



# Case Studies of IPV Introduction: Albania, Nigeria, and Tunisia

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# EXECUTIVE SUMMARY

Since its launch at the 44th World Health Assembly in 1988, the Global Polio Eradication Initiative (GPEI) has reduced the global incidence of polio by more than 99% and the number of countries with endemic polio from 125 to 3. While this progress is immense, a great deal of work is still required for full eradication of the disease.

There are two vaccines used to prevent polio: (1) the oral Polio vaccine (OPV) and (2) the inactivated polio vaccine (IPV). OPV is extremely safe and effective at protecting children against lifelong paralysis caused by the poliovirus. Over the past ten years, more than 10 billion doses of OPV have been given to nearly three billion children worldwide. More than 10 million cases of polio have been prevented, and the disease has been reduced by more than 99%. It is the appropriate vaccine through which to achieve global polio eradication. However, OPV contains attenuated (weakened) polioviruses. On extremely rare occasions, the use of OPV can result in paralysis due to vaccine-associated paralytic polio (VAPP) and circulating vaccine-derived polioviruses (cVDPVs). For this reason, the global eradication of polio requires the cessation of all OPV use in routine immunization (RI), as soon as possible after the eradication of wild poliovirus (WPV) transmission. This will leave only IPV in widespread use, which eliminates the chance of VAPP cases and the circulation of cVCPVs (IPV does not cause these), allowing for complete eradication of all polioviruses in the world.

At the end of 2012, global immunization experts made a landmark recommendation that every country in the world exclusively using the oral polio vaccine (OPV) should add at least one dose of the inactivated polio vaccine (IPV) to their national immunization schedule by the end of 2015. The primary role of introducing one dose of IPV into routine immunization programs is to mitigate risks associated with OPV withdrawal and possible reintroduction of polioviruses.

This recommendation for global IPV introduction means that 126 countries must change their national immunization schedule within the short timeframe of three years.

Since January 2013, these countries have been making the necessary plans to introduce IPV by year-end 2015. As of August 2015, 29 out of the 126 countries that need to introduce have done so.<sup>1</sup>

As countries prepare to introduce IPV, there is an opportunity to leverage lessons learned from countries that have already introduced the vaccine. The purpose of this document is to give an in-depth overview of IPV introduction in three countries:

Albania, Nigeria, and Tunisia. Each case study describes the decision-making process, the pre-introduction activities that were conducted, and the implementation process for each country. Each case study concludes with a synthesis of the lessons learned during IPV introduction that can be applied to other countries. Using the lessons learned from Albania, Nigeria, and Tunisia—both their successes and their challenges—other countries have the opportunity to take advantage of the strategies which were most effective and avoid common pitfalls.

Many of the findings from these case studies are programmatic and therefore applicable to not only IPV but also to the introduction of other vaccines.

Albania, Nigeria, and Tunisia were selected because they are geographically and economically diverse. Nigeria, is located in Africa and is eligible for financial support from Gavi, the Vaccine Alliance. Albania is located in Europe and is an upper-middle income country that was Gavi-eligible until 2013. Finally, Tunisia is located in the Eastern Mediterranean and is an upper-middle income country. Unlike Albania, Tunisia has never been Gavi-eligible and has always self-financed all vaccine introductions.

By comparing and contrasting this diverse set of countries for this case study, it is possible to illustrate some of the similarities and differences between countries related to these factors.

## *Reasons for success seen across countries*

- IPV was best accepted by caregivers in countries where there was a history of public trust in the immunization program.
- Strong, clear and simple messages are the most effective for caregivers. In some countries, the most effective messages did not specifically mention polio, IPV, or OPV. The messages simply stated that a new vaccine was being introduced to improve the immunization schedule.
- Many middle-income countries use data to customize global vaccine recommendations to their needs.

## *Cross-cutting challenges*

- It was difficult to revise and disseminate all immunization materials given the condensed timeline.
- There was confusion about eligibility in some countries, which led to vaccination of children outside of the target age range.
- Many countries experienced a delay when planning for IPV introduction. In some cases, the delay was short (2 months) while in other cases the delay was much longer.

Documenting vaccine introductions and case studies is a crucial part of the improvement process. Given the large number of countries about to introduce IPV, there is a unique opportunity to put this learning immediately into practice.

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<sup>1</sup> IPV/bOPV Implementation Working Group Implementation Call Report August 11, 2015

# INTRODUCTION

## THE PATH TO POLIO ERADICATION

Polio is a devastating, debilitating, and deadly disease; one of the largest social movements in human history – the Global Polio Eradication Initiative (GPEI) – aims to make polio a memory. GPEI is a public-private partnership established in 1988 to eradicate polio worldwide. It is a collaboration of national governments and multiple international organizations including the World Health Organization (WHO), Rotary International, the US Centers for Disease Control and Prevention (CDC), and the United Nations Children’s Fund (UNICEF). The goal of the GPEI is to completely eliminate polio so that no child will ever be paralyzed by polio again.

When the GPEI was created in 1988, polio was causing outbreaks around the world, and an estimated 350,000 children were being paralyzed by the poliovirus every year. Over the past 30 years, the number of annual polio cases has been reduced by more than 99%. In 2014, there were only 359 cases of polio reported in three countries: Afghanistan, Nigeria, and Pakistan. The world is closer than ever to eradicating polio permanently, but as long as wild poliovirus is allowed to paralyze children the job is not done.

## BRINGING IN EVERY POSSIBLE TOOL

There are two different vaccines used to vaccinate against polio: the Oral Polio Vaccine (OPV) and the Inactivated Polio Vaccine (IPV). For many years, OPV was the main tool used by the GPEI to eradicate polio. OPV has been used as the primary vaccine for the polio program because: (1) it provides good immunity after 3-4 doses, (2) it helps stop transmission of the virus by limiting its ability to replicate in the gut, (3) it is an oral, droplet vaccine that does not require a trained health worker to administer, and (4) it is inexpensive (less than \$0.15 per dose). One disadvantage of OPV is that in extremely rare circumstances the vaccine virus can mutate and cause polio. This is called vaccine-associated paralytic polio (VAPP) and happens in approximately 1 in 2-4 million children after receiving OPV. Furthermore, in even rarer circumstances, the virus can mutate to the point that it is again able to cause paralytic polio and even polio outbreaks; these viruses are called circulating vaccine-derived polioviruses or cVDPVs.

Because of these rare events, some countries use IPV to vaccinate against polio. The main advantages of IPV are that: (1) it provides very strong immunity after only 1-2 doses, and (2) it cannot mutate to cause polio. But IPV does not stop replication in the gut as well as OPV and can lead to more transmission, it is an injectable vaccine, can

only be given by a trained healthcare worker, and it is more expensive (between \$1-4 per dose) than OPV. Because of the advantages of OPV, it has been used in low- and middle-income countries where the risk of large polio outbreaks was the greatest.

However, following the significant progress towards polio eradication, in 2012, the Strategic Advisory Group of Experts on Immunization (a group of immunization experts which advise the World Health Organization on all matters related to immunization) recommended that every country in the world using only OPV should add at least one dose of IPV to the immunization schedule by the end of 2015. The rationale was that children that receive both vaccines have the best possible protection because there are important benefits from both vaccines. Additionally, the Global Polio Eradication Initiative recognized that because in extremely rare cases OPV can mutate into a poliovirus that causes paralysis, eliminating all paralytic polio disease would

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ultimately require completely stopping the use of OPV globally (once wild poliovirus is eradicated). It would need to come in phases – first switching from tri-valent OPV (tOPV), which contains all three types of polio, to a bi-valent OPV (bOPV) which does not contain type 2 poliovirus, which has been eradicated and no wild case seen since 1999. It does, however cause 90% of cVDPVs and 40% of all VAPP cases. The removal of type 2 will also improve immunity of the remaining two serotypes, 1 and 3. Introducing IPV globally became an important first step towards stopping the use of OPV globally and provides protection against all three types of polio.



When the landmark recommendation to introduce IPV in every country was made, there were 126 countries in the world that were only using OPV. This meant that 126 countries around the world had to change their national immunization schedule within the short timeframe of three years.

