



Poliovirus and Vaccination

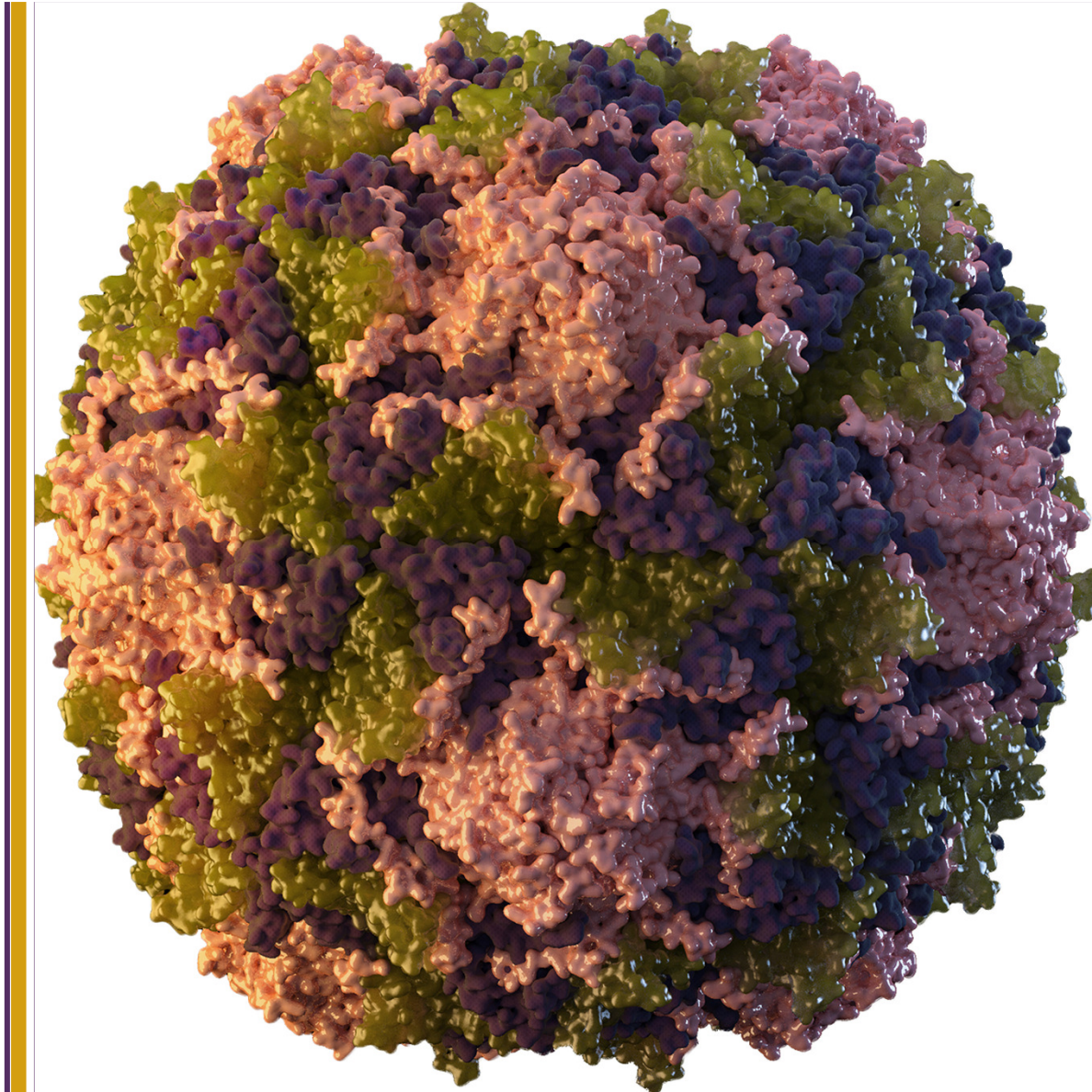
Polio Vaccine Work Group | October 19, 2022

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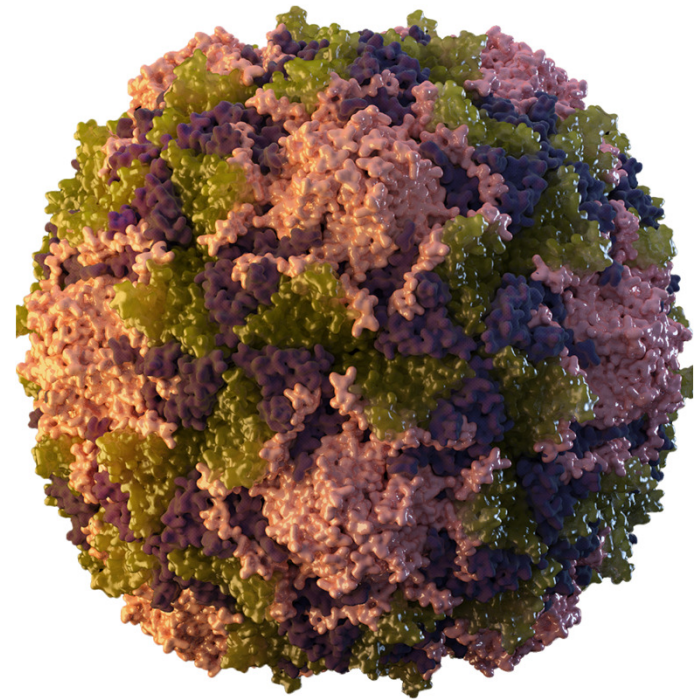
Objectives of the presentation

