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

COMPREHENSIVE MULTI-YEAR PLAN OF IMMUNIZATION

2014–2018

Annex E

Table of Contents

Executive Summary

The Royal Government of Bhutan is committed to provide best quality health services to its citizens. Public Health Service of the Kingdom, specially the EPI programme has received the government's high priority. Over the last three and a half decades the EPI programme in Bhutan has made great strides towards achieving targets in Millennium Development Goals.

Bhutan's EPI has shown great resilience over the years while serving its sparsely scattered population over one of the world's most difficult terrains. While it has achieved very high immunization coverage and maintained it over the years, EPI diseases have nearly disappeared which actualized the task of maintaining VPD knowledge among the country health care personnel. Bhutan achieved UCI status in 1991. The country remains polio free since 1986 and plays an important role in achieving polio-free certification for the region as a whole. The only case of neonatal tetanus in the country was registered in 2006 after reporting no cases since 1994. During 2014-2018, Bhutan is planning – with UNICEF support – to validate its neonatal tetanus elimination status.

Bhutan is also a pioneering country in new vaccine introduction. Hepatitis B monovalent vaccine was introduced in 1997, followed by tetravalent (DTP-HepB) vaccine in 2003 and, finally, by Pentavalent (DTP-HepB-Hib) vaccine in 2009-2011, thus introducing Hib antigen into the national immunisation schedule. MR vaccine was introduced in 2006 replacing monovalent measles vaccine. During the timeline of the next (2014-2018) cMYP the country is planning a switch to MMR vaccine.

The Royal Bhutan Government has remained and will continues 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 financing the country's co-payments towards Pentavalent GAVI support, the BHTF is expected to completely take over the business of financing procurement of all the vaccines phased over from donors to the Government.

Assistance to the RGOB during cMYP 2009-2013 cycle was provided by JICA– a long-term major external donor. JICA efforts were focused mostly on upgrading the cold-chain infrastructure. Apart from Japanese government, assistance to the EPI has been provided by the Japan Committee for "Vaccine of the World's Children" (JCV) – currently it finances procurement of all traditional and underused vaccines.

While GAVI continues to provide considerable support in financing Pentavalent vaccine procurement, Bhutan will graduate from this support line at the end of 2015.

In 2010, the Australian Cervical Cancer Foundation provided national immunisation Programme with the opportunity to introduce the state of the art HPV vaccine for the cohort of 12-year old girls. Starting from 2011, the HPV vaccine is included into regular immunisation schedule.

Traditionally, WHO and UNICEF are long term partners of Bhutan's EPI program and will continue to play this role in the future.

Bhutan's national planning follows 5 year cycles with financial year starting on July 1. 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.

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.

List of Acronyms

The following acronyms are used in this document

AEFI	Adverse event following immunization
AFP	Acute Flaccid Paralysis
BHTF	Bhutan Health Trust Fund
BHU	Basic Health Unit
BHW	Basic Health Worker
cMYP	comprehensive Multi Year Plan
DHO	District Health Officer
DT	Diphtheria and tetanus
DTP-HepB	Diphtheria Tetanus Pertussis Hepatitis B (vaccine)
EPI	Expanded Program on Immunization
EVSM	Effective vaccine store management
FSP	Financial Sustainability Plan
GDP	Gross Domestic Product
GIVS	Global Immunization vision and strategy
GNM	General Nurse Midwifery
HA	Health Assistant
ICC	Inter-sectoral coordination committee
JDWNRH	Jigme Dorji Wangchuk Referral Hospital
MDG	Millennium Development Goal
MNT	Maternal and Neonatal Tetanus
MOH	Ministry of Health
MR	Measles and Rubella
OPV	Oral Polio Vaccine
ORC	Outreach Clinics
PCM	Partner Coordination Mechanism
PHC	Primary Health Care
SEARO	South East Asia Regional Office
TT	Tetanus Toxoid
VHW	Village Health Workers
VPD	Vaccine Preventable Disease
VPDP	Vaccine Preventable Disease Program
VVM	Vaccine vial monitor
WHO	World Health Organization

List of Tables

List of figures

1. Introduction

1.1 Country Profile

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. The southern border touches with four Indian states of Sikkim in the far west, West Bengal, Assam, and Arunachal Pradesh in the far East. In the north, the mighty and majestic Himalayas form the natural border with the Tibetan Province of China.

Figure 1: Map of Bhutan (from Google maps)

Central Bhutan consists of rather broader valleys of Paro, Thimphu, Punakha, Wangdue and Trashigang. The northern region comprises of the main Himalayan range and has a sparse population, with many difficult to reach areas. The southern belt has a hot and humid climate. The central inner Himalayas have a cool temperate climate, while the higher and northern region has a severe alpine climate.

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 at61.5 per 1,000 live births. In 2012, Bhutan population was estimated at 720,679 and population growth rate declined substantially since the last census (See Figure 2).

Figure 2: Bhutan Population growth rate (World Bank)

Administratively, the country is divided into 20 Dzongkhags (districts) and these are further divided into 205 Gewogs (blocks). Each Dzongkhag is headed by a Dzongda (governor) appointed by the central government. The Dzongda is the overall in-charge of overall socio-economic development activities in the Dzongkhag.

1.2 National Health Policy

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.

1.3 Health care system in Bhutan

Bhutan adopted Primary Health Care (PHC) approach to the health delivery system in year 1979. Currently, health care is provided through a network of 29 hospitals, 178 Basic Health Units (BHUs), and 485 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 2012, Bhutan had 194 doctors (including expatriates), with a doctor per 10,000 population ratio of 2.7. The total number of nurses was 736 (10.2 per 10,000 population). The total staff strength of the Ministry of Health in 2012 constituted 4,280 health personnel of different categories serving in different health facilities. These include:

Table 1. Healthcare workers in Bhutan

Doctors (MBBS / Specialists)	194
Assistant Clinical Officers (ACO)	39
Nurses (Assistant Nurse/GNM/B. Sc. Nurse)	736
Health Assistants (HA)	416
Basic Health Workers	162
Medical Lab Technologists	27
Drungtshos (Indigenous physicians)	35
Technicians	780
Administrative and support staff	1202
General Service Personnel	439
Others	250

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 control programme.

1.4 Current Situation of Health Sector

The Royal Government initiated decentralization policy in 1981, and since then healthcare has been in the forefront in implementation of the decentralization policy. Today the health service system is fully decentralized to the dzongkhags and all primary health care programs are integrated into dzongkhag health care delivery system. Through this far-reaching health service delivery reforms, today, over 90% of the population have access to healthcare services. The remaining challenge, however, consists in reliably covering sparsely populated districts. The Royal Ministry of Health is fully committed to reaching out to the hard-to-reach population.

