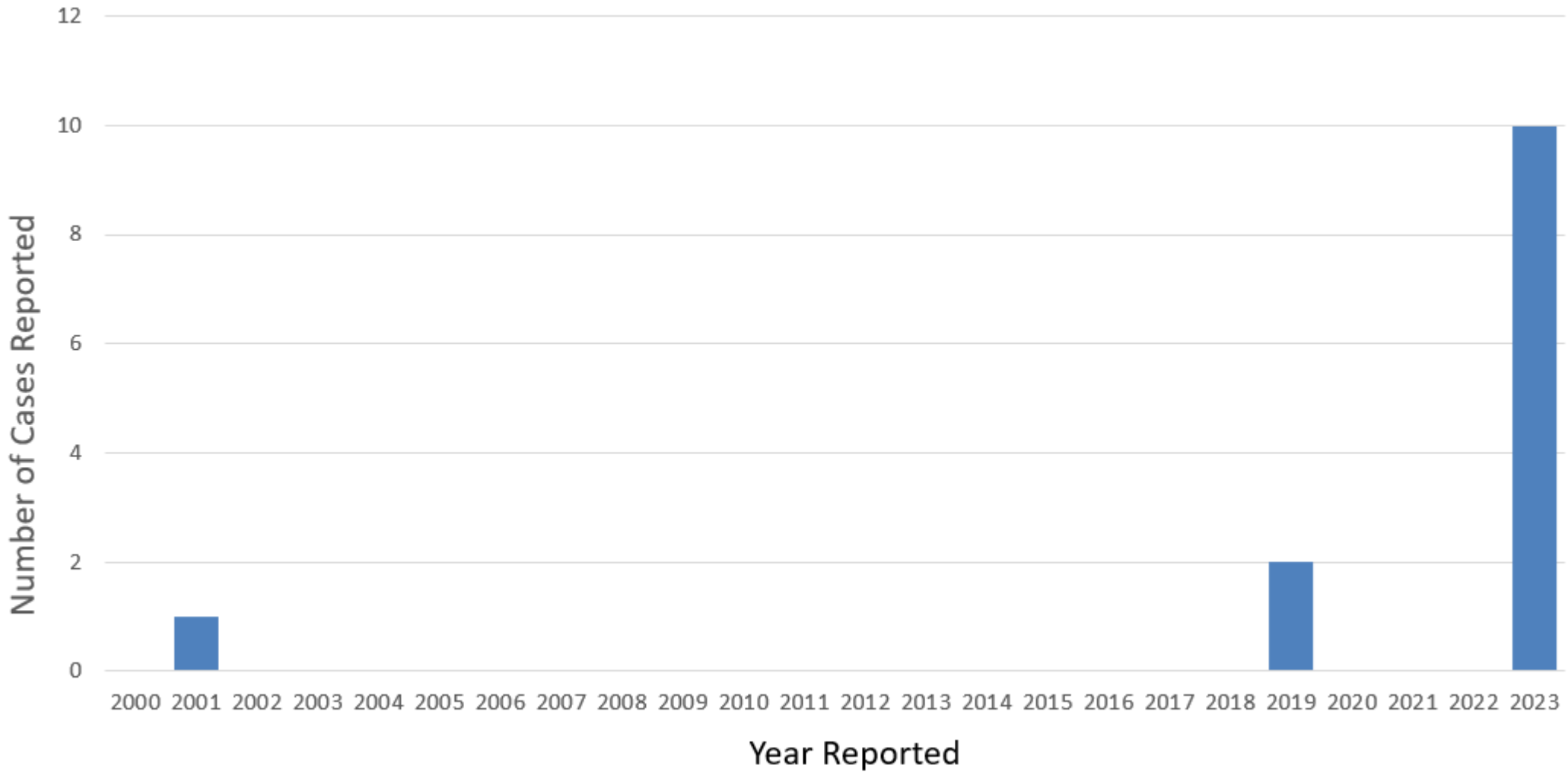
- Healthcare workers in Idaho exposed
  - 10 hospital staff
  - 1 EMS transport staff
  - 22 hospital patients and their visitors
  - Most had documented immunity; 15 considered susceptible

- Household and community members exposed
  - Airport
    - Driver from airport-- immune
  - Household
    - 9 susceptible family members
    - 2 immune household members
    - 1 visitor to home with reported, but unconfirmed, history of 2 doses MMR

Spread of measles, Idaho-- 2023

- Airline: no cases detected
- Healthcare settings: no cases detected
- Community:
  - No cases related to airport
  - No other cases in Idaho outside of household
- Household:
  - 9 unvaccinated and nonimmune members
    - all 9 developed measles
    - all fully recovered
    - none required hospitalization

Reported Cases of Measles: Idaho– 2000-2023



Current Concerns

- Risk of measles transmission is high in areas in the state with lower immunization rates
- Perception of risk from measles appears to be low
- High exemption rate may reflect values regarding privacy that might make it difficult to reach at-risk communities
- Low traveler awareness of risk of measles in traditionally “lower risk” countries, such as UK, other European countries
- Proposed legislative changes to vaccine program currently could impact our ability to prepare for and respond to outbreaks
  - e.g., changes to immunization registry, vaccine assessment board, ability to support vaccines which are under EUA

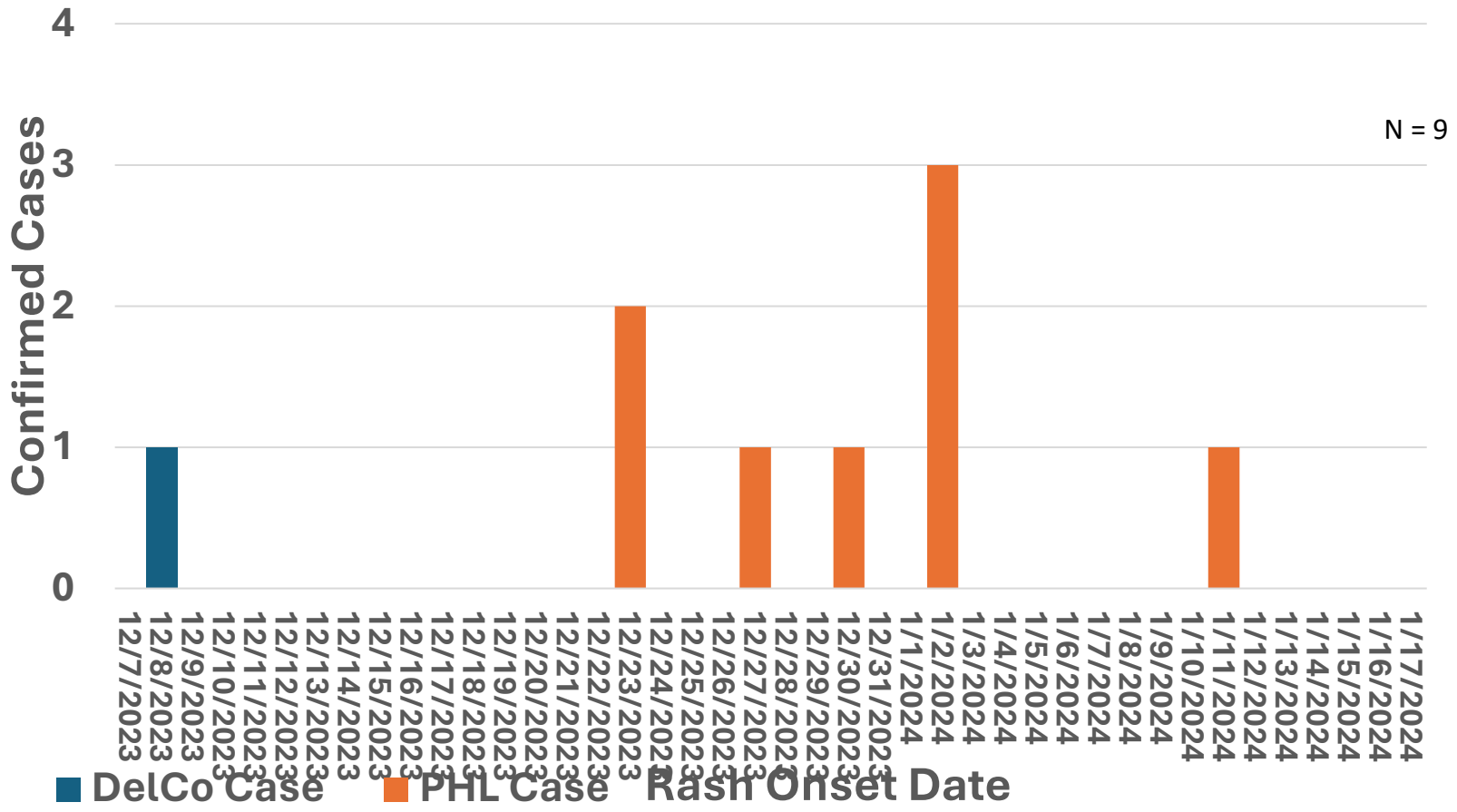
CITY OF PHILADELPHIA
DEPARTMENT OF PUBLIC HEALTH
DIVISION OF DISEASE CONTROL

Philadelphia Measles Cluster

February 22, 2024

Shara Epstein, MD
Medical Director, Division of Disease Control

Measles Outbreak Epi Curve



Philadelphia Measles Case Characteristics

Ages

- <12 months: 2
- 12 months–23 months: 2
- 2–3 years: 2
- >20 years: 2

MMR vaccination status:

- Non-eligible, <12 months: 2
- Over 12 months, unvaccinated: 5
  - All exemptions
- Reported MMR history, IgG positive: 1

Childcare Contacts

- All but one unvaccinated child contracted measles
  - That child was not present the days the case was in childcare
- No vaccinated children or staff contracted measles

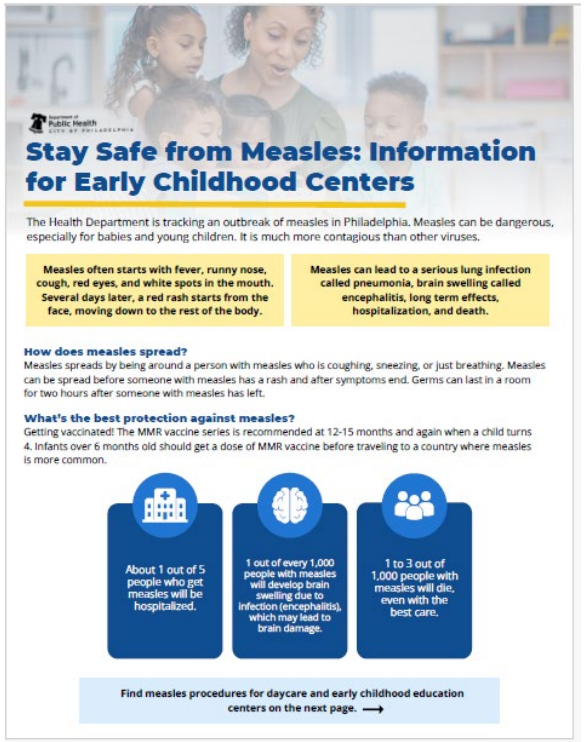
Hospitalizations

- 6 hospitalizations
- All were discharged home

PDPH actions

- Multiple meeting with early childhood education directors (English and Spanish)
- Townhall with the School District of Philadelphia scheduled for March
- Reactivated grocery delivery services for people who need to quarantine and don’t otherwise have access to food.
- Refined communication materials
  - Infographics
  - Translations
- Canvassing homes and ECEs in the neighborhood
- Home testing for PCR and serology collected by PDPH nurses

Materials



Department of Public Health
CITY OF PHILADELPHIA

Stay Safe from Measles: Information for Early Childhood Centers

The Health Department is tracking an outbreak of measles in Philadelphia. Measles can be dangerous, especially for babies and young children. It is much more contagious than other viruses.

Measles often starts with fever, runny nose, cough, red eyes, and white spots in the mouth. Several days later, a red rash starts from the face, moving down to the rest of the body.

Measles can lead to a serious lung infection called pneumonia, brain swelling called encephalitis, long term effects, hospitalization, and death.

How does measles spread?
Measles spreads by being around a person with measles who is coughing, sneezing, or just breathing. Measles can be spread before someone with measles has a rash and after symptoms end. Germs can last in a room for two hours after someone with measles has left.

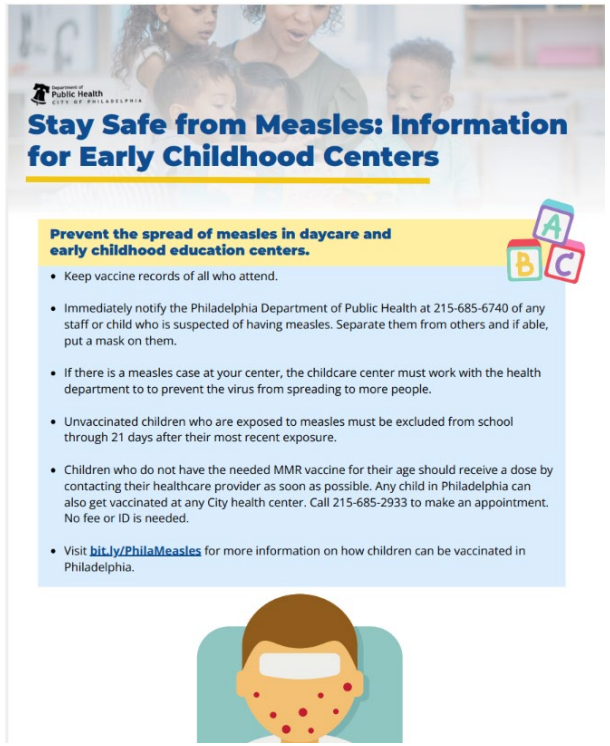
What's the best protection against measles?
Getting vaccinated! The MMR vaccine series is recommended at 12-15 months and again when a child turns 4. Infants over 6 months old should get a dose of MMR vaccine before traveling to a country where measles is more common.

About 1 out of 5 people who get measles will be hospitalized.

1 out of every 1,000 people with measles will develop brain swelling due to infection (encephalitis), which may lead to brain damage.

1 to 3 out of 1,000 people with measles will die, even with the best care.

Find measles procedures for daycare and early childhood education centers on the next page. ⟶



Department of Public Health
CITY OF PHILADELPHIA

Stay Safe from Measles: Information for Early Childhood Centers

Prevent the spread of measles in daycare and early childhood education centers.

- Keep vaccine records of all who attend.
- Immediately notify the Philadelphia Department of Public Health at 215-685-6740 of any staff or child who is suspected of having measles. Separate them from others and if able, put a mask on them.
- If there is a measles case at your center, the childcare center must work with the health department to to prevent the virus from spreading to more people.
- Unvaccinated children who are exposed to measles must be excluded from school through 21 days after their most recent exposure.
- Children who do not have the needed MMR vaccine for their age should receive a dose by contacting their healthcare provider as soon as possible. Any child in Philadelphia can also get vaccinated at any City health center. Call 215-685-2933 to make an appointment. No fee or ID is needed.
- Visit bit.ly/PhilaMeasles for more information on how children can be vaccinated in Philadelphia.

Department of Public Health
CITY OF PHILADELPHIA

Get Vaccinated to Prevent Measles

MMR Vaccination Clinic

Saturday
January 13, 2024
Catholic Social Services
7340 Jackson St, 19136
10am - 3pm

Open to ALL Philadelphia residents!
No insurance and no ID required!
No appointment needed!

FREE!

For more information about measles, visit bit.ly/Measles2024PHL

Materials

Department of Public Health
CITY OF PHILADELPHIA

Stay Safe from Measles: Get the Facts

The Health Department is tracking an outbreak of measles in Philadelphia. Measles can be dangerous, especially for babies and young children. It is much more contagious than other viruses.

Measles often starts with fever, runny nose, cough, red eyes, and white spots in the mouth. Several days later, a red rash starts from the face, moving down to the rest of the body.

Measles can lead to a serious lung infection called pneumonia, brain swelling called encephalitis, long term effects, hospitalization, and death.

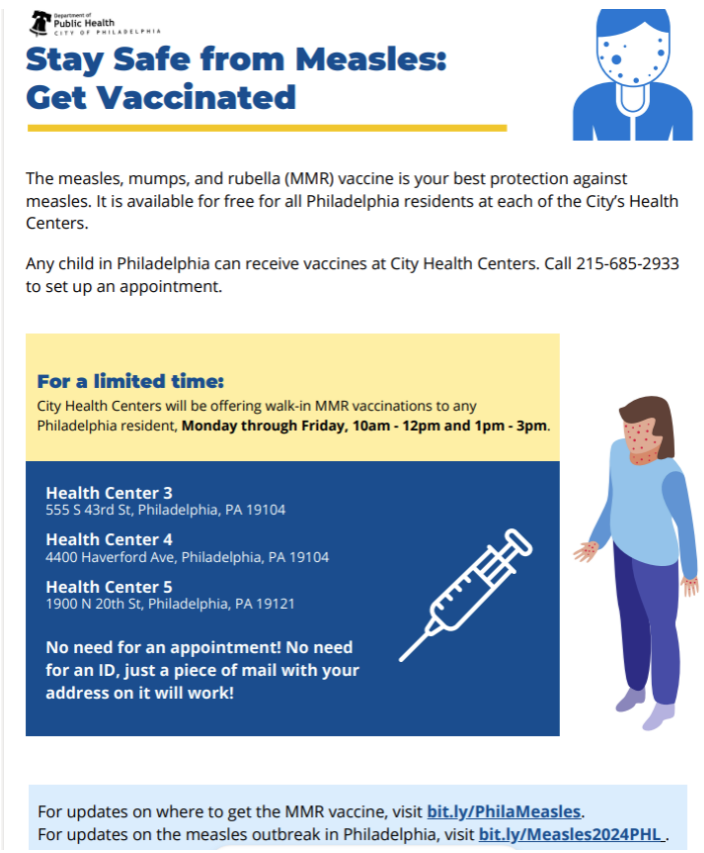
How does measles spread?
Measles spreads by being around a person with measles who is coughing, sneezing, or just breathing. Measles can be spread before someone with measles has a rash and after symptoms end. Germs can last in a room for two hours after someone with measles has left.

What's the best protection against measles?
Getting vaccinated! The MMR vaccine series is recommended at 12-15 months and again when a child turns 4. Infants over 6 months old should get a dose of MMR vaccine before traveling to a country where measles is more common.

About 1 out of 5 people who get measles will be hospitalized.

1 out of every 1,000 people with measles will develop brain swelling due to infection (encephalitis), which may lead to brain damage.

1 to 3 out of 1,000 people with measles will die, even with the best care.



Department of Public Health
CITY OF PHILADELPHIA

Stay Safe from Measles: Get Vaccinated

The measles, mumps, and rubella (MMR) vaccine is your best protection against measles. It is available for free for all Philadelphia residents at each of the City's Health Centers.

Any child in Philadelphia can receive vaccines at City Health Centers. Call 215-685-2933 to set up an appointment.

For a limited time:
City Health Centers will be offering walk-in MMR vaccinations to any Philadelphia resident, **Monday through Friday, 10am - 12pm and 1pm - 3pm**.

Health Center 3
555 S 43rd St, Philadelphia, PA 19104

Health Center 4
4400 Haverford Ave, Philadelphia, PA 19104

Health Center 5
1900 N 20th St, Philadelphia, PA 19121

No need for an appointment! No need for an ID, just a piece of mail with your address on it will work!

For updates on where to get the MMR vaccine, visit bit.ly/PhilaMeasles.
For updates on the measles outbreak in Philadelphia, visit bit.ly/Measles2024PHL.

PDPH actions

Recall	Recall messaging sent to families of residents age 12 months- 6 years without MMR vaccination in our IIS
AHS Vaccine Clinic	Walk in hours at several public health centers for MMR vaccination, additional Saturday hours
DDC Vaccine Clinic	Walk in clinic operated by the Division of Disease Control
Contact Tracing	Contact tracing of over 150 contacts

PDPH actions

- Weekly situation update meetings with surrounding local and state health departments and healthcare facilities, well attended by more than 100 participants
- Webinar with primary care providers
- Discussion with clinicians of each suspect case and testing options
- PA BOL weekend and holiday flexibility

Public Communications

- December 23, 2023: Press release regarding outpatient tower exposure
- January 2 and January 9, 2024: Health alert January 4, 2024: Press release
- Daily press releases
- Blog post updated whenever new exposure sites were identified https://www.phila.gov/2024-01-04-health-department-cautions-philadelphians-about-recent-measles-cases/

Vaccination Rates in Philadelphia

93% of children 6 and older up to date on MMR vaccine

97% of K-12 children in the school district of Philadelphia are up to date on MMR vaccine

A 30-Fold Surge In Measles Cases in 2023: Protecting the Unvaccinated

Discussion

NVAC

Innovation Insight: Analysis of the Pipeline and Industry Investment

David Thomas

NVAC

Biotechnology Innovation Organization

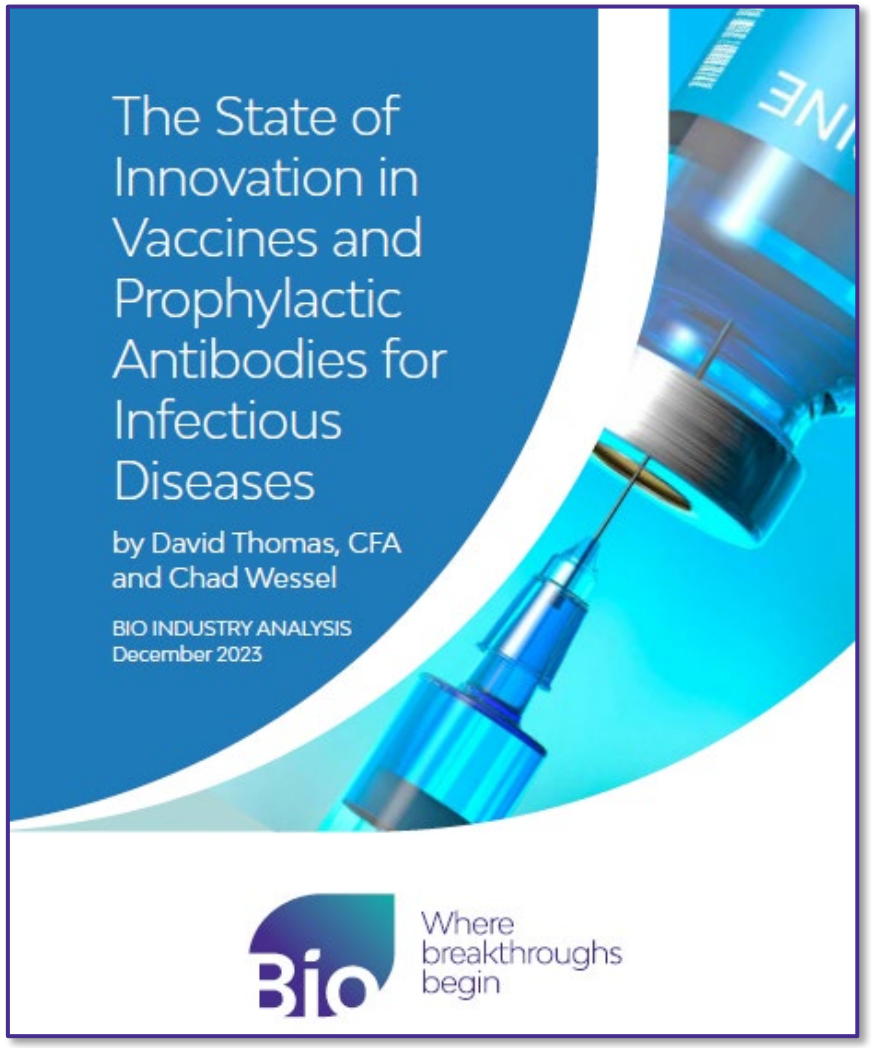
The State of Innovation in Infectious Disease Vaccines and Prophylactic Antibodies

David Thomas, CFA

BIO Industry Analysis

BIO CEO February 2024

What is in the New Vaccine Report from BIO?



www.bio.org/iareports

History
- Indications & Vaccine Types

Clinical Pipeline
- Indications & Vaccine Types

Investment

Success Rates

Antibodies

Pipeline primary sources: Citeline's Biomedtracker, Pharmaprojects, Company websites

History of Vaccines – 34 Pathogens

First Broad Usage	Disease	Pathogen Type
1800s	Smallpox	DNA virus
1800s	Cholera	bacteria
1910s	Rabies	RNA virus
1920s	Tuberculosis (TB)	mycobacteria
1930s	Diphtheria infection	bacteria
	Yellow fever	RNA virus
1940s	Tetanus	bacteria
	Whooping Cough	bacteria
	Infleunza (Flu)	RNA virus
1950s	Polio	RNA virus
1960s	Measles	RNA virus
	Mumps	RNA virus
	Rubella	RNA virus
1970s	Anthrax	bacteria
	Adenovirus	DNA virus
	Tick-borne Encephalitis	RNA virus
	Pneumococcal Disease	bacteria

First Broad Usage	Disease	Pathogen Type
1980s	Hepatitis B	DNA virus
	H. Influenza	bacteria
	Typhoid Fever	bacteria
1990s	Japanese Encephalitis	RNA virus
	Chickenpox	DNA virus
	Hepatitis A	RNA virus
	Lyme Disease (withdrawn)	bacteria
2000s	Meningococcal Disease	bacteria
	Shingles	DNA virus
	Rotaviral enteritis	RNA virus
	HPV	DNA virus
2010s	Dengue Fever	RNA virus
	Hand, Foot, Mouth Disease	RNA virus
	Ebola	RNA virus
2020s	Covid-19	RNA virus
	Malaria	Parasite
	RSV	RNA virus

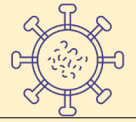
Total # of Pathogens

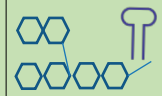
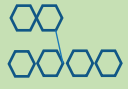
DNA virus	6
bacteria	10
RNA virus	16
Parasite	1
Total	**33**

*Chickungunya Nov 2023 (RNA virus)

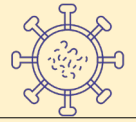
Total = 34

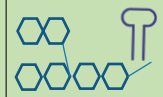
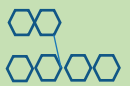
History of Vaccines – 11 Modalities

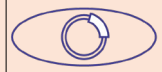
		# Pathogens
Live Attenuated Viral Pathogen		14
Inactivated Viral Pathogen		8 [3]
Recombinant Viral Vector, Replicating		2
Recombinant Viral Vector, Nonreplicating		1
mRNA		1
Purified Antigen Protein		6 [1]
Protein-VLP (Virus Like Particle)		4

		# Pathogens
Carbohydrate-Protein Conjugate (glyco-conjugate)		4
Capsid Carbohydrate		1 [1]
Live Attenuated Bacteria		3
Inactivated Bacteria		3 [2]

Vaccine Clinical Pipeline – 15 Modalities

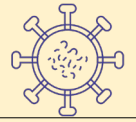
		# Pathogens
Live Attenuated Viral Pathogen		8
Inactivated Viral Pathogen		12
Recombinant Viral Vector, Replicating		3
Recombinant Viral Vector, Nonreplicating		9
mRNA		17
Purified Antigen Protein		28
Protein-VLP (Virus Like Particle)		12

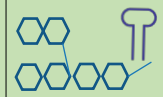
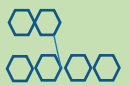
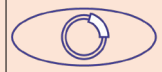
		# Pathogens
Carbohydrate-Protein Conjugate (glyco-conjugate)		9
Capsid Carbohydrate		0
Live Attenuated Bacteria		4
Inactivated Bacteria		4

