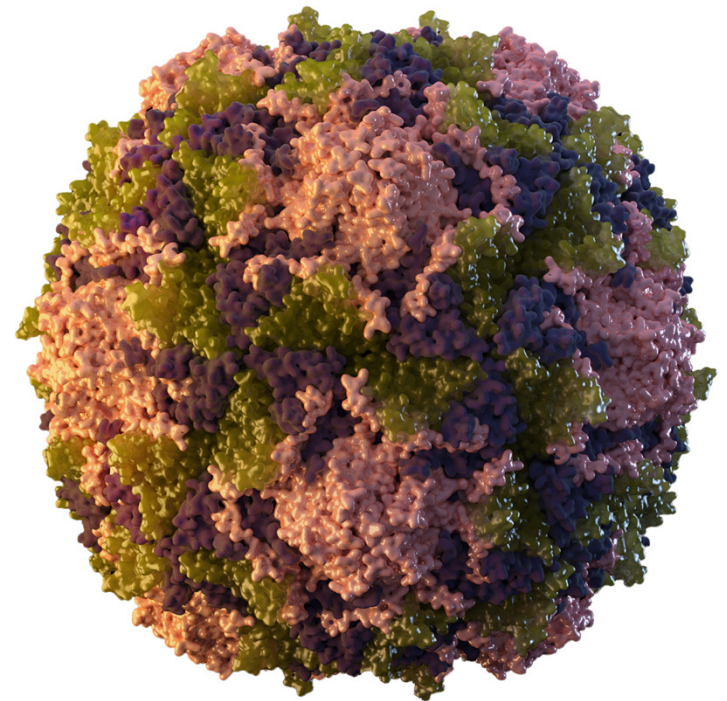


Adult Polio Vaccination

Sarah Kidd, MD, MPH

ACIP Meeting

February 23, 2023



Objectives for Today's Presentation

- Briefly summarize work group deliberations on adult polio vaccination
- Present proposed language for adult polio vaccination (anticipate ACIP vote in June)
- Solicit feedback and identify areas where more data are needed prior to an ACIP vote



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 should receive a primary vaccination series with IPV
- Adults who have had a primary series of OPV or IPV and who are at increased risk can receive another dose of IPV

2000 Statement on IPV Vaccination for Adults

Questions and problems that came up in 2022

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

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 OPV 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

Current Definition of Fully Vaccinated

An adult is considered fully vaccinated if they received:

- A primary series of ≥ 3 doses of trivalent OPV (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

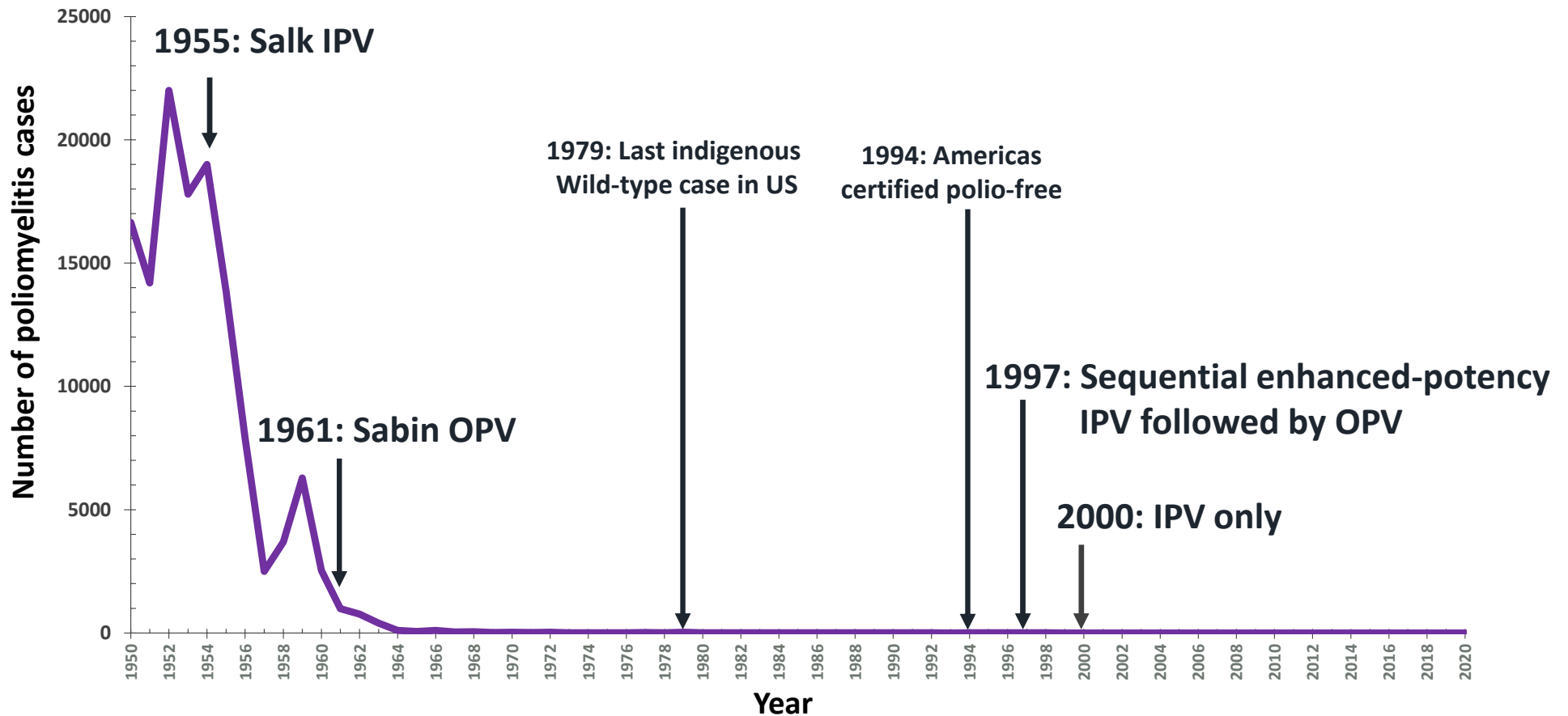
- The last dose in the series was given ≥ 6 months after the previous dose