### UNPRECEDENTED PACE FOR IPV INTRODUCTION

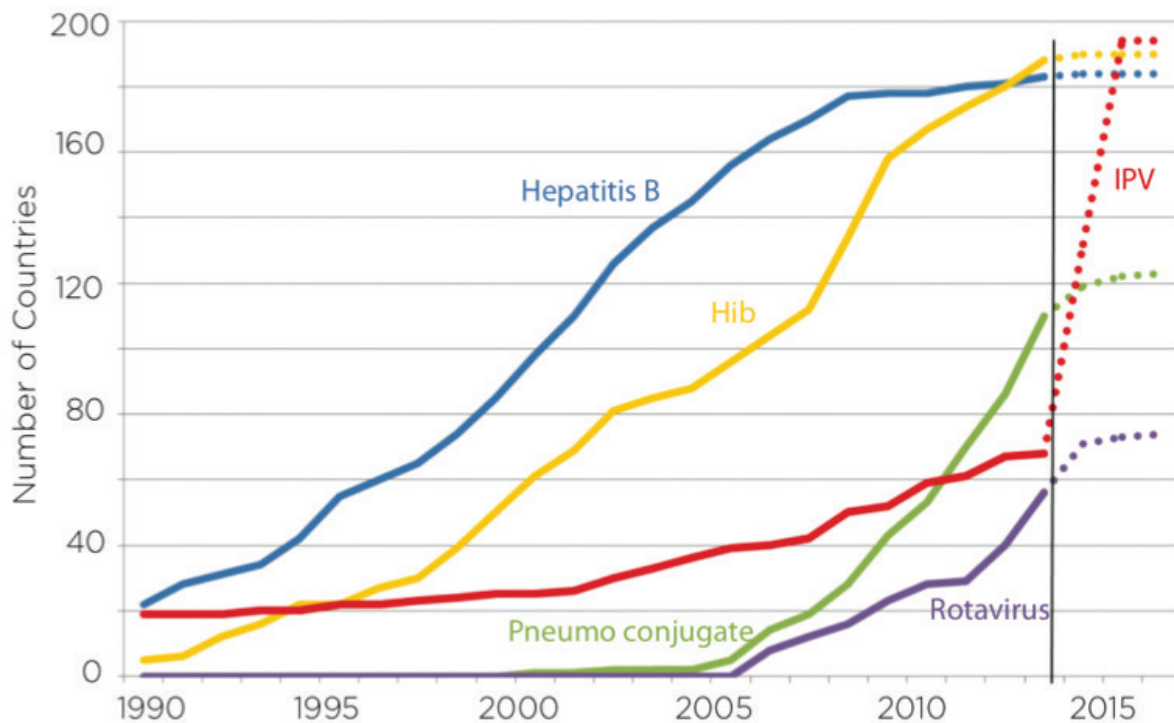
When the plan to introduce IPV in 126 countries in only 3 years was announced, it came as a shock to many in the immunization community. Given the historically slow pace of vaccine introductions, many people thought it would be impossible. As describe by Helen Rees, chair of the SAGE committee that made the recommendation, “I think when we heard the pace that the colleagues who are driving the eradication program put to [us], we were all astonished. We all raised our eyebrows and

said ‘Really? We are going to do this? Are you mad?’” National immunization programs were also surprised by the recommendation. As explained by Michel Zaffran, coordinator of the Expanded Program for Immunization at the World Health Organization: “It was sort of seen by everyone that heard that recommendation as something impossible to achieve... When [the timeline for IPV introduction] was first presented to countries it was received with a lot of skepticism. Another sort of global goal set by the international community that doesn’t really take into account the difficulty that countries are facing.”

### PROGRESS

Despite the skepticism from the global community, to date, 125 out of 126 countries (>99%) have formally committed to introducing IPV by the end of 2015. As of August, 2015, 29 out of the 126 countries have introduced IPV.

**Pace of IPV introductions compared with the historical pace of other vaccine introductions:**







**ALBANIA**



# ALBANIA

## INTRODUCTION

Albania is a country located in Southeast Europe, and it borders Montenegro, Kosovo, Macedonia, Greece, and the Mediterranean Sea. It has an estimated population of about 2.8 million and an annual birth cohort of approximately 35,760.<sup>2,3</sup> Albania is classified by the World Bank as an upper-middle income country.<sup>4</sup>

Albania has a strong immunization program, with routine immunization coverage estimated to be 99% for the third dose of the Diphtheria-Tetanus-Pertussis containing vaccine (DTP3).<sup>5</sup> In addition to having high immunization coverage, Albania has also introduced six new vaccines into the routine immunization program over the past 15 years.

In 2000, Albania added the rubella vaccine to the national immunization program by replacing their measles vaccine with the Measles-Rubella (MR) vaccine. The introduction of the MR vaccine was financed by UNICEF, the Government of Albania, and other partners. In 2000, the Government of Albania partnered with Gavi, the Vaccine Alliance, to finance the introduction of a standalone Hepatitis B (HepB) vaccine. The HepB vaccine was paid for by Gavi until 2006, at which point the government took responsibility for the total cost of all HepB vaccinations. In 2005, Albania added the Mumps vaccine to the national immunization program by replacing the MR vaccine with the Measles-Mumps-Rubella (MMR) vaccine. The introduction of the MMR vaccine was completely financed by the Government of Albania. In 2008, Albania partnered with Gavi again to introduce the Haemophilus influenzae type b vaccine (Hib). Hib was introduced by replacing the DTP vaccine and the HepB vaccine with a combination pentavalent vaccine. Although this vaccine was initially introduced with the financial support of Gavi, since mid-2013 the Government of Albania has taken responsibility for the total cost of the pentavalent vaccine. In 2011, the Government of Albania self-financed the introduction of the 10-valent pneumococcal conjugate vaccine (PCV-10). This was a significant achievement for the

national immunization program as PCV is relatively expensive when compared to other vaccines.

Albania has launched several initiatives in the past decade to strengthen vaccine delivery and operations. This includes the introduction of an electronic Immunization Information System (IIS) and an overhaul of cold chain equipment. The IIS was successfully piloted in one district and is now being scaled up nationwide. Additionally, many cold chain equipment units were replaced, and since 2013, all cold chain units in the country are pre-qualified.

### Vaccine introductions in Albania:

Year	Vaccine	Financing
2000	Rubella (as MR)	UNICEF, Govt
2000	Hepatitis B	Gavi until 2006
2005	Mumps (as MMR)	Govt
2008	Hib (as Penta)	Gavi until 2013
2011	PCV	Govt
2014	IPV	Govt

Endemic wild poliovirus transmission was interrupted in Albania in 1985. However, in 1996, a large outbreak of polio occurred following importation of the virus from another country. During the outbreak, the majority of cases were among 10-34 year olds. Poor cold chain maintenance and decreased coverage in the 1990s during political transition were thought to be the main reasons for the large pocket of susceptible individuals. The outbreak was stopped in December 1996 following two national immunization days. In total, the outbreak resulted in 138 cases of paralysis and 16 deaths. No cases of wild poliovirus have been detected since 1997. But, the legacy of this outbreak has resulted in strong and sustained commitment to polio eradication in Albania.

In 1989, a large measles outbreak affecting all age groups and continued circulation of the measles virus pushed the country to increased efforts on measles and rubella elimination. No measles cases have been documented in Albania since 2007.

## DECISION-MAKING

Immunization experts in Albania discussed the pros and cons of introducing IPV for many years. In Albania, the discussion surrounding IPV introduction pre-dated the SAGE global recommendation to introduce IPV in 2012.

The main reasons that Albania considered introducing IPV was a desire to: (1) harmonize the Albanian national immunization schedule with other European countries and (2) eliminate vaccine-associated paralytic polio (VAPP).

<sup>2</sup> CENSUS 2011, Government of Albania. Available at: <http://www.instat.gov.al/al/census/census-2011/t%C3%AB-dh%C3%ABnat-e-census-2011.aspx>

<sup>3</sup> Government of Albania, INSTAT. Available at: <http://www.instat.gov.al/al/themes/popullsia.aspx>

<sup>4</sup> World Bank, country and lending groups, 2014 revision. Updated annually in July. Available at: <http://data.worldbank.org/about/country-and-lending-groups>

<sup>5</sup> WHO-UNICEF estimates of DTP3 coverage, 2014 revision. Updated annually in July and available at: [http://apps.who.int/immunization\\_monitoring/globalsummary/timeseries/tswucoveredt3.html](http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveredt3.html)



In Albania, whenever a new vaccine is being considered for introduction, an evidence-based analysis is conducted to determine whether or not the evidence supports the vaccine introduction. In the analysis, the value of introducing the vaccine is evaluated using a standard set of criteria including the disease burden, other prevention and control measures, cost-effectiveness, alignment with global recommendations, vaccine supply, etc. The findings are then presented to the members of the Interagency Coordinating Committee (ICC) who make the final decision on whether or not to recommend the vaccine.

