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To: Healthcare Providers and Local Health Departments

From: New York State Department of Health (NYSDOH), Bureau of Immunization

HEALTH ADVISORY:

Updated Guidance for Assessment of Poliovirus Vaccination Status: Serologic Testing No Longer Recommended to Assess Poliovirus Immunity

Please distribute to Medical Director, Director of Nursing, Family Medicine, Pediatrics,
all Primary Care Providers

SUMMARY

The recommendations for use of serology to assess polio immunity and for assessing the vaccination status of individuals who receive oral poliovirus vaccine (OPV) have changed because of strategies implemented by the World Health Organization's (WHO's) Global Polio Eradication Initiative. Type 2 wild poliovirus disease was officially declared eradicated in 2015.

- Countries still using OPV are in the process of switching to inactivated poliovirus vaccine (IPV) containing all 3 poliovirus types in order to reduce the risk of vaccine-related polio outbreaks.
- The risk of importation of type 2 vaccine-derived poliovirus into the United States (U.S.) is low but not zero. Therefore, **the Advisory Committee on Immunization Practices (ACIP) continues to recommend that all U.S. infants and children be immune to all three poliovirus types.**
- All persons less than 18 years of age who do not have documentation of an age-appropriate series specifying receipt of either IPV or trivalent OPV (tOPV) should complete or repeat the series with IPV in accordance with the ACIP schedule.
 - Poliovirus vaccination outside of the U.S. is valid only if documentation indicates receipt of either IPV or tOPV or if the dose was administered before April 1, 2016. This is because doses of OPV given after April 1, 2016 are either bivalent (bOPV) or monovalent (mOPV) and do not contain type 2 poliovirus. Therefore, **children living in the U.S. who received OPV on or after April 1, 2016 should be revaccinated with IPV according to the ACIP schedule.**
- Handling of type 2 poliovirus has been limited to only a few essential facilities in the U.S. Since testing for antibodies to all three poliovirus serotypes is not available, **serologic testing is no longer recommended to assess polio immunity.**

GLOBAL POLIO ERADICATION INITIATIVE (GPEI)

The goal of the GPEI is complete eradication and containment of all polioviruses, such that no child ever again suffers paralytic poliomyelitis. Since 1988, when the GPEI was established, the number of polio cases globally has been reduced by more than 99%. Polio remains endemic in only three countries – Afghanistan, Pakistan, and Nigeria – where transmission of wild poliovirus

has not been completely stopped. In September 2015, wild poliovirus type 2 was officially declared eradicated worldwide.

OPV contains an attenuated live vaccine virus. On rare occasions, shedding of the vaccine virus can cause vaccine-derived polio in unvaccinated or undervaccinated individuals. For this reason, the U.S. discontinued use of OPV and switched to an all-IPV schedule in 2000. However, OPV is still in use in over 150 countries worldwide.

As the world gets closer to ending transmission of wild poliovirus, the risk of vaccine-derived polio increases in importance. No cases of type 2 wild poliovirus have been detected anywhere in the world since 1999. However, more than 650 cases of type 2 vaccine-derived polio have occurred since 2006, including several outbreaks in 2015. More than 94% of vaccine-derived polio cases have been caused by the type 2 component.

Eliminating the risk of vaccine-derived polio requires the eventual withdrawal of all OPV. The GPEI has implemented a multi-year global phase-out of OPV and replacement with IPV. The first step in this plan was to strengthen existing immunization systems. At least one dose of IPV was introduced into the routine immunization schedule of countries using OPV, as available supplies of IPV permitted, with a focus on the highest risk countries. IPV provides protection against poliovirus types 1, 2 and 3, reduces viral shedding and the risk of vaccine-derived polio outbreaks. As of August 31, 2016, 89% of WHO member states are using IPV.

The next step took place in April 2016, when all countries using OPV switched from use of tOPV to bOPV containing only types 1 and 3 polioviruses. The type 2 component was eliminated because the risks of vaccine-derived polio associated with the type 2 component outweighed the benefits. All doses of OPV administered in countries using OPV after April 1, 2016 are either bOPV or mOPV and do not contain type 2 poliovirus. The final step, at a future date that has not yet been determined, will be to stop the global use of OPV and replace it with an all-IPV schedule similar to the one used in the U.S.