Table 2: Key Health Indicators (Annual Health Bulletin 2013 & National Census 2005)

Indicator	1994	2000	2005	2012
General Fertility Rate	172.7	142.7	NA	85.9
Total Fertility Rate	5.6	4.7	NA	2.8
Crude Birth Rate (per 1000 population)	39.9	34.09	20.0	18.5
Crude Death Rate (per1000 population)	9.0	8.64	7.0	7.7
Infant Mortality Rate (per 1000 population)	70.7	60.5	40.1	40.0
U5 MR (per 1000 live births)	96.9	84.0	61.5	54
Maternal Mortality Rate (per 1000 live births)	3.8	2.55	NA	1.8
Population Growth Rate	3.1	2.5	1.3	1.3
Contraceptive Prevalence Rate	18.8	30.7	NA	65.6
Doctors per 10,000 population	NA	1.7	2.3	2.7

https://knoema.com/atlas/Bhutan

Bhutan has been demonstrating significant progress in health indicators as shown in the above table. 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 seven vaccine preventable diseases: TB, Diphtheria, Pertussis, Tetanus, Polio, Measles and Hepatitis B. Tetanus Toxoid (TT) immunization of pregnant mothers was introduced in 1983. 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) (see Figure 2). 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.

2. Situational analysis of immunization programme in Bhutan

2.1 Historical perspective

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 1997 as monovalent vaccine, was replaced with DTP-HepB (tetravalent) in 2004 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-year old girls, and, starting from 2011, the vaccine was introduced into regular immunisation schedule.

EPI is fully integrated in the general health system. The services are provided throughout the country from the fixed centres at hospitals/BHUs and outreach clinics. The primary health care workers, namely the Health Assistants (HA), Auxiliary Nurse Midwives (ANM) and Basic Health Workers (BHW) are responsible for providing immunization services to the children and pregnant women.

All 20 districts have updated micro-plans to raise immunization coverage.

2.2 Progress of control of vaccine preventable diseases

Polio

The last clinically compatible poliomyelitis case in Bhutan was reported in 1986 in Tsirang. 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 – is 70 %.

Surveillance for other diseases is gradually gaining strength. In particular, surveillance for measles and neonatal tetanus is being integrated into the AFP surveillance, building up on its strengths. At the same time, the program still needs improvement, facing problems such as incomplete reports and inadequate investigations.

Maternal and Neonatal Tetanus (MNT)

While there has not been a single case of MNT reported since February 2006, Bhutan is still believed to be at some risk of MNT although at much less one than decade ago. Estimated TT2+ coverage in 2012 was at 80% – substantial improvement from only 46.1% at 2002. Also importantly, the institution delivery rate has been increased from 50% to 63%. It is important to develop the MNT sustaining plan for the validation of MNT.

Measles

Estimated nation-wide measles coverage in 2012 was 95% for MCV1 but still only 90% for MCV2. However, nation-wide MR campaigns conducted in 2005, and rather high routine immunisation coverage sustained during 2009-2013 renders outbreaks of measles and/or rubella unlikely. In 2010 there were 21 measles cases and 10 cases in 2011, but only 1 case in 2012. No deaths were registered.

There was only one case of Pertussis In 2011, there were no reported cases of diphtheria. The following table shows EPI diseases reported 2003-2012

Table 3: EPI disease cases reported over 2003 – 2012

Year	Polio	Measles	Diphtheria	Pertussis	Tetanus Total/ Neonatal	Rubella	JE	Mumps
2003	0	0	0	0	0	350	ND	ND
2004	0	3	0	0	0	12	ND	ND
2005	0	11	0	1	1/0	81	ND	144
2006	0	2	0	1	59/1	11	ND	ND
2007	0	11	0	0	20/0	3	ND	ND
2008	0	7	0	0	7/0	2	ND	ND
2009	0	6	0	0	23/0	15	0	ND
2010	0	21	0	0	0	9	0	218
2011	0	10	0	1	3/0	3	3	262
2012	0	1	0	0	0	2	27	198

2.3 Organization of EPI Programme

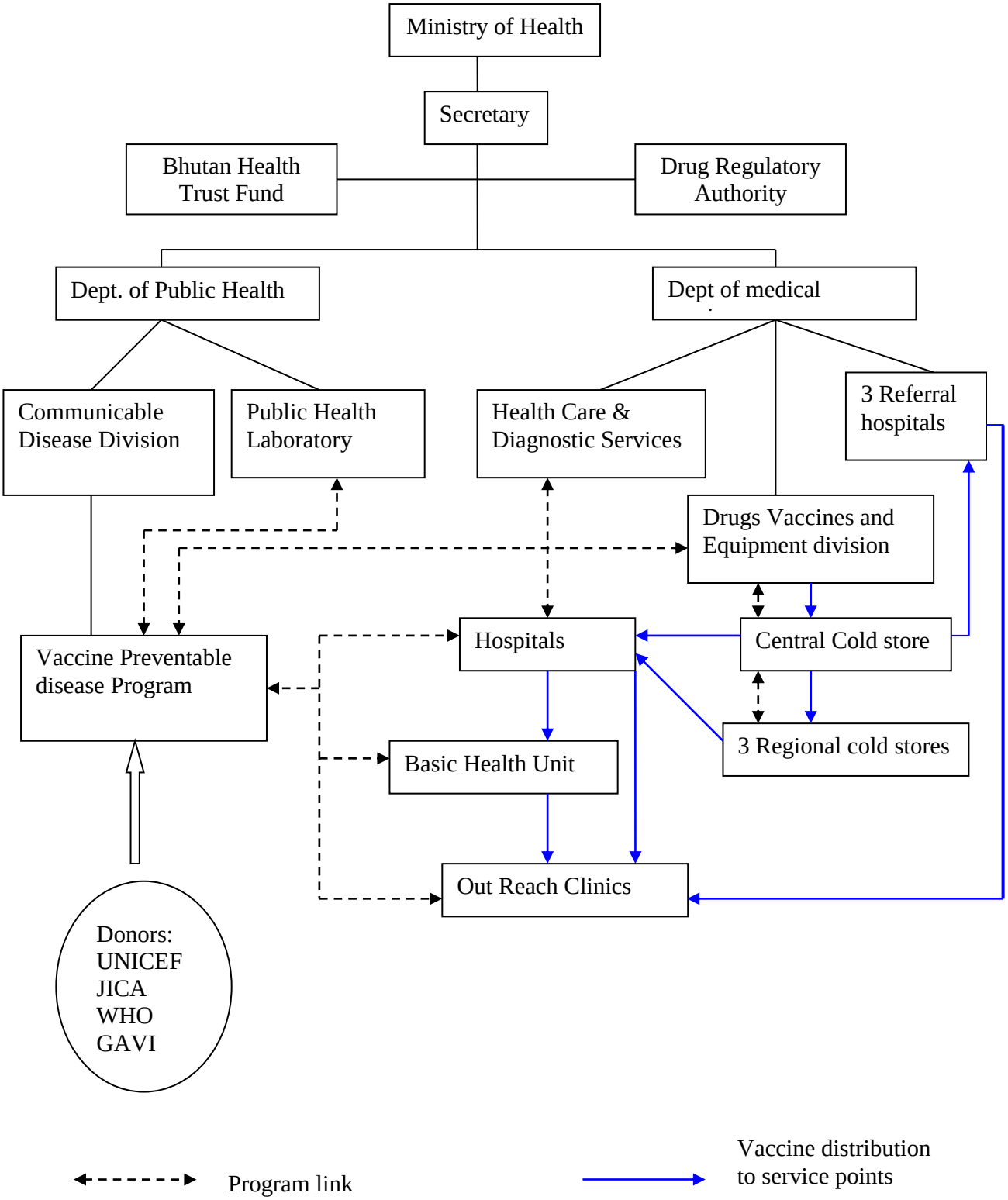


Figure 3. Organization of EPI programme in Bhutan

2.4. EPI Schedule

The current EPI schedule in Bhutan is given in following table:

