Annex A. IPV Introduction Plan

Countries are required to complete and submit a vaccine introduction plan for IPV. WHO has developed guidance to support countries in developing introduction vaccine introduction plans. For a template, please see the WHO web site:

<http://www.who.int/immunization/programmes_systems/policies_strategies/vaccine_intro_resources/nvi_guidelines/en/>

This generic template is to guide countries in developing a practical plan for introducing a new vaccine.

This template is intended to provide suggestions for key areas to be considered, and as such, may be missing some items relevant to a particular country or to a particular vaccine introduction, or equally may contain some items that are not relevant. Countries should report progress on vaccine introduction planning to GAVI as per activities laid out in the NVIP.

The IPV introduction plan is the primary document that the IRC will use in reviewing the readiness of a country to introduce IPV. Countries are strongly advised to ensure their IPV introduction plan is complete and provides at least the required information as listed in this document.

IPV introduction should not displace other new vaccine introductions planned in the same year. Countries are encouraged to find synergy for IPV introduction with existing plans for other new vaccine introductions scheduled in 2014 or 2015. Potential benefits and challenges of IPV introduction with other new vaccine introductions already scheduled should be carefully considered and planned for.

**Executive summary of the introduction plan**

* Brief justification for the introduction of IPV and key complementary considerations that have been taken into account, including comprehensive approaches for disease control.

Nicaragua adhered to the objectives of the Polio Eradication Endgame Strategic Plan based on:

1. The recommendations of the strategic advisory group of immunisation experts from the WHO (SAGE) and the PAHO Technical Advisory Group (TAG);
2. The epidemiological information relating to the presence of polio cases caused by wild virus or circulating vaccine-derived poliovirus (cVDPV);
3. The existence of vaccine-associated paralytic poliomyelitis cases (VAPP).

Despite the last case of polio in the country having taken place in 1981, the worldwide polio situation continues to pose a global challenge. Even countries where there are no cases are exposed to incoming cases from countries where polio continues to circulate.

* Outline of the benefits to the population of introducing IPV and the costs to the programme of its introduction and how the country plans to sustain those costs.

The main purpose of the IPV dose is to maintain immunity against the type 2 poliovirus during and after the worldwide withdrawal of the type 2 strain from the OPV and the change from tOPV (trivalent OPV) to bOPV (bivalent OPV).

Nicaragua is in the process of graduating from GAVI support. Hence, it is eligible to receive GAVI support for one dose of IPV. Introduction will be highly cost-effective, since the country would not have fixed co-financing until 2018. In addition to the donation of 1 IPV dose, there would be auto-disable syringes and sharps boxes at USD 0.80 per immunised child, or USD 100,000 (highest value).

* Overview of how the vaccine will be introduced (national or phased introduction) and key milestones and activities, such as when the vaccine will be introduced and when preparatory activities should begin.

Vaccine introduction is projected for the last quarter of 2015, to be performed on all children reaching two months of age throughout the country. For vaccine introduction, a plan has been designed with a timeline of activities to be carried out every month, which began in August with the expression of interest by MINSA authorities.

* Overview of the capacity of the immunization programme to introduce IPV, including all aspects of supply chain and logistics, health workforce capacity, etc.

Analysis of IPV storage capacity at every level establishes that this is sufficient at each level. Should problems be encountered in any of the health units, these would be resolved by either increasing frequency of distribution or by the delivery of the equipment that is being purchased. We can rely on support from GAVI Alliance funds to resolve storage difficulties at the intermediate and local levels, and the purchase of 76 items of refrigeration equipment and their spare parts is being transacted through the Pan-American Health Organisation (PAHO).

Thanks to World Bank support, 198 items of equipment are in the procurement phase, and funds from the GAVI Immunisation Awards are going into the purchase of 30 additional items. Further reference in **Annex A – 4.**

* Summary of preparatory activities completed or to be undertaken.

The activities undertaken to date are as follows: Expression of interest by MINSA authorities; the meeting and presentation of the intention to introduce this vaccine to the members of the Sector Council and the EPI technical committee; the proposal for introduction prepared, with the calendar of activities to undertake with regard to the different components; and the budget breakdown of each of these approved by the national authorities and sent to GAVI.

The other activities on agenda will be executed depending on GAVI's approval and the funds available in the country.

Brief description of main risks/challenges associated with the introduction of IPV and outline of the mitigating strategies put into place to address these risks.

The current Nicaraguan national schedule contemplates two injectable vaccines, PCV13 and pentavalent (DPTw+HIb+HB), the same ones administered at 2-4-6 months of age. IPV introduction adds one more injectable vaccine dose for the children starting on the schedule at 2 months of age. An information and education plan will be developed to obtain parental acceptance.

The introduction of a new vaccine makes it necessary for health workers to be able to rely on all the standard information about it — conservation in the cold chain, waste management, injection safety — so as to avoid programmatic errors or incomplete schedules. Moreover, they must be trained in the proper approach to parents' questions and preoccupations. Thus, a vaccinator guide will be developed to standardise operating and communication procedures in implementing IPV introduction.

Geographic, cultural and social barriers represent a risk to the achievement of targets; nonetheless, the Nicaraguan healthcare model has enabled immunisation coverage rates of over 95% in all vaccines and in more than 78% of the municipalities through different strategies, such as for example, penetration brigades, rapid coverage monitoring, and health fairs, among others.

**This document covers the following areas:**

1. Justification for the Introduction of IPV and the national decision-making process
2. Summary on IPV
3. Introduction and Implementation Considerations
4. Situational Analysis of the Immunisation Programme
5. Monitoring and Evaluation
6. Advocacy, Communication, and Social Mobilisation
7. **Justification for the Introduction of IPV and the national decision-making process**
* Provide evidence that all key decision-makers in relevant agencies (e.g., Ministry of Health, Ministry of Finance, etc.) have been participating in discussions on the introduction, have been involved in making the final decision about introducing IPV and have endorsed its introduction.

The decision-making process for IPV introduction with GAVI support was undertaken by the authorities of the Government of Reconciliation and National Unity and authorities of the Ministry of Health after analysis of the technical justification in accordance with the following criteria:

**Global Context of Polio Eradication**

In May 2012, the World Health Assembly declared the completion of polio eradication by 2020 “a programmatic emergency for global public health”.

The WHO Executive Committee approved the targets, objectives and timelines for the Integrated Strategic Plan for polio eradication (January 2013) and urged all countries solely using OPV to introduce at least 1 dose of IPV into their routine immunisation schedules. The main purpose of the IPV dose is to maintain immunity against the type 2 poliovirus during and after the worldwide withdrawal of the type 2 strain from the OPV and the change from tOPV (trivalent OPV) to bOPV (bivalent OPV).

Principal objectives of the Strategic Plan

• To detect and interrupt all poliovirus transmission

• To strengthen immunization systems and withdraw OPV

• To contain poliovirus and certify transmission interruption

• To plan the legacy of the polio eradication initiative

In addition, the WHO Strategic Advisory Group of Experts on immunisations (SAGE) presented the recommendation to withdraw OPV2, since: 1.- circulating vaccine-derived poliovirus (cVDPV) is a problem in several countries using the trivalent oral polio vaccine (tOPV) and showing low immunisation coverage; 2.- the majority of vaccine-derived polio cases (cVDPV) is due to the type 2 strain; and 3.- withdrawing virus type 2 from the OPV will reinforce the global eradication of polio through the elimination of the type 2 poliovirus and the acceleration of eradication for virus types 1 and 3, since bivalent OPV (1 and 3) gives much more protection against poliovirus types 1 and 3 than trivalent OPV.

