# Application Form for Country Proposals

*Providing support for IPV Introduction*

Submitted by
The Government of Papua New Guinea

Date of submission: 1 September 2014

This form is applicable to applications submitted in 2014

*Document date: February 2014*
*This document replaces all previous versions and incorporates revisions to the cover page only.*

**The completed application documents must be submitted electronically to the GAVI Secretariat at proposals@gavialliance.org by the application deadline.**

Enquiries to: proposals@gavialliance.org or representatives of a GAVI partner agency. The documents can be shared with GAVI partners, collaborators and general public. The application and attachments must be submitted in English, French, Spanish, or Russian.

Note: Please ensure that the application has been received by the GAVI Secretariat on or before the day of the deadline.

The GAVI Secretariat is unable to return submitted documents and attachments to countries. Unless otherwise specified, documents will be shared with the GAVI Alliance partners and the general public.

## Application specification

A list of required attachments is included at the end of this form.

*Summary*

| The Government of: Papua New Guinea | Date of Submission **1 September 2014** |
|---|---|
| IPV introduction date (month/year) | Current DPT schedule: **November 2015** |
| Co-financing (yes/no) No | If co-financing, please specify amount ($) per dose: |

| Procurement mean (UNICEF SD, PAHO, self-procurement): **UNICEF** | | |
|---|---|---|
| Vaccine preference (in order of first to third) | Reason for choice of presentation | Expected wastage rate* |
| 1. 5 dose | 1. This will provide the optimum balance between available space and wastage. | 1. 30% |
| 2. 10 dose | 2. This would conform to the dosage pattern of the available OPV vials | 2. 50% |
| 3. 1 dose | 3. This will address the reduction of potential wastage; however, the cold chain space would require a re-assessment | 3. 5% |
| | | ** Cannot exceed 50% for 10-dose vials, 30% for 5-dose vials, 10% for 2-dose vials, or 5% for 1-dose vials* |

| Year | Number in target population for IPV[1] | Number in birth cohort | Number of surviving infants |
|---|---|---|---|
| 2014 | 0 | 222,486 | 209,804 |
| 2015 | 38,900 | 247,505 | 233,397 |
| 2016 | 238,765 | 253,197 | 238,765 |
| 2017 | 244,257 | 259,021 | 244,257 |
| 2018 | 249,875 | 264978 | 249,875 |

## IPV introduction plan

**Using the guidance in Annex A, attach your detailed IPV introduction plan as Attachment 1 to this application form.**

## Timeline

Using the Excel template provided in Annex C, please complete a detailed timeline for all activities related to the IPV Introduction Plan. The completed Annex C should be attached to this application as Attachment 2.

## Budget and financing

[1] If there are differences between country and WHO-UNICEF coverage estimates, the Secretariat will refer to the latter when estimating targets.

Using the Excel template provided in Annex D, please complete the budget template in Table E1 detailing expected expenses and funding sources. An example worksheet (Table E2) is provided to assist with estimating detailed costs for items related to vaccine introduction. The completed Annex D should be attached to this application as Attachment 3.

## Fiduciary management arrangement data

Please indicate below whether the one-time vaccine introduction grant for IPV should be transferred to the government, or to WHO or UNICEF. Please note that WHO and/or UNICEF will require administrative fees of approximately 7% which would need to be covered by the operational funds.

The Government of Papua New Guinea requests GAVI Alliance that the one-time vaccine introduction grant for IPV be transferred to the government as being done for PCV introduction and planned MR campaign in 2015.

If the vaccine introduction grant for IPV should be transferred to the government, countries which have completed a financial management assessment (FMA) should confirm whether the financial management modalities – including bank details – agreed with GAVI are still applicable, or alternatively provide details of any modification they intend to submit relating to the existing financial management arrangements.

Countries without an existing signed Aide Memoire derived from an FMA, but who would like the vaccine introduction grant for IPV transferred to the Government, should provide as Attachment 4 a description of their proposed funding mechanism to manage the IPV introduction grant, covering the following processes:

1. Planning, budget and coordination
2. Budget execution arrangements including internal controls
3. Procurement arrangements
4. Accounting and financial reporting
5. External audit arrangements
6. Internal audit oversight

## Signatures

*Government*

The Government of Papua New Guinea acknowledges that this new vaccine introduction is intended to contribute to the eradication of polio as reflected the Global Polio Eradication Initiative's Polio Eradication and Endgame Strategic Plan (http://www.polioeradication.org/resourcelibrary/strategyandwork.aspx#strategyandwork.aspx?s=2&_suid=138237298338504993089253147377 5).

The Government of Papua New Guinea requests support from GAVI for the use of inactivated polio vaccine.

The Government of Papua New Guinea commits itself to improving immunisation services on a sustainable basis. The Government requests that the GAVI Alliance and its partners contribute

financial and technical a ssistance to support immunisation of the targeted population with one dose of IPV as outlined in this application.

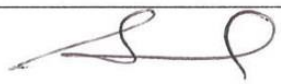
Annex D attached shows the amount of support requested from the GAVI Alliance as well as the Government of Papua New Guinea's and partners financial commitment for the introduction of IPV.

Please note that this application will not be reviewed by GAVI's Independent Review Committee (IRC) without the signature of the Minister of Health, Minister of Finance, and the ICC membership, or their delegated authority.

Please provide appropriate signatures below.

Enter family name in capital letters.

| **Minister of Health (or delegated authority)** | |
|---|---|
| **Name** | Mr. Pascoe KASE |
| **Date** | 10-9-2014. |
| **Signature** |  |

| **Minister of Finance (or delegated authority)** | |
|---|---|
| **Name** | Ms. Elva LIONEL |
| **Date** | 2-12-2014 |
| **Signature** |  |

This application has been compiled by:

Enter the family name in capital letters.

| **Full Name** | **Position** | **Telephone** | **Email** |
|---|---|---|---|
| Mr. Gerard Pai SUI | National EPI Manager | (675) 323 0976 | gerard.sui@gmail.com |
| Dr. William LAGANI | Manager, Family Health Services | (675) 301 3841 | lagani.william@gmail.com |
| Dr. Ornella LINCETTO | Team Leader & Medical Officer– MCH, WHO | (675) 325 7827 | lincettoor@wpro.who.int |
| Mr. Pierre SIGNE | Chief of Child Survival and Development Programme – UNICEF | (675) 308 7368 | spierre@unicef.org |

*National Coordinating Body – Inter Agency-Coordinating Committee (ICC) for Immunisation or equivalent*

We the members of the ICC, HSCC, or equivalent committee confirm that a quorum of the committee met on [Type text] to review this proposal. By the terms of reference for our committee, we endorsed this proposal at that meeting, based on the supporting documentation attached.

