**MINISTRY OF HEALTH, THE PLURINATIONAL STATE OF BOLIVIA**

**Expanded Programme on Immunisation**

**NATIONAL PLAN FOR THE INTRODUCTION OF**

**INACTIVATED POLIO VACCINE**

**Bolivia, January 2015**

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VIROLOGY LABORATORY

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**Acronyms and abbreviations**

ANR National Regulatory Authority

MV Measles vaccine

BCG TB vaccine

NIC National Immunisation Committee

CDC Centers for Disease Control and Prevention

DPT Diphtheria, Pertussis and Tetanus Vaccine

ESAVI Event Supposedly Attributable to Vaccination or Immunisation

GAVI GAVI Alliance

PAHO Pan American Health Organization

WHO World Health Organisation

EPI Expanded Programme on Immunisation

AFP Acute flaccid paralysis

PVP Post vaccination poliomyelitis

VDPV Vaccine-derived poliovirus

SEDES Departmental Health Services

NHIS National Health Information System

CRS Congenital Rubella Syndrome

MMR Measles, mumps and rubella vaccine

UNICEF United Nations Children’s Fund

IPV Inactivated (or Injected) Polio Vaccine

OPV Oral Polio Vaccine

bOPV Bivalent Oral Polio Vaccine

tOPV Trivalent Oral Polio Vaccine

**Introduction**

The Plurinational State of Bolivia has been involved in the process to eradicate poliomyelitis in the Americas since 1985, when the country joined the initiative launched by the Pan American Health Organization (PAHO), the International Rotary Club and the Centers for Disease Control and Prevention (CDC) for the elimination of the disease by 1990.

Following the strategies designed for this purpose, in 1986 Bolivia launched its National Polio Immunisation Days, during which oral polio vaccine (OPV) was given to all children aged under five years in the country, achieving immediate control of the disease. The country also began epidemiological surveillance of polio, using the acute flaccid paralysis (AFP) model. This model is highly sensitive and offers diagnostic specificity supported by high quality laboratory studies and the development of effective strategies for the control of outbreaks.

Twenty-four years after the last case of polio caused by the wild poliomyelitis virus on the continent, and after in-depth analysis of the advances made and the current epidemiology of the disease, the PAHO Polio Eradication and Endgame Strategic Plan 2013-2018 requires important changes in the fight against the disease, particularly with regard to the use of inactivated polio vaccine (IPV) and the gradual replacement of the oral vaccine.

The basic points of the Strategic Plan include the simultaneous global application of at least one dose of the inactivated vaccine to the entire child population and the replacement of the trivalent oral vaccine by a new bivalent formulation which eliminates the attenuated poliovirus 2 strain; this policy reduces the risk of infection by vaccine-attributable poliomyelitis and vaccine-derived poliovirus.

Although no cases of vaccine-attributable or vaccine-derived polioviruses have been reported in the country, Bolivia is taking part in this health coordination for the benefit of the international community, applying at least one dose of IPV. This will accelerate the effective control of the disease at world level, with a view to its total eradication by 2018.

Due to the importance of this new strategy, the national Government and the country’s healthcare community have undertaken to monitor the introduction process, with the aim of achieving effective coverage of more than 95% in the target population, as well as strengthening other disease monitoring and control strategies, to achieve global eradication of poliomyelitis by this deadline.

The introduction of the vaccine will suppose a major challenge for health workers and parents, inasmuch as it involves the simultaneous injection of three vaccines in children aged two months. Accordingly, health workers and the community in general are called on to support and promote the effective introduction of the vaccine, in the understanding that it vital for the eradication of the disease and to guarantee that all our children are fully protected.

**Dr Ariana Campero Nava, Minister for Health**

**Executive Summary**

The WHO Polio Eradication and Endgame Strategic Plan 2013-2018, requires fundamental changes to the actions and strategies for the worldwide eradication of the disease, including a transition from the trivalent oral polio vaccine (Sabin type, tOPV) to the bivalent type (bOPV), the eventual withdrawal of the oral vaccine and worldwide use of the inactivated vaccine (Salk type, IPV). The Strategic Plan contemplates a synchronised global switchover from tOPV to bOPV in April 2016 and the definitive switchover from OPV to IPV by 2018.

The plan calls on countries to introduce at least 1 dose of IPV into routine immunisation schedules in 2015. Accordingly, during the Regional Meeting on the Eradication of Polio, the countries of the Americas agreed to introduce the injected vaccine, with the aim of complying with the world eradication process and guaranteeing the immunity of the child population in the event of the reappearance of poliovirus in the region or the re-emergence of serotype 2.

The use of the injected vaccine will ensure immunity against poliovirus 2 during the transition phase and will reduce the risk of post-vaccination poliomyelitis (PVP) and vaccine-derived poliovirus (VDPV).

Bolivia’s expanded programme on immunisation (EPI), endorsed by country’s National Immunisation Committee (NIC), is following the Global Plan, adding a simultaneous countrywide dose of IPV as a first dose against polio at the age of 2 months, followed by four doses of oral vaccine at 4 months, 6 months, 18 months and 4 years of age, beginning in October 2015; depending on the worldwide availability of the vaccine, the country plans to apply two doses of IPV, at 2 months and 4 months of age, followed by three doses of OPV. In this case, one dose will be donated by GAVI Alliance (GAVI) and the second will be funded by Bolivia’s Exchequer.

This will allow the national EPI to maintain coverage of the country’s child population against all polio virus types, ensuring that the nationwide eradication of the disease is maintained and contributing to its eradication worldwide.