At the November 2013 meeting, the SAGE once more made several recommendations to combat the risks of wild poliovirus and polio in relation to IPV introduction on the global level in the context of the polio endgame. These included:

* Countries introducing 1 dose of the inactivated polio vaccine (IPV) into the routine immunisation schedule should administer the dose at or after 14 weeks of age, in addition to the 3 to 4 doses of oral polio vaccine (OPV) in the primary immunisation series.
* Countries may be flexible so as to take account of alternative schedules; for example, introducing IPV at an earlier stage, based on the local or epidemiological conditions of the region.
* To help accelerate the eradication and reduction of vulnerability, all countries endemic for polio should establish a plan for IPV.

The Technical Advisory Group for immunisations in America (TAG), at the extraordinary meeting of April 2014, was in agreement with the renewed efforts to eradicate polio and with the objectives or the eradication endgame. These efforts include the permanent elimination of the oral polio vaccine from the routine immunisation schedule.

It technically recommends that “Countries should consider IPV introduction in sequential schedules, ideally, 2 IPV + 2 OPV” and “should a country be considering the possibility of introducing a single IPV dose, this should be given with the first DTP dose (1 IPV + 3 OPV)”; it also recommends that countries should not consider changing directly to an exclusively IPV schedule at this time”.

**Disease burden**

The last case of poliomyelitis in Nicaragua occurred in 1981.

On the international scale, since the polio eradication initiative was launched by the World Health Assembly in 1988, the global incidence of polio has gone down by more than 99%, and the number of countries where polio is endemic has been reduced to 9, with a total number of 123 wild polio cases reported on 16 July of this year. Up to 2012, there were cases of type 3 virus, but all the cases for 2013 and 2014 are type 1 and the wild poliovirus type 2 has not been detected since 1999.

As of 19 August, 10 countries had active outbreaks of the wild poliovirus that could extend to other countries through human circulation: 131 cases, in comparison with the 170 of the same period in 2013. Nevertheless, the cases in countries endemic for polio have doubled, while they have decreased in non-endemic countries. The only type that has circulated during the last two years is type 1.

Efforts toward eradication are threatened by the presence of circulating vaccine-derived poliovirus (cVDPV), which in the greater part are type 2. Up to July 2014, 29 cases of cVDPV have been recorded, all of them corresponding to virus type 2.

On another side, the risk of vaccine-associated paralytic poliomyelitis (VAPP) in Latin America and the Caribbean is at 1 case for every 1.04-1.39 newborns and 1 case of every 6.73-8.95 million doses. There have been 191 cases of VAPP in Latin America and the Caribbean between 1992 and 2011, of which 72 were immunised and 119 were not; in accounting for VAPP amongst immunised subjects, 49% had the first dose, 21% had the second and 30% had the third or a higher dose. By introducing IPV as a first dose, the 49% of VAPP would decrease and with two first doses of IPV this would reduce 21% or more.

**Financial feasibility**

The financial feasibility of this introduction with prospective GAVI support was analysed as being highly cost-effective, since the country would not have fixed co-financing with one dose up to 2018.

Nicaragua is a country in the process of graduating from GAVI support. Hence, it is eligible for IPV support. The support consists of the donation of 1 IPV dose and the associated supplies (auto-disable syringes and sharps boxes).

Moreover, it would receive USD 0.80 for every immunised child, or USD 100,000 (highest value) as financial support for the introduction of the vaccine. Co-financing will not be required; this support will be valid up to 2018, with the possibility of extending up to 2014. (In 2018, the GAVI support phase for polio eradication will end, with the possibility of extending up to 2024).

Based on the information previously set forth, the authorities of the Ministry of Health made the decision to prepare submission of an expression of interest in the introduction of the IPV with GAVI support, channelling this thourgh the Pan-American Health Organisation of Nicaragua.

Expression of interest in the introduction of IPV signed by the Minister for Health is attached in **Annex A – 1.**

* Describe the involvement of other relevant stakeholders, e.g. Civil Society Organizations, community representatives, national regulatory authorities, academic and training institutions and, as applicable, the private sector, in the decision-making process.

The proposed introduction of IPV into the national immunisation schedule of Nicaragua was broadly disseminated to several sectors: the officials of the institutions comprising the sector council — UNICEF, USAID, UNFPA, PAHO; the proposal was also presented to the technical committee, to specialists from scientific associations who are opinion leaders, to representatives of the Nicaraguan community movement, universities, and to MINSA authorities from the different technical areas such as the Directorates of Health Surveillance, External Cooperation, Health Services, Planning and Development, and Education and Research.

Attached are the signed attendance sheet and minutes of the meetings of the Sector Council dated 15 and 29 August, and of the technical committee dated 21 August of this year. **Attachment 5.**

* Describe the technical and operational feasibility of introducing IPV, based on country experience with other new vaccine introductions.

The country has had experience in the introduction of the rotavirus and PCV13 vaccines in 2006 and 2010, respectively, in which all the components recommended in order to achieve the targets set were developed. The rotavirus vaccine achieved coverage rates of 94% nationwide in 2009; starting in 2010, the coverage rates achieved were 95% and over. In the case of PCV13, starting in 2011, coverage rates of 95% and over were achieved nationwide. This is due to the Family and Community Health Model (MOSAFC) implemented since 2007 by the Ministry of Health (MINSA) as a regulatory entity. This serves as a roadmap towards equity, a challenging commitment to guarantee access to health services and reduce the gaps in healthcare.

This Model responds to the needs and expectations of the population so that they may obtain a comprehensive quality healthcare with human warmth and respect that guarantees the right to health, a fundamental pillar of the policies of the Government of Reconciliation and National Unity, characterised in principle by being free and universal, in the spirit of solidarity. It is a highly inclusive and comprehensive model that covers the different strategies of the EPI, such as systematic immunisation in the health services, field visits, national immunisation days, school immunisation and monitoring campaigns. The EPI also relies on the immunisation brigades acting in geographical areas of difficult access, so as to attain the coverage levels recommended in order to keep the population protected against vaccine-preventable diseases.

Moreover, the country avails of the children's immunisation monitoring book, which ensures the recording and monitoring of their entire immunisation schedule. This is available in all health units and sectors and serves as a tool that allows for verification of vaccine status in the event of immunisation card loss.

Another strategy that has been implemented and improved during the last few years is the conduct of rapid coverage monitoring, which makes it possible to identify children who have not been immunised or are insufficiently immunised, and immunise them.

In addition, assessment has been made of cold chain storage capacity, which in Nicaragua's case will fulfil requirements at all levels once procurement of the cold chambers for the CENABI concludes and the refrigerators to be donated by the World Bank are available, along with those to be acquired with GAVI support and with the immunisation award given by GAVI.

Effective Vaccine Management (EVM) evaluation in the country will be conducted at the end of this year or at the beginning of 2016.

1. **Summary on IPV**
	1. **Vaccine preference** Work

Nicaragua is a country with health units of difficult geographic access. Population density is not high in either urban or rural areas. Hence the country prefers the following vaccine presentations:

**Table B1. IPV vaccine preferences and estimated date of introduction**

|  |  |  |  |
| --- | --- | --- | --- |
| **Preferred IPV vaccine** | **Month and year of first vaccination** | **Preferred second presentation** | **Preferred third presentation** |
| 1-dose presentation | October - 2015 | The three presentations, as per analysis  | 5-dose presentation |

* For more information on vaccine presentations, please consult the UNICEF Product Menu: <http://www.unicef.org/supply/index_66260.html>. A list of final product presentations will be available after the UNICEF tender has concluded (by March 2014) and will depend upon WHO pre-qualification processes.

* More information on current WHO pre-qualified IPV vaccines can be found at:

<http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html>.