The endorsed minutes of this meeting are attached as Attachment 5.

Enter the family name in capital letters.

| Name/Title | Agency/Organisation | Signature |
|---|---|---|
| Dr. Paison DAKULALA, Deputy Secretary for Health | National Department of Health | |
| Dr. Sibauk V BIEB, Executive Manager, Public Health | National Department of Health | |
| Dr. Pieter Van Maaren, WHO Country Representative | World Health Organization | |
| Dr. Geoff CLARK, Programme Director Health & HIV, AusAID | DFAT, Australia | for Geoff Clark |
| Mr. Baba DANBAPPA, UNICEF Country Representative | UNICEF | |
| Dr. Paulus RIPA, Paediatrician & Senior Curriculum Development Advisor | School of Medicine, University of PNG | |
| Mr. Joseph SIKA, Representative, Churches Health Services | PNG Churches Health Services | |
| Dr. James AMINI, Chief Paediatrician & President | Paediatric Society of PNG | |
| Ms. Elva LIONEL, Deputy Secretary, NHPCS | National Department of Health | |
| Mr. Noriyuki ITO, Assistant Resident Representative | JICA country Office | No Longer a Member !! |

In case the GAVI Secretariat has queries on this submission, please contact:

Enter family name in capital letters.

| | | | |
|---|---|---|---|
| **Name** | Mr. Gerard Pai SUI | **Title** | National EPI Manager |
| **Tel no** | (675) 323 0976 | | |
| **Fax no** | (675) 323 0976 | **Address** | AOPI Centre, 3rd Floor, Waigani, Port Moresby, National Capital District, Papua New Guinea |
| **Email** | gerard.sui@gmail.com | | |

## Attachments required

- Attachment 1. IPV Introduction Plan (see Annex A)
- Attachment 2. Detailed timeline for key activities of the IPV introduction plan (see Annex C)
- Attachment 3. Completed budget and financing Tables E1 and E2 (Annex D)
- Attachment 4. Fiduciary management arrangement data (only applies for countries without an existing signed Aide Memoire derived from an FMA but who would like the IPV introduction grant transferred to the Government).
- Attachment 5. Minutes of ICC meeting endorsing the IPV introduction plan
- Attachment 6. A copy of the most recent comprehensive multi-year plan (cMYP). The cMYP does not need to include IPV; however, countries should specify a plan for inclusion of IPV into their next cMYP, including date for revision.

- Attachment 7. A progress report on the implementation of the improvement plan from an EVM conducted within the preceding 36 months. If no EVM has been conducted or if the current EVM was conducted more than 3 years ago, GAVI requires countries to provide a description of the vaccine management system in place and commit to conduct an EVM within six months of the application being approved.
- Attachment 8. GAVI generally procures and delivers vaccines and supplies through UNICEF or the PAHO Revolving Fund. If an alternative mechanism is requested, or the vaccine will be self-procured by the country itself, please document the requirements as listed in Section 2.3 of the Guidelines.

**GAVI ALLIANCE**
**GRANT TERMS AND CONDITIONS**

Countries will be expected to sign and agree to the following GAVI Alliance terms and conditions in the application forms, which may also be included in a grant agreement to be agreed upon between GAVI and the country:

***FUNDING USED SOLELY FOR APPROVED PROGRAMMES***
The applicant country ("Country") confirms that all funding provided by the GAVI Alliance for this application will be used and applied for the sole purpose of fulfilling the programme(s) described in this application. Any significant change from the approved programme(s) must be reviewed and approved in advance by the GAVI Alliance. All funding decisions for this application are made at the discretion of the GAVI Alliance Board and are subject to IRC processes and the availability of funds.

***AMENDMENT TO THIS PROPOSAL***
The Country will notify the GAVI Alliance in its Annual Progress Report if it wishes to propose any change to the programme(s) description in this application. The GAVI Alliance will document any change approved by the GAVI Alliance, and this application will be amended.

***RETURN OF FUNDS***
The Country agrees to reimburse to the GAVI Alliance, all funding amounts that are not used for the programme(s) described in this application. The country's reimbursement must be in US dollars and be provided, unless otherwise decided by the GAVI Alliance, within sixty (60) days after the Country receives the GAVI Alliance's request for a reimbursement and be paid to the account or accounts as directed by the GAVI Alliance.

***SUSPENSION/ TERMINATION***
The GAVI Alliance may suspend all or part of its funding to the Country if it has reason to suspect that funds have been used for purpose other than for the programmes described in this application, or any GAVI Alliance-approved amendment to this application. The GAVI Alliance retains the right to terminate its support to the Country for the programmes described in this application if a misuse of GAVI Alliance funds is confirmed.

***ANTICORRUPTION***
The Country confirms that funds provided by the GAVI Alliance shall not be offered by the Country to any third person, nor will the Country seek in connection with this application any gift, payment or benefit directly or indirectly that could be construed as an illegal or corrupt practice.

***AUDITS AND RECORDS***
The Country will conduct annual financial audits, and share these with the GAVI Alliance, as requested. The GAVI Alliance reserves the right, on its own or through an agent, to perform audits or other financial management assessment to ensure the accountability of funds disbursed to the Country.

The Country will maintain accurate accounting records documenting how GAVI Alliance funds are used. The Country will maintain its accounting records in accordance with its government-approved accounting standards for at least three years after the date of last disbursement of GAVI Alliance funds. If there is any claims of misuse of funds, Country will maintain such records until the audit findings are final. The Country agrees not to assert any documentary privilege against the GAVI Alliance in connection with any audit.