For the introduction of IPV, the national immunization program followed the standard protocol and developed an evidence-based analysis of IPV introduction. Because Albania had discussed IPV introduction for many years, the analysis had already been mostly drafted, the national immunization program was able to rapidly finalize the IPV analysis and present it to the ICC for immediate consideration.

Following the SAGE recommendation to introduce IPV (as well as the additional recommendation to switch from tri-valent OPV (tOPV) to bi-valent OPV (bOPV) to reduce risk of VAPP and circulating vaccine-derived poliovirus (cVDPV) while increasing immunogenicity of types 1 and 3), the topic was raised at the ICC meeting in February 2013, and the ICC recommended that IPV be introduced into the routine immunization program. Because Albania had been debating the introduction of IPV for many years, the SAGE recommendation is not cited as the main reason for the national decision to introduce IPV in Albania. Rather, the SAGE recommendation could be seen as one of the “triggers” which accelerated the introduction of IPV in Albania.

After the ICC recommended the eventual switch from OPV to IPV and the Ministry of Health made the decision to introduce IPV into the routine program, the National Immunization Program (NIP) at Institute of Public Health had to make three key technical decisions about IPV rollout: the number of doses of IPV each child should receive, the age at which children should receive each IPV dose(s), and which IPV product should be introduced (standalone IPV, pentavalent containing IPV, or hexavalent).

When deciding on the number and timing of the IPV doses, Albania prioritized the following key factors: (1) the new schedule should ensure high seroconversion against type 2 polioviruses after the switch from tOPV to bOPV, (2) the new schedule should decrease, if not eliminate completely, VAPP, (3) the new schedule should be similar to schedules in neighboring European countries, and (4) if possible, the new schedule should minimize the number of injections a child receives at each visit.

In order to minimize VAPP and simultaneously achieve high

seroconversion against type 2 polioviruses, Albania decided to introduce two doses of IPV. It was then decided that the doses would be given at 2 months (replacing the first OPV dose) and 4 months (replacing the second OPV dose). Children would then receive a dose of OPV at 6 months (no dose of IPV would be given at 6 months). By using two doses of IPV at the first two immunization contacts, VAPP would be eliminated and type 2 immunity would still be high.

The next step was to decide which IPV product should be introduced. The three options being considered were: (1) introduce a standalone IPV to the schedule, (2) switch from the current pentavalent vaccine (DTwP-HepB-Hib) to a pentavalent vaccine that contained IPV (DTaP-Hib-IPV) and introduce a Hepatitis B standalone vaccine, or (3) introduce a hexavalent vaccine (DTaP-HepB-Hib-IPV). In order to make this decision, the National Immunization Program prepared an analysis of the advantages and disadvantages of each presentation and presented it to the Ministry of Health and the Ministry of Finance. The main advantage of the hexavalent vaccine was that children would receive fewer injections per immunization visit; the disadvantage of the hexavalent vaccine was that it was significantly more expensive than the other products. The main advantage of the pentavalent vaccine containing IPV (DTaP-Hib-IPV) was that it was cheaper than the hexavalent vaccine; the disadvantage of this vaccine is that it was more expensive than the DTwP-HepB-Hib pentavalent vaccine currently used by the national immunization program. Additionally, it is important to note that both the hexavalent and alternative pentavalent vaccines contain an acellular pertussis component. Because many countries in Europe use a vaccine with an acellular pertussis component, Albania has discussed switching from a whole cell pertussis vaccine to an acellular vaccine. However, the disadvantage of switching to an acellular vaccine is that the immunity from the acellular vaccine wanes over time and multiple boosters are needed to prevent pertussis outbreaks. After careful consideration, the Government of Albania decided to introduce a standalone IPV vaccine. The main driving factor for this decision was the lower cost of the vaccine.

It is important to note that at the time the ICC discussed IPV introduction, rotavirus vaccine was also being considered for introduction. However, it was decided to wait to introduce rotavirus vaccine, due to the cost.

## PRE-INTRODUCTION ACTIVITIES

Following the decision to introduce IPV, the first step was to develop a comprehensive guide on IPV for healthcare professionals. The guide covered information on IPV safety, immunity, and the rationale for introduction. These guides were then distributed to health facilities, and healthcare workers were trained on IPV introduction.

Next, key messages were developed about IPV introduction. The two key messages were: (1) “We are improving our immunization schedule!” and (2) “Our schedule is now comparable to the other European countries.” TV and radio spots were used to sensitize the public.

Single dose vials of IPV were procured from the government budget through the UNICEF supply division. The handling and stock management of IPV was the same as for all other vaccines. Because Albania had recently updated the cold chain equipment across the country, no changes needed to be made to the cold chain before IPV introduction.

Following the changes in the immunization schedule, instructions on how to use the new immunization cards were presented to the immunization healthcare professionals as part of the training for the introduction of IPV. They were instructed that on the immunization card of children born from 1 March 2014, OPV should be replaced with IPV at 2 and 4 months of age.

## IMPLEMENTATION

Albania introduced IPV in 2014 as planned. The eligibility policy was that any child born from 1 March 2014 onwards would receive two doses of IPV at 2 and 4 months of age and one dose of OPV at 6 months. Children born before 1 March 2014 were not eligible to receive IPV.

Preliminary findings suggest that the introduction of IPV has gone very smoothly. An analysis of coverage data shows that there were no changes in immunization coverage before and after IPV introduction. There is also no evidence for an increased number of refusals at the 2 and 4 month visits, indicating that IPV is highly accepted among caregivers.

When visiting some healthcare facilities, healthcare workers were asked whether or not caregivers were okay with their child receiving three injections in one visit. In most healthcare facilities, healthcare workers responded that caregivers had no problem allowing their child to receive three injections because it was recommended. In a few healthcare facilities, healthcare workers indicated that if a caregiver is very hesitant to let their child receive three injections in one visit, they give the child two shots (pentavalent and IPV) and then tell the mother she must come back for PCV in one week. Although it is possible that this could affect coverage of PCV due to a missed opportunity, findings have found that almost all caregivers return within 1 week for the PCV visit. This is most likely due to the strong cultural value placed on immunization in Albania.

## LESSONS LEARNED

### **Lesson 1—Strong political commitment to immunization made for the smooth introduction of IPV**

There is a history of strong political commitment to the immunization program in Albania. This commitment has been a central reason that Albania has successfully introduced numerous vaccines over the past decade. As eloquently stated by Klodjan Rjepaj, Deputy Minister for Health, “Immunization is one of the aspects that never failed in Albania. Even during 1997, when there was civil unrest and the government and the state failed to offer public services—immunization was still going on.” Furthermore, Albania is always looking for ways to strengthen and improve their system: “Immunization is something which is very important in Albania and it has been important for all times—even before 1990. So we didn’t start from scratch. We had a basis, and then we wanted to improve it.”

### **Lesson 2—Public trust in the immunization system was foundational to the acceptance of IPV**

In addition to political commitment, there is also a strong cultural commitment to immunization in Albania. As stated by Silvia Bino, Director of Infectious Disease at the Institute of Public Health, “Vaccination is a kind of culture in Albania. This is something very important, and we want to keep it.” The public acceptance of IPV (and of vaccines in general) was attributed to the public trust in the immunization system. This is related to a historical acceptance of immunization, which has been built over several decades. As explained by Klodjan Rjepaj, “Immunization has been a program that has been well-supported, well-accepted, and a program that Albanians trust.”