The global switch from tOPV to bOPV will markedly reduce the risk for vaccine-derived poliovirus type 2 importation into the U.S. However, until this risk is estimated by WHO to approach zero, the **ACIP continues to recommend that all U.S. infants and children be immune to all three poliovirus types**. All persons less than 18 years of age who do not have documentation of an age-appropriate series specifying receipt of either IPV or tOPV should complete or repeat the IPV series in accordance with the ACIP schedule.

ASSESSMENT OF POLIOVIRUS VACCINATION STATUS FOR SCHOOL ENTRY

Previous poliovirus vaccination with either IPV or tOPV will provide protection against all three poliovirus types and may be accepted as valid for school entry in NYS. Trivalent OPV was used for routine poliovirus vaccination before April 1, 2016 in all countries using OPV. Therefore, if an individual has documentation of OPV received before April 1, 2016 it can be counted as a tOPV dose, unless it was specifically notated that it was administered during a vaccination campaign. Either mOPV or bOPV were often used during mass vaccination campaigns. However, doses of OPV administered after April 1, 2016 are either bOPV or mOPV and do not meet the U.S. recommendations, nor the NYS school requirements, for protection against all three poliovirus types. **Children living in the U.S. with documentation of doses of OPV that were administered after April 1, 2016 should be revaccinated with IPV in accordance with the ACIP schedule.**

SEROLOGIC TESTING FOR POLIO IMMUNITY

On April 20, 2017, the Centers for Disease Control and Prevention released the General Best Practice Guidelines for Immunization, replacing the previous 2011 ACIP General Recommendations on Immunization. The new Guidelines **do not recommend the use of serology to assess polio immunity**. All persons less than 18 years of age who do not have documentation of an age-appropriate series specifying receipt of either IPV or tOPV should complete the IPV series in accordance with the ACIP schedule.

In addition, serology to assess immunity to type 2 poliovirus is no longer available in the U.S. To reduce the risk for reintroduction of wild poliovirus type 2, the GPEI has implemented a laboratory containment strategy which limits handling of poliovirus type 2 containing materials to certified poliovirus-essential facilities. All laboratories or other facilities that handle or store poliovirus type 2 materials are required to destroy all unneeded materials and transfer needed materials to a designated poliovirus-essential facility. As a result, serologic tests for antibodies against poliovirus type 2, which utilize live virus, are no longer available at U.S. laboratories.

NYS school immunization regulations authorize schools to accept a positive serologic test against all three serotypes of poliovirus in place of a complete polio vaccine series. Serologic tests demonstrating immunity to poliovirus types 1 and/or 3 but which do not test for immunity to type 2 do not satisfy the regulatory requirement to demonstrate immunity to all three poliovirus types and are **not** acceptable evidence of polio immunity. However, previous serologic testing, which was obtained when testing for type 2 poliovirus was still available in the U.S., will still be accepted as evidence of polio immunity if the test documents a separate positive result for each of the three poliovirus serotypes (types 1, 2, and 3).

ADDITIONAL INFORMATION

- Centers for Disease Control and Prevention. General Best Practice Guidelines for Immunization: Best Practices Guidance of the Advisory Committee on Immunization Practices. Available at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>
- Marin M, Patel M, Oberste S, Pallansch MA. Guidance for Assessment of Poliovirus Vaccination Status and Vaccination of Children Who Have Received Poliovirus Vaccine Outside the United States. MMWR Morb Mortal Wkly Rep 2017;66:23–25. Available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm>
- *Errata*: Vol.66, No.1. MMWR Morb Mortal Wkly Rep 2017;66:180. Available at: <https://www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm>
- Hampton LM, Farrell M, Ramirez-Gonzalez A, *et al.* Cessation of Trivalent Oral Poliovirus Vaccine and Introduction of Inactivated Poliovirus Vaccine – Worldwide, 2016. MMWR Morb Mortal Wkly Rep 2016;65:934-938. Available at: https://www.cdc.gov/mmwr/volumes/65/wr/mm6535a3.htm?s_cid=mm6535a3_w
- For additional questions or comments, please contact the NYSDOH Bureau of Immunization at 518-473-4437 or email immunize@health.ny.gov.