DNA		4
saRNA		3
Peptide Epitopes		6
Cell-based w/expression		3

Vaccine Clinical Pipeline – 15 Modalities

249 Vaccines

		# Pathogens	# Vaccines
Live Attenuated Viral Pathogen		8	14
Inactivated Viral Pathogen		12	14
Recombinant Viral Vector, Replicating		3	4
Recombinant Viral Vector, Nonreplicating		9	23
mRNA		17	40
Purified Antigen Protein		28	63
Protein-VLP (Virus Like Particle)		12	24

		# Pathogens	# Vaccines
Carbohydrate-Protein Conjugate (glyco-conjugate)		9	24
Capsid Carbohydrate		0	0
Live Attenuated Bacteria		4	4
Inactivated Bacteria		4	4
DNA		4	11
saRNA		3	13
Peptide Epitopes		6	7
Cell-based w/expression		3	3

Vaccine Pipeline – Phase & Pathogen Type

Pathogen Type	Phase I	Phase II	Phase III	BLA	Total	%
RNA viruses - non SARS-Cov2	49	22	10	3	84	34%
RNA viruses - SARS-Cov2	32	23	14	0	69	28%
DNA viruses	14	14	6	0	34	14%
Bacteria	12	20	11	1	44	18%
Parasites	4	4	0	0	8	3%
Multiple	8	2	0	0	10	4%
Total	**119**	**85**	**41**	**4**	**249**	100%

153
62%

Pipeline primary sources: Citeline's Biomedtracker, Pharmaprojects, company websites

Vaccine Clinical Pipeline – 51 Pathogens*

RNA virus vaccines	#
SARS Cov2	69
Influenza - Seasonal	17
Influenza - Universal	7
Influenza - Pandemic	5
RSV	11
HIV	8
Norovirus	6
Dengue	5
Rotavirus	4
Zika	3
Chikungunya	3
Nipah Virus	3
Ebola	2
Rabies	2
EEV	2
Lassa Virus	2
Coxsackie virus	1
Enterovirus	1
Yellow Fever	1
West Nile Virus	1
Total	**153**

Bacterial vaccines	#
Streptococcus pneumoniae	14
TB	4
Meningococcus	3
Shigella	5
E. coli	2
Clostridium difficile	2
Group B Streptococcus	2
Salmonella (non-typhoidal)	2
Bacterial - Urinary	1
Cholera	1
Staphylococcus	1
Lyme (Borrelia)	1
Plague (Yersenia)	1
Anthrax	1
Pertussis	1
Gonorrhea (Neisseria)	1
Klebsiella pneumoniae	1
Chlamydia	1
Total	**44**

DNA virus vaccines	#
HPV	12
Chickenpox	8
HBV	5
CMV	4
HSV	2
Varicella Zoster	2
EBV	1
Total	**34**

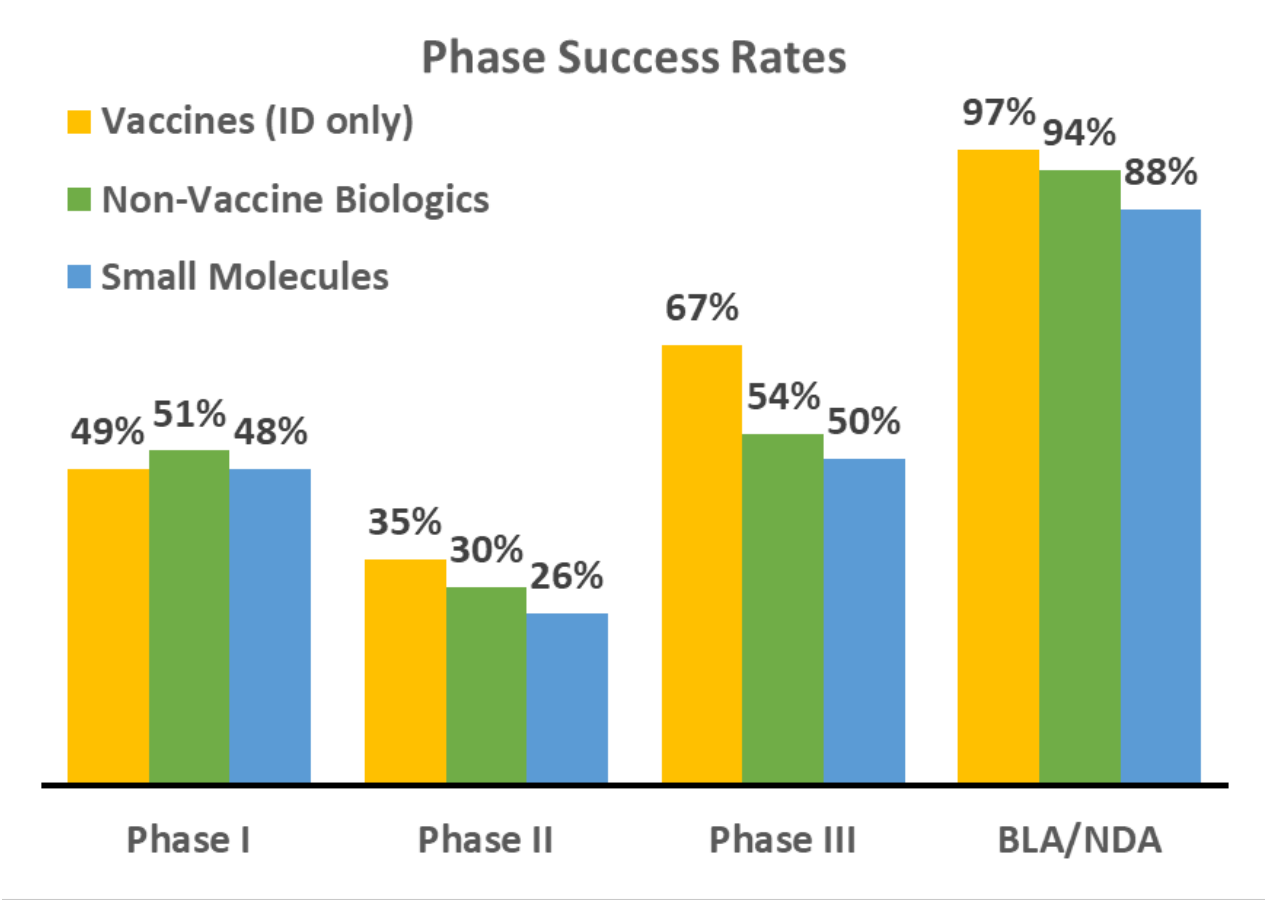
Parasitic vaccines	#
Malaria	6
Schistosomiasis	2
Total	**8**

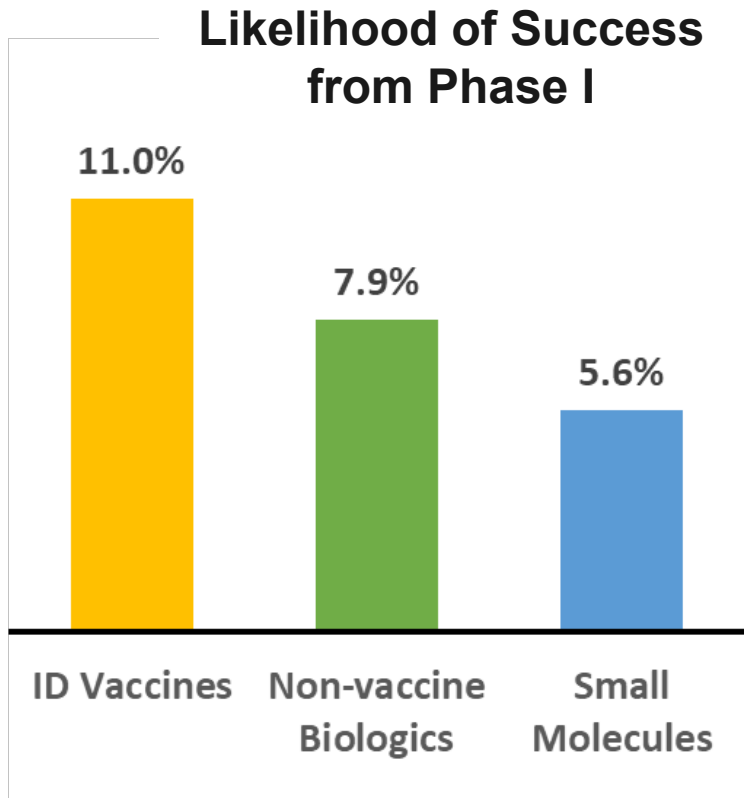
Combo Vaccines	#
COVID + Flu	3
RSV + MPV	2
COVID + Flu + RSV	1
RSV + Flu	1
MPV + PIV3	1
EV + CV	1
Shigella + E. coli	1
Total	**10**

= New

***31 pathogens represented in pipeline with no currently available vaccine**

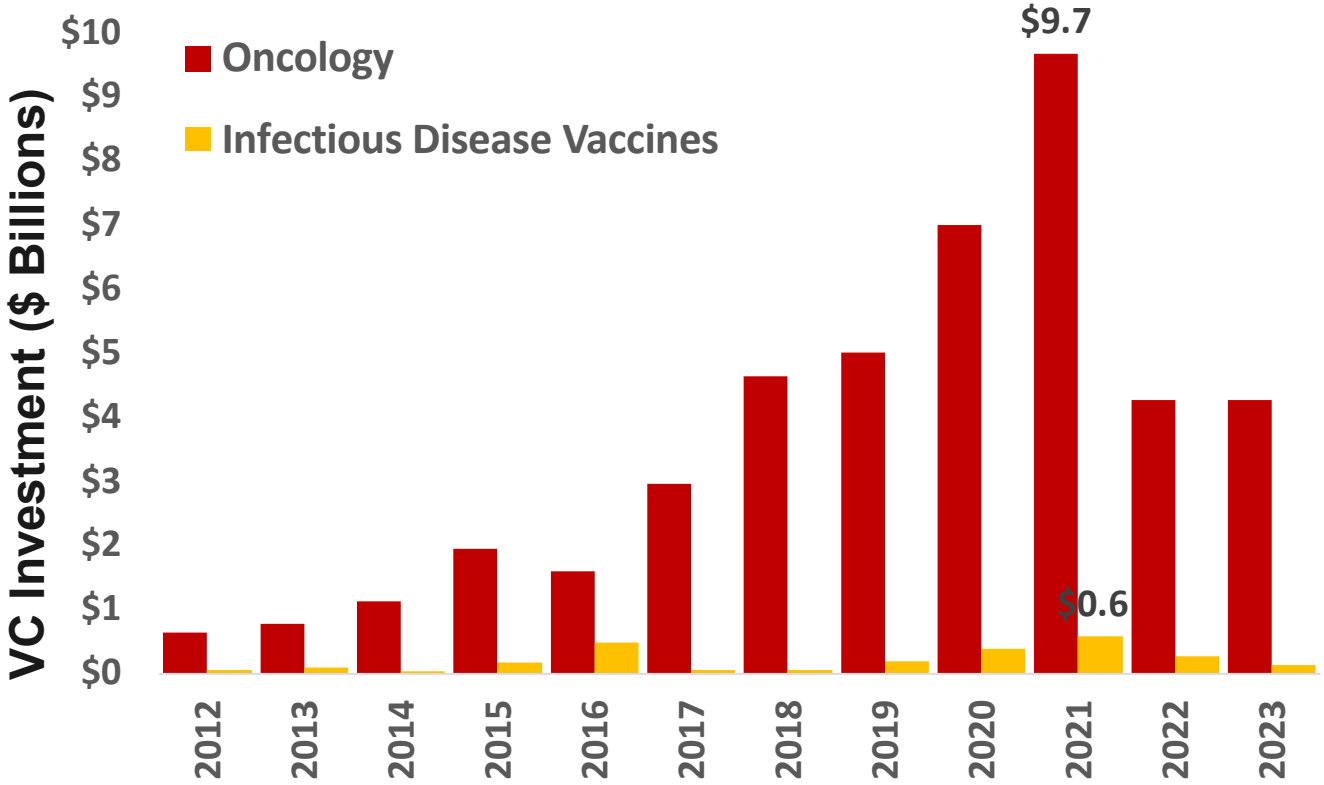
Clinical Success Rates
Novel Vaccines vs. Novel NCEs

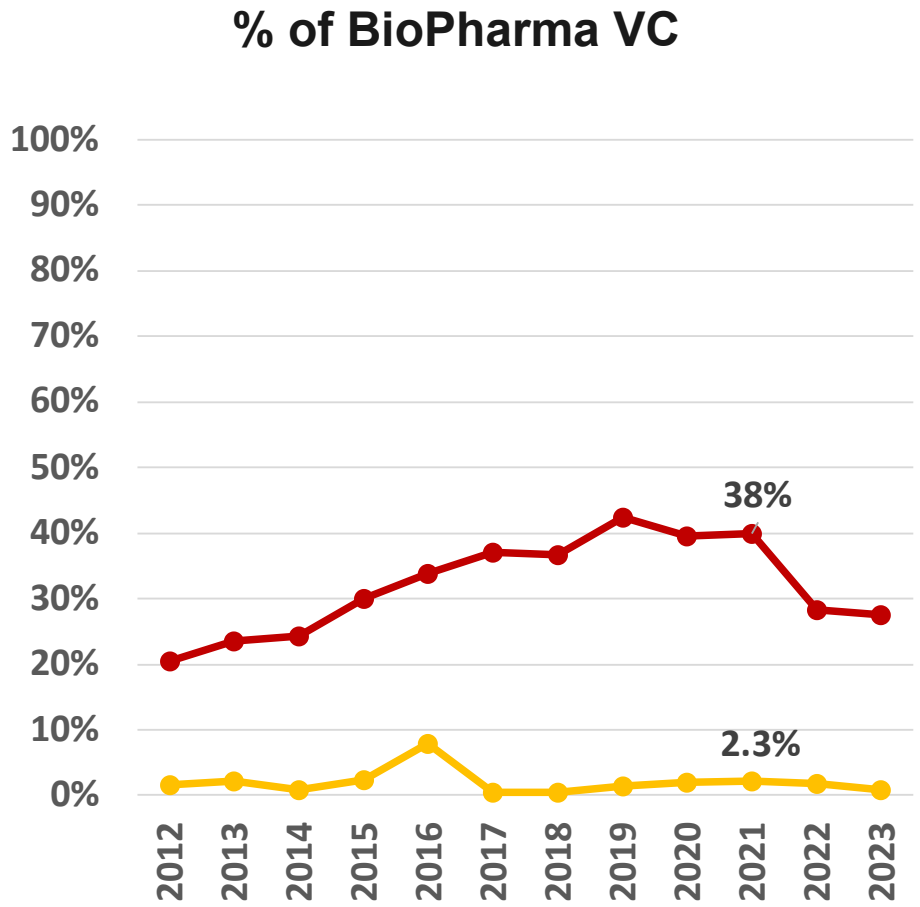




Pipeline success rate source: Citeline

U.S. Venture Capital into Infectious Disease Vaccines vs. Oncology





Pipeline venture capital sources: Pitchbook, Biocentury, Biomedtracker

Prophylactic Antibodies

Approval History*
7 pathogens

1. **Rabies** (polyclonal IG)
2. **RSV** (mAb)
3. **CMV** (polyclonal IG)
4. **Anthrax** (mAb)
5. **C. difficile** (mAb)
6. **HIV** (mAb vs CD4)
7. **Ebola (**mAb cocktail**)**
   [COVID-19 (mAbs)]*

Clinical Pipeline
7 new pathogens, 16 programs

1. COVID (4 mAbs)
2. **Staphylococcus** (2 mAbs)
3. HIV (2)
4. **Chikungunya** (1 mAb)
5. **CAP** (1 mAb)
6. **Marburg** (1 mAb)
7. **Tetanus** (1 mAb)
8. **Influenza** (1 polyclonal)
9. **Zika** (1 polyclonal)
10. RSV (1 mAb)
11. Rabies (1 mAb)

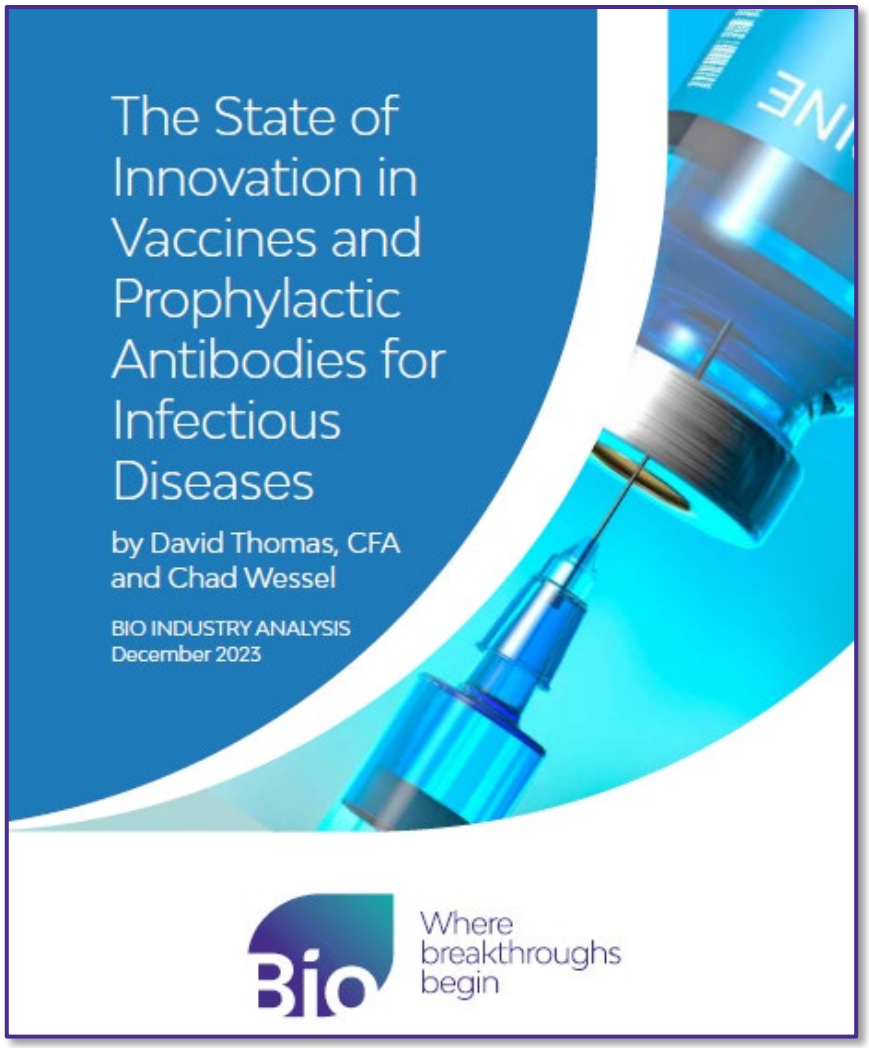
*post-exposure prophylaxis COVID-19 EUA [revoked in US]

(yellow = no current vaccine or mAb)

Pipeline primary sources: Citeline's Biomedtracker, company websites

Bio

Biotechnology
Innovation Organization



www.bio.org/iareports

Innovation Insight: Analysis of the Pipeline and Industry Investment

Discussion

NVAC

Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

February 22-23, 2024

Break

NVAC

Strong Supply Chains: Opportunities to Thwart Shortages

Dr. Manuel Osorio
Joe Figlio
Dr. Tanya Villafana
Dr. Iskra Reic
Dr. Jeanne Santoli

NVAC

CBER Advanced Technologies Program

Promoting the Development and Adoption of Advanced Manufacturing Technologies

Manuel Osorio, PhD

Senior Scientist for Emerging Technologies

Lead, CBER Advanced Technologies Program

CBER | FDA

NVAC Meeting February 22, 2024

CBER Advanced Technologies Program

Fund advanced research and development projects to support regulatory science and innovation

Build internal scientific and regulatory expertise

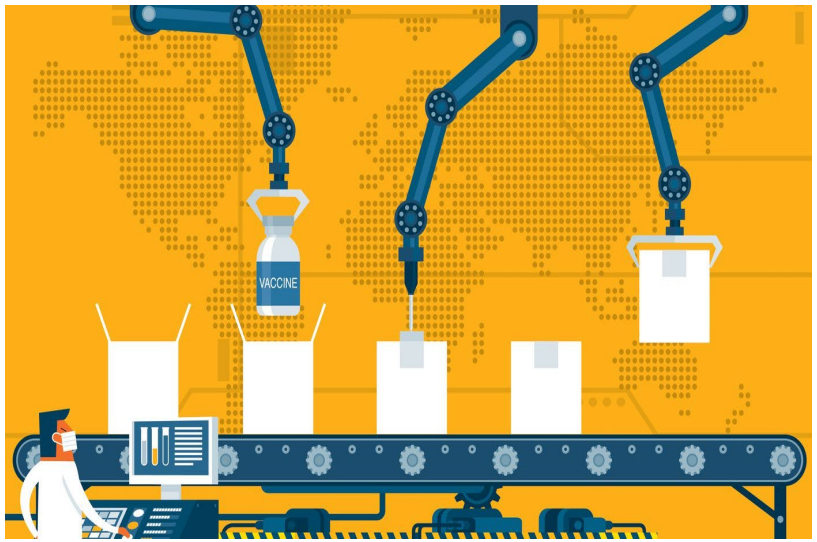
The CBER Advanced Technologies Team (CATT)

Extramural Advanced Manufacturing Funding Highlight

FY22 FDA Award to the Massachusetts Institute of Technology

"Development of an Integrated Continuous CGMP Facility for mRNA Manufacturing"

PI: Professor Richard Braatz



Project Goals:

- Enable end-to-end, continuous manufacturing of mRNA vaccines by developing new technology approaches
- Develop and incorporate in-line sensor systems
- Build a digital twin model for the entire process

Project Significance:

- Provide a flexible, efficient and advanced manufacturing platform to allow rapid and consistent production of mRNA-based vaccines
- Advance regulatory science by providing knowledge and experience to CBER staff

CBER Advanced Technologies Team (CATT)

WHAT	Established in 2019 to promote dialogue, education, and input among CBER staff and between CBER and prospective developers of advanced manufacturing technologies to encourage their implementation in the manufacturing sector.
WHO	Consists of a small cross-functional group representing CBER leadership, relevant policy, review and inspection programs. **Offices Represented: OD, OVRR, OTP, OBRR, OCBQ**
HOW	Provides access to early interactions with CBER, prior to filing a regulatory submission, to discuss technical and regulatory issues related to the implementation of innovative manufacturing and control strategies .

Examples of Technologies Discussed

- Continuous Manufacturing (vaccines, AAV vectors, exosomes)
- Fully closed, automated, scalable and remote-controlled systems for manufacturing cell therapy products
- Improved cell lines for vaccine antigen production and AAV vector manufacturing
- Use of AI and advanced imaging technologies for real time product quality assessment
- Multi-product manufacturing facility design
- CRISPR/Cas9 Genome editing

U.S. Department of Health and Human Services

ASPR Administration for Strategic Preparedness & Response

Industrial Base Expansion to Support Vaccine Development During Public Health Emergencies

Joe Figlio, Branch Chief, CGMP Capabilities Readiness Branch, PCI, BARDA

Evolution of the Public Health Industrial Base through COVID-19

Pre-COVID-19
before Jan 2020

Limited public health industrial base to address pandemic needs

- Reliant on “just-in-time" manufacturing inputs that were vulnerable to supply disruptions
- High dependency on a consolidated, geographically limited foreign supply, e.g.,
  - 90%+ gloves, syringes, needles from Asia
  - 95%+ generic drugs made in India and China

Peak COVID-19
2020-2022

Inadequate availability of critical medical supplies; USG & industry responded

- Accelerated global transport and domestic allocation of critical raw materials and medical countermeasures in shortage
- Increased domestic production capacities for PPE, vaccines, diagnostics, and pharmaceuticals

Today
October 2023

Demand & supply stabilizing, continued manufacturing investments required

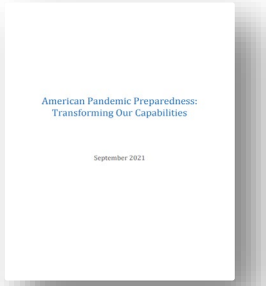
- Addressing new increased demand from virus variants, additional vaccinations, global support for vaccines
- Establishing acquisition workforce to actively manage supply and production capacities
- Ensuring investments are sustainable for long term competitiveness and needs

Future
(next 24 months)

Build resilient industrial base to respond to future pandemics

- Actively manage health and resiliency of our domestic public health industrial base
- Preserve production capacities in US supply chain as demand wanes
- Expand professional acquisition workforce
- Expand supply chain monitoring & industrial base analysis capabilities

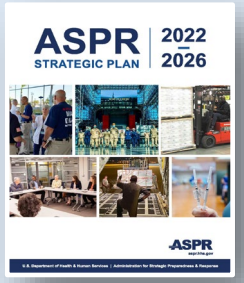
Industrial Base Expansion (IBx): Strategic Alignment



American Pandemic Preparedness: Transforming Our Capabilities

September 2021

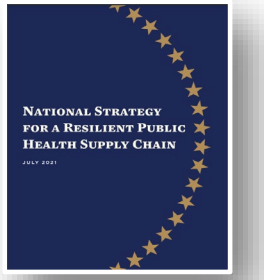
Rapidly make effective vaccines against any virus family (1.0) & enable population-scale production of vaccine within 100 days (1.2)



ASPR Strategic Plan

2022 – 2026

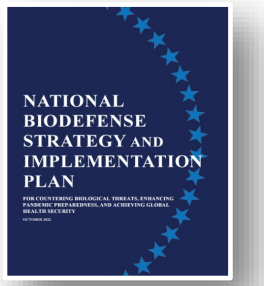
Develop & secure necessary public health emergency… capabilities … [and] accelerate the advanced development & procurement of MCMs (1.1); Establish … public-private partnership models to spur promising MCM innovation that will provide solutions to existing & emerging problems…(3.2)



National Strategy for a Resilient Public Health Supply Chain

July 2021

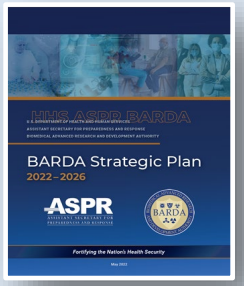
Build a diverse, agile public health supply chain and sustain long-term U.S. manufacturing capability for future pandemics (Goal 1)



National Biodefense Strategy and Implementation Plan

October 2022

Establish and maintain domestic capability and capacity to produce – population-scale human or animal vaccines (3.4.2)



BARDA Strategic Plan

2022 – 2026

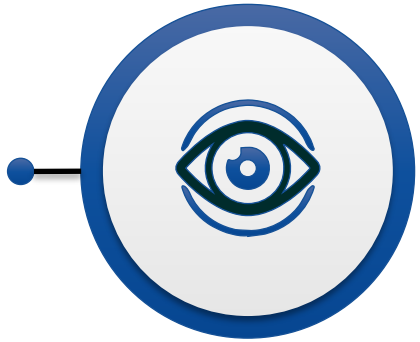
Accelerate the development of MCMs that can pivot and be brought to scale in response to new threats (1.1); Enhance BARDA's response posture by leveraging a diverse MCM portfolio of proven technologies (2.1); Build a resilient, surge-capable, flexible manufacturing ecosystem that prioritizes increased domestic capacity (2.2)

E.O. on Advancing Biotechnology & Biomanufacturing Innovation

September 2022

Improve & expand domestic biomanufacturing production capacity and processes…; Establish & maintain domestic capability & capacity to produce sufficient quantities of …vaccines… within 130 days …; [and] train & support a diverse, skilled workforce…to advance biotechnology & biomanufacturing

Pharmaceutical Countermeasures Infrastructure (PCI)



PCI VISION

Maintain manufacturing capability to respond to any pandemic or public health emergency (PHE)

PCI's INDUSTRIAL BASE EXPANSION (IBx) FOCUS AREAS

Product Development Process Expertise

Provide industry expertise to ensure manufacturing scalability in advanced research development efforts.