### **Lesson 3—A good recommendation from a healthcare professional was critical to caregiver acceptance of IPV**

In Albania, multiple informants felt that the healthcare professionals played the most important role in ensuring acceptance of IPV among caregivers. As stated by Klodjan Rjepaj, “I think it is crucial to understand that communication is not just media. It is training of our professionals in a capillary way so that they communicate with the parents in their area. It is that daily communication.” Furthermore, when caregivers were asked if they were hesitant to let their child receive multiple injections, many caregivers responded that they receive whatever vaccines the healthcare worker recommends. From the caregivers perspective, it didn’t matter how many injections the child received (one, two, or three), but rather the most important thing was that the child got all recommended vaccinations.

### **Lesson 4—Using date of birth to determine eligibility for IPV was easy and effective**

Unlike some countries, Albania used a date of birth cutoff to determine if a child was eligible to receive IPV. The formal policy was that “all children born on or after 1 March 2014 are eligible to receive IPV.” In contrast, some other countries used an “age-at-visit” eligibility policy such as “all children older than 14 weeks that come for immunization should receive IPV.” Using a Date of Birth cutoff proved to be a simple and easy to

enforce programmatically. As a result, very few children outside of the target age group received IPV. In contrast, in some of the countries that used “age at visit” to determine eligibility, healthcare workers vaccinated children outside of the target age group. Because each country’s supply is based on a calculated number of children eligible, in some countries the lack of clarity on eligibility actually led to a national IPV shortage.

#### **Lesson 5—It was not possible to revise, reprint, and distribute immunization cards by introduction date**

It is important to note that because IPV was introduced in a short timeline, there was not enough time to revise, reprint, and disseminate new vaccination cards and immunization records to each health facility. Luckily, healthcare workers were able to adapt and manually write in IPV. However, it should be noted that manual writing in of additional vaccinations is not ideal. Writing in vaccinations manually might lead to inaccuracies in documenting which vaccines were given to each child and/or might mean a healthcare worker is more likely to forget to administer a vaccine because it was not written on the vaccination card as a reminder. For this reason, the Albania immunization program is moving to an electronically based system.

#### **Lesson 6—Using an electronic Immunization Information System (IIS) simplified many aspects of IPV introduction**

Albania has successfully piloted and implemented an electronic Immunization Information System, which is functioning in multiple health centers in one district. The ISS is currently being scaled up and introduced nationwide. During IPV introduction, multiple advantages of using an ISS during a vaccine introduction were demonstrated. The major benefits of an electronic system were: (1) the IIS automatically calculates whether or not a child is eligible for IPV instead of relying on healthcare workers to enforce an eligibility policy, (2) the immunization system can easily be updated to include a new vaccine and there is no need to revise, reprint, and distribute immunization cards, and (3) the ISS delivers real-time data to

the central level which facilitates coverage monitoring.

#### **Lesson 7—Taking advantage of the opportunity of a new vaccine introduction to make other changes to immunization schedule was beneficial**

Albania used the opportunity of IPV introduction to make two other changes to the immunization schedule that the national immunization program had been planning on making. The two other changes made were (1) changing the PCV schedule to 2 plus 1 schedule and (2) changing the tetanus immunization policy. Thinking multiple years in advance and making multiple changes at once allows programs to use fewer resources and avoid having to conduct multiple trainings.

#### **Lesson 8—IPV might have impacted the introduction of rotavirus vaccine**

At the time when Albania recommended the introduction of IPV, the country was also contemplating the introduction of the rotavirus vaccine. At the time, the National Immunization Technical Advisory Group (NITAG) decided not to recommend rotavirus vaccine for introduction. While it is true that the decision to introduce IPV might have had some role in postponing the introduction of rotavirus vaccine, it is difficult to determine the exact effect since the overall cost of rotavirus introduction (\$8-9 per child) is 3 to 5 times more expensive than IPV (\$2.8 per child).

#### **Lesson 9—Clear, positive, and simple messaging to caregivers is effective**

Albania chose to emphasize two simple messages during IPV introduction: (1) “We are improving our immunization schedule!” and (2) “Our schedule is now comparable to the other European countries.” These messages are concise, clear, and easy to understand. Interestingly—neither of these messages mention IPV or polio. However, the messages cleverly appeal to the public and send a positive message about the way IPV is improving the immunization program.

## **TIMELINE**

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February 2013: ICC recommends switch from OPV to IPV

June 2013: Request to UNICEF to procure first 36,000 doses of IPV

September 2013: Forecast submitted to UNICEF for the year 2014 (two doses of IPV included for the whole year)

March-April 2013: Comprehensive manual on IPV for healthcare professionals prepared

December 2013: Meeting with healthcare workers regarding the switch from OPV to IPV

March 2014: Reversion of immunization schedule (by introducing IPV)

April 2014: Retraining of health care workers on IPV and revised immunization schedule

May 2014: Albania begins to administer two doses of IPV into routine immunization for children born from 1 March 2014 onwards

Since June 2014: Ongoing evaluation of vaccine coverage quarterly and annually as done for the other existing vaccines included in the Albanian immunization schedule





**NIGERIA**

# NIGERIA

## INTRODUCTION

Nigeria is a West African country that borders Benin, Chad, Cameroon, Niger, and the Gulf of Guinea. It has an estimated total population of 183.5 million and an annual birth cohort of 7.4 million, making it the most populous country in Africa and the seventh most populous country in the world.<sup>6</sup>

The WHO and UNICEF estimate the routine immunization coverage for the third dose of the pentavalent vaccine (DTP-HepB-Hib) to be 66%.<sup>7</sup> With regards to experience introducing new vaccines, Nigeria introduced two vaccines into the routine immunization system in recent years: the DTP-HepB-Hib pentavalent vaccine (penta) between 2012 and 2014 and the pneumococcal conjugate vaccine (PCV) in 2014.

Nigeria is one of three remaining wild poliovirus endemic countries in the world, meaning the country has never interrupted transmission of wild-type virus. However, on July 24, 2015, Nigeria marked one year of no reported cases of wild poliovirus.<sup>8</sup> The absence of wild polio cases has led to optimism that the country might have eradicated wild poliovirus completely. The country has one case in 2015 of circulating vaccine-derived poliovirus (cVDPV2) as of July 2015. Two more years must pass without a case of wild poliovirus for Nigeria to be certified as polio-free, along with the rest of WHO's African region.<sup>9</sup>

Polio is a sensitive topic in Nigeria both culturally and politically. Political support for polio eradication from the central government in Nigeria is strong. However, there is some local resistance (both political and cultural) to polio eradication. In 2003, there was a boycott of polio vaccination in select northern states following rumors that the vaccine was contaminated with anti-fertility agents, HIV, and carcinogens. Although the boycott has ended, there has been

a lasting impact and some individuals are still skeptical of vaccine safety. Additionally, repeated rounds of door-to-door immunization campaigns have led to healthcare worker fatigue in some areas. Similarly, caregivers who have had their child vaccinated over 10 times are sometimes unconvinced of the need for additional vaccinations. Terrorist activities have also negatively affected the polio eradication program in the northern part of the country. For instance, in February 2013, nine female polio vaccinators were killed in two shootings at health centers in a northern state. These factors contribute to the ongoing sensitivity of polio eradication.

## DECISION-MAKING

Following the World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE) recommendation for IPV in November 2012, IPV introduction was discussed at the WHO African Regional Committee of Health Ministers in September 2013. This prompted high-level discussions about the introduction of IPV in Nigeria.

### Vaccine introductions in Nigeria:

Year	Vaccine	Financing
2012-2014	Hib (as Penta)	Gavi
2014	PCV	Gavi
2015	IPV	Gavi

Because Nigeria is a polio endemic country, the rationale for the introduction of inactivated polio vaccine (IPV) in Nigeria was slightly different than the rationale for IPV introduction in most other countries. While in most countries, IPV is being introduced as a risk mitigation strategy to prevent cVDPV poliovirus outbreaks and cases of VAPP, in Nigeria, IPV is being introduced both as a risk mitigation strategy and as one of the strategies to accelerate the eradication of wild poliovirus.

It was the responsibility of the Inter-agency Coordinating Committee (ICC)—the main decision-making body in Nigeria related to immunization policy and new vaccine introductions—to decide whether or not IPV should be introduced into the routine immunization program of Nigeria. To make this decision, the ICC considered input from various stakeholders including the Core group<sup>10</sup>, the Nigerian Academy of Sciences, the Pediatric Association of Nigeria, traditional leaders, and religious leaders.