Table 4: Current EPI Schedule (as of 2013)

Antigen(s)	No. of doses	Children/ Age
BCG	1	At birth
HepB	1	At birth
OPV	4	At birth, 6 wks., 10 wks., 14 wks.
DPT-HepB-Hib	3	6 wks., 10 wks., 14 wks.
MR	2	9 months, 24 months
DTP	1	24 months
Td	2	6 and 12 years
Td	2	1st contact of pregnancy, +1 month
HPV	3	12 yrs., +2 months, +6 months (girls only)

2.5 Immunization Coverage

Bhutan launched the universal childhood immunization (UCI) in 1991. Since then, the nation has been successful in sustaining coverage of over 90% for all EPI antigens. The latest immunization coverage estimates by WHO in 2007, showed coverage at national level as follows:

Table 5: Immunization coverage survey data – WHO data 2008

Vaccine	result	method	% card seen
BCG	100	EPI	98
DTP1	100	EPI	98
DTP3	100	EPI	98
HepB3	100	EPI	98
MCV	99	EPI	98
Pol3	100	EPI	98
TT2plus	97	EPI	98

The EPI surveys are planned to be carried out once in 2-3 years following introduction of the Hib vaccine (as a component of Pentavalent DTP-HepB-Hib vaccine).

Out of 20 districts,19 (95%) had >80% coverage for DTP3, 14 (70%) had >90% coverage for MCV1 and 11 (55%) had >80% coverage for TT2+ in pregnant women. (EPI Fact Sheet, WHO 2011).

For intensification of routine immunization, Bhutan has a plan to reach high-risk areas, migrant/un-reached population and low performing areas.

Table 6: Immunization coverage (%) from 2006 to 2012

Antigens	2012	2011	2010	2009	2008	2007	2006
BCG	95	95	95	96	99	94	92
DTP3	97	95	95	96	96	95	95
HepB3	97	95	95	96	96	95	95
HepB BD	60	29	-	-	-	-	-

Hib3	97	-	-	-	-	-	-
MCV	95	95	95	98	99	95	90
MCV2	90	95	85	90	72	-	-
Pol3	97	95	95	96	96	93	96
Rubella	95	95	-	98	99	95	-
TT2+	79	80	80	80	82	64	67

National immunization coverage data has improves significantly since 2000 and the country plans to maintain these high coverage levels at national level and plans to focus in achieving similar high levels in each district too.

2.6 Vaccine wastage

High vaccine wastage, being one of the highest in the world, remains a hard-to-address problem and serious concern both for the Ministry of Health and its partners. Due to limited road infrastructure and sparsely distributed population in the mountainous areas, substantial reduction of wastage for multi-dose presentations may be unrealistic goal. It should be noticed though that with introduction of mono-dose vaccines – Pentavalent, HPV – wastage indicators improved substantially.

The program management is testing various strategies to reduce the waste rate, but the nature of the difficult geographic terrain and sparse & scattered communities poses a limiting factor. In an effort to reduce the vaccine wastage, the country introduced vaccine vial monitors on all vaccines, open-vial-policy for liquid vaccines at the fixed clinics and auto-disable syringes in 2003. The national policy of providing immunization services through outreach sessions for remote villages has improved the access to services and coverage at the cost of increased vaccine wastage.

Bhutan EVM assessment report (assessment carried out in Oct-Nov 2012) indicates that the poor stock control and cold chain monitoring contributed to considerable wastage from both opened vials and un-opened vials. Other main contributing factors were larger vial size and the smaller session size.

Table 7: Vaccine Wastage Rates – Year 2012

Vaccine	Wastage Rate (%)	Wastage Factor
BCG	84	6.25
Measles (MR)	65	2.86
OPV	38	1.61
DPT-HepB-Hib	5	1.05
TT	26	1.35

Improvement in vaccine wastages started to be observed from 2006, when Bhutan changed DTP-HepB from 10 dose vials to 2 dose vials. The situation further improved with transition to single-dose Pentavalent vaccine. Of special concern are cases of wastage due to expire in stores or non-use of frozen vaccines. Starting from 2007, the program initiated the monthly vaccine wastage reporting from all the health facilities.

Vaccine stock-outs are rare. At present, there are 6 EPI technicians posted in three regional cold stores with the sole responsibility of vaccine supply and cold chain management.

Monitoring of vaccine wastage

With introduction of newer vaccines, Bhutan started to closely monitor vaccine wastage. The newer vaccines are available at much higher prices than traditional vaccines. With graduating from GAVI (and likely other donors') support, immunization programme will no longer enjoy the luxury of paying low prices for vaccines. Financial analysis shows that introduction of Pentavalent vaccine alone increased vaccine-procurement budget by almost four times, not including personnel costs. It is, therefore, critical to keep the vaccine wastage to minimum feasible levels. Bhutan will need to take specific measures to reduce vaccine wastage and monitor this aspect constantly. EPI started this work with introduction of Pentavalent vaccine, using this as a surrogate for all EPI vaccines. Specific measures include:

1. Using single/small dose Pentavalent, HPV, and potentially other vaccine presentations
2. Introduced monitoring forms, to be filled and submitted by all vaccine storage points to respective districts.
3. Monthly review of vaccine utilization in each district
4. Taking specific measures in case higher wastage is recorded in a district
5. Training EPI and cold chain technicians in preventing vaccine wastage due to freezing or heat exposure.

Table 8: Vaccine wastage rates and targets to be achieved

Vaccine	**Current wastage**	**Target**				
	2012	**2014**	**2015**	**2016**	**2017**	**2018**
BCG	84	80	75	75	70	65
OPV	38	35	35	30	30	30
MCV	65	60	55	50	45	40
TT	26	25	20	20	20	20
Pentavalent	5	5	5	5	5	5
PCV	-	-	-	5	5	5
Rota	-	-	-	-	5	5
HPV	5	5	5	5	5	5

The target is to maintain the low wastage for Pentavalent vaccine and to reduce wastage rates for multi-dose presentation vaccines to GAVI-recommended levels for respective presentations.
It is also accepted by the EPI management that it would be unrealistic to achieve vaccine wastage less than 50% for some conventional vaccines since they are dispensed in 5, 10 or 20 dose vials. Technically, open vial policy is applicable for liquid Pentavalent formulation and this should help in reducing the wastage in the fixed clinics.

For actual waste management (i.e. disposal), National policy for health care waste management including waste from immunization activities is available and being applied throughout the country.

2.7 Adverse Events Following Immunization (AEFI)

A national system to monitor adverse events following immunization (AEFI) is implemented in Bhutan in standard format. Routine reporting has been gradually strengthened. Four AEFI cases were reported and no event was categorized as "serious" in 2011. No case required hospitalizations.

