

U.S. Support Essential to Ambitious Global Introduction of Inactivated Polio Vaccine

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Earlier this fall, Nepal became the first low-income country to introduce the inactivated polio vaccine (IPV) into its immunization system. Many more countries will have to follow suit to meet the ambitious deadlines laid out in the Global Polio Eradication Initiative's (GPEI)² *Polio Eradication & Endgame Strategic Plan 2013–2018*.³ The plan calls for global introduction of at least one dose of IPV into routine childhood immunization schedules followed by eventual withdrawal of the widely used oral polio vaccine (OPV). Currently, 75 mostly high- and middle-income countries use the injectable IPV in their immunization systems, leaving 119 that need to do so by the end of 2015 to keep with the plan's schedule.

The IPV introduction timeline called for in the strategy is extraordinarily quick; most vaccines are incorporated into national routine immunization programs over years if not decades. In calling for universal adoption of IPV over several years, "We'll be trying to do something that's never been done in terms of speed," said Bruce Aylward, the World Health Organization's assistant director-general for polio and emergencies.⁴

The move is necessary to complete and sustain global polio eradication. OPV has long been the vaccine of choice for many countries and is used in mass vaccination campaigns. It is inexpensive (as little as 14 cents per dose),⁵ easy to administer, and provides comprehensive immunity. But it has one serious drawback: since it uses a live, weakened virus, in rare instances, polioviruses in the vaccine can cause the disease. In countries with low immunization rates, a vaccine-derived poliovirus even can begin to circulate in the community person-to-person beyond those vaccinated, causing paralysis and sometimes death. IPV, a killed virus vaccine that carries no risk of causing disease, was substituted for OPV in many higher-income countries more than a decade ago as it became clear that remaining polio cases there were being caused by the oral vaccine.

As increased vaccination has reduced the prevalence of wild, or naturally occurring, poliovirus a growing percentage of polio cases in developing countries now is being linked to OPV. In 2012, more countries reported outbreaks caused by circulating vaccine-derived poliovirus than from

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² The Global Polio Eradication Initiative (GPEI) is led by national governments along with the World Health Organization, Rotary International, the U.S. Centers for Disease Control and Prevention, and UNICEF with additional technical and financial support from the Bill & Melinda Gates Foundation.

³ GPEI, *Polio Eradication & Endgame Strategic Plan 2013–2018* (Geneva: World Health Organization, 2013), http://www.polioeradication.org/Portals/0/Document/Resources/StrategyWork/PEESP_EN_US.pdf.

⁴ Bruce Aylward, "IPV Introduction: Are We on Track for 2014?," presentation, Geneva, May 22, 2014.

⁵ GPEI, "Oral Polio Vaccine Supply," <http://www.polioeradication.org/Financing/Budgetcomponents/Oralpoliovaccinesupply.aspx>.

wild poliovirus.⁶ To address the risk, the GPEI's current strategy calls for simultaneous elimination of polio cases caused by the wild poliovirus and those related to OPV. Immunizing with IPV will provide additional protection during OPV withdrawal and ward against vaccine-related disease. Since OPV is easier to provide on a broader basis, many countries will continue using both vaccines for the time being. After IPV is more widely available, the GPEI plans to remove from OPV the strain of the vaccine responsible for the vast majority of vaccine-derived polio cases (50 of 51 so far in 2014),⁷ a move now planned for April 2016.

As they have throughout the long drive to eradicate polio worldwide, the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID) will play pivotal roles in the vaccine transition. CDC is supporting vaccine purchases, providing technical assistance and laboratory support, as well as conducting implementation and operational research. It also will help countries determine whether and when they are ready to begin transitioning away from OPV, with one criterion being how broadly IPV is available.

USAID is aiding the introduction of IPV in areas where it has ongoing work including supporting facility and community-based surveillance. The agency is continuing its role in supporting social mobilization and communications operations and linking polio eradication activities with routine immunization programs. Contributions to this next phase of polio eradication from both U.S. agencies are invaluable and should be supported by Congress and the administration.

