Royal Government of Bhutan
Ministry of Health
Department of Public Health
Vaccine Preventable Disease Program

Proposal for Introduction of Inactivated Polio Vaccine (IPV)

Annex A IPV Introduction Plan

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Executive Summary

In accordance with the World Health Assembly mandate and the recommendation by the World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE), the Royal Government of Bhutan has developed a plan for the nationwide introduction of one dose of inactivated polio vaccine in the routine immunization program. The introduction of IPV is part of the country's ongoing efforts of disease eradication, elimination, and control through a comprehensive program that includes vaccination among other comprehensive strategies such as improved sanitation, hygiene, access to clean water, exclusive breastfeeding, handwashing, safe drinking water, and appropriate treatments, among other solutions. This comprehensive strategy has led to the interruption of polio transmission in 1986, and apparent elimination of pertussis, neonatal tetanus, measles and rubella. Sustaining these gains and building on this success through the introduction of new vaccines is a top priority for Bhutan.

Introduction of IPV supports the regional and global mission of achieving the polio Endgame, including the eventual cessation of OPV. The cessation of OPV beginning with the withdrawal of the type 2 component of OPV in 2016 increases the risk of type 2 vaccine derived polio virus and wild poliovirus outbreaks. IPV is a crucial part of the endgame as it would mitigate these risks resulting from a cumulative accumulation of children susceptible to type 2 polio. Introduction of IPV will also be an important opportunity to strengthen several components of routine immunization system in Bhutan.

The Royal Government of Bhutan is requesting full support from GAVI for introducing one dose of IPV and supplies without any country co-financing. Because Bhutan is a GAVI graduate at the end of 2015, full support from GAVI for IPV will facilitate the self-financing of other new vaccines such as Pneumococcal and Rotavirus will present a much greater challenge for the country EPI. Under the assumption that Bhutan would vaccinate 95% of the birth cohort during the first full year of IPV use, the annual cost to GAVI is estimated to be ~ USD 50,247 for the 1-dose presentation at $2.80 per dose according to the recent UNICEF tender price. Bhutan is requesting the GAVI vaccine introduction grant (VIG) in the lump sum of USD 100,000 to support the IPV introduction activities described in this Plan. It is understood that GAVI support is guaranteed through 2024 (subject to funding renewal for GAVI for providing IPV support to countries after 2018). The Royal Government of Bhutan is committed to financing the health system and recurrent costs for IPV beyond those covered by the VIG and no gap of funding is expected.

The Ministry of Health and Bhutan's EPI Programme are confident that the range of steps taken during 2014-2018 will allow the country to start smooth graduation from Donor support programmes while gaining financial self-sustainability with the maturing of Bhutan Health Trust fund. At the same time,

the Ministry will appreciate and explore every opportunity to continue productive cooperation with its development partners.

Bhutan's National Committee for Immunization Practice (NCIP) has opted to introduce IPV nationwide in July 2015. One dose of IPV would be administered at 14 weeks of age along with the third dose of oral polio vaccine (OPV) and the pentavalent vaccine. Considering the small birth cohort and high rates of wastage (65%) with the 10-dose presentation Bhutan prefers to go for 1-dose presentation.

In recent years, Bhutan has substantially strengthened the routine immunization system through the successful introduction of the pentavalent and the Human Papillomavirus (HPV) vaccines, and has robust capacity to absorb the introduction of IPV. The immunization delivery system is robust and provides above 90% coverage for all EPI antigens, including coverage of above 80% in all districts. Bhutan has functional cold chain system in place although there are ongoing efforts to address the concerns about the age of some of the equipment. Currently there is adequate space to accommodate the vaccines and the vaccine storage volume requirement per Fully Immunized Child (FIC) at the central level is about 240 $cm^{3.}$ With introduction of single-dose vial of IPV would require additional storage volume by about 6.4%. An Adverse Event Following Immunization (AEFI) reporting system is in place and has the capacity to handle more cases. As per the recent HPV post-introduction evaluation the immunization system capacity is adequate for vaccine management, supervision, training, and transportation which were found to be well planned and executed. An integrated and functional surveillance system for vaccine preventable diseases is in place at all levels, although the laboratory and epidemiology linkages need strengthening. Inadequate human resources, in terms of number and technical capacity at all levels has been a major barrier for the country's EPI program. The Ministry of Health has recognized the need to strengthen the health Human Resource capacity for sustainability of the EPI Program.

As per the Global Polio End-game Strategy, NCIP as a technical advisory body on immunization related issues has endorsed the introduction of one dose of IPV by July 2015. Key milestones for the next 12 months includes developing TORs for a national introduction planning team; development of the introduction strategy and timeline; and stakeholder engagement. Other activities for the new vaccine introduction will include cold chain readiness; advocacy, communications, and social mobilization; pharmaco-vigilance; training; and monitoring and evaluation.

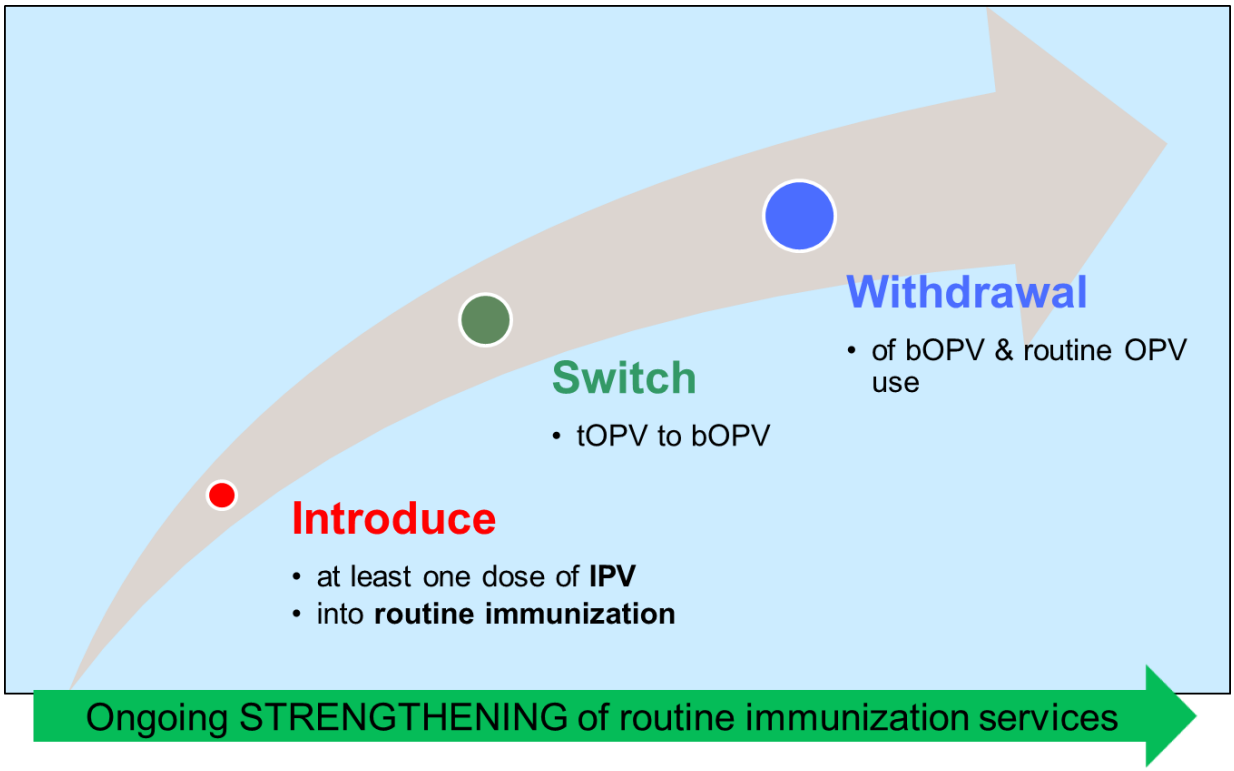
Key risks of introducing IPV include the financial burden from systems cost not covered by the VIG, the community acceptability of a second injection, safety monitoring of IPV, conducting acute flaccid paralysis surveillance after the Endgame, and concerns about freeze sensitivity of IPV. Efforts to mitigate include development of effective communications and advocacy strategy along with a crisis communication plan. Ensure appropriate cold chain management systems through temperature

