**Attachment 1**



# Plan for Inactivated Polio Vaccine (IPV) Introduction, Honduras 2015

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**Abbreviations and Acronyms**

AES: Health Statistics Division (Área de Estadística de la Salud)

AGI: Information Management Division (Área de Gestión de la Información)

ANB: National Vaccine Warehouse (Almacén Nacional de Biológicos)

NRA: National Regulating Authority

WHA: World Health Assembly

bOPV: Bivalent Oral Polio Vaccine

ICCH: Inter-Agency Coordinating Committee for Health

CCNI: National Immunisations Advisory Committee (Consejo Consultivo Nacional de Inmunizaciones)

NVC: National Vaccine Centre

CMMB: Catholic Medical Mission Board

CONEPO: National Committee on Polio Eradication (Comité Nacional de Erradicación de la Poliomielitis)

cVDPV: Circulating Vaccine-derived Poliovirus

DAPS: Primary Healthcare Department (Departamento de Atención Primaria de Salud)  
OD: Organizational Development

DPT: Diphtheria, Pertussia and Tetanus

ENDESA: National Survey on Demography and Health (Encuesta Nacional de Demografía y Salud)

VPD: Vaccine-Preventable Diseases

AEFI Adverse Events Following Immunisation

GAVI: Global Alliance for Vaccines and Immunisation

IHSS: Honduran Social Security Institute (Instituto Hondureño de Seguridad Social)

INE: National Institute of Statistics (Instituto Nacional de Estadística)

JRF: Joint PAHO/UNICEF Report Form on immunisation data

mOPV: Monovalent Oral Polio Vaccine

NHM: National Health Model

NCC: National Coalition for Cancer

MDG: Millennium Development Goals

NGO: Non-Governmental Organization

[WHO: World](OMS:Organization) Health Organization

PAHO: Pan American Health Organization

EPI: Expanded Programme on Immunisation

AFP: Acute Flaccid Paralysis

AOP: Annual Operating Plan

RISS: Integrated health services network (Redes Integradas de Servicios de Salud)

RTCA: Central American Technical Regulation (Reglamento Técnico Centroamericano)

SAGE: Strategic Advisory Group of Experts on immunisation

SESAL: Secretariat for Health (Secretaría de Salud)

SINOVA: Nominal Immunisation System (Sistema Nominal de Vacunación)

CRS: Congenital Rubella Syndrome:

WHO: World Health Organization

tOPV: Trivalent Oral Polio Vaccine

UAFCE: External Cooperation Fund Administration Unit (Unidad Administradora de Fondos de Cooperación Externa)

UCS: Social Communication Unit (Unidad de Comunicación Social)

UGI: Data Management Unit (Unidad de Gestión de la Información)

ULMIIE: Logistics, medicines, supplies, infrastructure and equipment unit (Unidad Logística, Medicamentos, Insumos, Infraestructura y Equipamiento)

UNICEF: United Nations Children’s Fund

UVS: Health Surveillance Unit (Unidad de Vigilancia de la Salud)

VAPP: Vaccine-Associated Paralytic Poliomyelitis

OPV Oral Polio Vaccine

IPV Inactivated Poliovirus vaccine

VSSM: Vaccination Supplies Stock Management

wMSSM: Web-based Medical Supplies Store Management

**Executive Summary**

Honduras supports the introduction of the Inactivated Poliovirus vaccine (IPV) in the framework of meeting the objectives (specifically, objective 2), targets and timelines of the Polio Eradication and Endgame Strategic Plan 2013-2018 approved by the Executive Committee of the World Health Organization (WHO) in January 2013, the recommendations of the WHO Strategic Advisory Group of Experts on immunisation (SAGE), the PAHO Technical Advisory Group (TAG) on Vaccine-Preventable Diseases in their extraordinary meeting of April 2014, and the resolutions of the 66th World Health Assembly of May 2014.

Decision-making took account of political and technical aspects, among which the international, regional and national polio burden are to be underscored. Between 1973 and 1989, 710 cases of polio were confirmed, with no cases reported since 1989. The first case of Vaccine-Associated Paralytic Polio (VAPP) was confirmed in 2005, there is a risk of importing cases from countries where polio is still endemic, and there are programmatic and feasibility aspects to consider, among them the successful country experience in the introduction of underused and new vaccines such as rotavirus and the pneumococcal conjugate, along with overall programme performance.

A process was undertaken, entailing meetings, consultations and analyses with different technical authorities: the Expanded Programme on Immunisation (EPI), the Health Surveillance Unit (UVS), the Directorate General for Standardisation (DGN); and administrative authorities (Administrative Management, Budget Division) of the Secretariat of Health (SESAL), technical authorities of the Secretariat of Finance (SEFIN): the Directorate General for the Budget, Health Analysis Unit, the National Immunisations Advisory Committee (CCNI), the National Committee on Polio Eradication (CONEPO), with the participation of the Pan-American Health Organization (PAHO) in the country and the national political authorities, from September to October 2014. The submission of the application was backed by the ICCH, with representatives from external cooperation, the professional colleges, the medical associations and the civil society organizations, among others.

The objectives of the introduction plan are oriented towards: 1) complying with the WHA resolution in the context of the polio eradication target and the target objectives and timeline of the Polio Eradication and Endgame Strategic Plan 2013-2018 for the progressive and permanent elimination of OPV from the routine immunisation schedule over the short and medium term, and 2) ensuring that the new infant cohorts can rely on some protection against type 2 poliovirus, whether wild or vaccine-derived.

The aims established were to introduce at least one dose of IPV into the national immunisation schedule of Honduras before the end of 2015 and to achieve homogeneous coverage on all the levels of the integrated health service networks with the first doses of injectable DPT-HepB-Hib (pentavalent) and conjugated pneumococcal vaccine applied simultaneously to the population under one year of age.

An analysis of financial sustainability with the introduction of an IPV dose to the national schedule were carried out and the following conclusions were drawn:

* The country is in a context of eligibility to opt for initial GAVI support in the donation of 1 dose of IPV and associated supplies (AD syringes and sharps boxes) for an estimated period of 4 to 10 years (from 2015 to 2024), during which period the country would have no co-financing.
* Honduras is a country in the process of graduating from GAVI support in the co-financing of rotavirus and pneumococcal conjugate by 2015, so that initial GAVI support for the introduction of the new vaccine would not increase the budget for vaccine expenditure over the short term and would not restrict the introduction of other new vaccines over the short and medium term.
* The support for operating expenses in the introduction of the vaccine offered by GAVI in the form of USD 0.80 per child to be vaccinated, or USD 100,000 (highest value) as financial support would facilitate the execution of the different activities required by component to ensure the success of introduction nationwide. In the case of Honduras this would be approximately USD 169,000.
* It is expected that once GAVI support has ended, the price of the vaccine will be accessible and will have decreased significantly so as not to hamper new vaccine introduction.

Vaccine introduction is projected on a national scale for the last quarter of 2015, on 1 October 2015, throughout the country, with one dose for those children completing two months of age, for which this IPV introduction plan was formulated, considering precedents, justification, objectives, goals, strategies, activities by component, timeline of activities and budget. In keeping with the timeline, preparatory activities would begin in January 2015.

The current capacity of the Expanded Programme on Immunisation (EPI) was analysed for the introduction of IPV in its essential components, coming to the conclusion that sufficient cold chain capacity exists on all levels of storage along with a functional supply chain, as well as technical and operative human resources available on all levels to ensure immunisation service management and delivery, including the new vaccine.

To date, activities have been undertaken in relation to technical analysis for decision-making, notification of interest to GAVI by the State Secretariat for the Bureau of Health, formulation of the GAVI application, submission of the proposal to the ICCH for review and endorsement, and the signing of the application.

The rest of the activities will be executed in accordance with the timeline, subject to approval and the availability of the national and external funding required.

Based on the current national context of SESAL and the experience of vaccine introduction, following have been identified as risks, problems and strategies to be met:

* Outbreaks of endemic diseases such as dengue fever and emerging diseases such as Chikungunya, since the vaccine will be introduced during a month of rains with a high incidence of vector-transmitted diseases. Given the early control measures that will begin in January 2015, they are expected to be kept under control.
* National process of reorganizing the integrated health service networks. If reorganization lasts up to the second half of the year, it will have programmatic implications on the target population for immunisation with new and other vaccines on the schedule per health establishment and municipality, and the scheduling of vaccines and supplies. Thus, close coordination must be maintained with the Directorate of Integrated Health Service Networks (RISS) in order to make convenient adjustments.
* Not assuring training for 100% of the vaccinators due to holidays, leaves, etc. Therefore, policy support will be procured so as not to offer vacation leaves during the training period and the start of immunisation. It is essential to ensure that staff are trained, since they will have to apply two injectable vaccines to children in different places of the same thigh for the first time and they must be properly informed to answer the parents' questions. Sufficient background in the technical and operative guidelines of IPV standards and procedures must be ensured for 100% of the vaccinator staff.
* The current immunisation schedule contemplates two injectable vaccines: pentavalent (DPT-HepB-Hib) and pneumococcal conjugate. These are applied at 2-4-6 months of age. The introduction of IPV adds one more injectable dose for children starting immunisation at 2 months of age, so parental acceptance has been identified as a problem and the development of a communication strategy will be essential.