2.2 Country licensure status

* Provide information on the status of the NRA in the country, i.e. whether functional and/or WHO-certified.

Although the national regulation authority has been constituted and has its functions, it does not have to intervene in what regards the release of vaccine batches entering the country through the Rotating Fund, since these are vaccines prequalified by the WHO; its regulatory mechanism is exercised on vaccines entering for the private sector.

State whether national vaccine licensure will be needed for IPV, in addition to WHO prequalification, and if so, describe the procedure and its duration. State whether the country accepts the Expedited Procedure for national registration of WHO-prequalified vaccines.

Vaccines entering the country through the Rotating Fund do not need any additional requirement. They are subject to the production protocols inherent in the vaccines.

* Provide the actual licensure status of the preferred presentation and of any alternative presentations.

N/A

* Describe local customs regulations, requirements for pre-delivery inspection, special documentation requirements that may potentially cause delays in receiving the vaccine. If such delays are anticipated, explain what steps are planned to handle these.

Vaccines requested through the PAHO Rotating Fund are subject to the following procedure: yearly programming is done in July of the preceding year and sent to PAHO Nicaragua to be forwarded to the Rotating Fund. Subsequently, in November, the reconfirmation for the first quarter of the following year is sent to the PAHO, and the next reconfirmations in the course of the following months, until all the vaccines for systematic administration are ensured, such as during Immunisation Day or campaigns programmed for the year.

The PAHO gives notice of purchase orders for vaccines placed in accordance with reconfirmations by email to the EPI.

The PAHO notifies the CIPS (health supplies office) and the EPI of the probable date of vaccine arrival, attaching all documentation supporting the date of vaccine arrival.

The CIPS performs all transactions for vaccine release from customs and delivers this to the biological products centre, CENABI, where the vaccine is received, inventoried and stored as per established standards. The same is done with the syringes, except that these are stored in the CIPS dry stockrooms, from where the SILAIS get them on a monthly basis, as with the vaccines.

2.3 Target population and vaccine supply

* Provide estimates of the target population for a single dose of IPV to be given with OPV3 at the DTP 3/Penta 3 health contact (or DTP 2, depending upon alignment with current DTP dosing schedule, as illustrated in section 2.3 of the IPV Guidelines) by year through 2018, starting with the first year of IPV introduction. Please adjust the targets for the first year of IPV introduction for the month when vaccinations begin.[[1]](#footnote-1)

In calculating the target population for IPV administration, account has been taken of the population identified by the Nicaraguan Institute of Development (Instituto Nicaragüense de Desarrollo, INIDE) for 2015, consisting of 135,905 children.

The first year of introduction, to be evaluated in 2016, is forecast to reach the target of 95% and more for doses applied to children under one year of age for that period.

The plan to be adopted shall be that of introducing IPV at 2 months of age, in accordance with the following schedule:

|  |  |
| --- | --- |
| **Programme for IPV doses**  | **Calendar for single IPV doses** |
| 2 months | Single IPV dose + 1st pentavalent + 1st rotavirus + 1st pneumococcal |
| 4 months  | 1st OPV dose + 2nd pentavalent + 2nd rotavirus + 2nd pneumococcal |
| 6 months | 2nd OPV dose + 3rd pentavalent + 3rd rotavirus + 3rd pneumococcal |
|  |  |
| 18 months | OPV reinforcement on National Immunisation Day + DPT reinforcement |

* GAVI procures and delivers vaccines through UNICEF or the PAHO Revolving Fund. If an alternative mechanism is requested, or the vaccine will be purchased by the country itself, please document the following:

 The country will acquire the IPV through the PAHO Rotating Fund.

* Other vaccines or immunisation commodities procured by the country and descriptions of the mechanism used; and

The same mechanism described, through the Rotating Fund, shall be used for the sharps boxes and syringes.

* The functions of the National Regulatory Authority (as evaluated by WHO) to show they comply with GAVI requirements for procurement of vaccines and supply of assured quality.

The country has a National Regulatory Authority; however, the vaccines acquired through the Rotating Fund do not need any requirement in addition to those sent by PAHO.

1. **Introduction and Implementation Considerations**
	1. Policy Development
* Describe any need to alter the National Immunization Policy to include IPV in the national immunization schedule, including any changes in schedule and the likely impact on existing vaccination contacts this may have. Be sure to clearly describe the timing of IPV to align with the current DTP dosing schedule (see section 2.3 of the IPV Guidelines).

IPV introduction does not require any changes in the immunisation policy; it is included in the national immunisation schedule of the country, which is described below:

|  |
| --- |
| **Immunisation Schedule of Nicaragua** |
| Vaccines | Diseases prevented | Age immunised | No. doses | Reinforcement dose | Administration |
| BCG | Serious forms of tuberculosis | Newborn | 1 dose (0.1 cc) | None | Intradermal, in the upper third part of the deltoid region, left arm, syringe 0.5 cc x 27G x 3/8 |
| Oral Polio | Polio | 4-6 mos. | 2 doses (2 drops) | 1 additional dose to 18-month children on Immunisation Day | Oral |
| IPV | Polio | 2 mos | 1 dose (0.5 cc) | None | Deep intramuscular in the median third of the outer anterolateral thigh |
| Pentavalent DTP/HB+Hib | Diphtheria, whooping cough, tetanus, hepatitis B, meningitis, and pneumonia caused by Haemophilus influenza type B | 2-4-6 mos | 3 doses (0.5 cc) | None | Deep intramuscular in the median third of the outer anterolateral thigh. Syringe 0.5 cc x 23G x 1 |
| Rotavirus | Severe diarrhoea through rotavirus | 2-4 mos. | 2 doses (1 cc) | None | Oral |
| Pneumococcal conjugate | Pneumonia, meningitis and other diseases caused by serotypes contained in the vaccine | 2-4-6 mos. | 3 doses (0.5 cc) | None | Deep intramuscular in the median third of the outer anterolateral thigh. Syringe 0.5 cc x 23G x 1 |
| MMR | Measles, mumps, rubella | 1 yr. | 1 dose (0.5 cc) | 1 MR dose to children aged 1-4 yrs. on monitoring campaigns | Subcutaneous, upper part of arm (deltoid muscle) Syringe 0.5 cc x 25G x 5/8 |
| DPT | Diphtheria, whooping cough, tetanus | 18 mos. (year after 3rd pentavalent dose) | 1 dose (0.5 cc) | 1 dose at 6 yrs. | Intramuscular, in the median third of the anterolateral thigh. Syringe 0.5 cc x 23G x 1 |
| Diphtheria, whooping cough, tetanus | 6 yrs. | 2 doses (0.5 cc) | None | Intramuscular, in the upper part of the arm for older children. Syringe 0.5 cc x 23G x 1 |
| Dt | Tetanus | 10 yrs. | 1 dose (0.5 cc) | If no record of basic schedule, administer 2nd dose after 4 weeks, a 3rd dose after 6 months, a 4th dose 1 year after the 3rd and a 5th dose 1 year after the 4th  | Intramuscular in the arm. Syringe 0.5 cc x 23G x 1 |
| Tetanus | Women at 20 (or first pregnancy). Men at 20 | 2 doses (0.5 cc) |
| Influenza | Seasonal flu, paediatric | 6 to 23 mos. w/ chronic diseases | 1 dose (0.25 cc) | 2 doses when administered for the first time | Intramuscular in the arm. Syringe 0.5 cc x 23G x 1 |
| Seasonal flu, adults | > 65 w/ chronic diseases, pregnant women | 2 doses (0.5 cc) | Yearly |

* Provide information on immunization practice decisions, e.g. injection site, order of injections, and which limb for two or more injections.