monitoring and use of freeze-tag/log-tag during vaccine transportation and storage. The Ministry of Health will strengthen the surveillance through use of the containment guidelines for polio during and after the Endgame.

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

In 2013, the World Health Assembly endorsed *The Polio Eradication and Endgame Strategic Plan*[1] which addresses the eradication and containment of polio caused not just by wild viruses but also cases associated with oral polio vaccine (OPV). To address risks associated with OPV use, the Plan calls for a phased withdrawal of OPV globally beginning with removal of the type 2 component of OPV through a switch globally from trivalent OPV (tOPV) to bivalent OPV (bOPV, containing only types 1 and 3) in 2016. To ensure that a substantial proportion of the **population is protected against type 2 polio** after OPV2 withdrawal, the WHO's Strategic Advisory Group of Experts (SAGE) has recommended that all countries **introduce at least one dose of inactivated polio vaccine (IPV) in their routine immunization programs** before end of 2015, prior to the tOPV-bOPV switch. SAGE recommends that all polio endemic and high-risk countries develop a plan for IPV introduction by mid-2014.[2]

Figure 1. Objective 2 of *The Polio Eradication and Endgame Plan 2013-2018* addresses the Endgame through three distinct stage.



[1] Available at http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx (Last accessed, 15 January 2014)

[2] SAGE position & WHO position paper [http://www.who.int/wer/2014/wer8901/en/index.html]

The last clinically compatible poliomyelitis case in Bhutan was reported in 1986 in Tsirang District. Since this last polio case, Bhutan joined the international polio eradication program in 1995 and has remained polio free. Bhutan has sustained a high level of OPV3 coverage and strong AFP surveillance. The joint national-international AFP surveillance review in March 2011 suggested that there was no evidence of wild polio circulation in Bhutan and its AFP surveillance system was strong enough to detect any emerging case if occurred. The quality of the AFP surveillance system was maintained at the appropriate level. In 2010 and 2011, 6 AFP cases were reported each year and none of them were proven to be polio. The (non-polio) AFP rate for Bhutan in 2011 was 2.74 and adequate stool collection rate at 70 %. Furthermore, Southeast Asia is certified polio free as of March 27, 2014.

The Royal Government of Bhutan wants to capitalize on these significant gains and complete the Endgame of polio by introducing one dose of IPV into the routine immunization program of the country. Introduction of one dose of IPV will mitigate the risks of removing the type 2 component of OPV and continue sustained protection against this serotype. This will reduce chances of importations of cVDPV2 and re-emergence of type 2 wild poliovirus in Bhutan. Similarly, after the complete withdrawal of OPV, protection from IPV will prevent emergence of any wild or vaccine derived poliovirus. In summary, introduction of IPV is critical to ensure Bhutan remains polio free as the global switch from tOPV to bOPV occurs, with withdrawal of all supplies of tOPV in 2016.

After a review of the recommendations and evidence, the NCIP members endorsed the need to introduce one does of IPV in July 2015 and the Ministry of Health's Vaccine Preventable Diseases program (ie., EPI) has undertaken the necessary planning activities for the introduction of the new vaccine.

In accordance with the World Health Assembly mandate and the recommendation by the World Health Organization's (WHO) Strategic Advisory Group of Experts (SAGE), the Royal Government of Bhutan has developed a plan for the nationwide introduction of one dose of inactivated polio vaccine in the routine immunization program. The introduction of IPV is part of the country's ongoing efforts of disease eradication, elimination, and control through a comprehensive program that includes vaccination among other comprehensive strategies such as improved sanitation, hygiene, access to clean water, exclusive breastfeeding, handwashing, safe drinking water, and appropriate treatments, among other solutions. This comprehensive strategy has led to the interruption of polio transmission in 1986, and apparent elimination of pertussis, neonatal tetanus, measles, and rubella. Sustaining these gains and building on this success through the introduction of new vaccines is a top priority for Bhutan.

2 Overview of IPV

2.1.1 Vaccine preference and introduction date

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
1-dose stand-alone IPV	July 2015	5-dose stand-alone IPV	10-dose stand-alone IPV

The planned date of IPV introduction nationwide will be July 1, 2015.

Bhutan prefers to use the WHO prequalified stand-alone IPV in the order of preference of 1-dose, 5-dose and 10-dose vials (Table 1). This preference will limit wastage that is expected to be high in Bhutan with multi-dose vials because of the small birth cohort and high proportion of rural population resulting in a low number of infants vaccinated during each session. The estimated capacity per FIC required for IPV during 2015 is **17 cm^3 for the 1-dose presentation** (@6.4% of total cold space) compared to the required estimated gross capacity of **7 cm^3 for the 5-dose presentation** (@2.6% of the total space).

The additional cost for IPV thus would be **an extra $3,822 for the 1-dose vial** compared to the 5-dose vial which has a higher wastage of 30%. Meanwhile, the incremental cold storage space investments of the 1-dose vial would only be an additional 6.4% of the total cold space. The 2012 EVM assessment determined that the cold chain storage in Bhutan can accommodate this amount of vaccine space required by the 1-dose presentation at all levels.

2.1.2 Licensing information and procurement obstacles

Bhutan Drug Regulation Authority (DRA) was established by Royal Government in June 2004 with the mission of ensuring safety, quality and efficacy of medicinal products in protection of consumer's health. Drugs Technical Advisory Committee provides advice to the board on all technical areas related to registration of medicinal products and other technical matters as and when required by the board.

Pre-marketing control and post marketing control are major functions performed by the DRA. Registration of vaccines, new vaccines under pre marketing control and monitoring of adverse drug reaction are now major activities related to the immunization program, carried out by the DRA.

Bhutan has no modern pharmaceutical industries and relies on imports for its entire requirements of medicines, vaccines and reagents. The country also relies on WHO collaborating laboratories in the

region for testing the quality of imported drugs and vaccines. However, with establishment of DRA, all the products must be registered with the authority prior to their arrival into the country.

