January 2014

THE POLIO ERADICATION ENDGAME

BRIEF ON IPV INTRODUCTION, OPV WITHDRAWAL AND ROUTINE IMMUNIZATION STRENGTHENING

The *Polio Eradication and Endgame Strategic Plan 2013-2018* was drawn up in response to the May 2012 World Health Assembly declaring the completion of poliovirus eradication to be a programmatic emergency for global public health.

Under this endgame plan to achieve and sustain a polio-free world, the use of oral polio vaccine (OPV) must eventually be stopped worldwide, starting with OPV that contains type 2 poliovirus (OPV type 2). At least one dose of inactivated polio vaccine (IPV) must be introduced as a risk mitigation measure.

The steps involved are:

1. **By end 2015, introduce at least 1 dose of IPV into all routine immunization systems**, at least 6 months before the switch from trivalent oral polio vaccine (tOPV) to bivalent oral polio vaccine (bOPV, containing types 1 and 3 poliovirus).
2. **During 2016, switch from tOPV to bOPV, which does not contain type 2 virus, in routine immunization and polio campaigns.**
3. **Plan for the eventual withdrawal of all OPV.**

The tOPV to bOPV switch is necessary because:

- **No wild poliovirus type 2 has been recorded over the past years and the risk of paralytic polio disease due to the type 2 component of OPV now outweighs its benefits.**
- Since OPV is a live attenuated vaccine, in rare cases it can cause paralytic disease in two ways: as Vaccine Associated Paralytic Poliomyelitis (VAPP) or in outbreaks of circulating Vaccine-Derived Poliovirus (cVDPV). The vast majority of cVDPV outbreaks and a substantial proportion of the total VAPP cases are due to the type 2 component of OPV.
- Replacing tOPV with bOPV is key to ensuring the eradication of type 2 poliovirus.
- The switch from tOPV to bOPV will serve as a ‘dry run’ for the withdrawal of the other types of OPV.

IPV needs to be introduced on an accelerated timeline so that OPV type 2 can be withdrawn.

- IPV should be introduced at least 6 months before the switch from tOPV to bOPV, i.e., by the end of 2015. Countries using only OPV in their routine immunization programmes should be prepared for a switch from tOPV to bOPV in 2016.

- The countries at highest risk for cVDPV emergence, wild poliovirus transmission and importations of either will be prioritized for earliest IPV introduction.
- Introducing at least 1 dose of IPV will ensure that a substantial proportion of the population is protected against type 2 polio after OPV type 2 withdrawal. It will also boost immunity to the remaining type 1 and 3 poliovirus serotypes.
- Introducing IPV will boost population immunity against polio and mitigate paralysis risks in the case of outbreaks by 'priming' the population against type 2 poliovirus and ensuring better immune responses to OPV if needed.
- IPV introduction sets the stage for ending OPV use entirely in 2019-2020.

In the endgame, polio eradication activities and strengthening routine immunization can be mutually beneficial.

- IPV will be introduced through routine immunization delivery systems.
- Strengthening routine immunization is necessary to achieve and maintain high population immunity against polioviruses, especially type 2, after OPV type 2 is withdrawn. The magnitude, number and length of both wild poliovirus (WPV) and cVDPV outbreaks are closely correlated with weaknesses in routine immunization systems.
- This is an opportunity for the global polio eradication initiative to use its infrastructure to contribute more systematically to strengthening routine immunization systems.
- One of the goals is to improve infant routine immunization coverage in a group of focus countries which have some of the lowest routine immunization coverage levels in the world and the greatest proportion of the world's unvaccinated children. The third dose of DTP-containing vaccine will be used to measure routine immunization coverage improvements.

This is a priority area for WHO, GAVI, UNICEF and other key immunization stakeholders, who are mapping out a plan to support countries in introducing IPV and strengthening their routine immunization programmes. Areas of work include:

- **Presentation**
    - Stand-alone IPV is the only presentation prequalified by WHO. 1, 2 and 10-dose vials are currently available and 5-dose vials are likely to be available in 2014 or at the latest in 2015. Multi-dose vials are less expensive and require less cold-chain capacity, but would incur more wastage. GPEI is exploring options to reduce cold storage requirements, expense and wastage.
    - Combination vaccines are available but at substantially higher costs. Combination vaccines with whole-cell pertussis are not currently available.

- **Immunization schedule**
    - In November 2013, the Strategic Advisory Group of Experts (SAGE) made a formal recommendation on the immunization schedule: for countries to add 1 dose of IPV to their routine schedule. Based on a detailed review of evidence, it recommended the IPV dose be added when the third dose of Diphtheria-Tetanus-Pertussis (DPT3) is given, i.e., at 14 weeks or at a contact soon thereafter.

- There are potential benefits to introducing IPV at the same time as other new vaccines. Experience has shown gains in cost and time efficiencies by introducing multiple new vaccines at once.

- **Financing**
  - A multi-faceted IPV financing strategy is being developed to assist countries to introduce 1 dose of IPV into their routine immunization programmes by the end of 2015. GAVI eligible and GAVI graduating countries are currently being invited to submit applications for IPV support.
  - Partners are working towards achieving a $1.00 or slightly below price per dose for GAVI countries for IPV standalone vaccine. For other low and middle income countries, the vaccine may be available at a price of US$1.30-1.50/dose. Further reductions in price may be achieved in the medium to long term with new IPV products under development (adjuvanted vaccines) or delivery methods (e.g., intradermal administration of fractional doses) yet to be licensed. The intradermal administration option may be accessible as early as end-2014/early 2015.

- **Supply**
  - There is enough production capacity for current IPV standalone products to meet the needs for all OPV-using countries to introduce one dose of IPV into their routine immunization programme.
  - However, to ensure sufficient IPV is available when countries are ready to introduce it, countries must define their target introduction dates as soon as possible (i.e., by mid to end-2014).