IPV will be applied through intramuscular administration at the outer thigh, in a dose of 0.5 ml. Since the IPV, the pentavalent and pneumococcal vaccines are administered at the same time, the IPV can be administered to the same thigh with the pneumococcal vaccine, with a separation of at least 2.5 cm; the pentavalent vaccine could be applied to the other thigh.

* Describe any integrated delivery of other health interventions that are planned.

Immunisation with IPV will be integrated into systematic immunisation activities in all health units and sectors. The penetration brigade activities coincide with other activities such as checking children's growth and development, prenatal check-ups, and medical and dental consultations.

The vaccine will be administered in the 19 SILAIS, 153 municipalities and 1,500 family and community health teams (ESAFC) as per the set-up of the new family and community health model (MOSAFC).

The ESAFC health teams are composed of health staff attending to populated areas (sectors) where communities, districts or areas group between 600 to 1000 families together, respectively equivalent to 3000-5000 rural and urban inhabitants.

* 1. National coordination mechanism to ensure successful introduction
		+ - Summarize the IPV introduction timeline, as presented in Annex C.

The timeline for the injectable polio vaccine introduction plan was prepared in consideration of all its components, organised by activity, to begin in the month of August; this timeline is reflected as **Attachment 2, Annex – C.**

Describe the national level management process to oversee IPV introduction, including any steering committee and/or subcommittee tasked with various activities for the introduction.

Oversight to attain objectives is projected on all levels for the stages prior to, during and after the introduction of the new vaccine, based on the competences of each level, ensuring that all components (organisation, planning, training, cold chain, distribution, information system, logistics, stock management and social communication) are being executed in accordance with the plan. The checklist of programmed activities will be used and consideration will be taken of the difficulties encountered to correct points, or the messages transmitted in the course of training that need to be reinforced.

Management capacities for supervision will be strengthened: supervision by levels of competence, from the national to the regional level, from this to the municipal level and from the municipal level to its health units. A management guide will be made available for the purpose, making it possible to check the progress of preparations before introduction, or the points to verify during introduction.

During IPV introduction, operational aspects will be supervised, such as compliance with standards in terms of the cold chain or injection safety; the administration schedule, the route of administration, and waste disposal. Two months after the introduction, another oversight session will be conducted to plan changes or strengthen strategies where necessary, in accordance with monthly indicator monitoring.

The National EPI conducts two evaluations with all the departments to measure progress in compliance with indicators. In this case, an internal evaluation will be conducted every fourth months, with continuous monitoring of target coverage by level of competence, so as to correct the difficulties encountered as regard the programme strategies.

|  |  |  |  |
| --- | --- | --- | --- |
| Committees |  | **Activities** | **2015** |
| **Monitoring of IPV introduction activities** |
| **May** | **June** | **July** | **Aug** | **Sept** | **Oct** | **Nov** | **Dec** |
| National | Presentation of approved proposal to the national committee and adjustment of plan |  |  |  |  |  |  |  |  |
| Information to the Sector Council and technical committee |  |  |  |  |  |  |  |  |
| Monitoring of activities |  |  |  |  |  |  |  |  |
| SILAIS | Start of committee operation |  |  |  |  |  |  |  |  |
| Monitoring of activities |  |  |  |  |  |  |  |  |
| Municipalities | Start of committee operation |  |  |  |  |  |  |  |  |
| Monitoring of activities |  |  |  |  |  |  |  |  |

* 1. Affordability and Financial Sustainability
* Summarize the budget and financing of IPV introduction, as presented in Annex D.
* Provide the method used to estimate these costs.

The costs were obtained from previous experience with other new vaccine introduction campaigns and programme operativity in other activities.

* Include the identification of the non-vaccine operational costs for introduction and whether funds are secured.

Costs not related to the vaccine, such as staff salaries, building maintenance, payments for basic utilities, etc., will be assumed by the Ministry of Health.

* Discuss the overall trend of country immunization financing, of both government funding and donor funding (if applicable), and plans to absorb the additional costs of IPV.

|  |  |  |  |
| --- | --- | --- | --- |
|  | 2011 | 2012 | 2013 |
| COMPONENT | Total expenses per external source | Total expenses per national source | Total expenses per external source | Total expenses per national source | Total expenses per external source | Total expenses per national source |
|  | Amt. | Amt. | % | Amt. | Amt. | % | Amt. | Amt. | % |
| 1. Biological Products | 26646150 | 3140584 | 10.4 | 125000025.98 | 3294420.74 | 20.9 | 3345482 | 5487590 | 62.1 |
| 1.1. Vaccines | 26605934 | 2851391 | 9.7 | 12400837 | 2978219.29 | 19.4 | 3345482 | 5009169 | 60 |
| 1.2. Syringes | 23272.65 | 180810.4 | 88.6 | 18600 | 233946.33 | 92.6 | 0 | 370038 | 100 |
| 1.3. Consumables | 16943.53 | 108382.7 | 86.5 | 80588.98 | 82255.12 | 50.5 | 0 | 108383 | 100 |
| 2. Cold Chain | 27698 | 0 | 0 | 11417 | 0 | 0 | 0 | 0 | 0 |
| 3. Training | 55520.2 | 0 | 0 | 139095 | 0 | 0 | 13497 | 0 | 0 |
| 4. Social Mobilisation | 11711.12 | 0 | 0 | 2853.66 | 0 | 0 | 13357 | 0 | 0 |
| 5. Operating Expenses | 258631.04 | 4991691 | 95.1 | 101389.47 | 5000000 | 98 | 38692 | 5000000 | 99.2 |
| 6. Oversight | 50225.33 | 0 | 0 | 46977.1 | 0 | 0 | 73951 | 0 | 0 |
| 7. Surveillance | 27962 | 0 | 0 | 665 | 0 | 0 | 87730 | 0 | 0 |
| 8. Research | 2300 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9. Evaluation | 6336 | 0 | 0 | 5259.75 | 0 | 0 | 30952 | 0 | 0 |
| 10. Health Information Systems | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 11. Legal Framework and Advocacy | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 12. Planning and Coordination | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 27086534 | 8132275 | 23.1 | 12807682.96 | 8294420.74 | 39.3 | 3603661 | 10487590 | 74.4 |

The tax fund financing percentage for costs related to immunisation has been increasing over the past few years. Financing for the years 2011 to 2013 has been taken in the analysis of this plan. Funding on the part of the Government increased from 23% in 2011 to 74.4% in 2013. In 2011 and 2012, the amount of foreign funding recorded is due to receipt of a donation in 23-valent pneumococcal vaccine at a cost of $ 54, which increased this portion of the funding. The country assumes guarantee for immunisation-related expenses within its fiscal budget.

* If co-financing, please indicate how the co-financing amounts will be paid (and who is responsible for this).

NA

* 1. Overview of cold chain capacity at district, regional and central levels
* Describe adequacy of storage capacity for IPV at each level of the cold chain, based on the vaccine supply and distribution system planned for the introduction.

To analyse IPV storage capacity, a detailed assessment was conducted on every level, based, first of all, on existing storage capacity for the rest of the vaccines, to which the preferred presentations of IPV were added, as previously indicated in point 2.1, vaccine preference.

On the national storage level, existing capacity is 120 m3. The vaccines currently in the national schedule plus IPV would use up full capacity.

For the 18 subordinate storage spaces, in 89%, vaccines currently on the regular schedule plus IPV would use up full capacity, while in 11%, accounting for two sub-national stockrooms, there would be storage problems.

In the stockrooms of the 153 municipalities, storage capacity is sufficient.

There is sufficient storage capacity for the existing schedule plus IPV in 75% of the 790 health establishments. In the remaining 25%, there are storage difficulties regarding the current vaccines.