1. **Background and National Context** 
   1. **General context of the country**

Honduras is a country located in the Central American region. It has a territorial extent of 112,492 Km2, bounded on the north by the Atlantic, on the east by the same ocean and the Republic of Nicaragua, on the south by Nicaragua, the Gulf of Fonseca and the Republic of  El Salvador, and on the west by the Republic of Guatemala. Over 65% of the territory is mountainous. As regards climate, it only has two well-defined seasons: the dry season and the rainy season.

Politically, it is divided into 18 departments and 298 municipalities. The population projected for 2015 as per the National Institute of Statistics (INE) is 8,894,975 inhabitants (49% male and 51% female). Life expectancy at birth is 74.9 years (78.6 in females and 71.3 in males). This showed an increase superior to 1 in comparison with the 2005-2010 five-year period. 40% of the population is under fifteen years old and 6% is over sixty; i.e., the population is young, with a high rate of economic dependence. The overall fertility rate has gone down to three live births per female in 2010 and the natural demographic growth rate went down from 3% in 2001 to 2.3% in 2010. A national population and housing census was conducted in 2013 and the publication of the projections are expected in 2015.

According to the official data on mortality and disease, Honduras is considered to be in the phase of demographic transition. The country has a serious problem in violence. The top three causes of death are related to non-transmissible chronic diseases; the fourth are injuries from external causes (at a rate of 43 homicides for every hundred thousand), mainly due to aggressions affecting the youth.

According to the National Survey on Demography and Health (ENDESA) 2011-2012, infant mortality is at 24 for every thousand live births. The top three causes of death relate to the early neonatal period, followed by the late neonatal period; the next-ranked causes are pneumonia and diarrhoea. Malnutrition appears in the under-five-year age group. Maternal mortality is high at 73 for every hundred thousand live births, most of the cases avoidable through quality institutional care.

SESAL is divided into 20 health regions corresponding to the 18 political departments and two metropolitan regions representing the municipalities of the Central District and San Pedro Sula.

The 2014-2018 Health Plan is oriented towards promoting and developing the Health System based on a sector reform process that will establish structural changes to improve service quality according to criteria of effectiveness, efficiency, equity and sustainability, thus providing quality responses to the needs and rights of the population in health.

In the context of the reform, the organizational development of SESAL is being promoted on the national and intermediate level along with the National Health Model (NHM). These processes in the implementation phase purport to strengthen governance and regulation.

Currently, the EPI is dependent on the Directorate General for Standardisation and, in the context of OD, is in the process of defining its structure and dependency.

**1.2 Basic EPI Information**

The Honduran SESAL implemented the EPI in 1979. Its current mission is to decrease disease and mortality due to vaccine-preventable diseases through the immunisation of the population under five years of age, with emphasis on the population under two, pregnant women, seniors over 60 and groups at risk; to maintain certification for the eradication of poliomyelitis until global declaration; and to maintain elimination of measles, rubella and congenital rubella syndrome (CRS), neonatal tetanus, control of serious forms of infant tuberculosis, pertussia, diphtheria, mumps, hepatitis B, invasive Hib diseases, severe diarrhoea caused by rotavirus and invasive diseases caused by pneumococcus, promoting the conscious participation of the population, local governments, public and private institutions and organized civil society.

The vision is that of a “standardised technical programme responsible for guaranteeing permanent and free access to immunisation services as per the national immunisation schedule and target population, capable of responding in a timely and effective manner to the population demand with regard to quality immunisation in equity and solidarity through standardised technical and administrative processes backed by broad social participation, in the framework of the decentralisation and co-management policies of the Secretariat for Health”.

The EPI stands in the context of one of the health policy thrusts: the guarantee of population access to efficient and equitable quality health services. Its impact on decreasing cases and deaths due to vaccine-preventable diseases (VPD) has contributed to the progress of the country towards achieving the Millennium Development Goals (MDGs).

Honduras guarantees free access to immunisation services. Currently, 15 vaccines are offered to its entire population throughout their life cycle. Public immunisation services are rendered in 1624 health establishments throughout the country, including 21 belonging to the Honduran Social Security Institute (IHSS). The IHSS contributes around 5% of the coverage and the private sector is estimated to contribute 1%. Hence, coverage depends mainly on the public health network production, through institutional immunisation and field activities.

Since 1991, coverage rates higher than 90% have been obtained in all the vaccines. The 2008-2013 period achieved immunisation coverage rates of between 87% and 105% for the pentavalent vaccine (DPT-HepB-Hib). These were higher than 100% starting in 2010, except for 2012 and 2013, when third dose coverage rates dropped to 88% and 87%, respectively. This outcome is mainly associated to the overestimation of the denominator for children under one, although in 2013, 2,407 children less were immunised with third pentavalent doses in contrast to 2012. It is also admitted that enrolment of the target population decreased. This applies to the other vaccines administered to the population under one year of age, except for MMR in the one-year age group (Table 1).

**Table 1. Trends of national coverage for EPI vaccines in children under two years of age, Honduras 2012-2013**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trends of national vaccine coverage (percentage)** | | | | | |
| **Vaccine** | **Vaccine Used** | **Target population**  **(number by age and sex, if availalbe)** | | **Coverage reported (JRF)** | |
| **2012** | **2013** | **Most recent year (2013)** | **Previous year**  **(2012)** |
| BCG | INTERVAX SERUM INSTITUTE OF INDIA (10-dose vial) | 220,060 | 220,983 | 87% | 89% |
| OPV 3 | SANOFI HAFFKINE (20-dose vial) | 220,060 | 220,983 | 87% | 88% |
| DPT-HB-Hib 1 | BIOLOGICAL E LIMITED (1-dose vial) | 220,060 | 220,983 | 88% | 88% |
| DPT-HB-Hib 3 | BIOLOGICAL E LIMITED (1-dose vial) | 220,060 | 220,983 | 87% | 88% |
| Rotavirus 2 | GLAXO SMITH KLINE (pre´filled syringe) | 220,060 | 220,983 | 87% | 87% |
| Pneumococcal 13-valent | PFIZER (1-dose vial) | 220,060 | 220,983 | 87% | 88% |
| MMR 1 | SERUM INSTITUTE OF INDIA (1-dose vial) | 205,238 | 214,999 | 89% | 93% |

A similar tendecy in immunisation coverage is observed for 2014.

Coverage rates by municipality during the 2008-2011 period shows that municipalities with rates under 95% decreased for Sabin, Rotavirus, Pentavalent and MMR. Nevertheless, starting in 2012, the number of municipalities at risk for all the vaccines rose when INE population projections were once more adopted, another evidence of the problems and uncertainties existing with regard to population denominators, which rose upon distributing the population under one by municipality (Table 2).

According to ENDESA data, in 2011-2012, 84.5% of the children from 12 to 23 months of age received all the vaccines, as against 74.9% in 2005-2006.

**Table 2. Number and percentage of municipalities by coverage level for traditional and new tracer vaccines in children under two, Honduras 2008-2013**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Years** | **Sabin** | | | | **Rotavirus** | | | | **Pentavalent** | | | | **Pneumococcus** | | | | **MMR** | | | |
| **< 95%** | | **> 95%** | | **< 95%** | | **> 95%** | | **< 95%** | | **> 95%** | | **< 95%** | | **> 95%** | | **< 95%** | | **> 95%** | |
| **No** | **%** | **No** | **%** | **No** | **%** | **No** | **%** | **No** | **%** | **No** | **%** | **No** | **%** | **No** | **%** | **No** | **%** | **No** | **%** |
| **2008** | 154 | 52 | 144 | 48 |  |  |  |  | 168 | 53 | 130 | 47 |  |  |  |  | 137 | 46 | 161 | 54 |
| **2009** | 99 | 33 | 199 | 67 | 243 | 82 | 55 | 18 | 100 | 34 | 198 | 66 |  |  |  |  | 95 | 32 | 203 | 68 |
| **2010** | 100 | 34 | 198 | 66 | 115 | 39 | 183 | 61 | 98 | 33 | 200 | 67 |  |  |  |  | 86 | 29 | 212 | 71 |
| **2011** | 52 | 17 | 246 | 83 | 58 | 19 | 240 | 81 | 52 | 17 | 246 | 83 | 58 | 19 | 240 | 81 | 47 | 16 | 251 | 84 |
| **2012** | 216 | 73 | 82 | 27 | 238 | 80 | 60 | 20 | 214 | 84 | 84 | 16 | 217 | 73 | 81 | 27 | 133 | 45 | 165 | 55 |
| **2013** | 217 | 73 | 81 | 27 | 223 | 75 | 75 | 25 | 215 | 83 | 83 | 28 | 215 | 72 | 83 | 28 | 197 | 66 | 101 | 34 |

The abandonment rate has always remained under 5% (optimal threshold) during the last eight years and, in the last three years, was reduced to 1% in 2013.

**Economic and Gender Barriers and Differences**

According to the national analysis, there are geographic, cultural and economic barriers limiting access to immunisation services. Hence, the profiling of municipalities is updated every year based on geographic, demographic, health and social indicators, for intervention by means of integrated health measures, including immunisation.

