FAQs ON THE SWITCH

In preparation for the eventual removal of all OPVs, WHO recommended in its position paper of January 2014 (Weekly Epidemiological Record, 28 February 2014) that all OPV-using countries begin strengthening immunization systems and introduce at least one dose of Inactivated Polio Vaccine (IPV) into routine programmes by the end of 2015. The global focus is now expanding to plan for the replacement of trivalent OPV (tOPV) with bivalent OPV (bOPV) in all OPV-using countries.

What is the switch?
The switch refers to the replacement of all tOPV with bOPV (containing types 1 and 3 only) in routine immunization and supplemental immunization activities (SIAs), in every country around the world within a 2-week timeframe. Currently, the switch from tOPV to bOPV is expected to take place in April 2016. A precise date will be established at least 6 months in advance of the planned date of the switch to bOPV. This will enable national health authorities and implementers to plan appropriately. Once the switch is made, tOPV will no longer be used anywhere in the world, and manufacturers will no longer supply tOPV (production will have stopped much sooner due to production lead times).

What is the objective of the switch?
The objective of the switch is to stop the emergence of cVDPV2 and VAPP caused by the attenuated type 2 strain of tOPV. The planned withdrawal of the type 2 component of tOPV is part of the global polio eradication endgame strategy for 2013-2018.

Why can't countries eliminate the use of OPV entirely, rather than switch to bOPV?
Because IPV is an inactivated vaccine and not a "live" attenuated vaccine, it carries no risk of VAPP. However, in contrast to OPV, since it does not replicate in the gut, IPV induces lower levels of intestinal immunity and does not confer protection to others. IPV is also less effective than OPV in reducing fecal-oral transmission. Using both vaccines together provides the best form of protection.

Will the switch from tOPV to bOPV eliminate all cVDPV cases?
No. The purpose of the switch is to eliminate persistent cVDPVs associated with the type 2 serotype and to boost protection against wild poliovirus types 1 and 3 (the switch will not prevent type 1 or type 3 cVDPVs). 'Persistent cVDPVs' refer to cVDPVs known to have circulated for more than six months.

Rationale for OPV cessation
Why stop using OPV?
OPV is made with attenuated (weakened) polioviruses. On extremely rare occasions, the vaccine

can cause cases of vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived polioviruses (cVDPVs). To prevent cVDPVs and VAPP, OPV must be withdrawn as soon as possible after the end of wild poliovirus (WPV) transmission.
tOPV contains all three poliovirus serotypes (1, 2 and 3), and the use of this vaccine has led to the successful eradication of wild poliovirus type 2 (WPV2), with the last case occurring in 1999. Today, over 90% of cVDPV cases, and approximately 40% of VAPP cases are due to the type 2 component of tOPV.
With at least one dose of IPV in place as a risk mitigation measure, OPVs will be removed in a phased approach, beginning with removal of the type 2 poliovirus strain in a switch from tOPV to bOPV. bOPV contains types 1 and 3, and therefore will continue to protect against transmission of WPV1 and WPV3. Once all wild polioviruses have been fully eradicated, then all OPVs will be withdrawn.

When is it expected we will cease all use of OPV?
The goal is to cease all use of OPV by 2020. Depending on the timing of the switch and the detection of further transmission of polioviruses, countries may be able to cease all use of OPV as early as 2019

About the switch from tOPV to bOPV
If the last wild poliovirus type 2 (WPV2) was reported in 1999, why is type 2 only now being removed from OPV?
This is taking place now for a number of reasons:
• Until recently, WPVs caused the vast majority of paralytic polio cases and attracted the vast majority of attention. During this time, tOPV has continued to be the best strategy for fighting polio. In recent years, great progress has been made in reducing polio transmission, particularly with the South East Asia region being certified as polio-free in March 2014.
• Developments in laboratory capacity have allowed for a better appreciation of the burden caused by cVDPV2s.
• Only in the last few years have data become available which show that switching to bOPV could aid eradication of WPVs, as bOPV provides better immunogenicity than tOPV to WPV1 and WPV3.
• Currently, WPV cases reached such low levels that cVDPVs are causing a relatively high proportion of paralytic polio cases.
• Bivalent OPV had to be available to make the switch to bOPV possible, and bOPV has only become available in the last few years.

Understanding risk and maintaining protection with IPV
Are there any risks associated with the switch from tOPV to bOPV?
The switch from tOPV to bOPV may lead to an increase in the number of individuals susceptible to poliovirus type 2, which in turn will increase the risk of new cVDPV type 2 outbreaks after OPV type 2 cessation, if a cVDPV2 appears. To help mitigate this risk, all countries are requested to introduce at least one dose of IPV (containing types 1, 2, and 3) into their routine immunization programmes by the end of 2015, and to destroy tOPV stocks immediately after the switch. Selected countries will also conduct SIAs with tOPV in the months leading up to the switch.
The introduction of IPV will help to reduce risks associated with the withdrawal of OPV type 2,

facilitate interruption of transmission with the use of monovalent OPV type 2 in the case of outbreaks, and hasten eradication by boosting immunity to poliovirus types 1 and 3.

