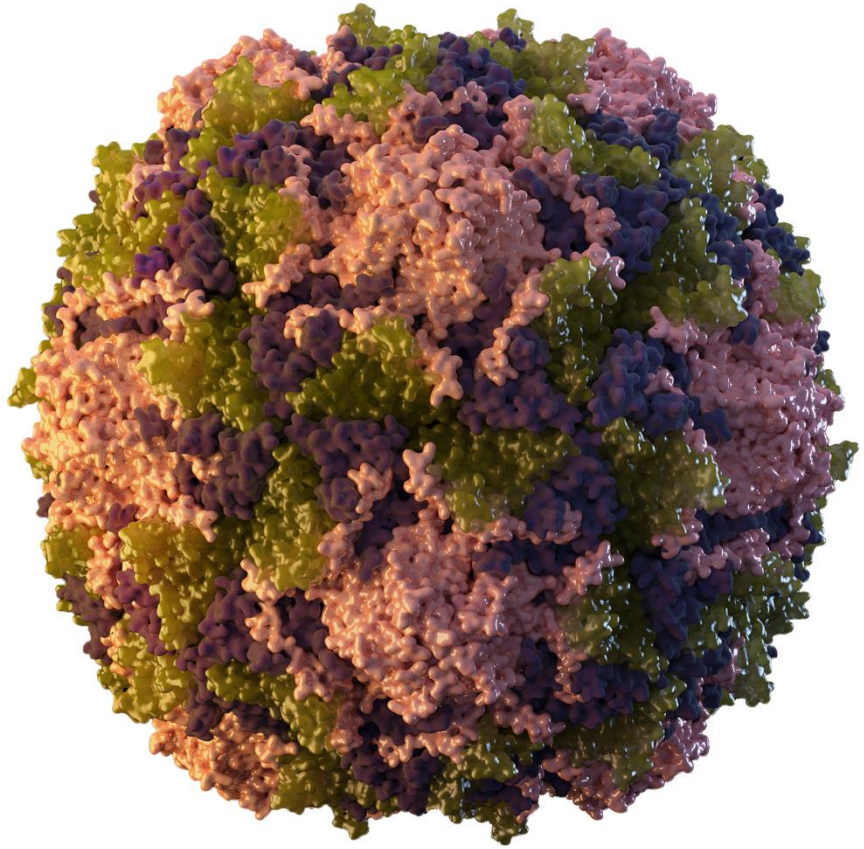
# Adult Polio Vaccination



Sarah Kidd, MD, MPH

ACIP Meeting

June 21, 2023

Photographs and images included in this presentation are licensed solely for CDC/NCIRD online and presentation use. No rights are implied or extended for use in printing or any use by other CDC CIOs or any external audiences.

# Objectives for Today's Presentation

- Summarize work group deliberations on adult polio vaccination
  - Recommendations for unvaccinated and incompletely vaccinated adults
  - Recommendations for booster doses of IPV

- Present work group's proposed language for an ACIP vote

# ACIP Evidence to Recommendations (EtR) Framework

- Problem
  - Is the problem of public health importance?
- Benefits & Harms
  - How substantial are the desirable anticipated effects?
  - How substantial are the undesirable anticipated effects?
  - Do the desirable effects outweigh the undesirable effects?
  - What is the overall certainty of this evidence for the critical outcomes?
- Values
  - Does the target population feel that the desirable effects are large relative to the undesirable effects?
  - Is there important uncertainty about or variability in how much people value the main outcome?
- Acceptability
  - Is the intervention acceptable to key stakeholders?
- Resource Use
  - Is the intervention a reasonable and efficient allocation of resources?
- Equity
  - What would be the impact on health equity?
- Feasibility
  - Is the intervention feasible to implement?

# 2000 Recommendations for Inactivated Polio Vaccine (IPV) Vaccination of Adults

- Vaccination is recommended for certain adults who are at greater risk for exposure to polioviruses than the general population
- Unvaccinated adults who are at increased risk of exposure should receive a primary vaccination series with IPV
- Adults who have had a primary series of oral polio vaccine (OPV) or IPV and who are at increased risk of exposure can receive another dose of IPV

Poliomyelitis Prevention in the United States (cdc.gov)

# 2000 Statement on IPV Vaccination for Adults Questions that arose in 2022

- 2000 statement focused on adults at **increased risk of poliovirus exposure**
- Uncertainty about how to define increased risk in setting of circulating vaccine-derived poliovirus (cVDPV) in US
- Unclear guidance for **unvaccinated** adults who were **not** known to be at increased risk of exposure
- Uncertainty about **vaccinated** adults and when/if a booster was advised

Poliomyelitis Prevention in the United States (cdc.gov)

# Policy Question #1 for Work Group

- **Should completion of a primary polio vaccination series with IPV be recommended for unvaccinated and incompletely vaccinated adults in the US?**
  - **Population:** Unvaccinated and incompletely vaccinated (with tOPV or IPV) US adults aged ≥18 years
  - **Intervention:** Completion of a primary vaccination series with IPV
  - **Comparison:** No vaccination or partial series completion
  - **Outcomes:**
    - Prevention of paralytic poliomyelitis
    - Serologic immunity to poliovirus types 1, 2, and 3
    - Serious adverse events following vaccination
    - Indirect effects, e.g., community transmission, impact on health systems

IPV = inactivated polio vaccine

tOPV = trivalent oral polio vaccine

# Current Definition of Fully Vaccinated

- A primary series of ≥3 doses of tOPV or IPV in any combination administered ≥4 weeks apart