Strengthen Industry Partnerships

Build and expand the collaboration between industry, BARDA, and others in the USG involved in responding to PHEs

Capacity Infrastructure Contracts

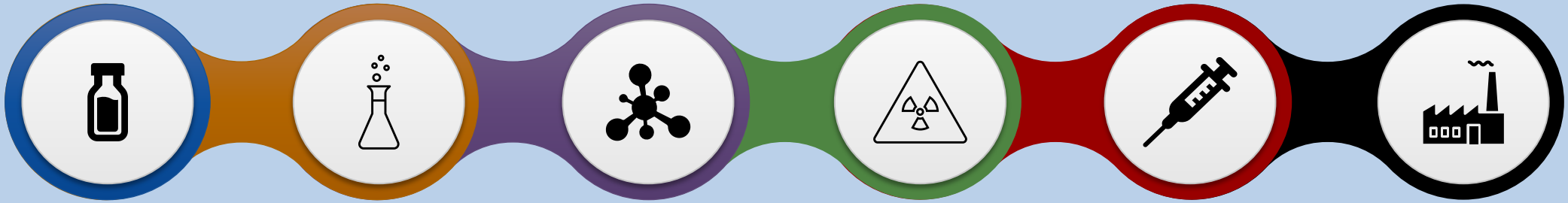
Strengthen the nation's biopharmaceutical manufacturing infrastructure to prepare and secure a comprehensive and resilient domestic MCM response PHEs

BARDA Industrial Base Expansion (IBx)

Objectives

- Mitigate bottlenecks for pandemic vaccine surge demand with appropriate redundancies and consideration for a wide range of potential vaccine scenarios.
- Increase domestic vaccine manufacturing capabilities to meet PHE demands, mitigate the risk of limited availability of other life-saving medicines, and reduce the need for rated orders.

Domestic Capacity Expansion in Six (6) Portfolio Areas



Background

COVID-19 revealed a crucial gap in the U.S.' preparedness to respond to public health emergencies (PHE).

The U.S. dependency on foreign companies for the most critical aspects of vaccine manufacturing (Needles & Syringes, Vials, Sterilization, Single Use Technologies (SUT), Raw Materials, and Fill/Finish) significantly impacted the nation's ability to rapidly and efficiently respond to the pandemic.

20+

CURRENT STATUS

BARDA awarded efforts during FY20-FY22

Most IBx agreement terms include cost-sharing between USG and industry partners and a negotiated 10-year priority access period post-construction to allow USG access during PHEs.

GOAL

BARDA's Industrial Base Expansion (IBx) program strengthens U.S. preparedness by ensuring that large-scale vaccine manufacturing capacity and the needed materials and services are available when pandemics emerge.

NEEDLES AND SYRINGES

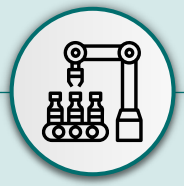
3 Active agreements

~$144M
Total USG value of contracts to date

~900M
Additional needles and syringes capacity added (per year) once all projects are completed

FILL/FINISH

6 Active agreements



~$684M
Total USG value of contracts to date

~28M
Additional fill/finish capacity added (in 10R vials/month) once all projects are completed

VIALS

4 Active agreements

~$568M
Total USG value of contracts to date

~1.36B
Additional vials capacity added (per year) once all projects are completed

SINGLE USE TECHNOLOGIES (SUT)

5
Active agreements

~$558M
Total USG value of contracts to date

Additional capacity being added for cell culture media, resins, assemblies and tubing, filters, bottles, single-use bags, and other SUT.

RAW MATERIALS

3
Active agreements

~$263M
Total USG value of contracts to date

Additional capacity being added for capping technologies, lipids, and other raw materials.

Contact Information

POC: Joseph Figlio

Email: Joseph.figlio@hhs.gov
Cell: 202-480-0145

Branch Chief, CGMP Capabilities Readiness Branch (CCR)
Division of Pharmaceutical Countermeasures & Infrastructure (PCI)
Biomedical Advanced Research and Development Authority (BARDA)
Administration for Strategic Preparedness and Response (ASPR)
US Department of Health and Human Services (DHHS)

AstraZeneca

Role of partnership in creating sustainable and resilient supply chains

Presentation to the National Vaccine Advisory Committee

Iskra Reic
Executive Vice President, Vaccines & Immune Therapies

Tonya Villafana
Global Franchise Head mAbs & Head of Scientific Affairs,
Vaccines & Immune Therapies

February, 2024

Developing and ensuring stable supply chains for public health through partnership and collaboration

Iskra Reic

Executive Vice President, Vaccines & Immune Therapies

Tonya Villafana

VP, Global Franchise Head mAbs & Head of Scientific Affairs, Vaccines & Immune Therapies

An AstraZeneca perspective on lessons learned to prevent immunization-related shortages

Acceleration

Rapidly establishing supply networks

Preparation

Planning for fast immunization uptake

Flexibility

Responding to a rapidly-changing environment

Our commitment to public health

An ambition to protect and treat patients with vaccines and antibodies that provide effective and long-lasting immunity

- Prioritisation of **pathogens with significant burden of disease** and pandemic threat
- **Ongoing commitment to vulnerable populations**, including infants, the immunocompromised and the elderly
- **Investment in next generation**, differentiated platforms and **innovative mechanisms** to improve access
- Addressing future public health priorities, including the **growing challenge of antimicrobial resistance**

Delivering highly targeted antibody therapies and differentiated vaccines

Vaxzevria COVID-19 Vaccine (ChAdOx1-S [recombinant])

FluMist Quadrivalent Influenza Vaccine Live, Intranasal

Beyfortus

EVUSHELD tixagevimab, cilgavimab

SYNAGIS PALIVIZUMAB

Acceleration

AZ's unmatched response to develop and deliver the COVID-19 vaccine required a rapid response

Expansive clinical trials

Global clinical trials, 20 trials recruiting ~65,000 volunteers

25+ supply partners in 15 countries

Established supply capacity to enable broad, equitable access towards 3bn doses worldwide

International Corporation

Cooperation with governments, health authorities and academia to establish supply agreements

AstraZeneca provided a COVID-19 vaccine for the world

6 million+

Lives saved during first 12 months of use[1]

3.1 billion+

doses of our vaccine released for supply[2]

180+

countries around the world[2]

>2/3

of these doses have gone to low- and low-middle income countries[2]

1. Data estimates based on model outcomes from separate analyses conducted by Airfinity and Imperial College, United Kingdom. AZ Data on File. Ref – 156573, 11 July 2022. AstraZeneca UK Ltd
2. AstraZeneca and COVAX supply data

Planning for the fastest pediatric immunization uptake in recent history with novel use of a mAb as passive immunization

Planning for Implementation Access and Coverage

Beyfortus is the **first mAb** to be used in **routine paediatric immunisation**

Early engagement with **regulators** and **recommending bodies** critical to drive positive AMDAC and ACIP recommendation and VFC coverage

Preparing for rapid scale-up and broad deployment

Advanced planning to prepare for scale-up of **production** and **distribution** to meet demand

- Availability of raw materials to create **drug substance**
- **Manufacturing** capabilities to **produce** and fill **product**
- Supply of **components** like syringes, stoppers and needles

Public-Private collaboration

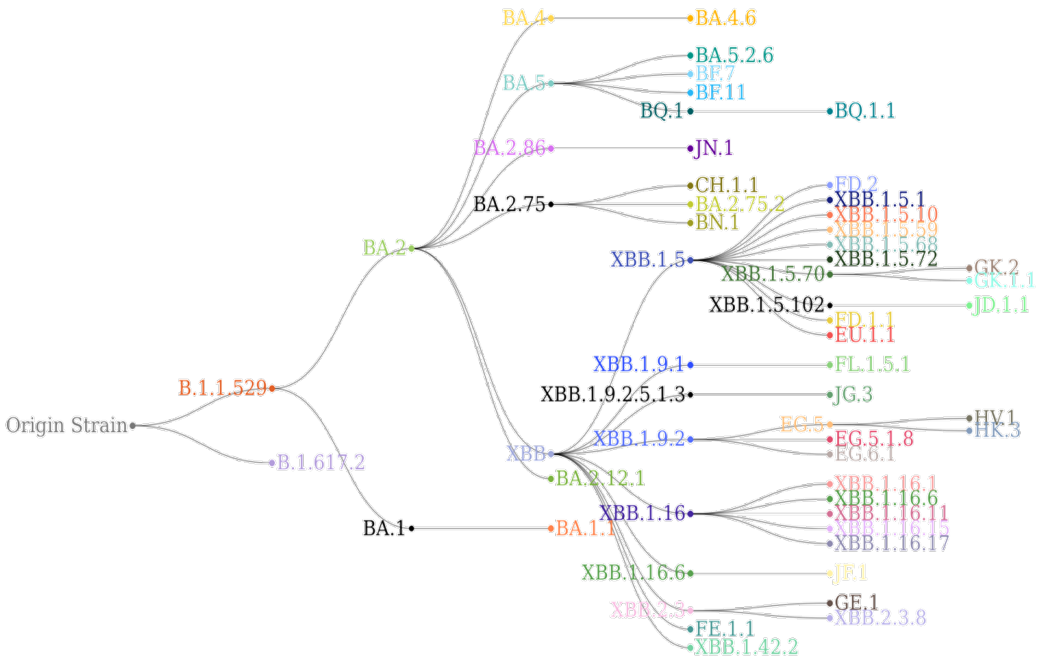
Unprecedented demand requires **expansion** of **network** and **government collaboration** against **shared goals**

…exceeding initial orders and delivering almost 2 **million doses**

Rapid scale-up to meet fastest uptake of the world's first immunization to protect all infants against serious lung disease caused by RSV

Addressing a volatile COVID-19 variant landscape requires flexibility in development, supply and regulatory strategy

Evolution of SARS-CoV-2 has resulted in a swarm of currently circulating variants



Sources: Centers for Disease Control SARS CoV-2 variantt tracking

Flexibility is critical to keep pace with viral evolution

Antibodies discovered early in the pandemic lost neutralizing ability ~1-2 years after authorization due to emergence of mutations

Antibody Discovery

Requirement for updated mAbs e.g. sipavibart (AZD3152) to protect immunocompromised and other high-risk patient populations

Innovative (e.g., AI enabled) discovery of multiple antibodies targeting diverse epitopes prior to emergence of variants

Regulatory and Clinical Frameworks

Regulatory and clinical pathways need to allow for rapid assessment, authorization and approval

Manufacturing and Supply

Investment in manufacturing capacity and supply networks to maximize lifespan of mAbs before emergence of escape variants delivering several hundred thousand doses

Observations and key recommendations

Partnership between health authorities, advisory committees and **industry is critical** to achieve shared public health goals

Ensure regulatory pathways exist to permit innovative clinical trial design and allow timely authorisation of new preventative solutions

Encourage recommending bodies support for broad and equitable access

Support availability of flexible supply infrastructures, including CMOs and manufacturing components

Align industry and public stakeholders on burden of disease, demand forecast and intervention monitoring

Thank you

Centers for Disease Control and Prevention
National Center for Immunization and Respiratory Diseases

Managing Vaccine Supply Shortages in the US

Role of CDC

Jeanne M. Santoli (ISD/NCIRD/CDC)

February 22, 2024, National Vaccine Advisory Committee Meeting

Agenda

- Monitoring
- Communication/Coordination
- Pediatric Vaccine Stockpile Program
- Controlled Vaccine Ordering
- Interim Vaccine Recommendations
- Examples:
  - Hepatitis A (2017)
  - Shingrix (2018)
  - Nirsevimab (2023)

Monitoring

- CDC purchases vaccines to vaccinate eligible children and adults with routinely recommended vaccines.

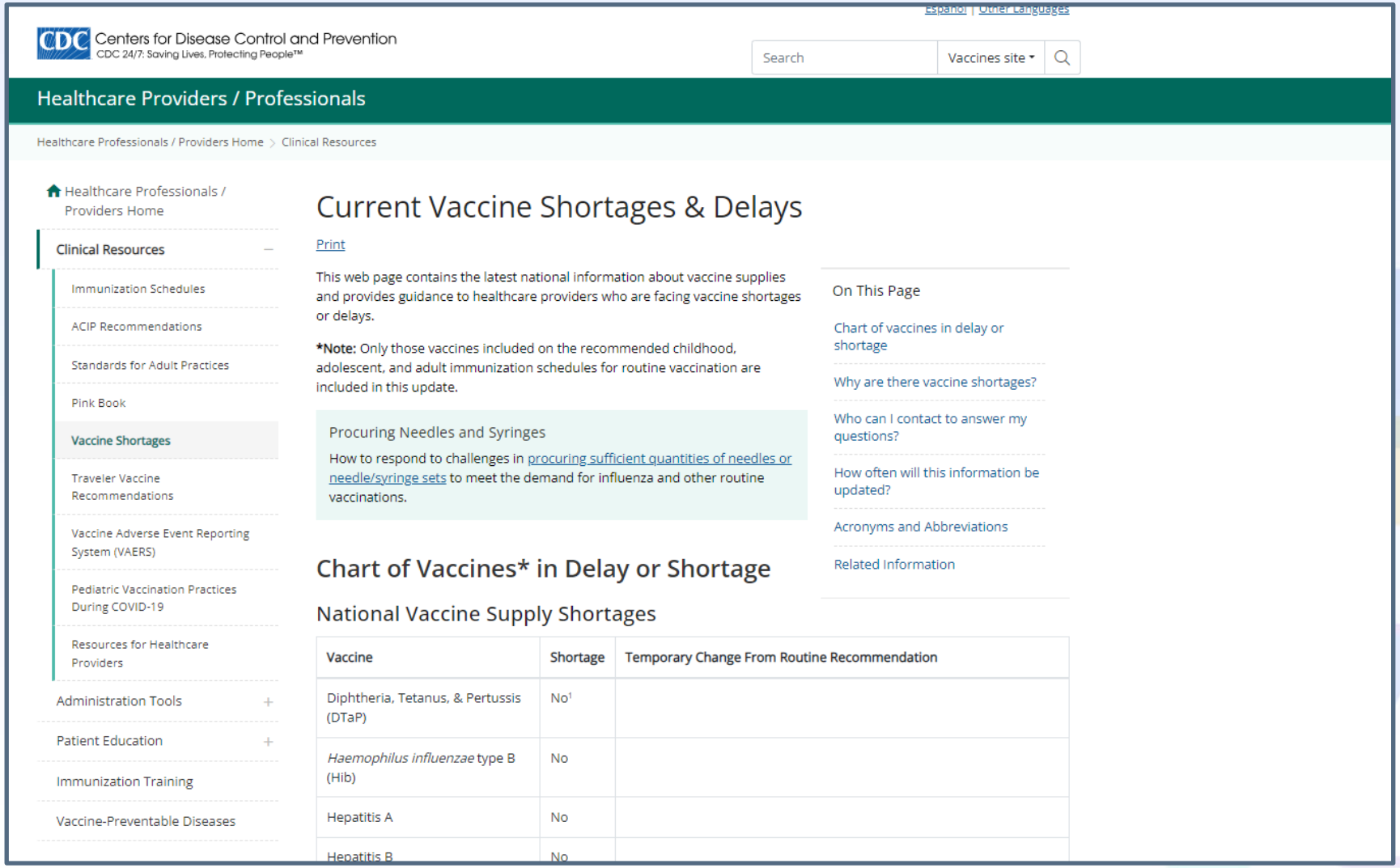
- The contracts have a requirement for manufacturers to provide advanced notice of vaccine supply issues to CDC as soon as they become aware of an inability to fill orders timely (e.g., a manufacturing problem that is expected to lead to decreased vaccine availability).

- This requirement provides CDC with visibility to anticipated supply issues.

Communication/Coordination

- Once notified by a manufacturer, CDC seeks permission to share confidential information with manufacturers of alternative vaccines for contingency planning.
- CDC maintains a point of contact and communicates as needed with the Product Shortage Coordinator in FDA's Center for Biologics Evaluation and Research (CBER).
- CDC program staff meet as needed to plan with/update key stakeholders, including provider organizations; public health organizations; US Food and Drug Administration; and CDC disease experts.
- CDC maintains a public-facing webpage to communicate with providers and the public about supply shortages and disruptions for routinely recommended vaccines.

CDC Vaccine Supply Shortage Webpage (Current Vaccine Shortages and Delays | CDC)



Español | Other Languages

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Search | Vaccines site

Healthcare Providers / Professionals

Healthcare Professionals / Providers Home > Clinical Resources

- Healthcare Professionals / Providers Home
- Clinical Resources
  - Immunization Schedules
  - ACIP Recommendations
  - Standards for Adult Practices
  - Pink Book
  - Vaccine Shortages
  - Traveler Vaccine Recommendations
  - Vaccine Adverse Event Reporting System (VAERS)
  - Pediatric Vaccination Practices During COVID-19
  - Resources for Healthcare Providers
- Administration Tools
- Patient Education
- Immunization Training
- Vaccine-Preventable Diseases

Current Vaccine Shortages & Delays

Print

This web page contains the latest national information about vaccine supplies and provides guidance to healthcare providers who are facing vaccine shortages or delays.

***Note:** Only those vaccines included on the recommended childhood, adolescent, and adult immunization schedules for routine vaccination are included in this update.

Procuring Needles and Syringes

How to respond to challenges in procuring sufficient quantities of needles or needle/syringe sets to meet the demand for influenza and other routine vaccinations.

On This Page

- Chart of vaccines in delay or shortage
- Why are there vaccine shortages?
- Who can I contact to answer my questions?
- How often will this information be updated?
- Acronyms and Abbreviations
- Related Information

Chart of Vaccines* in Delay or Shortage

National Vaccine Supply Shortages

Vaccine	Shortage	Temporary Change From Routine Recommendation
Diphtheria, Tetanus, & Pertussis (DTaP)	No[1]	
Haemophilus influenzae type B (Hib)	No	
Hepatitis A	No	
Hepatitis B	No	

Pediatric Vaccine Stockpile Program

- The Vaccines for Children program (VFC) statute authorizes CDC to purchase vaccine stockpiles of routinely recommended pediatric vaccines disruptions.
- Stockpiles are dynamic storage and rotation stockpiles (vendor-held), to ensure vaccine viability and reduce waste. Target size is defined as a six-month supply of VFC vaccine usage.
- CDC loans stockpiled vaccines to manufacturers to mitigate shortages.

Controlled Vaccine Ordering

- CDC implements controlled vaccine ordering in the public sector in the following circumstances:
  - Supply is not sufficient to meet the ACIP-recommended schedule.
  - Ample but tight supply (no redundancy).

- Controlled ordering works by placing limits on how much vaccine each jurisdiction can order; limits are calculated to facilitate each jurisdiction having access to an equitable share of available vaccine.
  - Ordering limits based on relative proportion of each jurisdiction's ordering for similar vaccines or cohorts when supplies are not constrained.

- Manufacturers often implement ordering controls in the private sector; the approach used varies by manufacturer.

Interim Vaccine Recommendations

- If insufficient vaccine is available to fulfill ACIP's recommended routine vaccination schedules, interim vaccine recommendations may be issued by CDC.
- An interim vaccine recommendation is a temporary change in the recommended vaccination schedule implemented to conserve limited supply and/or ensure protection of persons at highest risk.
- Interim recommendations may temporarily target limited vaccine to high-risk individuals and/or reduce the number of doses offered in a multi-dose series.

Shortage/Supply Constraint Examples

Example: Adult Hepatitis A Vaccine (2017)

- Root cause: Large outbreaks of Hepatitis A among adults in several US cities/states occurred starting in 2017, resulting in increased demand for adult vaccine well beyond routine usage.

- As an adult-only product, the vaccine is not held in CDC's stockpile, so stockpiled doses were not available to mitigate the shortage.

- The following actions were used to manage supply constraints:
  - Collaboration with both manufacturers of adult Hepatitis A vaccine to manage orders and increase national supply.
  - Provision of technical assistance to public health officials in jurisdictions with outbreaks to assist them in targeting doses.
  - Implementation of ordering controls in the public and private sectors to support outbreak responses, maintain availability nationally.

Example: Zoster Vaccine (2018)

- Root cause: Higher than anticipated levels of demand, along with a preferential recommendations for the newly licensed zoster vaccine from GSK (Shingrix) resulted in extended vaccine supply constraints beginning shortly after launch.
- As an adult-only product, the vaccine is not held in CDC's stockpile, so stockpiled doses were not available to mitigate the shortage.
- The following actions were used to manage supply constraints:
  - Manufacturer took steps to increase production/packaging capabilities and delayed non-US launches to support US demand.
  - Provision of guidance to emphasize the importance of the second dose in the series and reiterate that the series did not need to be restarted if the recommended interval between doses has been exceeded.
  - Implementation of ordering controls in the public and private sectors to facilitate equity across jurisdictions and customer segments.

Example: Nirsevimab Monoclonal Antibody (2023)

- Root cause: Demand for the product exceeded the quantity planned by the manufacturer for the first season; insufficient product, particularly for infants born prior to the season, was available at launch.
- As a new product, nirsevimab is not part of CDC's stockpile, so stockpiled doses were not available to mitigate the shortage.
- The following actions were used to manage supply constraints:
  - Collaboration between USG and manufacturers to manage orders and increase national supply
    - An additional ~ 300K doses for the public/private sectors during the 2023-2024 season (~30% increase).
    - Major focus on planning and identifying potential challenges for the 2024-2025 season.
  - Provision of guidance for prioritizing vaccine, particularly 100mg doses.
  - Implementation of ordering controls in the public and private sectors to facilitate equity across the country because initial ordering varied significantly by provider and jurisdiction.

Wrapping Up

- Vaccine supply constraints and shortages are not infrequent

- Causes include manufacturing issues and problems, vaccine preventable disease outbreaks, demand that exceeds supply

- CDC plays a role in managing and mitigating supply issues through:
  - Monitoring, communication and coordination
  - Maintaining and leveraging pediatric vaccine stockpiles
  - Implementing ordering controls in the public sector
  - Issuing interim vaccine recommendations for providers when necessary

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Strong Supply Chains: Opportunities to Thwart Shortages

Discussion

NVAC

A Cornerstone in Childhood Immunization: State Policies for School Entry

Darlene Huang Briggs
Dr. Georgina Peacock
Jennifer Fulcher
Dr. Dorit Rubinstein Reiss

NVAC

The Network for Public Health Law

Ideas. Experience. Practical Answers.

Navigating Changes to the Vaccine Policy Landscape

Darlene Huang Briggs, JD, MPH
dhbriggs@networkforphl.org

National Vaccine Advisory Committee | February 22, 2024

ACT for Public Health


ACT for Public Health


Health law partners addressing challenges to public health authority and infrastructure.

ChangeLab Solutions

Temple University Beasley School of Law

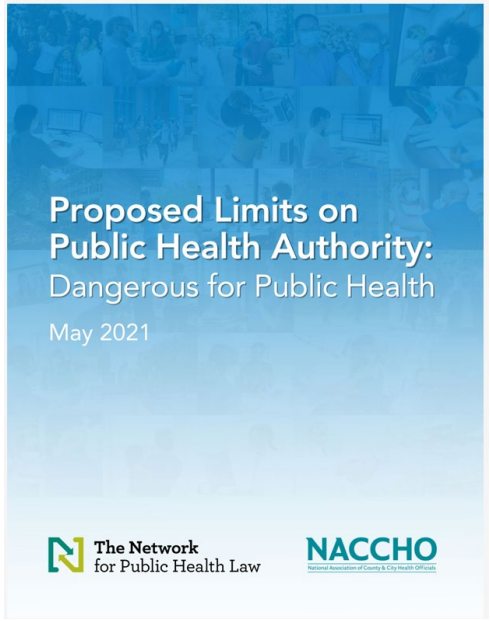
Public Health Law Watch

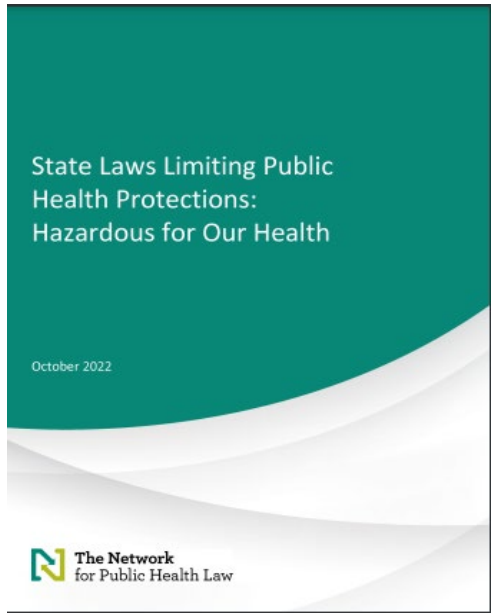
Public Health Law Center at Mitchell Hamline School of Law

The Network for Public Health Law

Perhaps more than at any other time in its history, public health is being directly and significantly impacted by how laws and policies are being implemented—or weakened.

Coordinated backlash





Prohibitions on Public Health Interventions

Shifts in Authority

Limitations on Public Health Orders

Elevation of Individual Rights Over the Common Good

Dataset Live on LawAtlas.org now!

Temple University Beasley School of Law | Center for Public Health Law Research

THE POLICY SURVEILLANCE PROGRAM
A LawAtlas Project

State Bills Relating to Vaccines in Schools and Provider Scopes of Practice

All 50 states and the District of Columbia require vaccinations for school entry. Since the emergence of the COVID-19 vaccine, a debate has emerged around compulsory vaccinations for school-age children and parental rights. In some states, COVID-19 vaccines became the newest battleground for anti-vaccine efforts more broadly, leading to the introduction of bills during the 2023 legislative session seeking to restrict the use of — or expand exemptions to — school requirements. At the same time, state legislatures continued to introduce bills expanding vaccination access by changing the scope of practice for providers like midwives, pharmacists, dentists and dental hygienists, and others to allow them to administer vaccinations.

This longitudinal dataset captures legislation addressing school entry vaccination requirements, non-medical exemptions to school vaccination requirements, the reallocation of authority to determine vaccination requirements for schools, and expansions to provider scope of practice to administer vaccines between January 1, 2023, and May 22, 2023, in all 50 US states and the District of Columbia.