Procurement of vaccines shall be as per the Drugs, Vaccines and Equipment Division (DVED) norms which state that:

1. The vaccines should be WHO pre-qualified
2. They should meet international test reports
    a. batch release certificates
    b. Quality analysis report

The DRA is not yet WHO certified, although this is not a pre-requisite for IPV licensure in Bhutan. The Ministry of Health is in the process of ensuring that stand-alone IPV is registered for use in Bhutan. The DRA does follow WHO expedited procedures for registration by the manufacturer.

Once a product is registered in country, no specific local customs regulations, requirements for pre-delivery inspection, or special documentations requirements are needed.

All vaccines for the country are procured through UNICEF.

2.1.3 Estimated target population for vaccination through 2018

Table 2: Estimated number of infants to be vaccinated with IPV in the RI programme, 2014-2018[3]

Number	Targets				
	2014	2015	2016	2017	2018
Live births	14,158	14,383	14657	14,935	14,999
OPV3 coverage (%)[2]	98%	98%	98%	98%	98%
DTP3 coverage (%)[2]	98%	98%	98%	98%	98%
IPV target in <1 (with DTP3/OPV3)	0%	49%	95%	98%	98%
Number of infants to be vaccinated) with IPV	0	6,943	13,461	13,886	13,914

[3] Population Projection of Bhutan 2005-2030, National Statistics Bureau

3 Introduction and implementation considerations

3.1.1 Policy development issues

Bhutan's national planning follows 5 year cycles with financial year July-June. The last 10th Five Year Plan covered years 2008-2013. The current 11th Five Year Plan will define government activities for 2013-2018. In line with these plans current comprehensive Multi Year Plan has been developed for 2014 to 2018.

The present cMYP continues tradition of its predecessor being an important management tool for the EPI programme. It both sets medium-term goals, objectives and strategies for the EPI programme and also defines financial sustainability plan for 2014-2018.

One of the explicitly stated cMYP 2014-2018 objectives is to introduce IPV in line with the Global Polio Endgame Strategy.

This application for GAVI support is for the **nationwide introduction** of stand-alone IPV beginning in July 2015, to meet the Endgame objective and support the global withdrawal of OPV use after the eradication of polio. The NCIP has recommended the introduction of one dose of IPV which would be administered at 14 weeks of age along with the third dose of pentavalent and OPV. This strategy is selected as recommended by SAGE to maximize the immune response to the single dose of IPV. Because the drop-out rate from Penta-valent 1 to Penta-valent 3 is low in Bhutan, the tradeoffs support the gains in immunogenicity to a single dose of IPV administered at 14 weeks of age when interference from maternally transferred antibodies is lower.

There will be no catch-up only children who are >14 weeks of age after the date of IPV introduction, (i.e. born after April 2015 for the July 2015 introduction) will be eligible.

IPV will be the second injection along with the pentavalent injection. The recommendation will be for IPV to be administered by intramuscular injection in the opposite thigh where pentavalent is currently administered.

3.1.2 National coordination mechanism to ensure the successful introduction of the vaccine

Key milestones during the process from decision to implementation are included in Table 3 and include: Pre-implementation planning and decision-making activities such as developing TORs for a national introduction planning team; development of the introduction strategy and timeline; and stakeholder engagement.

Additional activities to ensure a successful introduction include reviewing Routine Immunization data and improvement plans; identifying weak components of the immunization system and plans to rectify; identifying poor performing and high risk districts and targeted activities planned for improving their performance; establishing technical subcommittees for cold chain and vaccine management, training, monitoring and evaluation, advocacy/communications/social mobilization, and adverse events following immunization monitoring and mobilizing human resources and developing a budget and ensuring availability of sufficient funds for the operational costs of a successful IPV introduction process.

Table 3: Proposed timeline of activities for the introduction of IPV in Bhutan

	2014												2015											
Activity	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Draft implementation plan for nationwide introduction, including **identifying key activities** important for a successful IPV																								
Policy decisions, including ICC meetings																								
Ensuring licensuring and procurement pathway																								
Brief key stakeholders																								
Funding secured from GAVI and other partners																								
Establish procedures for implementation																								
Adapt Information, Education and Communication (IEC) materials & develop communication plan for educating																								
Review and revise immunization forms																								
Confirm space at regional and district cold stores																								
Clear vaccine supply from customs																								
Finalise budget																								
Financial resources received at central level																								
Pre-arranged budget is transferred from central to region and district levels																								
Develop training plan for introducing IPV with OPV3 at DTP3/Penta 3 health contact																								
Microplanning at distric levels																								
Implement training plan																								
Implement communication strategy																								
Transport vaccine to districts																								
Delivery of IPV to target population																								
Institute monitoring of adverse events following immunisation (AEFIs) for IPV																								
Supportive supervision visits central to district & health levels																								
Post-introduction monitoring (e.g., coverage, stockouts, safety monitoring, freezing assessment)																								
Monthly reporting of IPV doses delivered																								
Analyze reported IPV data																								

3.1.3 Affordability and sustainability

The Royal Government of Bhutan is requesting full support from GAVI for one dose of IPV and supplies without any country co-financing. Bhutan would need as estimated 8670 doses during 2015 and 17,340 during 2016. The annual cost to GAVI for IPV and freight would be approximately US$ 50,247 per year assuming vaccine costs of $2.80 per dose for the single dose vial, surviving infants in 2015 of 13,628, target coverage of 93%, and accounting for 25% buffer stock for year 1.

The Royal Government of Bhutan also requests to receive the Vaccine Introduction Grant (VIG) lump sum of $ 100,000 (birth cohort of 14,169). These funds will be important for meeting the accelerated IPV timeline and, in addition to leveraging existing resources and partnerships; they will support the preparation activities described in the introduction plan.

The costs of planning and implementing the IPV introduction are included in below Table 4. Detailed costs under each category are listed in the Annex table attached separately (Table E2).

Table 4. Cost estimate for planning and introduction of IPV

			Government support	Partners support*		GAVI support
	Cost Category	TOTAL COST US$	Amount US$	Name	Amount US$	Amount requested US$
1	Program management and coordination	1250				1250
2	Planning and preparations	750				750
3	Training and meetings	69,333	2000			67,333
4	Social mobilization, IEC and advocacy	5000	1000			4000
5	Reproduction of materials	6250				6250
6	Per diems for staff and volunteers	0				
7	Cold chain equipment & maintenance	30,000		UNICEF	21,833	8167
8	Vehicles and Transportation	5000	1000			4000
9	Immunization session supplies	0				
10	Waste management	0				
11	Surveillance and monitoring	8750	500			8250
12	Post-introduction evaluation	0				
13	Technical assistance	0				
14	Other (please specify)	5833		UNICEF	5833	
	Total	132,166	**4500**		**27,666**	**100,000**

Because Bhutan is a GAVI graduate at the end of 2015, full support from GAVI for IPV will facilitate the self-financing of other new vaccines such as Pneumococcal and Rotavirus, which will present a much greater challenge for the country EPI. It is understood that GAVI support is guaranteed through 2024 (subject to funding renewal for GAVI for providing IPV support to countries after 2018). The Royal Government of Bhutan is committed to financing the systems and recurrent costs of introducing IPV beyond those covered by the VIG; no gap of funding is expected.