It appears more severe forms of AEFI that needs hospitalization or medical attention are being reported. Although, In-service training programmes for health staff on AEFI surveillance, reporting and investigation is being conducted on regular basis, the AEFI surveillance system still needs to be strengthened.

2.8 Cold chain issues

Cold chain equipment inventory was updated in 2011.

An assessment of the cold chain system was carried out by a consultant in 2012. 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. 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.

2.9 Injection Safety

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.

2.10 Vaccine Regulation

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 Drug Regulatory Authority, all the products must be registered with the authority prior to their arrival into the country. Bhutan Medicine rules and regulation, 2005 also has a section on the vaccine import.

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

2.11 Health workforce

Human resource availability is a major issue in Bhutan. Inadequacy in terms of number and technical capacity of the staff at all levels has been a major barrier for the country's EPI program. Currently, EPI is manned by two officials at the central level, and assisted by 6 cold chain technicians at regional level. The problem at the central level contributes to weak program management and supervision of EPI activities at district levels. Due to decentralization of Dzongkhag (District) health sector, there are capacity problems with respect of program management.

Community level volunteers, called as village health workers (VHW), have been a crucial link between the health setting and community in Bhutan. It was introduced to supplement the work of rural health facilities since early 1980, after starting of PHC. Currently, about 1,200 VHWs are functioning in the country and their contribution to improve the rural health situation is highly recognized. They assist the BHU staff in delivering service to the target population. The main roles of VHW are 1) to facilitate increased access to health care services 2) to improve healthy lifestyle of the community, and 3) to provide first aid and treatment of minor ailments

Amongst 21 tasks identified in 1995 at the review meeting between the health Division and donor agencies (UNICEF and WHO), VHWs have a specific task in immunization to "help mothers to attend maternal and child health clinics regularly". They also have a task to "observe for any disease outbreaks in the community" and "notify the nearest health centre immediately". Besides, they are a good source of notifying the existence of new mothers, or migration of the target population to the BHU.

The work of VHWs contributed to the improvement of health status is highly praised. Results from the "Rapid Needs Assessment for Better Community Health: Focus on VHW" conducted by JICA in February 2005 suggested that supporting system for VHW needs to be improved.

1. refresher training should be carried out regularly
2. training for new VHWs should be held
3. drugs for VHWs from BHU should be appropriately supplied
4. VHW medical kit should be reissued
5. Government should commend VHWs with extraordinary work and giving VHW certain authority together with responsibility.

The Ministry of Health fully supported the suggestions and also recognized the need to strengthen the capacity of BHU staff to become strong supervisors for VHW. It is planned to strengthen the Human Resource Development unit of the Ministry of Health to take over training of the health staff, maintaining long-term sustainability.

2.12 Introduction of new vaccines

Since the very start of EPI in 1979, Bhutan is striving for a better immunization service to its population.

In 1997, hepatitis B vaccine was added to the EPI schedule of 6 traditional antigens; by 2004 it was replaced by combined DTP-HepB vaccine and, in 2009-2011, by Pentavalent combination of DTP-HepB-Hib vaccine. In 2006, Bhutan introduced combined measles-rubella (MR) vaccine to replace monovalent measles vaccine administered at 9 months and simultaneously introduced second dose of MR at 24 months of age. Taking into account considerable number of Mumps cases observed during 2010-2012, the country is further contemplating transitioning from MR to MMR vaccine.

In 2010, Bhutan became the first country in the South-East Asia region to introduce the human papillomavirus (HPV) vaccine. It was introduced with the assistance of Australian Cervical Cancer Foundation (ACCF) through school-based catch-up campaigns targeting all girls aged 12 to 18 years. More than 90% coverage was achieved in all three rounds. At the beginning of 2011, HPV vaccine was incorporated into the routine immunization for 12 years girls. While the ACCF support will continue through 2015, the country is currently considering the means to sustain HPV vaccination beyond 2015.

In Bhutan, respiratory and diarrheal infections remain a major cause of children's morbidity and, likely, mortality. In 2012, the incidence of reported pneumonia cases among children under 5 was 1,204 per 10,000 (9,939 cases in total), and diarrhoea – 2,368 cases per 10,000 (in total 19,553 cases). In the same year, 77 meningitis/encephalitis cases were reported among the same children group. Since until recently the country has had no capacity to conduct comprehensive microbiological studies of aetiological agents (types) for the above-mentioned diseases[1], it has to rely on the regional disease burden estimates, as well as on WHO recommendations, while taking decisions about introduction of newest vaccines. While at the moment the NCIP is discussing the feasibility of introducing into the national EPI schedule Pneumococcal and Rotavirus vaccines, the final decision about the new vaccines introduction will be taken based on the disease burden studies. To this end, Bhutan is currently actively strengthening Pneumococcal and Rotavirus surveillance systems and accumulating relevant clinical and epidemiological data.

It is taken into account by the country EPI management that the WHO in its 2012 position paper on pneumococcal vaccine recommends that inclusion of PCVs be given a priority in childhood immunisation programmes world-wide. It is also of particular importance for Bhutan, with its complicated access to remote and scattered population in the mountainous territories, that the

[1] It should be noted, however, that in 2002 a WHO study was conducted in the country to estimate the burden of Hib disease using Hib rapid assessment tool (Hib-RAT). According to the study results, in Bhutan, among children under 5 year old, the incidence of Hib meningitis was estimated at 16-54 cases per year, while the incidence of Hib pneumonia cases was estimated at 80-270 cases per year. These incidences were high compared to incidences in other countries. The study results played an important role in providing the basis for introducing Hib vaccine into the national EPI schedule.

immunogenicity and reactogenicity of the PCV vaccines under consideration have been shown not to be significantly altered when given concomitantly with other childhood vaccines, which will substantially facilitate administering the vaccine during outreach sessions. Bhutan is planning to introduce PCV antigen starting from January 2015.

Similarly, the National Committee takes into account the WHO 2013 position paper on Rotavirus vaccine, wherein the WHO recommends that every infant should receive his/her first dose of rotavirus vaccine as soon as possible after six weeks of age, along with vaccination against diphtheria-tetanus-pertussis (DTP), and subsequent doses as closely to the national immunization schedule as possible.

According to WHO, Rotavirus vaccines should be included in all national immunization programmes and considered a priority, particularly in countries with high RVGE-associated fatality rates, such as in south and south-eastern Asia. In line with the WHO recommendations, the MOH considers the introduction of rotavirus vaccines as part of a comprehensive strategy to control diarrhoeal diseases with the scaling up of both prevention (immunisation, promotion of early and exclusive breastfeeding, hand-washing, improved water supply and sanitation) and treatment packages. The strategy will be a constituent part of the broad IMCHI package implemented by the RMOH.

When introducing the Rotavirus vaccine, the EPI management will also take the necessary steps to develop a strategy to inform health staff and caregivers about the benefits (outweighing the risks), but also about a small potential risk of intussusception after rotavirus vaccination. Necessary counselling will be provided to caregivers to recognize danger signs of dehydration or intussusception and to seek immediate medical care for these conditions if necessary.