***CONFIRMATION OF LEGAL VALIDITY***
The Country and the signatories for the government confirm that this application is accurate and correct and forms a legally binding obligation on the Country, under the Country's law, to perform the programmes described in this application.

***CONFIRMATION OF COMPLIANCE WITH THE GAVI ALLIANCE TRANSPARENCY AND ACCOUNTABILITY POLICY***

The Country confirms that it is familiar with the GAVI Alliance Transparency and Accountability Policy (TAP) and will comply with its requirements.

***ARBITRATION***

Any dispute between the Country and the GAVI Alliance arising out of or relating to this application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either the GAVI Alliance or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The language of the arbitration will be English.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by the GAVI Alliance. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: The GAVI Alliance and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

The GAVI Alliance will not be liable to the country for any claim or loss relating to the programmes described in this application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. Country is solely responsible for all aspects of managing and implementing the programmes described in this application.

***USE OF COMMERCIAL BANK ACCOUNTS***

The eligible country government is responsible for undertaking the necessary due diligence on all commercial banks used to manage GAVI cash-based support, including HSS, ISS, CSO and vaccine introduction grants. The undersigned representative of the government confirms that the government will take all responsibility for replenishing GAVI cash support lost due to bank insolvency, fraud or any other unforeseen event.

# Annex A:
# Papua New Guinea IPV Introduction Plan

Table of Contents

## Executive Summary

In May 2012, the World Health Assembly declared the completion of poliovirus eradication to be a programmatic emergency for global public health and the Polio End Game Strategic Plan 2013- 2018 was launched in May 2013. Key to the success of the plan is the continued contribution of all nations in vaccinating every child against polio and ensuring a sensitive Acute Flaccid Paralysis (AFP) surveillance.

Although Papua New Guinea (PNG) attained poliomyelitis-free status in 2000, it continues to have an important part to play in global eradication. Pockets of low vaccination coverage in the country and weak surveillance systems, combined with a growingly mobile populations and an influx of international labour for recent economic activities in the country, PNG is at high risk for importation and spread of vaccine preventable diseases including poliomyelitis. PNG is classified as a Tier 2 Country on the Global Risk Tier scale for IPV introduction and prioritization. In recognition of the seriousness of this, PNG developed its own Polio Eradication Endgame Strategic Plan (PNG PEGS) in 2014.

Key to PNG PEGS is the eventual transition from OPV to IPV, prior to complete cessation of IPV following global eradication.

Unfortunately, in rare cases OPV has led to vaccine derived polio virus (VDPV). 2012 saw the first time when there were more cases of circulating VDPV than wild poliovirus. 90% of cVDPV cases were found to be derived from the type 2 component of OPV. Considering this, and the fact that WPV2 has already been eradicated, a key component of the PNG PEGS is to remove the use of specific OPV serotypes from all immunization activities. The first step in this is the introduction of IPV, which has the following benefits.

1. Risk reduction: As IPV helps to immunize against type 2 poliovirus it provides safety against risk of immunity loss through the withdrawal of tOPV, should type 2 ever be reintroduced.
2. Transmission interruption in the case of outbreaks: If mOPV type 2 is required to be given in response to a WPV2 or cVDPV2 outbreak following tOPV withdrawal, those who have been vaccinated with IPV will have a better immune response, thereby reducing transmission and outbreak risk.
3. Acceleration of WPV eradication: IPV will also act as an immunity booster for WPV1 and WPV3 in those who have received OPV, which may lead to swifter eradication

The Government of PNG (GoPNG) believes that the introduction of IPV will be beneficial to the country not only in terms of reducing the risk of importation and spread of polio, but also in regard to strengthening routine immunisation overall.

IPV will be introduced into routine immunisation program nationally across PNG in November 2015, in conjunction with the introduction of Measles Rubella (MR) vaccine after the completion of campaign. Experience in PNG has shown that frequent program changes can create heavy burdens in terms of operational cost, confusion and fatigue amongst health care workers, leading to a reduction in program outcomes. As such, the GoPNG sees multiple vaccine concurrent

introduction as the best method to pursue. In addition to this, IPV and other vaccine introduction will be part of wider current efforts to improve routine immunisation through continued microplanning, increased outreach efforts, improved cold chain and the introduction of default tracking to reduce the drop-outs.

Following the SAGE recommendation, IPV will be given at the third contact, at the same time as the third dose of OPV and Pentavalent. The vaccine will be introduced nationally. Preparatory activities such as the updating of tally sheets and immunisation cards will be done once the approval is received from GAVI however, registering of the vaccine and updating the immunization register have already begun. In addition to this, an internal cold chain assessment will be planned to be conducted in the fourth quarter of 2014, with follow up improvements to be made to increase capacity for new vaccines in the first and second quarters of 2015.

Key to the new vaccine introduction will be the training of health care workers. As part of current broader efforts to improve immunisation systems, a new training program has been developed that seeks to upskill workers in vaccine delivery, effective vaccine management, and AEFI (adverse event following immunisation) and AFP (acute flaccid paralysis) surveillance. The introduction of IPV will be a key part of the training program.

As the first year of introduction of IPV would involve introduction of the vaccine in November 2015, it would aim to target 38,900 children (Adjusted to the month of the introduction), will require 55,571 doses of IPV, after considering a target coverage rate of 80%, an estimated 30% wastage and a 25% buffer. At an estimated cost of $1 per dose, and an additional 10% for freight costs, this results in a request of USD 61,128. In addition to this, GoPNG for the first year is requesting assistance through the provision of auto-disable syringes and safety boxes to be used in the introduction of IPV. The required 61,128 AD syringes (using an estimated 1.1 wastage factor) at USD 0.55 each, and 672 safety boxes at USD 0.72 total to a cost of USD 35,128 for injection supplies. Finally, GoPNG is also requesting GAVI's assistance through the Vaccine Introduction Grant (VIG) of USD 0.80 per child for a total of USD 186,717.87. This grant will be used to assist with the training of health care workers, the reproduction of print materials and other essential activities that will ensure that IPV is successfully introduced by 2015. The total ask to GAVI for IPV introduction, including vaccines, injection supplies and the VIG is USD 282,973 in the first year, and approximately USD 600,000 each subsequent year.