Distribution every 15 days has been projected on the levels where this would be necessary and in the projects described in the following paragraphs to adapt storage capacity; details are given in **Annex A – 2 and 3**

* Where capacity is deficient, provide an estimate of needs and budget for increased transport and cold chain at central level (cold rooms, refrigerators, cold boxes and icepacks, vaccine carriers) to accommodate IPV.

During the last few years, the strengthening of the Expanded Programme on Immunisation and the incorporation of new vaccines, in addition to the growth of the vulnerable population and strategies to reach target population, have brought the capacity of the national stockrooms to their limit. For this reason, transactions are currently underway for the acquisition of two new refrigeration chambers which will increase useful volume up to 160 cubic metres, enabling the EPI to fully deploy its activities in the coming years and fulfil the purposes and objectives of the programme, such as the introduction of more vaccines.

Likewise projected is the acquisition of a 20-cubic metre refrigerated vehicle for the safe transport of vaccines from the central to the sub-national levels, maintaining the frequencies of distribution operations.

We are relying on the funding support of the GAVI Alliance to resolve the difficulties of storage on the sub-national and local levels, and the purchase of 76 items of refrigeration equipment with their spare parts is being transacted through the Pan-American Health Organisation (PAHO).

Thanks to World Bank support, 198 items of equipment are in the procurement phase, and funds from the GAVI Immunisation Awards are going into the purchase of 30 additional items. Further reference in **Annex A – 4.**

* Provide evidence of availability of sufficient funding at local levels for the ongoing power supply and maintenance of any new cold chain equipment.

Funding is available in the fiscal resources of the Ministry of Health to assume the costs of basic utilities, which include continuous power supply and the maintenance of any new cold chain equipment.

* 1. Waste Management and Injection Safety
* Describe existing injection safety and waste management activities and detail whether any changes are needed to accommodate IPV in line with national policies and how and when this will be ensured.

In the orientation sessions for health staff, they have been told that negligent handling of waste puts them and the general population in high risk of suffering injuries from needles, and hence, syringes and needles must never be thrown into open areas where the population might pick them up, step on them or come into any form of contact with them. Needles as well as syringes must be deposited in puncture-resistant sharps boxes placed as closely as possible to where these are to be used.

It has been made a standard to burn the sharps boxes in a metal barrel as the next best option to incineration. Health establishments in urban areas must have a barrel specifically for this procedure, which will be equipped with an iron grill. It will also be perforated to prevent the concentration of smoke.

In the case of rural health establishments, a barrel such as previously described will also be used, but part of this will be buried in the ground at a depth of approximately 20 cm. so that it remains fixed. Next, the boxes where the used syringes, needles and vials have been collected will be placed on the grill and fire will be set to them, taking care that all the materials are incinerated.

If all the above are not available, a deep pit will be dug to burn and bury the waste.

As regards the handling of waste from multi-dose vaccine vials, these must be discarded after 6 hours or at the end of the session, whichever comes first. The WHO-prequalified inactivated polio vaccine has no preservatives or is preserved using 2-phenoxyethanol. This means that the multi-dose vials must be discarded at the end of the immunisation session or after 6 hours of having been opened.

In order to prevent programmatic incidents, it will be ensured that, before introduction, the vaccinator guide will contain the topic dealing with the benefits of the IPV presentation in multiple doses without preservatives and its risks of contamination, vis-à-vis good immunisation practices.

After the introduction, evaluations will be performed to determine levels of knowledge and compliance among the health staff as regard the proper handling of IPV, and corrective training will be implemented if necessary.

Before the vaccine launching, signs will be placed on the refrigerators of all levels indicating that the open vials of the vaccine must be discarded at the end of the immunisation session or six hours after they are opened, whichever comes first,

* If a country self-procures vaccine delivery devices, provide information on whether these devices are WHO pre-qualified, and if not, the process in use at national level for the licensure of their use in country.

 NA

* 1. Health Worker Training and Supervision
* Describe the current adequacy of trained human resources to introduce IPV across all sectors of the immunization programme, e.g. for vaccine storage and management, in-country distribution, training of healthcare workers at peripheral levels, supervision, delivery, etc.

The persons responsible for the EPI at all levels are qualified doctors and nurses who have participated in the training sessions imparted in all previous introductions, annual Immunisation days and targeted training on immunisation topics and the cold chain; moreover, in the majority of the SILAIS, they enjoy the support of vaccine bank staff and cold chain technicians, whereby all of them are responsible for effective vaccine handling.

The procedures related to IPV will be standardised with a view to this vaccine introduction through workshops held in every region. The vaccinator guide will be made available for the purpose.

* Describe how any additional need will be addressed.

The plan is being prepared with all its components; should an unforeseen problem arise, it shall be up to the national committee to handle it immediately towards rapid solution.

* Provide information on the development and provision of training materials for IPV, e.g, handbook for health workers, FAQs, fact sheets, training video, posters, pre- and post-knowledge tests, etc.

The preparation of the vaccinator guides, the management instructions, frequently-asked questions and all material on Information, Education and Communication shall be designed, developed and distributed within the timelines projected in the calendar of introduction in Annex C.

* Describe the training plan, method, and any refresher training on immunization practices (e.g. injection safety, AEFI communications, etc.).

The procedures related to IPV introduction will be standardised with a view to this introduction drive through workshops held in every region. The vaccinator guide will be made available for the purpose.

Management capabilities for oversight will be strengthened and supervision will be conducted by level of competence, from the national to the regional level, from this to the municipal level, and from the municipalities to their health units.

The National EPI conducts two evaluations with all the departments to measure progress in compliance with indicators. In this case, an internal evaluation will be conducted every fourth months, with continuous monitoring of target coverage by level of competence, so as to correct the difficulties encountered as regard the programme strategies.

The introduction of a new vaccine entails changes in the information system from recording on the immunisation card and in the monitoring logbook to the report forms and the automated system, for which reason this entire process shall be strengthened to prevent data loss.

The highest percentage of vaccine administration is performed by nursing staff; i.e., in some places it is also administered by the doctor. Hence, training in management instructions, with the management details of oversight, monitoring, evaluation, vaccine distribution and indicators will be imparted to the SILAIS staff and the EPI implementors in the municipalities, and training on the operational contents included in the Vaccinator Guide will be conducted from the national level to the SILAIS, from these to the municipalities and from these to the health units.

In addition to the presentations and most frequent questions and answers, the training will be supported by a CD self-study aid that the health staff can review as many times as necessary in their work area.

* Outline any plans for increased supervision activities before, during and after the introduction of IPV.

Oversight to attain objectives is projected on all levels for the stages prior to, during and after the introduction of the new vaccine, based on the competences of each level, ensuring that all components (organisation, planning, training, cold chain, distribution, information system, and social communication) are being executed in accordance with the plan. The checklist of programmed activities will be used and consideration will be taken of the difficulties encountered to correct points that need to be reinforced.

In addition, the results achieved will be monitored to define changes or reinforce strategies wherever necessary.

* 1. Risks and Challenges
* Identify risks and challenges to the new vaccine introduction – e.g. financial, mobilization of communities, programmatic, etc., - and outline the plans to address them.

**Programmatic risks and challenges:**

The current Nicaraguan national schedule contemplates two injectable vaccines, PCV13 and pentavalent (DPTw+HIb+HB), the same ones administered at 2-4-6 months of age. IPV introduction adds one more injectable vaccine dose for the children starting on the schedule at 2 months of age. An information and education plan, to be set forth in the pertinent chapter, will be developed to obtain parental acceptance.