ENDESA data showed that equity in immunisation coverage for third pentavalent doses presented a slight difference (2.2%) between the upper economic quintile (98.1%%) and the lower economic quintile (95.8%).

With regards to gender, access to immunisation services in Honduras is universal, so that this condition does not pose an obstacle to service access, as per ENDESA data for 2011-2012, which showed that coverage by vaccine type and sex do not present differences: Pentavalent: males 95.5% and females 95%; rural 93.9% and urban 96.8%.

So as to avail of routine programme statistics differentiated by gender in the SESAL information system, the project to design and implement SINOVA, a nominal system for immunisation data, was started in 2011. Currently, it offers information by gender in 4 of the 20 health regions in which it operates.

As regards the impact of immunisation on the health of the population, the programme has managed to maintain polio eradication (last case in 1989), the elimination of measles (last case in 1997), congenital rubella syndrome (last case in 2001) and rubella (last case in 2004), and control of diphtheria, whooping cough, neonatal tetanus, hepatitis B, meningitis and pneumonia due to type b *Haemophilus influenza*, gastroenteritis due to rotavirus and mumps in children under five. Reduction in the incidence and mortality of pneumonia provoked by pneumococcus is expected over the short term.

**Experience in New Vaccine Introduction**

With regard to vaccine introduction, the country has accumulated experience with the introduction of underused vaccines since 1997: MMR was introduced in 1997, pentavalent in 2000, while new vaccines such as rotavirus were applied in 2009 and pneumococcus in 2011.

Honduras was the first country to introduce the rotavirus and pneumococcal vaccines with GAVI support. In addition, it was one of the first countries to introduce the pneumococcal conjugate through GAVI grants. The SESAL has announced the government decision to introduce the vaccine against the human papilloma virus (HPV) over the short term.

All the vaccines introduced since 1997 have gone through a process of analysing technical, political and programmatic aspects for decision-making and the subsequent formulation of their introduction plan.

In the process of introducing new vaccines, lessons learned to be considered for future new vaccines to be introduced into the country were identified, notable among which are:

* That the vaccine should ideally be introduced at the beginning of the year or the administration of doses should be standardised for the ages when the vaccines from the regular schedule are applied for optimum coverage.
* That the introduction plan must cover all the key activities ensuring the success of introduction by component.
* That the development of a national communication strategy addressing key players, with differentiated messages for its different audiences, is a determining factor for success in introduction.
* That guaranteed success in introduction requires supervised fulfilment of the activities in the introduction plan in all its components prior to, during and after the introduction, so as to conveniently identify and correct problems.
* That when a new vaccine with a schedule of more than one dose is introduced, this requires a monthly process of monitoring first, second and third doses per schedule, plus supervision in timely decision-making.

All prior experience and lessons learned on all levels will serve in the successful introduction of IPV and other new vaccines.

**Risks and Challenges**

Based on this vaccine introduction experience, following risks and challenges have been identified:

* Outbreaks of endemic diseases such as dengue fever and emerging diseases such as Chikungunya, since the vaccine will be introduced during a month of rains with a high incidence of vector-transmitted diseases.
* National process of reorganizing the integrated health service networks. If reorganization lasts up to the second half of the year, it will have programmatic implications on the target population for immunisation with new and other vaccines on the schedule per health establishment and municipality, and the scheduling of vaccines and supplies. Thus, close coordination must be maintained with the Directorate of Integrated Health Service Networks (RISS) in order to make convenient adjustments.
* Not assuring training for 100% of the vaccinators due to holidays, leaves, etc. Therefore, policy support will be procured so as not to offer vacation leaves during the training period and the start of immunisation. It is essential to ensure that staff are trained, since they will have to apply two injectable vaccines to children in different places of the same thigh for the first time and they must be properly informed to answer the parents' questions. Sufficient background in the technical and operative guidelines of IPV standards and procedures must be ensured for 100% of the vaccinator staff.
* The current immunisation schedule contemplates two injectable vaccines: pentavalent (DPT-HepB-Hib) and pneumococcal conjugate. These are applied at 2, 4, and 6 months of age. The introduction of IPV adds one more injectable dose for children starting immunisation at 2 months of age, so parental acceptance has been identified as a problem and the development of a communication strategy will be essential.

**Findings from recent programme reviews**

The following underscores the background and conclusions of recent international and national programme evaluations.

**International Evaluations**

* In July 2007, PAHO/WHO conducted the multidisciplinary evaluation of the EPI, underscoring its achievements and problems and proposing recommendations. At the same time, adjustments were made to EPI multi-year plan 2006-2010.
* From 20 to 25 November 2011, an evaluation was conducted by PAHO on the management and control of vaccine, syringe and supply stocks and the application of Vaccine Supplies and Stock Management (VSSM), version 4.7, assessing the national vaccine warehouse and four storage chambers pertaining to four health regions, with the following main conclusions:
* VSSM implementation has improved management processes in the handling and control of vaccine and supplies stocks for the immunisation programme.
* VSSM is a useful, effective and reliable tool that integrates all processes into a single database.
* Noteworthy progress is observed in the use of VSSM, given the short time since it was implemented.
* It provides all the critical data needed to manage vaccine, syringe and supply reception, storage and distribution.
* It enabled improvement of frequency and management in the working area.
* Recommendation to incorporate the VSSM software into the national information system as a module integrated into the other network systems.

**Effective Vaccine Management (EVM)**

The PAHO/WHO evaluation on Effective Vaccine Management (EVM) has been set for 24 August to 11 September 2015, which will coincide with the preparatory period for IPV introduction.

**National Evaluations**

* Every year, six-monthly EPI evaluations are conducted on the central level with the participation of regional technical teams, key standardising technical units that coordinate with the EPI and its cooperation partners. On the regional level, six-monthly health evaluations where the EPI is included are conducted.

Outstanding among the principal conclusions of the last EPI evaluation conducted between regional teams and cooperating partners in the municipality of Siguatepeque from 23 to 25 July are the following:

* During the 2010 to 2013 period, on the national level, coverage rates inferior to 95% were reported starting in 2012; in June 2014, a similar tendency was observed for all the vaccines administered to the population under two years of age, whereby the main causes identified were:
* Overestimation of the population under five in 16/20 health regions, except for the regions of Francisco Morazán, SPS metropolitan area, DC metropolitan area and Islas de la Bahía.
* Decrease in the number of immunised children starting in 2012 mainly due to weakening of the sustained field immunisation strategy in terms of health establishment information management, limited vaccinator resources, security problems, limited logistics, funding problems and lack of a promotion strategy for the immunisation service offer, among other reasons.
* Profiling of the municipalities at risk shows that as of May 2014, of the 298 municipalities in the country, 202 do not achieve coverage superior to 95% for pentavalent. 60% of the children under one year of age in Honduras live in these municipalities. By region, those of greater risk where over 80% of the municipalities report coverage lower than 95% are: Intibucá, Olancho, Valle, Copán, Choluteca, La Paz and Lempira.
* During the 2010 to 2014 period, the cold chain improved considerably due to electrification, changes in cold chain equipment, repairs done by the technicians and improvement of the means of communication to the health establishments.
* The tendency in incidence and mortality of vaccine-preventable diseases has been falling.
* In the context of the new organizational development process of SESAL, regional managers are obliged to consider continuing with responsible EPI resources in the management support unit, integrated networks department, in order to maintain the accomplishments achieved to date, who will gradually assume and transfer the main activities relating to the EPI (training, hands-on learning, written and digital documentation) to the pertinent regional authorities in an orderly way according to the functions manual.

Interventions and commitment plans by component based on problems identified were established.

* An evaluation meeting on the operation of the SINOVA in pilot regions was held on 27 November with the participation of PAHO/WHO, which underscored the following among its main conclusions:
* The SINOVA application still requires adjustments in data capture and reports on outcome.
* There is limited progress in the data digitising process due to limited permanent human resources in the regions exclusively dedicated to the task.
* Progress has been made in the regional implementation of the process as regards correct and complete filling up of SINOVA 1 forms, quality control, supervision, commitment monitoring and data processing on the application designed for such purpose.
* SINOVA expansion has begun on the level of selected municipalities in the two pilot regions: Francisco Morazán, 10 municipalities, and Comayagua, 3 networks and 1 health establishment. This decreases the digitising burden on the regional level by almost 50% and will enable greater progress and data analysis.

At the same time, action lines for 2015 were identified, which have been incorporated into the action plan.

Systematic analysis of the situation of the EPI in its priority components and evaluation of some of its critical components make it possible to identify its main problems and make recommendations, producing commitment plans by component with their respective managers by level and period of execution for monitoring.

Every year, these are transformed into activities by component in the yearly EPI action plan for the mobilisation of national and external resources.

**Funding**

Since 1996, the EPI has systematised the formulation of multi-year and five-year plans and annual action plans, the main objectives, indicators and budget of which are reflected in national health planning.

Financial sustainability for the EPI has been guaranteed since 1998, with the formulation and approval of the Act on Vaccine Acquisition by the Sovereign National Congress of the Republic, which incorporated the item for vaccines, syringes, sharps boxes and other EPI supplies into the General Budget of Income and Expenditure.