The Royal Bhutan Government has remained and will continue to be the major funding source of the EPI programme contributing more than 75% of its total cost, most of it through maintaining health care personnel and healthcare facilities, as well as covering current EPI costs. Increasingly, a considerable role in the EPI financing starts to be played by the Bhutan Heath Trust Fund (BHTF). While currently BHTF is co-financing for the procurement of Pentavalent with GAVI, the BHTF is expected to completely take over the financing of the procurement of all the vaccines after the donors withdraw their support.

Assistance to the Royal Government of Bhutan during 1995-2007 was provided by JICA. JICA efforts were focused mostly on upgrading the cold-chain infrastructure. Japan Committee for "Vaccine of the World's Children" (JCV) supports EPI Program in the area of procurement of traditional vaccines and some portion of cold chain equipment since 2008.

While GAVI continues to provide considerable support in financing Pentavalent vaccine procurement, Bhutan will graduate from this support line at the end of 2015. The Ministry of Health and Bhutan's EPI Programme are confident that the range of steps taken during 2014-2018 will allow the country to start smooth graduation from Donor support programmes while gaining financial self-sustainability with the maturing of Bhutan Health Trust Fund. At the same time, the Ministry will appreciate and explore every opportunity to continue productive cooperation with its development partners. In Table 5, the overall trend of Bhutan's immunizaton and funding sources for the immunization program costs are stratifeid by source of funding and type of costs.

Table 5: Overall trend of Bhutan's immunization funding sources[4]

Secure Funding	2014	2015	2016	2017	2018
Government	$1,429,400	$1,506,239	$1,572,037	$1,627,904	$1,691,956
GAVI - Vaccine Fund (not including IPV)	$54,000	$52,000	0	0	0
UNICEF	0	0	0	0	0
WHO	0	0	0	0	0
JCV (through UNICEF)	$125,000	0	0	0	0
ACCF	$150,665	$155,075	0	0	0
BHTF (Trust fund)	$131,807	$149,065	$159,813	$171,280	$177,408
Total Secure Funding	$1,890,872	$1,862,379	$1,731,850	$1,799,184	$1,869,364

The overall costing in 2012 was $1,799,601 of which 39% costs were for shared activities within the government HC system. Since there were no campaigns, the remaining 61% of the costs was for routine immunization. If one considers only immunization expenditures leaving out shared costs, the cost per capita would be just about $0.92, and cost per DTP3 child would be about $50. The high cost per DTP3 child is explained by Bhutan being a quite small country (14,197 births in 2012) with little opportunities for economies of scale and considerable costs of reaching hard-to-reach. This is typical of a small country - the non-vaccine fixed costs of the program cannot be spread over a large enough population, and therefore the unit costs of immunization are much higher.

The bulk of the expenditure comes from personnel costs (42%), followed by new and underused[5] vaccines (20%). traditional vaccine costs are just 4%. The personnel costs are high and the probable explanation is geographical inaccessibility as well as sparse population would require more personnel time for service delivery. The bulk of the health personnel in peripheral and outreach areas deliver a comprehensive package of MCH services, including immunization. Annual capital cold chain equipment and vehicle costs are 7% and 2% respectively. Transportation costs account for 6%, while other routine recurrent costs (including training) account for 15%.

[4] cMYP 2014-2018

[5] Here the term "underused vaccine" is applied according to its GAVI definition. Coverage by underused vaccines in Bhutan is practically equal to that by traditional vaccines.

3.1.4 Overview of cold chain capacity

Cold chain equipment inventory was updated in 2011 and is readily available. The cold chain system is intact although there are ongoing efforts to address the concerns about the age of some of the equipment. There is no cold volume shortage with current procurement practices. The vaccine storage volume requirement per Fully Immunized Child (FIC) at the national and district level and is about 240 cm^3 and 279 cm^3 at the district level. These requirements would increase by 6.4% (national and regional) and 5.6% (district) with the addition of 1 dose of single dose vial of IPV. The net storage capacity at the national level is 3.99 m^3 and with an annual shipment, the required volume of IPV can be absorbed at all levels.[6]

An assessment of the cold chain system was carried out by a consultant in 2012[7]. The cold chain system was studied at four levels: central stores, regional stores, district hospitals and basic health units). During the assessment period, no freezing of vaccines or the cold chain failure was observed. However, there were still lots of problems that required appropriate intervention. These include:

- Supply for new or replenishment CC equipment
- Cold chain preventive/replacement maintenance plan
- Training the vaccine handlers in cold chain equipment maintenance (CCEM) & vaccine logistics (VL)
- There is weak supervision of health workers

Freezing of vaccines is becoming a major concern with the newer vaccines such as IPV. Hepatitis B is the most freeze sensitive vaccine currently in the schedule and currently there is no very accurate method to monitor the vaccine cold chain for freezing. It is proposed to introduce freeze monitoring to the cold chain management during the next few years, and IPV introduction provides an important opportunity to initiate these modifications.

The immunization financing plan includes annual capital cold chain equipment and vehicle cost at local levels. In 2012, about 9% ($162,000) of the overall budget was allocated to capital cold chain equipment and vehicle costs.[8] Substantial increases in the recurrent costs have been budgeted through 2018 in the cMYP. The Royal Government of Bhutan is committed to the EPI program and will provide secure funds for immunization including funding at local levels for the ongoing power supply and maintenance of any new cold chain equipment.

[6] EVM Assessment Report 2012
[7] EVM Assessment Report 2012
[8] cMYP 2014-2018

Temperature monitoring of cold chain equipment at all levels is planned in 2014.

3.1.5 Provision for waste management and injection safety

The EPI injection safety policy stipulates 100 percent bundling of all vaccines with auto disable syringes and safety boxes. Waste management for EPI is a subset of a National policy for health care waste management policy including waste from immunization activities and is being applied throughout the country. No specific changes to this policy are needed to accommodate IPV.

Introduction of ADs has almost eliminated complications due to unsafe injections such as injection abscesses. However, biomedical waste generated by used ADs has created new problems because of non-compliance. This exposes the health workers and community, especially children, to higher incidence of needle sticks, and potential transmission of Hepatitis B and C. EPI program in collaboration with infection control and health waste management program is in the process of standardizing the protocols and providing refresher training to the health workers.

3.1.6 Planned health worker training and supervision

The Royal Government of Bhutan has placed top priority on training of health workers followed by supportive supervision across all levels of the immunization program. The introduction of IPV is an important opportunity to re-train health workers and EPI staff on all aspects of immunization practices, and to reinforce this training by supportive supervision and reporting requirements. The IPV introduction plan and timeline includes specific activities that will ensure successful development of training materials, IEC materials and messages, and an integrated training strategy that not only addresses IPV but also provides refresher training for HWs on immunization practices such as injection safety, AEFI communications, cold chain management, data collection, analysis, and use for action.

Using materials drafted by global partners as a starting point, the following materials will be drafted: a technical and an operational manual that covers policy, scientific, and operational aspects related to introduction of IPV; revision of EPI Manual incorporating IPV; FAQs; fact sheets on operational aspects including application of the multidose vial policy and multiple injections; training materials and posters.