- 1) Review poliovirus, polio vaccination, and polio epidemiology in the United States
- 1) Review the Terms of Reference and members of the ACIP Polio Work Group

Poliovirus & Polio Vaccines

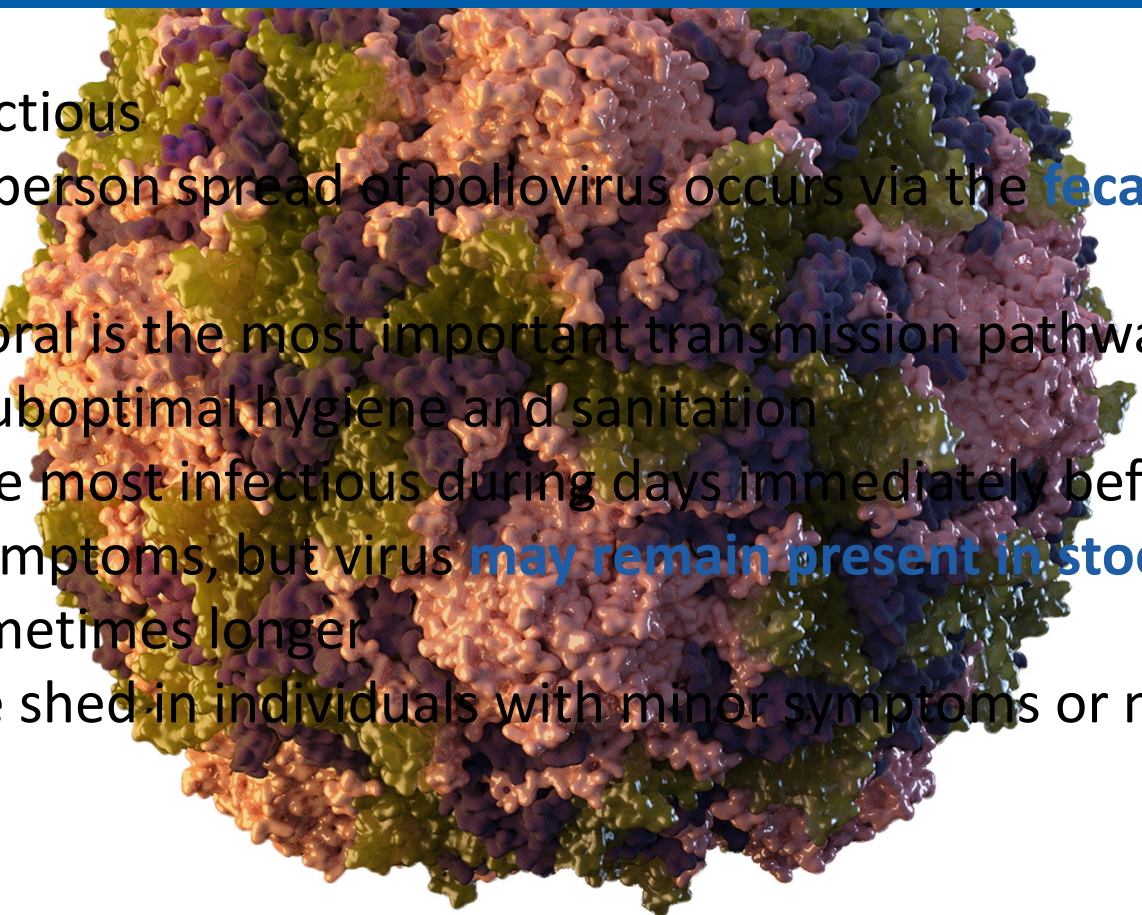
Poliovirus serotypes

- Poliovirus consists of an RNA genome enclosed in a capsid
- The slightly different capsids are the three serotypes: type 1, type 2, and type 3
- Immunity to one serotype does not produce significant immunity to the other serotypes