Another point to be addressed is that the introduction of a new vaccine makes it necessary for health workers to be able to rely on all the standard information about it — conservation in the cold chain, waste management, injection safety — so as to avoid programmatic errors or incomplete schedules. Moreover, they must be trained in the proper approach to parents' questions and preoccupations. Thus, a vaccinator guide will be developed to standardise operating and communication procedures in implementing the introduction.

Geographic, cultural and social barriers: The healthcare model of Nicaragua has allowed for immunisation coverage rates of over 95% in all vaccines in over 78% of its municipalities; nonetheless, there still are health units and municipalities with coverage levels under 95% for reasons of geographic accessibility or cultural and social causes.

To decrease this risk, in places of difficult access, the country implements different strategies to reach this population, such as penetration brigades, rapid coverage monitoring and health fairs, among others.

1. **Situational Analysis of the Immunisation Programme**
	1. Summarize the country context, health system, health priorities, and organizational structure of National Immunization Programme.

Nicaragua has a territorial extent of 130,373.4 square kilometres, of which 120,339.2 km2 is land area. Administratively, it is divided into fifteen departments and two autonomous regions, with a total number of 153 municipalities. Geomorphically, it has three well-defined regions: a) the Pacific Region, principally urban, which concentrates approximately 53.4% of the population; the main cities of the country are located here, centralising economic activity and communication routes; b) the Central Region, which concentrates 33.6% of the population; and c) the Caribbean Region, with an extensive alluvial plain furrowed by numerous rivers and broad expanses of rainforest, which covers 46% of the national territory and only accounts for 13% of the population; hence, a low population density (10 inhabitants/km2) and a larger indigenous population. The communication routes linking Pacific and Central areas with the Caribbean zone are limited, whereby the most common channels are aerial and fluvial.

The distribution of Departments per Region is as follows:

* Pacific region: Chinandega, León, Managua, Masaya, Carazo, Granada and Rivas.
* Central region: Nueva Segovia, Madriz, Estelí, Jinotega, Matagalpa, Boaco and Chontales.
* Caribbean region: Autonomous North Atlantic Region (Región Autónoma Atlántico Norte, RAAN), Autonomous South Atlantic Region (Región Autónoma Atlántico Sur, RAAS) and Río San Juan

Currently, for purposes of comparison as regards the Ministry of Health, the country is divided into 19 Local Systems of Integrated Healthcare (Sistemas Locales de Atención Integral en Salud, SILAIS), which, in the majority of cases, are similar to its political and administrative divisions, except for RAAN, which, due to geographic features and population dispersion, has been comprised of 2 SILAIS since April 2012: Bilwi and Las Minas. This also happened with the Chontales SILAIS, which was divided to form Zelaya Central SILAIS.

According to the last three census, Nicaragua has reduced its population growth rate from 3.5% (1971-1995) to 1.7% (1995-2005), and an average growth rate of 1.2 is forecast for the 2010-2015 period. According to estimates and forecasts of the National Institute of Information for Development (Instituto Nacional de Información para el Desarrollo, INIDE), the total estimated population for 2010 was 5,815,526 inhabitants, of which 49.5% are male and 50.5% are female, to a proportion of 98.3 males per 100 females. Of the total population, 56% live in the urban area and 44% in the rural area.

Poverty is the principal conditioning factor of the Nicaraguan population's state of health. Four out of every ten people (39.4%) live on less than a dollar day and three fourths of the population (75.8%) survive on less than two dollars. The rural areas and the Central Region are the parts that contribute most significantly to the overall and extreme poverty of the country.

The United Nations Inter-Agency Group for Child Mortality Estimation has calculated that the under-5 mortality rate went down from 32.4 per 1000 live births in 2006 to 25.6 per 1000 live births in 2011. The under-1 mortality rate went down from 26.8 to 21.6, while neonatal mortality has gone down from 15 to 12.5 per 1000 live births for the same period (UN Inter-Agency Group for Child Mortality Estimation, IGME 2012).

This progressive mortality drop in infants and children under five is associated to the increase of immunisation coverage, sanitation programmes, breast-feeding promotion and the control of diseases. Moreover, this behaviour on the part of neonatal mortality is associated to prenatal care and the coverage and quality of institutional response to childbirth.

* 1. Geographic, economic, policy, cultural, gender and social barriers to immunization described under Risks and problems, 3.7
* Please complete Table B2 below to report immunisation coverage data for the two most recent years. As a part of the priority for gender parity and equity, please report coverage data disaggregated based on sex if available.

**Table B2. Trends in national vaccine coverage**

|  |
| --- |
| **Trends of national vaccine coverage (percentage)**  |
| **Vaccine** | **Vaccine Used** | **Target population****(number by age and sex, if available)****)** | **Coverage reported (JRF)** |
| **Most recent year (2013)** | **Previous year****(2012)** |
| BCG | INTERVAX (10-dose vial) | 140146 | 114.54 % | 118.06 % |
| OPV 3 | NOVARTIS (20-dose vial) | 140146 | 108.37 % | 108.75 % |
| DPT-HB+Hib 3 | HEBER BIOTEC (1-dose vial) | 140146 | 108.29 % | 108.43 % |
| Rotavirus 3 | MERCK/GLAXO SMITH KLINE | 140146 | 106.47 % | 106.06 % |
| Pneumococcal 13-valent  | WYETH PHARMACEUTICALS | 140146 | 107.91 % | 107.11 % |
| MMR 1 | SERUM INSTITUTE OF INDIA | 139575 | 113.54 % | 114.37 % |
| DPT 1 | BIO FARMA | 139575 | 95 % | 84 % |
| DPT 2 | BIO FARMA | 537.321 | 45 % | 15 % |

* Please describe any specific geographical, economic, policy, cultural, gender and social barriers to immunization. Given the priority of GAVI to ensure gender parity and reduce inequity in immunisation services, please describe any gender and/or equity analyses that have been conducted including actions taken to mitigate barriers.

Nicaragua has 153 municipalities, within which there are difficulties of geographic access and economic and cultural problems defined as social determinants that have influenced low immunisation coverage. Based on these social determinants, the MINSA has delimited 36 municipalities, given priority in integrated health interventions since 2012; these municipalities are part of the health service strengthening project with emphasis on immunisation supported by GAVI.

* 1. Findings from recent programme reviews

* Highlight key competencies/strengths of the immunization programme that make it feasible to carry out IPV introduction – including recent changes to address any weaknesses previously identified.

The principal achievements attained by the EPI are:

1. Increase in the municipalities with coverage rates of 95% or more, from 59% to 75% at the close of 2012.
2. International quality indicators met on measles, rubella and acute flaccid paralysis (AFP) surveillance at over 80%, which is the established standard.
3. 7 citizen power immunisation days (JVPC) conducted, with results of 95% and over in terms of fulfilment.
4. 2 measles and rubella monitoring campaigns conducted, in 2008 and 2012, with compliance of 95% and over.
5. 2 contingency plans prepared and implemented in 2012 on the national and SILAIS levels against the risk of imported cases of measles and polio, with results of 95% and over in terms of compliance.
6. The new software of the EPI information system facilitating entry of the data records on introduced new vaccines implanted in 2011, making it possible to see doses administered and coverage of the 18 SILAIS in the country in terms of all vaccines on-line.
7. The Information, Education and Communication (IEC) Guide for the local communication plan and the immunisation booklet for community leaders designed in 2011 and the process of their training implemented at SILAIS and municipal levels.
8. The immunisation card to record the full basic immunisation schedule according to age updated in 2011.
9. The immunisation monitoring book for children updated and strengthened in 2011 to ensure recording and monitoring of full schedule per person, for life.
10. The document for the process of measles, rubella and CRS eradication prepared in 2012, and the plan for sustainability with optimum results under development, as per PAHO external evaluation visit.
11. 300 community leaders trained as local facilitators in 100% of the SILAIS in 2011 and 2012, to ensure strengthening of systematic community participation in the activities of the immunisation programme.
12. Sentinel surveillance of pneumonia and meningitis in 2 Managua hospitals and CRS surveillance in 17 regional hospitals initiated, while rotavirus surveillance was reinitiated in 4 hospitals in the country in 2011.
13. Inventory of the cold chain on the national level conducted in 2010, with a 5-year plan for requisitions and a proposal for strengthening.
14. Pilot experience with the vaccine supplies stock management system implemented in 16 SILAIS in the country and in the national EPI in 2012 and 2013. This has been installed in 100% of the SILAIS and is being expanded to the municipalities.