The current multi-year plan corresponds to the 2011-2015 period and purports to improve effectiveness and efficiency in terms of immunisation coverage equal or superior to 95% in the population under two, the eleven-year-old population, pregnant women and groups at risk in every vaccine; to maintain cold chain operation throughout the service network for the 20 health regions; to maintain active epidemiological surveillance on the occurrence of vaccine-preventable diseases in the process of eradication, elimination and control; and to consciously promote the spontaneous supply and demand for immunisation services on the level of health workers and the beneficiary population, ensuring safe immunisation and the supply of vaccines, syringes and sharps boxes.

Strategies and lines of action to achieve these ends are clearly defined for 14 components: political priority and legal bases, planning and scheduling, organization and coordination, vaccines-supplies-infrastructure, the cold chain, training, communication and social mobilisation, operating expenses, supervision and monitoring, execution, information system, epidemiological surveillance, research and evaluation.

The plan takes the funding required for the 2011-2015 period per year and per component into consideration as part of the Health Sector Plan up to 2021, the National Plan up to 2038, the Accelerated Reduction of Maternal and Child Mortality Strategy (RAMNI), the Millennium Development Goals (MDGs), GAVI support, and the recommendations of the PAHO/WHO Technical Advisory Group (TAG) on vaccine-preventable diseases, which represent the basic elements behind EPI Multi-year Plan 2011-2015.

In comparison to the previous five-year plan, the multi-year plan for 2011-2015 is backed by an increase in external cooperation with regard to vaccines and supplies, associated to the co-financing of the rotavirus and pneumococcal vaccines through GAVI, with an average annual budget of 17 million USD. The main sources of external funding contemplated in the plan are GAVI, PAHO/WHO and UNICEF. Resource mobilisation through projects is considered a possible source for overcoming the gaps.

The national budget for the purchase of vaccines and other supplies shows a sustained increase. It varied little between 2000 and 2005, but increased by over 50% in 2006, growing progressively until financing was doubled in 2009 (almost 11 million USD). It fell by one-third in 2010 and afterwards gradually recovered up to almost the same level as 2009. The Vaccines Act protects the budget for vaccine acquisition by declaring it a "fixed expense”, such that the item is exclusively used for the purchase of EPI supplies.

In 2014, the operating costs of the EPI amounted to USD 35,485,824, of which USD 3,111,344 (91%) were national funds and USD 32,374,479 (9%) were external funds brought in by GAVI, PAHO/WHO, UNICEF and other donors: Catholic Medical Mission Board (CMMB) and the National Coalition for Cancer (NCC).

In January 2014, the Vaccine Act of the Republic of Honduras was approved, regulations for which are still pending, which will ensure — apart from the vaccine, supplies and cold chain equipment budget — the recurrent expenses of the EPI in its critical components.

The EPI 2015 action plan has covered the activities of the plan for IPV introduction by component. In the second half of 2015, a new multi-year plan 2016-2020 will be formulated, which will include IPV and key activities per component to strengthen immunisation service delivery.

This year, the State will be obliged to assume almost 80% of the cost of the new vaccines co-financed by GAVI: rotavirus and pneumococcal conjugate. Nevertheless, additional support will be received to strengthen strategic areas that can ensure the sustainability of the health services contributing to vaccination and immunisation.

1. **Justification for IPV introduction and description of the national decision-making process**

**2.1 Justification**

IPV introduction is backed by the drive to meet the objectives (specifically, objective 2), targets and timelines of the Polio Eradication and Endgame Strategic Plan 2013-2018 approved by the Executive Committee of the WHO in January 2013, the recommendations of the WHO Strategic Advisory Group of Experts on immunisation (SAGE), the PAHO Technical Advisory Group (TAG) on Vaccine-Preventable Diseases in their extraordinary meeting of April 2014, and the resolutions of the 66th World Health Assembly of May 2014.

**2.2 Description of the National Decision-making Process**

Decision-making took account of analyses on policy and technical as well as programme and feasibility aspects, entailing a procedure of meetings, consultations and analyses held with different SESAL technical divisions (EPI, the Health Surveillance Unit, the Directorate for Standardisation) and administrative divisions (Administrative Management, Budget Division), SEFIN technical offices (Budget Directorate and Health Analysis Unit), the National Immunisations Advisory Committee (CCNI), and the National Committee on Polio Eradication (CONEPO), with the participation of the PAHO/WHO country office and national political authorities throughout September to October 2014.

The submission of the application to GAVI was backed by the ICCH, which includes external cooperation representatives, professional associations, medical societies and civil society organizations, among others. Attached are the minutes of the ICCH meeting held on 21 January 2015, when the application for IPV introduction was presented and approved (**Attachment 5 of the application)**.

Below is a breakdown of the analysis conducted by aspects as per the main criteria:

**Policy and Technical Aspects:**

The introduction of IPV into the national immunisation schedule of the country with GAVI support has been a high-priority subject of discussion in the context of the aim of eradicating polio, as per resolution passed in September 1985 at the 31st Meeting of the PAHO Directing Council and the Global Polio Eradication resolution adopted at the 41st World Health Assembly (WHA) of 1988.

**Global Context of Polio Eradication**

In 1988, the WHA approved the goal of Polio Eradication and the 1988 – 2013 period saw a reduction from approximately 350,000 cases in 1988 to 416 cases in 2013. The last case of this disease caused by the wild poliovirus in the Americas Region was detected in Peru in 1991. In 1994, the International Commission for the Certification of Poliomyelitis Eradication reviewed the evidence available in each country or territory and concluded that the autochthonous circulation of the wild poliovirus had been interrupted on the continent, making the Americas the first region to achieve this goal in the world.

Over the following years, three other regions received the polio eradication certificate: the West Pacific Region in 2000; the European Region in June 2002; and the Southeast Asian Region (including India) in March 2014.

Currently, only three endemic countries remain: Afghanistan, Nigeria and Pakistan. Nevertheless, there are non-endemic countries that, after several years without wild poliovirus circulation, reported imported cases of poliomyelitis that gave rise to secondary cases.

In May 2012, the WHA declared the eradication of the poliovirus "a programmatic emergency for global public health” to be fulfilled in the year 2020 and asked the WHO to develop a global strategy for the polio eradication endgame.

At the WHA of May 2013, the countries supported the Polio Eradication and Endgame Strategic Plan 2013-2018 of the Global Polio Eradication Initiative (GPEI). This plan includes the eradication and containment of the polio caused not just by wild poliovirus but also the elimination of circulating vaccine-derived poliovirus (cVDPV).

That same year, the WHO SAGE recommended suspending the use of the type 2 component of the trivalent oral polio vaccine (tOPV) from all national immunisation programmes. This recommendation is based on the fact that the type 2 poliovirus was eliminated in 1999 and continued use of tOPV in the areas where coverage is inadequate contributes to the appearance of cVDPV cases. Before switching from tOPV to the bivalent oral polio vaccine (bOPV), the SAGE recommends for all the countries to introduce at least one dose of IPV in their infant immunisation schedules as a measure to mitigate risks, since this offers immunity against the resurgence or reintroduction of the type 2 virus.

In January 2013, the WHO Executive Committee approved the goals, objectives and timelines for the Polio Eradication and Endgame Strategic Plan 2013-2018, which has four objectives:

1. To detect and interrupt poliovirus transmission.
2. To strengthen routine immunisation and withdraw oral polio vaccine (OPV).
3. To contain poliovirus and certify interruption of its transmission.
4. To plan for optimisation of the legacy left by the fight against polio.

In this context, the PAHO TAG on vaccine-preventable diseases, at its July 2014 meeting, issued recommendations for the Americas Region regarding IPV introduction. On this occasion, the TAG reiterated the recommendations presented during its extraordinary meeting of April 2014:

* The TAG supports the renewed efforts to eradicate poliomyelitis and subscribes the objectives of polio eradication endgame. Among other objectives, these efforts address the permanent elimination of OPV (Sabin) from the routine immunisation schedule.
* During IPV introduction, countries must take sequential schedules into account; the ideal scheme would be for countries to consider using two doses of IPV, followed by two doses of OPV. Nevertheless, should a country be considering the possibility of a single IPV dose, this should be administered with the first dose of the diphtheria-pertussia-tetanus vaccine (DPT), followed by three doses of OPV.
* At the moment, countries should not consider directly changing to purely IPV immunisation against polio unless they meet the criteria previously recommended by the TAG and the WHO (low transmission and importation risk, high and homogeneous coverage and good sanitation).

**Disease Burden**

**Globally**: since global polio eradication was resolved as a goal by the WHA in 1988, the global incidence of poliomyelitis has gone down by over 99% and the number of countries with endemic polio has been reduced.

Eradication efforts are threatened by the presence of cVDPV cases, which are largely type 2. According to WHO data, as of December 2014, 52 cases of cVDPV have been recorded, of which 51 correspond to the type 2 virus and 1 to type 1.

**In the Americas:** poliomyelitis is a disease that has been eliminated since 1994. The only cVDPV outbreak due to P1 occurred in 2000-2001 in Haiti-the Dominican Republic.

In 2010: Phase 1 of wild poliovirus containment was completed in the laboratories of the region and VAPP incidence was lower than the theoretical estimate.

Epidemiological surveillance remains at the same levels as of the time of certification.