Identifying and securing financial resources to pay for a vaccine is a key part of the decision-making process. In most countries, vaccines that are recommended by the government are provided free of charge to all children. Therefore, any vaccine recommendation has significant implications for local and national governmental budgets.

<sup>6</sup> United Nations, Department of Economic and Social Affairs, Population Division (2013). World Population Prospects: The 2012 Revision, CD-ROM Edition. - See more at: <http://www.gavi.org/country/albania/#sthash.1APrPOiP.dpuf>

<sup>7</sup> WHO-UNICEF estimates of DTP3 coverage, 2014 revision. Updated annually in July and available at: [http://apps.who.int/immunization\\_monitoring/globalsummary/timeseries/tswucoveredtp3.html](http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveredtp3.html)

<sup>8</sup> World Health Organization (WHO) (2014) Acute flaccid paralysis (AFP) surveillance data and polio case count. Available at: <https://extranet.who.int/polio/public/CaseCount.aspx> (accessed 6 June 2015).

<sup>9</sup> Global Polio Eradication Initiative Available at: <http://www.polioeradication.org/Infectedcountries/Nigeria.aspx> (accessed 11 August 2015)

<sup>10</sup> The Core group is a coalition of technical stakeholders and includes members from the following immunization partners: NPHCDA, WHO, UNICEF, BMGF, IVAC, CDC, CHAI, Rotary, and the members of the Partnership for Reviving Routine Immunization in Northern Nigeria, Maternal Newborn and Child Health Initiative (PRRINN MNCH).



Prior to IPV introduction, Nigeria partnered with Gavi to introduce two new vaccines into the routine immunization system (penta and PCV) and to conduct vaccination campaigns against yellow fever, measles, and meningitis. Due to recent economic growth, Nigeria is now considered by Gavi to be preparing for transition from Gavi support. This means that over the next few years Nigeria will incrementally take over all financial responsibility for vaccination. In a couple of years, once the country has graduated, Nigeria will no longer be eligible to receive any funding for vaccines from Gavi.

In November 2013, the Gavi Board of Directors agreed to support the introduction of IPV in Gavi-eligible and Gavi-graduating countries. It is important to note that Gavi's support for IPV differs from their support for other vaccines (PCV, penta, Rota, and HPV). For example, in order to be eligible to apply for other vaccines, countries must have achieved DTP3 coverage >70% and commit to co-financing the vaccine introduction. However, in the case of IPV introduction, Gavi waived the minimum coverage requirement and did not require countries to co-finance any part of the introduction.

Gavi's special IPV policy had major implications for the introduction of IPV in Nigeria because without these exceptions, Nigeria would not have been eligible to apply for IPV support and would have had to self-finance IPV introduction. In this situation, the Government of Nigeria would have had to find alternative mechanisms to pay for the cost of IPV. Gavi's unique support for IPV was pivotal in pushing forward the national decision for introducing IPV.

The New Vaccine Introduction (NVI) task team, which is comprised of representatives from Nigeria's National Primary Health Care Development Agency (NPHCDA) and immunization partners (WHO, UNICEF, the Bill & Melinda Gates Foundation, the International Vaccine Access Center (IVAC), the US Centers for Disease Control and Prevention (CDC), and the Clinton Health Access Initiative (CHAI), was responsible for compiling all the relevant documents that were used by the Core Group and ICC for the decision making.

In March 2014, the ICC reviewed and endorsed the decision to introduce IPV in Nigeria. The ICC decided that one dose of IPV would be administered at 14 weeks of age, at the same immunization visit as OPV3, penta3, and PCV3. Following this decision, Nigeria submitted an application to Gavi requesting financial support to introduce IPV. In December 2014, Gavi approved Nigeria's request for IPV support and thereby agreed to provide funding for 6.8 million IPV doses and associated supplies each year from 2015-2018 (approximately \$12-14 million USD per year). Gavi also agreed to provide financial support for IPV introduction activities in the form of a Vaccine Introduction Grant (VIG) (approximately \$5.8 million USD).

## PRE-INTRODUCTION ACTIVITIES

### Coordination

The NVI task team coordinated all activities related to IPV introduction in Nigeria. The different phases of the pre-introduction activities developed by the NVI task team were reviewed by the Routine Immunization Working Group (RIWG), then Core Group, and finally approved by ICC.

### Community Acceptability Studies

Due to history of polio immunization rejection in Nigeria and fear that IPV would not be accepted in some communities, a large emphasis was placed on developing a strong communication plan and messages. As explained by Dr. Emmanuel Abanida, Director of the Disease Control & Immunization team at the Ministry of Health Nigeria, "IPV is a polio vaccine, and we know there has been problems with the polio vaccine before. The introduction process required serious sensitization – serious sensitization. We needed to get the buy-in of various stakeholders: traditional leaders, religious leaders, communities, ministries of health, NGOs, CSOs."

In April 2014, community acceptability studies were conducted in four different states (Borno, Cross River, Kano, and Sokoto) by the USA Centers for Disease Control and Prevention (US-CDC). Borno, Kano, Sokoto, and Cross River were chosen because they represented a high-risk security state, a polio reservoir state, a state at high-risk for polio importation, and a low-risk state respectively.

Findings from the acceptability studies showed that IPV was highly acceptable and its administration with OPV was perceived to be beneficial to the child's health. Despite these positive views, concerns were raised about its side effects, safety, and the need to continue OPV use. To address these concerns, immunization managers and health officers were sensitized and trained on how to communicate with caregivers on the importance of vaccines, effects of polio and consequences of not taking IPV and OPV. In addition, the findings from the acceptability studies were used to develop targeted messages for IPV introduction. The key messages were: (1) Give your child double protection today against Polio with IPV and OPV; (2) IPV for children 14 weeks of age. OPV for children from birth to 59 months; and (3) Take your child to the nearest health center for vaccination with IPV and OPV today! It is safe! It is effective!

### Preparation of Materials

Information, Education, and Communication (IEC) materials were developed for caregivers, while IPV training materials were developed for both facilitators and participants in May 2014. Subsequently, follow-up meetings to finalize IPV materials were held in December 2014.

The RI data tools (child immunization cards, immunization



registers, tally sheets, and summary forms, monthly vaccination performance chart, and vaccine management tools) were revised in June 2014 to include IPV; and immunization managers and officers were trained on how to use the tools to capture IPV vaccination data. However, prior to the introduction, health workers were made to use the old tools, which made a provision for IPV before the distribution of the revised tools.

A cold chain readiness assessment (also known as an effective vaccine management (EVM)) was conducted in 2013. The assessment revealed that Nigeria had adequate storage capacity to include IPV. The recent expansion of the cold storage capacity to accommodate PCV and Rotavirus vaccine was 40% more than what was needed for IPV across all levels. In-country development partners such as CHAI also provided analytical support to NPHCDA and UNICEF on the cold chain inventory update.

### **Accelerated Ipv Introduction In High-Risk States**

An accelerated vaccine introduction was conducted in June 2014 in the 3 high-risk states (Borno, Yobe and Kano) with funding from the Bill and Melinda Gates Foundation. This was driven by the need to quicken the timeline for polio interruption starting in the most security compromised states and underserved populations. Lessons learned from the limited introduction were used to improve planning strategies for training, community mobilization, and communication for the nationwide rollout of IPV.

### **Timeline For Introduction**

Although the national introduction of IPV into routine immunization was originally planned for 1 December 2014, the introduction was delayed due to: (1) global shortage of IPV, (2) inadequate human capacity at the Local Government Area (LGA) and health facility levels, (3) competing priorities, and (4) logistics challenges at the federal level. IPV introduction was rescheduled for early 2015. It was decided that instead of a single nationwide introduction, IPV would be introduced through a phased strategy. In this strategy, IPV would be launched in the Federal Capital Territory (FCT), which includes the capital Abuja, and several priority states (i.e. high-risk states in the north-east and north-west) on the 11th of February 2015. All remaining states would introduce on the 16th of March 2015.

However, at beginning of 2015, a decision was taken to further delay IPV introduction because the Gavi decision letter was delayed and the VIG funds were still not available. Consequently, most state level trainings were postponed until the VIG funds arrived. Only priority states conducted trainings. Additionally, only a limited number of training manuals were produced leading to the unavailability of manuals in some states, and the revised immunization tools were still not available at the LGA level.