Training from national to health facility level will be conducted using cascade training through a series of workshops, beginning with training the trainer sessions at the national level. The effectiveness of the appropriate training methods will be evaluated through pre- and post-knowledge tests and surveys of its acceptability and usefulness such that it facilitates ongoing and future training/retraining efforts. Specific emphasis will be placed on inter-personal communication as a key vaccinator skill. Training will be integrated to combine material and better utilize training time, to re-train the frontline HWs on immunization practices such as injection safety, AEFI communications, cold chain management, data collection and analysis.

Supportive supervision will be emphasized as a key component of successful training. Supportive supervision is ongoing but will be enhanced through IPV introduction. IPV introduction will be leveraged to emphasize skill improvement for the staff to ensure provision of quality services, assessment of the performance of the EPI and its staff, and provision of feedback and necessary remedies, including on-the-job training. Each supervisory team will be expected to carry out a debriefing to facility staff at the end of each visit. It is recommended that the national level staff should undertake supervision at least once every year and districts once per quarter. The supervisory visits will include a review of the monitoring data, injection practices, social mobilization, logistics, stock management, and vaccine handling practices at the healthcare center.

3.1.7 Risks, challenges, and mitigation strategies

Key risks of introducing IPV include the financial burden from systems cost not covered by the VIG, the community acceptability of a second injection, safety monitoring of IPV, conducting acute flaccid paralysis surveillance after the Endgame, and concerns about freeze sensitivity of IPV. Efforts to mitigate include updating the cMYP to include IPV, consultations with stakeholders and development of effective communications and advocacy strategy and a crisis communication plan, temperature monitoring evaluations and freeze-tag procurement for all vaccine transports. The Ministry of Health also will closely follow the surveillance and containment guidelines for polio and ensure that these guidelines are effectively implemented during and after the Endgame.

These risks and mitigation strategies are summarized in Table 6.

Table 6: Risks and mitigation strategies for IPV introduction

Risks	Mitigation
Financial: although GAVI is supporting the introduction of IPV, the financial and operational impact of the introduction on systems costs and recurrent costs not borne by the VIG may be considerable especially when vaccines for other target diseases such as pneumonia and diarrhea have yet to be introduced in Bhutan.	The cMYP has considered this risk and included IPV in the 2014-2018 plan with specific budget for recurrent costs associated with IPV and other new vaccines during this time frame. The Bhutan Health Trust Fund initiative which was developed as a tool to address such rising financial needs and is already being used for co-financing the Pentavalent Vaccine. Future strengthening of this Fund is expected to help sustain vaccine financing and reduce the country's dependence on external sources of support.
Community acceptability: the acceptability of introducing a vaccine for a disease that has been eliminated in the region could be low with decision-makers, health workers, and parents, jeopardizing trust in the immunization program and pose barriers for introduction of other priority new vaccines that are crucially needed in Bhutan.	A strong communications and advocacy strategy will be needed with clear, succinct, and convincing messages for the rationale for introducing IPV and withdrawing OPV. Leveraging partnerships with stakeholders and international organizations to gain broad buy-in from decision makers for the introduction of IPV as a critical step in the eradication and endgame of polio globally. Ensuring that funding will exist beyond 2018 will also be necessary for continued support from decision-makers. Timely development and dissemination of IEC materials.
Safety of IPV: Previous serious/fatal AEFI events temporally associated with the Pentavalent vaccine leading to temporary discontinuation of the use of this vaccine has placed safety concerns of new vaccines at the forefront of the community, particularly the media in Bhutan. AEFIs temporally associated with IPV could derail Bhutan's strong EPI and diminish trust the health care services provided by the Royal Government of Bhutan.	Focused efforts to strengthen the national AEFI system including updated definitions, ensuring reporting mechanisms are in place, validation is standardized and documented, and timely and appropriate causality assessment is conducted. Ensure that the system is capable of handling more cases. Conduct refresher training in AEFI management and reporting for staff at the district and health centre levels and encourage robust reporting of AEFIs through the system
Cold chain: IPV is freeze sensitive and potency may be affected if subjected to extreme cold. International shipping cartons and WHO-prequalified cold boxes are used for distribution of vaccines, which are requested to be packed with conditioned icepacks. Although packaging requires freeze indicators for freeze sensitive	Training and supervision to ensure appropriate icepack conditional practices; including Freeze-tags/log-tags/data-logger for all IPV vaccine shipments packed with conditioned icepacks; evaluations and intervention strategies to ensure compliance and proper maintenance of cold chain.

vaccines, these indicators are not currently available for transportation and icepack conditioning practices may vary.	
Surveillance: Environmental surveillance and containment of polioviruses is a crucial component of the Eradication and Endgame Strategy. Containment and surveillance particularly in many of the remote areas of Bhutan could be challenging and risk undetected persistence of virus in the community.	Timely development of an updated global and regional strategy for surveillance and containment, with emphasis on environmental surveillance; ensuring effective implementation and compliance with this strategy.

4 Situational analysis of the immunization programme

4.1.1 General country context, health system overview and priorities

Bhutan is a small landlocked South-East Asian country located in the Eastern Himalayas, covering an area of 38,394 square kilometres. More than 72.5% of the area is covered by forest. Bhutan is the least populated country in the South East Asian Region. The population and housing census of Bhutan in 2005 enumerated Bhutan's total population 672,425, with a population growth rate of 2.6. Urban population constituted 31% and sex ratio was 111 males per 100 females. The crude birth rate and crude death rate was 20 per 1,000 population, and 7 per 1,000 populations respectively. Infant mortality rate stood at 40.1 per 1,000 live births, and under-five mortality rate at 61.5 per 1,000 live births. In 2012, Bhutan population was estimated at 720,679 and population growth rate declined substantially since the last census.

Bhutan adopted Primary Health Care (PHC) approach to the health delivery system in year 1979. Currently, health care is provided through a network of 32 hospitals, 192 Basic Health Units (BHUs), and 550 outreach clinics (ORCs) spread over 205 Gewogs (blocks). These facilities are manned by doctors, nurses, paramedics and technicians. At the community level, village health workers assist regular health staff in reaching out healthcare to the communities, particularly in the far flung areas of the country. The low density of the population and poor communication, especially in the northern region, are an important reason for lower productivity in terms of coverage and relatively higher system wastage. In Bhutan Primary Health Care is provided through several public health programmes each focusing on their respective areas. EPI programme and surveillance of vaccine preventable diseases comes under the Vaccine Preventable Disease Programme.

Bhutan has been demonstrating significant progress in health indicators. Substantial decline in infant mortality rate and under-five mortality rate is a very encouraging sign towards achieving the 4th millennium development goal.

The Expanded Program on Immunization was first launched in the country on 15 November 1979, in the International Year of Child, with the objective of reducing morbidity and mortality from six vaccine preventable diseases: TB, Diphtheria, Pertussis, Tetanus, Polio and Measles. Tetanus Toxoid (TT) immunization of pregnant mothers was introduced in 1983. Hepatitis B vaccine was introduced in 1996. And in 1987 the National Plan of Action for the acceleration of EPI was formulated. The strong government commitment and the community mobilization resulted in the achievement of the Universal Child Immunization (UCI) in 1991.

