March 2014

PLANNING FOR IPV INTRODUCTION

Frequently asked questions (FAQs)

In May 2012 the World Health Assembly declared the completion of poliovirus eradication to be a programmatic emergency for global public health and called for a comprehensive polio endgame strategy. In response, the *Polio Eradication and Endgame Strategic Plan 2013-2018* was developed.

The plan outlines a comprehensive approach for completing eradication including the elimination of all polio disease (both wild and vaccine-related).

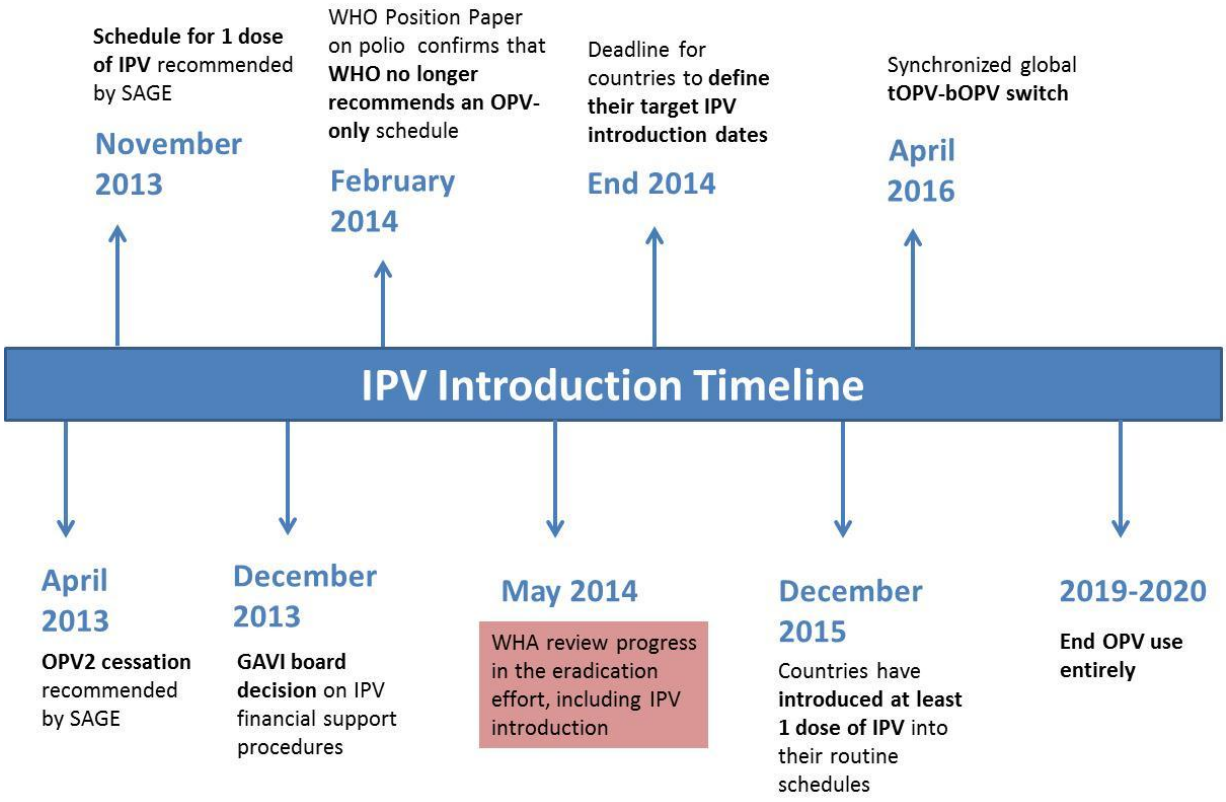
As one of its four major objectives, the plan calls on countries to **introduce at least 1 dose of Inactivated Polio Vaccine (IPV)** into routine immunization schedules**, strengthen routine immunization** and **withdraw Oral Polio Vaccine (OPV)** in a phased manner, starting with type 2-containing OPV. This sheet provides information on the rationale behind this objective.