The vaccine to be used will be in single-dose format (independent single-dose vials) for intramuscular administration, to be applied from October 2015, corresponding to 25% of the birth cohort for the year. From 2016 onwards it will be applied to all infants in the country, with an estimated coverage of 95% of children and wastage of 5% each year, for a total of 63,471, 251,033, 248,278 and 245,435 doses between 2015 and 2018. As soon as sufficient vaccine becomes available on the international market, this figure would be doubled.

The recent pneumococcus vaccine introduction process demonstrated the capacity of the health system for the introduction of new vaccines and delivered several important lessons regarding the need for careful planning and organization, a staff training and guidance phase and a strong social outreach plan, to guarantee that health workers and parents alike consent to the application of simultaneous injected doses. Direct assessment will be performed throughout the first half of 2015, and monitoring of simultaneity with other current injected doses (pentavalent and pneumococcus) will be intensified, making the necessary adjustments to guarantee that the third injected vaccine, IPV, is also accepted.

During the preparation and roll-out phases, the backing of the Departmental Health Services (SEDES) and the NIC will be crucial in order to secure the support of scientific associations, health workers, social organisations and the community in general. The NIC has analysed the IPV introduction process at three of its technical sessions, concluding that the vaccine needs to be included on the national vaccination schedule as soon as possible; the issue has also been discussed with the Departmental EPI coordinators as part of the National EPI Assessment of September 2014 and during the meeting held to analyse new vaccines (December 2014), securing the commitment of the departmental teams.

In order to guarantee the capacity and quality of the cold chain, the PAHO has been asked to evaluate nationwide and departmental storage capacities, to support training for technical personnel at these levels, and to perform preventive and corrective maintenance on cold chambers, to ensure they are operating under optimum conditions. The formal preparatory phase for the introduction process commenced in 2015 and involved the production of personnel training material, updating the cold chain, designing record formats, adapting IT systems, creating supervision and evaluation system, conducting in-the-field research on simultaneous injections and developing a social outreach plan.

The budget for the vaccine introduction process (based on one dose of IPV in each child’s vaccination schedule) amounts to US$1,103,240, 48.2% of which will be funded by the Bolivian Exchequer, 48.8% by GAVI Alliance (808,216 doses of vaccine and US$222,500 dollars in cash, as support for the introduction process), and approximately 3.1% by health cooperation agencies including PAHO and UNICEF. Assuming that the vaccine will have become sufficiently available by 2017, the cost will be increased at the expense of national funds, to include the purchase by the State of one dose for every Bolivian child.

**National background and circumstances**

Bolivia is a plurinational, inter-cultural, decentralised state made up of Autonomous Regions and based on the Nation’s Political Constitution of (2009). There are four official types of autonomous government: departmental, regional, municipal and the aboriginal indigenous peoples. The country is home to 39 ethnic groups, with an indigenous population of 75%.

The plurinational State of Bolivia has a population of 10,027,254 inhabitants (census 2012) and a population density of 9.13 inhabitants per km2. During the period between the 2001-2012 censuses, the Bolivian population grew by more than two million inhabitants. The population is a young one, with 62.86% aged between 15 and 64 years. The National EPI has acknowledged that there were inaccuracies in the most recent census and so continues to use population estimates based on the 2002 Census, which are closer to actual figures, at least for children under five years.

Bolivia’s National Health System is comprised of public, social and private sectors. According to 2011 figures, 47% of the population is covered by the Bolivian Health Service (Sistema Único de Salud, SUS); 53% has no type of health coverage and more than half the population uses traditional medicine (PAHO, 2011). Approximately 82.7% of health services are provided by the Ministry of Health, 5.6% by short-term Social Security insurance and 11.7% by private providers. At his inauguration in January 2015, President Evo Morales mentioned achieving Universal Health Insurance as a health priority during this mandate; this would guarantee increased family vaccination coverage.

Vaccination and immunisation are considered public health priorities and the most successful strategy from health, social and economic standpoints.

The EPI was set up in 1979, with the application of four basic vaccines: BCG, DPT, OPV and MV; the expansion process commenced in 2000, with the application of the pentavalent and MMR vaccines, opening the way for the introduction of new and underused vaccines: rotavirus (2008), seasonal flu (2010) and pneumococcus (2014). The current vaccination scheme is very comprehensive (Table 1), offering protection against 14 serious childhood diseases. The Ministry of Health is also currently studying the introduction of the Human Papilloma Virus vaccine in the short term. This would have a positive effect on one of the main causes of morbidity and mortality among the country’s women of child-bearing age.

Bolivia’s EPI has been consolidated down through the years, and has major strengths, including the National Vaccines Act, which guarantees its financial sustainability. The programme has become strongly rooted among the population and the health services, and is widely accepted by users of the Health System. Bolivia has achieved the eradication of the wild poliovirus, the elimination of measles, rubella and congenital rubella syndrome (CRS) and has brought other vaccine-preventable diseases under control.

Table 1

**Vaccination schedule for children aged under five years**

**Administrative Vaccination Coverage 2013 and 2014 and ENCOVA**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Vaccine** | **Age applied** | **Target population 2014\*** | **Administrative Coverage 2013** | **Administrative Coverage 2014** | **ENCOVA Coverage\*\*** |
| BCG | RN | 269,662 | 88.1 | 91.7 | 93.6 |
| IPV\*\*\* | 2 months | NA | NA | NA | NA |
| OPV | 2, 4, 6, 18 mos. and 4 years | 269,662 | 80.8 | 82.4 | 90.6 |
| Rotavirus | 2 and 4 months | 269,662 | 77.6 | 83.0 | 83.1 |
| Pentavalent | 2, 4, 6, 18 mos. and 4 years | 269,662 | 81.4 | 82.5 | 90.4 |
| Pneumococcus | 2, 4 and 6 mos. | 269,662 | NA | 48.7 | NA |
| MMR | 12 months | 266,329 | 82.6 | 86.0 | 86.5 |
| YF | 12 months | 266,329 | 81.0 | 83.4 | 81.1 |
| \* The child population estimation from the 2002 census is used for scheduling and calculating coverage, as it is closer to reality  \*\* ENCOVA according to written records; Coverage: OPV, pentavalent and pneumococcus third dose; Rotavirus second dose; MMR first dose  \*\*\*Introduction from October 2015, replaces the first dose of OPV | | | | | |

Polio vaccination coverage stabilised in the 90s, with record-taking problems in the previous years. Actions for the eradication of poliomyelitis commenced in 1982 with the People’s Health Mobilisations, as part of which OPV was given indiscriminately to all children aged under five years.