The Church Health Services support the GoPNG is delivering nearly 80% of the health services in the rural community. Also, the GoPNG partners with local national and international NGOs at the provincial and health centre level for delivery and supervision of the services. All these mechanism will be activated during the introduction of IPV.

The main challenges that surround the introduction of IPV include historically low coverage rates and a heavy reliance on weak outreach systems. However, these challenges have been acknowledged by the government and work is being done to overcome them, including the re-introduction of the child health register, the promotion of defaulter tracking and improved microplanning through the RED-REC (reaching every district to reach every child) strategy.

In addition to this, challenges in surveillance have been addressed through the procurement of a new staff position National Surveillance designated specifically for vaccine preventable diseases, including AFP, and the appointment of a surveillance officer within the EPI team with additional responsibility for data management. Innovative methods are also being applied, such as the roll out of an SMS reminder system for AFP reporting. Health systems risks are being addressed through a National Human Resource for Health Crisis strategy underway, and innovative funding solutions being implemented such as Direct Health Facility Funding (DHFF). The GoPNG believes that the increased efforts on EPI as a result of the introduction of multiple vaccines in 2015 will bolster the motivation and ability of staff to reach the unreached.

## 1. Justification for introduction of IPV and national decision-making process

In May 2012, the World Health Assembly (WHA) declared the completion of poliovirus eradication to be a programmatic emergency for global public health. In response, the Polio End Game Strategic Plan 2013-2018 was launched in May 2013. Following on from the Global Polio Eradication Initiative Strategic Plan 2010-2012, the plan aims to eradicate both wild and vaccine derived poliovirus and also seeks to utilize the current efforts of polio programs to strengthen routine immunization programs in order to reach the world's most vulnerable and under-immunized children. Key to the success of the plan is the switch towards bOPV from tOPV, with cessation of OPV2 which has been found to be the main cause of vaccine derived poliovirus and vaccine-associated paralytic poliomyelitis. In order to reduce the risk associated with this withdrawal, the introduction of inactivated polio vaccine (IPV) must happen first.

The introduction of IPV has three benefits:

1. Risk reduction: As IPV helps to immunize against type 2 poliovirus it provides safety against risk of immunity loss through the withdrawal of tOPV, should type 2 ever be reintroduced.
2. Transmission interruption in the case of outbreaks: If mOPV type 2 is required to be given in response to a WPV2 or cVDPV2 outbreak following tOPV withdrawal, those who have been vaccinated with IPV will have a better immune response, thereby reducing transmission and outbreak risk.
3. Acceleration of WPV eradication: IPV will also act as an immunity booster for WPV1 and WPV3 in those who have received OPV, which may lead to swifter eradication.

Although Papua New Guinea (PNG) was declared poliomyelitis free in 2000 it continues to have an important part to play in global eradication. While poliovirus still exists in any part of the world, it poses a threat of importation to any country; for example in 2007 an adult Pakistani student brought the virus to Australia when returning from a visit. In particular however, countries with low vaccination coverage and vulnerable surveillance systems are at a significant risk.

PNG is classified as a Tier 2 Country on the Global Risk Tier scale for IPV introduction and prioritization. This Tier includes large/medium sized countries with

any history of cVDPVs (types 1 and 3) since 2000 or countries that have repeatedly reported routine immunization coverage estimates of less than 80% over the past three years with under - performing surveillance system. Based on the risk assessment evaluation the Western Pacific Regional Certification Commission for Polio has classified PNG at high risk of polio re-importation within the WHO WPRO region.

PNG's risk of importation of wild poliovirus is exacerbated by its low vaccination coverage (69% in 2012) and a weak AFP (acute flaccid paralysis) surveillance system. This is compounded by the current economic boom driven by the extractive industries, which has led to an influx of expatriate workers from different parts of the world including some of the polio-endemic countries. The rapid spread of any disease within the country is also now a higher risk as the population becomes more transient as it seeks new economic opportunities. PNG also now faces a new risk from "boat people" under a new agreement between Australian and PNG, whereby refugees seeking asylum in Australia via sea are processed in a center on Manus Island. This has the potential to open the way not only for polio importation but also for other vaccine preventable diseases.

In light of this, in March 2014 the PNG Polio Endgame Strategic Plan was developed by the PNG National Certification Committee (NCC) in collaboration with NDoH, WHO, UNICEF the Child Health Advisory Committee and the Paediatric Society. This plan, which is aligned with the global version, outlines a pathway forward for PNG to contribute to eradication and the endgame and was approved by the Secretary for the National Department of Health on 3 April, 2014.

A key component of this plan is the decision to introduce IPV by 2015. As per the SAGE recommendation, one dose of IPV will be given in conjunction with the current third doses of OPV and DPT-HepB-Hib at the third contact (12 weeks). As such, PNG is requesting the assistance of GAVI for one dose of IPV.

The successful introduction of DTP-HepB-Hib vaccine in 2008 proved that PNG is capable of such programmatic changes, and lessons learned from this experience will be used in planning for IPV introduction.

2015 will also see PNG introduce Measles Rubella vaccine into the routine schedule. Experience in PNG has shown that frequent program changes can create heavy burdens in terms of operational cost and fatigue for health care workers, leading to a reduction in program outcomes. As such, the GoPNG sees vaccine multiple concurrent introduction as the best method to pursue. It is envisioned that this will provide opportunity to streamline training and reduce printing efforts, as well as other benefits. In addition to this, IPV and other vaccine introduction will be part of wider current efforts to improve routine immunisation through continued microplanning, increased outreach efforts, improved cold chain and the introduction of default tracking.

## 2. Overview of IPV

### 2.1 Vaccine preference

**Table 1. IPV vaccine preferences and estimated date of introduction**

| Preferred IPV vaccine | Month and year of first vaccination | Preferred second presentation | Preferred third presentation |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 5 dose stand-alone IPV | November 2015 | 10 Dose stand-alone IPV | No preference (would not prefer a single dose vial) |

PNG's first preference would be the 5 dose vial of the WHO pre-qualified stand-alone IPV (followed by 10 doses, then 1 dose). This would provide the optimal balance of waste reduction and storage capacity. When taking in to consideration PNG's target population of 233,397 children for 2015, with a target of 80% coverage rate for IPV, estimated 30% wastage and a 25% buffer, this will require 333,245 doses of IPV annually. With the 5 dose vials having a volume of 4.44cm$^3$ per dose in total this will require an additional 1,480,405.97 cm3 of cold chain volume. It is estimated that PNG will be able to adequately meet this requirement.