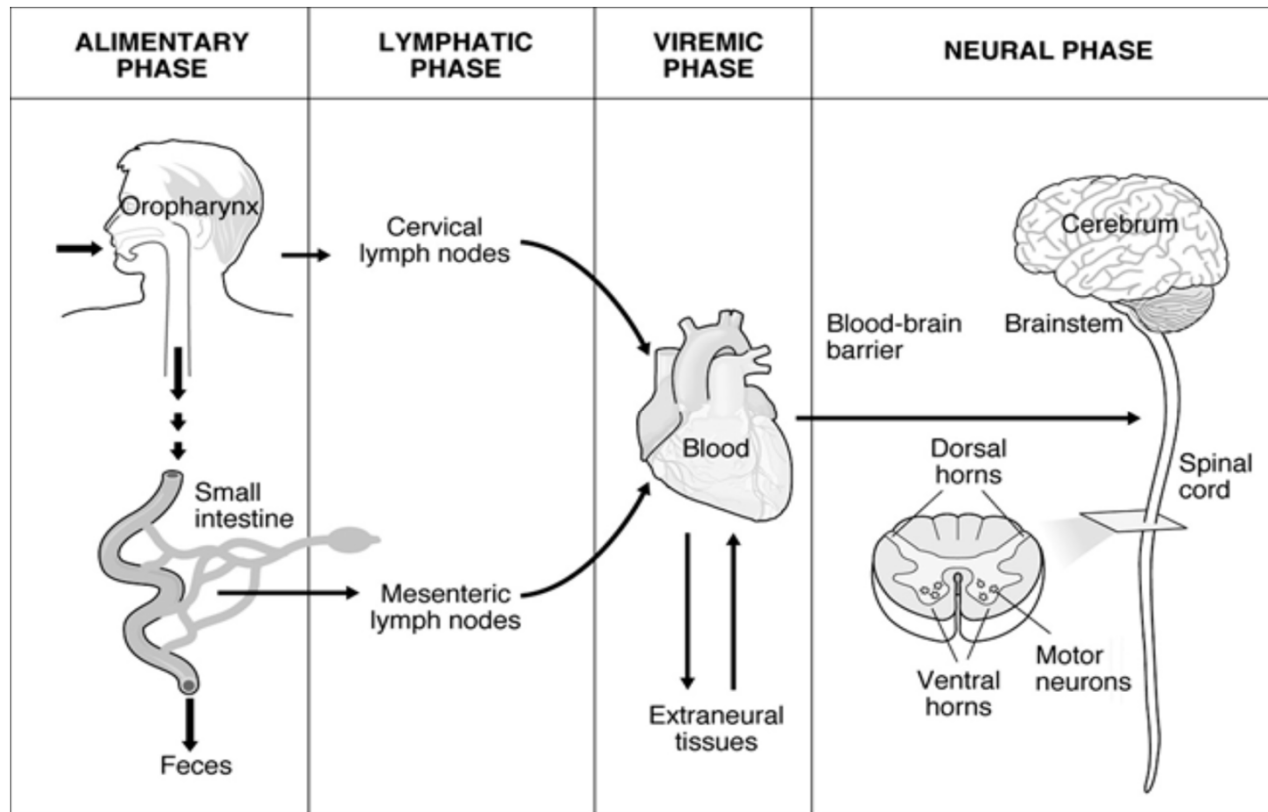


Poliovirus is highly infectious

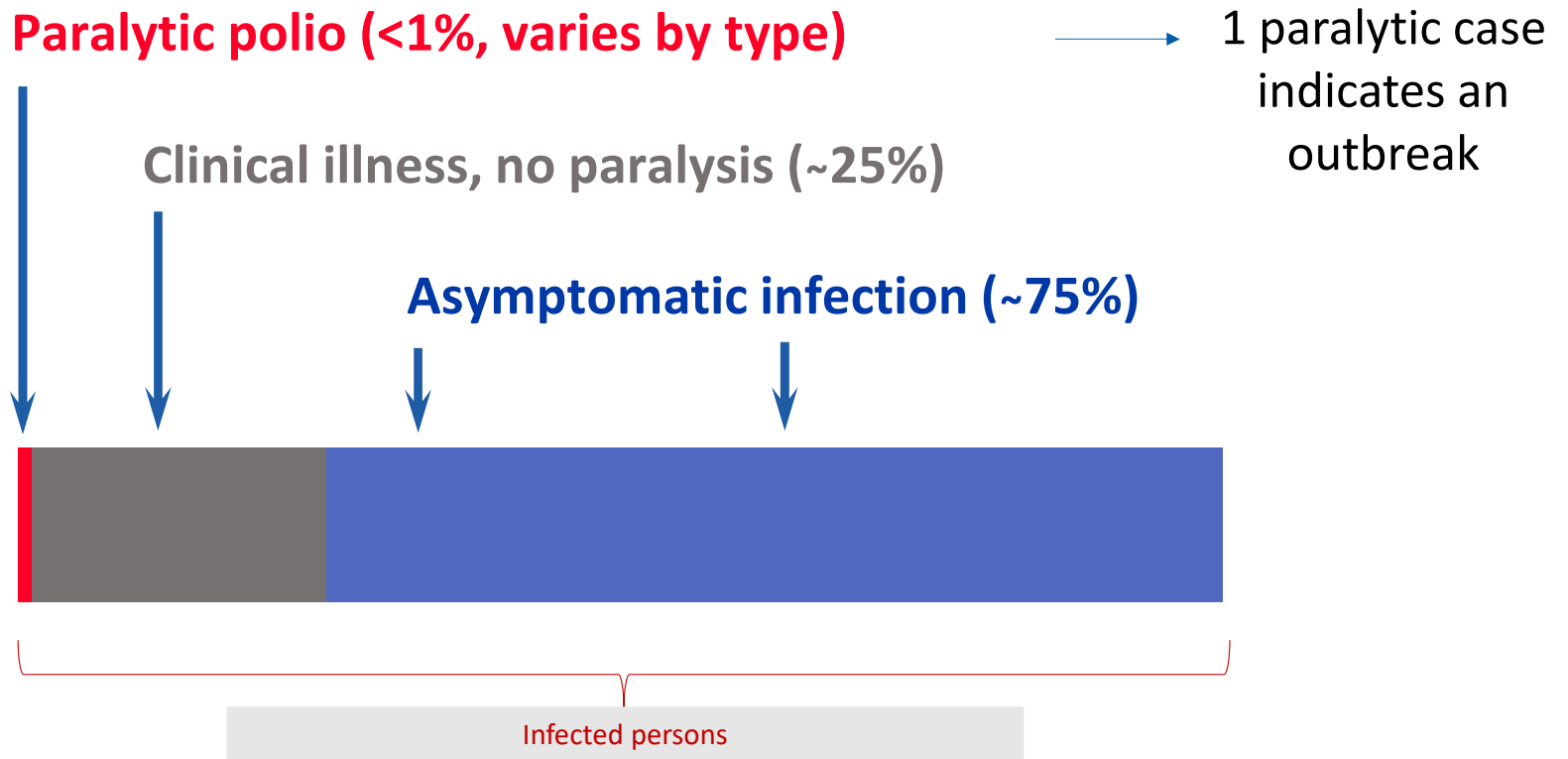
- Highly infectious
- Person-to-person spread of poliovirus occurs via the **fecal-oral** or oral-oral routes
 - Fecal-oral is the most important transmission pathway in settings with suboptimal hygiene and sanitation
- Patients are most infectious during days immediately before and after onset of symptoms, but virus **may remain present in stool for up to 6 weeks**, sometimes longer
 - Can be shed in individuals with minor symptoms or no illness