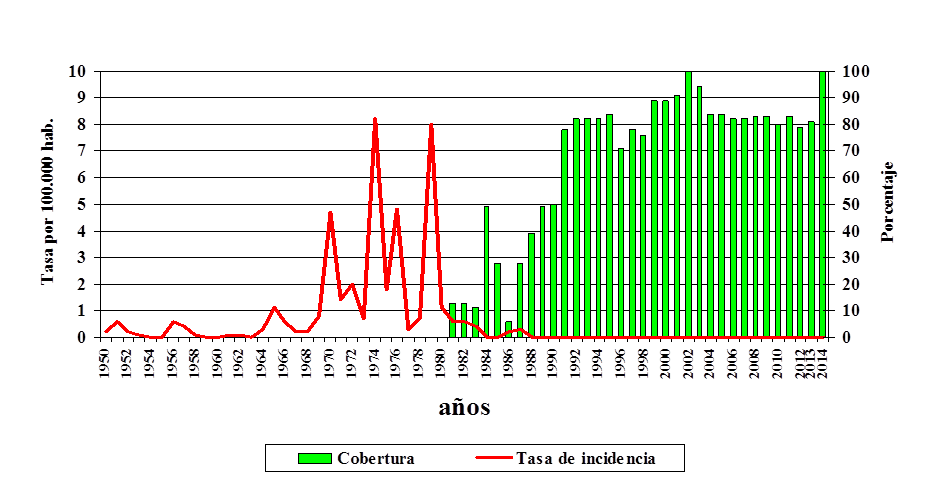
The last case of polio in the country was recorded in 1986 in the city of El Alto (Figure 1). Bolivia obtained the Eradication Certificate, along with the rest of the countries of the Americas, in 1994, after a comprehensive documentation and certification process.

GAVI has played a decisive role in the introduction of new vaccines, supporting the pneumococcus and rotavirus vaccine introduction processes; it has also been instrumental in strengthening health services in the country in support of the EPI, through the 2012-2015 HSS Project, which has derived in a new proposal for the 2016 - 2018 period. The EPI Maintenance Plan is also undergoing revision, as part of Bolivia’s GAVI graduation process.

Figure 1.

**Incidence of poliomyelitis and polio vaccination coverage**

**Bolivia, 1950 - 2014**



*Left axis: Rate per 100,000 inhabitants*

*Right axis: Percentage*

*Below: year*

*Key: Coverage Incidence*

An important step in Bolivia’s EPI was the national vaccination survey (ENCOVA) undertaken in 2013. ENCOVA is a probabilistic, population-based survey, representative at departmental level and for the municipality of El Alto; the survey was designed by a team of immunisation experts and the fieldwork was conducted by an independent team with extensive experience in population-based field studies. ENCOVA 2013 collated written information from children’s vaccination booklets (86%) and health facilities records (5%), to ensure that the information obtained was of high quality. According to ENCOVA, only 6 out of 3,600 children surveyed had received no vaccine; real coverage rates are 10 to 15% above administrative records for each vaccine; 90.7% of children aged 12-59 months have the full basic scheme (94.0% in rural areas and 87.1% in urban areas); the lowest rates of adhesion to the full scheme were recorded in La Paz, El Alto and Pando; the equality of the programme is very high with regard to gender, membership of indigenous groups, mother’s age and level of education and other variables; access to vaccination is high: 99.4% in the case of BCG and 93.6% for rotavirus first dose.

ENCOVA 2013 also revealed structural, technical and operative problems in the EPI, including the wide range of vaccination booklets used - each municipality prints its own booklets and most do not have space for all the vaccines (particularly rotavirus, polio and pentavalent boosters and, currently, pneumococcus); non-optimised vaccination opportunities (BCG: 90.6%, Penta3: 75.6% and MMR: 93.0%); non-simultaneous vaccination (MMR-YF: 69%); drop-out (Penta1-Penta3: 4.7%, Rota1-Rota2: (6.6%); and very low booster coverage.

An analysis of the reasons of failure to vaccinate (RFV) and missed vaccination opportunities (MVO) [Preliminary data], performed as part of ENCOVA 2013 in the urban area of La Paz and the municipality of El Alto, provides valuable information for an analysis of the weaknesses of the EPI. Reasons for failure to vaccinate have to do with parents (42.5%), health services (41.1%), communication and information problems (13.0%) and family factors (3.4%). With regard to service-related factors, 51.4% have to do with quality of care, 20.3% with how the service is organised, 15.9% with errors in the application of rules and procedures, and 12.4% with factors relating to how the service operates. The main lines of action of the current HSS proposal are based on the findings of ENCOVA, and RFV and MVO surveys undertaken in the La Paz and El Alto urban areas.

60% of RFV may be attributed to personnel, and 40% to services. Missed Vaccination Opportunities are estimated at 26.5%. Another challenge is refusal by vaccination and/or health personnel to accept simultaneously-injected doses. This is apparent in the simultaneity of the MMR and YF vaccines (69%) and is perhaps the greatest challenge facing IPV, which requires that at least one dose be applied simultaneously with the pentavalent and pneumococcal vaccines.