## 2.2 Country licensure status

IPV is registered for use in PNG which was approved by pharmaceutical regulatory unit (PNG's national regulatory authority) and thus the product has been licensed to be used in the country.

## 2.3 Target population and vaccine supply

| Number | Targets | | | | |
|---|---|---|---|---|---|
| | 2015 (adjusted for November as introduction month) | 2016 | 2017 | 2018 | 2019 |
| Total Infant Population | 233,397 | 238,765 | 244,257 | 249,875 | 255,622 |
| OPV3 Coverage (%) | 80% | 80% | 80% | 80% | 80% |
| IPV target (%) | 80% | 80% | 80% | 80% | 80% |
| Number of infants to be vaccinated with IPV | 38,900 | 191012 | 195406 | 199900 | 204498 |
| Doses required including 30% wastage rates and 25% buffer | 55,571 | 341,094 | 348,939 | 356,964 | 365,174 |

## 3. Introduction and implementation considerations

### 3.1 Policy development

PNG's Child Health Policy and Plan indicates that the maintenance of PNG's polio-free status is a key aim, as well as the introduction of new vaccines against major killer diseases of children. This plan is aligned with the National Health Plan 2011-2020, which forms the basis of all health planning in the country.

PNG's cMYP 2011-2015 is aligned with Child Health Policy and Plan and has specific reference to the maintenance of polio-free status and commits to the introduction of new vaccines based on available evidences in the country. The introduction of IPV and the eventual switch from tOPV to bOPV are not outlined in the current plan, however will be included as it is updated for the 2016-2020 version. The consultative process for this update will begin shortly (Q3/4 2014).

The decision to deliver IPV at the third contact at the same time as the third doses of OPV and DTP-HepB-Hib means that the immunisation schedule will not need to be altered, other than adding an extra injection at the third contact. As such, the introduction of IPV is not expected to have a negative effect on the overall EPI.

| | **Immunization given at:** | | | | |
|---|---|---|---|---|---|
| **Vaccine** | 1 Month | 2 Months | 3 Months | 9 Months | 18 Months |
| DTP-HepB-Hib | ☑ | ☑ | ☑ | | |
| OPV | ☑ | ☑ | ☑ | | |
| IPV | | | ☑ | | |
| PCV | ☑ | ☑ | ☑ | | |
| MR | | | | ☑ | ☑ |

IPV will be administered by intramuscular injection on the right thigh. Once PCV is introduced the two injections will be given on the same (right) thigh, two centimetres apart. DTP-HepB-Hib will be given on the left thigh due to the fact that it is more reactogenic than the other two vaccines. The standard practice (as outlined in the EPI manual) of monitoring the patient for 30 minutes following the injections will be applied.

### 3.2 National coordination mechanism to ensure the successful introduction

Initial preparations have already begun for the introduction of IPV, beginning with the stakeholder engagement and approval of the PNG Polio Endgame Strategic Plan. Throughout the implementation phase of the introduction more stakeholders will be engaged. Throughout the introduction of IPV, the National Certification Committee for Polio Eradication, Inter agency Coordination Committee and the Child Health Advisory Committee will continue to monitor and provide technical advice.

The Paediatric Society of Papua New Guinea will provide the required technical support along with WHO and UNICEF who will continue to extend the required technical and other support towards the introduction. Other donor partners at the national level as DFAT Australian Government and others at the provincial and districts level will provide the required support as need be; upon the consultation by the ICC members. The Provincial Family Health Coordinators through the involvement with the Provincial Governors and the Provincial Administrators will provide the ground for introduction of the vaccine in their respective provinces.

It is expected that if approved, the funding for the Vaccine Introduction Grant will be available to PNG by November 2014.

### 3.3 Affordability and financial sustainability

Considering the fact that PNG already procures 100% of its traditional vaccines, and exceeds the minimum contribution for Pentavalent and pneumococcal co-financing to GAVI, the GoPNG is in this case is requesting full support from GAVI for the introduction of IPV and upon completion of the support from GAVI, the vaccine will be supported completely by the GoPNG funds.

As the first year of introduction of IPV would involve introduction of the vaccine in November 2015, it would aim to target 38,900 children (Adjusted to the month of the introduction), will require 55,571 doses of IPV, after considering a target coverage rate of 80%, an estimated 30% wastage and a 25% buffer. At an estimated cost of $1 per dose, and an additional 10% for freight costs, this results in a request of USD 61,128. In addition to this, GoPNG for the first year is requesting assistance through the provision of auto-disable syringes and safety boxes to be used in the introduction of IPV. The required 61,128 AD syringes (using an estimated 1.1 wastage factor) at USD 0.55 each, and 672 safety boxes at USD 0.72 total to a cost of USD 35,128 for injection supplies. Finally, GoPNG is also requesting GAVI's assistance through the Vaccine Introduction Grant (VIG) of USD 0.80 per child for a total of USD 186,717.87. This grant will be used to assist with the training of health care workers, the reproduction of print materials and other essential activities that will ensure that IPV is successfully introduced by 2015. The total ask to GAVI for IPV introduction, including vaccines, injection supplies and the VIG is USD 282,973 in the first year, and approximately USD 600,000 each subsequent year.

Historically the GoPNG has shown a strong commitment to its immunisation program and will continue to do so. NDoH is currently working on strengthening routine immunisation through ongoing training, supportive supervision, the re-establishment of outreach and the introduction of defaulter tracking. These costs are being borne principally by GoPNG and if required by its development partners. This environment will ensure that IPV will be effectively sustained as a routine immunisation. In addition to this, the introduction of other new vaccines including MR and PCV will enable the program to benefit from vaccine multiple introduction through the reduction of upfront costs. Training of health care workers at district level is being planned.