AND

- The last dose in the series was given on or after the 4th birthday

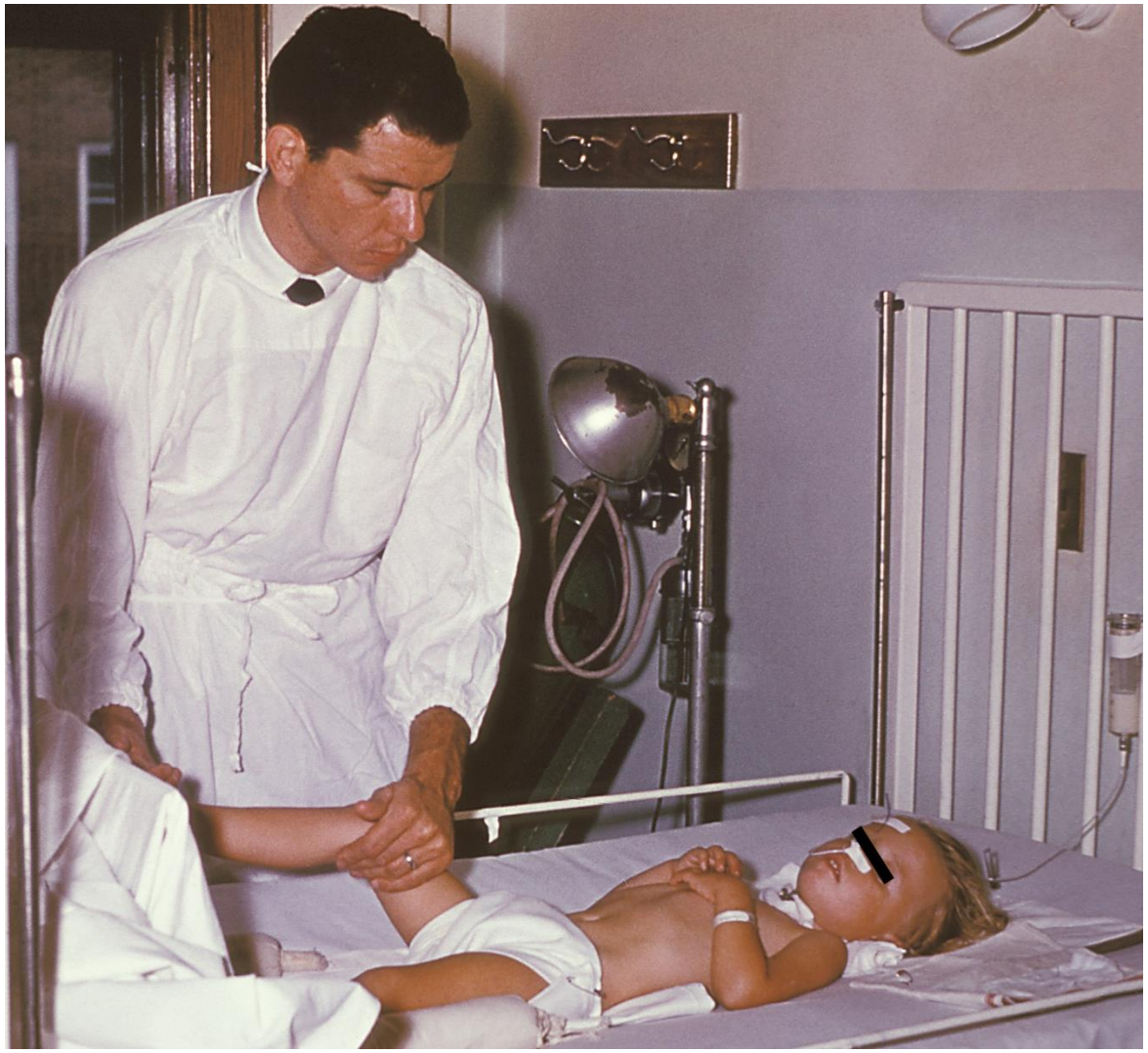
AND

- The last dose in the series was given ≥6 months after the previous dose

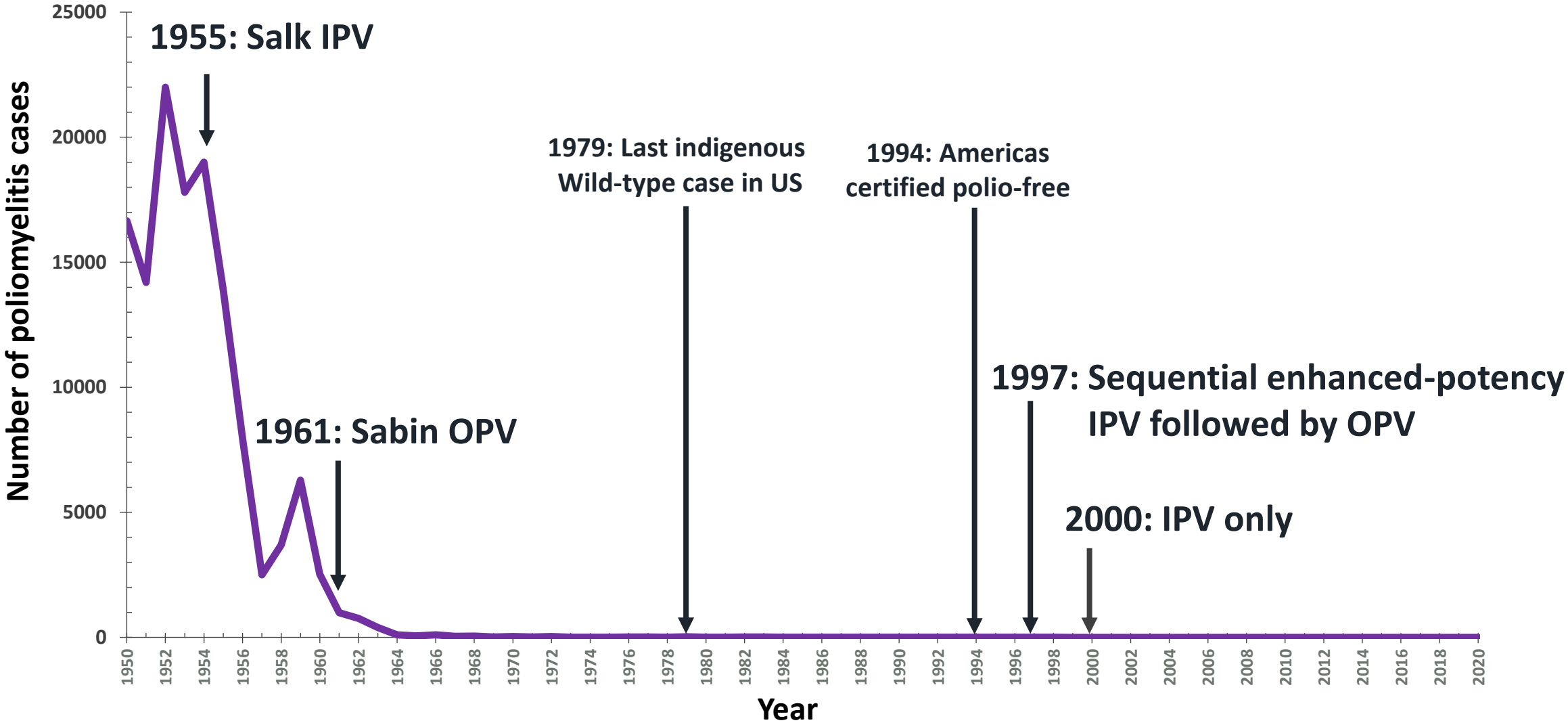
Updated Recommendations of the Advisory Committee on Immunization Practices (ACIP) Regarding Routine Poliovirus Vaccination (cdc.gov); Poliomyelitis Prevention in the United States (cdc.gov)

# Public Health Problem

- Poliovirus infection can cause poliomyelitis and lifelong paralysis
  - Paralytic disease occurs in <1% of infections (varies by serotype)
  - Non-paralytic clinical illness occurs in ~25%, including 1%–5% with aseptic meningitis
  - Approximately 75% of infections are asymptomatic

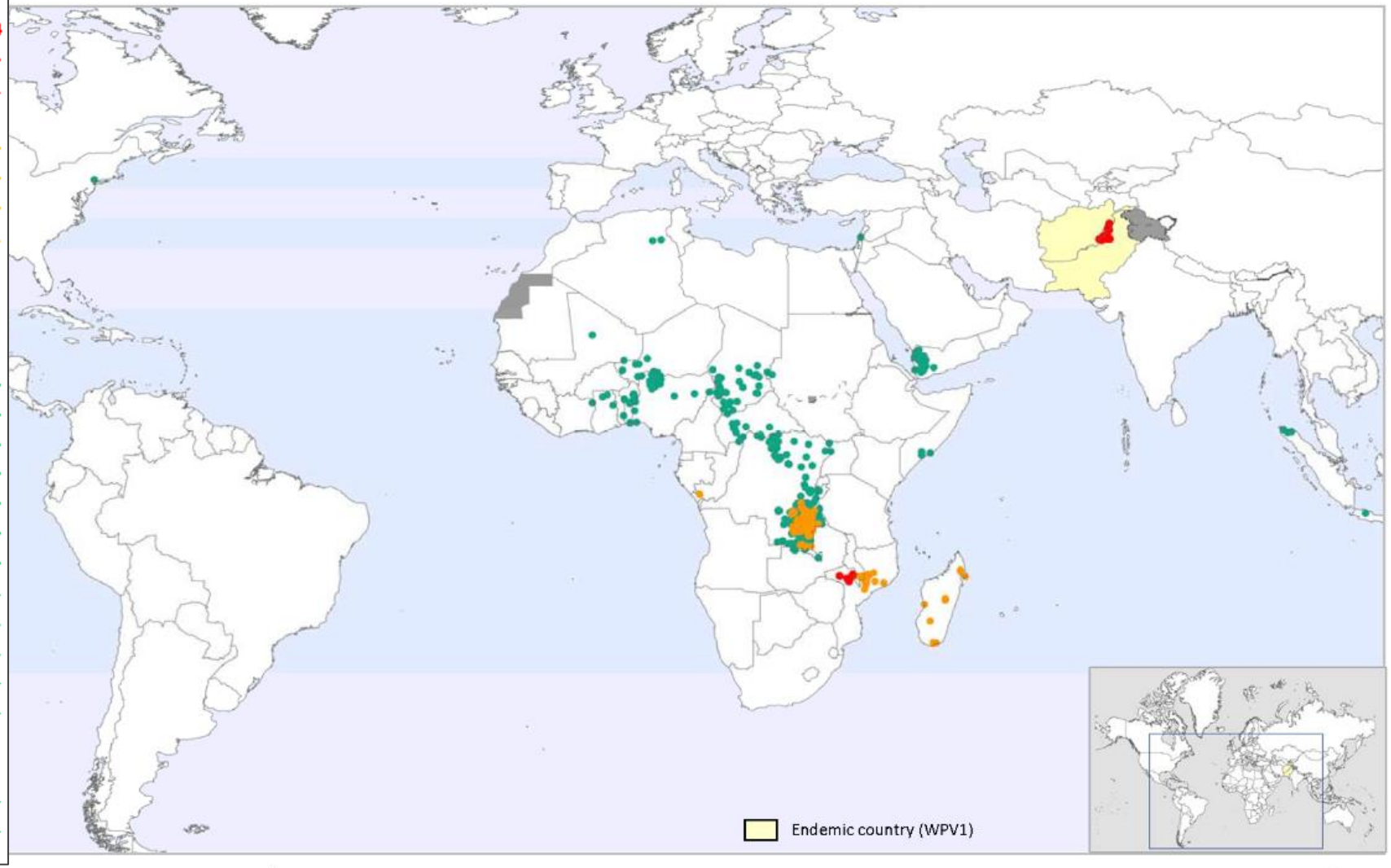


# Paralytic polio decreased rapidly in the US after introduction of polio vaccine



# Global Paralytic WPV1 and cVDPV Cases[1], Previous 12 Months[2]

| | | |
|---|---|---|
| **WPV1 cases (latest onset)** | | |
| Afghanistan | 4 | 08-May-23 |
| Pakistan | 11 | 20-Feb-23 |
| Mozambique | 5 | 10-Aug-22 |
| **cVDPV1 cases (latest onset)** | | |
| DR Congo | 156 | 06-Mar-23 |
| Madagascar | 15 | 01-Mar-23 |
| Mozambique | 23 | 27-Feb-23 |
| Malawi | 4 | 01-Dec-22 |
| Congo | 1 | 15-Oct-22 |
| **cVDPV2 cases (latest onset)** | | |
| Nigeria | 22 | 03-Apr-23 |
| CAR | 13 | 01-Apr-23 |
| Côte d'Ivoire | 1 | 22-Mar-23 |
| Chad | 39 | 10-Mar-23 |
| DR Congo | 311 | 05-Mar-23 |
| Somalia | 4 | 02-Mar-23 |
| Benin | 11 | 23-Feb-23 |
| Indonesia | 4 | 20-Feb-23 |
| Israel | 1 | 13-Feb-23 |
| Niger | 6 | 25-Dec-22 |
| Cameroon | 3 | 22-Dec-22 |
| Yemen | 49 | 14-Dec-22 |
| Algeria | 2 | 13-Dec-22 |
| Burundi | 1 | 24-Nov-22 |
| Sudan | 1 | 31-Oct-22 |
| Mali | 2 | 26-Oct-22 |
| Togo | 1 | 30-Sep-22 |
| Ghana | 3 | 14-Sep-22 |
| USA | 1 | 20-Jun-22 |