The latest international assessment of the EPI was conducted in August 2010 in association with PAHO and UNICEF. It included the drafting of the EPI 2011-2015 five-year-plan, which did not contemplate the introduction of the IPV, although it did include components for the consolidation of the elimination of polio and the acute flaccid paralysis (AFP) monitoring system. The Ministry of Health has proposed a new international assessment of the EPI in 2015, along with an assessment of the effective management of the programme, following GAVI methodology.

The IPV introduction process was analysed by the NIC at three technical sessions. The sessions studied the bases of the Polio Eradication and Endgame Strategic Plan 2013-2018, the international prospects for the production and availability of inactivated vaccine and, more recently, the conclusions of the Regional Meeting for the Introduction of IPV. The NIC is comprised of representatives from associations for professionals in paediatrics, infectious diseases and gynaecology and obstetrics, as well as leading healthcare professionals, Bolivia’s National Reference Laboratories and international health cooperation agencies (PAHO and UNICEF), representing the best of the country’s technical and professional capacity.

The role of organised civil society is fundamental in Bolivia and, accordingly, social organisations, municipal coordinators, scientific associations, the business sector and the media will be invited to participate actively in the promotion and dissemination of IPV.

The conclusions and recommendations of the NIC and the Regional Meeting have been submitted to the country’s highest health authorities, who accept and support the introduction of this new vaccine.

1. **Targets, objectives and expected impacts and difficulties of the introduction process**

The aim of the IPV introduction process is to reduce the risk of PVP and PVDV, in line with the World Eradication Plan, and to advance the transition from the oral to the inactivated vaccine. The objectives are the following:

* To contribute to the worldwide eradication of the disease by 2018
* To introduce a dose of IPV in the population aged two months, at national level, from October 2015 onwards
* To apply a second dose of IPV at four months of age, once sufficient vaccine becomes available on the international market
* In the medium term, to replace tOPV by bOPV and eventually by the inactivated vaccine, as per the Worldwide Polio Eradication Plan.
* To keep the country free of polio in any form

These strategies are expected to maintain Bolivia polio free until the worldwide eradication of the disease has been certified, and the polio vaccine will eventually be removed from the national vaccination schedule. This will be of huge importance to the national economy and health services, by eliminating five doses from the child vaccination schedule.

From an economic point of view, part of the financial burden will be absorbed by GAVI, who will donate one dose of vaccine for every child aged two months in the country; the additional burden (training, supervision, outreach, logistics, strengthening of the cold chain, etc.) will be borne by the Bolivian Exchequer, which will provide the national EPI with supplies and direct financial support. Likewise, once sufficient vaccine becomes available on the international market, the EPI will bear the cost of acquiring a second dose of IPV, to establish a schedule of two injected doses followed by three doses of the oral vaccine.

The recent introduction of the pneumococcal vaccine has provided an experience with which to anticipate the main challenges, strategies and activities for the introduction of IPV, including:

* Dissemination of the IPV Introduction Plan, including scheduling, planning and coordination at the different levels of the national health system, as well as in the various sectors of society
* Advocacy and inter-sector coordination at the highest levels, to secure the support and assistance of the authorities and of civil society in order to ensure the success of the introduction process
* Strengthening the logistical capacity for the acquisition, reception, storage and transportation of a new vaccine
* Training of personnel in all components of the programme, particularly in the application of a third dose of injected vaccine at 2 and 4 months of age, and in the importance of preventing the vaccine from freezing
* Strengthening the capacity, quality and management of the cold chain
* A social outreach plan to promote the implementation of a new vaccine and the acceptance of a simultaneously-injected third dose of vaccine
* Development of a specific record system for IPV, covering the different written formats, the IT system and, when the time comes, the nominal immunisation record
* Development of supervision, monitoring and evaluation systems for the timely analysis of vaccination services, including population surveys to establish the level of gender, social-economic and territorial equality of the application of the vaccine.

1. **Strategies and policies for the inclusion of the vaccine in the national immunisation programme**

The basic strategy at national level is vaccination included within vaccination services, whether at health outposts, healthcare centres or secondary and tertiary care hospitals; in inaccessible rural areas and in urban areas with special conditions (e.g. where many mothers work outside the home) vaccination is conducted in the field, with house-to-house visits or mobile vaccination posts. The same strategies will be followed for the application of the IPV, depending on regional conditions.

The population to be vaccinated comprises children aged two months. From October 2015 onwards, coverage is expected to reach 95% of the target population each year (Table 2) with maximum wastage of 5%; as soon as sufficient vaccine becomes available worldwide, two doses of vaccine will be applied (at 2 and 4 months), and the target will therefore be doubled.

To reduce the risk of vaccine-associated cases, IPV should be applied in first and second doses. Accordingly, the vaccination schedule will be as shown in Table 3.

Table 2

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Estimated population of two-month-olds** | | | | | |
| **for application of the Injected Polio Vaccine** | | | | | |
| **Bolivia, 2015 - 2018** | | | | | |
| **YEAR** | **Births** | **Infant deaths** | **Surviving children** | **Vaccination target (95%)** | **Necessary doses (5% wastage)** |
| **2015\*** | 267,798 | 13,279 | 254,519 | 60,448 | 63,471 |
| **2016** | 264,802 | 13,140 | 251,662 | 239,079 | 251,033 |
| **2017** | 261,900 | 13,000 | 248,900 | 236,455 | 248,278 |
| **2018** | 258,900 | 12,850 | 246,050 | 233,748 | 245,435 |

\* In 2015 children born in October and later will be vaccinated, i.e. 25% of the birth cohort

Table 3

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Polio vaccination schedule,** | | | | | |
| **depending on the availability of one or two doses of IPV** | | | | | |
| **Bolivia, 2015 - 2018** | | | | | |
| **Age** | 2 mos. | 4 mos. | 6 mos. | 18 mos. | 4 yrs. |
| **One dose of IPV** | IPV | OPV | OPV | OPV | OPV |
| **Two doses of IPV** | IPV | IPV | OPV | OPV | OPV |

In order to systematise the order and site of the vaccines, the following sequence has been defined for simultaneous doses:

* Rotavirus vaccine, oral
* Polio vaccine, oral (second dose onwards)
* Inactivated polio vaccine (first dose), right thigh
* Pentavalent vaccine, left thigh
* Pneumococcus vaccine, right thigh, 2.5 cm below IPV site

Ministry of Health policy is to provide a bottle of paracetamol immediately after vaccine application, to reduce fever and local reactions, if necessary.