Table 2: Vaccine Cost

| IPV | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|
| Estimated # Surviving Chidren | | 233,397 | 238,765 | 244,257 | 249,875 | 255,622 | 261,501 |
| Adjusted for November 2015 start date | | 38,900 | | | | | |
| Coverage estimates (for IPV) | | 80% | 80% | 80% | 80% | 80% | 80% |
| Doses in schedule | | 1 | 1 | 1 | 1 | 1 | 3 |
| Total # of doses needed (excluding wastage) | | 31,120 | 191,012 | 195,406 | 199,900 | 204,498 | 627,603 |
| Wastage estimates | | 30% | 30% | 30% | 30% | 30% | 30% |
| Wastage factor | | 1.43 | 1.43 | 1.43 | 1.43 | 1.43 | 1.43 |
| Total # of doses needed (including wastage) | | 44,457 | 272,875 | 279,151 | 285,571 | 292,140 | 896,576 |
| Buffer stock needed (additional per year) | | 11,114 | 68,219 | 69,788 | 71,393 | 73,035 | 224,144 |
| Total vaccine to be procured incl wastage and buffer | | 55,571 | 341,094 | 348,939 | 356,964 | 365,174 | 1,120,720 |
| Price of vaccine/dose | | $1.00 | $1.00 | $1.00 | $1.00 | $1.00 | $1.00 |
| Freight cost | | 10% | 10% | 10% | 10% | 10% | 10% |
| IPV cost | 0 | $61,128 | $375,203 | $383,833 | $392,661 | $401,692 | $1,232,792 |

Table 3: Injection Supply Costs

| | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 |
|---|---|---|---|---|---|---|---|
| Total # of doses needed (excluding wastage) | | 31,120 | 191,012 | 195,406 | 199,900 | 204,498 | 627,603 |
| Total # of doses needed (including wastage) + 25% buffer stock | | 55571 | 341094 | 348939 | 356964 | 365174 | 1120720 |
| AD syringes needed (estimated wastage factor 1.1) | | 61,128 | 375,203 | 383,833 | 392,661 | 401,692 | 1,232,792 |
| Total number of safety boxes needed | | 672 | 4127 | 4222 | 4319 | 4419 | 13561 |
| Price of AD syinge1 | | $0.55 | $0.55 | $0.55 | $0.55 | $0.55 | $0.55 |
| Price of Safety box | | $0.72 | $0.72 | $0.72 | $0.72 | $0.72 | $0.72 |
| Total AD syringe cost (including freight cost) | | $34,629 | $212,552 | $217,441 | $222,442 | $227,558 | $698,377 |
| Safety box (including freight cost) | | $499 | $3,061 | $3,131 | $3,203 | $3,277 | $10,057 |
| Total injection supplies | | $35,128 | $215,613 | $220,572 | $225,645 | $230,835 | $708,434 |

### 3.4 Overview of cold chain capacity at district, regional and central levels

The recent 2013 EPI Review found that cold chain capacity varied between provinces, districts and facilities. The availability of equipment was found to be high, however significant challenges were found with maintenance including ageing of equipment. A lack of skilled mechanics was noted, however some provinces have taken the initiative to train people in the required skills specific for cold chain maintenance.

The introduction of IPV will require additional cold chain space and assurance of quality control and continued maintenance. Considering the 5 dose vial has a volume of 4.44 $cm^3$, an additional 1,480,405.97 $cm^3$ of cold chain volume will be required, which is believed to be currently available. However, in order to guarantee preparedness not only for IPV introduction but also for other new vaccines, a cold chain capacity assessment will be carried out in the 4th quarter of 2014. Following this assessment improvements and modifications will be made as required. These costs will be borne by GoPNG and, if required, its partners. The GoPNG sees this as a valuable opportunity to improve cold chain capacity for the entire immunization program.

### 3.5 Waste management and injection safety

Current waste management practice in PNG sees that incinerators are used for waste disposal when available. Where there is no availability, sharps and waste are burnt and buried. This procedure is outline in the EPI manual and is followed nationwide.

In regards to injection safety, a policy is currently being drafted and is expected to be completed shortly. Currently AD syringes are used program wide, and this practice will continue with the introduction of IPV.

### 3.6 Health worker training and supervision

Currently, the national EPI program is working to train immunisation providers nationwide. It is planned that new vaccine introduction training will be a part of this comprehensive program. Again, the opportunity will be taken to benefit from vaccine multiple introduction by delivering this training concurrently and thereby reducing costs.

Historically, the EPI program has found that cascade training, or training of the trainers, is not beneficial in PNG, and that rather a concentrated, health centre targeted personal approach is more effective. As such, the training is provided at district level and will continue to be done in such a manner. As an integral part of this training program, all sites will be followed up with supportive supervision. In addition to this, training is designed to be integrated with other programs such as maternal and child health. The training material consists of basic understanding of the principles of routine immunization and involves dealing with hands-on training of health centre staff. The technical and other logistical support is being provided by both WHO and UNICEF on this.

The National EPI programme of PNG will also develop a guide book for health workers on use of IPV and will be incorporated with the health facility level, competency-based training including basics of EPI, cold chain, vaccine stock management and microplanning. The communication and social mobilization material production, technical support will be sought from UNICEF and WHO in consultation with the Health promotion unit of National Department of Health.

### 3.7 Risks and challenges

**Low coverage rates and the heavy reliance on (currently weak) outreach:** PNG continues to suffer from coverage rates that are lower than the country's targets. This is partly attributed to a poor health system, but mainly to the harsh geographical terrain of PNG and the difficulty found in reaching health facilities. A lack of paved roads or means of transport mean that many mothers are unable to bring their children for vaccination. As such, routine outreach is extremely important in the country. However, reviews of the program have shown that outreach services have considerably declined over the last decades. This poses a risk to the introduction of IPV through the possibility that children will remain unreached.

In order to address this the National EPI team is currently working on several initiatives as part of its overall strengthening of routine immunisation. This includes the re-introduction of the child health register, the promotion of defaulter tracking and improved microplanning through the RED-REC (reaching every district to reach every child) strategy. In addition to this, the GoPNG believes that the increased efforts on EPI as a result of the introduction of multiple vaccines in 2015 will bolster the motivation and ability of staff to reach the unreached.