VAPP risk is at 1 case for every 1.04-1.39 million newborn children and 1 case for every 6.73 – 8.95 million doses in Latin America and the Caribbean. From 1992 to 2011, there have been 191 cases of VAPP in Latin America and the Caribbean, of which 72 were detected in immunised subjects and 119 in non-immunised subjects; on tallying the VAPP among the immunised subjects, 49% occurred with the first dose, 21% with the second and 30% in the third or higher dose. Should IPV be introduced as a first dose, the 49% of VAPP would decrease and if these were two first doses of IPV, the 21% would decrease and so on.

**Nationwide:** during the period from 1973 to 1989 the total number of polio cases in Honduras was 710. No cases have been reported since 1989. In 2005, the first case of vaccine-associated paralytic polio (VAPP) was confirmed. The country maintains active surveillance of Acute Flaccid Paralysis (AFP).

**Financial Analysis**

Based on previous experiences in new vaccine introduction, analysis of financial sustainability on the introduction of one IPV dose into the national immunisation schedule was conducted, with the following conclusions:

* The country is in a context of eligibility to opt for initial GAVI support in the donation of 1 dose of IPV and associated supplies (AD syringes and sharps boxes) for an estimated period of 4 to 10 years (from 2015 to 2024), during which period the country would have no co-financing.
* Honduras is a country in the process of graduating from GAVI support in the co-financing of rotavirus and pneumococcal conjugate by 2015, so that initial GAVI support for the introduction of the new vaccine would not increase the budget for vaccine expenditure over the short term and would not restrict the introduction of other new vaccines over the short and medium term.
* The support for operating expenses in the introduction of the vaccine offered by GAVI in the form of USD 0.80 per child to be vaccinated, or USD 100,000 (highest value) as financial support would facilitate the execution of the different activities required by component to ensure the success of introduction nationwide. In the case of Honduras this would be approximately USD 169,000.
* It is expected that once GAVI support has ended, the price of the vaccine will be accessible and will have decreased significantly so as not to hamper new vaccine introduction.

Based on the previous conclusions, the political authorities of the SESAL notified GAVI of their decision to submit a support application for IPV introduction through PAHO Honduras by means of official letter no. 2321-SS-2014 dated 13 October 2014.

**Programmatic and Feasibility Aspects**

IPV introduction is technically and operatively feasible considering:

* Successful experiences accumulated in the introduction of underused vaccines such as MMR and pentavalent, and new vaccines such as rotavirus and pneumococcal conjugate; and in the formulation and implementation of introduction plans, including all the activities essential to each component, with demonstrated results in the achievement of homogeneous coverage with vaccines applied simultaneously at the same age starting from the year after introduction.
* Installed cold chain capacity on all levels is available for IPV introduction without need for modifying the supply chain (standardised distribution flows, etc). This will be strengthened on two levels (central and municipal) with GAVI Health Services Strengthening (HSS) support.
* Technically, one OPV dose is being substituted by an injectable, easier for the vaccinator staff.
* Vaccines are available through the PAHO Rotating Fund, a mechanism that assures the regular and systematic flow of safe quality vaccines based on proper national scheduling.

Based on the foregoing points, the ICCH recommended IPV introduction in a schedule of two doses at 2 and 4 months of age. However, due to the non-availability of vaccines for 2015 through the PAHO Rotating Fund, only one dose will be introduced.

1. **Goals and Objectives**

**3.1 Objectives**

**3.1.1** To comply with the WHA resolution in the context of the goal to eradicate polio as per the objectives, goals and timeline of the Polio Eradication and Endgame Strategic Plan 2013-2018 as regards the permanent and progressive elimination of OPV from the routine immunisation schedule over the short and medium term.

**3.1.2** To ensure that the new infant cohorts can rely on some protection against type 2 poliovirus, whether wild or vaccine-derived.

**3.2 Goals**

**3.2.1** To introduce at least one IPV dose into the national immunisation schedule of Honduras before the end of 2015.

**3.2.2** To achieve homogeneous coverage on all the levels of the integrated health service networks with the first doses of injectable IPV, DPT-HepB-Hib (pentavalent) and pneumococcal conjugate, simultaneously applied to the population under one year of age.

1. **IPV and Target Population Summary**

**4.1. Vaccine Presentation and Introduction Date Preferences**

Based on the offer of current and future vaccine availability through the PAHO Rotating Fund, national cold chain storage capacity and the updated policy on open multi-dose IPV vials, Table 3 presents preferences and introduction date:

**Table 3. IPV preferences and approximate date of introduction, Honduras 2015**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **First shipment date** | **Date of introduction** | **Preferred vaccine presentation** | **Preferred second presentation** | **Preferred third presentation** |
| August 2015 | 1 October - 2015 | 5-dose vial | 10-dose vial | 1-dose vial |

* 1. **Country Licensure Status**
* The SESAL has a functional National Regulating Authority (NRA) that depends on the Sub-secretariat for Health Regulation, responsible for the fulfilment of six basic functions.
* Considering that the vaccines in the national immunisation schedule acquired by the SESAL through the PAHO Rotating Fund are pre-qualified by the WHO, they benefit from a legal framework covered in the Regulation on Health Products that ensures a special procedure based on the review of documentation for batch-to-batch vaccine release, different from those acquired through the private sector.
* Nevertheless, there is a mechanism admitting an accelerated procedure for vaccine registration, Central American Technical Regulation (RTCA) 11.01.0410, which enables this in three instances: 1-upon first registration, 2-when the product undergoes modifications in excipients, and 3-when it undergoes changes in primary packaging.
* IPV is a vaccine that, since 2001, has already formed part of the national immunisation schedule of Honduras for groups at risk in one-dose presentations. In line with national procedures, the form of the basic table of medicines will be updated to give notice of changes in presentation.
* In line with the updated EPI 2010-2011 standards, the WHO policy on multi-dose vials shall apply.
* Established national operating procedures exist to ensure receipt of the vaccine acquired by the SESAL through the PAHO Rotating Fund. These consist of:
* Programming of annual requirements every year in July on the PAHO 173 form.
* Reconfirmation of six-monthly requirements (November and May) by quarter, PAHO 174 form.
* PAHO sends the EPI a pro-forma invoice for review and approval as per requirement applied for in previous forms.
* PAHO processes the purchase order and sends the EPI all the required documentation in digital form.
* The EPI sends the logistics, medicines, supplies, infrastructure and equipment unit (ULMIIE) the purchase order and digital documents.
* The supplier sends ULMIIE the original documentation for the shipment programmed at least one week prior to cargo arrival for customs clearance: packing list, bill of lading and original invoice and, for release by the NRA: certificate of country of origin, certificate of batch release and production protocol.
* PAHO notifies ULMIIE of product arrival data at least one week in advance.
* The ULMIIE customs office is responsible for vaccine customs clearance and delivery to the National Vaccine Warehouse. The syringes and boxes are entered into the National Medicine Warehouse.
* The EPI notifies the PAHO of receipt of the vaccines by sending the PAHO 183 established receipt form.
* ULMIIE notifies PAHO of receipt of the syringes, supplies, equipment and cold chain elements by sending the PAHO 183 established receipt form.

* 1. **Target Population and Vaccine Supply**

**Target population**

In programming the target population for immunisation for the year of vaccine introduction, following were considered:

* Estimate of total population under one year of age drawn up by the INE for 2015: 222,256 children.
* Considering that introduction is set for 1 October 2005, the target population goal was calculated for a four-month period from October to December: 55,564.

(Attachment 1)

**Vaccine Supply**

Following were considered in IPV programming:

* Immunisation schedule to be adopted by the country: one IPV dose with the first doses of pentavalent at two months of age.
* Target population for the fourth quarter of 2015, plus wastage percentage of multi-dose vial (15%), plus 50% in emergency reserves for a four-month period. 50% was calculated instead of 25% in view of the PAHO/WHO recommendation on vaccine availability.
* Given that the emergency reserves required by the country are for one year, this will be adjusted for 2016 in keeping with the balance of stocks from the year preceding; for 2015, emergency reserves are only requested for one quarter.
* In line with the existing legal framework, the country will acquire vaccines and supplies through the PAHO Rotating Fund.

1. **Introduction Strategies**

**Development and Approval of the Plan**

The introduction plan was formulated under the leadership of the EPI with the participation of different SESAL technical authorities in line with their technical competencies, backed by the national PAHO/WHO and reviewed by the regional PAHO/WHO. Subsequently, it was presented to the ICCH for review based on the recommendations made in the decision-making process, and lastly it was approved by the political authorities.

**Resource Mobilisation**

The plan will be sent to the ICCH members for national and foreign technical and financial resource mobilisation. At the same time, the ICCH will participate in reviewing the support application to be sent to GAVI.

**Implementing the Plan**

Once resources are mobilised, the plan will be implemented nationwide.

1. **Technical Components of the Introduction Plan**

To implement the plan, activities by component have been taken into consideration. These are given below:

* 1. **Planning and Scheduling**

**Planning**

Based on the national IPV introduction plan, each health region, spearheaded by the Planning Unit, will form its technical integration team in line with the new SESAL OD: RISS department technicians, the EPI technical manager, the logistics unit, the health surveillance unit (UVS), the information management division (AGI), health communications (UCS), the cold chain, administration, etc., to formulate the regional introduction plan considering all the activities proposed by component and others they may identify, observing the national timeline and simultaneous introduction date nationwide in the RISS.