[1]Excludes viruses detected from environmental surveillance; [2]Onset of paralysis: 31 May 2022 to 30 May 2023

Data in WHO HQ as of 30 May 2023

[Polio Now – GPEI (polioeradication.org)](polioeradication.org)

WPV1 = wild poliovirus type 1; cVDPV = circulating vaccine-derived poliovirus

# Paralytic Polio Case in New York State, July 2022

- A case of paralytic polio caused by vaccine-derived poliovirus type 2 (VDPV2) was confirmed in an unvaccinated young adult from Rockland County, New York, on July 21, 2022
- Genetic sequencing has indicated a linkage to polioviruses collected in wastewater in Israel, United Kingdom, and Canada
- Rockland County has reported overall low vaccine coverage for over 20 years
  - In summer 2022, 60% of children under 2 years of age had received 3 doses of IPV (zip code level as low as 37%)

- No additional paralytic cases have been identified

# Wastewater Testing for Poliovirus in New York

- Poliovirus type 2 genetically linked to the case detected in wastewater samples in New York (Rockland, Orange, Sullivan, and Nassau counties and New York City)
- Retrospective testing detected poliovirus as early as April 2022
- Only 2 positive samples since November 1st (December 15th in Orange; February 22nd in Rockland)
- No detections in samples collected in last 15 weeks


WWS Report (ny.gov)

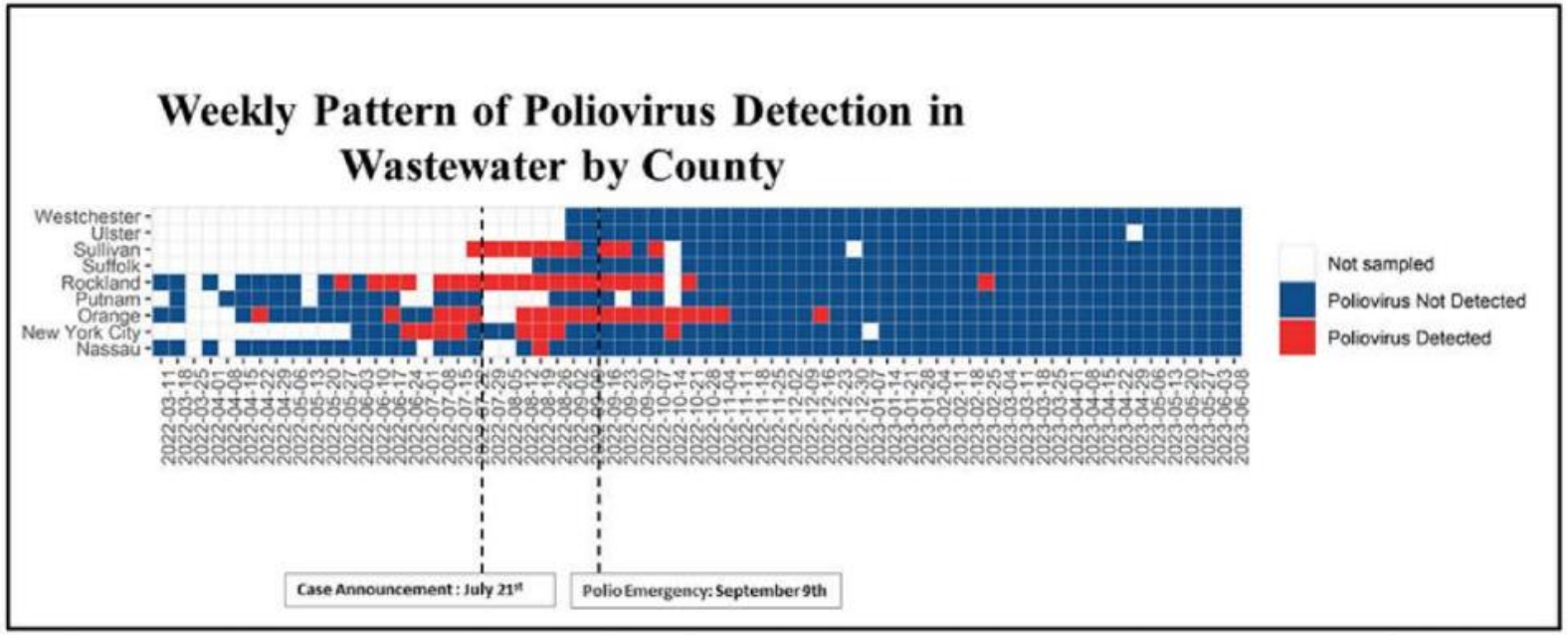
# Poliovirus in New York, 2022

- One paralytic polio case in unvaccinated young adult in Rockland County, NY in 2022
- Likely indicative of ≥1–2 thousand mostly asymptomatic infections

NEW YORK STATE | Department of Health

JUNE 20, 2023

## Weekly Poliovirus Detection in Wastewater By County




Poliovirus detected indicates samples with any detection of a poliovirus Type 2, including samples that have not been definitively genetically linked to the individual case in Rockland County.

Source: Polio WWS Report (ny.gov)

# National Salk Vaccination Coverage by September 1961 by Age and Race,
## Household US Immunization Survey (USIS)

| Birth year | Age in 1961 | Number of doses (%) 0 | 1–2 | ≥3 |
|---|---|---|---|---|
| **1957–1960** | **1–4 years** | | | |
| | White | 11% | 11% | 78% |
| | Non-white | 26% | 21% | 53% |
| **1952–1956** | **5–9 years** | | | |
| | White | 6% | 5% | 89% |
| | Non-white | 13% | 16% | 72% |
| **1947–1951** | **10–14 years** | | | |
| | White | 6% | 5% | 89% |
| | Non-white | 12% | 12% | 77% |
| **1942–1946** | **15–19 years** | | | |
| | White | 14% | 7% | 78% |
| | Non-white | 25% | 11% | 64% |

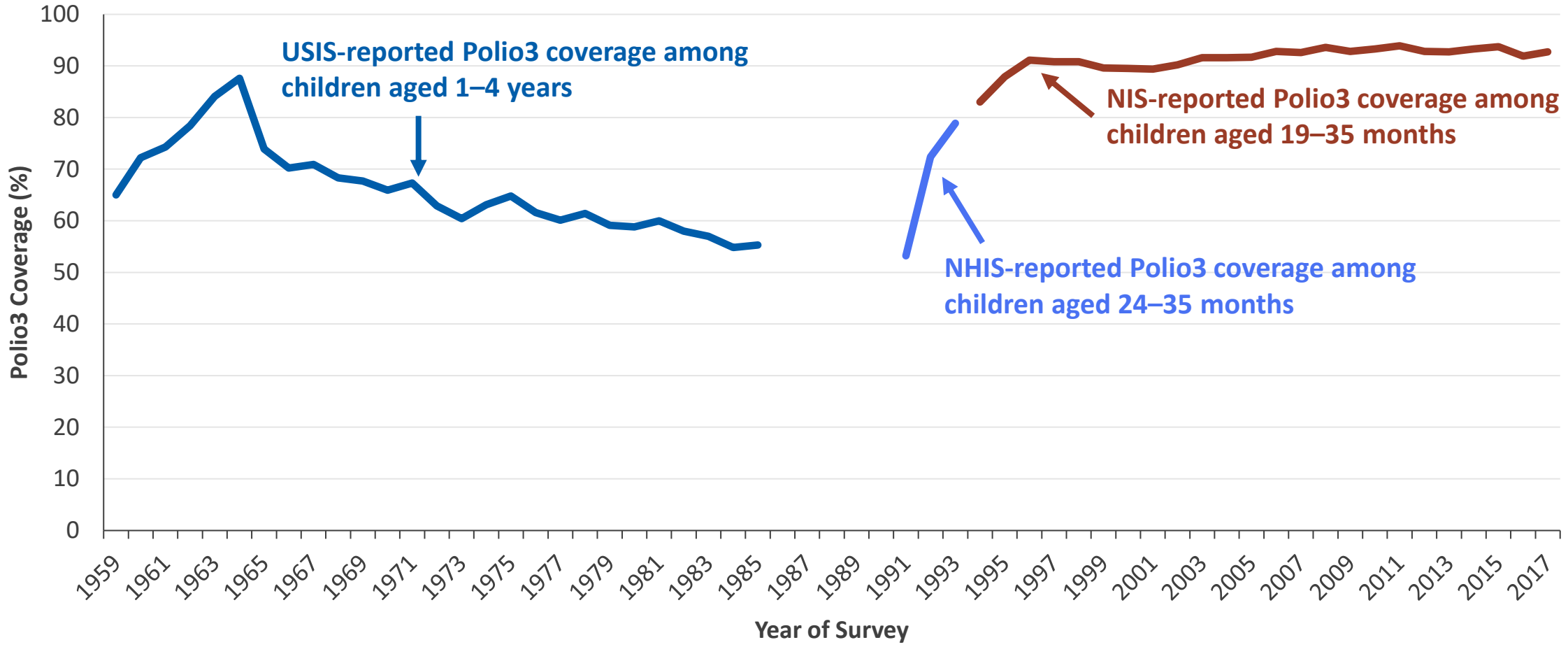
Source: Morris, Public Health Reports 1964.