**Weak surveillance:** In addition to low coverage, PNG also faces weak AFP surveillance and has not attained the goal of at least one non-polio AFP rate per year with adequate stool samples. A Provincial Surveillance review conducted by the Polio NCC of PNG and WHO in PNG in 2011 and 2013 detected significant gaps in the performance of surveillance in the country. The GoPNG is already working to address this and has introduced a new staff position in the National Surveillance designated specifically for vaccine preventable diseases, including AFP. In 2012 the National EPI team also appointed a surveillance officer with additional responsibility for data management. In addition to these new human resources, an SMS reminder project has been established to notify paediatricians each month report any cases of AFP. Initial analysis of this project has shown an increase in the non-polio AFP rate, from an annualized non-polio rate of 0.21 (5 AFP cases) per 100,000 children under 15 years of age in October 2012, compared to a rate of 0.79 (18 cases) in September 2013 and the project is being continued as part of the PNG Polio Endgame Strategic Plan.

**Health systems risks:** The success of health initiatives in PNG are directly related to the performance of the health systems, which have shown to be of poor quality. The 2013 EPI Review found this to be a significant challenge to the immunisation program with high rates of health facility closure, an ageing workforce and reoccurring delays with fund distribution. However, these sector-wide issues are being addressed by GoPNG, with a National Human Resource for Health Crisis strategy underway, and innovative funding solutions being implemented such as Direct Health Facility Funding (DHFF).

**Multiple Injections and vaccine rumours:** The introduction of IPV will require a third injection at the third contact and poses a risk that carers and health care workers may find this too stressful for the child. However, experience in PNG has shown that this is generally not a major concern. In order to prevent this risk though, extra efforts will be made in the communication strategy to reduce this. Overall, the risk of this concern is by far outweighed by the risk of loss to follow up and additional resources that would be required if IPV as given at a different contact. In addition to this, recent experience with the 2013 Tetanus Toxoid campaign showed that negative rumours around vaccines are a risk to PNG's immunisation program. Again, the combined

advocacy and social mobilisation activities that are planned to address routine immunisation and the multiple introductions will address this, and media (both traditional and social) will be monitored throughout the introduction and roll out.

**Challenge of frequent and complex changes to the immunisation schedules:** Experience has shown that making many changes to health programs creates an environment of risk in PNG. The weak linkages between national policy and provincial and health facility implementation mean that it can take considerable time for changes to be implemented, and that these changes are at times implemented poorly. It can also lead to dissatisfaction amongst health care workers who are taken out of their daily work too frequently. In particular, the introduction of IPV and the foreseeable switch from tOPV to bOPV is a complex move that will require thorough understanding. Decision makers, health care workers and carers may not understand the reasoning behind such changes. There is also the challenge of the complexity of the vaccine type. Considering that health care workers are used to freezing OPV they may do the same with IPV which would make it ineffective. The decision for multiple concurrent introduction of IPV, MR and PCV is hoped to help to reduce some of these burdens through the reduction of operational costs. But more so, the training around these introductions is being planned to form a part of a larger product of overall routine immunisation strengthening that focuses on district level training. It is hoped that these concentrated efforts will reduce the associated risks, and will reduce the amount of time health care workers are outside of their normal duties. In addition, renewed efforts to implement supportive supervision programs will help to reduce risks.

# 4. Situational analysis of the immunisation programme

## 4.1 General context of the country

Papua New Guinea is the most populous country in the South Pacific, with a population of approximately 7.1 million (2011 census) distributed throughout four administrative regions (Southern Coastal, Northern Coastal, Highlands, and New Guinea Islands). A culturally diverse nation, approximately 800 languages are spoken with over 100 dialects and a vast number of distinct ethnic groups exist. Large disparities exist in health and development indicators between provinces and districts.

The geographical terrain of PNG is diverse and consists of extensive mountain ranges, dense rainforests, complex river systems and over 600 islands. The majority of the population (86%) lives in remote, rural communities which can make accessing health services extremely difficult. It is estimated that only 3% of roads in the country are paved; many villages can only be reached by foot or canoe. In addition to this, there is a growing challenge associated with migration to urban areas with low employment, frequently leading to settlement living and an increasing pressure on limited health services.

PNG has significant natural resources which have led in recent years to an economic boom, particularly due to Exxon Mobile's $15 billion liquefied natural gas project. While this has led to an increase in gross national income (World Bank GNI per capita 2012 (US$): 1,790), it has also led to rapid inflation and the rise in cost of living which has not been met by an equal rise in salaries, leading to decreased standards of living. Particular challenges exist in law and order difficulties in PNG.

The majority of health services in PNG are provided jointly by the Government and church health services, both of which are primarily publicly funded. A small private

sector also exists, in addition to enterprise based services and traditional healers. Churches play a particularly important role in rural areas where they provide approximately 80% of rural health services. PNG's health system has undergone several transformations since the country's independence. The Organic Law on Provincial Governments and Local Level Governments (1977) delegated much of the management functions of health service delivery to the provincial and local level governments, while the New Organic Law (1995) further devolved financial power to them, leaving NDoH with mainly an advisory role and responsibility for major hospitals.

The Expanded Program on Immunization (EPI) has been a key program of the National Department of Health (NDoH) since 1977, and polio was one of the first 6 vaccine preventable diseases targeted by the program. The National Health Plan 2011-20 identifies improvement in vaccination of children and women as priority programs in Key Result Area (KRA) 4 (Improve Child Survival) and KRA 5 (Improve Maternal Health). A country Multi Year Plan (cMYP) has been developed for 2011-2015 which has been fully costed and outlines activities for coming years. The GoPNG continues to consider EPI as an important, cost effective intervention for reducing the morbidity and mortality of children from communicable diseases.

The majority of routine immunization services are provided by government and church fun facilities, which are primarily publicly funded, although a small number of private sector and non- governmental organization (NGO) providers exist as well. The GoPNG provides the majority of all traditional routine vaccinations, while GAVI assists with the procurement of Pentavalent and Pneumococcal Conjugate vaccine.