Why should countries introduce IPV?

Introducing IPV is a key element of the endgame plan and global readiness to manage risks associated with OPV type 2 withdrawal. The endgame plan calls for the introduction of IPV in all OPV-only using countries by the end of 2015. The primary role of IPV will be to maintain immunity against type 2 poliovirus while removing OPV type 2 globally. More specifically, IPV needs to be introduced for the following reasons:

- ***To reduce risks.*** Once OPV type 2 is withdrawn globally, if no IPV is used, there will be an unprecedented accumulation of children susceptible to type 2 poliovirus. IPV use will help maintain immunity to type 2. This will help prevent emergence of type 2 viruses should they be introduced after the type 2 component is removed from OPV. Thus, a region immunized with IPV would have a lower risk of re-emergence or reintroduction of wild or vaccine-derived type 2 poliovirus.
- ***To interrupt transmission in the case of outbreaks***. Should monovalent OPV type 2 (mOPV type 2) be needed to control an outbreak, the immunity levels needed to stop transmission will be easier to reach with use of mOPV type 2 in an IPV-vaccinated population compared to use of mOPV type 2 in a completely unvaccinated population. Thus, introducing IPV now could facilitate future outbreak control.
- ***To hasten eradication***. IPV will boost immunity against poliovirus types 1 and 3 in children who have previously received OPV, which could further hasten the eradication of these two wild viruses.

Further, a WHO Position Paper on polio vaccines published in February 2014 confirms that WHO no longer recommends an OPV-only vaccination schedule. For all countries using OPV only, at least 1 dose of IPV should be added to the schedule. The polio position paper is available online at: http://www.who.int/wer/2014/wer8909.pdf



Why will countries need to switch from tOPV to bOPV?

There are three types of wild poliovirus (WPV) - type 1 (WPV1), type 2 (WPV2) and type 3 (WPV3) - each of which is targeted by a different component of the trivalent oral polio vaccine (tOPV).

Live attenuated vaccines are very effective against the wild virus, but in very rare cases can lead to paralysis. There are two ways this can occur:

- Vaccine Associated Paralytic Poliomyelitis (VAPP): for every birth cohort of 1 million children in OPV-only using countries, there are 2-4 cases of VAPP. This translates to an estimated 250 – 500 VAPP cases globally per year. Of these, about 40% are caused by OPV's type 2 component.
- Circulating Vaccine Derived Poliovirus (cVDPV) outbreaks: these rare outbreaks occur when a vaccine-related virus is passed from person-to-person, mutating over time and acquiring wild virus transmissibility and neurovirulence characteristics. Almost all cVDPV outbreaks in recent years have been caused by a type 2 vaccine-derived virus.

Although wild poliovirus type 2 appears to have been eradicated globally in 1999, vaccine-related type 2 viruses continue to cause the majority of cVDPV outbreaks and many VAPP cases. Therefore, OPV type 2 now carries more risk than benefit and undermines global polio eradication efforts. Thus, tOPV will be replaced with bivalent OPV (bOPV), which will continue to target the remaining polio types (WPV1 and WPV3). Once these types are eradicated, bOPV will also be withdrawn.

When do countries need to introduce IPV and switch to bOPV?

OPV type 2 withdrawal would be achieved by switching from trivalent OPV (tOPV) to bivalent OPV (bOPV) (containing only types 1 and 3 vaccine poliovirus) in routine immunization programs.The World Health Organization (WHO) Strategic Advisory Group of Experts on immunization (SAGE) has called for a global withdrawal of type 2-containing OPV during 2016. This sets the stage for ending bOPV use entirely in 2019-2020. As a risk mitigation measure, SAGE recommends that prior to the 'tOPV-bOPV switch' all countries that currently use only OPV in their routine immunization programmes introduce at least 1 dose of IPV into their routine schedules (i.e., by the end of 2015). More information on the SAGE recommendation can be found at http://www.who.int/immunization/sage/report_summary_november_2013/en/index.html.