CREATED BY: Center for Public Health Law Research Staff
MAINTAINED BY: Center for Public Health Law Research Staff
VALID FROM: January 1, 2023
UPDATED THROUGH: May 22, 2023

Data Codebook Protocol

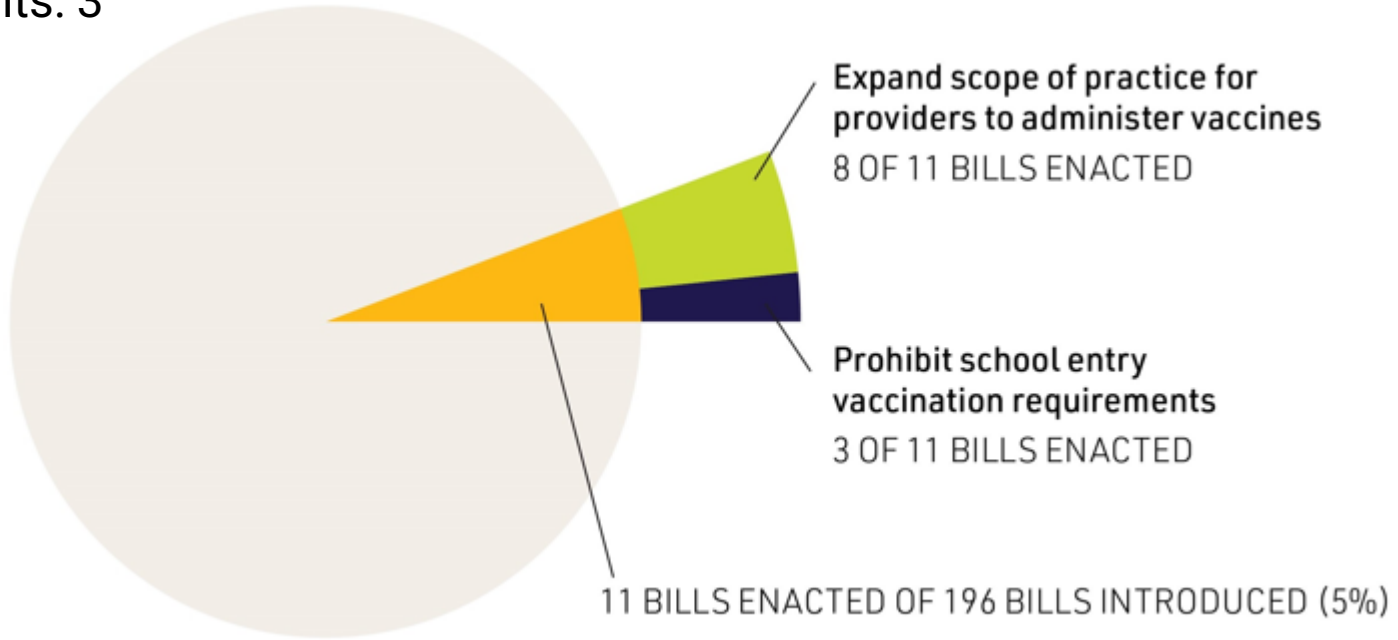
See all related maps

https://lawatlas.org/datasets/act-for-public-health-vaccine-bills

Temple University
Beasley School of Law
Center for Public Health Law Research

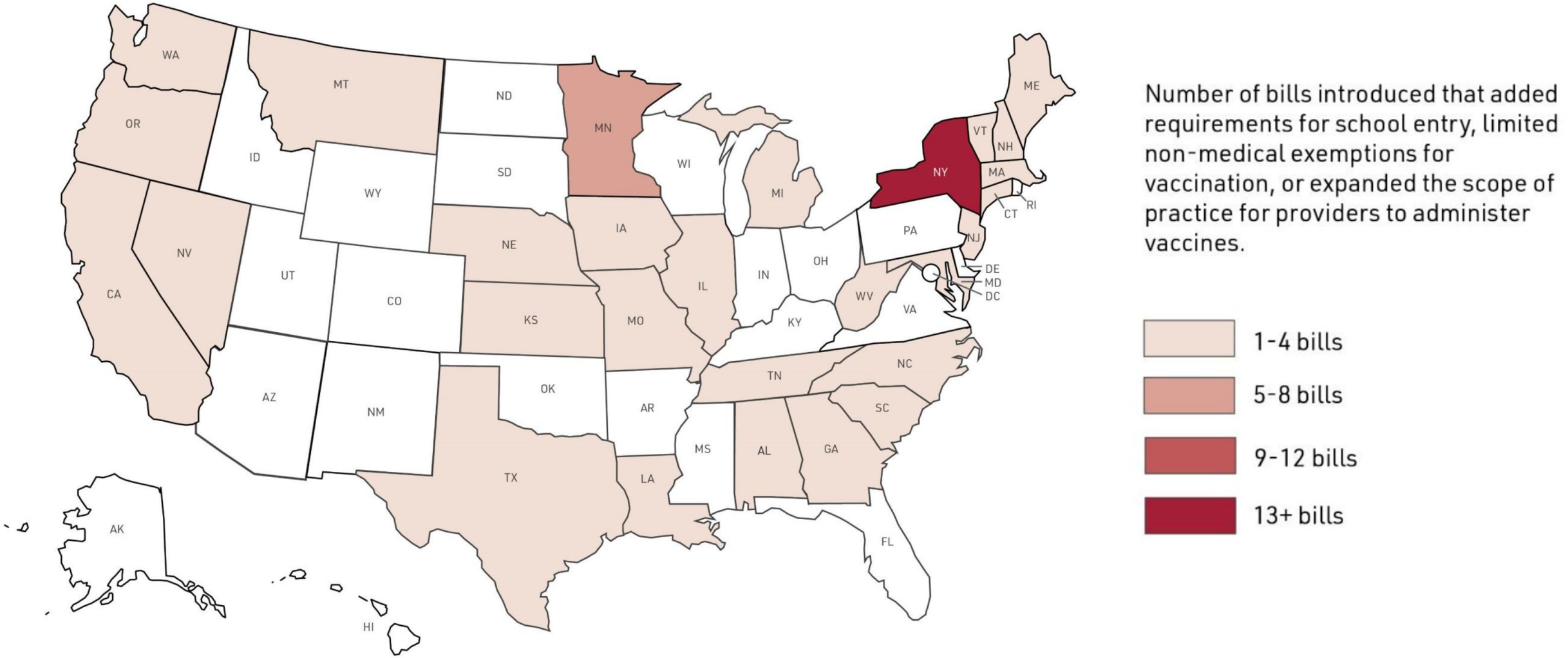
196 Total Introduced Bills
January 1 – May 22, 2023

- Total Enacted Bills: 11
  - Expanding SOP: 8
  - Prohibit school vaccine requirements: 3
- Passed First Chamber: 13
- Passed Second Chamber: 5
- Didn't pass either chamber: 167



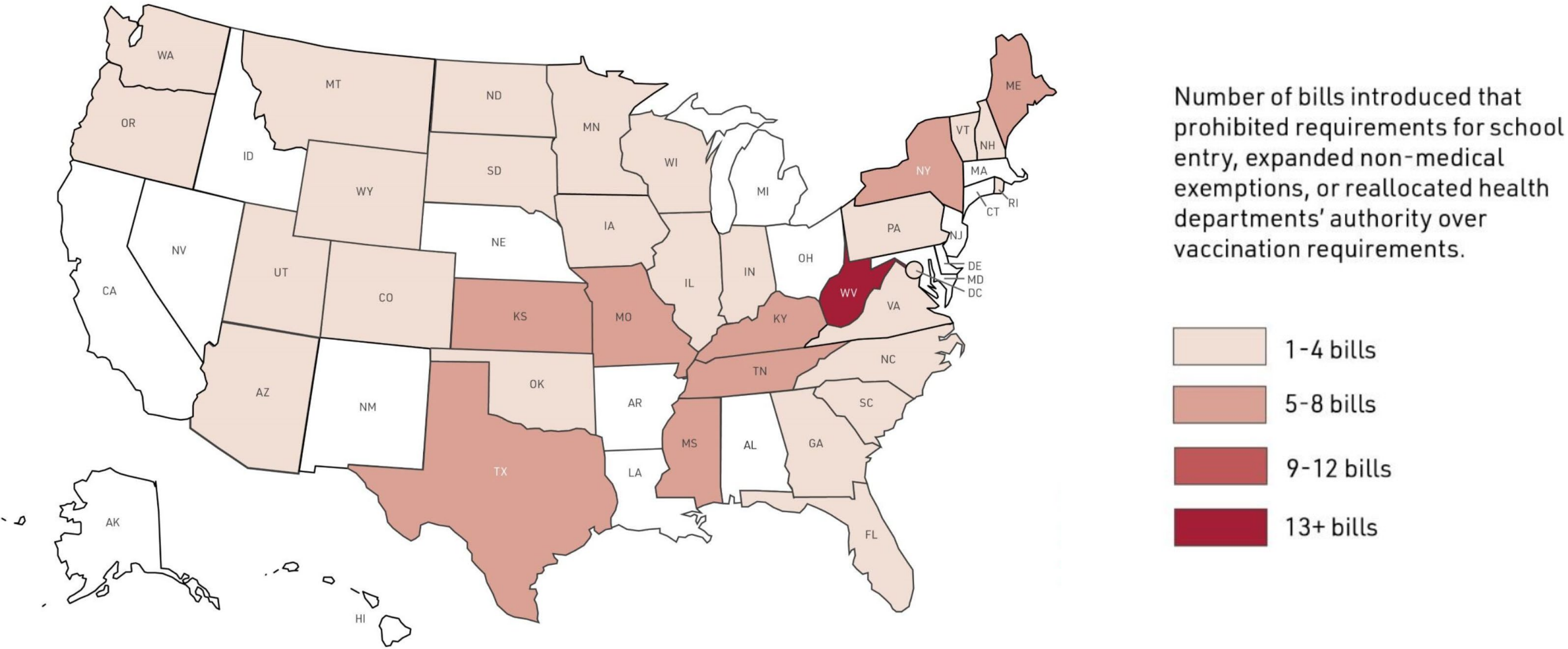
Bills Promoting Vaccination

Added Vaccination Requirements for School Entry, Limited Non-Medical Exemptions, or Expanded Provider Scopes of Practice to Administer Vaccines



Bills Limiting Vaccination

Prohibited Vaccination Requirements for School Entry, Expanded Non-Medical Exemptions, or Reallocated Health Agency Control Over Vaccination Requirements



Doctrinal Roots of Vaccine Law

"Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof."
1st Amend., US Cons't.

A **3-legged stool**

Jacobson v. Mass.

Employment Division v. Smith

Church of Lukumi Babalu Aye v. Hialeah

Almost all traditional public health laws including vaccine mandates survived FE challenges

But federal & state statutes, including RFRA & Title VII provided extra protections for religious objectors.

PUBLIC HEALTH LAW WATCH

COVID Litigation: The Decline of Deference

Jacobson v. Massachusetts (1905)

South Bay United Pentecostal Church v. Newsom (2020)

Chief Justice Roberts, quoting *Jacobson*: "Our Constitution principally entrusts '[t]he safety and the health of the people' to the politically accountable officials of the States 'to guard and protect.'"

Throughout pandemic, less and less deference afforded to public health agencies

PUBLIC HEALTH LAW WATCH

Impact on Childhood Vaccines

- Since the start of the pandemic, support for childhood vaccine mandates has fallen
- Litigants are now using the COVID cases to challenge childhood vaccine laws
- ***Bosarge v. Edney,* No. 1:22-cv-00233-HSO-BWR (S.D. Miss. Aug. 29, 2023)**
  - If the state offers medical exemptions, they must also provide religious exemptions to not violate Free Exercise
- ***Fox v. Makin,* No. 2:22-cv-00251-GZS (D. Me. Aug. 16, 2023)**
  - Case recently allowed to move forward
  - Argues that Maine's medical exemptions have loopholes, so the state barring all religious exemptions may violate Free Exercise

PUBLIC HEALTH LAW WATCH

Non-Medical State Exemptions from School Immunization Requirements

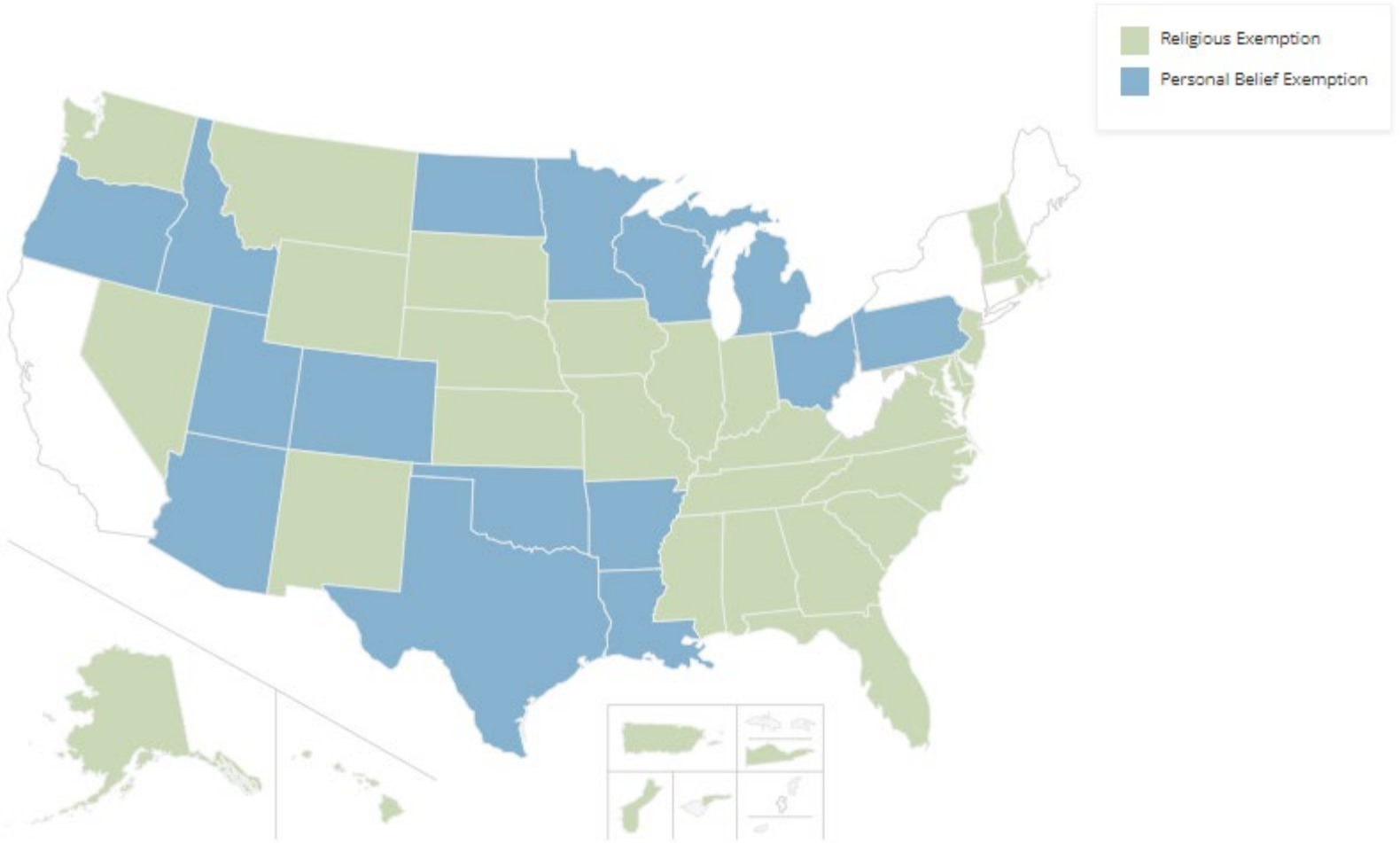


Image credit: https://www.ncsl.org/health/states-with-religious-and-philosophical-exemptions-from-school-immunization-requirements


ACT for Public Health


Visit the Act for Public Health Website

actforpublichealth.org

- Request assistance
- Join the email list
- Learn about public health authority
- View resources
- Sign up for events

ChangeLab Solutions

Temple University Beasley School of Law

PUBLIC HEALTH LAW WATCH

PUBLIC HEALTH LAW CENTER at Mitchell Hamline School of Law

The Network for Public Health Law

Increasing Vaccination Coverage Among Children in Kindergarten

Georgina Peacock, MD, MPH, FAAP
Director, Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)

CDC's National Center for Immunization and Respiratory Diseases/ Immunization Services Division

Vision: Increase vaccination coverage to support healthier living for all

Mission: Protect individuals and communities from vaccine-preventable diseases

Immunization Services Division (ISD) Goals

- Increase Vaccine Access
- Promote Vaccine Confidence & Demand
- Enhance Data, Research, and Evaluation
- Strengthen Program Support for Partners
- Improve Vaccine Equity
- Enhance Vaccination Response Readiness

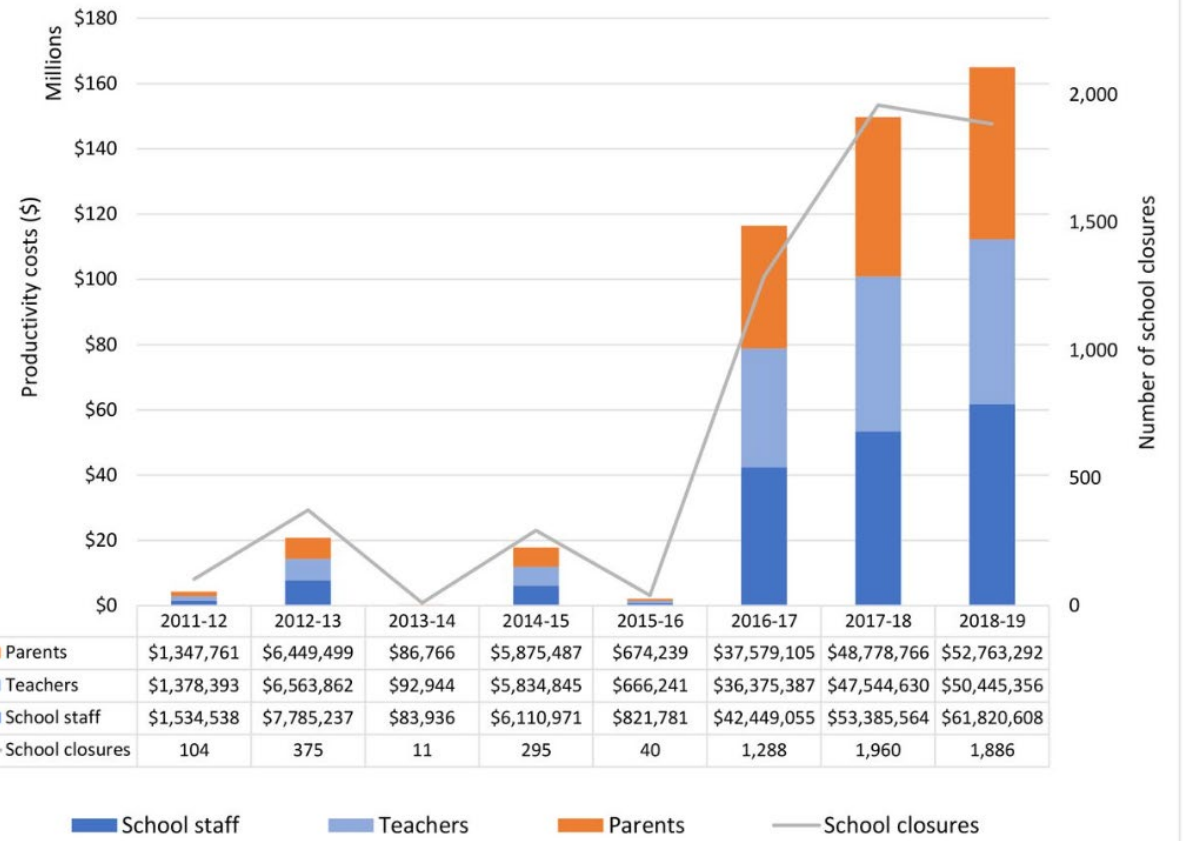
Why does high vaccination coverage matter for families and schools?

Vaccinations optimize student health

- **Provide immunity** and prevent disease outbreaks.
- **Reduce the spread of disease** and the:
  - Number of students and teachers that get sick and are absent.
  - Probability of an unplanned school closure due to illness.
- **Reduce the number of missed school days** due to poor health.

Illness contributes to student absences and unplanned school closures

Frequency of school closures due to Influenza like illness (ILI) from 2011/12 to 2018/19 school year

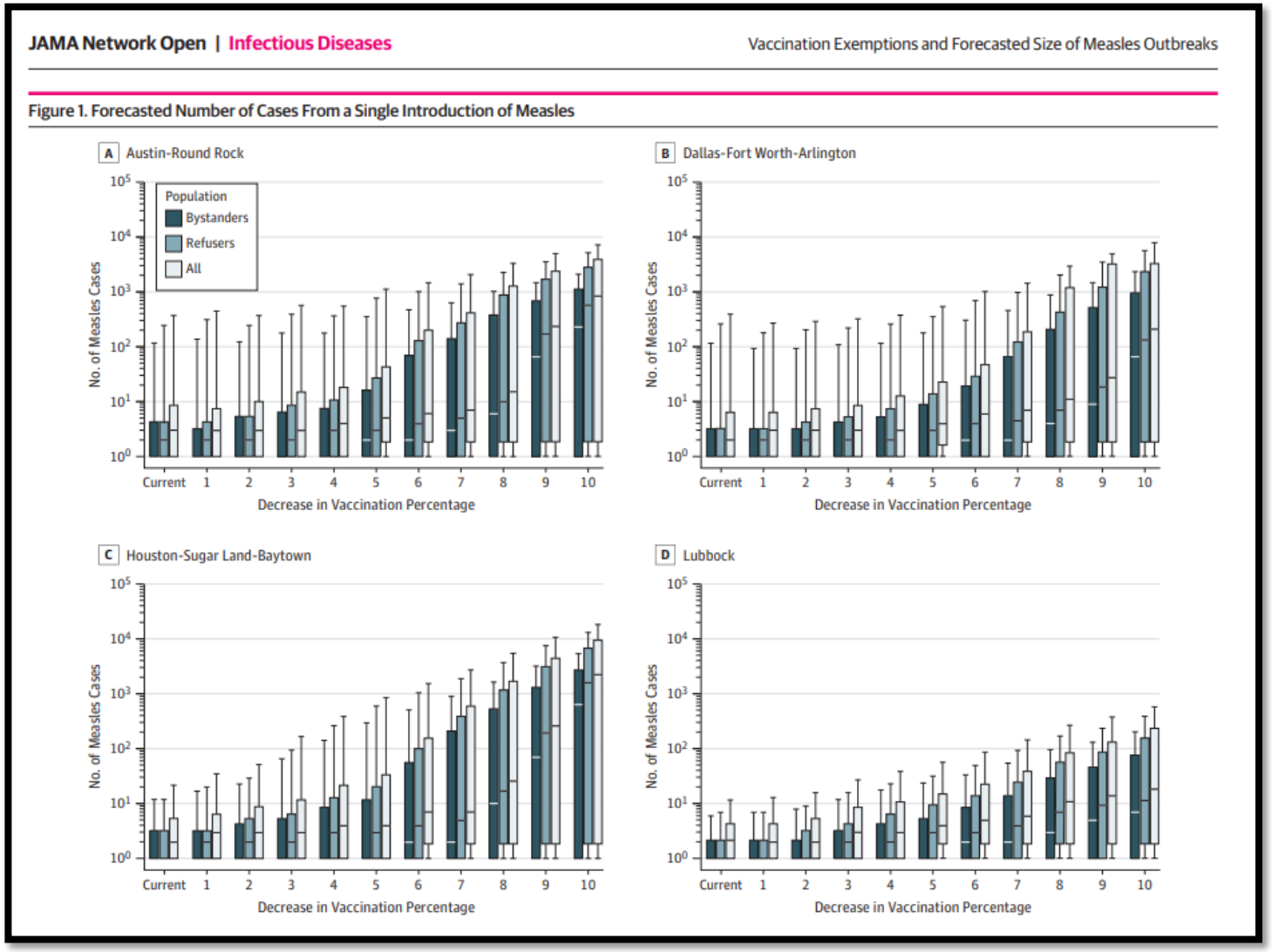


	2011-12	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19
Parents	$1,347,761	$6,449,499	$86,766	$5,875,487	$674,239	$37,579,105	$48,778,766	$52,763,292
Teachers	$1,378,393	$6,563,862	$92,944	$5,834,845	$666,241	$36,375,387	$47,544,630	$50,445,356
School staff	$1,534,538	$7,785,237	$83,936	$6,110,971	$821,781	$42,449,055	$53,385,564	$61,820,608
School closures	104	375	11	295	40	1,288	1,960	1,886

- On average, students/teachers **miss 3–5 days of school per ILI illness.**
- Quarantine for measles exposure is 21 days for unvaccinated students.
- **5,959 total** ILI related school **closures, 96%** were in **public schools.**
- Most school closures **lasted an average 2 days.**
- Average productivity cost per closure **~$53,000.**

Productivity costs associated with reactive school closures related to influenza or influenza-like illness in the United States from 2011 to 2019

Drops in vaccine coverage put schools at risk for exponentially larger disease outbreaks



Forecasted Size of Measles Outbreaks Associated With Vaccination Exemptions for Schoolchildren

Even missing a few days of school can negatively impact student's academic performance

Percentage distribution of 8th-graders and percentage at or above *Basic* on the National Assessment of Educational Progress (NAEP) mathematics assessment, by the number of days absent from school in the past month and race/ethnicity: 2009

Race/ethnicity	Total	No absences	1–2 absences	3 or more absences
		Percentage distribution		
Total[1]	**100**	**45**	**35**	**20**
White	100	44	37	19
Black	100	45	32	23
Hispanic	100	45	34	22
Asian/Pacific Islander	100	63	26	11
American Indian/Alaska Native	100	35	36	28
		Percentage at or above *Basic*		
Total[1]	**73**	**78**	**74**	**60**
White	83	87	84	73
Black	50	56	50	38
Hispanic	57	63	58	44
Asian/Pacific Islander	85	89	84	68
American Indian/Alaska Native	56	64	59	43

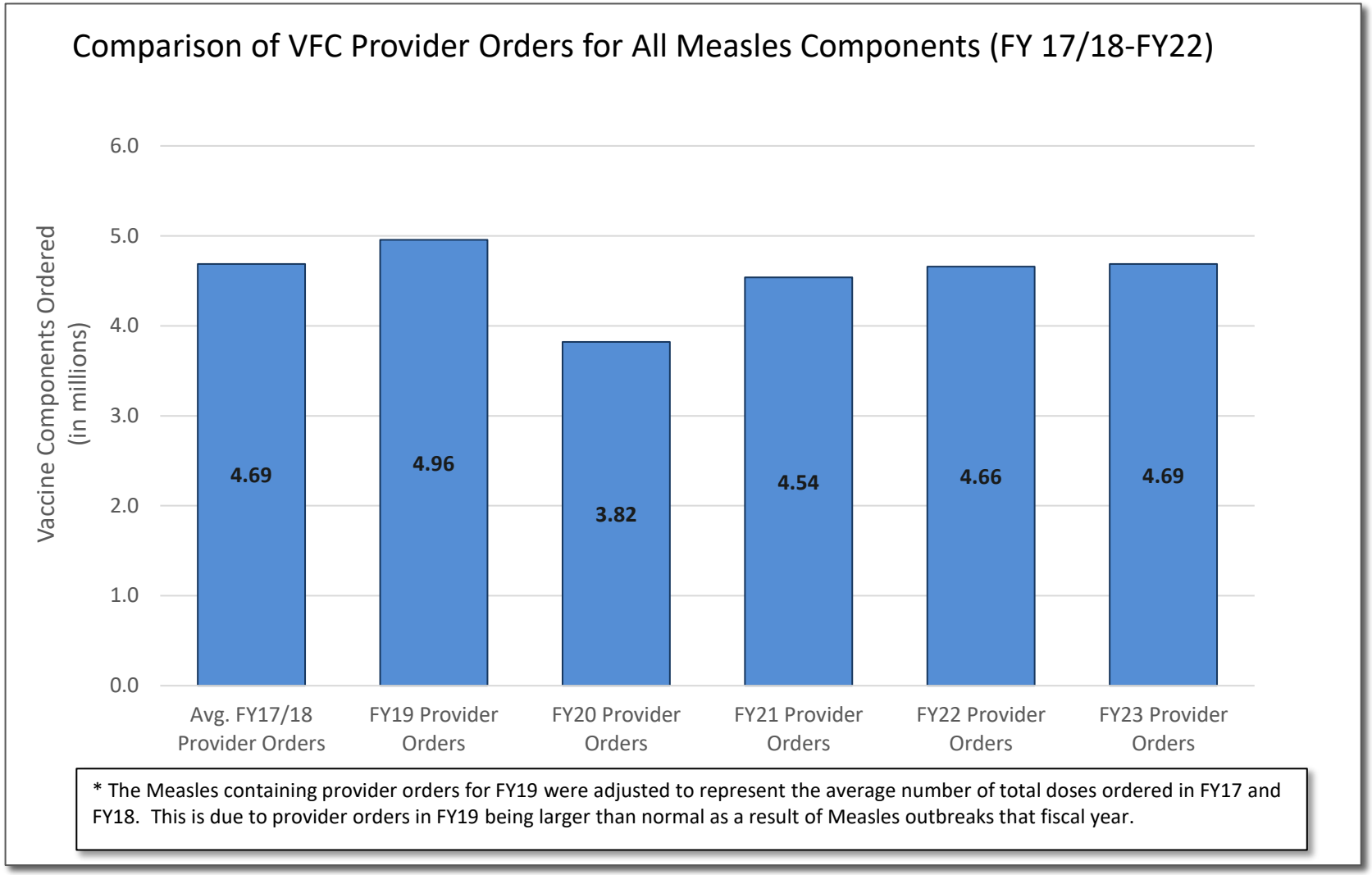
[1] Total includes other race/ethnicity categories not separately shown.
NOTE: Race categories exclude persons of Hispanic ethnicity. Detail may not sum to totals because of rounding.
SOURCE: U.S. Department of Education, National Center for Education Statistics, National Assessment of Educational Progress (NAEP), 2009 Mathematics Assessment, retrieved November 18, 2009, from the NAEP Data Explorer (http://nces.ed.gov/nationsreportcard/nde).

