The Immunization Systems Management Group (IMG)

September 2013

PLANNING FOR IPV INTRODUCTION

Technical Fact Sheet

How does IPV introduction differ from other vaccines introduced in the past?

For the most part, IPV introduction will involve the same process as other new vaccine introductions. However, there are some notable differences:

- *Unprecedented timelines* - the urgency of eradication necessitates an accelerated introduction plan— all OPV-using countries should introduce a dose of IPV by end-2015;
- *Global scope* - its objective focuses on achieving a global good; and
- *Lack of direct impact indicators* - evaluation will be based on routine immunization coverage in contrast to indicators used to measure the impact of other vaccines (e.g. reduced mortality or infection rates at national level).

What steps will be necessary to introduce IPV?

Once the decision to introduce IPV has been made by the national authorities, the first step in IPV introduction will be for the GPEI, GAVI Alliance and other immunization partners to support national authorities to develop annual integrated action plans for strengthening immunization services in the countries that need it most. Details will be elaborated and a model workplan with milestones and deadlines finalized by the end of 2013. Within this framework, focus will be on the following four areas:

- *Programme management* - including use of accountability frameworks, data management, evidence-based planning, training and supply management;
- *Microplanning* - including population mapping, harmonization of routine immunization microplans with polio SIA microplans to enable more complete session planning, vaccine supply management and cold-chain logistics;
- *Advocacy and communication* - including top-level advocacy, engagement of local community leaders and household-level outreach.
- *Immunization delivery* - monitoring of immunization sessions, local community coverage and vaccine acceptance, social mobilization efforts, availability of health workers, vaccine delivery and other immunization session logistics and overall quality and impact of services.

Why are the timelines for IPV introduction so tight? How will countries achieve introduction targets in such a short period?

Recently we achieved the lowest level of wild polio cases in history. With the prospect of eradicating WPV transmission realistic and achievable in the near-term, aggressive timelines are required to avoid missing this window of opportunity.

Technical and financial support for vaccine purchase will be available to most countries from immunization partners such as WHO and UNICEF, in conjunction with the GAVI Alliance. In particular, the *Polio Eradication and Endgame Strategic Plan* specifically calls for strengthening routine immunization, which will be supported by international partners and donors. This will facilitate the introduction of IPV according to the proposed timelines in close coordination with other routine immunization activities.

What schedule should countries be using for IPV, and how many doses are recommended?

SAGE will make its final recommendation on the immunization schedule for IPV in November 2013 on the basis of available evidence. A detailed review of that evidence in June 2013 showed that the optimal timing for administering 1 dose of IPV in a routine immunization schedule in low and middle income countries is when the third dose of Diphtheria-tetanus-pertussis (DTP3) is given[1].

In countries with a 6, 10, and 14-week immunization schedule, this would mean that IPV would be administered at 14 weeks of age. For countries with a 2, 3, and 4-month schedule, the IPV dose would be administered at 4 months of age. In most cases IPV will be administered during the same visit as the third dose of OPV. National recommending bodies are responsible for evaluating country needs and in some cases, they may wish to follow an alternative schedule (e.g. go directly to an IPV-only schedule).

What IPV vaccine presentation options exist?

Currently, IPV is prequalified by WHO as a stand-alone vaccine in 1-dose, 2-dose and 10-dose presentations. WHO expects a 5-dose presentation to be available in 2014. These products are preserved with 2 phenoxy-ethanol. This means that any open vials of this vaccine must be discarded at the end of the immunization session or six hours after opening, whichever comes first. These vaccines are licensed for use as a 0.5 ml dose administered intramuscularly.

IPV-containing combination presentations with diphtheria, tetanus, acellular pertussis, hepatitis B, or Hib antigens in tetravalent, pentavalent, or hexavalent formulations are also available but at substantially higher cost. A combination product with whole-cell pertussis is not currently available.

[1] *The scientific rationale for administering IPV with DTP3 is because IPV performance is negatively affected by the higher levels of maternally-derived antibody at the younger ages when DTP1 and 2 are typically administered, even after taking into account the potentially lower vaccine coverage due to drop-out rates between DTP1 and DTP3.*

What will the IPV vaccine cost?

Discussions on prices are underway with manufacturers, but have not yet been finalized. Final price will be impacted by a number of variables including the number of doses per vial. It is expected that that the price of the IPV standalone vaccine for the 72 OPV using GAVI-eligible and graduating countries will be around US$ 1.00/dose for a 10 dose vial. For other low and middle income countries, one company has indicated it would make the vaccine available at a price of US$1.30-1.50/dose.

The current IPV-containing combination vaccines, which use an acellular pertussis component, are substantially more expensive (currently priced at US$20-40/dose).

Is the vaccine's cost expected to drop over time?

Achieving an IPV price substantially below US$ 1.00 per dose will require new products or delivery methods to be licensed. Possible options include the administration of a fractional dose (i.e. 1/5th of a full dose of IPV) through the intradermal (ID) route, or the intramuscular administration of a new IPV product containing a lower level of antigen with an adjuvant to enhance immune response. While one product may soon be licensed for intradermal administration, the adjuvanted products are unlikely to be licensed and accessible before 2015-2018.

However, intradermal administration of IPV brings additional programmatic complexities. Countries that wish to utilize intradermal IPV will need to ensure they have an appropriately trained workforce as well as equipment.

The development of an IPV-containing combination vaccine with whole-cell pertussis, which would be affordable for low and middle income country markets and could replace the currently used pentavalent (DTP-Hep B-Hib) vaccine, is not expected before 2020.

How do countries apply for the financial support?

The streamlined process for obtaining financial support will be developed by end-2013; fast-track financial support will be available to all countries introducing IPV that can demonstrate a need.

GAVI-eligible and GAVI-graduating countries will likely receive support through the GAVI Alliance, pending a final Board decision, in a process similar to that followed for other new vaccines introduction support. Financing mechanisms for non-GAVI countries are being explored. More information on this will be available towards the end of 2013.

To establish a comprehensive global financing and supply strategy for fast-track IPV, introduction partners will need country-specific IPV introduction plans and timelines by the end of 2014 at the latest.

Is there technical assistance available to support IPV introduction?

Support for IPV introduction is available from WHO and UNICEF regional office technical focal points as well as from NGOs and other immunization partners. Work is underway to develop guidance and tools to help country immunization staff discuss IPV introduction.

Many countries are already planning to introduce other vaccines before 2016. How does IPV introduction affect these plans?

There are potential benefits to introducing IPV at the same time as other new vaccines. Studies in Ghana showed efficiencies in cost and time can be gained by introducing two new vaccines at once. Countries planning to introduce other new vaccine(s) in 2014 or 2015 may therefore wish to consider a joint introduction. This option should be discussed with regional immunization staff as soon as possible in order to ensure adequate time for planning.

Will the introduction of IPV interrupt routine immunization or take the focus away from it?

Objective 2 of the *Polio Eradication and Endgame Strategic Plan* aims to systematically use the GPEI infrastructure to more effectively strengthen immunization services. The key milestones on this objective's path include achieving at least a 10% year-on-year increase in DTP3 coverage in the majority of worst-performing districts in focus countries from 2014, thereby contributing to global immunization targets.

Is there enough IPV vaccine available globally?

Yes. There is enough production capacity for current IPV standalone products to meet the needs for all OPV-using countries to introduce one dose of IPV into their routine immunization programme.

However, to ensure sufficient IPV is available when countries are ready for its introduction, it is essential that all countries define their target introduction dates as soon as possible (i.e. by end-2013 if possible, by mid to end-2014 latest).