The health sector has made remarkable progress in all areas of health developments over the last four decades since the modern health service was introduced in the country. The Infant Mortality Rate has reduced from 102.8 in 1984 to 40.1 in 2005, and Maternal Mortality Rate has reduced from 7.7 in 1984 to 2.55 per 1000 live births in 2000. Population Growth Rate also has seen a marked decrease from 3.1 in 1994 to 1.8 in 2005 (PHCB). The life expectancy at birth has increased remarkably from 47.5 in 1985 to 68.1 in 2012. These vital indicators speak well of the rapid socio-economic development in the country. During 2008-2012 the country has also managed to improve the top ten disease morbidity trends and EPI coverage trends in particular, conquer measles, rubella and tetanus morbidity and mortality. Marked improvements were also registered in safe water supply provision, sanitation and hygiene. The challenge for the health care delivery system and health professionals consist in maintaining high achieved indicators and in gradually expanding the focus from the coverage to also quality of immunisation services.

The Royal Government of Bhutan acknowledges that the Expanded Program on Immunization has significantly contributed towards improving the health status of children in Bhutan. The EPI service started on November 15, 1979, with an objective of reducing morbidity and mortality from 6 vaccine preventable diseases, namely, tuberculosis, diphtheria, pertussis, tetanus, polio and measles.

- Tetanus toxoid for pregnant women was introduced in 1983.
- The last clinically compatible polio case was reported in 1986 and since then Bhutan maintained “zero” polio status.
- Bhutan’s successful implementation of the EPI program resulted in achieving Universal Child Immunization (UCI) in 1991.
- One case of Neonatal tetanus reported in 2006 after 12 years of last case in 1994.
- Hepatitis B was introduced in 1996 as monovalent vaccine, was replaced with DTP-HepB (tetravalent) in 2003 and with DTP-HepB-Hib (Pentavalent) in 2009-11.

- No cases of Diphtheria and Pertussis were registered in the country over the past twelve years from 2001 to 2012.

- Unfortunately, Measles cases (clinical diagnosis) continued to be registered in 2008-2012 although in much smaller numbers than before. Currently, laboratory diagnosis for suspected cases of measles and rubella is being regularly provided.

- The measles-rubella (MR) vaccine was introduced in early 2006, replacing monovalent measles.

- The country is planning to switch to MMR vaccine during the next cMYP cycle.

- In 2010, HPV vaccine started to be administered to 12-18 year old girls through catch-up campaign, and, starting from 2011, the vaccine was introduced into regular immunisation schedule.

4.1.2 Barriers to immunization

The concept of health in Bhutan must be seen in the context of the overall development strategy that defines development as the preservation of spiritual and emotional, as well as economic well-being. Therefore, the health sector policy objectives reflect the national ones: equity, social justice, sustainability and efficiency, in the context of preservation of national culture. The long term objective of the health services is to "facilitate, through a dynamic professional health care, the attainment of a standard of healthy living by the people of Bhutan to lead a socially, mentally and economically, enhanced quality of life of the people in the spirit of social justice and equity". The focus of health sector is to improve the quality of services and bring new technologies and advanced health facilities including new vaccines to the country. Basic health care services and essential drugs are provided free of charge to all Bhutanese citizens and foreign nationals working or visiting Bhutan.

A standing technical advisory group on immunization is available. It has formal written terms of reference.

No gender inequities in vaccination exist in Bhutan as is evidenced by the generally high vaccine coverage for all antigens and Bhutan being one of the first developing countries globally to offer HPV vaccines to girls in Bhutan.

One particular barrier exists for high risk populations of people living and working in areas bordering the Indian states of West Bengal and Assam as well as nomadic populations throughout the country. The children from these groups are not adequately enumerated and consequently not adequately targeted for immunization and surveillance activities. Efforts are ongoing to map these high-risk areas and groups, to enumerate and track these children for immunization and surveillance activities.

4.1.3 Summary findings from previous programme reviews

A team comprising national and international experts reviewed the EPI, VPD surveillance system and HPV vaccine introduction in Bhutan in 2011. The review identified:

VPD surveillance: a surveillance system for VPD is in place at all levels and is functioning; norms and standards are defined and available at all levels; surveillance is an integrated system with AFP, measles, neonatal tetanus, and acute encephalitic syndrome existing on the same platform. The surveillance reporting did not include traditional healers. There was confusion on case definitions and laboratory and epidemiologic case data are not always linked. Supervision of surveillance was inadequate or irregular by district level staff and there was limited capacity for analysis and interpretation of data by district level staff.

Immunization delivery: systems are in place and able to provide coverage >90% for all antigens; communities are well informed about the importance of childhood immunization and location of services; immunization delivery system is able to absorb new vaccines; AEFI system is in place and has capacity to handle more cases; lack of standardization of waste management with space being a critical issue in some places; cold chain system intact but there were concerns about the age of some equipment; high risk migrant groups and nomads were not well enumerated and consequently not adequately targeted for both immunization and surveillance activities. The reviews recommended conducting mid-level management training for existing health staff and incumbents focusing on district health officers and assistant district health officers; ensuring that adequate training on AEFI management was provided before pentavalent reintroduction in June 2011; mapping high-risk areas and tracking migrant children; clarifying sharps/waste management and universal precaution issues; and conducting cold chain risk assessment.

HPV post-introduction evaluation: high coverage achieved during 2010 school-based campaigns; piloting provided important lessons for national campaigns; vaccine management, supervision, transportation, and learning were well planned and executed; IEC materials and messages might be overly complicated; concerns about freeze sensitivity and lack of VVM on current stock of vaccines; and need for clarity on sustainability of HPV after 2015. The recommendations included reassessing integration of HPV vaccine into the RI schedule in 1 year; conducting refresher training for transition from campaign to RI; modifying and simplifying IEC materials; using freeze tags and cold chain monitoring tools; requesting VVM for HPV; and assessing sustainability of HPV after 2015.

The introduction of IPV will be an excellent opportunity to evaluate the implementation of these recommendations which have been ongoing since the programme review. Recommendation which have begun and are ongoing include: mid-level management training for existing health staff and incumbents focusing on district health officers and assistant district health officers; AEFI refresher training and strengthening; mapping of high-risk populations; integration of HPV into RI; VVMs for

HPV; and ensuring sustainability of HPV after 2015. In addition, specific pre IPV introduction activities described in the previous sections that will help strengthen the RI system and close the gaps in immunization delivery will include emphasis on supervision and staff training in immunization deliver and monitoring, as well as refresher training on AEFI surveillance. Improvements in cold chain, in particular including Freeze tags/ Log tags in shipments of freeze sensitive vaccines such as IPV that are packed with conditioned icepacks.

4.1.4 EVM assessment findings and improvement plan

Based on the provisions of the Bhutan Multi-Year Plan for Immunization 2009-2013 an EVM assessment was carried out between 15 Oct- 06 Nov 2012, and an evidence-based plan to improve management, monitoring and supervision of the country immunization supply chain was developed.