At this time, it was decided that priority states that had completed all preparatory activities (e.g. training, revised tools, etc.) would introduce IPV as soon as possible, while other states would wait to introduce until they were ready.

There were fears that if the financial support was not provided on time, IPV introduction would be postponed again. To ensure successful IPV pre-introduction activities and to avoid postponements related to the delays in the receipt of VIG, the country made alternative plans to provide funds for programmatic activities needed for IPV introduction. UNICEF served as a fiduciary agent responsible for managing the VIG for IPV introduction and also offered to pre-finance some activities including the development of IEC materials for the vaccine introduction pending the receipt of VIG. CHAI provided supplementary resources to support pre-introduction activities such as funding for the development of IPV training manuals, nationwide IPV stakeholder sensitization meeting, and support for NPHCDA staff to monitor state level training. UNICEF and CHAI provided these funds because the delivery of the VIG from Gavi was yet again delayed.

### **Training**

On 14 January 2015, a national meeting was held to inform key stakeholders (state-level decision makers, state-level immunization technical officers, the Nigerian Pediatric and Medical Associations, and partner organizations) about IPV introduction. At this meeting, NPHCDA and in-country development partners presented and discussed the country's plan for IPV introduction. Other highlights of the discussion included sharing the progress and challenges of immunization in Nigeria, major findings from the community acceptability studies on IPV and identifying state specific challenges with IPV introduction.

On 19 January 2015, immunization managers and officers were trained by NPHCDA and in-country development partners on how to use the training manuals (both the facilitators' guide and healthcare worker manuals). This training also included a session on effective communication on IPV, which focused on the importance of vaccination and the consequences of non-compliance. Finally, participants were trained on safe administration and storage of IPV as well as adequate reporting of adverse events. During the training, the participants had an opportunity to voice what they perceived would be the key challenges facing IPV introduction in their individual states.

On 27th of February 2015, UNICEF received the VIG for IPV introduction in Nigeria. Following the receipt of the grant, other remaining states commenced pre-introduction activities.

## IMPLEMENTATION

Two states (Jigawa and Bauchi) introduced IPV on 11th and 12th of February 2015, respectively. A national launch ceremony was held in Abuja on the 20th of February 2015. As of June 2015, 28 of 36 states plus the FCT have introduced IPV, leaving 9 states still to introduce.

A single dose of IPV is administered at 14 weeks to children less than one year of age. According to the country's immunization schedule, this dose is administered along with OPV3, penta3 and PCV3. In terms of eligibility, children who have received their penta3 but are less than 1 year at the date of IPV introduction are eligible for IPV vaccination. In contrast, children older than one year by the date of IPV introduction are NOT eligible for IPV vaccination. This eligibility policy is practical and in-line with supply and cost consideration, in order to improve stock management and minimize stock-outs.

The country made the decision to introduce the WHO prequalified 5-dose stand-alone presentation of IPV. This dose was chosen because it strikes a balance between reducing cost/wastage and optimizing storage capacity (the benefits of the cost-savings of 5-dose vial outweighs the benefits of the small saving in space from the 10-dose vial). In addition, the multi-dose vial policy (MDVP) followed at the time of introduction was that the 5-dose vial introduced MUST be discarded at the end of the immunization session or within six hours of being opened, as recommended by WHO until vial could be received with vaccine vial monitors (VVMs) on the label.<sup>11</sup> Health workers were trained on the current multi-dose vial policy with the understanding that refreshed training would be needed when new vials were received. The new policy enables vials that met certain criteria to be discarded after 28 days to reduce wastage.

In states that have already introduced IPV, preliminary findings suggest that IPV has been well accepted. Healthcare workers attributed their acceptance of IPV to the fact that IPV is administered by a trained health worker (which is in contrast to OPV that does not require a skilled worker for its administration). There were no perceived concerns around multiple injections as injectable vaccines were seen to be effective. However, there were worries surrounding the side effects of IPV.

## LESSONS LEARNED

### **Lesson 1—It is possible to introduce a vaccine rapidly if there is consensus among all stakeholders**

Compared to previous vaccine introductions in Nigeria, the

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<sup>11</sup> Application of WHO Multi-Dose Vial Policy for Inactivated Polio Vaccine. November 2014. Available at: [http://www.who.int/immunization/diseases/poliomyelitis/inactivated\\_polio\\_vaccine/MDVP\\_Nov2014.pdf](http://www.who.int/immunization/diseases/poliomyelitis/inactivated_polio_vaccine/MDVP_Nov2014.pdf) (accessed 11 August 2015)

time from the national decision to introduce IPV (March 2014) to the national launch ceremony (February 2015) was very short (11 months). Multiple factors enabled this condensed timeline including: (1) a strong global WHO recommendation for the rapid introduction of IPV, (2) Gavi did not require co-financing for IPV, (3) technical assistance was provided to help develop the IPV introduction plan and Gavi application, (4) stakeholders were able to use their experience from two recent new vaccine introductions (PCV and penta) to help the planning process, and (5) partners were determined to overcome obstacles (e.g. determination to overcome the obstacles presented by the health worker strike in Nigeria by sending letter from the RIWG to the Union of Healthcare workers requesting permission to have workers break ranks in order to attend IPV trainings, partners provided supplementary funding from UNICEF and CHAI when Gavi funds were delayed, etc.). As stated by Dr. Pascal Mkanda, Team Leader for Immunization at WHO Nigeria, "I think the important lesson is consensus from the beginning. It was very important that everybody was brought along from the beginning."

### **Lesson 2—Shortened timelines have disadvantages**

While the introduction of IPV was rapid, the condensed timelines came with some disadvantages. During preparation it became clear that the original timeline did not allow enough time for preparation activities (trainings and revising materials). As a result, Nigeria had to transition from a single nationwide introduction to a phased introduction in order to introduce IPV in some select areas by early 2015.

### **Lesson 3—Training manuals were found to be a better way to maintain consistency in training content in contrast to PowerPoint Presentations**

During PCV training, trainers found that it was challenging to maintain consistency in trainings at the state and local level. To mitigate this challenge, a more effective training delivery approach was used for IPV. This approach utilized printed training manuals instead of the usual PowerPoint presentations, in order to maintain consistency at the different levels' trainings.

### **Lesson 4—The program should engage stakeholders at the state and Local Government Area (LGA) level to improve planning**

It is critical to engage stakeholders at the state and LGA level to help improve the planning process at these levels. For IPV, activities were conducted at the national level, but fewer activities were conducted at the state and LGA level.

### **Lesson 5—In-country immunization partners were instrumental in IPV introduction**

Many different organizations were involved in supporting IPV introduction: (1) the Gates Foundation funded the

accelerated limited introduction of IPV in three high risk polio states, (2) the CDC helped conduct the community acceptability study for IPV prior to introduction, (3) CHAI provided analytical support for the cold chain inventory update and supplementary funding for IPV introduction activities, (4) IVAC helped facilitate the state level training, (5) UNICEF served as a fiduciary agent responsible for managing the VIG for IPV introduction and also offered to pre-finance some activities for the vaccine introduction pending the receipt of VIG, and (6) WHO oversaw the development of IPV introduction guideline, provided technical assistance to NPHCDA, and aided in capacity building trainings for the vaccine introduction.

### **Lesson 6—Last-minute financial support from partner organizations was needed to provide immediate relief after delays in the Vaccine Introduction Grant**

Because the disbursement of the Vaccine Introduction Grant from Gavi was delayed, as of December 2014, there was still no funding available to conduct a variety of essential preparation activities. This led to the fear that the introduction of IPV would be delayed a third time. However, two partner organizations (UNICEF and CHAI) stepped in and provided funding to cover programmatic activities while the government waited for the arrival of the Vaccine Introduction Grant (VIG). This allowed the introduction to move forward as planned. Other countries should be aware of the potential delays in the arrival of the VIG and should arrange a back-up plan in case this happens again.

### **Lesson 7—Sustainable financing mechanisms must be developed for future vaccine introductions**

The majority of delays in IPV introduction were a result of the delay in the delivery of the vaccine introduction grant from Gavi. This underlines the disadvantages of relying on donors to fund programmatic activities and highlights the benefits of self-financing programmatic activities. Relying on donors for essential activities (sensitizations, training, and material development) creates dependence and can result in delays. Considering that Nigeria will be graduating from Gavi support in the coming year, the program needs to identify and secure reliable resources to fund program-related costs.