ENCOVA revealed that most mothers prefer their children to be vaccinated at health units, and so the EPI encourages this practice; however the survey on the reasons for failure to vaccinate has revealed a number of obstacles to timely vaccination, which must be studied and analysed at local level in order to apply the corresponding measures.

On the recommendation of the NIC, the National EPI has selected the monovalent presentation of the vaccine. This will reduce wastage and, particularly, missed vaccination opportunities, as it has been observed that multidose vials (like the YF vaccine) mean that many units establish immunisation days during the week to prevent wastage. However, this means that many vaccination opportunities and, in certain cases, vaccination itself are missed

Given that, according to ENCOVA, OPV3 vaccination coverage is acceptable (about 94%), booster doses of IPV are not considered necessary. Nevertheless, health teams must do their best to ensure IPV coverage maintains these levels.

Other aspects that require attention in order to reduce failure to vaccinate and missed vaccination opportunities have to do with vaccination timetables, delivery of a number of limited vaccination sheets, vaccination personnel shortages, constant staff rotation, the lack of services in the evenings and on weekends and holidays, and communication shortfalls, among others. The Bolivian EPI plans to conduct a local analysis of the reasons for failure to vaccinate and lost vaccination opportunities, in order to draw up specific plans to guarantee a better quality of service and optimum coverage.

1. **Resources, costs, financing and sustainability**

Bolivia’s Vaccination Act guarantees the necessary funding for the Expanded Program of Immunisation, including acquisition of vaccines and supplies, payment of the corresponding taxes and implementation of all its components, from the planning of activities, scheduling at all levels of the health system, training of staff, social outreach, operation and maintenance of the cold chain, logistics for the storage and distribution of vaccines and supplies, supervision and evaluation, research and special activities.

The Ministry of Health respects the autonomy of the country’s Departments and Municipalities, under which each is responsible for the implementation and performance of their respective vaccination programmes, while coordinating vaccination processes, strategies and goals at national level.

Funding from international cooperation agencies (basically UNICEF and the PAHO) has been reduced in recent years, due to the financial autonomy of Bolivia’s EPI. Accordingly, more than 95% of total programme spending comes directly from national funding.

The introduction of new vaccines has received significant support from GAVI: rotavirus vaccine in 2008, pneumococcus vaccine in 2013 and IPV from October 2015 onwards. Throughout the process, Bolivia has always met its vaccination co-payment obligations and is one of the Member States that makes its annual payment to the PAHO Revolving Fund for Vaccines in advance, thus ensuring the availability and timeliness of vaccines.

As pointed out in Chapter 2, the main areas to be strengthened to ensure the success of the IPV introduction process include:

1. The need to ensure the acceptance of simultaneously-injected vaccines by health workers and parents. To achieve this, a vaccination team training and information programme is being put in place, to emphasise the characteristics of the new vaccine, the risk of atypical forms of poliomyelitis, the worldwide transition from oral to inactivated vaccine, and the importance of the timely application of the different vaccines. The social outreach plan will promote community participation and will emphasise the safety of simultaneously-injected vaccines, the importance of worldwide polio eradication, the impact of the expanded programme on immunisation and the frequency of adverse reactions to vaccines.
2. Expansion and strengthening of the cold chain. This will require a situational diagnosis of cold chain capacity and operation at national and departmental level, refresher training for technical personnel, acquisition of equipment and materials to ensure preventive and corrective maintenance at national level.
3. An analysis of the causes of failure to vaccinate and missed vaccination opportunities at operative (municipal) levels, in order to develop and implement intervention plans at regional and local levels to allow for the application of full and timely schedules, comprising all the vaccines included under the national vaccination schedule, reducing barriers and offering services of a high technical and human quality.
4. At the same time, specific staff vaccination personnel will be assigned to the health units where they are required (particularly at secondary and tertiary care levels), and regulations will be put in place to ensure the retention of personnel with experience in immunisation services.

The introduction of a dose of IPV will have no direct cost to the country with regard to the acquisition of vaccines and syringes, which will be donated by GAVI, with no co-payment obligation on the State. This donation is guaranteed until at least 2018. Once sufficient vaccine becomes available on the international market, Bolivia will add a second dose, funded by the National Exchequer, to the regular immunisation schedule. The financial implications of the application of a second dose are outlined in Table 4.

In the effort to meet the target of introducing the vaccine from 2015, GAVI will provide 6.2 million dollars until 2024; the cost of the polio vaccines for Bolivia, both oral and inactivated, will amount to 7.2 billion dollars, of which just more than six million will correspond to the introduction of a second dose of IPV, probably from 2016.