* National coverage rates remain at 95% in all vaccines in children under one year of age, reaching 114.5 % for BCG, 108.4 % for OPV, 108.3% for pentavalent, 106.5 % for rotavirus and 108.9% for pneumococcal, using the under-one year population as denominator, which is that established for the country, and not surviving children (one-year old population) defined by GAVI.
* Pentavalent coverage rates by municipality under 95% decreased from 63 of the 153 municipalities in 2011 to 36 of the 153 municipalities in 2012 and 33 of the 153 municipalities in 2012, an achievement that is due to the strengthening of systematic immunisation, the immunisation activities targeting municipalities at risk and remote municipalities and the contribution of National Immunisation Day, as may be observed from the following table.

|  |  |
| --- | --- |
| **Percentage by coverage range** | **Years** |
| **2009** | **2010** | **2011** | **2012** | **2013** |
| No | % | No | % | No | % | No | % | No | % |
| <80% | 13 | 8 | 12 | 8 | 18 | 12 | 10 | 7 | 13 | 9 |
| 80-94% | 50 | 32 | 50 | 33 | 46 | 30 | 24 | 16 | 22 | 14 |
| 95-100% | 30 | 19 | 20 | 13 | 22 | 14 | 31 | 20 | 25 | 16 |
| >100% | 61 | 40 | 71 | 48 | 67 | 44 | 88 | 67 | 93 | 61 |
| Total | 154 | 100 | 153 | 100 | 153 | 100 | 153 | 100 | 153 | 100 |

As regards the number of third doses of vaccine administered in 2013 in comparison with 2012, the year saw 1,055 additional doses of OPV administered, 1,389 of pentavalent, 2,133 of rotavirus and 2,720 of pneumococcal in its third year of introduction.

* Summarize findings from recent programme reviews, indicating whether the recommendations are part of a subsequent national Plan of Action, and describe the status of implementation of recommendations and how these will impact on the proposed new vaccine introduction.

International Evaluation of the National Immunisation Programme (NIP) was conducted in October 2010. The following findings were observed:

* Nicaragua considers immunisation a national priority, and this is backed by legal foundations and policy decisions.
* The new Family and Community Healthcare Model (MOSAFC) beings health services closer to the communities and has a high correspondence with the immunisation programme through its focus on disease prevention, health promotion and education.
* The country purchases vaccines, syringes and biosafety boxes though the PAHO Rotating Fund, which guarantees the timely supply of quality consumables at accessible prices.
* Human resources are highly aware, motivated and committed to the programme, giving their best under difficult circumstances.
* Immunisation is done continuously and avails of sufficient supplies.
* During the past year, there was an improvement in the epidemiological surveillance (ES) indicators for vaccine-preventable diseases (VPDs).
* Community participation is a strength in the implementation of the NIP.
* Immunisation data quality monitoring has started on the municipal level.
* In some establishments, the high rotation of operations staff affects proper programme functioning.
* It is necessary to assign resources to the intermediate and local levels for supervision, training and other operating expenses.

In May 2013, the evaluation instruments for the Epidemiological Surveillance System and Rapid Coverage Monitoring (RCM) to maintain the eradication of measles, rubella and Congenital Rubella Syndrome (M/R/CRS) were validated. The significant conclusions were as follows:

1. The national epidemiological surveillance system of Nicaragua is in perfect condition for the timely detection of circulating measles and rubella virus.
2. Nicaragua has the capacity for immediate response to the importation of measles and rubella virus.
3. RCM indicates coverage levels superior to 95% against M/R in high risk areas.
4. The tools for the evaluation of the measles, rubella and CRS surveillance system and Rapid Coverage Monitoring require changes for improved operation in the field.

November 2013 saw the evaluation of the Vaccine Supplies Stock Management (VSSM) software in controlling the inventories of vaccines, syringes and supplies, which yielded the following findings:

* VSSM was installed and implemented in the CENABI and in 89% of the SILAIS.
* At the central and regional level, the biological product stockrooms avail of computers designed for the use of VSSM.
* The retrieval of data and timely vaccine stock information has been facilitated and expedited.
* Improvement in the organisation and programming of vaccine stocks.
* Improvement in the control of vaccine inventories.
* Tallying of physical stocks against the reports generated by VSSM and Kardex is periodically conducted (on a fortnightly and monthly basis).
* Programming and timely distribution of the vaccines.
* On the level of the SILAIS, positive acceptance of the change from the manual register to an automated system.
* A management commitment is in place.
* Highlight whether there are resource constraints in implementing recommendations from recent reviews and how these will be overcome.

All the evaluations have yielded improvement plans that have been fulfilled in keeping with established timelines, in accordance with the existing resources proper to the country and resources from foreign aid.

* Describe any previous experience with introducing a new vaccine and how lessons learnt will be used to ensure a smooth introduction of the new vaccine under consideration.

With every introduction of a new vaccine, we have learnt that availing of an introduction plan helps to organise each of its components towards timely fulfilment: likewise, well-trained health staff with standardised procedures, a vaccinator guide and an information system adapted to the needs of the new vaccine facilitate the fulfilment of the objectives formulated.

Another lesson has also been that a developed national strategy for communication and advocacy addressing different audiences, partners, interested parties, communities and parents is a vital component for the success of a new vaccine introduction programme.

We have also learnt that oversight is a valuable support tool for all components, before, during and after introduction.

* 1. Stock management
* Provide a brief overview of the stock management system in use in the country, i.e. whether computerized, manual or other, highlighting foreseeable issues in stock management with IPV introduction and how these will be addressed.

In 2012 and 2013, improvements to vaccine and supply inventory management were made with the implementation of the Vaccine Supply Stock Management (VSSM) software for inventory control of vaccines, syringes and supplies on the national level, in all SILAIS and in 23 municipalities. VSSM is a useful, effective and reliable tool that integrates all processes into a single database, providing all the critical information required to administer vaccines correctly.

100% of the 18 SILAIS in the country are supplied with vaccines and consumables and their stocks are monitored on a weekly basis.

The implementation of the vaccine and auxiliary supplies inventory system has improved management processes in the handling and control of EPI vaccine stocks on the central and SILAIS levels.

* Provide a description of the transport system available for delivery of vaccines to the periphery, how this will accommodate IPV, whether the frequency of deliveries needs to be increased, and if so, whether there are sufficient funds, e.g. for vehicles, drivers, fuel, and per diem for distribution of the new vaccine at all levels.
* The central warehouse (CENABI) delivers vaccines to 14 SILAIS monthly and to 4 other SILAIS on a quarterly basis. In turn, the SILAIS deliver vaccines every 4 weeks to the municipalities and in other cases every 2 weeks. As regards the municipalities, these deliver supplies to the health establishments every one or two weeks.
* There is also a calendar for the delivery of vaccines to the different operative levels for their timely dispatch. The current transport type is institutional and conventional (pick-up tricks), with no refrigeration chamber.
* The acquisition of the refrigerated vehicle will guarantee vaccine transport from the national warehouse to those sub-national stockrooms that are accessible by land. Distribution for other storehouses will continue without modification.
1. **Monitoring and Evaluation**
	1. Updating of monitoring tools
* Describe measures to update, print and distribute EPI monitoring and supervision tools (recording and reporting formats, including tally sheets, registers, immunization cards, wall charts, computerized database, other) to include IPV and other new vaccines envisioned in the current cMYP, prior to the launch of IPV.