### **Lesson 8—Compared to other vaccines, communication about IPV was crucial because there is less demand for polio vaccines**

As explained by Dr. Emmanuel Abanida, Director of the Disease Control & Immunization team at the NPHCDA, “The difference between penta and IPV is that penta is felt to be a “needed” vaccine. Nobody wants a child to die of meningitis or pertussis. So it is not difficult for people to accept penta. But IPV is a polio vaccine, and so we needed to convince people that this polio vaccine is supposed to help us to quickly end polio. So the need for the advocacy was stronger. The need to build trust was stronger. The need to be transparent was stronger.” This underscores the need to build strong communications plans particularly in countries with a lot of polio activity.

## **TIMELINE**

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- November 2012: SAGE recommendation for all countries to introduce at least 1 dose of IPV
- September 2013: African Regional Committee discusses IPV introduction
- February 2014: Technical assistance provided to develop IPV introduction Plan and Gavi Application
- March 2014: Nigeria ICC recommends IPV introduction
- March 2014: Government of Nigeria submits application to Gavi
- April 2014: IPV acceptability studies conducted in partnership with CDC
- May 2014: National level training materials developed
- June 2014: An accelerated IPV introduction was conducted in select northern states
- October 2014: Gavi conditionally approves IPV application
- December 2014: National level training materials developed
- December 2014: Gavi approves IPV introduction
- January 2015: UNICEF pre-finances some IPV introduction activities pending the receipt of the VIG
- January 2015: CHAI provides supplementary funding to support introduction activities
- January 2015: National sensitization meeting and state level training conducted
- February 2015: Jigawa and Bauchi state introduce IPV on 11th and 12th of February
- February 2015: Abuja hosts national launch ceremony for IPV on 20th of February 2015
- February 2015: Vaccine introduction grant arrived in country on 27th February 2015
- March-June 2015: An additional 25 states introduce IPV





**TUNISIA**



# TUNISIA

## INTRODUCTION

Tunisia is a country located in North Africa and borders Libya, Algeria, and the Mediterranean Sea. It has an estimated population of about 11.2 million and an annual birth cohort of approximately 190,000.<sup>12</sup> It is classified by the World Bank as an upper-middle income country.<sup>13</sup>

Tunisia has a strong immunization program, with routine immunization coverage estimated to be 98% for DTP3 (2013).<sup>14</sup> Tunisia is not eligible and has never been eligible for financial support from Gavi. As a result, the Government has self-financed every new vaccine introduction. Since 2000, Tunisia has added vaccines against two additional antigens to the immunization schedule: Haemophilus influenzae type b (Hib) and rubella. The Hib vaccine was originally introduced in October 2002 as a standalone vaccine. In early 2006, due to the high cost of the vaccine and limited financial resources, the Hib vaccine was removed from the national immunization program. Evidence from the Children's Hospital of Tunis showed that the removal of the vaccine was followed by a resurgence of Hib meningitis cases, justifying its re-introduction. In 2011, the Hib vaccine was reinstated in the form of the pentavalent vaccine (DTwP-HepB-Hib). The rubella vaccine was introduced in 2005 as a combination Measles-Rubella (MR) vaccine that replaced the stand-alone measles vaccine.

Although endemic wild poliovirus transmission was interrupted in Tunisia in 1992, Tunisia is geographically located in the same region as two polio endemic countries—Afghanistan and Pakistan. Due to the geographic location, it is possible that a poliovirus could be imported into Tunisia. Maintaining high population immunity against polio through immunization is crucial in order to prevent an outbreak. The risk of a polio importation has been demonstrated in other countries in the region including the outbreak in Syria in 2013, the detection of polio in the sewage in Egypt, and the prolonged silent circulation of wild poliovirus in Israel. For this reason, the government of Tunisia is committed to maintaining high vaccination coverage for polio and strong surveillance for polioviruses.

<sup>12</sup> United Nations, Department of Economic and Social Affairs, Population Division (2013). World Population Prospects: The 2012 Revision, CD-ROM Edition.

<sup>13</sup> World Bank, country and lending groups, 2014 revision. Updated annually in July. Available at: <http://data.worldbank.org/about/country-and-lending-groups>

<sup>14</sup> WHO-UNICEF estimates of DTP3 coverage, 2014 revision. Updated annually in July and available at: [http://apps.who.int/immunization\\_monitoring/globalsummary/timeseries/tswucoveredtp3.html](http://apps.who.int/immunization_monitoring/globalsummary/timeseries/tswucoveredtp3.html)

## DECISION-MAKING

The national Vaccine Technical Committee (CTV) is the main decision-making body for immunization policies and recommendations in Tunisia.

The membership of the CTV is multi-disciplinary and consists of experts in relevant medical disciplines (virology, pediatrics, infectious disease, and epidemiology), representatives from the regulatory authorities, government entities including the Director of the Primary Care Division of the Ministry of Health (DSSB) and the National Vaccination Program Manager, and other individuals as needed. The CTV makes all initial recommendations regarding vaccinations. After the committee makes a new vaccine recommendation, the DSSB develops a budget and product specifications for the vaccine. Next, the Ministry of Health requests a budget allocation from the Ministry of Finance to cover the cost of the vaccine. It is also important to note that unlike some middle-income countries, Tunisia procures vaccine independently and not through the UNICEF Supply Division. For each vaccine in the national immunization program, the government submits a public tender, negotiates a price, and purchases the vaccine without support from external partners.

### Vaccine introductions in Tunisia:

Year	Vaccine	Financing
2002	Hib	Government
2005	Rubella (as MR)	Government
2006	Hib removed	Government
2011	Hib (as Penta)	Government
2014	IPV	Government

In 2012, the National Vaccination Program of Tunisia drafted a Five-Year Plan (Plan Quinquennal). Among other things, this plan indicated that IPV would be introduced in 2014. However, by mid-2013, there was still no formal recommendation or plan for IPV introduction.

During the CTV meeting on 13 December 2013, the CTV of Tunisia discussed the introduction of IPV. At this meeting, the committee decided that IPV introduction would only become a priority of the immunization program if there were supply problems with OPV. Subsequently, during the second half of 2013, Tunisia experienced two major problems with OPV supply. First, the Ministry of Health received a shipment of 20-dose vials instead of 10-dose vials as requested. Second, only one supplier indicated intent to respond to the upcoming OPV tender, which meant Tunisia had no choice of suppliers. Following these issues with the supply of OPV, in December 2013, the CTV made a formal recommendation to introduce IPV in order

to ensure that polio immunity in the country would remain strong despite OPV supply issues. As stated by Dr. Nabil Ben Salah, Director General of Health, Tunisia, “Polio is a disease that is practically eliminated from Tunisia, but we have to acknowledge that there is a possibility that it could come back. So the objective in introducing IPV is to achieve the complete eradication of polio, which means avoiding even one new case. For us, Tunisia, the elimination of polio has been a great success and we want to prevent any re-emergence of the disease.”

After deciding to introduce IPV, Tunisia had to decide: (1) how many doses of IPV would be administered and (2) at which age children would receive the IPV dose(s).

Following the recommendation for IPV, in February 2014, the National Vaccination Program (PNV) submitted a budget request to the Ministry of Finance requesting funds to support the introduction of IPV. Recognizing the difficulty in mobilizing enough funding to support two doses of IPV within the short time frame, the national immunization program decided to introduce one dose of IPV in September 2014 with the intent of introducing a second dose of IPV in January 2016 when additional funding could be made available.

Regarding the timing of the IPV dose, the initial recommendation made by the CTV in December 2013 was to replace the first dose of OPV (given at two months in Tunisia) with a dose of IPV, and then replace all doses of OPV with IPV over time. However, because of the SAGE recommendation, which stated that (1) IPV should be given in addition to OPV and (2) that the dose should be given at or after 14 weeks—in March 2014 the CTV revisited their original recommendation. Currently, OPV is administered at 2 months, 3 months, and 6 months of age. Some committee members argued that the dose should be given at 6 months of age in order to optimize seroconversion of infants against type-2 polio. Others wanted to introduce IPV at 2 months of age, particularly after examining Tunisian VAPP data, which suggested that VAPP in Tunisia tended to occur following the first dose of OPV. Ultimately, the committee decided that one dose of IPV at 6 months of age would be most appropriate, given that VAPP was very rare in Tunisia and that there was a large benefit to waiting until 6 months to administer IPV.