WHO/UNICEF standard EVM tool was used to assess the quality and sufficiency of nine criteria and seven component elements of an effective supply chain.

The EVM tool is based on nine basic criteria, each of which is divided into a number of requirements and sub-requirements that characterize the fundamental qualities of a good vaccine supply chain. Compliance with each of these sub-requirements was tested during the assessment using a series of tightly focused questions, which are numerically scored. According to EVM initiative, vaccine management is considered effective when scores exceed 80% by each of the nine criteria.

Table 7: Mean EVM criteria scores (%) by facility levels

	Criteria								
	E1	**E2**	**E3**	**E4**	**E5**	**E6**	**E7**	**E8**	**E9**
	Vaccine arrival	Tempe rature	Storage capacity	Building, equip., transport	Maintena nce	Stock mangt.	Distribu tion	Vaccine mangt	MIS, supporti ve function s
Central Store	68	41	94	77	75	74	56	63	69
Regional Stores	N/A	79	78	91	79	80	64	58	55
District Stores	N/A	74	92	73	76	71	48	55	45
BHUs	N/A	76	100	86	72	72	88	77	N/A

Since the EVM, the following improvements and plans are in place:

- Procured 30 DTR (400 Log tabs) and Fridge tags
- Trained EPI staff on the Vaccine Supply Stock Management (VSSM) and are using this tool for vaccine supply management
- Cold room temperature mapping was done as part of EVM assessment
- Vaccine packing SOPs exist in the EPI manual
- To use Freeze indicators during vaccine shipment from Central to Regional cold stores and from Regional to District cold stores initiated
- Temperature monitoring of non-prequalified (domestic) refrigerators being done in 10 health facilities
- Cold chain inventory being updated regularly by EPI programme
- Procurement plan in place to replace domestic refrigerators with WHO prequalified refrigerators in future
- Provision of additional walk-in cooler for Gelephu Regional Cold store planned
- A complete assessment of the cold chain at all levels is planned in 2014.

4.1.5 Brief description of vaccine stock management

The 2012 EVM assessment concluded that the overall level of compliance with vaccine stock management was close to certification level. At that time all vaccine arrivals and vaccine dispatches were recorded manually to a stock book. Assessment of the manual stock records showed that stock balances are kept up-to-date. The stock keeping tools were standardized. However some stores create their own stock keeping registers. Usually the following information is available for all vaccines:

- Type of vaccine
- Vaccine presentation (vial size)
- Quantity received/issued/used (usually in vials)
- Manufacturing batch or lot number
- Expiry date of each vaccine batch
- VVM status

The vaccine stock records are secured in lockable locations.

Stock records do not include a specific field for lost/damaged/expired commodities. Store managers prepare narrative reports in case of commodity losses. These reports are checked by the supervisors during routine visits.

Central store defines safety stock level for each vaccine as 30 per cent of annual consumption. But, assessors found several vaccine stock-outs during the review period. Maximum stock levels according to the current inventory management practices are calculated as 12 months at central store, 4 months at regional and district stores, 2 months at BHUs

Physical inventories take place quarterly at the central store and monthly at lower storage levels. Store keepers do physical counts before requesting or indenting vaccines. However, physical inventories are not recorded on a separate form. Storekeepers at all levels know EEFO rule and can make exceptions if needed (e.g. because of changing VVM status). Vaccine damages are quite rare and, most store keepers know that expired and damaged vaccines should be clearly labelled and stored out of the cold chain until their final disposal.

Country level cold chain equipment inventory was updated in 2012.

The 2012 EVM assessment recommended that standard stock management forms and ledgers should be updated according to WHO guidelines (WHO/IVB/06.12) and printed for all stores. Concerned staff should be trained for using these tools effectively.

In October 2013, Vaccine Supply Stock Management (VSSM) was introduced at the National EPI Central Store and Regional Stores for vaccine supply management. EPI staff were trained on the VSSM and are using this tool for vaccine supply management at the National and Regional levels. Future plans for refresher training are in place.

4.1.6 Immunization coverage for past two years

Table 8. Immunization coverage in Bhutan for past two years

Trends of national vaccine coverage (percentage)					
Vaccine	Vaccine Used	Target population (number by age and sex, if available)	Coverage reported (JRF)		
			2013	2012	2011
BCG	20-dose	14,169	93%	95%	95%
OPV 3	10-dose	13,628	96%	97%	98%
DTP 1 / Penta 1	1-dose (Cruclle)	13,628	97%	97%	98%
DTP 3 / Penta 3	1-dose	13,628	96%	97%	95%
HPV 1	1-dose (merck)	7231	86%	76%	59%
HPV 3	1-dose	7231	72%	68%	59%
Measles 1	10-dose MR (SII)	13,628	97%	95%	95%
Measles 2	10-dose MR	13,825	89%	89%	89%

5 Monitoring and evaluation

The EPI program in Bhutan is being monitored at four levels – impact, outcomes, outputs and inputs. The following is illustrative list of indicators used for monitoring EPI program in Bhutan.

Table 9. Indicators used for monitoring and evaluation of the EPI program in Bhutan

Attribute	*Indicator/s*	*How will it be verified*
Program Impact		
Reduction in infant and under five mortality	IMR (baseline – 40.1) Target 30/ 100 live births by 2018. U5MR (baseline 54) Target 38/100 live births by 2018.	National Statistical Bureau Report Annual Health Bulletin HMIS
Program outcomes		
Disease reduction and elimination	Zero Polio status Elimination of Measles cases/deaths Reduction of other VPDs	Routine surveillance system, reviewed monthly in districts and quarterly nationally

Attribute	*Indicator/s*	*How will it be verified*
	Reduction of Pneumonia and meningitis cases/deaths Maintaining and documenting MNT Elimination status	
Reduction in morbidity and mortality due to VPDs	Number of cases and deaths due to VPDs	Annual health Bulletin HMIS
Immunization coverage	Districts >90% DTP-HepB-Hib-3 coverage. Baseline 16, target 20 by 2018.	EPI coverage evaluation survey
Program evaluation	Strengths and weaknesses in EPI program	National EPI review
Uptake of PCV and Rotavirus vaccines	Proportion of utilization of PCV and Rotavirus vaccines as compared with Pentavalent (DTP-HepB-Hib) vaccine	Routine HMIS in each district bi-monthly
Improved immunization quality through vaccine logistics and safety	Absent vaccine stock outs Eliminated vaccine wastage of unopened vials Comprehensive reporting and management of AEFI cases	Vaccine supply register HMIS reports AEFI Reporting format
Cold chain management	Elimination of vaccine wastage due to freezing or excessive heat	Reports from supervisory field visits
Strengthened human resource and institutional capacity	Improved technical capabilities	Reports from supervisory field visits
<u>Program outputs</u>		
Vaccine wastage	Wastage factor for Pentavalent vaccine	Monthly analysis and review in each district
<u>Program inputs</u>		
Micro planning and scheduling of immunization sessions	Sessions conducted versus planned Per session coverage of children	Monthly monitoring at district level
Training and capacity building of direct service providers	Number of HAs/BHWs/GNMs completing refresher training Number of VHWs trained (integrated training)	District wise assessment of training status

Attribute	*Indicator/s*	*How will it be verified*
Capacity building of District Medical Officers and District Health Supervisors	Integrated training on Health management	

As evidenced by this broad plan, EPI monitoring, evaluation, and supervision are basic processes that facilitate the collection and analysis of the data required to verify whether activities planned under the program are being implemented effectively, or to what extent the objectives and targets defined have been achieved.