Poliovirus infection



Paralytic polio occurs in <1% of infections



Sources: CDC, Sutter, Kew, Cochi, and Aylward. Poliovirus vaccine-live. Vaccines, 6th Edition, 2013. NB: Other sources cite different percentages.

Inactivated polio vaccine



Inactivated polio vaccine (IPV)

- IPV contains types 1, 2, and 3 polioviruses that have been chemically killed
 - **Viruses cannot replicate, infect, or cause disease**
- IPV induces effective humoral immunity → **prevents paralysis**
 - 90% seroprotection after 2 doses
 - 99% seroprotection after 3 doses
- IPV induces some **nasopharyngeal mucosal immunity** but **limited intestinal immunity**
- Only vaccine currently used in the U.S. since 2000

Oral polio vaccine (OPV)

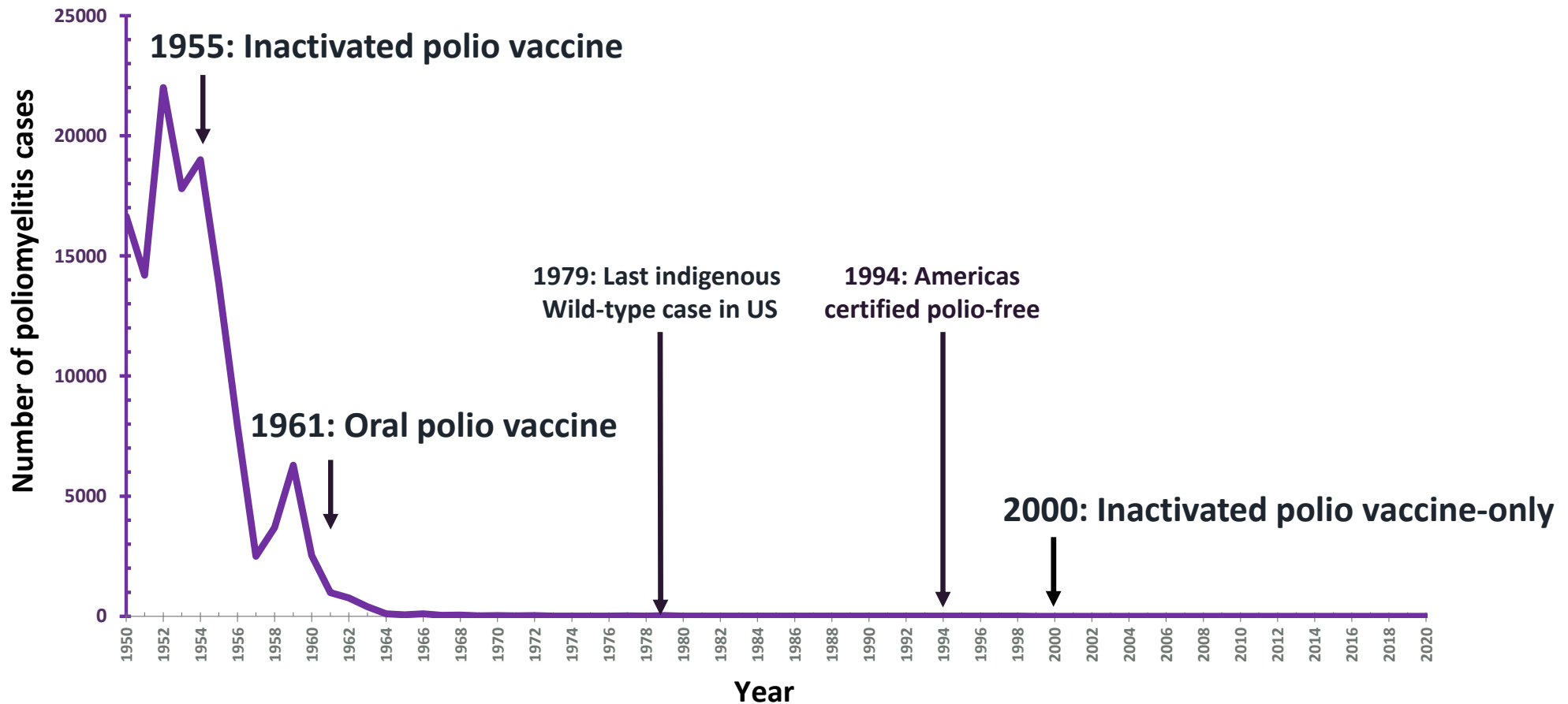
- Live attenuated vaccine (contains live, weakened polioviruses)
 - Replicates in gut, is shed in stool
- **Prevents paralysis and transmission** of polio
- Given orally (two drops)
- Vaccine of choice for developing countries or countries experiencing polio outbreaks
- If allowed to circulate in under-immunized populations for long enough, **attenuated virus can revert to a form that causes paralysis.**