**Scheduling**

National estimate of vaccine and supply requirements in accordance with target population, immunisation schedule and request to the PAHO Rotating Fund (see Section 4.1.3).

Scheduling of requirements in vaccines and supplies per health establishment, municipality and region based on national technical and operational guidelines.

* 1. **Policy Groundwork (Standardisation)**

IPV is a vaccine forming part of the national immunisation schedule of Honduras since 2001 for groups at risk. The introduction of one dose for the infant population, substituting one dose of OPV with IPV, will require a policy change in the immunisation schedule, which will include:

-Preparation of a document of technical and operational guidelines for public sector health staff on RISS and Honduran Social Security Institute (IHSS) levels, including:

* Guidelines for programming target population, vaccines and supplies.
* Modification of the technical immunisation standard: vaccine type, presentation, dose, immunisation schedule, mode and place of administration, specification of the technique of administering two injectable vaccines in different places of the anterolateral thigh separated by 2.5 cms., the administration of pneumococcal conjugate and IPV to the same limb, co-administration with other vaccines, and policies on open vials (28 days), preservation, and discarded used vials and syringes.
* Updated immunisation schedule that includes IPV:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **National Immunisation Schedule, Honduras 2015** | | | | | | | |
|  |  | | | | | | |
| **Vaccine** | **Age for Administration** | | | | | | |
| **Newborn** | **2 mos.** | **4 mos.** | **6 mos.** | **12 mos.** | **18 mos.** | **4 yrs.** |
| **Children** | | | | | | | |
| **BCG 1** | Single dose |  |  |  |  |  |  |
| **Paediatric HepB 2** | Single dose |  |  |  |  |  |  |
| **Inactivated polio (IPV)** |  | **1st dose** |  |  |  |  |  |
| **Oral Polio (Sabin) 3** |  |  | 2nd dose | 3rd dose |  | Booster |  |
| **DPT-HepB-Hib (pentavalent)** |  | 1st dose | 2nd dose | 3rd dose |  |  |  |
| **Rotavirus 4** |  | 1st dose | 2nd dose |  |  |  |  |
| **Pneumococcal conjugate** |  | 1st dose | 2nd dose | 3rd dose |  |  |  |
| **MMR 5** |  |  |  |  | Single dose |  |  |
| **DPT** |  |  |  |  |  | 1st booster | 2nd booster |
| **Adolescents & Adults** | | | | | | | |
| **Hepatitis B** | First contact: 1st dose | | | | | | |
| 1 mo. after 1st dose: 2nd dose | | | | | | |
| 6 mos. after 2nd dose: 3rd dose | | | | | | |
| **Td (Tetanus Diphtheria Toxoid)** | **11 yrs.** Booster followed by 1 dose every 10 yrs | | | | | | |
| **Unimmunised pregnant women:**  1st contact: 1st dose  1 mo. after 1st dose: 2nd dose  **Complete 5-dose schedule after pregnancy**  3rd dose: 6 mos after 2nd dose 4th dose: 1 yr. after 3rd dose 5th dose: 1 yr. after 4th dose | | | | | | |
| **Groups at Risk**  First contact: 1st dose  1 mo. after 1st dose: 2nd dose 6 mos. after 2nd dose: 3rd dose Every 10 yrs.: Booster | | | | | | |
| **Groups at Risk** | | | | | | | |
| **Paediatric DT 6** | 2nd dose: 4 mos. | | | | | | |
| 3rd dose: 6 mos. | | | | | | |
| Booster: 18 mos. | | | | | | |
| Booster: 4 years | | | | | | |
| **Inactivated polio (IPV)** | 1st dose: 2 mos. | | | | | | |
| 2nd dose: 4 mos. | | | | | | |
| 3rd dose: 6 mos. | | | | | | |
| **YF** | Single dose for children older than 1 year (traveling to areas at risk of transmission) | | | | | | |
| **Influenza 7** | Chronic patients from 6 mos. to 59 yrs.: Annual dose in the population from 6 mos. to 8 yrs., applying 2nd dose with an interval of 1 mo. after first dose. | | | | | | |
| Health workers, poultry farm workers and adults over 60, single annual dose. | | | | | | |
| 1.- BCG: administer to newborns weighing 2,500 grs. or more. | | | | | | | |
| 2.- Paediatric Hepatitis B: Administer to healthy newborns regardless of birth weight | | | | | | | |
| 3.- Oral Polio ( Sabin): also applied every 4 years on national immunisation days to the population from 2 mos. to 4 yrs. old, 11 mos. old, 29 days old | | | | | | | |
| regardless of their immunisation status. | | | | | | | |
| 4.-Rotavirus: first dose to be applied between 2 and 31/2 mos. of age and second dose between 4 mos. and 8 mos. | | | | | | | |
| 5.- MMR: Also applied every 4 years in monitoring campaigns to the population from 1 to 4 yrs. old, 11 mos. old, 29 days old | | | | | | | |
| 6.- Paediatric DT: Apply to children with severe adverse reactions to the Pertussis component of the combined DPT-HepB-Hib vaccine. | | | | | | | |
| 7.- Influenza: Administer 2 separate doses at an interval of 4 weeks to children aged 6 mos. to 8 yrs. who are receiving the vaccine for the first time. To those previously vaccinated, apply one dose. | | | | | | | |

* Modified IT system forms
* Communication and social mobilisation strategy
* Surveillance of Adverse Events Following Immunisation (AEFI)
* Monitoring, supervision and evaluation process.

IPV will be integrated into the sustained internal and field immunisation programme nationwide in the public sector's integrated health service networks, which includes: growth and development monitoring, vitamin A supplementing, disease and dental consultations.

* 1. **Coordination**

Coordination with authorities and key players on all levels will be undertaken to ensure satisfactory vaccine introduction:

**Intra-institutional**: integration teams for every level will be formed, composed of all the authorities obliged to execute the various activities:

**Central level**: the EPI, the Human Resources Department, the Data Management Unit (UGI), the Health Statistics Division (AES), UVS, ULMIIE, UCS, the Primary Healthcare Department (DAPS), the Standards Surveillance Department, Administrative Management and External Cooperation Fund Administration Unit (UAFCE).

**Regional level**: the Health Promotion Unit, AGI, RISS department, Logistics Unit, Planning Unit, UCS, UVS, Standards Surveillance Department and Administration.

**Extra-institutional**: ICCH members: other state departments, the IHSS, medical associations, civil society: the CCNI, professional associations, medical societies, municipal mayors' offices, non-government organizations (NGOs), communications media, etc.

Existing coordination mechanisms will be used: official announcements, meeting agendas, committee meetings, aide-memoirs/minutes of every meeting specifying commitments, persons in charge and timeline in order to monitor fulfilment.

* 1. **Cold Chain and Supply Chain**

**6.4.1 Cold Chain**

Vaccine storage and distribution logistics in Honduras avails of a National Vaccine Warehouse (ANB) that distributes the vaccines every quarter to 8 regional warehouses, which function as supply centres for 20 health regions. These latter in turn distribute vaccines on a monthly basis to 216 municipalities covering the 298 municipalities in the country and to 1625 national health establishments as per an established flow chart.

Cold rooms and freezers for preserving the vaccines exist in these warehouses. In addition, they have human resources trained in handling, storage and distribution and obliged to observe the existing standards.

The storage capacity at temperatures of +2º to +8º C existing at the ANB amounts to 73,300 litres. On the regional level, it amounts to 115,700 litres; on the municipal level, 25,800 litres and on the local level, 49,610 litres (Table 4).

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| TABLE 4: VACCINE STORAGE CAPACITY AT TEMPERATURES OF +2 TO +8 | | | | | | | | | |
| ON THE DIFFERENT LEVELS OF THE COLD CHAIN, HONDURAS 2015 | | | | | | | | | |
|  | | | | | | | | | |
| Level | Place | No. Estab. | Cold Room Temps. | Total capacity available in L. | Occupied capacity / Quarter Current Vaccines | Required capacity IPV 5-dose / Quarter  Oct. - Dec. 2015 | Total capacity required incl. IPV | % Occupied capacity | % Unoccupied capacity |
| Central | Nat’l Vaccine Warehouse (Tegucigalpa) | 1 | 2º  to 8º C | 73,300 | 60,990.00 | 862.63 | 61,852.63 | 84.4 | 15.6 |
| Regional | Regional Cold Rooms | 10 | 2º to 8º C | 115,700 | 30,495.00 | 431.32 | 30,926.32 | 26.7 | 73.3 |
| Municipal | Municipal Cold Rooms | 216 | 2º to 8º C | 25,800 | 20,330.00 | 287.54 | 20,617.54 | 79.9 | 20.1 |
| Local | Health Establishments | 1625 | 2º to 8º C | 49,610 | 10,165.00 | 143.77 | 10,308.77 | 20.8 | 79.2 |

For IPV introduction in line with target population and schedule, a quarterly storage capacity of 862.63 litres is required, as per the preference for the 5-dose vaccine vial offered by the Rotating Fund and chosen by the country. The analysis conducted for each supply centre found existing storage capacity in the 8 warehouses sufficient for the IPV (Attachment 2).