Apart from introducing the PCV and Rotavirus vaccines, the country is also analysing the feasibility of switching from attenuated oral Polio vaccine (OPV) to inactivated polio vaccine (IPV).

Following the provisions laid down in the National Health Policy, the process of introducing any new vaccines (as well as any other HC technology for that matter) will be subject to thorough examination and comparison of its potential costs and benefits. Also taken into account will be issues of vaccine affordability, financial and operational impact on the immunization delivery system, and necessity to alter current immunization practices.

Then, it should be noted that introduction of the new PCV and Rotavirus (and possibly other) vaccines will present a much greater challenge for the country EPI than the introduction of, for example, Pentavalent vaccine in the past – due to GAVI graduation at the end of 2015, Bhutan will have to rely either on its own resources or look for alternative donor support for procuring new vaccines. The country is resolute to explore all possible avenues while assuring best possible VPD protection for the target groups. In particular, the Government will explore potential opportunities offered by the GAVI/WHO-backed initiatives for pooled procurement of new vaccines and for support of new vaccine introduction in Middle Income Countries.

The final decision to introduce new vaccines will depend on several factors, including Bhutan's ability to sustain them beyond GAVI support. While at this point in time no specific decisions have been made, the Royal Government is quite confident that all the recently introduced vaccines, together with other routine vaccines can be sustained particularly with the Bhutan Health Trust Fund actively taking up support for immunization.

The vaccine preventable disease control programme will start pneumococcal surveillance activities as a sentinel surveillance based at Thimphu JDWNRH hospital. It is planned to communicate and collaborate with the existing regional surveillance networks through WHO regional office.

The Ministry of Health also plans to upgrade facilities at the Public Health Laboratory in Thimphu to establish and continue Rotavirus surveillance activities. It is also planned to collaborate with existing regional Rotavirus surveillance networks.

During 2009-2012, Bhutan began reporting Japanese Encephalitis (JE) cases – standard case definition has been developed and adopted in the clinical settings. Especially high risk of JE outbreaks exists in southern areas of the country bordering India. Through routine surveillance & reporting of malaria cases, the data gathered so far indicate the existence of epidemiological factors conducive for JE. JE vectors (*Cx. vishnui, Cx. pseudovishnui and Cx. tritaeniorhynchus*) are present in high density along with malaria vectors in all malaria endemic areas. Therefore, the threat of JE outbreak looms large over all malaria endemic areas of the country. It is planned both to upgrade the capacity of National Laboratory to support diagnosis and surveillance of JE and to strengthen links with regional laboratories to investigate any future suspected meningitis/encephalitis outbreaks/syndromes to verify diagnoses and identify any possible JE cases.

3. Objectives of the Comprehensive Multi Year Plan of Immunization

The validity period of the previous cMYP was from 2009 to December 2013 and a supplementary cMYP was prepared in alignment with the extension of the 10th five year plan, for the period of January 2013 to December 2013. The present cMYP covers period of January 2014 to December 2018.

Bhutan underwent transition towards a democratically elected government in 2008. In July 2013 parliamentary elections were won by opposition party which is likely to form the next government. As the country follows five year planning cycles and the 10th five year plan ended in June 2013, the next 11th plan will be from July 2013 to June 2018. This will enable the newly elected government to align the planned activities along with its long-term agenda. It is expected, however, that the new government will continue with existing policies and activities with respect to the health sector.

Current cMYP was developed based on information and analysis of various plan documents such as the Health Sector Review of the 10th five year plan, Mid-term review of 10th five year plan, MYP for period 2009-2013, National EPI review (2011), Joint WHO/National Review of Surveillance (2005), EVM Assessment (2012), Population & Housing Census of Bhutan (2005), Annual health Bulletin (2013), and RGOB Budgets/Expenditures and related data from Ministries of Health and Finance. Critical inputs and feedback was obtained from a series of discussions and meetings with stakeholders like WHO, UNICEF and JICA, policy makers, and ICC members.

3.1 National Goal

To reduce child mortality and morbidity associated with vaccine preventable diseases to achieve the Millennium Development Goal 4 of reduction of under-five child mortality by two thirds by year 2015 (somehow mention MDG-4 and then go on to achieve 2014-2018 -- check with the public).

3.2 National Objectives

1. Sustain high national immunization coverage level at or above 95% for all children less than one year of age.
2. Achieve polio free certification during 11th FYP.
3. Prevent congenital rubella syndrome. Eliminate rubella infection by maintaining high immunization levels through the routine immunization services.
4. Eliminate measles morbidity and mortality in children by 2016
5. Maintain and document elimination status of neonatal tetanus.
6. Integrate and strengthen surveillance of vaccine preventable diseases.
7. Strengthen AEFI surveillance.
8. Improve the vaccine logistics, safety, quality and cold chain management at all levels.
9. Introduce new and underutilised vaccines based on disease burden studies.
10. Introduce IPV vaccine in line with the global Polio Endgame Strategy as recommended by the WHO.
11. Assure reliable long-term resource mobilization for the VPDP.
12. Maintain high level of public awareness about immunisation benefits.
13. Maintain high level of professional VPD knowledge and readiness among healthcare personnel.

3.3 Strategies

1. Increasing the immunization coverage (more than 93%) and the quality of immunization services
2. Providing continued advocacy, social mobilization and program communication
3. Assuring efficient vaccine logistics and cold chain system management
4. Assuring effective monitoring and integrated surveillance of vaccine preventable diseases
5. Strengthening technical capacity and resources for VPDP
6. Introduction of appropriate new vaccines and technologies
7. Establishing and strengthening partnerships with international and national agencies for resource mobilization and technical support
8. Building up capacity of community health workers and village volunteers

3.4 Activities

Objective	Strategy	Activities
Sustain high national immunization coverage level at or above 93% for all children less than one year of age.	Increasing the immunization coverage (more than 93%) and the quality of immunization services	• Development of annual micro-plans in each district • Close monitoring in 2 districts with less than 90% coverage • Ensuring uninterrupted vaccine supplies and logistics • Improved registration of pregnancy and TT vaccination • Use routine data for district level monitoring
	Supportive supervision	• Finalize checklists and supervision plans • Analyse most frequently reported issues in the reporting forms • Hold joint checklist analysis drills in the districts addressing/providing resolution plan for most frequent reported issues
	Capacity building of Village Health Workers (Volunteers)	• Train district Supervisors • Implement the plan for semi-annual field visits to all vaccine storage points and providing feedback to district level • Providing refresher training for all vaccinators (HAs, ANMs and BHWs) • Providing integrated health training of 1,200 VHWs • Update and distribute revised EPI manual
	Introduction of appropriate new vaccines and technology	• Provide cost-effectiveness analysis of introducing Pneumococcal and Rotavirus vaccine • Estimate cost-effectiveness of OPV-to-IPV transition