Oral polio vaccine

Polio in the United States & Global Eradication Efforts

Paralytic polio in the U.S. decreased rapidly after introduction of polio vaccine



Global Polio Eradication Efforts

1988:

Global Polio Eradication Initiative (GPEI) established

2016:

Sabin Type 2 virus withdrawn from OPV

2022:

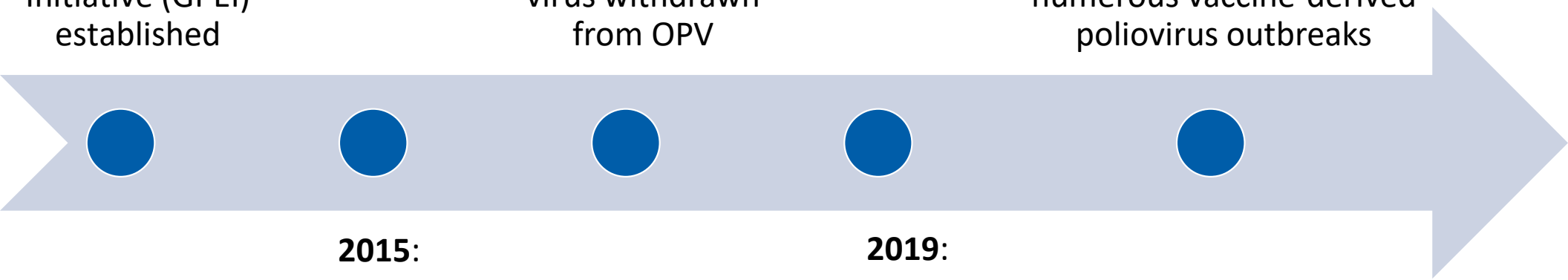
Only 2 countries with endemic wild poliovirus 1; numerous vaccine-derived poliovirus outbreaks

2015:

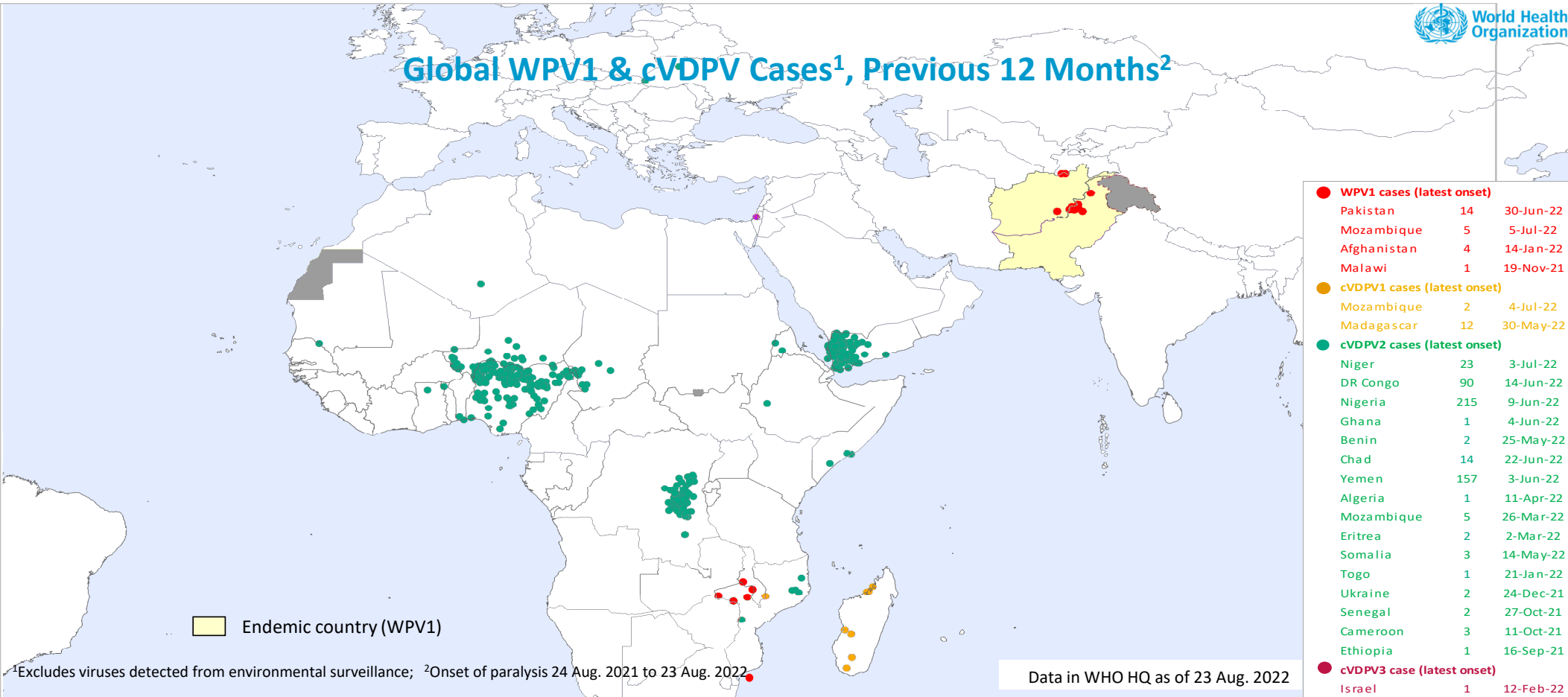
Wild poliovirus 2 eradicated

2019:

Wild poliovirus 3 eradicated



Global WPV1 & cVDPV Cases¹, Previous 12 Months²



Polio outbreaks continue to be identified globally with 249 laboratory-confirmed cases this year.

