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

- 1955: Salk IPV
- 1961: Sabin OPV
- 1979: Last indigenous Wild-type case in US
- 1994: Americas certified polio-free
- 1997: Sequential enhanced-potency IPV followed by OPV
- 2000: IPV only
### Global Paralytic WPV1 and cVDPV Cases\(^1\), Previous 12 Months\(^2\)

<table>
<thead>
<tr>
<th>WPV1 cases (latest onset)</th>
<th>cVDPV1 cases (latest onset)</th>
<th>cVDPV2 cases (latest onset)</th>
<th>cVDPV3 case (latest onset)</th>
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<tbody>
<tr>
<td>Pakistan 20 15-Sep-22</td>
<td>DR Congo 92 16-Dec-22</td>
<td>Indonesia 2 03-Jan-23</td>
<td>Israel 1 12-Feb-22</td>
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<td>Afghanistan 1 29-Aug-22</td>
<td>Malawi 4 01-Dec-22</td>
<td>CAR 5 26-Dec-22</td>
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<td>Mozambique 8 10-Aug-22</td>
<td>Mozambique 19 20-Nov-22</td>
<td>Algeria 3 13-Dec-22</td>
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<td>Madagascar 11 25-Sep-22</td>
<td>DR Congo 260 10-Dec-22</td>
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<td>Yemen 121 02-Dec-22</td>
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<td>Benin 10 09-Oct-22</td>
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<td>Somalia 4 23-Aug-22</td>
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<td>USA 1 20-Jun-22</td>
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<td>Ethiopia 1 01-Apr-22</td>
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<td>Mozambique 4 26-Mar-22</td>
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<td>Eritrea 1 02-Mar-22</td>
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\(^1\) Excludes viruses detected from environmental surveillance; \(^2\) Onset of paralysis: 08 Feb. 2022 to 07 Feb. 2023

[Polio Now – GPEI](polioeradication.org)
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
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

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<tr>
<th>Birth years</th>
<th>Age in 2009–2010</th>
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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\(^1\)
  - 70%–100% seropositive after 2 doses
  - 88%–100% seropositive after 3 doses

- Estimates of vaccine effectiveness against paralytic polio\(^2\)
  - 36%–89% for 1 dose
  - 89%–98% for 2 doses

- Paucity of data on adults receiving a primary series

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IPV and Mucosal Immunity

- **Intestinal immunity**¹
  - 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**²
  - Evidence to suggest similar, low rates of NP shedding (0%–4%) among OPV and IPV vaccinees

Sources:
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

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.

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

- Individual-level;
- Opportunity to anticipate risk and vaccinate prior to potential exposure
Considerations for a Risk-Based vs. Uniform Recommendation for Unvaccinated Adults

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• 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
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

CDC MMWR 1977; CDC MMWR 1986.
## Unclear Need for IPV Booster in Vaccinated Adults: Seroprevalence of Poliovirus Antibodies by Age, United States NHANES Serosurvey, 2009–2010

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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.

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

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
  - 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

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

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

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