Objective	Strategy	Activities
		under currently assumed vaccine pricing terms.
		• Start pneumococcal surveillance activities at the JDWNRH based at clinical laboratory
		• Start sentinel Rotavirus diarrhoea surveillance activities based at the Public Health laboratory
	Strengthen AEFI surveillance	• Strengthen AEFI monitoring through primary health care system • Operationalize AEFI investigation team • Monitor AFEI reporting at national level
Achieve polio free certification during 11th FYP	Consistently implement polio-free certification requirements; Achievement and maintenance of global AFP surveillance criteria	• Agreeing with partners – WHO and UNICEF – content and timeline for polio-free certification process • Carry out training of health staff to improve timeliness and completeness of sample collection from AFP cases • Conduct refresher training of health staff with AFP surveillance guidelines • Development, revision and printing of manuals, reporting and investigation forms (AFP/MR/AEFI manual, zero and active surveillance and AEFI reporting forms) • Conduct regular active AFP surveillance and expansion of new active surveillance site in the health facilities
Prevent congenital rubella syndrome. Eliminate rubella infection by maintaining high immunization levels through the routine immunization services.	Achieve near 100% MR/MMR coverage in the target age group by 2016	• Monitor MR coverage in routine immunization • Analyse, systematise and address causes for DTP-to-MR drop-outs. • Organise, in case of necessity MR mop-up outreach vaccination sessions/ campaigns for target groups
Eliminate measles-related morbidity and mortality in children by 2016.	Achieve 100% MR/MMR coverage	• Monitor MR/MMR coverage in routine immunization • Analyse, systematise and address causes for DTP-to-MR drop-outs • Organise, in case of necessity MR mop-up outreach/ campaigns for target groups
Maintain and document elimination status of neonatal tetanus.	Improve TT2+ coverage for antenatal group	• Agreeing with partners – WHO and UNICEF – content and timeline for the process of documenting NT elimination status • Update guidelines for HC and aligned personnel on integrated management of maternal and child care problems (including for providing TT vaccination) • Regularly analyse pregnancy registration reports and address root causes for untimely registration

Objective	Strategy	Activities
		and TT vaccination of pregnant women.
Integrate and strengthen surveillance of vaccine preventable diseases	Develop partnerships with international and national agencies for resources mobilization and technical support Initiate surveillance activities for new vaccine preventable diseases	• Update VPD surveillance guidelines for district and BHU facilities • Adopt standard surveillance, clinical and laboratory methods • Conduct ToT training for district HC personnel on VPD surveillance and reporting routines • Conduct refresher training for national level management on VPD surveillance • Schedule regular internal and external reviews of surveillance activities • Participate in external quality control for surveillance laboratories
Strengthen AEFI surveillance	Update personnel skills in AEFI surveillance Update and test the system of responding to AEFI	• Update/adopt guidelines on detection, reporting and management of AEFI for HC personnel to clearly define the roles in the process of HC personnel, EPI management and NRA • Conduct training for the District and BHU personnel on detection, reporting and management of AEFI with role playing for HC personnel, EPI management and NRA in monitoring and responding to vaccine safety issue • Implement and test the system/process of public relation management of AEFI
Improve vaccine logistics, safety, quality and cold chain management at all levels	Assuring efficient vaccine logistics and cold chain system management Optimal mobilizing Cold chain equipment	• Monitoring of vaccine wastage by 6 EPI technicians every month • Assessment of central vaccine store • Conduct EVSM • Procure 10 refrigerators through UNICEF for Pentavalent vaccine at regional stores • Conduct refresher training of cold chain personnel • Introduce freeze monitoring to the cold chain • Re-evaluate National Cold Chain capacity and prospective needs pending implementation of PCV and Rotavirus vaccines
	Capacity building of cold chain handlers	• Monitoring during supervisory field visits • Training of all vaccinators (integrated with refresher training)
Introduce new and underutilised vaccines based on disease burden studies	Conduct cost-effectiveness studies/assessment for PCV and Rotavirus vaccines Create enabling environment for smooth introduction of PCV and Rota vaccines	• Hold pre-introduction trainings for District and BHU HC personnel on PCV and Rotavirus vaccines • Launch media campaign explaining the country strategy in (benefits of) introducing the PCV and Rotavirus vaccines. • Launching PCV vaccine in January 2016 • Launching Rota vaccine in January 2017 • Switching from MR to MMR in January 2015

Objective	Strategy	Activities
Introduce IPV vaccine in line with the global polio end game as recommended by WHO	Conduct cost-effectiveness studies/assessment for replacing OPV by IPV vaccine Create enabling environment for smooth transition from OPV to IPV vaccine	• Hold pre-introduction trainings for District and BHU HC personnel on IPV vaccine • Launch media campaign explaining the country strategy in (benefits of) switching from OPV to IPV vaccine. • Launching IPV vaccine in January 2015
Assure reliable long-term resource mobilization for the VPDP	Assure accuracy of resource needs projection for the National EPI Assure predictability of financial commitments to EPI	• Adopt methodology for long-term resource needs projection for all the EPI components • Institutionalise Cost-Effectiveness Analysis (CEA) and develop communication strategy for working with financial sources. • Institutionalise the process of resource needs communication to current and prospective development partners • Negotiate as long-term as possible commitments with donors and partners • Develop contingency plans/strategies for emergency phase-in of national financing sources in place of abruptly stopped partner financing
Maintain high level of public awareness about immunisation benefits		• Development, printing and distribution of IEC materials on polio, measles & other VPDs • Conduct advocacy through different media (print, radio, TV) on essence of immunization and VPD • VHWs training/awareness program on community participation/ empowerment for immunization and VPD surveillance
Maintain high level of professional VPD knowledge and readiness among healthcare personnel		• Assure inclusion of VPD modules into continuing education courses for doctors and nurses as well as access to telemedicine facilities and courses • Provide regular updates on VPD situation region-wide. • Hold regular district dry-runs/drills on actual in-country and literature-described VPD cases

4.Indicators, Monitoring and Evaluation

4.1 System Indicators for monitoring

System component	***Suggested indicators***	***Indicator baselines***	
		2012	***2014***
Routine coverage	DTP-3 coverage (%)	97	98
	% of district with > 80% coverage	98	98
	National DTP1-DTP3 drop out (%)	4	2
	Percentage of district with drop out rate DTP1-DTP3 > 10	0	0
New vaccine Coverage	DTP-HepB-Hib3 coverage	97	97
	MR coverage	5	97
Routine surveillance	% of surveillance reports received at national level from districts compared to number of reports expected.	90	100
Cold chain/logistics	% of districts with adequate numbers of functional cold chain equipment	100%	100%
Immunization safety	% of districts that have been supplied with adequate number of AD syringes for all routine immunization	100%	100%
Vaccine supply	Shortage of vaccines stocks at national level	No	No
Communication	Availability of a plan	No	Available
Financial sustainability	% of total routine vaccine purchase financed using govt. funds. (including loans and excluding external public financing)	30%	40%
Human resource availability	Number of health workers/vaccinators per 10000 population		14/10000
Management planning	Collection of district level indicators regularly at national level.	Yes	Yes
NRA	Number of functions conducted	3	5
ICC	Number of meetings held per year	2	3
Waste disposal	Availability of a waste management plan		Yes
Program efficiency	Vaccine wastage monitoring at national level for all vaccines	Partial	Yes