If both OPV and IPV are given to the same child, is a vaccine overdose possible?
No. In fact, the vaccines can work together to induce a stronger immune response, especially in areas where wild poliovirus and/or VDPVs are still circulating. Many countries have used OPV and IPV sequentially in their routine schedules for decades.

What risks are associated with the switch in areas with low immunization coverage?
Countries or areas with low routine immunization coverage will be more vulnerable to any emergence of cVDPV type 2 after the switch, because these areas will have pockets of individuals who are not reached with IPV and therefore have no direct protection against poliovirus type 2, even if they are reached in campaigns with bOPV.
For this reason, countries with low population immunity against type 2 poliovirus will need to undertake risk mitigation activities consisting of additional SIAs with tOPV during the 6 months prior to the switch. The criteria for which countries need these additional SIAs will be based on an epidemiological assessment of risk levels and recommendations by SAGE in October 2014.

Timing of the global switch from tOPV to bOPV
When will the switch happen?
The switch is tentatively planned for April 2016. If no persistent cVDPV2s have been identified for six months prior to September 2015, a final decision will be made to proceed with the switch in 2016. If persistent cVDPV2s continue to circulate in the six months prior to September 2015, the switch may be postponed until at least 2017.
Once the final decision to proceed with the switch is made, the decision is irrevocable and must be implemented by all countries simultaneously during the identified switch window, even if a new cVDPV type 2 is detected.

Will the switch still take place if a new cVDPV2 emergence occurs before September 2015?
If there is a new VDPV2 emergence before September 2015, targeted SIAs will be implemented to respond to this outbreak, but the switch will proceed.

Preparing for the switch from tOPV to bOPV
What do countries need to do now to prepare for the switch from tOPV to bOPV? When should countries begin planning for the switch?
Preparation for the switch at the national level should begin now. Countries have already started to introduce IPV in order to help mitigate risks related to the switch. As soon as possible, countries that require national licensure of bOPV should begin the process of registering bOPV for use in routine immunization. Those countries that currently rely on national OPV production will need to develop and license bOPV by the end of 2015. The Global Polio Eradication Initiative (GPEI) will prioritize its work with manufacturers in these countries to ensure sufficient access to bOPV in advance of tOPV withdrawal.

Supply and forecasting bOPV
Will there be enough supply of bOPV for all countries to make the switch at the same time?
Considering that the established manufacturing capacity of tOPV is going to be used for bOPV, a

sufficient supply of bOPV is expected for all countries to make the switch at the same time.

How much will bOPV cost? Will it cost more, less, or the same as tOPV?
The price of bOPV will be the same as or less than tOPV, depending on the supplier.

How should countries forecast quantities needed of tOPV and bOPV?
Close ongoing management and monitoring of tOPV stocks and requirements up to April 2016 will be critical at both public and private sector facilities. In addition to closely tracking remaining quantities of tOPV to identify and minimize the quantities that need to be disposed of, countries should be calculating the projected quantity of bOPV that will be needed. Up-to-date inventories paired with historical consumption figures should give countries an accurate forecast of quantities needed for both tOPV and bOPV.

Disposal of remaining inventories of tOPV
What should happen to unused supplies or inventories of tOPV after the global switch to bOPV?
After the switch date, all remaining tOPV supplies or stocks should be collected from both public and private facilities and destroyed. There are several ways to dispose of unused tOPV vials; by encapsulation and disposal in a landfill site, direct disposal in an engineered landfill site, or through incineration in high- or medium-temperature incinerators.
The collection and proper disposal of all tOPV stocks should be well-documented, and the overall switch plan should include these activities and corresponding financing. After the switch, the national registration of tOPV should be cancelled and only bOPV should be used in routine immunization programmes and SIAs.

Why do unused supplies or inventories of tOPV need to be destroyed immediately after the switch?
The accidental or deliberate use of tOPV after the switch could cause outbreaks of cVDPV2, particularly because the number of individuals susceptible to infection with poliovirus type 2 will increase after the switch. Destroying all tOPV will eliminate the risk of such cVDPV2 outbreaks.

Outbreak response
What will happen if a country has a type 2 poliovirus case, outbreak, or accidental release, after it has switched to bOPV?
Following the switch, monovalent OPV type 2 (mOPV2) will be the vaccine of choice for responding to any cVDPV type 2 outbreak or any accidental WPV2 release from a laboratory or facility. An initial stockpile of 500 million doses of mOPV2 is being procured and will be available prior to the switch date for outbreak response.

Will a country be able to obtain tOPV in the event of a type 2 poliovirus case or outbreak?
No. No additional tOPV will be produced or available after the switch.

Will countries have access to mOPV2 for outbreak response, or should they put some aside now? How will countries pay for mOPV2?

Countries will have access to the global stockpile of mOPV2 and should not need to establish a national stockpile. The global stockpile is being completely financed by global partners, and countries will be provided mOPV2 at no cost to them in the event of an outbreak. They will not need to procure mOPV2.