Present, Engaged, and Accounted For: The Critical Importance of Addressing Chronic Absence in the Early Grades; Table 16.

NCES National Center for Education Statistics

How has the pandemic affected routine school vaccination among kindergarteners?

Vaccines For Children Provider Orders for All Measles Components by Fiscal Year



Compared to FY17/18

- FY2020: Total vaccine orders **decreased 18.5%**
- FY2021: Total vaccine orders **down 3%**
- FY2022: Total vaccine orders **down 1%**
- FY2023: Total vaccine orders are **similar**

CDC Vaccine Tracking System (VTRckS)

Steady decline in vaccination coverage among kindergartners during the pandemic

Estimated vaccination coverage among kindergartners by vaccine— United States, 2019–20, 2020–21, 2021–22, and 2022–23 school years

Kindergarten Coverage	2019–20 (pre-pandemic)	2020–21 (pandemic)	2021–22 (pandemic)	2022–23 (pandemic)
MMR	**95.2%**	93.9%	93.0%	**93.1%**
DTaP	**94.9%**	93.6%	92.7%	**92.7%**
Polio	**95.0%**	93.9%	93.1%	**93.1%**
Varicella (UTD)	**94.8%**	93.6%	92.8%	**92.9%**

2% drop in Kindergarten vaccination coverage since the start of the pandemic

725,000 children, who entered kindergarten during the pandemic, **are susceptible to vaccine preventable disease**

Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2019–20, 2020–21, 2021–22, and 2022–23

Lingering pandemic effects on kindergarten vaccination

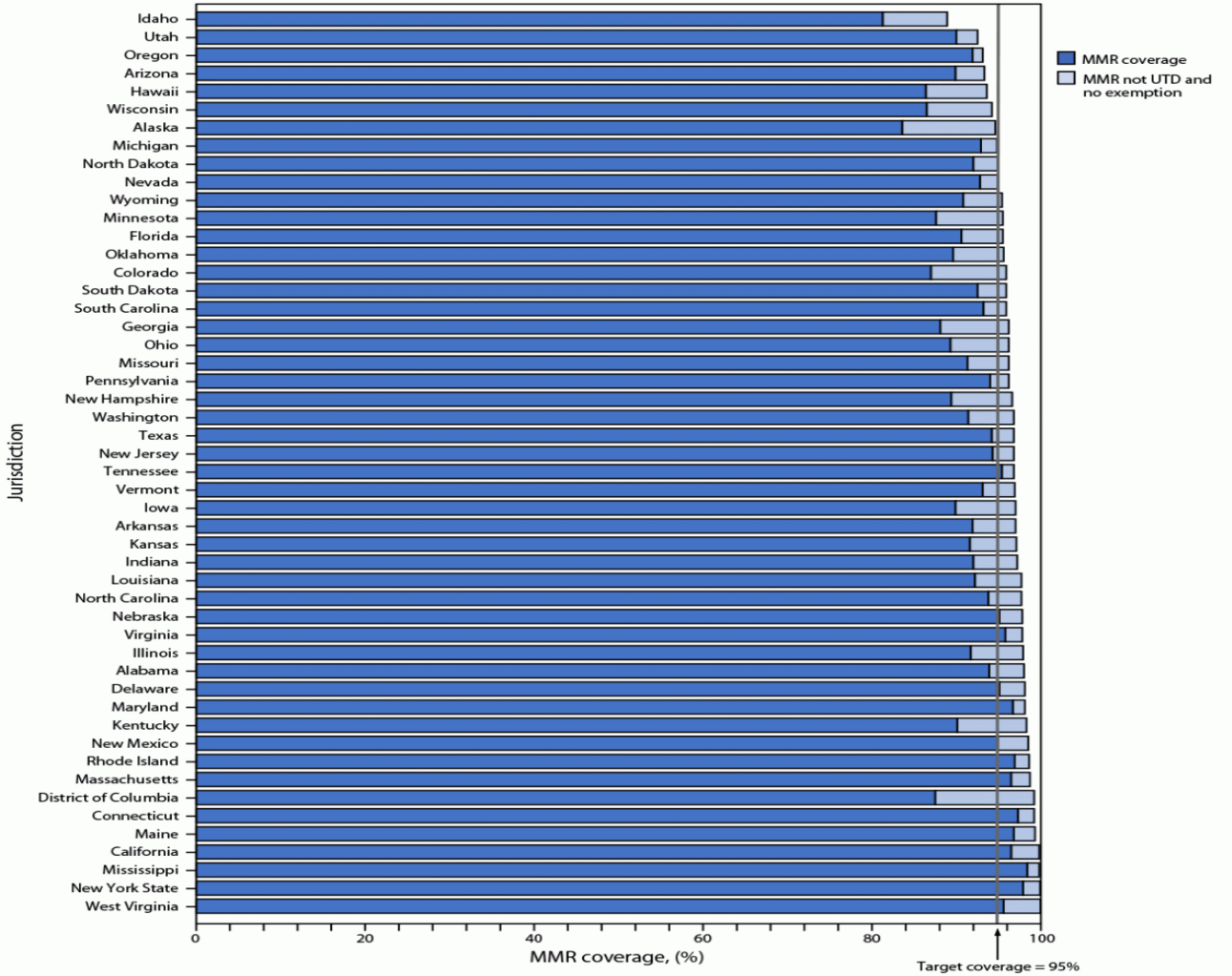
- Decrease in reported **kindergarten enrollment** compared to 2019–20 school year
  - Decrease of 10% (~400,000 students) in 2020–2021
  - Decrease of 4.7% (~190,000) students) in 2021–2022
  - Decrease of 4.8% (~193,000) students) in 2022–2023

- Increase in **grace period**/provisional enrollment
  - 1.6% in 2019–2020 school year
  - 2.0% in 2020–2021
  - 2.4% in 2021–2022
  - 2.5% in 2022–2023

- Increase in **exemption** rates compared to 2019–20 school year
  - 2.5% in 2019–2020 school year
  - 2.2% in 2020–2021
  - 2.6% in 2021–2022
  - 3.0% in 2022–2023

Most states can achieve at least 95% MMR vaccine coverage among kindergartners

Potentially achievable coverage*,†,§ with measles, mumps, and rubella vaccine among kindergartners, by jurisdiction — United States, 2022–23 school year



Nationwide, 3.9% of kindergarten students were not fully vaccinated and not exempt.

- 10 states reported that >5% of kindergartners were exempt
- **All but these 10 states could potentially achieve ≥95% MMR coverage if all nonexempt, not up-to-date children were vaccinated**, compared with all but four states during the 2021–22 school year

Abbreviations: MMR = measles, mumps, and rubella vaccine; UTD = up to date.
* Jurisdictions are ranked from lowest to highest potentially achievable coverage. Potentially achievable coverage is estimated as the sum of the percentage of students with UTD MMR and the percentage of students without UTD MMR and without a documented vaccine exemption. Montana did not report kindergarten vaccination coverage for the 2021–22 and 2022–23 school years and is excluded from this analysis.
† The exemptions used to calculate the potential increase in MMR coverage for Alaska, Arizona, Arkansas, Colorado, Delaware, District of Columbia, Idaho, Illinois, Maine, Massachusetts, Michigan, Minnesota, Missouri, Nebraska, Nevada, New York, North Carolina, Oklahoma, Oregon, Rhode Island, Texas, Utah, Vermont, Washington, Wisconsin, and Wyoming are the number of children with exemptions specifically for MMR. For all other jurisdictions, numbers are based on an exemption for any vaccine.
§ Potentially achievable coverage in Alaska, Arizona, Hawaii, Idaho, Michigan, Nevada, North Dakota, Oregon, Utah, and Wisconsin is <95%.

Source: Coverage with Selected Vaccines and Exemption from School Vaccine Requirements Among Children in Kindergarten — United States, 2022–23 School Year

MMWR summary

- Nationwide vaccination coverage among kindergarten students remains below pre-pandemic levels.
- Exemptions have increased in 40 states.
- There are several strategies that have shown to be effective in increasing vaccination coverage.
- It's important that immunization programs, schools, and clinicians ensure children are fully vaccinated before school entry or, if necessary, before provisional enrollment periods expire to prevent outbreaks.

Morbidity and Mortality Weekly Report

Coverage with Selected Vaccines and Exemption from School Vaccine Requirements Among Children in Kindergarten — United States, 2022–23 School Year

Ranee Seither, MPH[1]; Oyindamola Bidemi Yusuf, PhD[1,2]; Devon Dramann, MPH[1,3]; Kayla Calhoun, MS[1]; Agnes Mugerwa-Kasujja, MD[1,2]; Cynthia L. Knighton[1]

Abstract

U.S. states and local jurisdictions set vaccination requirements for school attendance and conditions and procedures for exemptions from these requirements. States annually report data to CDC on the number of children in kindergarten who meet, are exempt from, or are in the process of meeting requirements. National- and state-level estimates for complete vaccination with measles, mumps, and rubella vaccine (MMR); diphtheria, tetanus, and acellular pertussis vaccine (DTaP); poliovirus vaccine (polio); and varicella vaccine (VAR); exemptions from vaccination; and legally allowed kindergarten attendance while meeting requirements were based on data reported by 49 states and the District of Columbia (DC) for the 2022–23 school year. This kindergarten class became age-eligible to complete most state-required vaccinations during the COVID-19 pandemic. National coverage remained near 93% for all vaccines; exemptions were low but increased to 3%, compared with those during the 2021–22 school year (2.6%). At the state level, coverage with MMR, DTaP, polio, and VAR decreased in 29, 31, 28, and 25 states, respectively, compared with coverage during the 2021–22 school year. Exemptions increased in 40 states and DC, with 10 states reporting an exemption from at least one vaccine for >5% of kindergartners. Schools and providers should work to ensure that students are vaccinated before school entry, such as during the enrollment process, which is often several months before school starts. State and local provisional enrollment periods that allow students to attend school while on a catch-up schedule also provide the opportunity to fully vaccinate students and to prevent nonmedical exemptions resulting from lingering undervaccination due to COVID-19 pandemic–related barriers to vaccination, such as reduced access to vaccination appointments.

Introduction

State and local school vaccination requirements promote vaccination to protect students, schools, and communities against vaccine-preventable diseases (*1*). After 10 years of near 95% nationwide vaccination coverage, measles, mumps, and rubella vaccine (MMR)*; diphtheria, tetanus, and acellular pertussis vaccine (DTaP)†; poliovirus vaccine (polio)§; and varicella vaccine (VAR)¶ coverage declined approximately 1 percentage point during the 2020–21 school year and fell an additional percentage point during the 2021–22 school year, to approximately 93% (*2*). For both the 2020–21 and 2021–22 school years, states reported impacts of the COVID-19 pandemic and response for both vaccine administration and data collection (*3,4*). This analysis summarizes data collected and reported by state and local immunization programs** on vaccination coverage and exemptions to vaccination among kindergartners

* All states except Wyoming require 2 doses of a measles-containing vaccine. Seven states (Alaska, Georgia, New Jersey, New York, North Carolina, Oregon, and Virginia) require only 1 dose of rubella vaccine. Alaska, New Jersey, and Oregon require only 1 dose of mumps vaccine; mumps vaccine is not required in Iowa. Wyoming requires 1 dose of MMR for kindergarten entry, allowing students until the day before their seventh birthday to receive their second dose, but reported kindergarten coverage with 2 doses of MMR at the time of the assessment.

† Nebraska requires 3 doses of DTaP; Maryland and Wisconsin require 4 doses; Wyoming requires 4 doses of DTaP for kindergarten entry, allowing students until the day before their seventh birthday to receive their fifth dose; all other states require 5 doses, unless dose 4 was administered on or after the fourth birthday. The reported coverage estimates represent the percentage of kindergartners with the state-required number of DTaP doses, except for Kentucky, which requires 5 doses of DTaP by age 5 years, but reported 4-dose coverage for kindergartners, and Wyoming, which reported kindergarten coverage with 5 doses of DTaP at the time of the assessment.

§ Two states (Maryland and Nebraska) require only 3 doses of polio; Wyoming requires 3 doses of polio for kindergarten entry, allowing students until the day before their seventh birthday to receive their fourth dose; all other states require 4 doses unless the last dose was given on or after the fourth birthday. The reported coverage estimates represent the percentage of kindergartners with the state-required number of polio doses, except for Kentucky, which requires ≥4 but reports ≥3 doses of polio, and Wyoming, which reported kindergarten coverage with 4 doses of polio at the time of the assessment.

¶ Five states require 1 dose of VAR; 44 states and DC require 2 doses. Wyoming requires 1 dose of VAR for kindergarten entry, allowing students until the day before their seventh birthday to receive their second dose, but reported kindergarten coverage with 2 doses of VAR at the time of the assessment.

** Federally funded immunization programs are in 50 states and DC, five cities, and eight U.S. territories and freely associated states. Two cities (Houston and New York City) reported data to CDC, which were also included in data submitted by their state. State-level data were used to calculate national estimates and medians. Immunization programs in U.S. territories reported vaccination coverage and exemptions; however, these data were not included in national calculations.

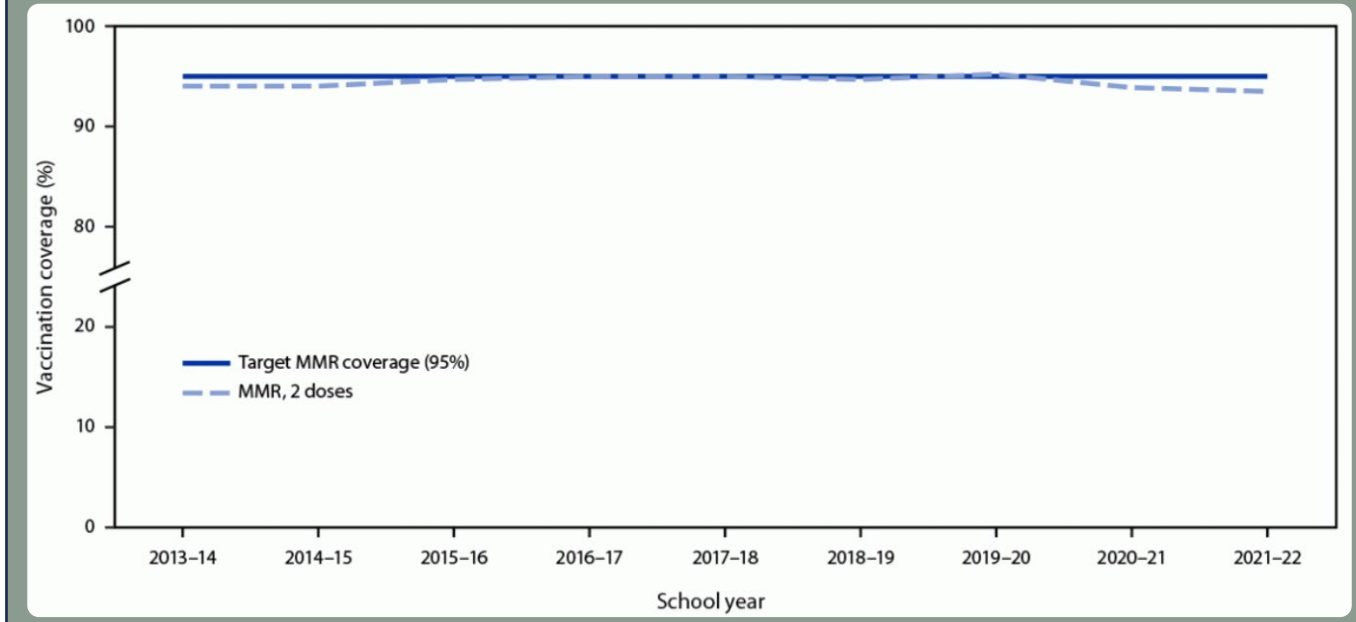
Coverage with Selected Vaccines and Exemption from School Vaccine Requirements Among Children in Kindergarten — United States, 2022–23 School Year

How can we encourage catch-up on routine childhood immunizations?

School immunization requirements help maintain high immunization levels

- School immunization requirements were enacted and enforced by state and local governments as a part of the 1977 Childhood Immunization Initiative.
- Prior to the COVID-19 pandemic in 2020, immunizations rates have remained high and stable in schools since 1980s.
- In 2000, measles was declared eliminated in the United States, in no small part due to the role that immunization requirements and schools played.
- However, communities and schools with coverage below Healthy People 2030 target of 95% are still at risk for measles outbreaks today.

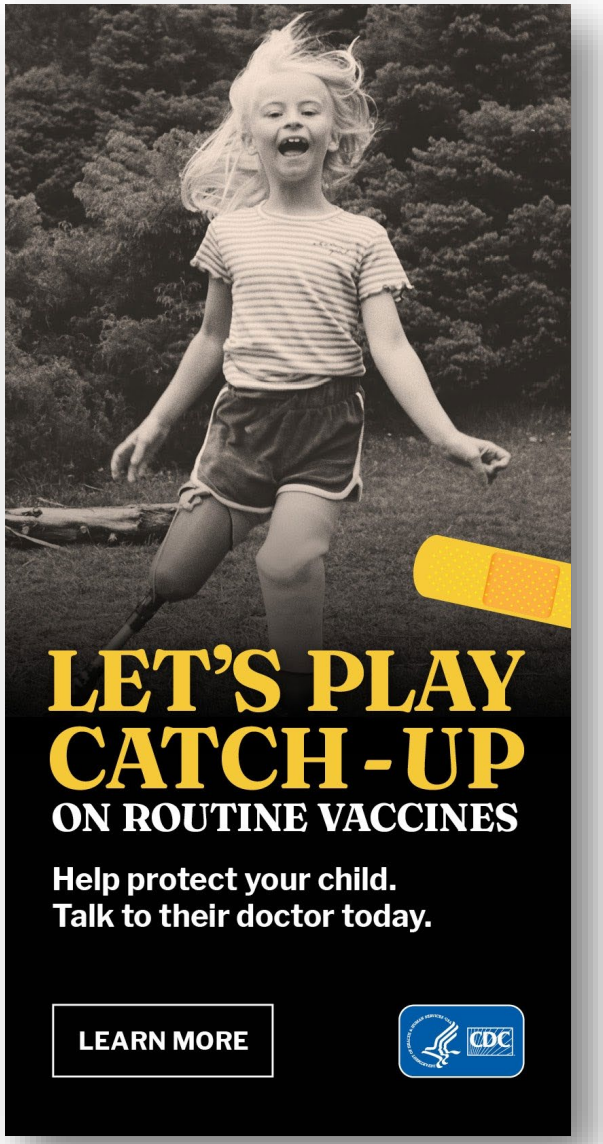
Estimated national measles vaccine coverage among kindergartners in U.S. schools



Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2021–22 School Year. *MMWR Morb Mortal Wkly Rep* 2023;72:26–32. http://dx.doi.org/10.15585/mmwr.mm7202a2.

Sources: Measles History; Current Trends Childhood Immunization Initiative, United States -- 5-Year Follow-Up (cdc.gov), Population Immunity to Measles in the United States, 1999; *J Infect Dis*, Volume 189, Issue Supplement_1, May 2004, Pages S17–S22, https://doi.org/10.1086/377694

CDC is encouraging catch-up on routine childhood immunizations



Promoting routine childhood vaccination through multi-media and multi-channel communications
Developing creative assets and encouraging routine vaccination through social media.

Publicizing Catch-up Immunization Schedule
Posting easily accessible resources for healthcare providers, parents, and other stakeholders on when children, adolescents, and adults should get vaccinated.

Delivering a Call to Action for healthcare systems and providers
Encouraging providers to identify families whose children have missed doses, reaching out to the families to schedule appointments, and delivering due or overdue vaccines to these children when seen.

National Immunization Awareness Month (August)
Leveraging routine immunization campaigns with jurisdictions for school vaccinations to get kids caught up.

Developing a toolkit for clinicians to encourage catch-up
Centralizing information and resources on routine childhood vaccination that can be leveraged by clinicians.

Medscape
Published expert Commentary Question & Answer on Routine Childhood Vaccination including what providers can do to get patients caught up on routine vaccinations.

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

Routine Immunizations on Schedule for Everyone

Partners can take action to encourage catch-up on routine childhood immunizations

Community leaders, health care professionals, and partners can

- ❑ Prioritize ensuring everyone catches up on routine vaccination.
- ❑ Identify individuals behind on their vaccinations.
- ❑ Encourage vaccination catch-up through reminders, recall, and outreach.
- ❑ Make strong vaccine recommendations.
- ❑ Make vaccines easy for everyone to find and afford
  - Help children get free vaccines.
  - Find providers enrolled in the Vaccines for Children (VFC) Program.

Thank You!

Centers for Disease
Control and Prevention
National Center for Immunization
and Respiratory Diseases

Jennifer Fulcher

A Cornerstone in Childhood Immunization: State Policies for School Entry

NVAC

UNIVERSITY OF CALIFORNIA LAW
SAN FRANCISCO

Legal and Enforcement Options: School Mandates

Dorit R. Reiss

Disclosures:

- The family owns stock (regular) in GSK.

- Served as a volunteer (unpaid) advisor on Moderna's ethics advisory group

Lesson plan

Structure:

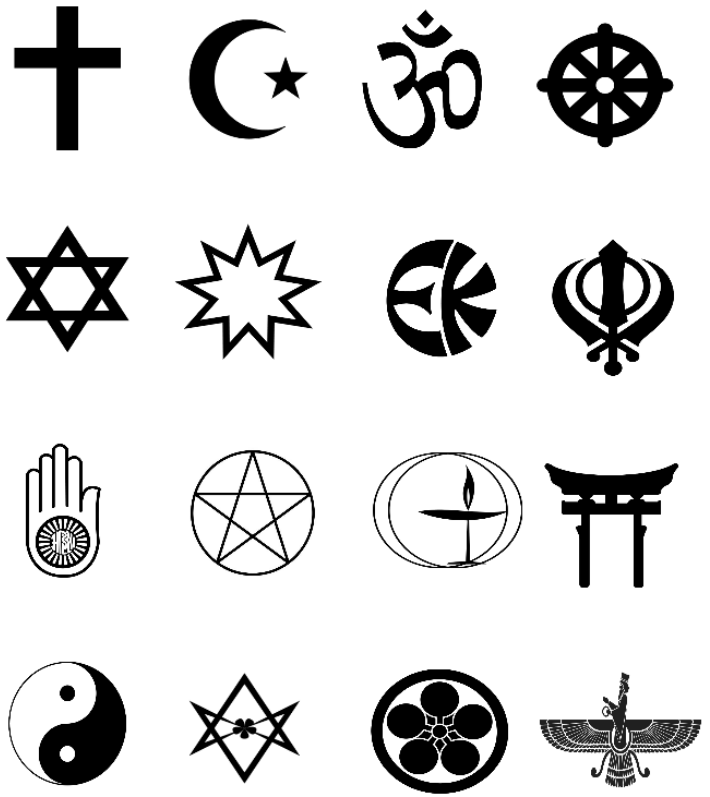
- Legal Constraints: review.
- Procedural options.
- Content options.
- Additional enforcement issues.

Take-Home Points:

- Open questions about the law complicate matters.
- There are procedural options.
- More procedures=less exemptions, less outbreaks.
- Remember conditional enforcements.

Limits from legal constraints:

- If First Amendment requires a religious exemption, it may limit burden you can attach.
- Legal uncertainty:
  - Is a religious exemption required.
  - What are the limits on burden?
- Can burden religious & secular exemptions similarly.



Requirements, generally:

- Easier to obtain exemptions=
  - More exemptions.
  - More outbreaks.
- Various procedural options available.
- Limit: committed opponents will follow procedures.
- Reminder: requirements burden the disadvantaged more.

Procedural options:

Yang & Silverman, "Legislative Prescriptions for Controlling Nonmedical Vaccine Exemptions," JAMA 2015.

- Standard exemption form?
- Online/paper submission?
- Require notarization?
- One time/annual filing?
- Educational component?
- Visit health department?
- Require explanation for exemption?

Content Options:

- Require explanation?
- Titer/ disease alternative to vaccination?
- Assess sincerity of religious objections?
- Cannot:
  - Require letter from religious leader.
  - Limit to organized religion.
  - Assess reasonableness.

Additional enforcement points:

- Solving access problems.
  - School clinics?
- Records issues.
- Special treatment may be given to some students, e.g. –
  - Homeless.
  - Military.
- Conditional entrants

Conditional entrants:

- Conditional entrants received some but not all immunizations.
- These students started one or more vaccine series, but will take time to finish.
- Need to follow up.

Thank you!