## 4.2 Geographical, economic, policy, cultural, gender and social barriers to immunization

The geographical complexity of the country means that outreach activities play an extremely important role in the program due to the remote location of the majority population and ongoing issues with transport and access to services. It is estimated that 30% of children access immunization through outreach (cMYP 2011-2015). Supplementary immunization activities (SIAs) continue to play an important part in addressing specific disease needs and assisting in reaching the hard to reach. SIAs were first used to assist with polio eradication in 1996, and measles SIAs have been conducted since 2003. More recently tetanus toxoid SIAs have also been implemented and were used to integrate other services, including OPV.

Clashes between tribes often result in violence, which has the ability to prevent access to services. Gender based violence is also largely prominent and can prevent equitable access to health. However, the available data in the country does not signify any gender-related barriers in accessing and delivering of the immunization services.

**Table 4. Trends in national vaccine coverage**

| Trends of national vaccine coverage (percentage) (admin) | | | | |
|---|---|---|---|---|
| **Vaccine** | **Vaccine Used** | **Target population (number by age and sex, if available)** | **Coverage reported (JRF)** | |
| | | | **Most recent** | **Previous year** |

| | | | year | |
|---|---|---|---|---|
| BCG | Serum Institute of India | Live births 215,543 | 80% | 80% |
| OPV 3 | Biopharma | Surviving infants 205,886 | 69% | 55% |
| DTP 1 / Penta 1 | Berna Biotech Korea Corp. | Surviving infants 205,886 | 82% | 80% |
| DTP 3 / Penta 3 | Berna Biotech Korea Corp. | Surviving infants 205,886 | 59% | 57% |
| Measles 1 | Serum Institute of India | Surviving infants 205,886 (only 9 month dose coverage figure provided) | 64% | 56% |

### 4.3 Findings from recent programme reviews

The 2013 EPI Review revealed that despite a slow increase in immunisation coverage the immunisation program is still facing challenges that prevent it from reaching its targets.

The review found that the GoPNG is highly committed to its immunization program and MDG 4, which is demonstrated through its emphasis on the program in the National Health Plan 2011-20 and other key policies, as well as the 100% procurement of traditional vaccines. However, challenges arise in securing commitment at the sub-national level, where effective leaders are shown to make a pivotal difference in programmatic outcomes. It was also found that national planning does not always translate in to implementation at the provincial and health facility levels. The review found that low immunisation coverage is related to a lack of access to services by the rural majority and urban disadvantaged communities. There was also found to be challenges arising over denominator uncertainty and an absence of defaulter tracking. Issues with closure of health facilities and an ageing workforce were also revealed. Cold chain capacity and vaccine management varied between province and facilities, with concerns over maintenance of equipment and a lack of understanding of temperature monitoring procedures.

The EPI team is already working towards progressing many of the recommendations that were made as a result of the review. These included: drafting of immunisation performance standards and the further definition of roles. Routine immunisation was recommended to be strengthened through the re-establishment and intensification of outreach, using the RED-REC strategy to plan activities and track defaulters, and through the use of supplementary immunisation activities (SIAs) to when required to address specific program needs. The final recommendation was to establish health facility level, competency-based training including basics of EPI, cold chain, vaccine stock management and microplanning.

An Effective Vaccine Management assessment was conducted in May 2011 which

revealed that there were various quality and logistics challenges. However, work has since been done to improve vaccine management. A cold chain assessment along with revising the cold chain training manual will be conducted along with training on cold chain management has been incorporated in the district-level EPI training which is being carried out in the country.

### 4.4 Stock management

The stock management system in Papua New Guinea at all levels (national, provincial and district including that in the health centre) is a dual system with computerised at the national level and other system is a manual system. The National Cold Chain and Vaccine Manager maintains the stock levels in a computerised system which is shared with the National EPI manager and the development partners at a monthly basis. IPV when introduced, this stock update management at all levels will be subsequently embedded into the current stock management system.

The provinces send a vaccine indent request to the National Vaccine store and National EPI office based on the stock level. The vaccine is transported to the provincial vaccine store using mostly airline services. The provinces distribute the vaccine to the districts and health centre using local transport system. The IPV vaccine will be accommodated using the same system. As GoPNG bears all the cost of the vaccine transportation of the vaccine; this will also be borne when IPV is introduced. Any additional cost for the transportation will be borne by the GoPNG, if need be.1

## 5. Monitoring and evaluation

### 5.1 Updating of monitoring tools

The coverage of this new vaccine will be monitored and reported using the established monthly routine immunization report to the National Health Information System. The reporting of the coverage will be done by each district. Although the reporting formats will have to be updated, the introduction of other new vaccines including MR and PCV will enable the program to benefit from multiple introduction through the reduction of upfront costs. Tally sheets are already being printed and training of health care workers at district level has already begun.

The routine immunization coverage data in its present form does not collect sex-disaggregated data. However, the National Health Information System in consultation with all development partners and with technical advice from the Child Health Advisory Committee has started the process to incorporate the reporting of routine vaccine doses by sex of the child. The data when made available by the National Health Information System will be analyzed by the National EPI unit and steps will be taken to address any disparity if any.

### 5.2 Adverse Event Following Immunisation (AEFI) monitoring and reporting

NDoH is currently working to develop the national AEFI policy, covering areas including implement pharmacovigilance, AEFI investigation and response to AEFIs, to address relevant rumors and potential allegations. The country will develop methods on establishing causality assessments of AEFIs including monitoring of adverse events following IPV introduction at local, district, region/provincial and national levels.

## 6. Advocacy, communication, and social mobilisation

As part of the new vaccine introduction schedule and greater immunization programme, NDoH is developing a comprehensive advocacy, communication and social mobilization aimed at politicians and decision makers, religious leaders, health care professionals and village health volunteers, as well as families and communities.

The communication package for any of these beneficiaries will highlight the rationale for OPV and IPV administration, the relevance of the planned switch and acceleration of the existing polio program. This planned activity will ensure that messaging is not being seen as a move to resolve any type of vaccine failure. The lessons learnt from the recent controversies involving the tetanus toxoid campaigns will be used for developing the communication strategy for IPV introduction at the community level using different communication channels as radio, television and print media for greatest impact. The communication messages will be distributed using the channels of non-government organizations and village health volunteers. The introduction of this vaccine will include plan for national launch, sub-national ceremonies, to highlight the need of the introduction to the community and use this opportunity to promote immunization in general.