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The Globally Synchronized Switch—Another Milestone Toward Achieving Polio Eradication

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To avoid the risks for vaccine-associated paralytic polio[1] and circulating vaccine-derived poliovirus (cVDPV) outbreaks,[2] the Polio Eradication and End-game Strategic Plan[3] 2013-2018 directs the phasing out of all oral poliovirus vaccine (OPV) use after wild poliovirus (WPV) is eradicated. This has started with the type 2 component in the vaccine. From April 17 through May 1, 2016, 155 countries using trivalent OPV (tOPV) (Sabin strains of types 1, 2, and 3) in their national immunization schedules removed it and introduced bivalent OPV (bOPV) (Sabin strains of types 1 and 3).[3] This massive public health event required the engagement of every health facility providing vaccines in each of these countries. This unprecedented, synchronized vaccine introduction and withdrawal is termed the *switch*.[4,5]

The switch was only possible owing to the efforts of thousands of health care professionals working in a coordinated manner across the globe. Successful implementation of the switch required extensive planning by national governments in partnership with Global Polio Eradication Initiative (GPEI) partners (World Health Organization [WHO], United Nations Children's Emergency Fund, Rotary International, the Bill and Melinda Gates Foundation, and the US Centers for Disease Control and Prevention) in collaboration with Gavi, the Vaccine Alliance, and other key stakeholders and partners. Independent monitors in each country, both national and international, visited health facilities and vaccine stores to check that tOPV was no longer being stored and that bOPV was in stock for use.

Milestones in Global Polio Eradication

The switch is one more milestone on the road toward achieving certification of global polio eradication. Other major milestones achieved include the certification of the eradication of

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WPV type 2 in September 2015, not detected since 1999, and the absence of reported WPV type 3 since November 2012. Since the adoption of the resolution to eradicate poliovirus at the World Health Assembly in 1988, 4 of the 6 WHO regions have been certified free of polio, the most recent being the Southeast Asia region in 2014; 80% of the world now lives in an area certified free of WPV paralytic polio. In September 2015, Nigeria was removed from WHO's polio-endemic country list, and the African continent has been free of a reported WPV case for more than a year and a half (August 2014 was the last case).[3] There has been a 99.9% reduction from an estimated 350 000 WPV cases in 1988 to a record low of 74 reported cases in 2015. As of May 10, 2016, 14 WPV cases have been reported in the remaining 2 endemic countries: Pakistan (9 cases) and Afghanistan (5 cases).[3]

Within the context of these milestones, the adverse consequences of using a live, attenuated OPV have increased in importance relative to its benefits. While a rare event, vaccine-associated paralytic polio is a real outcome of vaccination of children and accounts for an estimated 400 cases of paralytic polio per year.[1] In communities with very low vaccination coverage, rare outbreaks of paralysis due to cVDPV can also emerge.[2] Since 2000, more than 800 cVDPV cases have been reported (423 in Nigeria alone); of these, more than 85% have been caused by cVDPV type 2.[2,3] The recognized ongoing risks of OPV led the WHO Strategic Advisory Group of Experts on Immunization (SAGE) in 2011 to recommend the planning and execution of a synchronized global switch for routine and supplemental immunization.

Components of the Switch and Mitigating Risks

The switch required global synchronization to ensure that no country is put at risk of an importation of an OPV type 2 or a type 2 cVDPV from another country. Stopping tOPV use will reduce cVDPV type 2 outbreak risk for the long-term; however, in the short-term, we do expect some cVDPV type 2 outbreaks. Outbreak response protocols were developed and disseminated, and a stockpile of monovalent type 2 OPV was created before the switch. This stockpile will be dispensed for any cVDPV type 2 outbreak after the switch at the authorization of the WHO Director General.

To mitigate switch-associated risks, SAGE recommended that countries introduce at least 1 dose of inactivated poliovirus vaccine (IPV) in their routine immunization schedules.[5-7] One IPV dose will induce an immunity base (seroconversion and/or priming) to poliovirus type 2 and boost immunity against types 1 and 3.[7]

All 126 countries that were only using tOPV in the routine immunization schedule in 2013 had plans to introduce IPV before the switch. The commitment from the countries to implement this recommendation was remarkable. To date, 94 countries have introduced IPV.[8] This undertaking was made possible through the collaboration of GPEI and Gavi, as 73 countries rely on Gavi support for the introduction of new vaccines. The GPEI is supporting IPV introduction into many middle-income countries and Gavi negotiated with vaccine manufacturers on pricing. However, stand-alone IPV supply is currently constrained owing to a series of setbacks by the 2 manufacturers in scaling up production and the quantity available is markedly less than originally projected.

In October 2015, SAGE concluded that the risks of continued tOPV use is greater than the risks of switching to bOPV for epidemiological, programmatic, and financial impact, and it recommended that even with the further changes in IPV supply, the switch date should not be changed; this recommendation was reiterated at the April 2016 meeting.[8] Therefore, the principles for allocation of IPV endorsed by SAGE were applied and criteria were used to identify countries considered to be at high risk. To date, 25 of 26 countries with a history of cVDPV outbreaks have introduced IPV into the routine immunization schedule, with the last (Indonesia) scheduled to introduce it in June 2016. Many countries considered at lower risk could not introduce IPV before the switch or may face IPV stockouts if IPV has already been introduced owing to the supply shortage.

Regarding future risks, steps are being taken to destroy or safely contain all type 2 polioviruses in laboratories and vaccine manufacturing facilities and to develop drugs to help chronic excretors of polioviruses clear infections. Efforts to improve IPV and to develop a new genetically engineered OPV that is much less likely to cause cVDPVs are also under way.

Achieving Polio Eradication and Beyond

The switch is an important milestone, but continued efforts and focus remain on interrupting endemic WPV transmission in Afghanistan and Pakistan and responding to remaining cVDPV outbreaks. If achieved by 2019, eradication is poised to save the world US$40 billion to $50 billion over the subsequent 20 years.[9] Achieving this feat will signify that the world has eradicated the second human disease, smallpox being the first. However, vigilance is necessary until the entire world is certified free of indigenous WPV; all countries need to maintain strong systems to prevent poliovirus transmission if it is imported and to detect poliovirus through quality surveillance of reported cases of acute flaccid paralysis and sampling of the environment. The GPEI remains laser-focused on interrupting poliovirus transmission. Meanwhile, planning is under way to ensure essential polio functions are mainstreamed and GPEI's assets at country, regional, and global levels are leveraged and built on for other public health needs in the post-polio period. The world has truly never been closer to polio eradication and the window of opportunity to achieve this accomplishment is upon us.

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