Questions? Comments?

reissd@uclawsf.edu

415-5654844

A Cornerstone in Childhood Immunization: State Policies for School Entry

Discussion

NVAC

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

February 22-23, 2024

Break

NVAC

Celebrating 30 Years of Saving Lives: The Vaccines for Children Program Now and in the Future

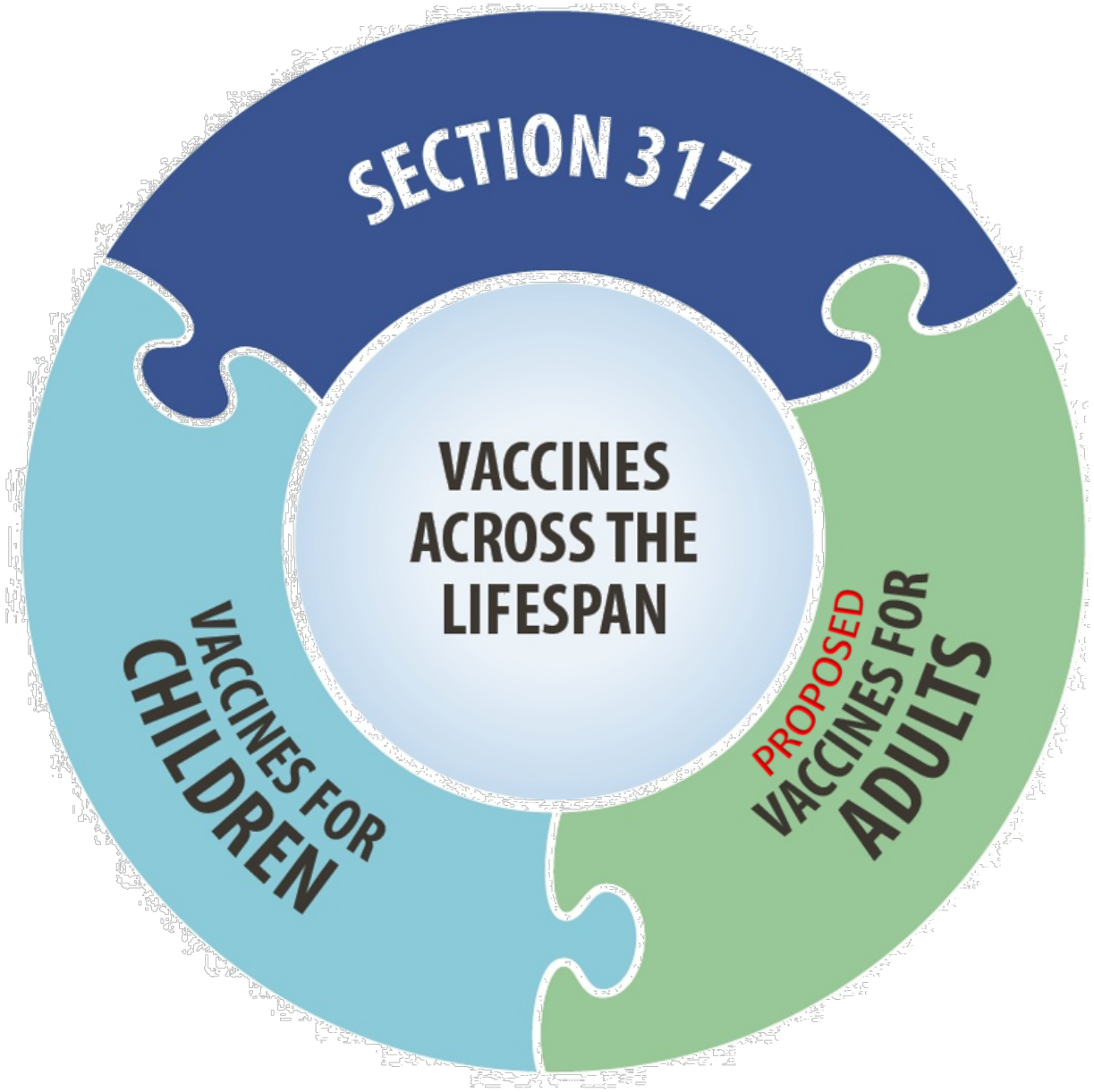
Dr. Georgina Peacock
Dr. Sean O'Leary
Dave McCormick

NVAC

Vaccines for Children (VFC): Now & In the Future

Georgina Peacock, MD, MPH, FAAP
Director, Immunization Services Division
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)

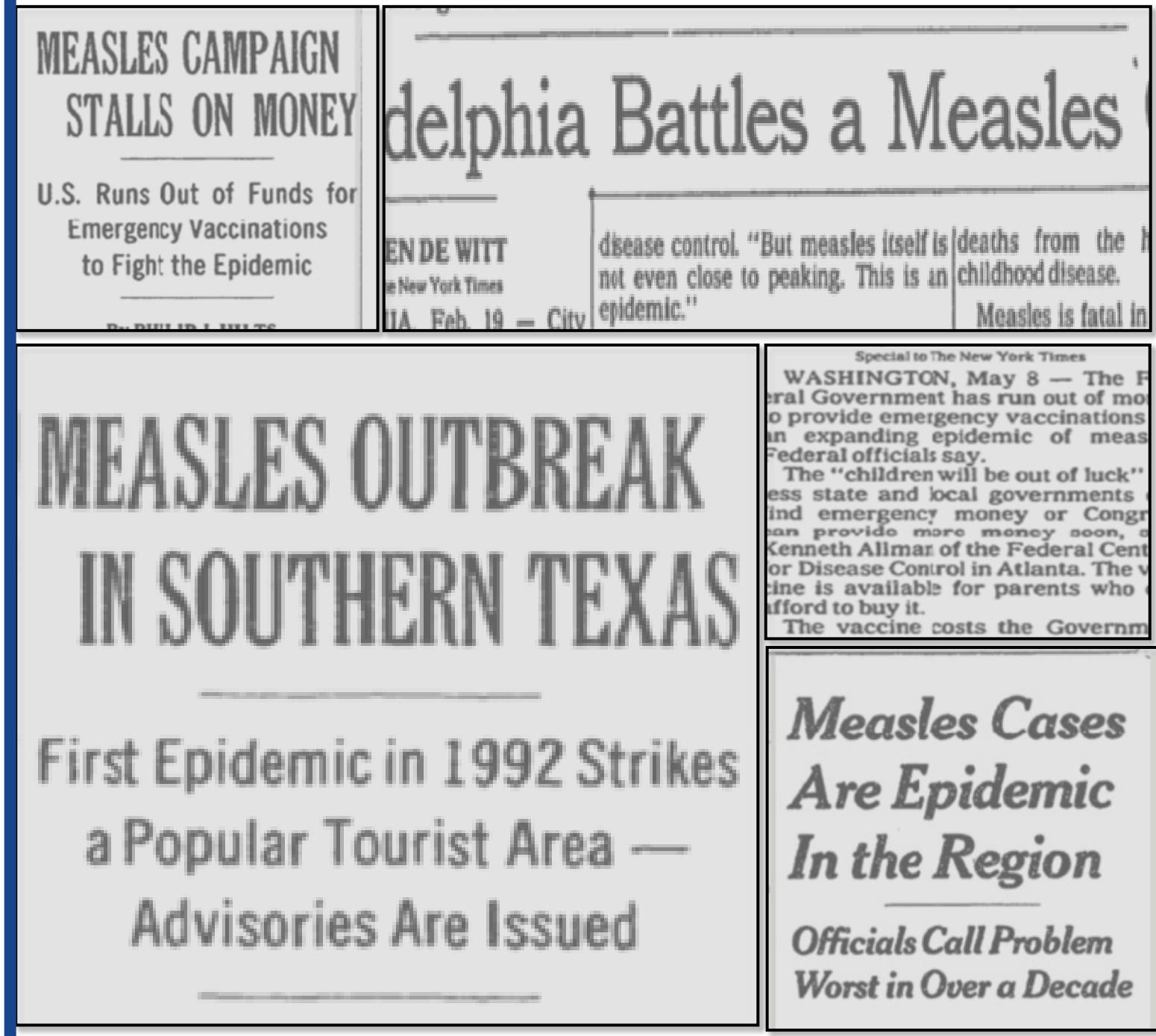
CDC's Immunization Programs



Vaccines for Children Program (VFC)

Section 1928 of the Social Security Act

- **Enacted in 1993 (Omnibus Budget Reconciliation Act); implemented in 1994**
  - Response to measles resurgence of 1989-1991
  - Part of Childhood Immunization Initiative
- **Entitlement program**
  - Funding from Medicaid Trust Fund
  - CDC delegated responsibilities for vaccine
  - CMS delegated responsibility for administration fee
  - ACIP responsible for VFC formulary
  - Entitlement is to the child



MEASLES CAMPAIGN STALLS ON MONEY

U.S. Runs Out of Funds for Emergency Vaccinations to Fight the Epidemic

delphia Battles a Measles

EN DE WITT
e New York Times
IA, Feb. 19 — City

disease control. "But measles itself is not even close to peaking. This is an epidemic."

deaths from the h
childhood disease.
Measles is fatal in

MEASLES OUTBREAK IN SOUTHERN TEXAS

First Epidemic in 1992 Strikes a Popular Tourist Area — Advisories Are Issued

Special to The New York Times
WASHINGTON, May 8 — The F
eral Government has run out of mo
o provide emergency vaccinations
n expanding epidemic of meas
Federal officials say.
The "children will be out of luck"
ess state and local governments
ind emergency money or Congr
an provide more money soon,
Kenneth Allmar of the Federal Cent
or Disease Control in Atlanta. The v
ine is available for parents who
fford to buy it.
The vaccine costs the Governm

Measles Cases Are Epidemic In the Region

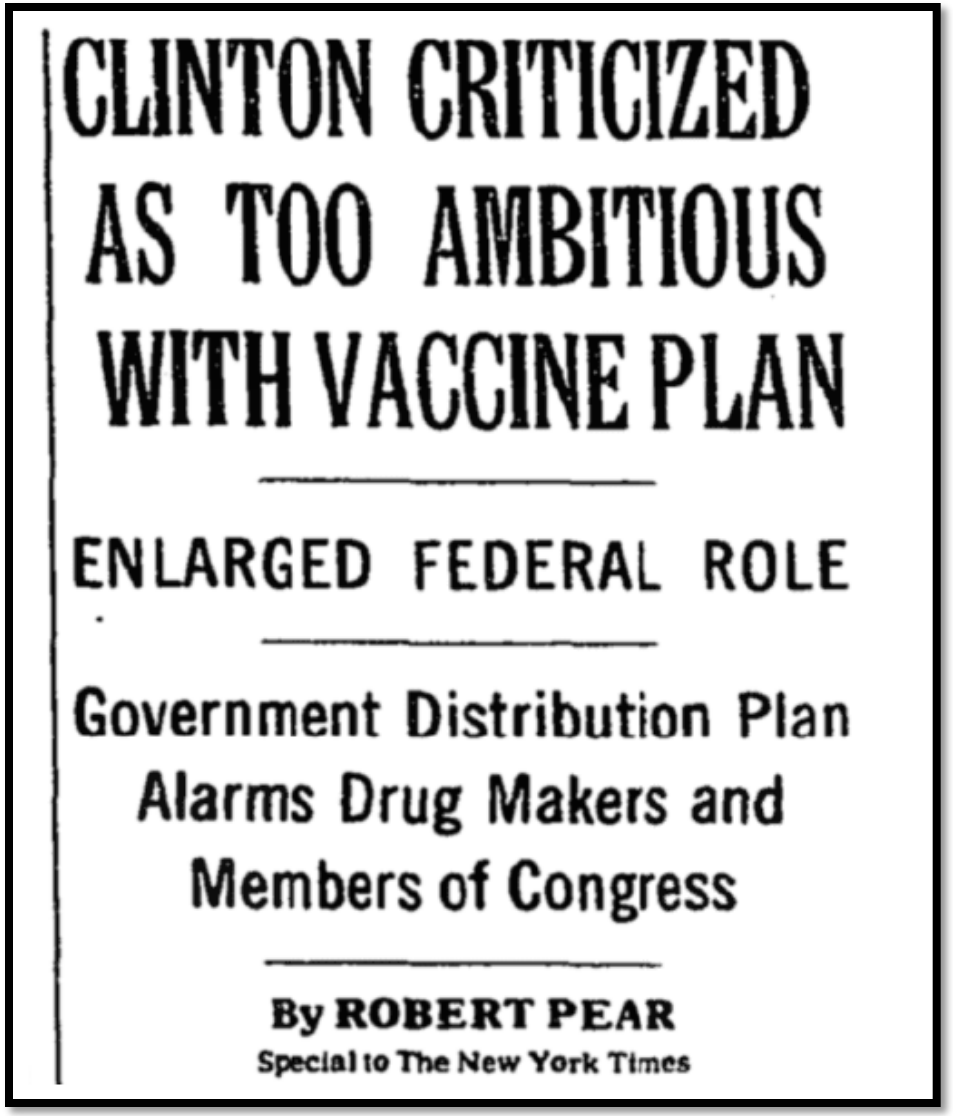
Officials Call Problem Worst in Over a Decade

VFC Program Benefits

- Allows children to receive vaccination services in the medical home
- Eliminates or reduces vaccine cost as a barrier to vaccinating eligible children
- Entitlement allows new vaccines to be provided more quickly than through annual appropriation
- Incentivizes innovation with price caps on legacy vaccines
- No state contribution for vaccine purchase for children on Medicaid
- Helps assure vaccine availability through stockpiles
- Opportunities for public health to work with providers on quality improvement of vaccination services

Early Years of VFC Program

- Program faced opposition
- Early concerns regarding
  - VFC's ability to provide oversight, accountability, and evaluation
  - Federal government ability to safely handle and deliver vaccine products for the first time
- In 1997, implemented annual reporting requirements and developed a provider site visit protocol
  - In-person evaluations of record keeping
  - Vaccine storage and handling procedures



CLINTON CRITICIZED AS TOO AMBITIOUS WITH VACCINE PLAN

ENLARGED FEDERAL ROLE

Government Distribution Plan Alarms Drug Makers and Members of Congress

By ROBERT PEAR

Special to The New York Times

A New York Times article published May 30, 1994, discussing challenges encountered during early program development.

VFC Program Growth & Reach

$5.5B program

76M doses distributed

600K routine shipments

38K provider locations

As of February 2024

VFC Program Eligibility

- Children 0 through 18 years of age who meet at least one of the criteria:
  - Medicaid eligible
  - Uninsured, or
  - American Indian/Alaska Native, or
  - Underinsured*

VFC eligibility by age group (Population Estimate Survey [PES], FY 2023)

<1 year	1 to 2 years	3 to 6 years	7 to 18 years	Total
53.5%	54.8%	54.3%	53.2%	**53.6%**

*Eligible to receive vaccine only through an enrolled Federally Qualified Health Center (FQHC), Rural Health Center (RHC) or a deputized provider under Delegation of Authority

How VFC Works

- Healthcare providers enroll in the program through their respective awardee immunization programs
- Providers can then order vaccine for their eligible patients through their awardee immunization program
- Participating providers are responsible for
  - appropriate storage and handling of vaccine
  - administering vaccine to eligible children
  - cooperating with quality assurance (compliance) visits
  - participating in quality improvement activities
  - completing required annual training

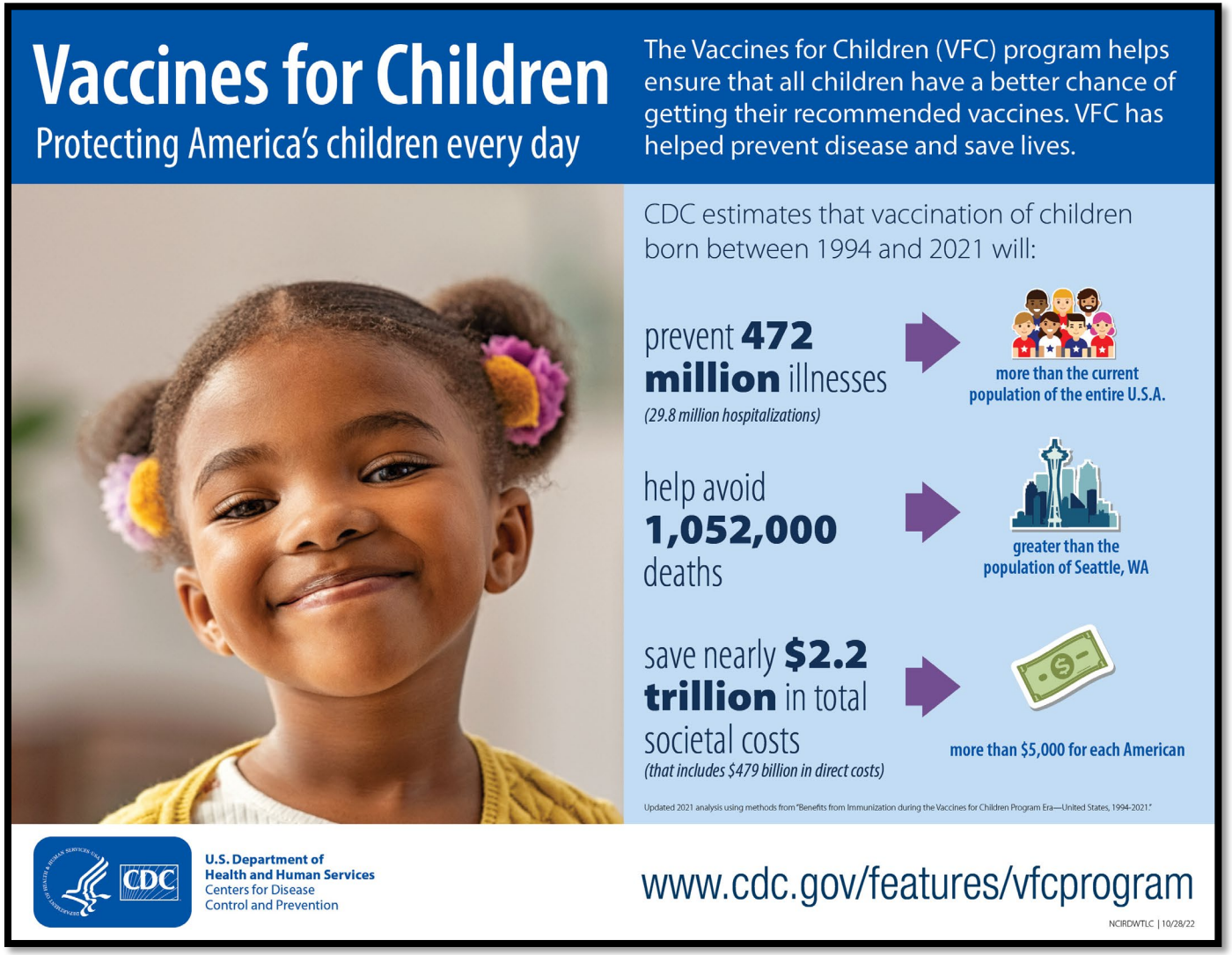
- Providers can bill parents for a vaccine administration fee but cannot exclude children if parents cannot pay

VFC Providers: Key to Program Success

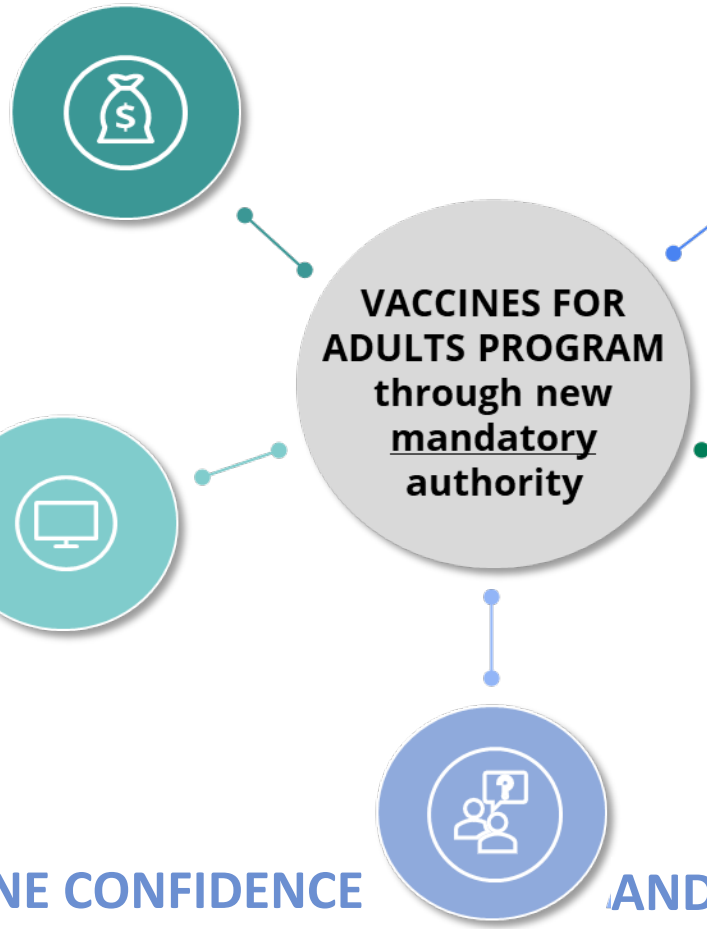
- Providers are critical to extending the reach of the VFC program by
  - Increasing the potential number of children vaccinated
  - Allowing VFC-eligible children to stay in their medical homes
- Working to build provider enrollment and retention
  - Temporary flexibilities for 2023–2024 respiratory season for COVID-19 and nirsevimab (private inventory requirements, ordering minimum packaging, borrowing)

VFC Program: 30 Years Strong

- Centerpiece of the US vaccination program, providing over half of all childhood vaccine doses purchased
- Increased vaccination coverage rates
- Decreased racial and ethnic disparities within vaccination coverage rates



Future Planning: Vaccines for Adults Program



VACCINE PURCHASE

Adequate supplies of **all ACIP-recommended vaccines** for all uninsured adults likely to seek vaccination

PROVIDER FEES

Covers cost of supplies, patient education, storage, and staffing for **all ACIP-recommended adult vaccines**

PROGRAM OPERATIONS

Long-term CDC staff and systems to support science, policy, program monitoring, and vaccine safety and distribution

PROVIDER FEE REIMBURSEMENT MECHANISM

New authority to reimburse any adult vaccination service provider participating in VFA

VACCINE CONFIDENCE AND EQUITY ACTIVITIES*

Long-term, reliable CDC funding and support for vaccine equity through partnerships, communications, and technical assistance

*These activities are funded in the FY24 CDC Budget with base immunization funding, not the newly proposed mandatory funding proposal that would support the rest of these activities.

Future Planning: VFC Program Opportunities

- Working to identify priority provider types (birthing hospitals, safety net providers [FQHCs and RHCs], etc.) to increase vaccine access for vulnerable populations
- Updating materials to incorporate best practices for provider/parent conversations, and to increase vaccine confidence in communities
- Working with immunization partners and program awardees to restore and improve childhood vaccination rates

Thank You!

Centers for Disease
Control and Prevention
National Center for Immunization
and Respiratory Diseases

VFC Now and in the Future

Perspectives from Pediatricians and the American Academy of Pediatrics

Sean O'Leary, MD, MPH, FAAP

Professor, University of Colorado/Children's Hospital Colorado

Investigator, ACCORDS

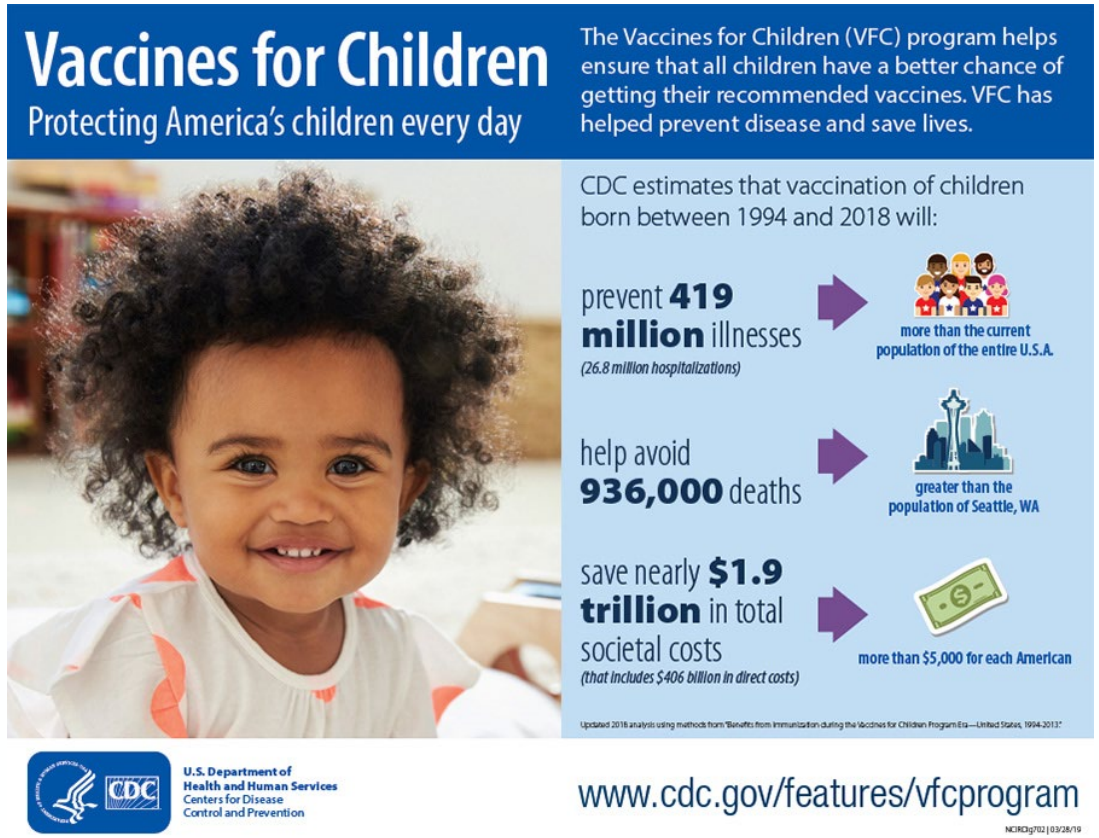
Chair, Committee on Infectious Diseases, AAP

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

AAP Strongly Supports the Vaccines for Children Program

- AAP has supported the Vaccines for Children program since its inception and continues to be an ardent champion
- The AAP believes that the VFC program has proven its effectiveness over the past 30 years, as it has been instrumental to achieving high vaccination coverage rates and reducing disparities in access
  - ✓ Vaccination rates increased across all races, ethnicities, and income groups following the introduction of the VFC program
  - ✓ Disparities among race and ethnic groups narrowed considerably over time since the introduction of the VFC program



Outline

- Nationally representative survey of pediatricians regarding VFC program
- Perspective from the American Academy of Pediatrics

PEDIATRICS®

Content Authors/Reviewers Collections Multimedia Blogs Su

Volume 145, Issue 3

March 2020

ARTICLES | MARCH 01 2020

Pediatricians' Experiences With and Perceptions of the Vaccines for Children Program

Sean T. O'Leary, MD, MPH ✉; Mandy A. Allison, MD, MSPH; Tara Vogt, PhD, MPH; Laura P. Hurley, MD, MPH; Lori A. Crane, PhD, MPH; Michaela Brtnikova, PhD, MPH; Erin McBurney, MPH; Brenda L. Beaty, MSPH; Nathan Crawford, MPH; Megan C. Lindley, MPH; Shannon K. Stokley, MPH; Allison Kempe, MD, MPH

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Study Objectives

To assess among a nationally representative sample of pediatricians:

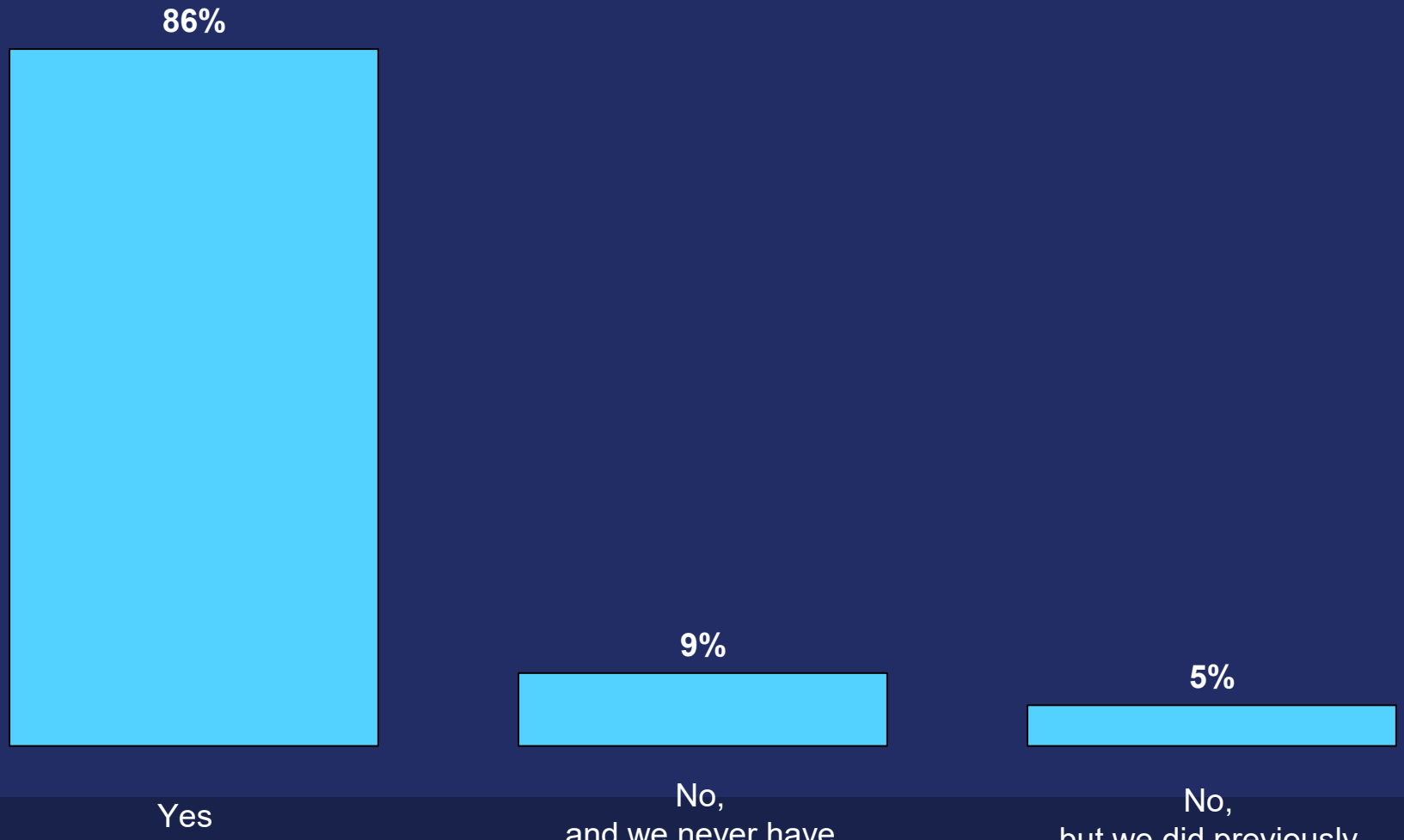
- Participation in VFC and consideration of stopping participation
- Perceived burden vs benefit of participation

VFC Survey of Primary Care Pediatricians

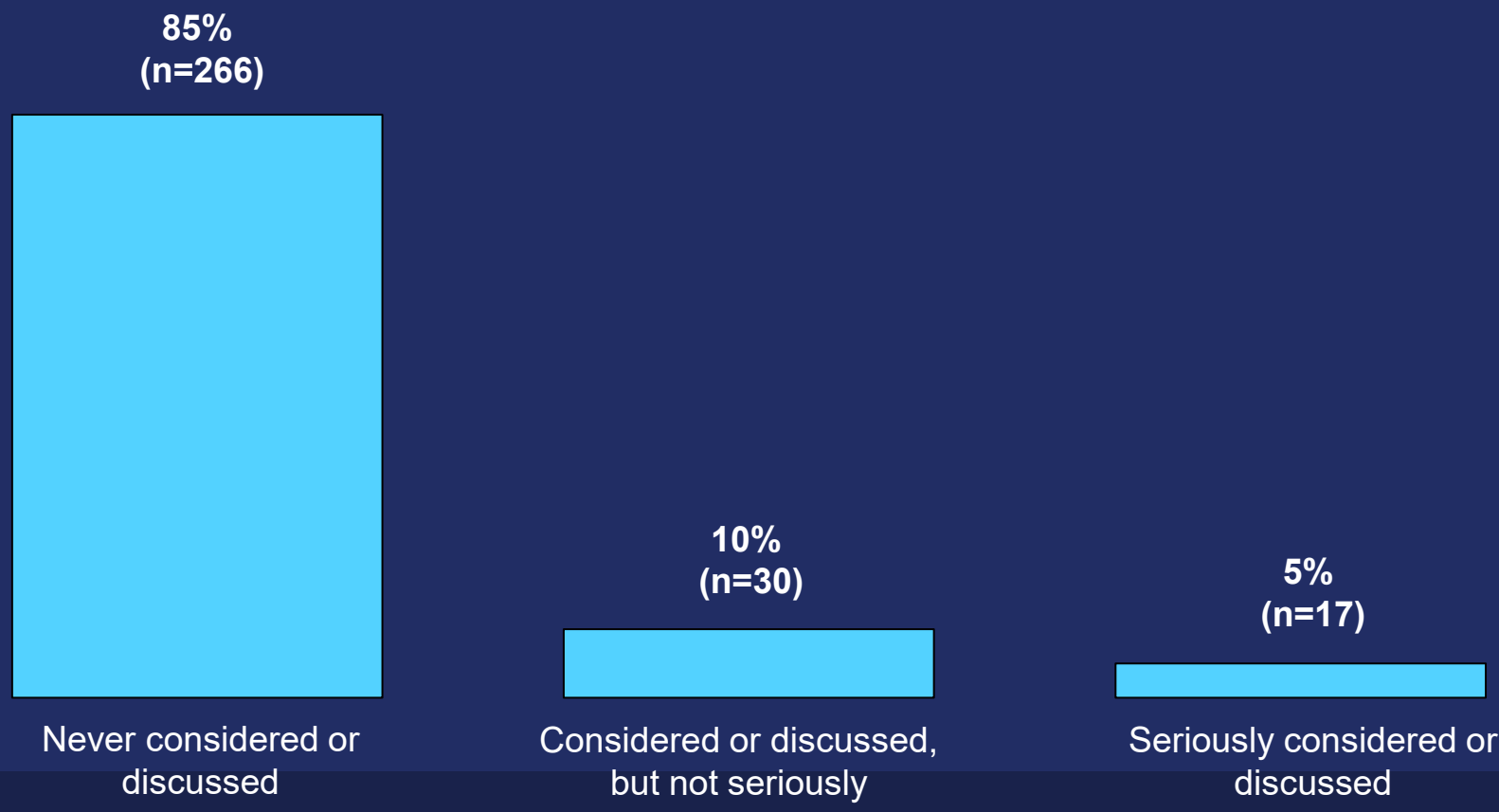
- Conducted from June to September, 2017

Response Rate:	**79%**	**(372/471)**

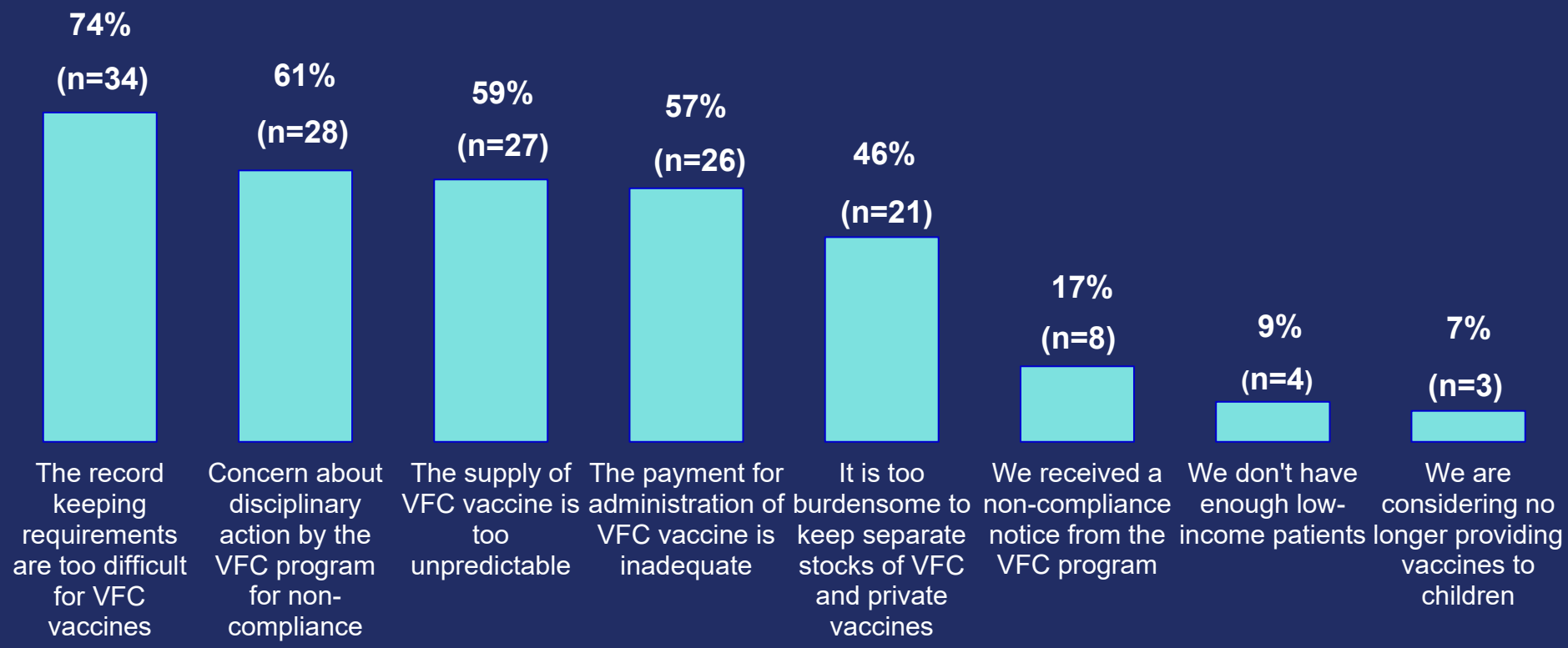
Participation in VFC (n=367)



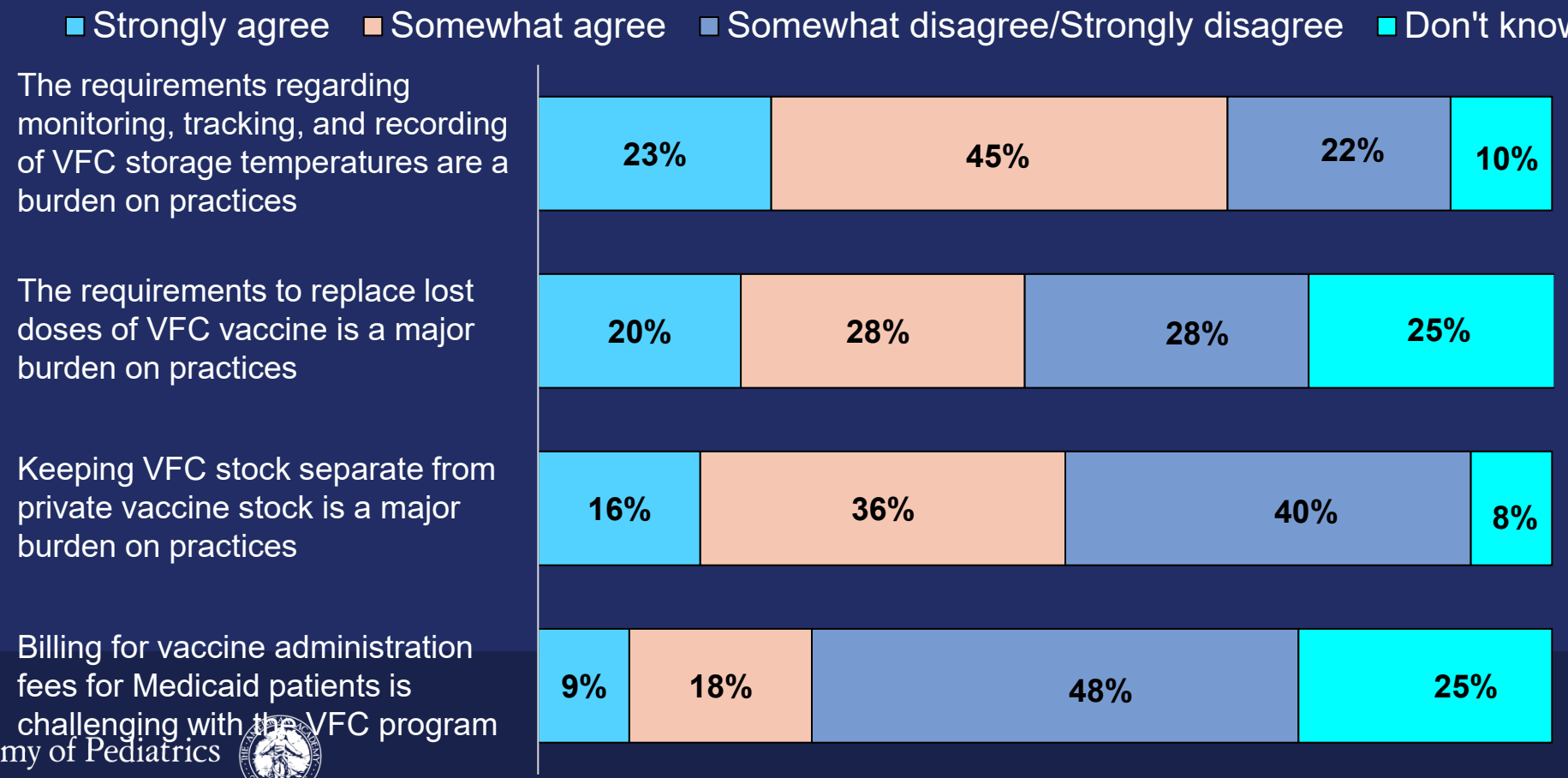
Among VFC participants, have you considered no longer participating in the past year? (n=316)



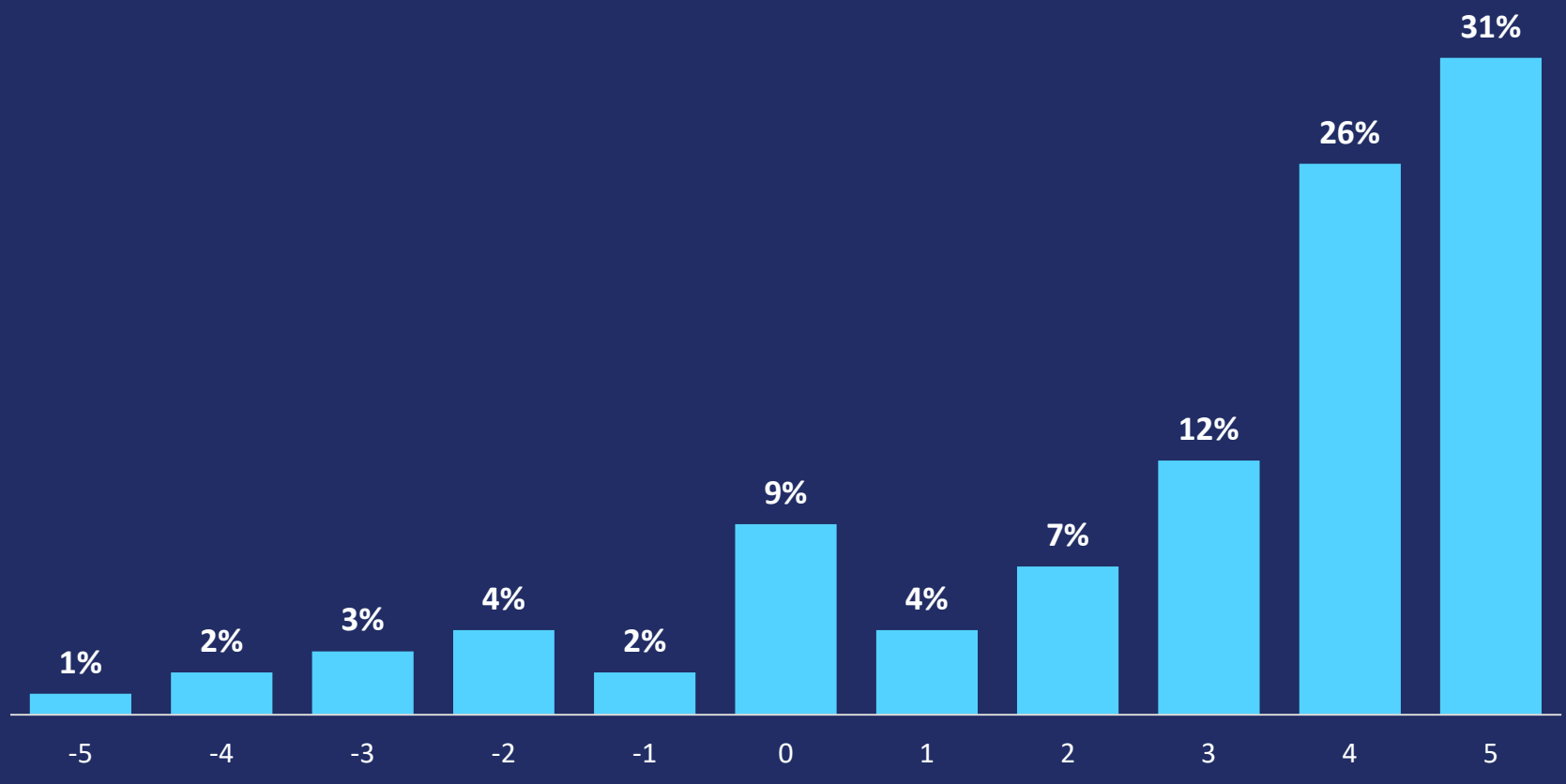
Among those who considered no longer participating in VFC, why? (n=47)



Regardless of whether or not you are participating in VFC, how strongly do you agree or disagree with the following statements related to providing VFC vaccine, cont. (n=372)



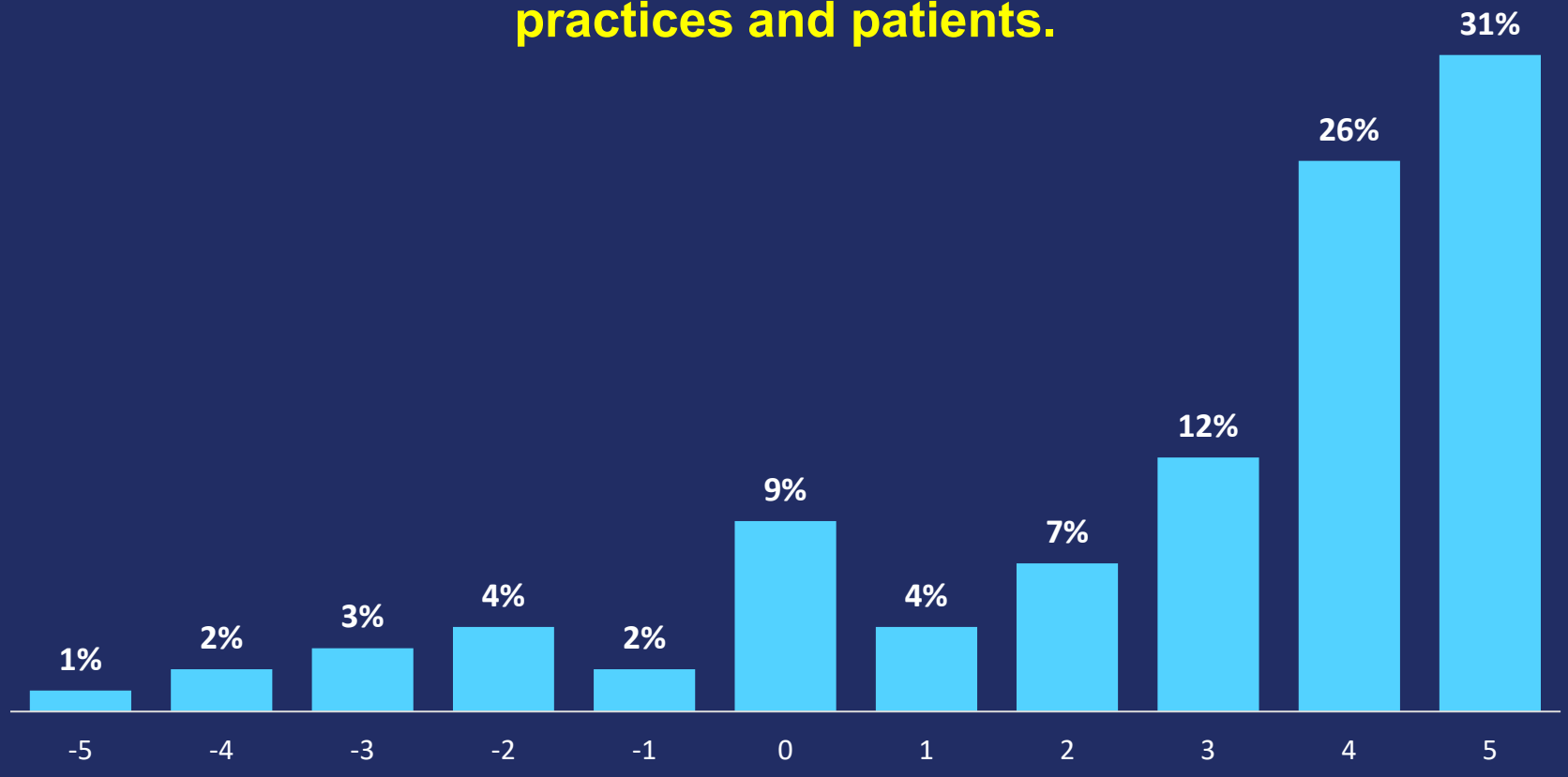
Pediatricians' perception of relative burden vs benefit of VFC participation (n=372)



Participating in the VFC program is more of a BURDEN

Participating in the VFC program is more of a BENEFIT

Whether or not your practice participates in VFC, taking all factors into consideration, on the scale below, please indicate the extent to which participation in the VFC program represents a benefit versus a burden for practices and patients.



Participating in the VFC program is more of a BURDEN

Participating in the VFC program is more of a BENEFIT

Summary

- The vast majority of pediatricians participate in VFC and believe that the benefits outweigh the burden of participating
- However, large percentages of providers identify the following factors as burdensome for their practices:
  - Requirements for monitoring tracking and recording of VFC storage temperatures (68%)
  - Lower payments for VFC vaccine administration than from private health plans (54%)
  - Need to keep VFC stocks separate from private vaccine stock (52%)
  - Requirement to replace lost doses of VFC vaccine (48%)

Vaccine Policy Collaborative Initiative

University of Colorado Denver

PI: Allison Kempe, MD, MPH

Sean O'Leary, MD, MPH

Mandy A. Allison, MD, MSPH

Laura P. Hurley, MD, MPH

Lori A. Crane, PhD, MPH

Michaela Brtnikova, PhD, MPH

Brenda L. Beaty, MSPH

Erin McBurney, MPH

CDC Collaborators

Megan C. Lindley, MPH

Nathan Crawford

Tara M. Vogt, PhD MPH

Shannon Stokley, PhD

ACCORDS

ADULT AND CHILD CONSORTIUM FOR HEALTH OUTCOMES RESEARCH AND DELIVERY SCIENCE

UNIVERSITY OF COLORADO | CHILDREN'S HOSPITAL COLORADO

Funding

This investigation was funded by the Centers for Disease Control and Prevention and administered through the University of Colorado Denver (Grant #1U01P000849-03).

The content is solely the responsibility of the authors and does not necessarily represent the official views of the Centers for Disease Control and Prevention

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN®

AAP Perspective

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Vaccines For Children: Challenges

- Although the AAP is a strong supporter of VFC, several challenges need to be addressed to bolster the program moving forward.
- Substantial changes in health care landscape since 1993
  - Dramatic increases in childhood vaccination rates, though rates have tempered since the pandemic
  - Increase in childhood poverty both pre- and post-pandemic (and thus, VFC eligibility)
- Operational requirements and overhead costs (storage, paperwork, borrowing restrictions)
- State programs vary widely in their levels of program monitoring and compliance activity
- Low payment for vaccine administration
  - May pay on CPT codes 90460, 90471, or product code, but cannot pay for 90461, which restricts payment for administering multi-component vaccines
  - Bound by Maximum Regional Charges (caps), which have not been updated since 2012

Vaccines For Children: Challenges

- Restrictions on where underinsured children can receive VFC vaccines
  - Underinsured children can only receive VFC vaccine through FQHCs, RHCs, and deputized VFC providers
- Intersection between Medicaid and CHIP eligibility varies among states
  - Currently, CHIP enrollees in Medicaid Expansion and Combination programs are eligible for VFC, but children enrolled in Separate CHIP programs are not eligible.
- Newer, high-cost immunizations exacerbate financial pressures on VFC providers, leading many to question program participation
  - COVID-19
  - RSV
- Longer discussion times with families, with shifts in demographics of vaccine hesitancy from primarily college-educated white to now include all demographics, including low SES
  - Mis- and disinformation campaigns targeting Black and Hispanic communities

Vaccines For Children: AAP Recommendations for Modernization

- Provide $10,000 incentive payments to help increase provider participation and help alleviate operational burdens
- Update Maximum Regional Charges for vaccine administration
  - Have not been updated since 2012
- Allow payment for CPT code 90461 code
  - Recognizes the time spent on vaccine counseling and education
- Expand VFC eligibility to all CHIP enrollees, regardless of CHIP program structure
  - Ensures that all CHIP and Medicaid children are eligible for VFC
- Allow underinsured children to receive vaccines at any participating VFC provider, not just at FQHCs and RHCs
- Permit payment for stand-alone vaccine counseling for all VFC enrollees, not just Medicaid eligible children

VFC Addendums for COVID-19 and Nirsevimab

- The AAP appreciates the recent flexibility for participating VFC providers issued for COVID-19 and nirsevimab
  - Under the new guidance, VFC providers will have until March 31, 2024, to meet the private stock requirements for COVID-19 and until August 1, 2024, for nirsevimab
  - CDC will also allow bidirectional borrowing of VFC and private stock for both products in certain circumstances for the 2023-'24 season, although CDC guidance does not supersede jurisdictional policies
- As both flexibilities were affected by the shortage of nirsevimab, the AAP encourages CDC to continue these flexibilities for the next RSV season
- In addition, we encourage CDC to ease enrollment of birthing centers as "specialty providers" to administer nirsivimab and Hep B vaccine

National Center for Immunization and Respiratory Diseases

CDC's Vaccines for Children Program Addendum: Special Considerations for COVID-19

Updated 10/18/2023

This addendum to the *2023-2024 VFC Operations Guide* provides supplemental information and guidance related to the addition of COVID-19 vaccine to the VFC formulary.

Vaccines for Children

Inventory

- VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for COVID-19 vaccine. During this time awardees will not require VFC providers to meet the private inventory minimum requirements for COVID-19 vaccine if they do not intend to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than March 31, 2024.
  - This includes VFC providers who serve only Medicaid-eligible patients and no privately insured children; they are not required to privately purchase COVID-19 vaccine.
- If VFC providers utilize this flexibility to not maintain private stock during this season, providers should share information with their privately insured patients about other ways to access COVID-19 vaccine in their areas, including through local pharmacies and health departments.
- In locations where providers report that demand for COVID-19 vaccine is low, awardees should allow providers to order the minimum packaging size of VFC COVID-19 vaccines, as feasible.
  - In these cases, site visit reviewers may observe that COVID-19 inventory is a much lower quantity than other ACIP-recommended vaccines.
  - Based on information that CDC has received from all three COVID-19 vaccine manufacturers, presentations for most of the new fall vaccines will be more typical (i.e., unit dose presentations rather than multidose vials), which will significantly reduce vaccine minimum order quantities.