4.2 Program Monitoring and Evaluation

The EPI program will be monitored at four levels – impact, outcomes, outputs and inputs. The following is illustrative list of indicators to be used for monitoring 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 Reduction of Pneumonia and meningitis cases/deaths Maintaining and documenting MNT Elimination status	Routine surveillance system, reviewed monthly in districts and quarterly nationally
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
Program outputs		

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

5. Risks and challenges in the Health Sector

5.1 Shortage of human resource

Shortage of human resources has been and remains one of the most deriding factors in the Bhutan health care system. To strengthen the overall health service performance and particularly the decentralized management of health services, human resources are required at all levels: from program management and promotional areas to curative services. The government has been able to train only about 3-5 medical doctors annually, which barely meets the attrition of medical doctors due to retirement, transfer to other ministries, and other reasons. The situation has been improving with more candidates joining the medical line in the recent years. The number of specialists trained in medical and management areas are even less. As the training of paramedics can be carried out within the country, the situation is much better in this area. It is this category of people who manage the primary health care system as well as service delivery. It is also mainly this category of people who manage most of the public health program in the department of health services. Because of the same reason of human resource shortage, one or two program personal have to cover a lot and many times it leads to inefficiency and managing the program.

As the government's own fund is limited, the ministry relies much on collaborating partners to develop human resources for health. However, as many collaborating partners do not want to commit funds for long-term training, it will take a long time to achieve self-sufficiency in human resources for health and unless the gap in this key component is filled, the programs will continue to suffer.

The Ministry has identified Human Resource Development unit as a strong part of long term training need of health staff. It is planned to strengthen this unit to take over training needs of the ministry.

5.2 Geography and scattered settlement

Bhutan is situated in one of the world's most rugged surfaces and hence, the settlements are scattered and far-flung. This makes delivery of health and other social services extremely difficult and expensive. Coupled with the lack of qualified specialists at the district and regional levels, this poses a great challenge to efforts in curbing mortality that could have been prevented with timely care. In order to overcome this problem, the Government, with support from WHO, initially started the solar-powered radio communication system to link the basic health units (BHUs) to the district hospitals. To complement this initiative, the government has then embarked upon the telemedicine program in collaboration with WHO and the Japanese government. As electricity and the basic telecom infrastructure were also getting developed slowly at that time, the progress in this area has been slow but the country has been able to connect at least one of the two Regional Referral Hospitals to the National Referral Hospital and improving the referrals and consultations between them. The facility is also being used by the hospital staff to access important health literature. But much needs to be done, and materials required for this program are usually very expensive.

5.3 Dependency on imports for all health products

Be it equipment or drugs and vaccines, the country has to depend on supplies from outside the country. Even if the quality of drugs and vaccines can be assured by purchasing them from WHO authenticated suppliers in the region, hospital equipment and other supplies remain to be a problem.

The long time it takes to procure the equipment or their spare parts and supplies (like reagents and x-ray films) continues to hinder surveillance and other vital works at the hospitals.

5.4 Shift from coverage to quality of services

Having achieved desired level of coverage by health services (including immunisation) the country now focuses on improving the quality of health care services. There have been cases of enormous structures in the districts with no doctor and hence, patients. The situation has been steadily improved over the years yet there remain large rooms for improvements. As three people – one health assistant, one assistant nurse, and one basic health worker staff the basic health units, their functions can hardly be distinguished, as one has to substitute the other every now and then. Similarly, not all the district hospitals have similar facilities. Hence, the whole of next five years will be devoted to setting and implementing standards of services and facilities and working towards fulfilling them.

5.5 Sustainability of development in the health sector

Much of the new technologies (including new vaccines) being currently introduced into the HC sector in Bhutan is quite expensive and requires considerable financial investments. The Health Trust Fund initiative was launched in 2007 as a tool to address these rising financial needs and by now accumulated considerable capital that very soon may start to be used to finance priority HC interventions for Bhutanese nationals. It is only after the Fund starts disbursing interest proceeds, however, that Bhutan will be able to assess how much impact the Trust fund initiative has made on making health care services sustainable. On the other hand, the factors contributing to health status extend far beyond the health sector. So, unless due attention is given to coordinate efforts with other important government organizations like Environment, Trade, Industries and Mines, Agriculture, Education, Municipal corporations, Ministry of Health will land up containing the problems caused by other sectors and this aspect is viewed seriously in order to consolidate the progress that has already been made in various areas of health.

5.6 Meeting the Challenges

With the major challenges in mind, the Government has developed its vision for the future. In the document, Bhutan Vision 2020, the Government has set its priorities for all the sectors for the next 15 to 20 years. Eight priorities have been spelled out in this same document to guide the health sector during this entire period. These long-term priorities are further taken into priority consideration during the formulation of the Five-Year Plans of the Health Sector.

6. Financial analysis

6.1 Introduction

The long-term objectives of the health services is to improve the quality of life by promoting the health of the population and providing better health care in the spirit of social justice and equity. Absolute increase in GDP and projected considerable increase of health sector allocations will translate into significant increase in government allocations – either direct or through the Health Trust Fund. This will reduce the country's dependence on external resources. For the sake of Immunisation financing, private sector participation hardly exists and it is the Government that drives health sector in Bhutan.

The total GDP estimated in 2011 was Nu 78,824 million (1.732 billion USD) and the GDP per capita was 2,346 USD in the same year. Throughout 2000-2011 Bhutan had an average GDP growth rate of 7.5%. The planned health budget for 2010-2011 was Nu 2280 million (51.4 million USD), which was 12% of the total budget. (Source: National Budget report, Ministry of Finance). It should be noted that with the GDP per capita of US$2,346 and a robust economic growth Bhutan has been recently classified by GAVI as graduating country and will therefore seize receiving GAVI support after 2015.

The present c-MYP examines the current status of funding for EPI and projects the future need. As mentioned earlier, the baseline year is 2012 and the projections are for 5 years, 2014 – 2018.

6.2 Funding of immunization

While currently the greater share of funding for vaccine procurement is provided by donors, ever greater share is gradually being taken over by the national sources. At the same time, all the personnel expenses for immunization are borne by the Royal Government of Bhutan. The key donors include GAVI (co-financing Pentavalent vaccine), ACCF (financing HPV vaccine) and JCV (financing remaining vaccines). These donors are keen that the funding for vaccines provided by country's internal resources increases with time. Bhutan Health Trust Fund (BHTF) was initiated as a long term strategy to provide funding for routine health care activities covering the basic medicine and vaccines. Although the targeted principal amount of the trust fund has not been achieved yet, the trust has already been utilized for few activities. In 2013 the Trust Fund financed the country share of co-financing for Pentavalent vaccine procurement. The Trust Fund is expected to in the future to finance procurement of all vaccines in the EPI schedule, starting with 50% funding for purchase of basic EPI vaccines.

6.3 Bhutan Health Trust Fund (BHTF)

BHTF was conceived as a solution for providing recurrent funding for medicines and vaccines. It was expected to raise a corpus of $24 million and till date, $ 21.5 million have been raised. The fund is expected to be saturated and completely functional by 2015. The conventional donors are keen that this fund is made operational early and the country should take responsibility for buying vaccines.