In summary, based on the analysis of available storage capacity taken up by the vaccines in the national schedule and required for IPV introduction, installed storage capacity for the existing vaccines and the new IPV is conclusively found sufficient on all levels. However, introducing this new vaccine will make it needful to strengthen central and municipal capacities for the introduction of other vaccines.

In this context, the Expanded Immunisation Programme, through the vaccine act, assures the purchase of cold chain equipment on a yearly basis within the national budget. Through the project approved by GAVI-HSS for 2015-2016, cold chain strengthening on the different levels is guaranteed for an amount of 2.4 million USD.

The 2015-2016 GAVI-HSS project contemplates strengthening the cold chain and the supply chain through the following activities:

* Remodelling and expansion of storage capacity on the central level (National Vaccine Centre) by installing 2 new cold rooms, increasing the storage capacity of 73,300 to 113,300 litres (increase of 40,000 litres).
* Remodelling and expansion of storage capacity on the regional level (5 supply centres) by installing 5 new cold rooms, increasing the storage capacity of 115,700 to 190,700 litres (increase of 75,000 litres).
* Acquiring cold chain equipment for the municipal level, increasing storage capacity from 25,800 to 44,175 litres (Increase of 18,375 litres).
* Acquiring cold chain equipment for the local level, increasing storage capacity from 49,610 to 58,985 litres (Increase of 9,375 litres).
* Acquiring spare parts for cold chain maintenance.
* Strengthening cold chain supervision and evaluation.
* Strengthening vaccine distribution logistics by acquiring 5 refrigerated vehicles and 5 non-refrigerated vehicles for supplies distribution.
* Implementation of web-based Medical Supplies Store Management (wMSSM) version 5.0 nationwide.

Each level formulates an Annual Operating Plan (AOP) into which operating expenses for preventive and corrective maintenance and payments for electric power are programmed to keep health establishments, municipal directorates and health regions operating, including the cold chain. Hence, no additional payments are required for new vaccine introduction.

The budget is approved for execution at the start of each year and drawn down by the implementing units (health regions), which purchase cold chain spare parts. In addition, by way of strengthening, the GAVI-HSS 2015-2016 project contemplates acquiring spare parts for cold chain maintenance.

**6.4.2 Supply Chain**

The new vaccine will be integrated into the supply chain established in accordance with standard distribution flow. No modification to the existing chain is required.

**Distribution management**

The following logistic elements are available to ensure the national supply of vaccines, syringes and sharps boxes:

**Central to regional level:**

**Vaccine distribution:** two refrigerated ANB vehicles distributing vaccines to 10 regional warehouses every quarter by land as per schedule. Air transport is used to supply the regions of Gracias a Dios and Islas de la Bahía.

**Distribution of syringes and sharps boxes**: an ANB truck delivers these every six months to 13 regional supplies warehouses by land as per schedule. Sea transport is used to supply Gracias a Dios and air transport for Islas de la Bahía.

**Regional to municipal level:**

Two regional vaccine warehouses (Atlántida and Valle) distribute vaccines to each municipality in (unrefrigerated) institutional vehicles. In the rest of the regions, every municipality collects the vaccines and supplies from the regional vaccine warehouse monthly, in institutional or commercial transport.

**Municipal to local level:**

The local level collects the vaccines, syringes and sharps boxes from the municipal level monthly in commercial transport.

IPV distribution as per availability during the period for the year of introduction will be included in the central level vaccine delivery for the fourth quarter of the year. In the case of the syringes and sharps boxes required for IVP, as these have a six-monthly distribution flow, an additional trip will be required in August 2015.

Temperature will be controlled in line with standards on all storage levels and during transport (regional, municipal and local) using alcohol thermometers.

**Stock management**

In 2010, VSSM was implemented on the level of the National Vaccine Warehouse. Implementation spread progressively to 19/20 health regions, except for that of Gracias a Dios. It currently operates in 18 health regions.

This tool has improved vaccine and supplies stock management regionally and centrally with regard to timely stock availability, inputs, outputs, availability of emergency reserves, control of vaccines about to expire, in general, improving the handling and control of vaccines and supplies.

During the second half of 2014, implementation of the on-line version for inventory control over vaccines, syringes and sharps boxes (wMSSM) began in 4/20 health regions, with the technical and financial support of PAHO/WHO. This will be expanded in 2015.

* 1. **Vaccine safety**

Chapter XIII of the manual on EPI standards and procedures, on vaccine safety, establishes the standards and procedures for the administration of safe injections and AEFI surveillance.

* + 1. **Injection Safety and Waste Management**

The section on safe injection practices establishes good practices for administering vaccines, the policy on open multi-dose vaccine vials recommended by the WHO, types and vaccine administration modes and techniques, and the safe elimination, disposal and management of sharps waste and used vaccine vials.

Among the technical and operational guidelines for IPV introduction, following will be considered:

* Strengthening the already-standardised know-how on: the use of AD syringes, not recapping, the use of portable needle destroyers, disposal of syringes with used needles in sharps boxes, disposal of used vials in sharps boxes, final disposal of sharps boxes in urban areas (incineration, sanitary landfill and municipal dumps) and rural areas (burying the boxes in a sharps pit).
* Incorporating the standard policy on open multi-dose vials recommended by the WHO, for use during a maximum of 28 days once the vial is opened.

**6.5.2 AEFI Surveillance**

As was said at the beginning of the section, AEFI surveillance is standardised on the national level. It covers surveillance over serious events, adverse event classification, definitions of some AEFI cases and procedures for handling related to reporting, filling up report forms, investigation, sample taking, autopsy, activation of the crisis committee by levels, distribution of information to health staff and the population, classification, feedback on all levels, etc.

With regard to operation, the EPI is the authority responsible for AEFI surveillance. There is no national committee exclusively devoted to AEFI surveillance, but rather, the National Immunisations Advisory Committee (CCNI) is tasked with participating by appointing a subcommittee to analyse the reasons for serious AEFIs, inviting clinical, laboratory and surveillance experts, NRAs and others it may consider appropriate.

The creation of a pharmacovigilance unit is underway on the national plane.

IPV introduction will bring about the updating of crisis plans on all levels in the context of SESAL OD.

* 1. **Health Staff Training**

Depending on existing installed capacity, the SESAL relies on technical and operative human resources to ensure IPV introduction on every level, for conducting the process, training, vaccine and supplies storage and distribution, promotion of immunisation, vaccine administration, supervision and evaluation.

The process of training public sector health staff (including the IHSS and decentralised models) will be done on all levels. The steps to be taken are set forth in the plan's implementation timeline (Attachment 2 of the application) and is summarised as follows:

* Preparation of key documents: manual of technical and operational guidelines cited in Section 6.2 and informative and educational materials cited in Section 6.7.
* Formulation of a national training plan covering objectives, goals, methodology (setting forth the staff obliged to participate per level using the cascade method; training agenda for regional and local levels), resources required (documents, presentations to be used in print and digital format), activities, timeline and budget. This will serve as reference for formulating the 20 regional plans.
* Nationwide distribution of training material.
* Health staff training in accordance with the national timeline, by level.
* Preparation of training report.

* 1. **Communication and Social Mobilisation**

The EPI is backed by a national health promotion plan 2013-2017 emphasising the EPI, formulated under the guidance of the National Health Promotion Programme, now the UCS, based on analyses of the existing studies on lost immunisation opportunities and surveys conducted during mass immunisations, among others.

The development of this component takes place in the context of the aforementioned plan, which will start implementation in 2015 with approved GAVI-HSS 2015-2016 support.

The UCS, dependent on the Secretariat for Health, in coordination with the EPI managers, will prepare the communication and social mobilisation strategy for IPV introduction, which will form part of the document on technical and operational guidelines for IPV introduction. This strategy will be validated on the technical level and on the operational levels to guarantee comprehension and orientation of the implementation process, to raise awareness among opinion leaders and the population in general. The awareness-raising projected will be conducted through awareness events with the key players previously mentioned on the central as well as the regional and local levels. Initial awareness-raising among political leaders, for public opinion and strategic allies, purports to obtain defence and support for the cause of IPV introduction, pinpointing its benefits for the population and defining its contribution to the Polio Eradication and Endgame Strategic Plan in Honduras.

The comprehensive strategy includes the design, validation, reproduction and distribution of communication material to be used in the different media available. For the purpose, the technical and methodological orientations for the appropriate use of each communication material or tool will be determined, so as to prepare the pertinent methodological instrument.

The national communication and social mobilisation strategy along with the methodological process of its implementation will be circulated through face-to-face meetings held by levels, to guarantee the proper use of the educational material and the achievement of the objectives aimed at in the national communication and social mobilisation strategy for IPV implementation.