NCIRDwt | 10/18/23

National Center for Immunization and Respiratory Diseases

CDC's Vaccines for Children Program Addendum: Special Considerations for Nirsevimab

Updated 10/18/2023

Nirsevimab is an FDA-licensed monoclonal antibody that provides passive immunity against RSV-associated infection. On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) voted to recommend nirsevimab as an immunization for all infants aged <8 months, as well as some children up to age 20 months (see ACIP recommendations), and a VFC resolution was passed to include nirsevimab in the VFC program. This addendum provides supplemental information and guidance related to the addition of the nirsevimab immunization to the VFC formulary.

Vaccines for Children

Inventory

- VFC providers will be allowed a flexible, time-limited ramp-up period to meet the private inventory requirement for nirsevimab. During this time, awardees will not require VFC providers to meet the private inventory minimum requirements for nirsevimab if they do not intend to vaccinate their private pay patients. VFC providers are required to meet the private inventory requirement no later than August 1, 2024.
  - This includes VFC providers who serve only Medicaid-eligible patients and no privately insured children; they are not required to privately purchase nirsevimab.
- If VFC providers utilize this flexibility to not maintain private stock during this season, providers should explore if other in-network options exist for their nirsevimab-insured private patients to access nirsevimab (i.e., from another local in-network practice or system that does have private inventory of nirsevimab, or FQHC, RHC, or deputized VFC provider authorized to immunize underinsured children).
  - CDC recognizes that with current supply and demand issues, this may not be possible, but if supply changes, we encourage providers to assist their private patients in identifying access routes.
- In locations where providers report that demand for nirsevimab is low, awardees are to allow providers to order the minimum packaging of VFC nirsevimab that is feasible. In these cases, site visit reviewers will observe that nirsevimab inventory is a much lower quantity than other ACIP-recommended vaccines.
- At the discretion of the awardee, certain specialty VFC providers, including birthing facilities (e.g., birthing hospitals or centers), may offer a limited formulary of VFC vaccines, based on the populations served in their facility. VFC-enrolled birthing facilities offering nirsevimab must offer hepatitis B vaccine at birth as well (and vice versa).

Eligibility Criteria

- A child's eligibility criteria for VFC nirsevimab are the same as for other VFC vaccines.

Borrowing

- For those VFC providers who maintain private stock of nirsevimab and vaccinating privately insured children, bidirectional borrowing of nirsevimab will be allowed for the 2023-2024 respiratory virus season as described below.
- CDC's borrowing guidance does not supersede jurisdictional policy related to borrowing. VFC providers should refer to awardee or jurisdictional policy to determine if borrowing is allowed in their jurisdictional.

NCIRDwt | 10/18/23

Thank you!

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Indiana Department of Health

INDIANA IMMUNIZATION PROGRAM

DAVE MCCORMICK
DIRECTOR, IMMUNIZATION DIVISION

02/22/2024

Vaccine Coverage Rates

Average Age, Median Age & Standard Deviation by Vaccine for the Current Year

DTaP

	Dose 1	Dose 2	Dose 3	Dose 4
Avg Age	5.87	7.12	10.14	22.17
Median Age	2.16	4.29	6.45	16.77
Std Dev	12.32	10.07	11.01	13.21

Polio

	Dose 1	Dose 2	Dose 3
Avg Age	6.07	7.33	10.64
Median Age	2.16	4.29	6.45
Std Dev	13.09	10.92	12.50

PCV 13

	Dose 1	Dose 2	Dose 3	Dose 4
Avg Age	3.92	5.72	8.52	16.22
Median Age	2.16	4.29	6.48	15.19
Std Dev	6.93	5.21	6.12	6.24

Hep B

	Dose 1	Dose 2	Dose 3
Avg Age	2.13	5.09	8.99
Median Age	.00	2.19	6.06
Std Dev	9.28	10.36	12.09

MMR

	Dose 1
Avg Age	17.70
Median Age	12.52
Std Dev	13.08

Varicella

	Dose 1
Avg Age	18.52
Median Age	12.58
Std Dev	14.20

HIB

	Dose 1	Dose 2	Dose 3
Avg Age	3.87	5.71	10.42
Median Age	2.16	4.29	6.77
Std Dev	6.59	5.30	7.01

- Vaccine series initiation is being delayed according to recent data.
  - Birth dose hep B – 2 months
  - MMR – approximately 6 months
- Appointment availability
- 1:5, 1:4, 1:3 – school immunizations

Start Smart

Indiana's Routine Vaccination Campaign

Start Smart – Reminder Recall Letter

- Extrapolated vaccination data from CHIRP
- Missing one or more school required immunizations
- Ages 5-18
- Sent letter to healthcare providers 2 weeks prior to parent letter being sent
- ACIP recommended vaccines

Indiana Department of Health

Eric J. Holcomb
Governor
Kristina M. Box, MD, FACOG
State Health Commissioner

Date]

To the Parent/Guardian of:
[Child's Name]
[Street Address]
[City, State Zip]

Protecting the health of Indiana's youth is one of our top priorities at the Indiana Department of Health (IDOH), and routine childhood immunizations help us achieve that goal. As a result of the recent pandemic, however, childhood immunization rates have decreased by approximately 10 percent across the state. To ensure that every Indiana child is protected from vaccine-preventable diseases, IDOH has conducted a review of all immunization records reported to the state immunization registry, Children and Hoosier Immunization Registry Program (CHIRP).

According to the information reported to CHIRP, your child may have missed a vaccine that is included in the recommended immunization schedule. This includes immunizations that are required for school entry and those that are recommended to keep your child safe from vaccine-preventable illnesses and cancers. Please contact your child's healthcare provider to find out if you need to schedule an appointment.

IDOH is working with local health departments and community partners to hold community vaccination events in each county this summer. For a list of sites offering immunizations, please go to Startsmart.Health.IN.gov.

Please note that IDOH regularly reviews all immunization records that are automatically reported to the state immunization registry, pursuant to Indiana Code 16-38-5. If you would like your child's information permanently removed from the CHIRP registry, you may fill out the exemption form found at: http://www.in.gov/isdh/26603.htm.

In 2012, IDOH introduced MyVaxIndiana, a web-based tool that allows an individual to view their immunization record after receiving a secure personal information number (PIN) from their healthcare provider. This tool is one of the first in the nation and enables an individual to view, print or electronically store their record. Please ask your healthcare provider how you can access your child's record.

Thank you for everything you do to protect the health of your child.

Immunization Division
Indiana Department of Health

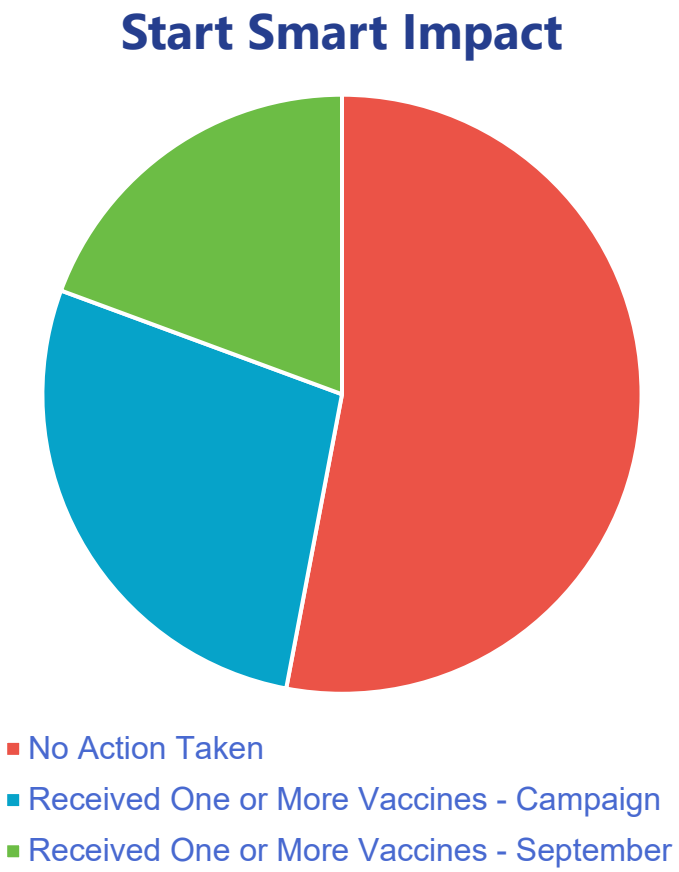
To promote, protect, and improve the health and safety of all Hoosiers.

2 North Meridian Street • Indianapolis, Indiana 46204 • 317-233-1325 • health.in.gov
An equal opportunity employer.

Indiana Department of Health

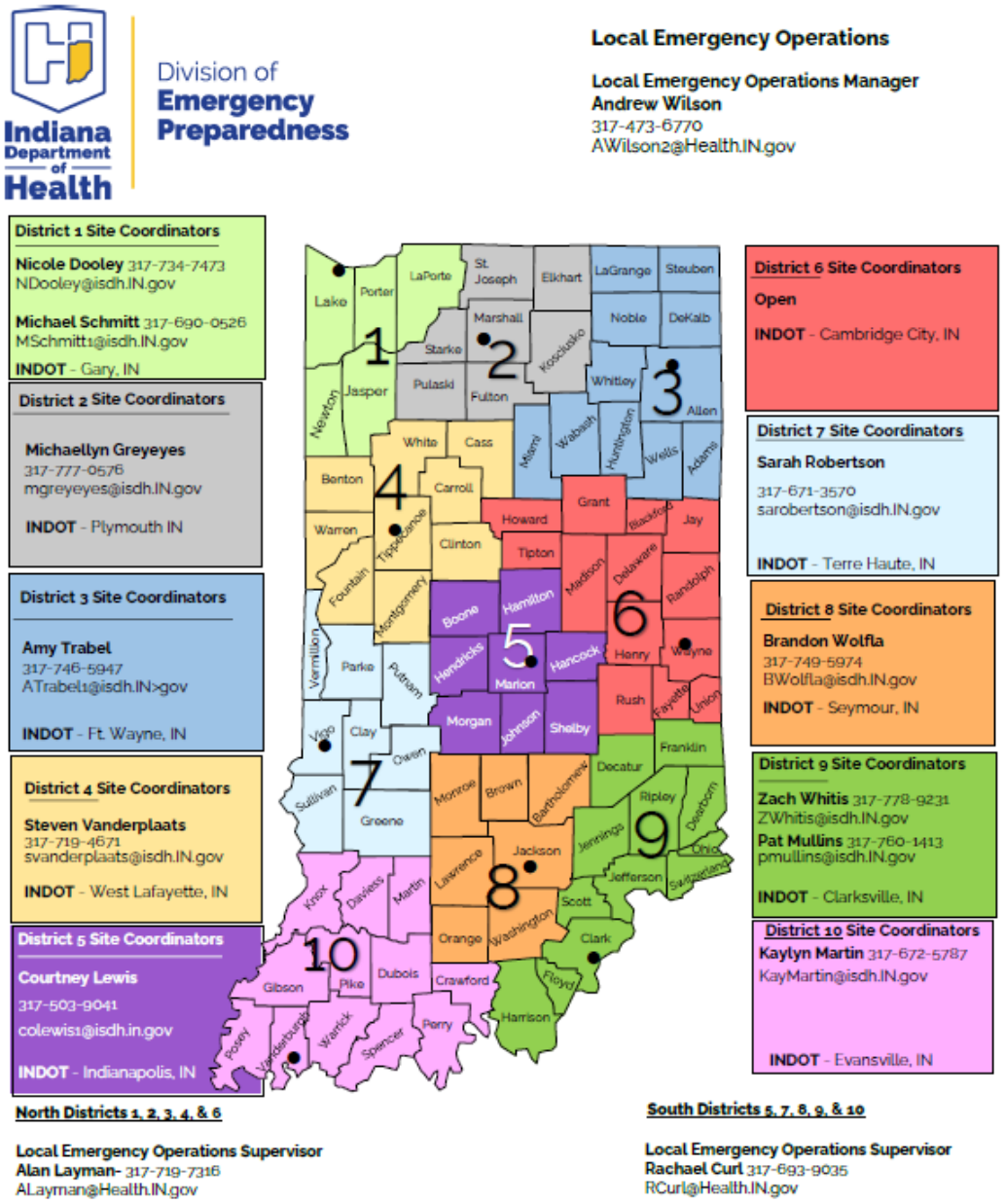
Start Smart Data

- 524,476 children were missing one or more required vaccinations
- 144,983 children received one or more vaccinations during the 6-week campaign
- 101,607 children received one or more vaccines in the month after the campaign.



IDOH Mobile Units

- 10 mobile units through a partnership with Preparedness
- Staffing for vaccination and testing
- School health
- Outbreak response
- Homebound Hoosiers

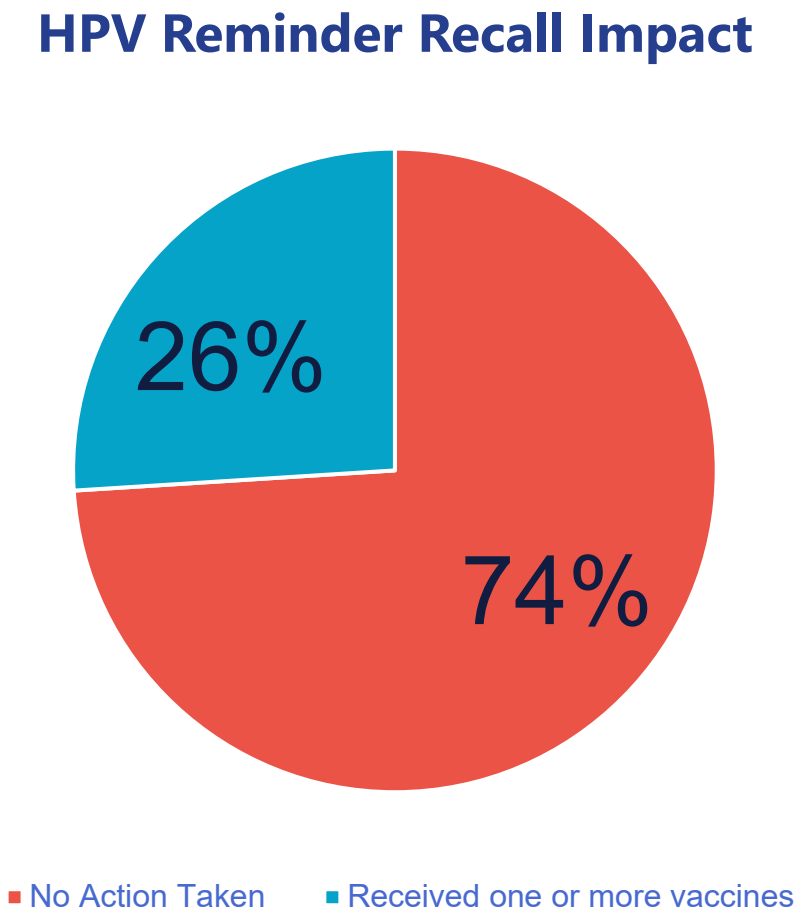


Pharmacies as VFC Providers

- Important need for vaccination touchpoints in the adolescent space
- Expanded hours for vaccinations
- COVID-19 Bridge Access Program – exact same process for enrollment and management
- Streamlined processes for enrollment – moving to all electronic process
- Marketing options

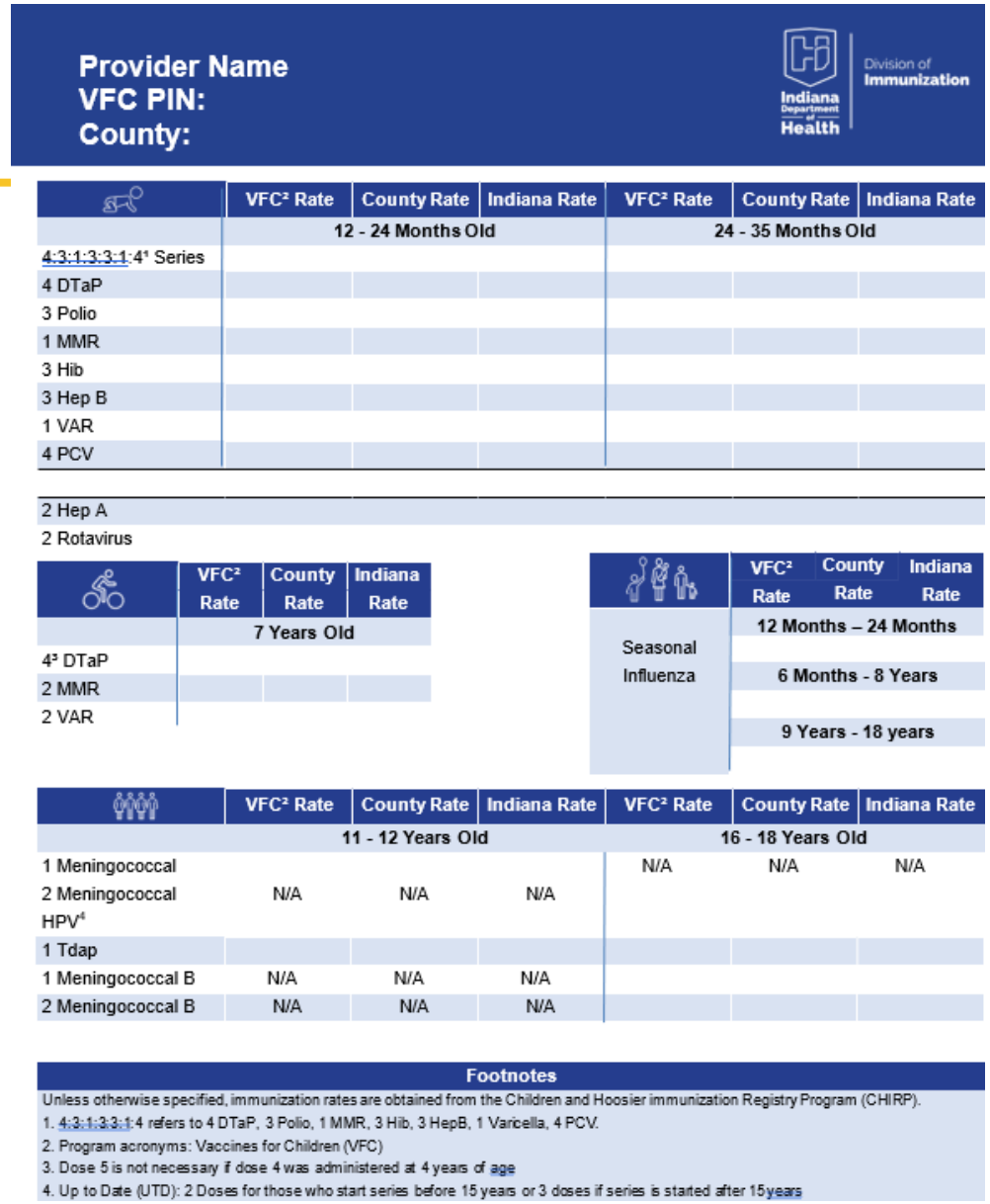
HPV Reminder Recall

- 106,469 individuals were missing one or more HPV doses for completion.
- Sent letters to parents/guardians stating that an additional dose was needed for series completion.
- 27,382 individuals, or 26%, that received a letter completed the series.



VFC Coverage Report

- Feedback to providers on coverage rates by practice
- Replaces individual antigen report cards
- Data quality measure
- Excellent communication tool



Provider Name
VFC PIN:
County:

Indiana Department of Health — Division of Immunization

	VFC² Rate	County Rate	Indiana Rate	VFC² Rate	County Rate	Indiana Rate
	12 - 24 Months Old			24 - 35 Months Old		
4:3:1:3:3:1:4[1] Series						
4 DTaP						
3 Polio						
1 MMR						
3 Hib						
3 Hep B						
1 VAR						
4 PCV						
2 Hep A						
2 Rotavirus						

	VFC² Rate	County Rate	Indiana Rate
	7 Years Old		
4[3] DTaP			
2 MMR			
2 VAR			

	VFC² Rate	County Rate	Indiana Rate
Seasonal Influenza	12 Months – 24 Months		
	6 Months - 8 Years		
	9 Years - 18 years		

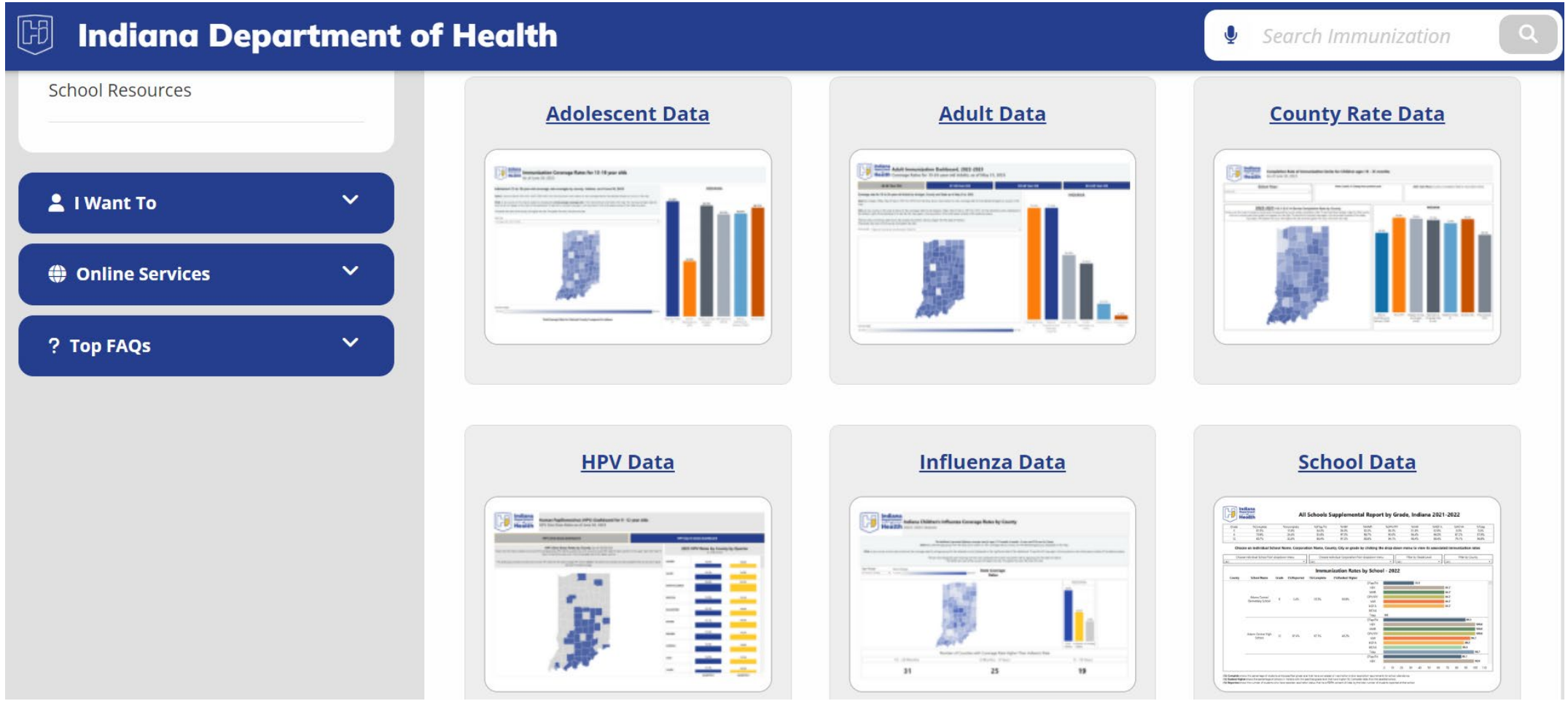
	VFC² Rate	County Rate	Indiana Rate	VFC² Rate	County Rate	Indiana Rate
	11 - 12 Years Old			16 - 18 Years Old		
1 Meningococcal				N/A	N/A	N/A
2 Meningococcal	N/A	N/A	N/A			
HPV[4]						
1 Tdap						
1 Meningococcal B	N/A	N/A	N/A			
2 Meningococcal B	N/A	N/A	N/A			

Footnotes

Unless otherwise specified, immunization rates are obtained from the Children and Hoosier immunization Registry Program (CHIRP).
1. 4:3:1:3:3:1:4 refers to 4 DTaP, 3 Polio, 1 MMR, 3 Hib, 3 HepB, 1 Varicella, 4 PCV.
2. Program acronyms: Vaccines for Children (VFC)
3. Dose 5 is not necessary if dose 4 was administered at 4 years of age
4. Up to Date (UTD): 2 Doses for those who start series before 15 years or 3 doses if series is started after 15 years

Indiana Department of Health

Immunization Dashboards



Questions?

Dave McCormick, Director
Immunization Division
dmccormick@health.in.gov

Celebrating 30 Years of Saving Lives: The Vaccines for Children Program Now and in the Future

Discussion

NVAC

Innovation in Immunization Subcommittee Update

Dr. Jewel Mullen
Bob Swanson

NVAC

National Vaccine Advisory Committee

Innovation in Immunization (III) Subcommittee

NVAC Update: February 22, 2024

Bob Swanson and Jewel Mullen, III Subcommittee Co-Chairs

Subcommittee Members

Co-Chairs:
- Jewel Mullen
- Bob Swanson

NVAC Public Members:
- Bob Hopkins (NVAC Chair)
- Daniel Hoft
- Molly Howell

NVAC Ex-Officio Member:
- Robert Johnson, Administration for Strategic Preparedness and Response

Public Members:
- Phyllis Arthur, Biotechnology Innovation Organization
- Karin Bok, National Institutes of Health
- Fred Cassels, PATH
- Tim Cooke, Omniose
- David Dowling, Boston Children's Hospital and Harvard
- Bonnie Maldonado, Stanford University
- Kimberly Taylor, National Institutes of Health
- Nicholas Wohlgemuth, Kansas Health Science Center

Charge Overview

NVAC should write a report that includes:

- A review of both conventional and promising novel approaches for vaccine discovery and development.
- A set of recommendations for actionable, high-impact activities.
- An evidence-based approach for identifying and prioritizing vaccine candidates and immunization technologies, including their criteria for prioritization.
    - NVAC should take the potential impact on disease burden, population health outcomes, health equity, economic impact, national health priorities, and scientific feasibility into account in the development of the approach.
- A list of vaccination innovation priorities, including target antigens, molecular platforms, and immunization delivery technologies.
- A forward-looking approach to introduce vaccines for special patient populations and neglected diseases to portray their value and importance.
- A scientific agenda outlining a framework of research direction and identifies scientific needs and gaps that should be addressed by the end of 2028.

Activities Since Last Update

- Hosted presentations on
  - Novel T-Cell Vaccines
  - Influenza Virus Case Study
  - ACIP Processes
  - Vaccine Innovation Law and Policy

Activities Since Last Update

- Developed and refined a report outline
- Working on finalizing a first draft of the report for editing
- Participating in group discussion of potential recommendations
- Developed and are reviewing a table of current vaccine-preventable diseases, which outlines the disease severity, the current vaccine efficacy, and any identified opportunities for innovation

Next Steps

- Refining recommendations
- Revising draft and table
- Asking NVAC for feedback on a draft
- Revise draft post NVAC feedback
- Present on progress at next NVAC meeting in June

Public Comment

NVAC

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Meeting

NATIONAL VACCINE ADVISORY COMMITTEE

February 22-23, 2024

NVAC