Update on the OPV switch and short term supply constraints for IPV

This document provides a summary of the SAGE decision to confirm the global Oral Polio Vaccine (OPV) switch for April 2016 and an update on the current Inactivated Polio Vaccine (IPV) supply constraints for all product presentations procured through UNICEF, including actions being taken to proactively manage and minimize the implications.

SAGE has confirmed the global OPV switch date for the period 17 April-1 May 2016

On 20-22 October the Strategic Advisory Group of Experts (SAGE) on Immunization to WHO met and reviewed type 2 Vaccine Derived Poliovirus (VDPV2) epidemiology and all readiness criteria for the switch. SAGE reaffirmed April 2016 for the globally coordinated withdrawal of type 2 containing Oral Polio Vaccine (OPV2), by switching from use of trivalent OPV (tOPV) to bivalent OPV (bOPV).

SAGE confirmed that every country should stop using tOPV and introduce bOPV on a single day of its choosing between 17 April and 1 May 2016, then remove all stocks of tOPV within two weeks of that date and confirm its removal from service delivery points to WHO.

SAGE’s landmark decision follows the endorsement by the World Health Assembly (WHA) in May 2015, when Ministers of Health from 194 Member States adopted a resolution on the global effort to eradicate polio.

In a milestone towards the switch, wild poliovirus (WPV) type 2 was recently declared as eradicated worldwide. WPV type 3 has not been detected globally since November 2012, and the only remaining endemic WPV type 1 strains are now restricted to Pakistan and Afghanistan.

The withdrawal of type 2 containing OPV will ultimately eliminate the risk of the emergence of new type 2 circulating VDPVs (cVDPV) in the future, and will prevent upwards of 200 cases of vaccine associated paralytic poliomyelitis that currently occur each year as a result of the type 2 component in trivalent OPV. The globally synchronised switch will therefore be of great significance for the polio eradication programme with tremendous public health benefits.

As part of the Polio Eradication and Endgame Strategic Plan (the Polio Endgame) 2013-2018, and as recommended by WHO, all 126 countries which, at the start of 2013 were only using OPV, were required to introduce at least 1 dose of the IPV into routine immunization schedules as part of preparations for the global withdrawal of the type 2 containing OPV now confirmed for April 2016.

The level of commitment from countries to meet this timeline has been exceptional and all countries have committed to introduce IPV before the end of 2015 and many (481) have already introduced IPV as of today. Unfortunately the rapid scale-up of IPV production required to meet this timeline has encountered various challenges, including supply constraints.

The global supply constraints currently experienced mean that countries that have not already received their first IPV shipment through UNICEF may experience a delay. In addition, other countries considered at lower risk for polio outbreaks will not be able to introduce IPV in 2015, and are expected to receive their first IPV shipments in July 2016. These delays, while unfortunate, are unavoidable.

1 Data on IPV introductions, updated monthly, is available at: www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/
It is important to note that all countries must implement the globally synchronized switch from tOPV to bOPV in April 2016, regardless of their IPV introduction date.

Why are there supply constraints?

In March 2014, UNICEF issued awards to two manufacturers for the supply of IPV in 1, 5 and 10 dose vials and long term supply agreements have been established through to 2018.

Due to technical challenges in scaling up IPV bulk production, and its quality control testing and releases, there is now reduced availability from both manufacturers. The availability of supply for routine introductions has also been reduced by new unanticipated requests for IPV doses for use in eradication-related supplementary immunization activities (SIAs), including requirements for volumes to be set aside for potential outbreak response SIAs that may be carried out post-switch to control either WPV transmission or cVDPV2 outbreaks.

The constrained situation is projected to remain through the end of 2016 for all IPV product presentations procured through UNICEF. Regular updates will be shared with WHO and UNICEF regional staff, country offices and partners as soon as new information becomes available.

WHO, UNICEF and partners are taking action to limit the number of countries impacted by the delays and minimise the consequences of this situation. Frequent discussions have taken place with manufacturers to identify steps to manage the reductions. Coordination with regional offices has helped to inform the most suitable allocation of supply, taking into consideration each country’s level of risk for a cVDPV type 2 (VDPV2) outbreak after the switch and the size of its national birth cohort.

How is the available supply being allocated?

When the Polio Endgame Strategy was launched, countries were divided into four tiers, primarily for purposes of planning and prioritization. These tiers represent each country’s level of risk (tier 1 being at highest risk) for a cVDPV2 outbreak after the switch from tOPV to bOPV.

There are four criteria used to determine to which tier a country was assigned, and therefore their prioritization for the allocation of IPV supply:

- Circulation of wild polio virus
- History of cVDPV outbreaks
- Routine immunization coverage levels (and therefore level of population immunity to type 2)
- Shared borders with higher risk countries

In the current context of supply constraints, this grouping of countries into tiers is the primary consideration for supply allocation, and countries at higher risk of cVDPV2 outbreaks are being prioritized for IPV supply.

SAGE emphasized that even in the event of further changes in IPV supply, the switch date will not be changed. SAGE requested its Polio Working Group to provide urgent guidance on the optimal management of IPV supply if it is further reduced, and endorsed the following approach to prioritizing for allocation of supplies:

- First ensuring the introduction of IPV in routine immunization in tier 1 and 2 countries before the switch;
- Making stocks available for outbreak response after the switch; and,
- Minimizing delays in introduction in routine immunization and stock-outs.
What is the impact on country introduction plans?