Based on the broad experience of the country in new vaccine introduction, massive immunisation events and campaigns, the activities described below will be conducted to implement this strategy:

* Technical meetings of the National Committee for communication and social mobilisation to organize preparation and implementation of the National Communication and Social Mobilisation Strategy in the process of IPV introduction.
* Preparation of the communication and social mobilisation strategy for IPV introduction.
* Field visits to prepare photo shoots based on the target images proposed by the committee to draw up the design of communication material.
* Technical and field validation of the communication material in the urban and rural area health establishments.
* Design of communication material for target population awareness-raising:
* Poster with updated national immunisation schedule reflecting the incorporation of IPV, intended for health staff and the population.
* Promotional IPV implementation poster intended for health establishments, strategic inter-sector allies and opinion leaders.
* Updated poster of immunisation techniques including IPV (administration of 2 simultaneous injectable vaccines) for health establishments.
* Pocket guides containing the national immunisation schedule for health staff conducting immunisation activities.
* Preparation of promotional banners for the official national and regional launching.
* Definition of promotional messages and material on social networks.
* Radio and television spots.
* Meeting with health region Social Communication coordinators to circulate the national communication and social mobilisation strategy for IPV introduction.
* Meetings with strategic allies, social communicators, opinion leaders and external funding agencies to circulate the IPV introduction strategy.
* Nationwide distribution of promotional material.
* Preparation of an informative bulletin on national IPV introduction to standardise messages from political and technical authorities and cooperation partners on all levels.
* Official launching of IPV Introduction and the Communication and Social Mobilisation Strategy on the central level.
* Preparation and dissemination of press bulletins.
* Support of a technician for every health region in preparing, implementing and monitoring the local Communication and Social Mobilisation strategy for IPV introduction.
* Nationwide dissemination of promotional material in health establishments, over SESAL social networks, to other key organizations and to radio and television communication media.
  1. **Information System**

IPV introduction will require the revision and adaptation of the manual and digital information subsystem of the EPI. Below are the activities to conduct in coordination with the pertinent departments:

* Revision of the record forms of administered doses Vac-1, Vac-2, SINOVA-1, Vac-SINOVA 2 and the Immunisation Subsystem (SIVAC) and the Nominal Immunisation System (SINOVA), in coordination with the AES.
* Form for SG-1 and SG-2 (special groups).
* Integrated surveillance list of children (LINVI) by town
* Immunisation coverage graph
* National immunisation cards and children's cards, in coordination with the Directorate General for Standardisation.
* Monthly immunisation coverage monitoring database.
* Monthly request form for vaccines, syringes and sharps boxes.
* Daily and monthly control form for vaccine inputs and outputs.
* Daily and monthly control form for syringe inputs and outputs.
  1. **Implementing Immunisation**

IPV will be incorporated into the national immunisation schedule on the national level starting 1 October 2015 through the sustained programme of internal and field immunisation.

* 1. **Monitoring and Supervision**

The monitoring and supervision process is essential to ensure the success of IPV introduction, to identify progress made and problems encountered and help in decision-making. Conduct of the following activities will be the responsibility of the central and regional level integration teams:

**Monitoring**

* Monitoring fulfilment levels of the plan of IPV introduction activities by component and timeline.
* Monitoring OPV and IPV immunisation coverage by dose, by health establishment, by municipality and by health region.

**Supervision**

* Preparation of an exclusive guide for supervision before, during and after the introduction process.
* Revision and adaptation of the EPI supervision guide to incorporate IPV.
* Supervision of the introduction process in the scheduling phase (August to September), during implementation (October) and after (November to December) on all levels (central, regional, municipal and local) through the competent technical authorities, with the participation of the different technical personnel responsible for the plan components: Directorate for Standards Surveillance, EPI, Planning Unit, AES, logistics unit, UVS,UCS, etc.
  1. **Evaluation**

The central level EPI conducts six-monthly evaluations ever year with the participation of health region technical teams, other SESAL technical departments and cooperation partners in which, in keeping with established method, programme operation by component is evaluated, giving rise to a schedule of commitments.

In the context of IPV introduction, the following activities are proposed:

* To include the evaluation of IPV introduction in the national evaluation meeting for the second half of 2015. Funds are available through GAVI-HSS, which requires complementing for the inclusion of IPV evaluation.
* To include IPV introduction in the regional evaluation meetings and specific EPI meetings in selected regions (GAVI-HSS funds are available).

1. **IPV Introduction Timeline of Activities**

Attachment 3 presents the timeline of activities for the implementation of the national IPV introduction plan by components.

1. **Introduction Plan Budget**

Annex 4 of the plan (Attachment 3 of the application) presents the budget estimates for the conduct of the activities proposed by component, breaking down the total amount required by cost item in both Lempiras and USD, the national and foreign funding sources, the amount requested from GAVI and the available amount approved by GAVI in other lines of support such as the Transition Plan and GAVI-HSS.

The estimate of costs per activity is based on the estimated calculation of the EPI 2014 action plan by unit, considering the scale of national travel expenses, the estimated national market costs of printed material and the EPI 2011 national costing database for the calculation of salaries and other operating expenses related to basic services.

The EPI 2015 action plan reflects all the activities and costs of the IPV introduction plan.

1. **References**
2. GAVI. Supplementary Guidelines for Inactivated Polio Vaccine (IPV) Applications in 2015, October 2014.
3. Pan-American Health Organization Practical Guide: Inactivated Poliovirus Vaccine (IPV) Introduction. Washington DC: PAHO, 2014.
4. Pan-American Health Organization Introduction and Implementation of New Vaccines: Field Guide Washington D.C.: PAHO, 2009. (Scientific and Technical Publication No. 632).
5. Secretariat for Health [Honduras], National Institute of Statistics (INE) and ICF International. 2013. *Encuesta Nacional de Salud y Demografía* [National Survey on Demography and Health] 2011-2012. Tegucigalpa, Honduras: SS, INE and ICF International.
6. Honduran Secretariat for Health Transition Plan of the Republic of Honduras, Global Alliance for Vaccines and Immunisation, Tegucigalpa, April 2014.
7. Honduran Secretariat for Health Proposal for Health System Strengthening, Honduras 2015-2016, Tegucigalpa, May 2014.
8. Secretariat for Health. Evaluation of the Expanded Programme on Immunisation in Honduras 2010-2013, Tegucigalpa MDC, 2013.
9. **Annexes**

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| **Attachment 2 ANALYSIS OF COLD CHAIN STORAGE CAPACITY REQUIRED** | | | | | | | | |
| **FOR IPV INTRODUCTION IN 5-DOSE VIALS, HONDURAS 2015** | | | | | | | | |
|  |  |  |  |  |  |  |  |  |
| **Vaccine Warehouse** | **Health Regions where vaccines are supplied** | **Total IPV Doses per Quarter** | **Volume in litres required IPV** | **Volume in litres Current Vaccines** | **Required capacity current vaccines + IPV** | **Capacity of each storage facility** | **% Occupied Capacity** | **% Unoccupied Capacity** |
| \*National Vaccine Warehouse (Tegucigalpa) Central Level | 8 Regional vaccine storage facilities (supply centres) | 82,365 | 741.3 | 60,990.0 | 61,852.6 | 73,300.0 | 84.4 | 15.6 |
|  | Francisco Morazán | 3,237 | 29.1 |  |  |  |  |  |
|  | DC Metropolitan Area | 10,244 | 92.2 |  |  |  |  |  |
|  | **SUBTOTAL** | **95,849** | **862.6** |  |  |  |  |  |
| Atlántida | Atlántida | 4,416 | 39.7 | 4,624.8 | 4,703.8 | 9,100.0 | 51.7 | 48.3 |
|  | Colón | 3,812 | 34.3 |  |  |  |  |  |
|  | Islas de la Bahía | 550 | 5.0 |  |  |  |  |  |
| Comayagua | Comayagua | 5,875 | 52.9 | 3,955.6 | 4,067.6 | 7,300.0 | 55.7 | 44.3 |
|  | Intibuca | 3,751 | 33.8 |  |  |  |  |  |
|  | La Paz | 2,818 | 25.4 |  |  |  |  |  |
| Copán | Copán | 4,974 | 44.8 | 4,558.6 | 4,663.2 | 7,300.0 | 63.9 | 36.1 |
|  | Lempira | 4,956 | 44.6 |  |  |  |  |  |
|  | Ocotepeque | 1,692 | 15.2 |  |  |  |  |  |
| Cortés | Cortés | 9,756 | 87.8 | 8,131.6 | 8,384.9 | 46,000.0 | 18.2 | 81.8 |
|  | SPS Metropolitan Area | 6,549 | 58.9 |  |  |  |  |  |
|  | Santa Bárbara | 5,097 | 45.9 |  |  |  |  |  |
|  | Yoro | 6,740 | 60.7 |  |  |  |  |  |
| Choluteca | Choluteca | 5,582 | 50.2 | 3,408.2 | 3,476.9 | 15,200.0 | 22.9 | 77.1 |
|  | Valle | 2,052 | 18.5 |  |  |  |  |  |
| El Paraíso | El Paraíso | 5,391 | 48.5 | 2,515.4 | 2,563.9 | 15,200.0 | 16.9 | 83.1 |
| Gracias a Dios | Gracias a Dios | 1,402 | 12.6 | 150.8 | 163.4 | 400.0 | 40.9 | 59.1 |
| Olancho | Olancho | 6,952 | 62.6 | 3,150.0 | 3,212.6 | 15,200.0 | 21.1 | 78.9 |
| **SUBTOTAL REGIONAL FACILITIES** | | **82,365** | **741.3** | **30,495.0** | **31,236.3** | **115,700** | **27.0** | **73.0** |

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