# National Salk Vaccination Coverage by September 1961 by Age and Race,
## Household US Immunization Survey (USIS)

| Birth year | Age in 1961 | Number of doses (%) | | |
|---|---|---|---|---|
| | | 0 | 1–2 | ≥3 |
| **1932–1941** | **20–29 years** | | | |
| | White | 34% | 11% | 55% |
| | Non-white | 55% | 12% | 33% |
| **1922–1931** | **30–39 years** | | | |
| | White | 43% | 10% | 48% |
| | Non-white | 65% | 11% | 24% |
| **1912–1921** | **40–49 years** | | | |
| | White | 70% | 6% | 24% |
| | Non-white | 83% | 6% | 11% |
| **1902–1911** | **50–59 years** | | | |
| | White | 90% | 3% | 8% |
| | Non-white | 92% | 4% | 4% |

Source: Morris, Public Health Reports 1964.

# National Surveys of 3-dose Polio (Polio3) Vaccination Coverage among Children, United States, 1959–2017




Sources: Simpson et al, AJPM 2001 Forty years and four surveys: How does our measuring measure up? – ScienceDirect. CDC, MMWR 2001 National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19--35 Months --- United States, 2000 (cdc.gov). CDC, MMWR 2006 National, State, and Urban Area Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2005 (cdc.gov). CDC, MMWR 2011 National and State Vaccination Coverage Among Children Aged 19--35 Months --- United States, 2010 (cdc.gov). Hill et al, MMWR 2016 Vaccination Coverage Among Children Aged 19–35 Months — United States, 2015 | MMWR (cdc.gov). Hill et al, MMWR 2018 Vaccination Coverage Among Children Aged 19–35 Months — United States, 2017 | MMWR (cdc.gov).

# Seroprevalence of Poliovirus Antibodies by Age, United States NHANES Serosurvey, 2009–2010

| | | Percent positive (95% Confidence Interval) | | |
|---|---|---|---|---|
| Birth years | Age in 2009–2010 | Poliovirus Type 1 | Poliovirus Type 2 | Poliovirus Type 3 |
| 1998–2004 | 6–11 years | 97.2 (94.7–98.8) | 98.0 (96.4–99.0) | 93.8 (91.8–95.4) |
| 1990–1998 | 12–19 years | 94.7 (92.0–96.6) | 98.2 (96.6–99.2) | 84.3 (81.0–87.2) |
| 1970–1990 | 20–39 years | 92.7 (90.0–94.2) | 96.9 (95.2–98.2) | 78.6 (74.6–82.2) |
| 1960–1970 | 40–49 years | 93.9 (91.6–95.7) | 95.8 (93.8–97.3) | 85.8 (82.3–88.8) |

Source: Wallace et al, BMC Public Health 2016.

# Seroprevalence of Poliovirus Antibodies by Age & Race/Ethnicity, United States NHANES Serosurvey, 2009–2010

| Birth years | Age & Race/Ethnicity | Percent positive (95% Confidence Interval) | | |
|---|---|---|---|---|
| | | Poliovirus Type 1 | Poliovirus Type 2 | Poliovirus Type 3 |
| **1998–2004** | **6–11 years** | | | |
| | Mexican-American | 98.5 (96.4–99.5) | 98.2 (96.0–99.4) | 97.7 (94.7–99.3) |
| | Other Hispanic | 98.8 (93.5–100.0) | 99.2 (94.7–100.0) | 93.8 (87.0–97.7) |
| | Non-Hispanic White | 96.9 (93.1–98.9) | 97.6 (94.9–99.1) | 92.3 (88.5–95.2) |
| | Non-Hispanic Black | 99.1 (96.0–99.9) | 99.1 (96.3–99.9) | 96.1 (90.6–98.8) |
| | Non-Hispanic Other | 92.8 (83.1–97.9) | 97.6 (87.6–99.9) | 91.1 (81.0–96.9) |
| **1990–1998** | **12–19 years** | | | |
| | Mexican-American | 93.7 (90.5–96.1) | 98.4 (96.3–99.4) | 80.4 (74.5–85.4) |
| | Other Hispanic | 96.1 (90.2–98.9) | 99.1 (94.7–100.0) | 88.5 (81.0–93.8) |
| | Non-Hispanic White | 94.7 (89.5–97.8) | 97.7 (95.1–99.2) | 84.3 (79.3–88.5) |
| | Non-Hispanic Black | 93.8 (89.4–96.7) | 99.6 (97.7–100.0) | 84.6 (79.3– 89.0) |
| | Non-Hispanic Other | 97.1 (90.7–99.6) | 98.6 (93.0–100.0) | 88.5 (79.3–94.6) |

Source: Wallace et al, BMC Public Health 2016.

# Seroprevalence of Poliovirus Antibodies by Age & Race/Ethnicity, United States NHANES Serosurvey, 2009–2010

| Birth years | Age & Race/Ethnicity | Percent positive (95% Confidence Interval) Poliovirus Type 1 | Poliovirus Type 2 | Poliovirus Type 3 |
|---|---|---|---|---|
| **1970–1990** | **20–39 years** | | | |
| | Mexican-American | 91.2 (86.1–94.9) | **93.7 (90.2–96.2)** | 76.2 (71.5–80.4) |
| | Other Hispanic | 86.7 (78.5–92.6) | 94.2 (89.8–97.1) | 78.4 (70.5–84.9) |
| | Non-Hispanic White | 93.6 (91.2–95.5) | 97.2 (95.3–98.5) | 79.2 (75.1–82.9) |
| | Non-Hispanic Black | 94.7 (91.5–96.9) | **98.4 (96.4–99.5)** | 81.6 (75.8–86.6) |
| | Non-Hispanic Other | 90.5 (82.4–95.8) | 98.9 (92.4–100.0) | 74.3 (54.9–88.6) |
| **1960–1970** | **40–49 years** | | | |
| | Mexican-American | 89.1 (83.9–93.1) | **88.7 (80.9–94.1)** | **75.8 (69.5–81.3)** |
| | Other Hispanic | 89.4 (81.6–94.7) | 91.3 (82.4–96.7) | 85.4 (72.5–93.8) |
| | Non-Hispanic White | 94.9 (91.7–97.1) | **97.0 (94.3–98.6)** | **87.0 (82.1–91.0)** |
| | Non-Hispanic Black | 94.7 (90.0–97.6) | 96.9 (92.1–99.2) | 87.3 (78.7– 93.8) |
| | Non-Hispanic Other | 92.9 (75.0–99.2) | 96.1 (87.2–99.5) | 86.2 (68.9–95.9) |

Source: Wallace et al, BMC Public Health 2016.

# Summary of Problem

- US remains at risk of poliovirus importations as long as there is ongoing transmission of poliovirus globally
- Data indicate that most US adults have serologic immunity to poliovirus types 1–3
- However, unvaccinated and incompletely vaccinated adults remain susceptible to paralytic polio if exposed to poliovirus

# EtR Domain: Public Health Problem

Work group interpretation

**Is paralytic poliomyelitis a problem of public health importance?**

| No | Probably no | Probably yes | **Yes** | | Varies | Don't know |
|---|---|---|---|---|---|---|

# Effectiveness of Enhanced-Potency IPV

- Presence of detectable neutralizing antibody is a correlate of protection against paralytic disease.
  - Immunity against paralytic disease may be present even in absence of detectable antibodies.
- Serologic immunogenicity among infants and children
  - 70%–100% seropositive after 2 doses
  - 88%–100% seropositive after 3 doses
- Estimates of vaccine effectiveness against paralytic polio
  - 36%–89% for 1 dose
  - 89%–98% for 2 doses
- Paucity of data on adults receiving a primary series

Sources: Vidor et al review, PIDJ 1997. Stoeckel et al, Rev Infect Dis 1984. CDC, MMWR 1988. John, Rev Med Virol 1993.

# IPV and Mucosal Immunity

- Intestinal immunity
  - No significant difference between IPV and unvaccinated individuals in the **odds of shedding**
  - IPV vaccination appears to reduce the mean **quantity of shed poliovirus** by 63%–91%
  - Some data to suggest that IPV vaccination reduces **duration of shedding;** recent modeling study indicated no impact of IPV

- Nasopharyngeal (NP) immunity
  - Evidence to suggest similar, low rates of NP shedding (0%–4%) among OPV and IPV vaccinees

Sources: Hird and Grassly meta-analysis, PLoS Pathogens 2012. Kok et al, Bulletin of WHO 1992. Onorato et al, JID 1991. Brouwer et al, J R Soc Interface 2022.

# Safety

- Local reactions at injection site reported in trials
  - Tenderness in 14%–29%
  - Induration in 3%–11%
  - Erythema in 0.5%–1.4%

- Combining IPV with other vaccines is not associated with increased frequency or severity of reported adverse reactions compared with the other vaccines alone

- No severe adverse events have been causally associated with use of the current formulation of IPV

Sources: Sanofi Pasteur Package Insert - IPOL (fda.gov) . Vidor et al, PIDJ 1997. Murdin et al, Vaccine 1996. Wattigney et al, Pediatrics 2001. IOM 1994.

# Vaccine Adverse Event Reporting System (VAERS) Data, 2000–2012

- >250 million IPV-containing vaccine doses distributed 2000–2012
- 41,792 adverse event reports submitted for IPV-containing vaccines
  - 34,880 (88%) were for non-serious events
  - 95% were among persons <7 years of age
- Most events were associated with IPV co-administered with other vaccines
- Standalone IPV accounted for just 0.5% of reports
- VAERS is passive reporting system, cannot assess causal associations

Source: Iqbal et al, Lancet ID 2015.