A case of paralytic polio in New York State, 2022

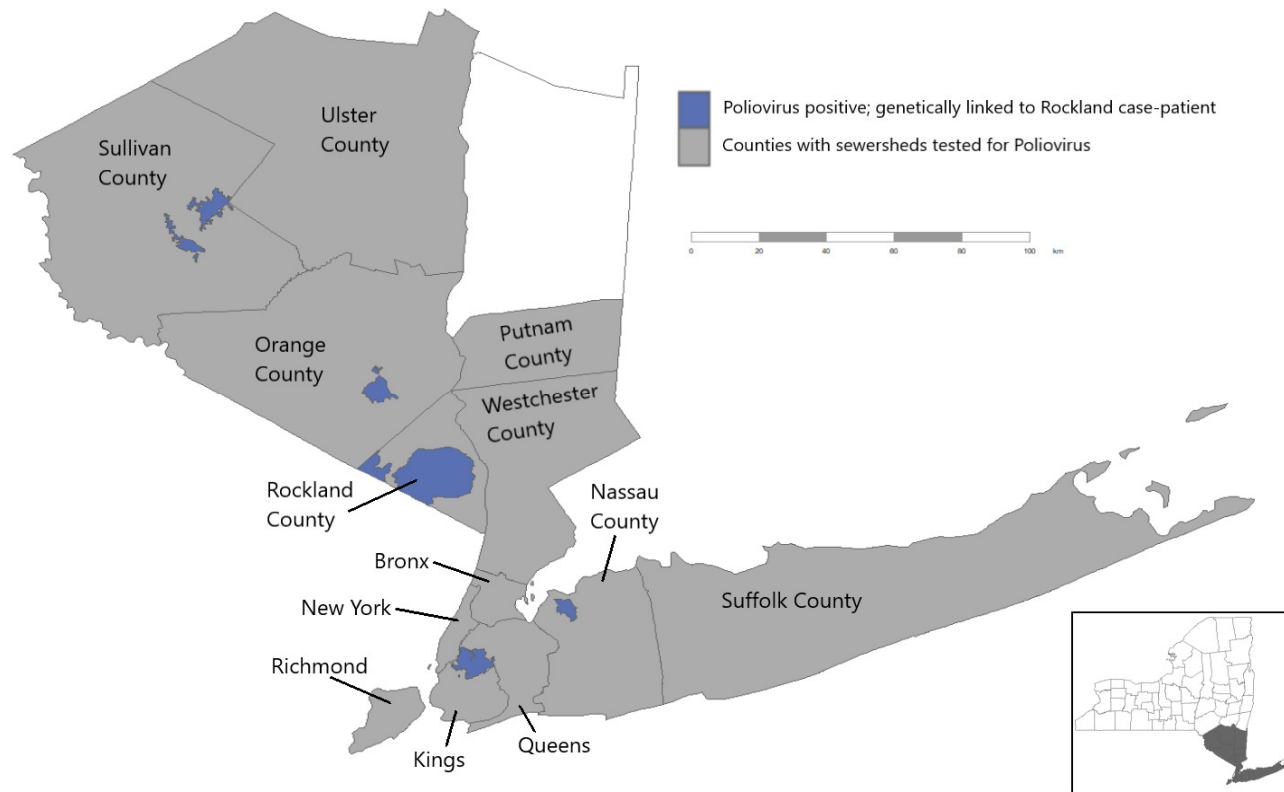
Polio case-patient presentation

- Unimmunized, immunocompetent young adult
- Developed fever, neck stiffness, back pain, abdominal pain, constipation
- 3 days later developed lower extremity weakness
- 2 days after weakness began, presented to an ED and admitted to the hospital with flaccid weakness
- As part of the differential diagnosis, worked up for Acute Flaccid Myelitis (AFM)

Polio case-patient diagnosis

- Submitted specimens for pathogen specific testing (stool, nasopharyngeal swab, oropharyngeal swab, cerebrospinal fluid)
- Stool specimens positive by enterovirus PCR (other specimens negative)
- Subsequent sequencing identified vaccine-derived poliovirus, type 2 (VDPV2)
 - Confirmed by CDC polio laboratory
 - 10 nucleotide changes in region encoding viral capsid protein (VP1) compared to Sabin 2 strain
- A single paralytic case implies hundreds-thousands of infections

New York Wastewater Poliovirus Testing Map (as of October 11, 2022)



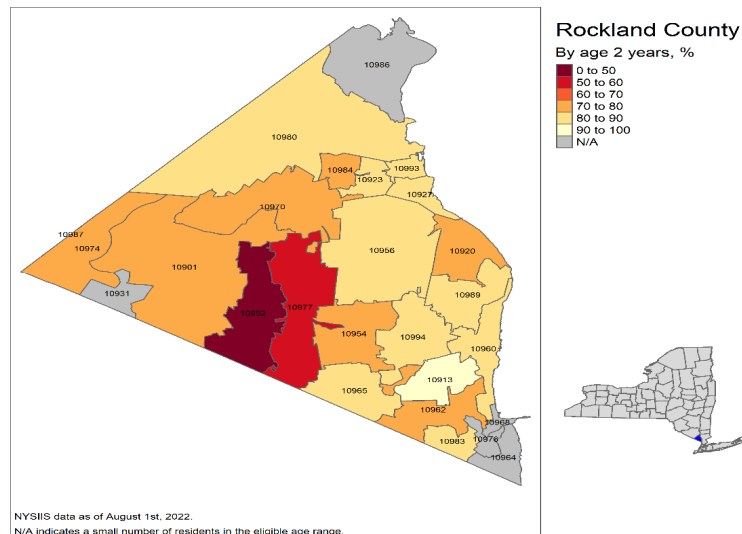
Transmission throughout
the NY metropolitan region,
persisting over months



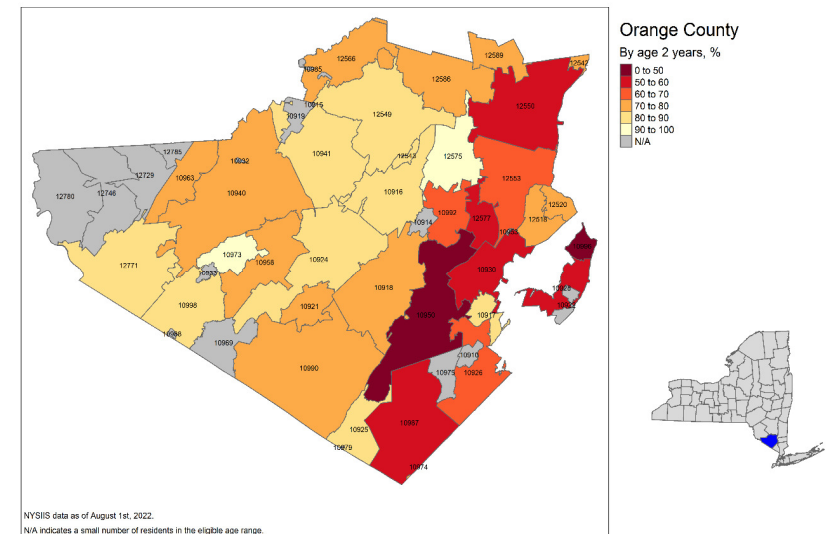
cVDPV2

Polio vaccination 3-dose coverage among children 2 years old

Rockland County



Orange County



- As of August 1, 2022, Rockland and Orange counties had several zip code areas with $\leq 70\%$ 3-dose polio vaccination coverage by 2 years among children aged 2 years

Source: NYSIIS data provided by NYSDOH.