Public Health Problem

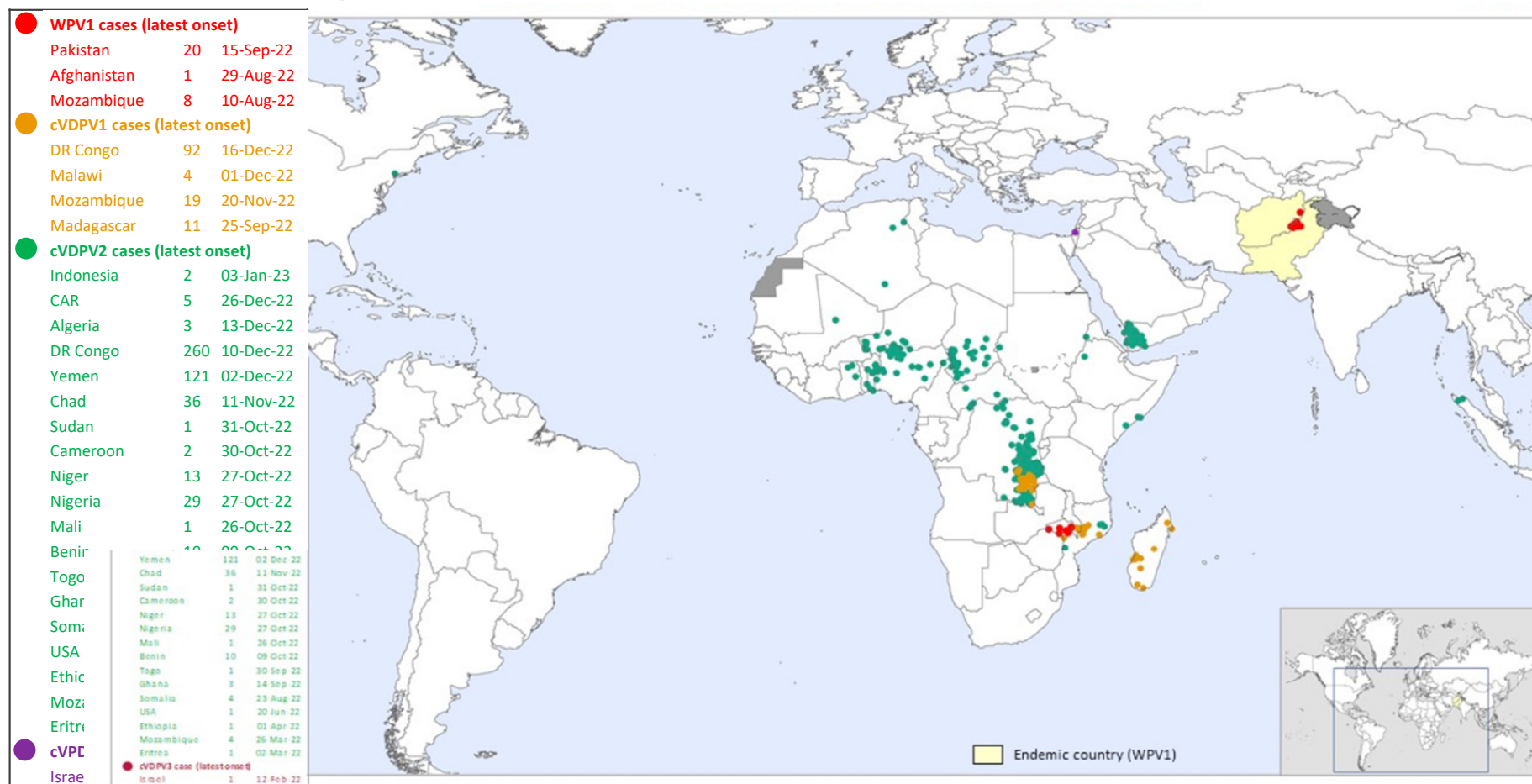
- Poliovirus infection can cause poliomyelitis and lifelong paralysis
 - Paralytic disease occurs in <1% of infections (varies by serotype)
 - Non-paralytic clinical illness occurs in ~25%, including 1%–5% with aseptic meningitis
 - Approximately 75% of infections are asymptomatic