# EtR Domain: Benefits & Harms

Work group interpretation

**How substantial are the desirable anticipated effects of completing a primary polio vaccination series in unvaccinated adults?**

| Minimal | Small | Moderate | **Large** | | Varies | Don't know |
|---|---|---|---|---|---|---|

# EtR Domain: Benefits & Harms

Work group interpretation

**How substantial are the <u>undesirable</u> anticipated effects of completing a primary polio vaccination series in unvaccinated adults?**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Minimal** | Small | Moderate | Large | | Varies | Don't know |

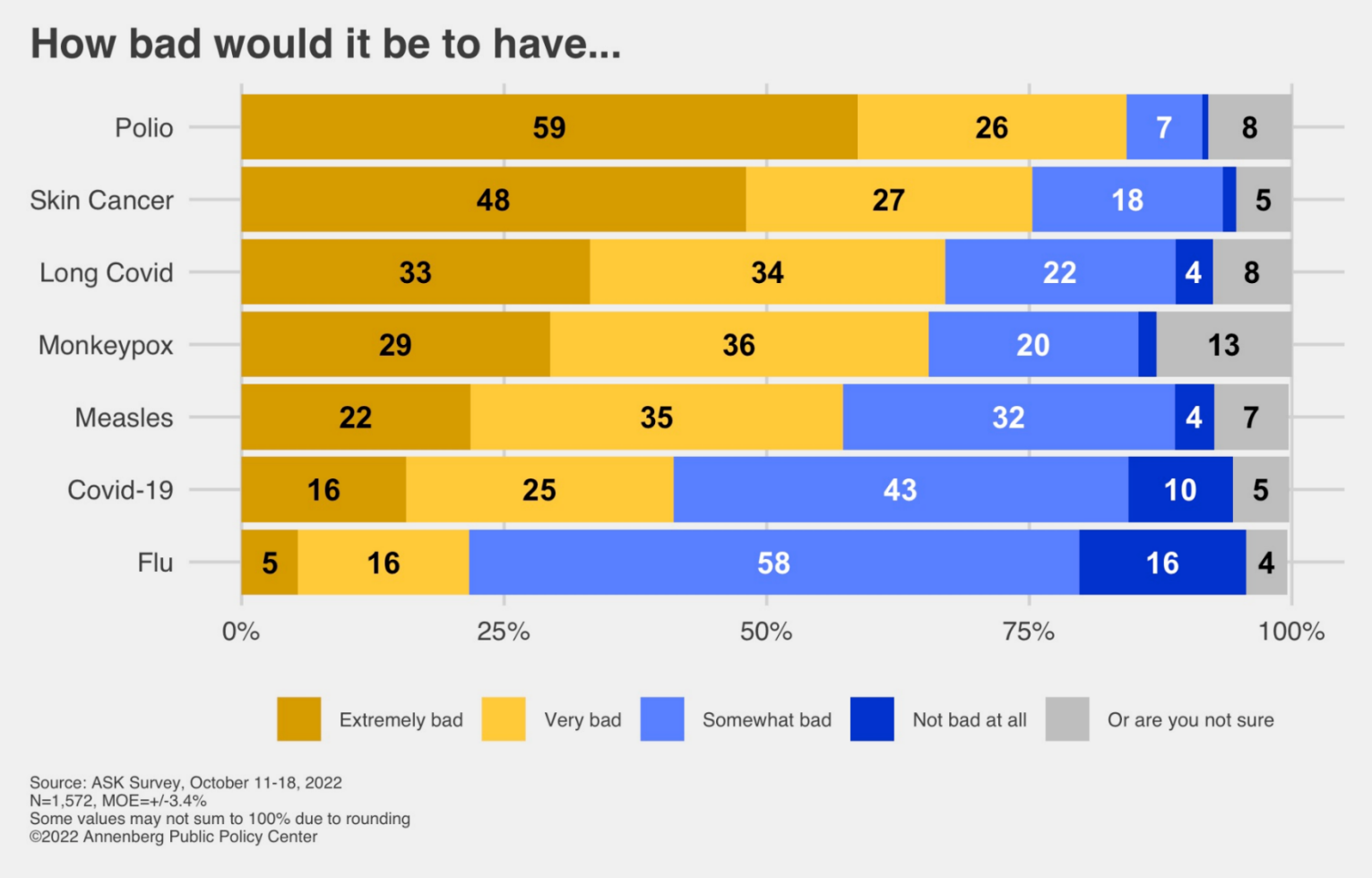
# EtR Domain: Benefits & Harms

Work group interpretation

**Do the desirable effects of completing a primary polio vaccination series outweigh the undesirable effects in unvaccinated adults?**

| | | | | |
|---|---|---|---|---|
| **Anticipated benefits outweigh anticipated harms** | Anticipated harms outweigh anticipated benefits | | Varies | Don’t know |

# Public Knowledge and Beliefs about Poliovirus Annenberg Science Knowledge (ASK) Survey*, October 2022




- **85%** said they were likely to recommend that an eligible person in their household get vaccinated with the polio vaccine

*Nationally representative panel of 1,572 US adults surveyed by SSRS for the Annenberg Public Policy Center of the University of Pennsylvania from October 11-18, 2022; this was 9th wave of the ASK survey whose respondents were first empaneled in April 2021.

What U.S. Adults Know and Believe About Polio and the Bivalent Covid Booster | The Annenberg Public Policy Center of the University of Pennsylvania

# Considerations for Values of Population in Question (Unvaccinated or Incompletely Vaccinated Adults)

- Values of unvaccinated adults might differ from those of general population
- Unvaccinated adults are likely a heterogeneous group
  - Persons whose families chose for them to not be vaccinated as children
  - Persons who missed opportunities to be vaccinated as children
- Lack of data on how these populations perceive their risk of polio and perceive the potential positive vs. negative effects of polio vaccination

# Additional Considerations for Acceptability to Key Stakeholders

## Pros

- Context of global polio eradication efforts
- Prevention of paralytic polio has been a public health priority for decades

## Cons

- Competing priorities for clinicians and local public health departments
- Uncertainty about eligibility for vaccination and true level of risk to adults in the US outside of outbreak setting

# EtR Domain: Values of Target Population

Work group interpretation

**Does the target population (unvaccinated or incompletely vaccinated adults) feel that the desirable effects of vaccination are large relative to undesirable effects?**

| | | | | | | |
|---|---|---|---|---|---|---|
| No | Probably no | Probably yes | Yes | | **Varies** | Don't know |

# EtR Domain: Values of Target Population

Work group interpretation

**Is there important uncertainty or variability in how much people value the main outcome (prevention of paralytic poliomyelitis)?**

| | | | | | |
|---|---|---|---|---|---|
| Important uncertainty or variability | **Probably important uncertainty or variability** | Probably not important uncertainty or variability | No important uncertainty or variability | | No known undesirable outcomes |

# EtR Domain: Acceptability to Key Stakeholders

Work group interpretation

**Is the intervention (vaccination of adults known or suspected to be unvaccinated or incompletely vaccinated) acceptable to key stakeholders?**

| | | | | | | |
|---|---|---|---|---|---|---|
| No | Probably no | **Probably yes** | Yes | | Varies | Don't know |

# Resource Use and Feasibility: Potential Supply and Demand

**Potential supply:**

- Currently just one US-licensed manufacturer of stand-alone IPV (Sanofi)
- Three US-licensed manufacturers of combination vaccines that include IPV (Sanofi, Merck, GSK)

**Potential demand:**

- Difficult to quantify: Uncertain number of adults who know they are unvaccinated or undervaccinated

# Resource Use and Feasibility: New York Experience

- Paralytic polio case identified in July 2022
- Persistent wastewater detections in area during summer to early fall 2022
- National and local media attention
- Calls for unvaccinated to get vaccinated
- Concerted health department efforts to reach unvaccinated persons
- **No significant supply issues**

# Additional Resource and Feasibility Considerations

- Access to vaccination sites that stock IPV
- Potential effects on health system screening and recall algorithms
  - Will need clear guidance for who is eligible for vaccination
- Feasibility of implementing risk-based recommendations, particularly if risk of exposure in the population changes over time

# EtR Domain: Resource Use

Work group interpretation

**Is the intervention (vaccination of adults known or suspected to be unvaccinated or incompletely vaccinated) a reasonable and efficient allocation of resources?**

| No | Probably no | **Probably yes** | **Yes** | | Varies | Don't know |
|---|---|---|---|---|---|---|

# EtR Domain: Feasibility

Work group interpretation

**Is the intervention (vaccination of adults known or suspected to be unvaccinated or incompletely vaccinated) feasible to implement?**

| | | | | | | |
|---|---|---|---|---|---|---|
| No | Probably no | **Probably yes** | Yes | | Varies | Don't know |

# Equity Considerations

- Different rates of childhood vaccination and poliovirus immunity
- Opportunity to receive catch-up polio vaccination as an adult likely increases equity
- No known differences in vaccine effectiveness among immunocompetent persons in the US setting
- Assuring equitable access to vaccination sites with IPV will be an important consideration for implementation

# EtR Domain: Equity

Work group interpretation

**What would be the impact (of vaccinating adults known or suspected to be unvaccinated or incompletely vaccinated) on health equity?**

| Reduced equity | Probably reduced equity | Probably no impact | **Probably increased equity** | Increased equity | Varies | Don't know |
|---|---|---|---|---|---|---|

