

Evidence to Recommendation Table

Question: Does the WG reaffirm the date for the OPV2 withdrawal in April 2016?		
Population: All children in OPV-using countries		
Intervention & Comparison: Withdrawing tOPV from the routine immunization schedule and replacing it with bOPV		
Setting (if relevant): n/a		
Decision domain	Summary of reason for decision	Subdomains influencing decision
Quality of evidence (QoE) <i>Is there high or moderate quality of evidence</i> Yes x No <input type="checkbox"/>	Quality of Evidence for benefits: High x Moderate <input type="checkbox"/> Low <input type="checkbox"/> Very Low <input type="checkbox"/> Quality of Evidence for harms: High <input type="checkbox"/> Moderate x Low <input type="checkbox"/> Very Low <input type="checkbox"/>	Reasons for upgrade or downgrade: (i.e. risk of bias, indirectness) Quality of Evidence for benefits: We have documented cases of type 2 related vaccine derived poliovirus (VDPV) as well as estimates of vaccine associated polio paralysis (VAPP). Quality of Evidence for harms: There is a potential risk of poliovirus transmission from the facility due to the delayed containment implementation. Although this risk is difficult to quantify, containment efforts are currently being strengthened in preparation for OPV withdrawal.
Balance of benefits and harms <i>Is there certainty</i>	Benefit of the switch in April 2016: 1) Eliminating type 2 related VAPP and VDPV, 2) taking advantage of	Is the baseline risk for benefit similar across age, gender, and SES?

<p><i>that the benefits outweigh the harms?</i></p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>	<p>unprecedented level of surveillance and response capacity at GPEI, which will begin to diminish by April 2017, 3) taking advantage of the relatively stable situation in Nigeria and Pakistan, 4) benefiting from country readiness and support (if the switch is delayed, the delayed switch date will have less credibility and therefore readiness for it may well be reduced). There is a risk related to proceeding with April 2016: potential risk of accidental release of type 2 due to the delayed implementation of containment. The Working Group concluded that the risks of delaying the switch significantly outweigh the risks of proceeding with it as planned (please refer to the notes from the WG meeting). The potential risk of type 2 circulation due to the failed containment may be higher among countries that have gaps in tOPV coverage and will be switching from tOPV to bOPV than in those countries already having a full IPV schedule with high vaccination coverage.</p>	<p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Should there be separate recommendations for subgroups based on risk or disease severity levels?</p> <p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Is the baseline risk for harm similar across subgroups? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Should there be separate recommendations for subgroups based on harms? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>
<p>Values and preferences</p> <p><i>Is there confidence in the estimate of relative importance of outcomes and</i></p>	<p>Poliovirus circulation (either cVDPV or WPV) disproportionately affects disadvantaged populations. Therefore, we advocate that all countries worldwide using OPV</p>	<p>Are the benefits, harms and costs of the intervention valued differently by disadvantaged populations compared to the privileged populations? Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>

<p><i>patient preferences?</i></p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>	<p>withdraw OPV2 to ensure the elimination of type 2 related paralysis. In WHA 2015, all member states (including polio-affected countries) agreed to withdraw OPV2 from their routine immunization schedule in April 2016.</p> <p>We will continue monitoring the outcome of the OPV2 withdrawal (e.g. disappearance of OPV2 from the environment or number of type2 related paralysis).</p>	<p>Source: There has been extensive consultation with WHO regions and counties as well as experts in polio-infected countries</p> <p>Source of variability, if any: Methods for determining values satisfactory for this recommendation?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>All critical outcomes relevant to disadvantaged populations measured?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>
<p>Resource implications</p> <p><i>Are the resources worth the expected net benefit?</i></p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p>	<p>Proceeding with the switch in April 2016 would save the program the expense of an estimated USD 170 million. However, in the context of a USD 5.5 billion budget to complete polio eradication, this is relatively modest and does not weigh heavily in the WG's recommendation.</p>	<p>Feasibility: Is this intervention accessible, acceptable to patients and providers and affordable to disadvantaged populations?</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>Is there a risk of discrimination?</p> <p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Opportunity cost: Is this intervention and its effects worth withdrawing or not allocating resources from other interventions? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Evidence from: Background information on equity Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>Health equity impact assessment</p> <p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Analysis of opportunity cost of equity</p>

		<p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Equity weighing of health outcomes</p> <p>Yes <input checked="" type="checkbox"/> No <input type="checkbox"/></p> <p>Is there variability in resource requirements and feasibility across settings and populations? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p> <p>Is there a need for additional recommendations?</p> <p>Yes <input type="checkbox"/> No <input checked="" type="checkbox"/></p>
Overall strength of recommendation:	<p>The WG carefully assessed pros and cons and concluded that there is a strong evidence to support the recommendation. As mentioned, this recommendation (tOPV-bOPV switch) will primarily benefit disadvantaged populations (who are currently affected and will continue to be affected due to the highest risk of poliovirus type 2 circulation)</p>	
Remarks and values and preference and statement	<p>The WG made a decision based on evidence among population in polio-affected areas or at high risk</p>	
Implementation and considerations	<p>In WHA 2015, all member states adopted a resolution to withdraw type 2 OPV simultaneously in April 2016. In addition, the program will invest more than USD 24M to monitor all vaccine cold chain stores that stock tOPV down to district level where large stocks are held for several months. In addition, a risk based purposive sampling method will be implemented to conveniently sample 10% of health care service delivery points where although small quantities of tOPV are held, there is a higher risk of non-compliance.</p>	
Research priorities	<p>We will continue monitoring the progress through strengthened surveillance including expanded environmental surveillance in high risk areas to ensure the disappearance of the type 2 virus from the environment as well as measuring the immunogenicity under the new routine immunization schedule with bOPV.</p>	