Table 4

**Year**

**Schedule**

**Estimated**

**population**

**(1)**

**Target**

**population (2)**

**Doses**

**required**

**(3)**

**GAVI**

**support**

**(USD$)**

**IPV**

**(USD)**

**OPV (6)**

**(US$)**

**Total cost**

**polio**

**vaccination**

2015 (4)

IPV + OPV+OPV + OPV +OPV

254,519

60,448

63,471

177,718

0

38,793

38,793

2016

IPV + OPV + OPV + OPV + OPV

251,662

239,079

251,033

702,892

0

153,431

153,431

2016 (5)

IPV +IPV + OPV + OPV + OPV

251,662

239,079

251,033

702,892

702,892

115,073

817,965

2017

IPV +IPV + OPV + OPV + OPV

248,900

236,455

248,278

695,178

695,178

113,811

808,988

2018

IPV +IPV + OPV + OPV + OPV

246,050

233,748

245,435

687,218

687,218

112,507

799,725

2019

IPV +IPV + OPV + OPV + OPV

243,200

231,040

242,592

679,258

679,258

111,204

790,462

2020

IPV +IPV + OPV + OPV + OPV

240,350

228,333

239,749

671,298

671,298

109,901

781,199

2021

IPV +IPV + OPV + OPV + OPV

237,500

225,625

236,906

663,338

663,338

108,598

771,935

2022

IPV +IPV + OPV + OPV + OPV

234,650

222,918

234,063

655,377

655,377

107,295

762,672

2023

IPV +IPV + OPV + OPV + OPV

231,800

220,210

231,221

647,417

647,417

105,991

753,409

2024

IPV +IPV + OPV + OPV + OPV

228,950

217,503

228,378

639,457

639,457

104,688

744,146

**TOTAL (6)**

**6,219,150**

**6,041,432**

**1,181,293**

**7,222,725**

(1) Surviving infants aged under 6 months

(2) 95% coverage of target population

(3) 5% wastage

(4) During rollout, an estimate 25% of the annual birth cohort will be vaccinated, from October onward

(5) If sufficient vaccine is available for two doses by 2016, one of them to be paid by the EPI

(6) Based on 4 doses of OPV in 2015-2016; 3 doses as from the second option for 2016 [note (5)]; and 20% wastage

Cost of IPV = USD 2.8000 (GAVI price)

Cost of OPV = USD 0.1337 (Revolving Fund price)

**EPI / Bolivia expenditure**

**Estimated cost of IVP Introduction process**

**(Cost of vaccines only)**

**Bolivia, 2015 - 2024**

The operating expenses associated with the introduction process (planning, coordination, training, social promotion and outreach, adaptation of the cold chain, supervision, evaluation, etc.) will be funded out of the regular EPI budget with the support of international organisations such as PAHO/WHO and UNICEF, in addition to support from GAVI Alliance in the form of a grant of USD 222,500 for the vaccine introduction process. The bulk of the cost corresponds to the first three quarters of 2015.

The total cost of the IPV introduction process, not including the cost of vaccines, has been estimated at USD 1,103, 240. The MOH will bear 36.6% of total expenditure, while GAVI funds will cover about 50% of the total cost, through existing national funds (28.6%) and the specific grant for the introduction of the vaccine (20.2%). Departmental and municipal governments are expected to contribute 11.6% of the total expense of the introduction process.

1. **Strategies and activities relating to the introduction process, including the opportunities it provides to improve the immunisation programme and the health system in general** 
   1. Coordination and supervision of the preparation and implementation of the introduction process.

The introduction process will be overseen by the national EPI technical-administrative team, which will set up a National Steering Committee for the IPV Introduction Process, reporting to the National EPI Coordinator. The team will include experts in cold chain management, epidemiological monitoring, supervision and training, laboratory coordination and administration. The team will distribute the remaining programme functions among itself, covering the necessary components for the planning, scheduling and implementation of EPI activities, as well as having direct support from UNICEF and the PAHO. The national team will work full-time during the preparation, implementation and evaluation phases, holding weekly meetings to analyse and assess the progress of the process, in accordance with the corresponding timeline and checklist.

The Bolivian National Immunisation Committee (NIC) supports the EPI with advisory services, coordination and advocacy before the national authorities, the public, social and private health sectors, scientific associations, civil society and the media. It is also responsible for coordinating and implementing the outreach plan and the crisis plan. The NIC will hold monthly meetings to evaluate the progress of the introduction process and any obstacles encountered, implementing the necessary corrective actions.

Operational coordination with the health services falls to the group of Departmental EPI coordinators, who are officials with extensive experience in the programme and are appointed by the Management of the respective Departmental Health Services (SEDES).

The SEDES are autonomous and decentralised from the Ministry of Health. Accordingly, EPI policies, strategies and actions must be agreed and supported by the EPI Coordinators. Thus, each SEDES must develop and implement its own Introduction Plan, following the indications of the National EPI, developing their own checklists, timelines and budgets. Each SEDES will set up its own IPV Introduction Committee.

The Departmental Coordinators will attend the monthly NIC meetings, outlining their progress according to the standardised checklist. If necessary, special meetings and field visits will be conducted to support coordination and planning.

Information and training meetings will be held with the media, scientific associations, health sector workers and organised civil society, to report on the progress of polio eradication worldwide, the need for the new vaccine, IPV introduction policies and strategies, and the characteristics of the vaccine and its importance within the framework of the Global Eradication Plan. Strategic alliances with these sectors will be vital to ensure the success of the introduction process, and their support and assistance will be essential throughout.

* 1. Planning for the acquisition and distribution of the vaccine.

The country currently has two WHO-prequalified vaccines in single-dose format. Both can be provided by GAVI through the Revolving Fund for Vaccination. Regardless of the laboratory by whom they are produced, vaccines acquired through the Revolving Fund do not need to be authorised by Bolivia’s Regulatory Body, as WHO-prequalification is presumed to mean that they were produced in accordance with Good Manufacturing Practices.