# Work Group Judgement: Balance of Consequences Completing a Primary Polio Vaccination Series

**For unvaccinated/incompletely vaccinated adults known to be at increased risk of poliovirus exposure:**

| | | | | | |
|---|---|---|---|---|---|
| **Undesirable** consequences **clearly** outweigh desirable consequences in most settings | **Undesirable** consequences **probably** outweigh desirable consequences in most settings | The balance between desirable and undesirable consequences is closely balanced or uncertain | **Desirable** consequences **probably** outweigh undesirable consequences in most settings | **Desirable consequences clearly outweigh undesirable consequences in most settings** | There is insufficient evidence to determine the balance of consequences |

# Work Group Judgement: Balance of Consequences Completing a Primary Polio Vaccination Series

**For unvaccinated/incompletely vaccinated adults NOT specifically known to be at increased risk of poliovirus exposure:**

| | | | | | |
|---|---|---|---|---|---|
| **Undesirable** consequences **clearly** outweigh desirable consequences in most settings | **Undesirable** consequences **probably** outweigh desirable consequences in most settings | The balance between desirable and undesirable consequences is closely balanced or uncertain | **Desirable consequences probably outweigh undesirable consequences in most settings** | **Desirable** consequences **clearly** outweigh undesirable consequences in most settings | There is insufficient evidence to determine the balance of consequences |

# Considerations for a Risk-Based vs. Uniform Recommendation for All Unvaccinated Adults

## Situations that put adults at increased risk of exposure to poliovirus include:

- **Travelers** who are going to countries where polio is epidemic or endemic (For additional information, see Polio: For Travelers).
- **Laboratory and healthcare workers** who handle specimens that might contain polioviruses.
- **Healthcare workers or other caregivers** who have close contact with a person who could be infected with poliovirus.
- Unvaccinated or incompletely vaccinated **adults whose children will be receiving oral poliovirus vaccine** (for example, international adoptees or refugees).
- **Unvaccinated or incompletely vaccinated adults living or working in a community where poliovirus is circulating.**

# Considerations for a Risk-Based vs. Uniform Recommendation for All Unvaccinated Adults

**Situations that put adults at increased risk of exposure to poliovirus include:**

- **Travelers** who are going to countries where polio is epidemic or endemic (For additional information, see Polio: For Travelers).
- **Laboratory and healthcare workers** who handle specimens that might contain polioviruses.
- **Healthcare workers or other caregivers** who have close contact with a person who could be infected with poliovirus.
- Unvaccinated or incompletely vaccinated **adults whose children will be receiving oral poliovirus vaccine** (for example, international adoptees or refugees).
- **Unvaccinated or incompletely vaccinated adults living or working in a community where poliovirus is circulating.**

- Individual-level;
- Opportunity to anticipate risk and vaccinate prior to potential exposure

# Considerations for a Risk-Based vs. Uniform Recommendation for All Unvaccinated Adults

**Situations that put adults at increased risk of exposure to poliovirus include:**

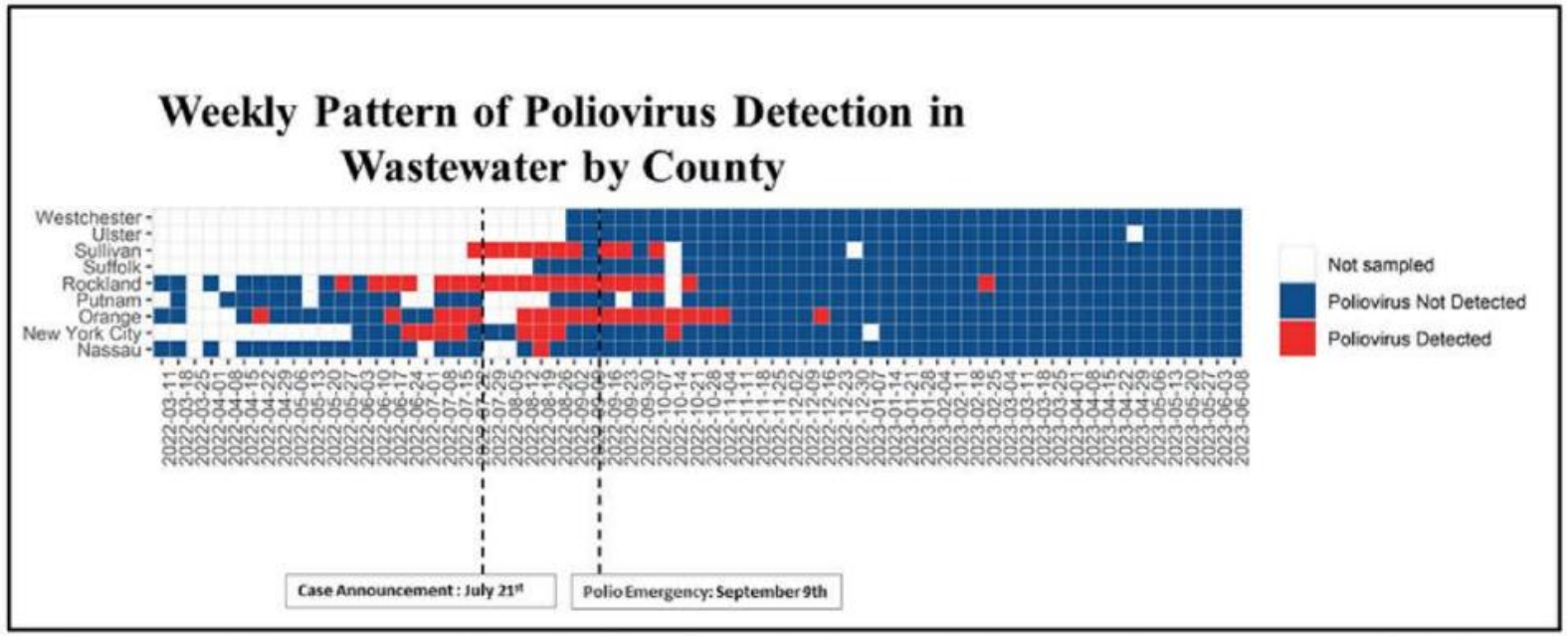
- **Travelers** who are going to countries where polio is epidemic or endemic (For additional information, see Polio: For Travelers).
- **Laboratory and healthcare workers** who handle specimens that might contain polioviruses.
- **Healthcare workers or other caregivers** who have close contact with a person who could be infected with poliovirus.
- Unvaccinated or incompletely vaccinated **adults whose children will be receiving oral poliovirus vaccine** (for example, international adoptees or refugees).
- **Unvaccinated or incompletely vaccinated adults living or working in a community where poliovirus is circulating.**

- Population-level;
- Group already at increased risk at time risk is recognized;
- Potential missed opportunities for vaccination prior to exposure

NEW YORK STATE | Department of Health

JUNE 20, 2023

## Weekly Poliovirus Detection in Wastewater By County




Poliovirus detected indicates samples with any detection of a poliovirus Type 2, including samples that have not been definitively genetically linked to the individual case in Rockland County.

[WWS Report_6_19_23 (ny.gov)]

## Challenges in 2022:

- In which of these counties are unvaccinated adults considered at increased risk of exposure?
- When are unvaccinated adults in these counties no longer at increased risk of exposure?
- Are unvaccinated adults traveling to these counties at increased risk of exposure?

# Pros and Cons of a Uniform Recommendation for Unvaccinated and Incompletely Vaccinated Adults

**Pros:**

- Allows unvaccinated adults and their health care providers to take advantage of opportunities to get vaccinated before they are at increased risk of exposure
- Brings adult polio vaccination policy closer in line with other routine childhood vaccines, e.g., MMR and varicella vaccines
- Is less complicated policy to communicate and understand (i.e., recommendation doesn't change based on latest wastewater data)

# Pros and Cons of a Uniform Recommendation for Unvaccinated and Incompletely Vaccinated Adults

**Cons:**

- Most adults in the United States have a low risk of poliovirus exposure and paralytic polio, and most adults received primary polio vaccination series as children
- Demand for IPV could potentially exceed supply, particularly if a large number of adults without documentation of polio vaccination status assume they were not vaccinated
  - However, this issue can be mitigated by providing guidance for this group in the clinical considerations

# Proposed Language for Unvaccinated and Incompletely Vaccinated Adults

- Majority of work group believe pros of uniform recommendation outweigh cons; approximately 1/3 favor current risk-based recommendation (and adding language for those not known to be at increased risk of exposure)

**Proposed Language:**

**Adults who are known or suspected to be unvaccinated or incompletely vaccinated against polio should complete a primary vaccination series with IPV.**

# Important Context to Be Included in Clinical Considerations

- In general, unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children. Polio vaccination has been part of the routine childhood immunization schedule for decades and is still part of the routine childhood immunization schedule. Adults who received any childhood vaccines almost certainly were vaccinated for polio.

# 2nd Policy Question: Adult IPV Boosters

# Policy Question #2 for Work Group

- **Should a booster IPV dose be recommended for adults at increased risk of poliovirus exposure who have previously completed a primary polio vaccination series?**
  - **Population:** US adults aged ≥18 years at increased risk of poliovirus exposure who have completed a primary polio vaccination series (with tOPV, IPV, or a combination of both)
  - **Intervention:** Booster dose of IPV
  - **Comparison:** Adults who completed a primary series but did not receive a booster dose
  - **Outcomes:**
    - Prevention of paralytic poliomyelitis
    - Serologic immunity to poliovirus types 1, 2, and 3
    - Serious adverse events following vaccination
    - Indirect effects, e.g., community transmission, impact on health systems

# Boosters: 2000 Statement and Rationale

- 2000 Statement: "**Adults who have had a primary series of OPV or IPV and who are at increased risk [of exposure to poliovirus] can receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults**."