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



Global Paralytic WPV1 and cVDPV Cases¹, Previous 12 Months²



¹Excludes viruses detected from environmental surveillance; ²Onset of paralysis: 08 Feb. 2022 to 07 Feb. 2023

Data in WHO HQ as of 07 Feb. 2023

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 yrs of age had received the recommended 3 doses of IPV (zip code level as low as 37%)
- No additional paralytic cases have been identified



Wastewater Testing for Poliovirus

- 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
- Most recent positive sample was collected on December 15, 2022; no detections in samples collected in last 7 weeks
- No additional paralytic polio cases identified



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.

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 children¹
 - 70%–100% seropositive after 2 doses
 - 88%–100% seropositive after 3 doses
- Estimates of vaccine effectiveness against paralytic polio²
 - 36%–89% for 1 dose
 - 89%– 98% for 2 doses
- Paucity of data on adults receiving a primary series

1. Vidor et al review, PIDJ 1997.

2. Stoeckel et al, Rev Infect Dis 1984. CDC, MMWR 1988. John, Rev Med Virol 1993.



IPV and Mucosal Immunity

- Intestinal immunity¹
 - 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) immunity²
 - Evidence to suggest similar, low rates of NP shedding (0%–4%) among OPV and IPV vaccinees

Sources:

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

Safety: IPV is well-tolerated.

- 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

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
- Reported adverse events were similar and proportional to other vaccines

Source: Iqbal et al, Lancet ID 2015.



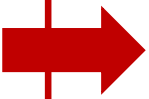
Considerations for a Risk-Based vs. Uniform Recommendation for Unvaccinated Adults

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.**
- 

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- **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

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- **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

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 maintaining the current risk-based recommendation

Majority Recommendation:

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

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.



Policy Question #2 for Work Group

- **Should a booster IPV dose be recommended for adults in the US who have previously completed a primary polio vaccination series?**
 - **Population:** US adults aged >18 years who have completed a primary polio vaccination series (with trivalent OPV, 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 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

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

| Birth years | Age in 2009 2010 | Percent positive (95% Confidence Interval) | | |
|-------------|------------------|--|-------------------|-------------------|
| | | 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) |
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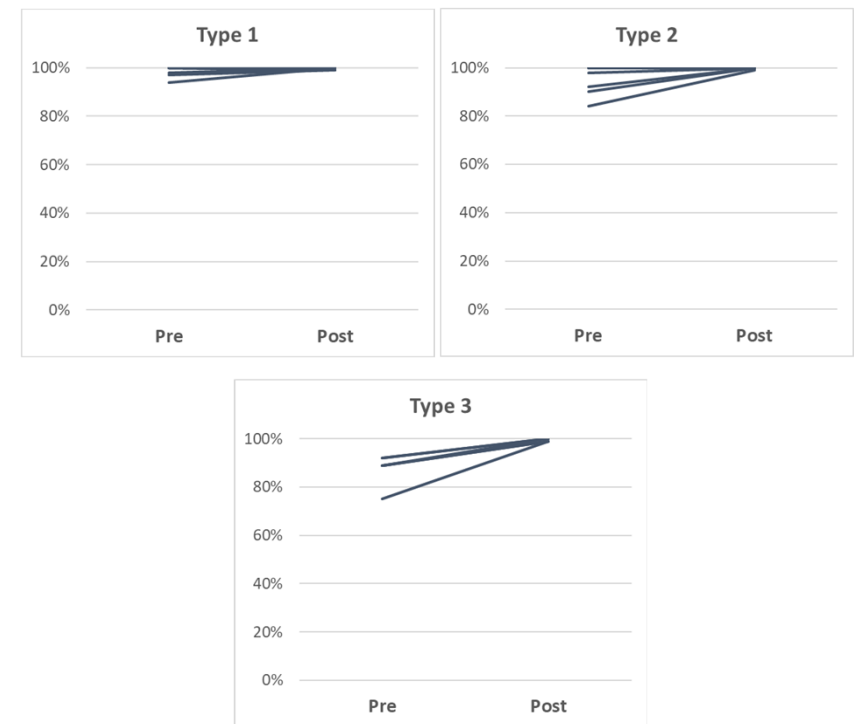
NOTE: Presence of detectable neutralizing antibody is a correlate of protection against paralytic disease. Immunity against paralytic disease may be present even in absence of detectable antibodies.

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.

Strong 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.**

Thank you to the ACIP Polio Work Group Members

■ ACIP voting members

- Oliver Brooks (Chair)
- Lynn Bahta

■ 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
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- Mary Wilson, International Society of Travel Medicine
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