Why should countries introduce IPV prior to the tOPV-bOPV switch?

The withdrawal of OPV type 2 would leave a gap in population immunity against type 2 poliovirus. Thus, immediately following global withdrawal of OPV type 2, countries that have not introduced IPV would be at an increased risk of outbreaks in the case of reintroduction of a type 2 virus. A reintroduction or emergence of circulating vaccine-derived poliovirus type 2 (cVDPV2) could potentially result in a substantial polio outbreak or even re-establishment of global transmission. Such an outbreak could be rapidly interrupted through mOPV type 2. Vaccinating the population with IPV through routine immunization would lessen the risk that reintroduction would lead to sustained transmission. If reintroduction of type 2 polioviruses does occur post-eradication, having a population that has received IPV would also facilitate rapid control through targeted use of mOPV type 2.

What is the risk for countries if they do not introduce IPV?

Two main risks are associated with OPV type 2 withdrawal:

- immediate time-limited risk of cVDPV2 emergence; and
- medium and long-term risks of poliovirus re-introduction from a vaccine manufacturing site, research facility or diagnostic laboratory. While all countries face a time-limited (1-2 years) risk of cVDPV2 outbreak during OPV type 2 withdrawal if they do not introduce a dose of IPV, certain countries are at higher risk than others. Risk assessments conducted by the Global Polio Eradication Initiative (GPEI) and WHO have led to the grouping of OPV-only using countries into four tiers. Countries have been assigned a level of risk based on:

1. previous wild poliovirus and history of VDPV emergence;
2. DTP3 coverage; and
3. the risk status of neighbouring countries.

Countries in tier 1 are considered at highest risk, while those in tier 4 have the lowest risk level. The endgame plan calls for countries in all tiers to cease use of OPV type 2 by 2016 and to consider introducing at least one dose of IPV for mitigating the risk of type 2 poliovirus reintroduction.

What happens if an outbreak of type 2 polio occurs following OPV type 2 withdrawal?

An internationally-managed global stockpile of monovalent OPV (types 1, 2 and 3) is being developed for use in the event of a polio outbreak after the complete withdrawal of all types of OPV. Such a stockpile will allow a type-specific response, which in a population primed with IPV will ensure rapid outbreak control and interruption of transmission.

Why can't OPV withdrawal occur immediately and all countries switch entirely to IPV use instead of 1 dose in routine immunization?

Until polio transmission is interrupted globally, OPV will be a critical component of the eradication strategy. OPV is the appropriate polio vaccine for achieving the eradication of wild polioviruses worldwide because it is inexpensive, easy to administer and offers good oral and intestinal immunity, which is needed to interrupt person-to-person spread of the virus, particularly in settings of high population density and poor sanitation.

Why does the endgame plan specifically call for strengthening routine immunization as an essential step for polio eradication?

For the right reasons, much of the polio eradication efforts previously focused on campaigns. However, in the endgame, routine immunization and polio eradication can no longer occur independently; both have strengths which enable the other.

The central reason for strengthening routine immunization is to achieve and maintain high population immunity against polioviruses, especially type 2, after OPV type 2 is withdrawn. The number and length of both WPV and cVDPV outbreaks are closely correlated with weaknesses in routine immunization systems. This is also a golden opportunity to strengthen systems in some of the countries with the lowest routine immunization coverage levels and offer immediate and direct benefits to countries. Many of the polio eradication efforts in country can contribute to the strengthening of routine immunization to further enhance the delivery of vaccines through the use of the GPEI assets and expertise: human resources, tracking of target populations, training venues and systems, monitoring strategies for improving coverage and monitoring and evaluation efforts. This is already occurring in Africa and India, where substantial portions of the GPEI efforts support routine immunization. The partnership between GPEI, GAVI and other organizations further provides an opportunity to strengthen routine immunization through improved planning, technical assistance and accountability.