- Rationale
  - Longstanding recommendation since tOPV was used in routine immunization
  - Actual need for supplementary dose not established, but "there is value in assuring protection against infection with wild polioviruses when exposure can reasonably be expected." (1977 ACIP Statement)
  - At least 2 reported cases of paralytic polio in adult travelers who had completed a primary vaccination series with Salk IPV and/or tOPV

CDC MMWR 1977; CDC MMWR 1986.

# 2014 Interim Guidance

## In Response to WHO Polio International Health Regulations (IHR) Emergency Committee Temporary Recommendations

- IHR Emergency Committee recommendation for travelers DEPARTING countries with poliovirus circulation, to prevent exportation
  - Applies to residents and travelers staying >4 weeks
  - If implemented by a country, proof of polio vaccination (IPV or tOPV) within the last 12 months could be required prior to leaving the country
  - Still included in most recent Polio IHR Statement

- 2014 MMWR:

  "Adults who have completed a routine series of polio vaccine are considered to have lifelong immunity to poliovirus but data are lacking. **As a precaution, persons aged ≥18 years who are traveling to areas where there has been WPV circulation in the last 12 months and who have received a routine series with either IPV or OPV in childhood should receive another dose of IPV before departure.** For adults, available data do not indicate the need for more than a single lifetime booster dose with IPV."

Wallace MMWR 2014; Statement of the thirty-fifth Polio IHR Emergency Committee (who.int)

# Unclear Need for IPV Booster in Vaccinated Adults: Seroprevalence of Poliovirus Antibodies by Age, United States NHANES Serosurvey, 2009–2010

| | | Percent positive (95% Confidence Interval) | | |
|---|---|---|---|---|
| Birth years | Age in 2009–2010 | Poliovirus Type 1 | Poliovirus Type 2 | Poliovirus Type 3 |
| 1998–2004 | 6–11 years | 97.2 (94.7–98.8) | 98.0 (96.4–99.0) | 93.8 (91.8–95.4) |
| 1990–1998 | 12–19 years | 94.7 (92.0–96.6) | 98.2 (96.6–99.2) | 84.3 (81.0–87.2) |
| 1970–1990 | 20–39 years | 92.7 (90.0–94.2) | 96.9 (95.2–98.2) | 78.6 (74.6–82.2) |
| 1960–1970 | 40–49 years | 93.9 (91.6–95.7) | 95.8 (93.8–97.3) | 85.8 (82.3–88.8) |

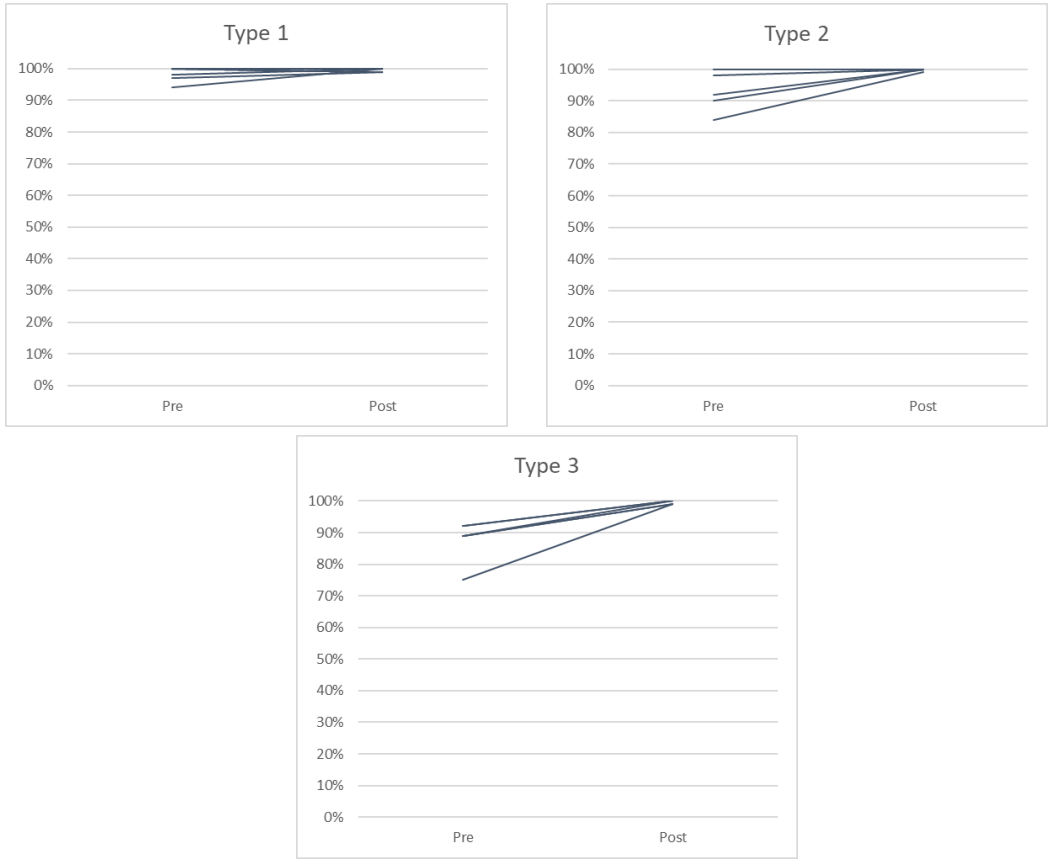
NOTE: Presence of detectable neutralizing antibody is a correlate of protection against paralytic disease. Immunity against paralytic disease may be present even in absence of detectable antibodies.

Source: Wallace et al, BMC Public Health 2016.

# Benefits of IPV Booster

- No data on vaccine effectiveness of primary series + booster vs. primary series only
- Serologic studies in adults with heterogeneous pre-booster vaccination histories/seropositivity: **98%–100% were seropositive 1 month after an IPV-containing booster**
- One study followed up trial participants 10 years post-booster: 98%–100% still seropositive

Data from Grimprel et al, Vaccine 2005: Seropositivity before and 1 month after IPV-containing booster by study group and poliovirus serotype




Sources: Broderick et al, Vaccine 2015; Domenicus et al, Vaccine 2014; Fukushima et al, Vaccines 2022; Grimprel et al, Vaccine 2005; Kovac et al, Vaccine 2015; Larnaudie et al, Human Vaccines 2010; Zimmermann et al, Vaccine 2013.

# Safety of IPV

- Local reactions at injection site reported in trials
  - Tenderness in 14%–29%
  - Induration in 3%–11%
  - Erythema in 0.5%–1.4%

- Combining IPV with other vaccines is not associated with increased frequency or severity of reported adverse reactions compared with the other vaccines alone

- No severe adverse events have been causally associated with use of the current formulation of IPV

Sources: Sanofi Pasteur Package Insert - IPOL (fda.gov) . Vidor et al, PIDJ 1997. Murdin et al, Vaccine 1996. Wattigney et al, Pediatrics 2001. IOM 1994.

# EtR Domain: Benefits & Harms

Work group interpretation

**For adults at increased risk of poliovirus exposure who were previously vaccinated, how substantial are the desirable anticipated effects of receiving a booster dose of IPV?**

| | | | | | | |
|---|---|---|---|---|---|---|
| Minimal | **Small** | **Moderate** | Large | | Varies | Don't know |

# EtR Domain: Benefits & Harms

Work group interpretation

**For adults at increased risk of poliovirus exposure who were previously vaccinated, how substantial are the undesirable anticipated effects of receiving a booster dose of IPV?**

| | | | | | | |
|---|---|---|---|---|---|---|
| **Minimal** | Small | Moderate | Large | | Varies | Don't know |