As noted, the introduction process is due to commence in October 2015, with one dose of vaccine to be given to all children reaching two months of age from the launch date onwards; children having reached the age of 2 months before the launch date will complete their vaccination schedule (including booster doses) with the oral vaccine. An expected coverage rate of 95% is expected to be reached in the corresponding cohorts, with 5% wastage. Accordingly, the following numbers of doses and syringes will be required for each year:

2015: 63,471

2016: 251,033

2017: 248,278

2018: 245,435

TOTAL: 808,216

In accordance with the instructions established at the Regional meeting for the vaccine introduction process, countries will initially avail of only one dose per child in the target group. As global production increases, countries wishing to do so may add further doses to their vaccination schedules. Thus, the vaccine for Bolivia will be provided by GAVI, through the Revolving Fund for Vaccination and coordinated by UNICEF.

In order to ensure the availability of the vaccine, countries will begin vaccinating when the vaccine necessary for an annual birth cohort becomes available. Since Bolivia has scheduled the roll-out of vaccination for the fourth quarter of 2015, and taking the country’s pneumococcus vaccine introduction process as reference, vaccination will begin once the vaccines necessary for 2015 and 2016 (1.25 birth cohorts) are in store, so establishing a strategic emergency reserve.

PAHO form 173 has been used to apply to the Revolving Fund for IPV, requesting delivery in the third quarter of 2015. If the application is successful, the country will be in a condition to retrieve the vaccine and syringes from customs in the same quarter, delivering them immediately at departmental and municipal level, so that roll-out may commence on the established date. During the meeting with the departmental coordinators, it was pointed out that, in the event of any delay in the delivery, retrieval or distribution of the supplies, roll-out would be postponed under the necessary conditions to ensure total availability of the vaccine in the 2015-2016 period had been met.

The EPI plans to include a second dose of IPV in the national vaccination schedule, although this will depend on its international production and availability and on the chance of including it in the corresponding Annual Operating Programme (issued in June each year).

* 1. Expansion or improvement of the cold chain, logistics and vaccine management.

In November 2014, Bolivia’s EPI began to assess the capacity and performance of the cold chain at national and departmental level, finding it necessary to acquire refrigeration equipment (compressors) for a cold chamber, to remodel cold chain facilities at national level, to relocate the cold chamber in the city of El Alto in the department of La Paz, and to remodel cold chain facilities in the department of Santa Cruz de la Sierra. These measures would guarantee the capacity and efficiency of the cold chain in Bolivia’s major cities, where almost 60% of the population lives. Immediate distribution of the vaccine at municipal level, along with the strengthening of cold rooms in the country’s major cities will guarantee the necessary capacity for proper IPV storage.

The national and departmental cold chain has a total actual capacity of 368 cubic meters, with six cold rooms in the National Warehouse and XX in regional warehouses; according to the recent evaluation, this capacity is sufficient for the distribution and proper conservation of vaccines, including the IPV introduction process.

General information on the cold chain (latest inventory, current capacity, etc.)

Over the coming months, the cold chain inventory will be updated at national level (departments, municipalities and towns), establishing the requirements of the different levels. For this purpose, the national EPI has scheduled the acquisition of refrigeration equipment.

The PAHO regional cold-chain advisor will arrive in February, to conduct on-site evaluation in all of Bolivia’s departments, as well as holding a workshop on preventive and corrective maintenance for SEDES refrigeration technicians, who will receive tool kits and spare parts to ensure that the cold chain operates correctly nationwide.

With support from the regional advisor, rules and procedures will be updated to ensure that the cold chain is operated correctly, stressing vaccine storage and transport at all levels and during vaccination activities, in order to ensure that the vaccine is not frozen during activities.

A refrigerated vehicle has been acquired with GAVI support, to be delivered in February 2015. Additional funds are available for a second refrigerated vehicle and there are plans to acquire a further two to transport syringes and other supplies. This infrastructure will allow the EPI to guarantee the safe delivery of vaccines and supplies in the country’s difficult mountainous areas.

Vaccine and supplies management at national and departmental level is currently based on the WHO VSSM system and implemented manually at municipal and local level, using record sheets designed specifically for the purpose. The SALMI-SIAL drug management information system will be modified to include EPI vaccines in real time throughout all Ministry of Health Units. This will give up-to-date information on vaccine movement and management throughout the country. This process will require vaccination personnel to perform additional procedures. Accordingly, it needs to be included in personnel training and carefully assessed before current management processes are eliminated.

* 1. Plans to meet growing needs in waste management and injection security in order to accommodate the new vaccine.

Waste management and injection safety procedures are regulated by the national EPI and are included in the ongoing supervision and assessment of vaccination services.

Syringes and needles are deposited in sharps boxes, which are then incinerated. Empty vaccine vials and other waste are classified and disposed of in special bags, according to their potential risk.

There is a monitoring system in place for effects supposedly attributable to vaccination or immunisation (ESAVI), under the responsibility of the EPI; technical support, training and logistics are currently being coordinated to make the National Regulatory Authority (NRA) responsible for ESAVI monitoring.

Bolivia applies the WHO Open Vial policy. According to the measures decided at the Regional Meeting for IPV Introduction, multidose presentations of pre-qualified vaccines, including vaccines donated by GAVI, have been proved to be effective and safe up to 28 days after vials are opened, providing the right handling and storage procedures are followed. Accordingly, this policy will be applied if the single-dose presentation is not available.

* 1. Review of forms and systems for the collation of health and immunisation management information and figures

Several vaccination record formats are in use in Bolivia. On the one hand written records, including the children’s health booklets and vaccination booklets kept by parents to keep a record of their children’s vaccination, the vaccination booklets kept by each Health Unit for every child they vaccinate, and the vaccination booklets kept by the Health Units where all doses are recorded against the names of the children vaccinated - these two booklets are used to verify that children are vaccinated if the family booklet is lost and to monitor non-vaccinated children. Each of the country’s 264 municipalities prints their own versions of these three booklets.