The necessary changes to all the forms of daily, monthly and yearly data-gathering will be made. IPV introduction will be reflected on children's immunisation cards, as well as in the monitoring books and in the automated immunisation database system. The changes mentioned will be coordinated with the areas of Planning and Development, including Statistics, and training with the forms designed for the purpose will be imparted on all levels.

* In line with GAVI’s policy advocating for gender equality as a means to improve coverage and access to services, please be sure all immunisation tracking forms can collect and report vaccine delivery by sex, if current forms do not already do so.

A guideline of equality in the population's access to health is established in the Institutional Plan of Nicaragua and the immunisation programme offers the vaccines equally to both sexes. The current immunisation schedule covers all the age groups, regardless of gender. Although the administrative record does not log information by gender, there is the Immunisation Monitoring Book, which permits manual recording of immunisation history by name, from the newborn to the adult phase, making it possible to monitor schedule completion for every child. Moreover, results are available from the ENDESA survey for 2011-2012, which reflects similar data from individuals surveyed by vaccine and sex.

By the coverage rates achieved as well as the results of the ENDESA survey, we consider both boys and girls to have the same opportunities of access to the immunisation programme.

* 1. Adverse Event Following Immunisation (AEFI) monitoring and reporting
* Provide information on the national AEFI policy, e.g. describe the national capacity to implement pharmaco-vigilance, AEFI investigation and response to AEFIs, to address relevant rumours and potential allegations.
* Provide information on a national AEFI Expert Review Committee (if available) and methods of establishing causality assessments of AEFIs.
* Describe process and procedures for monitoring adverse events following IPV introduction at local, district, region/provincial, and national levels.

The Nicaraguan Expanded Programme on Immunisation avails of the AEFI surveillance component in its updated standards. This component was created on the basis of injection safety policies, which include the AEFI concept, the purpose of such surveillance, classifications, cause algorithm and classification of adverse events. Moreover, the operations manual describes the differentiated handling of cases, which includes reporting, completing the form, immediate investigation, analysis of cause, the risk of the event by interval of post-immunisation events, classification on the local level — which must be done by a multidisciplinary analysis team based on the type of patient affected by AEFI and the vaccine received — and afterwards, final classification of serious AEFIs, which must be done by the national committee. All the information is subject to feedback at all the levels.

According to the literature, serious AEFIs caused by IPV are extremely rare. The appearance of a serious AEFI coinciding with IPV administration along with other vaccines may cause sensationalist news in the media that could affect immunisation activities to a great extent, including acceptance and coverage for this new vaccine and the other vaccines in the schedule.

The introduction of a new vaccine and its administration may give rise to a crisis situation that could escape the control of immunisation programmes, making it necessary to be prepared, to have a plan for confronting possible crises that may arise, have good media relations and a communication plan, and rely on an appropriate dissemination of immunisation policies in the country with regard to this new vaccine.

The objectives of the communication strategy will be: to revert mistrust by the Nicaraguan population and ensure continued maintenance of immunisation activities within the shortest time possible.

Moreover, specific objectives are oriented to: providing timely, true and transparent information and ensuring the continuity of activities, preserving the corporate image and reputation of the Ministry of Health as an asset.

A crisis is a situation that entails real or potential loss of confidence in the vaccines and/or the immunisation services, generally unleashed by real or presumed adverse event reporting.

To prevent this, we must plan the activities to implement and the manner in which we must act in the face of an event that can give rise to crises.

One of the aspects to strengthen within AEFI surveillance will be the reactivation of the national committee.

1. **Advocacy, Communication, and Social Mobilisation**
* Describe plans to sensitize political and opinion leaders at national, regional, and district levels on IPV introduction, benefits to the population, and contribution to the polio Endgame Strategy.

A communication plan to raise awareness amongst the population has been developed to achieve successful introduction of this new vaccine, with the following objectives:

* To establish strategic alliances with health staff, universities imparting training in health, SILAIS directors and municipal managers, interviewers, decisive media and opinion leaders, in order to report on the incorporation of IPV into the immunisation schedule to contribute to the Polio Endgame.
* To promote the participation of family, community and life councils and other social players.

The plan is backed by the following activities:

* Promotion of the active participation of mayors, community leaders, family, community and life councils and other social players in immunisation campaign organisation, dissemination and/or execution.
* Providing material and basic information to the different players, making them participative agents, promoters and spokespersons for the cause.
* Calling upon media leaders to inform about IPV, so as to contribute to disseminating the spot, press releases, spaces for interviews with the spokespersons, as well as coverage of press conferences. All of this is aimed at establishing strategic alliances and commitments for communication activities before, during and after the campaign.
* Press conferences will be held at the central as well as local levels to raise awareness among the media regarding the importance of immunisation.
* Conduct of reportages and the writing of press releases on the subject in places where health staff execute immunisation activities.
* Spokespersons should be equipped with a single informative folder enabling them to offer uniform information.
* To prepare press releases on the subject that will make it possible to provide official information to the media for publication.
* To monitor the different communication media so as to evaluate tendencies as to how news evolves regarding IPV administration.
* Describe development of a communication strategy for IPV introduction at the community level with identification of key messages, communication channels, and methods for greatest impact. If relevant, describe how results of knowledge, attitude, practice, and behaviour (KAPB) and/or barriers to immunization studies were used to inform the communication strategy for IPV introduction.
* Identifying national personalities to form part of the campaign (as visible faces).
* Preparing the informative folders to be handed over to the media, opinion leaders and key players contributing to disseminating IPV information.
* Disseminating the basic messages among the official spokespersons of the Ministry of Health, so as to unify statements into a single message.
* The distribution of graphic material (posters, brochures, banners) must target strategic points.
* Dissemination of the importance of IPV on the websites of MINSA and its partners.
* Conducting information fairs offering data on the importance of administering the vaccine to children, ensuring population participation.
* Describe development of information, education and communication (IEC) materials, focus groups and anthropological assessments, and media outlets for key target audiences as appropriate.

The IPV graphic image and slogan will be designed with the approval of the pertinent authorities. Moreover, print, radio and television material will be prepared. Programmes of greater following will be identified for effective communication.

IEC materials projected are as follows:

* Legal-sized triptychs
* Posters (1/2 sheet)
* Flyers, 8.5 x 5.5 "
* Graphic and painted banners
* Programming of television spots and radio skits 6 times a day, from Monday to Sunday at prime times
* Describe plans for a national launch ceremony, if required, and sub-national ceremonies if appropriate including the potential promotion of immunization in general, as well as of relevant comprehensive approaches to disease control.

The launch of the introduction of this vaccine will be graced by the participation of national authorities, support organisations and the community in general, and its structure will be reflected in a specific plan.

As evidenced by previous experience in the introduction of other vaccines, in the launching of the yearly National Immunisation Days and in the specific campaigns such as upgrading, monitoring and the acceleration of measles and rubella eradication, all the levels have the necessary experience in the execution of these events in their territories.

1. GAVI will calculate vaccine and AD syringe supply based on target population totals given and vaccine preference specified, factoring in appropriate wastage rates for the vaccine preference in this application and buffer stock allowances (25% in the first year). If there are differences between country and WHO-UNICEF coverage estimates, the Secretariat will default to the latter when estimating vaccine requirements. [↑](#footnote-ref-1)