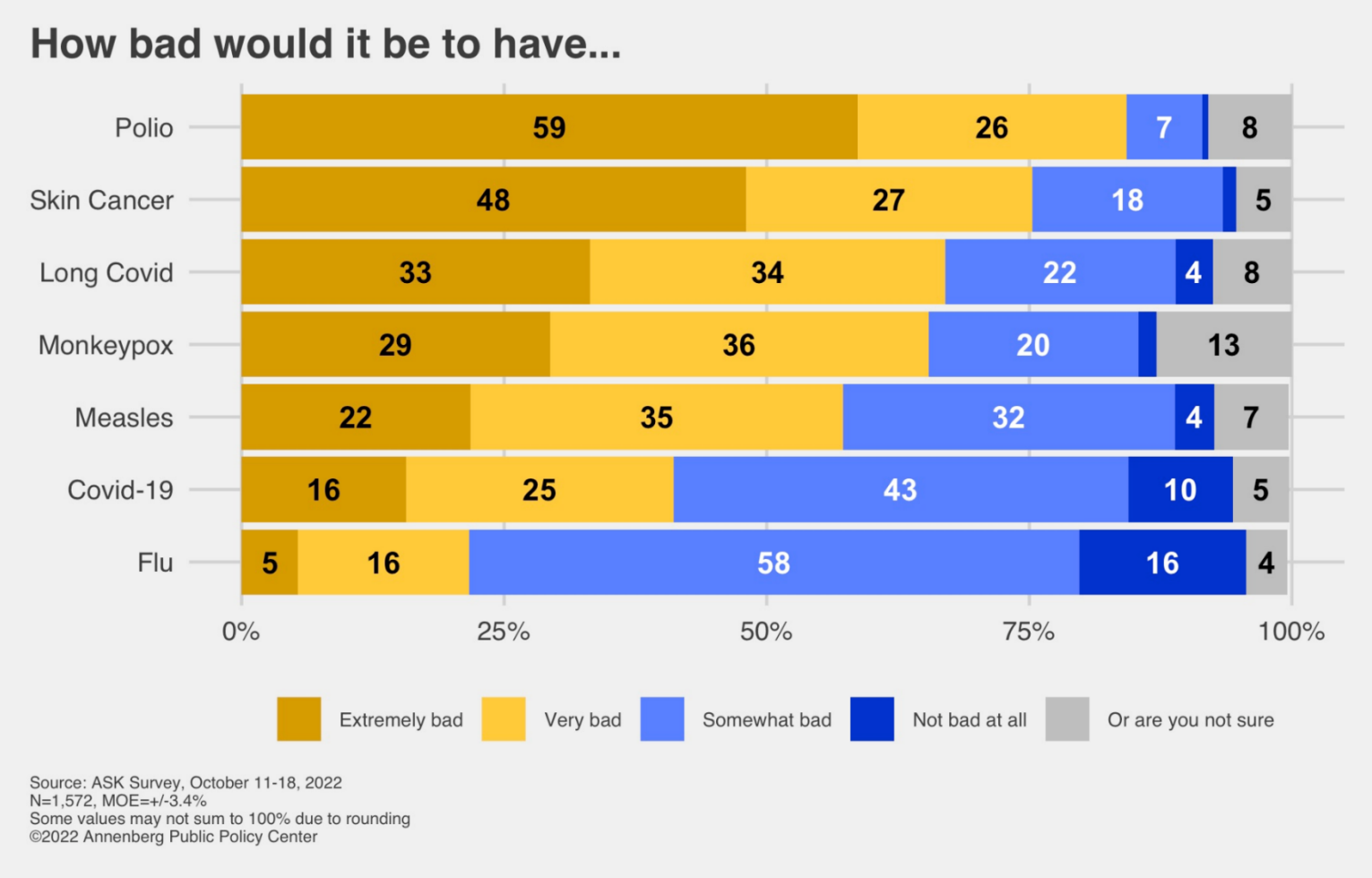
# EtR Domain: Benefits & Harms

Work group interpretation

**For adults at increased risk of poliovirus exposure who were previously vaccinated, do the desirable effects of receiving a booster dose of IPV outweigh the undesirable effects?**

| | | | | |
|---|---|---|---|---|
| **Anticipated benefits outweigh anticipated harms** | Anticipated harms outweigh anticipated benefits | | Varies | Don’t know |

# Public Knowledge and Beliefs about Poliovirus Annenberg Science Knowledge (ASK) Survey*, October 2022




- **85%** said they were likely to recommend that an eligible person in their household get vaccinated with the polio vaccine

*Nationally representative panel of 1,572 US adults surveyed by SSRS for the Annenberg Public Policy Center of the University of Pennsylvania from October 11-18, 2022; this was 9th wave of the ASK survey whose respondents were first empaneled in April 2021.

What U.S. Adults Know and Believe About Polio and the Bivalent Covid Booster | The Annenberg Public Policy Center of the University of Pennsylvania

# EtR Domain: Values of Target Population

Work group interpretation

**Does the target population (adults at increased risk of poliovirus exposure who were previously vaccinated) feel that the desirable effects of a booster dose are large relative to undesirable effects?**

| No | Probably no | **Probably yes** | Yes | | Varies | **Don't know** |
|---|---|---|---|---|---|---|

# EtR Domain: Values of Target Population

Work group interpretation

**Is there important uncertainty or variability in how much people value the main outcome (prevention of paralytic poliomyelitis)?**

| | | | | | |
|---|---|---|---|---|---|
| Important uncertainty or variability | Probably important uncertainty or variability | **Probably not important uncertainty or variability** | **No important uncertainty or variability** | | No known undesirable outcomes |

# Considerations for Acceptability, Feasibility, and Resources

- Current recommendation ("Adults who have had a primary series of OPV or IPV and who are at increased risk [of exposure to poliovirus] can receive another dose of IPV.") is long-standing and is generally accepted and feasible

- If "at increased risk of exposure" group is expanded (e.g., to include previously vaccinated adults in certain US areas with poliovirus circulation), feasibility might be affected

- New York State and New York City experience in 2022
  - No significant IPV supply issues

# EtR Domain: Acceptability to Key Stakeholders

Work group interpretation

**Is the intervention (providing a booster IPV dose to adults at increased risk of poliovirus exposure who previously completed a primary polio vaccination series) acceptable to key stakeholders?**

| No | Probably no | **Probably yes** | **Yes** | | Varies | Don't know |
|---|---|---|---|---|---|---|

# EtR Domain: Resource Use

Work group interpretation

**Is the intervention (providing a booster IPV dose to adults at increased risk of poliovirus exposure who previously completed a primary polio vaccination series) a reasonable and efficient allocation of resources?**

| | | | | | | |
|---|---|---|---|---|---|---|
| No | Probably no | **Probably yes** | Yes | | Varies | Don't know |

# EtR Domain: Feasibility

Work group interpretation

**Is the intervention (providing a booster IPV dose to adults at increased risk of poliovirus exposure who previously completed a primary polio vaccination series) feasible to implement?**

| No | Probably no | **Probably yes** | **Yes** | | Varies | Don't know |
|---|---|---|---|---|---|---|

# Equity Considerations from Work Group

- No known differences in response to primary series by socioeconomic group in US setting
- No groups or settings known to be disadvantaged by current recommendation

- Potential increased equity by boosting immunity in those at increased risk of exposure, especially persons with potential occupational exposures to poliovirus

# EtR Domain: Equity

Work group interpretation

**What would be the impact (of providing a booster IPV dose to adults at increased risk of poliovirus exposure who previously completed a primary polio vaccination series) on health equity?**

| | | | | | | |
|---|---|---|---|---|---|---|
| Reduced equity | Probably reduced equity | Probably no impact | **Probably increased equity** | Increased equity | Varies | Don't know |

# Work Group Judgement: Balance of Consequences

## IPV booster for adults at increased risk of poliovirus exposure who have previously completed a primary polio vaccination series

| | | | | | |
|---|---|---|---|---|---|
| **Undesirable** consequences **clearly** outweigh desirable consequences in most settings | **Undesirable** consequences **probably** outweigh desirable consequences in most settings | The balance between desirable and undesirable consequences is closely balanced or uncertain | **Desirable** consequences **probably** outweigh undesirable consequences in most settings | **Desirable** consequences **clearly** outweigh undesirable consequences in most settings | There is insufficient evidence to determine the balance of consequences |

# Majority of Work Group Agree with Current Recommendation for Adult IPV Booster

- Risk-based
- Shared clinical decision-making

**Proposed Language:**

- **Adults who have received a primary series of tOPV or IPV in any combination and who are at increased risk of poliovirus exposure may receive another dose of IPV. Available data do not indicate the need for more than a single lifetime booster dose with IPV for adults.**

# Clinical Considerations

## Situations that put adults at increased risk of exposure to poliovirus include:

- **Travelers** who are going to countries where polio is epidemic or endemic (For additional information, see Polio: For Travelers).
- **Laboratory and healthcare workers** who handle specimens that might contain polioviruses.
- **Healthcare workers or other caregivers** who have close contact with a person who could be infected with poliovirus.

# Polio Work Group Members

- ACIP voting members
  - Oliver Brooks (Chair)
  - Lynn Bahta
  - Sybil Cineas

- Liaisons
  - Lynn Fisher, American Academy of Family Physicians
  - Chandy C John, American Academy of Pediatrics
  - Sandra Fryhofer, American Medical Association
  - Kathy Kudish, Association of Immunization Managers
  - Marcus Plescia, Association of State and Territorial Health Officials
  - Paul R Cieslak, Council of State and Territorial Epidemiologists
  - Christine Hahn, Council of State and Territorial Epidemiologists
  - Tina Q. Tan, Infectious Diseases Society of America
  - Adenike Shoyinka, Infectious Diseases Society of America
  - Mary Wilson, International Society of Travel Medicine
  - Jaqueline Lawler, National Association of County and City Health Officials
  - Kathy Edwards, Pediatric Infectious Diseases Society
  - Joseline Zafack, Public Health Agency of Canada*
  - Oliver Baclic, Public Health Agency of Canada*

- Consultants
  - Edwin Asturias
  - Doug E Campos-Outcalt*
  - Emily Lutterloh
  - Walt Orenstein
  - Jennifer Rosen
  - Eli Rosenberg

- Ex Officio
  - Robin Levis, FDA*
  - Robin Wisch, FDA*

- CDC*
  - Achal Bhatt
  - Stephanie Bialek
  - Thomas Clark
  - Brian Edlin
  - Concepcion Estivariz
  - Halle Getachew
  - Sarah Kidd
  - Janelle King
  - M. Steve Oberste
  - Janell Routh
  - Eileen Yee

*In the event of a Work Group poll, CDC, FDA, and Public Health Agency of Canada members are not included.

# Questions and Discussion

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.

Photographs and images included in this presentation are licensed solely for CDC/NCIRD online and presentation use. No rights are implied or extended for use in printing or any use by other CDC CIOs or any external audiences.