Polio vaccine doses administered July 21–September 25, 2022

- Compared to the same period in 2021,* polio vaccine uptake among persons aged <19 years
 - Rockland County: **↑ 42%**
 - Orange County: **↑ 29%**
 - Sullivan County: **↑ 27%**

* Comparison with 2021 data may have limitations because immunization rates declined markedly during the first years of the COVID-19 pandemic.
Source: NYSIIS data provided by NYSDOH.

ACIP Recommendations for Polio Vaccination

ACIP Polio Immunization Recommendations Routine Childhood Schedule

| IPV Dose | Routinely Recommended Age |
|----------|---------------------------|
| 1 | 2 months |
| 2 | 4 months |
| 3 | 6–18 months |
| 4 | 4–6 years |

Polio-Containing Vaccine Products

| Vaccine name | Vaccine components | Age indication | Dose in polio series | Injection route |
|------------------------|--------------------|---|----------------------|-----------------|
| Ipol (SP) | IPV | 6 weeks and older, any dose in the series | Any | IM or SC |
| Pentacel (SP) | DTaP-IPV/Hib | 6–4 yrs | 1, 2, 3, 4 | IM |
| Vaxelis (Merck) | Dtap-IPV-Hib-HepB | 6 wks–4 years | 1, 2, 3 | IM |
| Pediarix (GSK) | DTaP-HepB-IPV | 6 wks–6 yrs | 1, 2, 3 | IM |
| Kinrix (GSK), | DTaP-IPV | 4–6 yrs | 4 | IM |
| Quadracel (SP) | DTaP-IPV | 4–6 yrs | 4, 5 | IM |

IM = Intramuscular; SC = Subcutaneous; All vaccines in the table above are non-live

Safety

Contraindications

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component

Precautions

- Pregnancy
- Moderate or severe acute illness with or without fever

IPV Adverse Reactions

- Local reactions (pain, redness, swelling) - 3.2-18%
- Severe reactions - rare

ACIP Polio Immunization Recommendations: Adults

- Adults who are unvaccinated or have incomplete vaccination for poliovirus should talk to their doctor about getting vaccinated
- Adults at increased risk of exposure to poliovirus may receive one lifetime booster dose
- Adults at increased risk of exposure
 - Travelers who are going to countries where there is an increased risk of exposure
 - Laboratory and healthcare workers who handle specimens that might contain polioviruses
 - Healthcare workers/caregivers who have close contact with a person who could be infected with poliovirus
 - Unvaccinated adults whose children will be receiving oral poliovirus vaccine (for example, international adoptees or refugees)
 - Unvaccinated adults living or working in a community where poliovirus is circulating

Innovations in Polio Vaccination

Novel OPV2

- To better respond to the evolving risk of cVDPV2
- nOPV2 is more genetically stable and less likely to be associated with the emergence of cVDPV2
- Can provide mucosal immunity to limit the spread among IPV vaccinated people
- Approved for use under WHO Emergency Use Listing (EUL) in Nov 2020
- Review of safety data on the first 65 million doses of nOPV2 used for outbreak response by the independent Global Advisory Committee on Vaccine Safety (GACVS) concluded that there were no obvious red flags or safety concerns
- WHO SAGE recommends vaccine response to cVDPV2:
 - Routine/catch-up immunization with bOPV and/or IPV should continue
 - Countries consider use of nOPV if IPV response does not stop cVDPV

Safety and immunogenicity of two novel type 2 oral poliovirus vaccine candidates compared with a monovalent type 2 oral poliovirus vaccine in healthy adults: two clinical trials: [https://doi.org/10.1016/S0140-6736\(20\)32541-1](https://doi.org/10.1016/S0140-6736(20)32541-1)

Fractional-Dose IPV

- Many countries are switching to IPV only schedules
- Global IPV supply shortage has limited the number of available doses
- Fractional IPV (fIPV), administered intradermally using one fifth of regular dose, stretches the limited supplies of IPV^{1,2}
- Use of fIPV has been recommended by WHO as a response strategy for VDPV2 outbreaks
- Currently fIPV are not recognized as a dose to satisfy immunization requirements in the U.S.


1. Immunogenicity of supplemental doses of poliovirus vaccine for children aged 6–9 months in Moradabad, India: a community-based, randomised controlled trial [https://doi.org/10.1016/S1473-3099\(11\)70190-6](https://doi.org/10.1016/S1473-3099(11)70190-6)

2. Immune responses after fractional doses of inactivated poliovirus vaccine using newly developed intradermal jet injectors: A randomized controlled trial in Cuba. <https://doi.org/10.1016/j.vaccine.2014.11.025>

ACIP Polio Work Group

Terms of Reference

Policy topics under consideration:

- 1) Whether more specific guidance on adult vaccination, including use of adult booster doses, can be provided in the context of circulating poliovirus.
 - 2) Whether adults who are immunocompromised should be recommended an additional adult booster of a polio-containing vaccine.
 - 3) Whether fractional doses of IPV (fIPV), as prequalified by WHO, should meet polio vaccination requirements, including for people immigrating to the United States.
 - 4) Consider criteria under which novel oral polio vaccine (nOPV) might be used in areas with outbreaks or persistent circulation of poliovirus.
- 

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Thank You!

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