Along with CDC and USAID, other organizations also are pitching in to support global IPV introduction. UNICEF is developing communications strategies, negotiating lower prices for vaccines, and helping with vaccine purchases. The World Health Organization (WHO) is using polio program personnel to help strengthen immunization systems. A new partner in the polio effort, Gavi, the Vaccine Alliance,⁸ is offering financing to 73 lower-income countries for polio vaccine purchase through enhanced processes: countries can receive grants without co-financing requirements and limited funding is available for lower-middle-income countries that have become ineligible for Gavi funding for other vaccines. To aid in the GPEI goal of getting as many countries involved as possible, Gavi also has waived its usual requirements for routine vaccine coverage levels.⁹ All told, Gavi has committed \$430 million to aid low-income countries in IPV introduction for the years 2014–2018.¹⁰

Aid levels can be considerable. Nepal, for example, will receive a total of \$3 million from Gavi for the end of 2014 through 2016 for the purchase of vaccine, syringes, and safe syringe disposal

⁶ GPEI, *Polio Eradication & Endgame Strategic Plan 2013–2018*, 52.

⁷ GPEI, "Circulating Vaccine-Derived Poliovirus Cases, 2000–2014," December 16, 2014, <http://www.polioeradication.org/Dataandmonitoring/Poliothisweek/Circulatingvaccinederivedpoliovirus.aspx>.

⁸ Gavi is an international public–private partnership that offers grants and technical expertise to developing countries to facilitate the introduction of new and underused vaccines.

⁹ Gavi, "GAVI Alliance to Support Introduction of Inactivated Polio Vaccine in 73 Poorest Countries," press release, November 22, 2013, <http://www.gavi.org/library/news/press-releases/2013/gavi-alliance-to-support-introduction-of-inactivated-polio-vaccine-in-worlds-73-poorest-countries/>; and Gavi, "Inactivated Polio Vaccine Support," <http://www.gavi.org/support/nvs/inactivated-polio-vaccine/>.

¹⁰ Author communication with Emily Wootton, program manager, vaccine introduction, Gavi, September 16, 2014.

equipment.¹¹ It also has received \$462,000 in a “vaccine introduction grant” that will fund activities such as communications, health worker training, and cold chain enhancement.¹²

Despite the support, significant challenges remain. Health communicators must explain why an additional polio vaccine is necessary. This requirement could create adverse publicity for the rare possibility of OPV-related paralysis, something that so far has not created much of a stir. Health workers need to be taught to distinguish between the two polio vaccines since they are administered differently and because OPV must be kept frozen while IPV loses potency if its temperature drops too low. IPV introduction involves strengthening routine immunization programs in countries that currently cannot deliver IPV broadly.¹³ It also requires ensuring enough vaccine is available at affordable prices since IPV is significantly more expensive than OPV: UNICEF and Gavi announced early this year that while low-income countries could receive the vaccine for as little as \$1 per dose, middle-income countries could pay around \$3 per dose.¹⁴ Vaccine technology improvements that could make the change easier and less expensive—widespread availability of smaller multiple-dose vials that reduce vaccine wastage, alternative administration methods, and inclusion of IPV as part of an affordable combination injection—are still under development.

Bolstered by strong government commitment and solid public–private partnerships supporting childhood immunizations, Nepal was an eager partner and its experience provides an instructive example of how IPV introduction could unfold in other countries. Although it is one of the world’s poorer countries and is continuing to recover from a 10-year civil war that ended in 2006, Nepal has made steady progress in improving its health situation. It is judged as likely to meet Millennium Development Goal (MDG) 4 relating to reductions in child mortality and already has achieved a target in MDG 5 measuring reductions in maternal mortality.¹⁵ Nepal also has been a strong supporter of global polio eradication. Despite suffering repeated polio importations from its giant neighbor, India, it recorded its last case of polio in 2010. Further, overall vaccine coverage is high in Nepal—more than 90 percent of children are estimated to have received three doses of the diphtheria, tetanus, pertussis vaccine (DTP), a measure of how thoroughly a child has been immunized.¹⁶

But there are potential complications. While the current vaccine cold chain in Nepal is expected to be adequate for IPV, it might become overburdened as the country plans introduction of pneumococcal and other vaccines in the near future. International organizations currently are working with the government to assess the system and plan for necessary improvements in

¹¹ Gavi, letter to Dr. S. R. Upreti, director, Child Health Division, minister of health, Royal Government of Nepal, July 2, 2014, <http://www.gavi.org/country/nepal/documents/#approvedproposal> [the letter is the fourth listed under the heading Decision Letters and Partnership Agreements at the opening page of this URL].