Several months before the introduction, the Ministry of Health will update information systems to facilitate collection of core indicators related to IPV introduction as described in following sections.

The Ministry of Health of Bhutan emphasizes the need to evaluate administrative data to document trends in indicators of routine immunization and IPV offers an opportunity to assess efficiency and accuracy of reporting. Introduction of IPV offers an opportunity to emphasize use of information to improve EPI and improve the quality of routinely reported data as well as using that data to improve program performance at all levels.. Particular emphasis will be placed on improving data quality through ensuring adequate availability and use of monitoring tools (charts, tables, monthly summary forms, defaulter tracking), understanding outcome measures (doses administered, coverage, access, utilization/drop out), and monitoring activities (community feedback on immunization services and supervision visits).

Evaluation of IPV introduction will be based on monitoring vaccine coverage and other indicators of successful introduction activities (e.g., vaccine stockouts, cold chain, AEFI) and not on disease burden. Thus, emphasis will be placed during training that record keeping of IPV use must not be aggregated with OPV use.

5.1.1 Plans for updating monitoring tools

To accommodate the addition of IPV, the Ministry of Health will update the following monitoring tools:

- ✓ Patient registers
- ✓ Vaccination cards
- ✓ Tally sheets
- ✓ Stock ledgers
- ✓ Bhutan Health Information Management System (electronic database; will be done with planned future revision)

Additional updates will include systems that aggregate immunization coverage data from health facility level upwards, including reporting at the national level to UNICEF/WHO. Changes to the Bhutan Health Information Management System which captures data from the District to the National level will be done with the next update.

The main recording tools that are used for immunization-related activities will be adapted to include IPV vaccine.

- ☑ Immunization or child health card: The IPV dose should be recorded on the child's immunization card, which is kept with the child to report their vaccination status, and other information such as monitoring of growth. The updated card will clearly indicate the clinic **where the IPV dose was received** and **date of administration** should be entered. If a child already has an older card without space for recording IPV administration, the information should be transferred to a new updated card.
- ☑ Tally sheet: Tally sheets are important for monitoring vaccine demand by supervisors.
  - Using the new tally sheets, record the monthly tally and the count for children immunized with IPV, alongside all other vaccines.
  - Also record the number of open vials and unopened vials with reason (VVM change, expiry, freezing, breakage, other)
- ☑ Register: New books with a column for IPV will be provided for recording the date when IPV is administered, alongside all other vaccines at the same contact.
- ☑ Stock record: Accurate vaccine forecasting and ordering depends on knowing the quantity of vaccines in stock at all times
- ☑ Integrated monthly report: Stock record forms will vary for the health facility versus the district and subnational levels.

Monitoring the introduction of IPV will be done through:

- Regular monitoring of core indicators of the implementation of the IPV immunization plan to identify achievements and gaps that need to be addressed. These core indicators will include:
  - IPV doses administered in relation to the target population under 1
  - Vaccine stock & wastage
- At the district level, reports are received from health centers on a monthly basis; at the national level, reports are received on a quarterly level.

6 AEFI monitoring and reporting policy

Adverse events following immunization (AEFI) monitoring in Bhutan will be a critical component of the IPV introduction strategy and the introduction will be leveraged to strengthen the existing national pharmaco-vigilance efforts.

According to the national AEFI policy, all that should be reported to the relevant manager by mobile phone immediately upon detection by a health worker, include:

1. Serious AEFI (i.e., untoward medical occurrence that at any dose results in death, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is life-threatening);
2. Signals and events associated with a newly introduced vaccine;
3. AEFIs that may have been caused by an immunization error;
4. Significant events of explained cause occurring with 30 days after a vaccination;
5. Events causing significant parental or community concern;
6. Swelling, redness, soreness at the injection site IF it lasts for more than 3 days or swelling extends beyond nearest joint.

Although serious AEFI caused by IPV are extremely rare, coincidental occurrence of a serious AEFI and sensational media coverage may seriously undermine immunization activities. Program managers have been trained to plan in advance a special communication strategy regarding AEFI, so that the program is prepared to respond if there is a problem.

The policy emphasizes that risk communication is important to build trust with the public. Development of materials prior to introduction will include information on possible side effects, education and communications (IEC) materials and when communicating with parents and the community. Efforts will also be placed on increasing awareness among health workers and the public of possible adverse events which will also facilitate early recognition and treatment of side effects, which may reduce their consequences. As part of the national AEFI policy, Bhutan has in place a crisis plan, the basic elements of which include:

- an AEFI committee at different levels that can meet immediately to discuss an action plan; identified, well-respected spokespersons at all levels;
- clear channels of communication with various media;
- engaging with credible opinion and traditional leaders to address misconceptions and rumors;
- training of health workers in how to communicate with the public about AEFIs and safety concerns;

and having an AEFI action plan with specific roles for immunization program partners.

The AEFI system in Bhutan is functioning well according to the recent HPV post-introduction evaluation. Definitions are available, reporting mechanisms are in place, and validation is standardized and documented. The review team observed that the system for reporting serious cases functions with an AEFI committee at the central level that meets to review serious cases for causality assessment. The AEFI system is capable of handling more cases (minor cases) and which was deemed to be important for additional new vaccine introduction such as IPV.

During this post introduction evaluation, areas of strengthening AEFI system were identified including:

- Conducting refresher training in AEFI management and reporting for staff at the district and health center levels
- Encouraging robust reporting of AEFIs through the system

These recommendations were implemented with the re-introduction of Pentavalent vaccine in Bhutan in 2011. The introduction of IPV will be leveraged to ensure that these recommendations are reinforced.

7 Advocacy, communications, and social mobilization

An important component of the IPV introduction plan includes development of a robust national communication and advocacy strategy geared towards different audiences, decision-makers, stakeholders, communities, and parents. The Ministry of Health will collaborate with WHO, UNICEF and other global partners to leverage the use of existing tested messages and materials to develop a strategy appropriate for the needs of the Bhutanese population.

Emphasis will be placed on the following aims:

- To create awareness and demand for IPV and other vaccines
- To foster trust
- To counter rumors and misinformation with facts and data
- To improve immunization coverage
- To enhance reporting and detection of potential AEFI
- To build strong community support for the immunization program
- To bring positive attitude change on immunization

Key strategies for successful deployment of the communications and advocacy strategy in Bhutan will include:

1. Development of contextually appropriate messages and consultations with key decision-makers and scientific community to obtain buy-in before introduction of IPV in the country.
2. Leverage and customize existing tools, including advocacy and global communications materials, to be packaged in a way that is useful for regional and country level advocacy activities
3. Selecting and leveraging potential advocates for training (pediatricians and civil society)—providing them with materials and advocacy and communications training.
4. Developing a crisis communications plan