Based on the latest information from manufacturers on supply availability and the most optimum scenarios, the vast majority of countries – including high and medium risk countries, those in tier 1 and 2 – will receive their first IPV shipment in time to introduce the vaccine before the end of 2015.

Of the low risk countries, approximately 20 countries will experience delays in deliveries until July 2016. This will affect only a 4-month birth cohort, and these infants would have received 1, 2 or 3 doses of trivalent OPV from routine services in advance of the switch, depending on their exact age and coverage, and hence would benefit from humoral and mucosal immunity to type 2.

The countries for which supply is delayed will receive direct communications from UNICEF Supply Division in the first week of November about the timing of their first shipment, to allow planning for the introduction of IPV soon after the receipt of vaccines. WHO and UNICEF regional and country offices are facilitating discussions to identify new launch dates and support the revision of introduction plans for these countries.

What is the role of IPV in the Endgame Strategy?

The short term risk of a cVDPV2 outbreak after the switch is higher in countries with low routine immunization coverage or a history of cVDPV2 or wild polio virus outbreaks, as well as in countries sharing borders with higher risk countries. This risk will be reduced by boosting population immunity through high quality tOPV campaigns in the months before the switch to bOPV.

In tier 1 and 2 countries at risk of cVDPV2, should an outbreak of cVDPV2 occur after the switch, having IPV already introduced will enable a more effective and rapid outbreak response, due to its role in priming the immune system for a more rapid and robust response to OPV. A global stockpile of monovalent type 2 OPV (mOPV2) and IPV will be available for outbreak response in the event of a VDPV2 being detected in any country after the switch.

What is the level of risk for the countries that are delayed for IPV introduction?

The SAGE considered the following as a compelling risk management rationale:

- IPV has a limited role in preventing VDPV2 emergence, however is very effective in preventing paralytic disease in any outbreak. This value will increase with time after the switch, as the birth cohorts that have not received OPV2 grow;
- The risk of VDPV2 emergence is principally being reduced by an extensive use of tOPV in SIAs in the months before the switch;
- In addition to tOPV SIAs, the highest risk (tier 1 and 2) countries will introduce IPV in routine immunization before the switch;
- The majority of countries affected by the delay are in lower risk tiers 3 and 4. Population immunity against type 2 is high in these countries (due to consistently high routine immunisation coverage) so the risk of VDPV2 emergence and spread is minimal;
- It is anticipated that all countries will receive IPV supplies within approximately three months of the switch.
- Finally, a global stockpile of mOPV2 and IPV will be available for outbreak response in the event of a VDPV2 being detected in any country after the switch.
If affected by the delays, what can a country do to mitigate risks?

Countries affected by delays in the receipt of IPV should:

- Make all efforts to optimize type 2 population immunity prior to the switch with effective use of remaining tOPV stocks. Where supply allows, countries should conduct tOPV campaigns before the switch.
- Ensure that preparations for IPV introduction are completed well in advance so that IPV roll out can start as soon as the vaccine becomes available.
- Plan for the vaccination of any eligible infants who missed a scheduled dose of IPV after the OPV switch in April 2016 but prior to IPV introduction (e.g. came for DTP3 after switch, but IPV was not yet available). When supplies become available, affected countries will be offered additional doses to cover needs.

What is the importance of containment ahead of the switch?

Certifying the world as polio-free requires not only stopping the circulation of wild poliovirus in human populations, the only natural reservoir, but also minimizing the risk of an accidental reintroduction of poliovirus into the community from a laboratory or vaccine production site.

With wild poliovirus type 2 (WPV2) already eradicated globally, the destruction of all WPV2 and Sabin 2 viruses (Phase 1) and the security of all remaining WPV2 and Sabin type 2 viruses under appropriate bio-containment levels in a limited number of ‘poliovirus essential facilities’ are key risk management measures to be taken in preparation for the OPV switch in April 2016.

What is the risk of the ongoing cVDPV2 outbreaks in Guinea and South Sudan?

At the time of writing, there are two continuing cVDPV2 outbreaks in non-endemic countries; Guinea and South Sudan. Circulating VDPV2s tend not to be as transmissible as wild polioviruses, however it is critical that ongoing outbreaks are fully stopped.

An outbreak of cVDPV2 in Guinea, along the border area with Mali, was identified in September 2015. In Guinea and Mali, an immediate outbreak response was started upon detection of the outbreak.

The VDPV2 isolate from a case with onset in April 2015 detected in South Sudan is being considered as a cVDPV2 strain and poses a risk of further spread in the conflict affected areas. Aggressive response activities are ongoing and the strain has not been detected since April.

All efforts are being undertaken to ensure all cVDPV2s are fully stopped before the April 2016 switch.

The IPV supply situation remains dynamic and is being closely monitored. Should anything change from these current projections, WHO and UNICEF will contact affected regional colleagues and countries.

Our organizations remain at your disposal for further information or support related to the introduction of IPV and preparations to implement the switch.

For more information on IPV introduction and the switch, please visit: http://www.who.int/immunization/diseases/poliomyelitis/endgame_objective2/en/