¹² Ibid.

¹³ GPEI focus countries for immunization strengthening are Afghanistan, Chad, Democratic Republic of the Congo, Ethiopia, India, Nigeria, Pakistan, Somalia, South Sudan, and Angola. See GPEI, *Polio Eradication & Endgame Strategic Plan 2013–2018*, 53.

¹⁴ UNICEF, “Joint GPEI-GAVI Statement on the Availability and Price of Inactivated Polio Vaccine,” February 28, 2014, http://www.unicef.org/media/media_72738.html; and UNICEF, “Inactivated Polio Vaccine,” March 4, 2014, <http://www.unicef.org/supply/files/IPV.pdf>.

¹⁵ United Nations, *Nepal: Millennium Development Goals Progress Report 2013* (Kathmandu: United Nations, September 2013), 3, http://www.np.undp.org/content/dam/nepal/docs/reports/millennium%20development%20goals/UNDP_NP_MDG_Report_2013.pdf.

¹⁶ Gavi, “Nepal,” <http://www.gavialliance.org/country/nepal/>.

refrigerator capacity and vaccine transportation. Nepal also is working on improving hospitals' medical waste disposal systems, many of which do not meet international standards.¹⁷ Further, while there is no evidence of harm associated with giving infants multiple injections at one visit, Nepalese authorities are adding an additional visit to their childhood vaccination schedules to ensure that no more than two injections will be given at one time. International vaccine experts are concerned other countries may adjust their vaccine schedules similarly raising apprehensions that the additional health visit required under the new schedules could discourage parents from ensuring children receive all recommended vaccines.

A stated goal of the polio eradication end game is improvement of routine immunization systems and the plan includes several associated markers of progress. Gradual progress is being made in this area, but more needs to be done. Along with motivated countries like Nepal, IPV must be introduced in areas with much worse immunization infrastructures. In South Sudan, for example, only 56 percent of children have been fully vaccinated.¹⁸ In Somalia, the rate is 34 percent.¹⁹ And even in proactive countries, introducing a new vaccine into a national immunization system is a complicated endeavor. Ensuring new vaccines strengthen an immunization system rather than cause it stress requires thoughtful long-term planning, an activity to which the accelerated IPV introduction timeline is not conducive. Depending on its effects on immunization systems, IPV introduction could either placate or disappoint some routine immunization system advocates who argue that polio eradication activities bypass or even overload existing systems in the countries with the weakest health services rather than strengthening them.

While the GPEI plan is ambitious and its effects on immunization programs uncertain, countries and international vaccine partners are making progress toward wider IPV use. As of early December 2014, 96 countries had made formal commitments to introduce IPV into their routine immunization systems by the end of 2015, while another 20 have signaled their intention to do so, according to WHO.²⁰ Two countries have said they will introduce IPV in 2016 while one has not communicated its plans to the international health body. Given the numbers, officials at both WHO and Gavi say they are pleased with progress so far, although they note the Ebola outbreak in West Africa could slow movement in some areas.

The U.S. government has contributed more than \$2 billion to polio eradication activities and largely through CDC and USAID, provided critical technical resources, vaccine funding, and outreach strategies. The difficult "last mile" in polio eradication requires finishing off the wild poliovirus and eliminating cases caused by the oral polio vaccine. As key partners in the drive to eradicate polio, CDC and USAID will be instrumental to this latest effort. They should be given support and adequate resources to continue playing their pivotal roles.

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¹⁷ Author communication with Rajendra Bohara, Nepal national coordinator, World Health Organization, September 24, 2014.

¹⁸ Gavi, "South Sudan," <http://www.gavi.org/country/south-sudan/>.

¹⁹ Gavi, "Somalia," <http://www.gavi.org/country/somalia/>.

²⁰ World Health Organization, "IPV Introduction, OPV Withdrawal and Routine Immunization Strengthening," December 4, 2014, http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/en/ [see the PowerPoint presentation, "Status Updates on Country Planning for IPV Introduction," at bottom right of the opening page of this URL].

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