On the other hand, the national health information system (SNIS), dependent on the Epidemiology Unit at departmental and national level, handles vaccination calculations and statistics, using the daily and consolidated monthly vaccination records of the health units.

ENCOVA found a plethora of record types at municipal level, most of which lack the necessary space to record new vaccines (rotavirus and pneumococcus), boosters or 4th and 5th doses of the polio and pentavalent vaccines.

Introducing IPV requires making a distinction between the inactivated and oral vaccines. Accordingly, the record formats will have to be changed at all levels of the information system. This will provide an opportunity to unify and update records. This unification should also be reflected in the statistical information systems, so that vaccine information calculation and analysis can be adapted and updated.

The Bolivian EPI will define the content and basic format of vaccination records in the first quarter of 2015. The new formats may not then be changed. Municipalities who wish to add variables or content to their information systems will have to respect the basic content in order to ensure the homogeneity of information.

* 1. Planning the supervision and evaluation of the new vaccine introduction process.

The EPI is supervised from the central level down through the different levels of the system. Likewise, the departments, health networks and municipalities are responsible for supervising lower levels under their area of influence. The PAI has developed a standardised monitoring system which includes all components of the programme, including information quality (as per the PAHO model).

During assessment and coordination with Departmental EPI coordinators, it was agreed to add specific content to monitor simultaneous dosing (OPV/IPV-Rotavirus-Pentavalent-Pneumococcus and MMR-YF) in order to identify reasons for failure to vaccinate and missed opportunities and to implement immediate corrective measures.

In order to introduce IPV, the Bolivian EPI/SEDES have drawn up checklists and timelines to monitor advances in preparation and planning, and critical points in the launch of the process, as well as producing indicators for the monitoring and supervision of the process and evaluation of its results.

As mentioned above, the most important challenge in introducing IPV will be simultaneous application of three injected vaccines. Accordingly, intensive personnel training and social outreach will be needed, with results being verified through intensive supervision of activities; the crisis plan should anticipate rejection by the population and vaccination personnel, including emergency measures to mitigate and if possible eliminate any resistance. One method of motivating staff and reassuring the population will be to record and monitor ESAVI associated with simultaneously injected Pentavalent-Pneumococcal-IPV vaccines, to determine the actual frequency of moderate to severe reactions associated with the administration of the three vaccines, comparing them with the application of one or two injected doses.

The Departmental Immunisation Committees will also be reactivated and motivated, with updated functions and activities, including a meticulous study of any reported ESAVI, reporting the results to the corresponding authorities, the community and the media.

No cases of polio caused by the wild polio vaccine have been reported in Bolivia since 1986 and neither have any vaccine-associated or vaccine-derived cases been reported. This situation is expected to be maintained over the coming years, until the worldwide eradication of polio has been certified. Accordingly, the indicators of the impact of IPV may be summarised as follows:

* The non-incidence of polio, in all its forms, is maintained.
* No significant increase in the number of ESAVIs is reported in relation to the application of IPV or the simultaneous application of injected vaccines.
* Coverage rates are sufficient (over 95%) and timely (window of opportunity of less than one month) for all doses of the infant vaccination schedule (for children aged under one year) in all the country’s municipalities.

In order to verify the impact evaluation parameters, AFP monitoring, ESAVI monitoring and vaccination coverage recording and analysis (for all vaccines) will have to be intensified and optimised at municipal level. The Coverage and Reasons for Failure to Vaccinate Surveys will provide additional support for the verification of results.

* 1. Training of health personnel (and other professionals involved in vaccination activities)

The introduction of a new vaccine requires training of vaccination personnel at all levels of the health system, as well as information and advocacy before health authorities and leaders, community leaders, the media, scientific associations and health sector trade unions throughout the country. For this purpose, information and training plans will need to be drawn up for specific groups, as well as a social outreach and mobilisation plan.

An interactive training CD will be produced which will describe the composition and characteristics of IPV, the foundations of the Global Polio Eradication Plan and regional and national endgame policies, as well as outlining the specific technical, programmatic, and administrative aspects of the vaccine introduction process, the transition towards the bivalent oral vaccine and the subsequent transition to IPV and withdrawal of OPV. This material will form the basis for cascade training, from national to operational level, and can be kept and checked by health workers at any time.

Persons to receive training will include officials from the intermediate level of the national health system, scientific associations, the media, health unit and vaccination staff and field vaccination brigades - in total, around 4000 officials.

* 1. Planning and implementation of social mobilisation, outreach and promotion activities.

ENCOVA and surveys on reasons for failure to vaccinate have provided valuable information on the running of vaccination services and alerted the health authorities regarding specific aspects that limit the results of the EPI. It is also acknowledged that the pneumococcus vaccine introduction process did not give sufficient importance to the problem of rejection of simultaneously-injected vaccines. This matter affects both health workers and parents, making a social outreach plan to persuade vaccination service suppliers and users of the need and importance of vaccines, vaccination opportunities and completing the vaccination schedule crucial to the success of the IPV introduction process.

To this end, the national EPI aims to recruit national experts in communication who would produce an IPV Communication Plan and Crisis Plan and develop an interpersonal communication workshop for immunisation officials. The WHO, PAHO, GAVI and other cooperation agencies have compiled and developed communication content and materials to facilitate the introduction process and the acceptance of simultaneously-injected vaccines; this will be included along with nationally-produced materials.

Experience in other countries indicates that issues with simultaneously-injected vaccines may be overcome by convincing and motivating health workers. Accordingly, most work in this area will focus on health teams.

**Annexes**

1. Checklist of activities for the introduction of the new vaccine and Timeline
2. Budget