## PRE-INTRODUCTION ACTIVITIES

In March 2014, Tunisia began preparing for IPV introduction. The national immunization program revised the National Health Booklets and the national vaccine database to include IPV. In April, technical training documents were created for healthcare workers. Next, the

national immunization managers were sensitized on IPV. The National Managers then trained regional staff at a “training of trainers” meetings. From June-July 2014, the regional trainers trained the vaccinators. Prior to introduction, radio spots were produced and a press release was created by the DSSB to advertise IPV.

## IMPLEMENTATION

IPV was originally planned to be introduced in July 2014, but it was delayed until September 2014. IPV introduction was postponed by two months because it took longer than anticipated to train all of the healthcare personnel involved in the introduction. This was mostly a result of training being originally scheduled during times that overlapped with summer vacation and Ramadan (June 28-July 28). Otherwise, the introduction went according to the original planned timelines.

In Tunisia, the National Healthcare Booklets were revised and disseminated prior to IPV introduction. The Regional Report of Vaccination Program Activities was also amended to include IPV, so that IPV administration in clinics could be tracked at the regional level. However, the vaccine registers used at each clinic to record which vaccines each child received were not amended prior to introduction. As a solution, the nurse/vaccinator used the area previously used for OPV to record that the child received both IPV and OPV at 6 months.

Preliminary findings have shown that the acceptability of IPV among healthcare professionals and caregivers is high. One reason cited for strong acceptance is the overall trust of the public in the immunization program. It should also be recognized that IPV has been used in the private sector as part of the hexavalent vaccine. The availability of IPV in the private sector has meant that Tunisian healthcare personnel—as well as the average citizen—were aware of IPV and its use. This established familiarity with IPV made both public sector healthcare personnel training and parental education significantly easier.

## LESSONS LEARNED

### Lesson 1—Rapid introduction is possible in a strong routine immunization program

One of the most remarkable aspects of IPV introduction in Tunisia was the speed with which it was executed. In total, there were nine months between the initial decision to introduce (December 2013) to the actual introduction (September 2014). A key factor that enabled this rapid introduction was the strength of the existing routine immunization program in Tunisia. The strong routine program provided a solid base that made introducing a new



vaccine relatively simple. This underscores the importance of continued efforts to strengthen the routine immunization program.

### **Lesson 2—General public demand for immunization enabled smoother introduction of IPV**

IPV was widely accepted by caregivers and the public in Tunisia. As described by Professor Souad Bousnina, President of the Vaccine Technical Committee, “Vaccination is very well established in our country. Parents already view it as a necessity. So when we make a change from one vaccine to another that is supposed to be better, it’s something that is very well accepted by parents, by vaccinators, and by doctors.”

### **Lesson 3—A political and historical legacy of commitment to vaccination contributed to the high acceptance of IPV**

Following independence, the Government of Tunisia placed a high priority on health and education. This has resulted in a historical legacy of political commitment to immunization. Tunisians take pride in the national immunization program and see the program as one of the major successes of Tunisia. As eloquently described by Dr. Nabil Ben Salah, Director General of Health, Tunisia, “Since its independence in 1956, Tunisia has been seriously committed to health and education. Consequently, vaccines have been introduced very quickly in our country and Tunisians are able to adapt very quickly to new vaccines. Now, the average Tunisian demands vaccines. This has meant that introducing a new vaccine, even an injectable vaccine, is not problematic. On the contrary, it is something that the average Tunisian citizen finds reassuring.”

### **Lesson 4—OPV supply issues accelerated the decision to introduce IPV**

Due to OPV supply concerns in 2013, the vaccine supply committee recommended the introduction of IPV in 2014. Because there was concern about the future supply of OPV and because IPV had previously been included in the original Five Year Immunization Plan, Tunisia was able to accelerate the decision to introduce IPV.

### **Lesson 5—Limited resources meant that trade-offs had to be made for IPV and other new vaccine decisions**

Despite a desire to introduce two doses of IPV, the CTV recommended that initially a single dose of IPV at 6 months of age should be introduced because of difficulties in rapidly mobilizing funds to pay for both doses. The CTV recommended that resources could be secured for a second dose of IPV, which would be added to the national immunization schedule at 2 months to eliminate the rare risk of VAPP. The second implication of limited resources was that the CTV did not decide to introduce the pneumococcal conjugate vaccine (PCV) in 2014 despite the fact that

this vaccine would prevent a higher level of mortality and morbidity. At more than twice the Tunisian budget, the pneumococcal conjugate vaccine was considered too expensive given that the IPV vaccine needed to be prioritized.

### **Lesson 6—A standardized and centralized decision-making process was important for IPV introduction**

National Immunization Technical Advisory Groups (NITAGs) are multidisciplinary groups of experts responsible for providing independent, evidence-informed advice to governments on vaccine policy-related issues. In Tunisia, the National Vaccine Technical Committee (CTV) is the NITAG equivalent that meets quarterly to discuss all things related to vaccine policy. In regards to IPV introduction, the existence of a functional NITAG with centralized decision-making power allowed the government to take swift action regarding IPV introduction. Once the CTV recommended IPV introduction, the national immunization program immediately began preparation for the nationwide introduction of the vaccine. This experience underscores the benefits of having a functional NITAG that can translate global recommendations on immunization into national policies.

### **Lesson 7—The availability of data and a strong NITAG can lead to evidence-based decisions**

The availability of VAPP data in Tunisia in addition to a fully functional NITAG ensured that the decision for the new polio immunization schedule was evidence-based and tailored to Tunisia’s needs. Before making a decision, the CTV had an important debate about the advantages and disadvantages of the different dosing schedules. Because the NITAG was comprised of a diverse set of stakeholders (national, regional, programmatic, scientific), they were able to consider all aspects of IPV introduction when making a decision. Following the discussion, the CTV chose the schedule that they felt was the best fit for the Tunisian context. One dose of IPV would be introduced in 2014 at 6 months (to ensure strong immunity) and in 2016 a second dose of IPV would be added at 2 months (to prevent VAPP).

### **Lesson 8—The availability of certain vaccines in the private sector can influence local perceptions**

In Tunisia, IPV has been available for purchase in the private sector for many years. As a result, many caregivers were familiar with IPV and saw it as a safe and effective vaccine. In Tunisia, this contributed to the overall positive perception of IPV and is cited as another factor in its high acceptance among caregivers. However, national immunization programs should be aware that the availability of certain vaccines in the private sector and how this can influence local perceptions of a vaccine (positive and negative). Additionally, it should be noted that the immunization schedule and

vaccine formulations available in the private sector are often different from those available in the public sector. In some circumstances, this can contribute to confusion among healthcare workers and parents. Programs should be aware of this and be prepared to manage the confusion.

**Lesson 9—It is difficult to mobilize funding when financial budgets have already been set years in advance**

Health budgets are often set years in advance. This can be a big hurdle during the rapid introduction of a vaccine. In the case of IPV in Tunisia, the national immunization program was able to rapidly mobilize enough funding for a single dose of IPV in 2014, but it should be noted that it was not possible to secure enough funding for two doses of IPV. For this reason, Tunisia decided to wait until 2016 to introduce a second dose of IPV.

**TIMELINE**

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April 2012: Drafted Five-Year immunization plan with intention to introduce IPV in 2014

December 2013: Vaccine Technical Committee recommends IPV to be introduced

January 2014: WHO/UNICEF joint letter to the Minister of Health encouraging IPV introduction

February 2014: Ministry of Finance approves funding for 1 dose of IPV to be introduced

March 2014: Vaccine Technical Committee (CTV) decides IPV will be given to children at 6 months of age

March 2014: Order placed for IPV vaccine

March 2014: Revised hard copy documents and national vaccine database

April 2014: Creation of training materials and communication of new immunization schedule

June 2014: Dissemination of the IPV introduction memo

June 2014: Delivery of the vaccine and new hard copy materials

June-August 2014: Training of managers, regional trainers, and vaccinators

September 2014: IPV introduced into routine immunization







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