It is planned to keep on building the fund beyond the initial target of $24 million so that in the future the fund will be able to cope up with increasing global costs. The fund is meant for buying all vaccines

and essential medicines in the future. The fund is already committed to co-finance current and planned GAVI new vaccines and will continue to co-finance other new vaccine to come.

7. Analysis of current immunization finances

Costing of baseline as well as projections are undertaken using the c-MYP tool after taking into account the costs of salaries, allowances, campaigns and program goals with proposed new and underused vaccine introductions.

7.1 Baseline cost indicators

Table 9: Baseline financial indicators for 2012

Baseline Indicators	2012
Total Immunization Expenditures	$1,090,080
Routine Immunization only	$1,090,080
per capita	$1.51
per DTP3 child	$82.46
% Vaccines and supplies	28%
% National funding	58%
% Total health expenditures	1.63%
% Gov. health expenditures	1.94%
% GDP	0.07%
Total Shared Costs	$709,521
% Shared health systems cost	39%
TOTAL	**$1,799,601**

The overall costing in 2012 was $1,799,601 of which 39 percentage costs were for shared activities within the government HC system. Since there were no campaigns, the remaining 61 percentage 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 pie chart presented below breaks down the total cost by items: as can be seen the bulk of the expenditure comes from personnel costs (42%), followed by new and underused[2]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. Annualised capital cold chain equipment and vehicle costs are respectively 7% and 2%. Transportation costs account for 6%, while other routine recurrent costs (including training) account for 15%.

[2] 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.

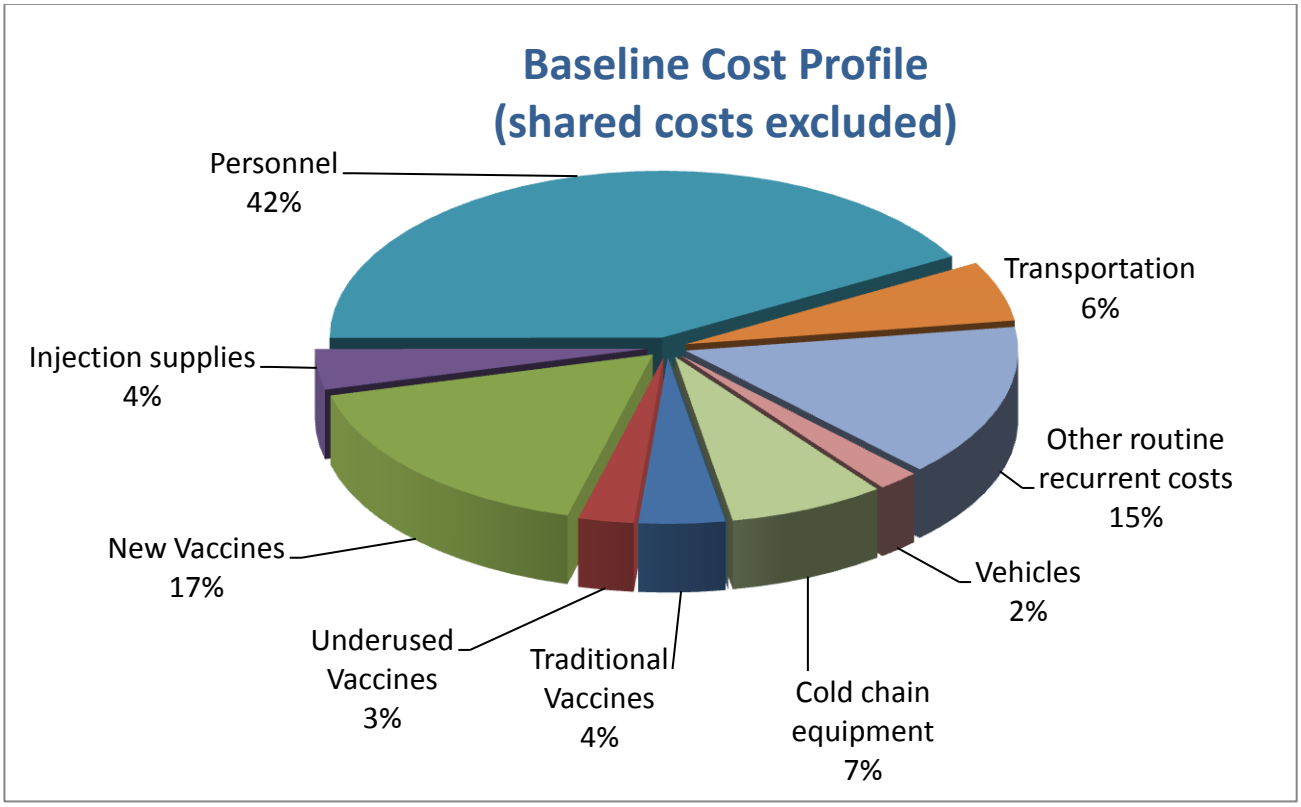


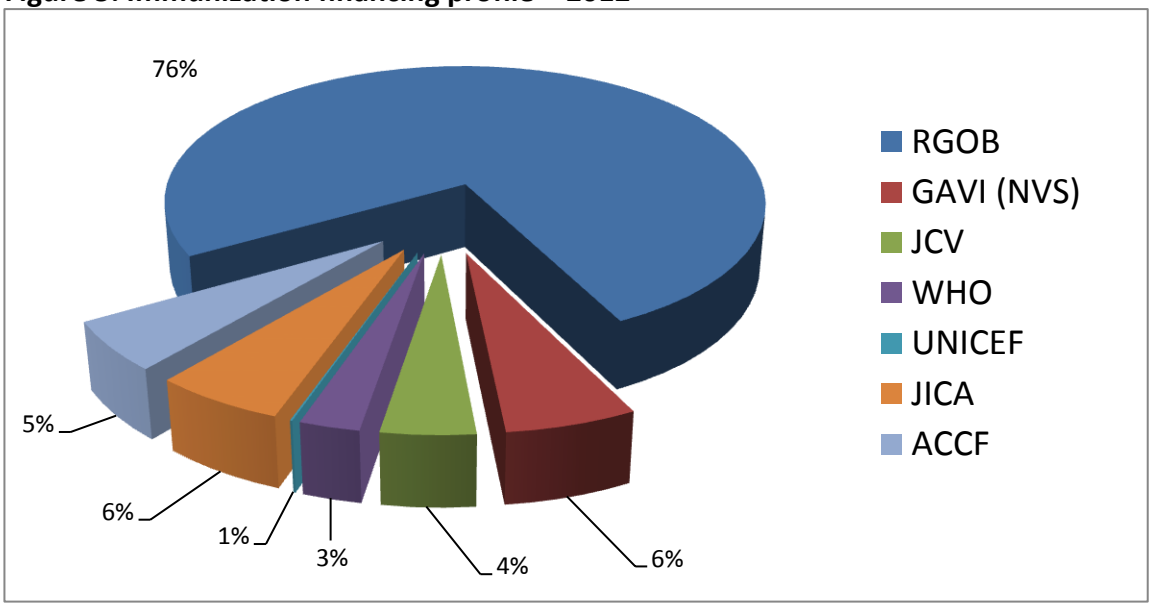
Figure 4: Baseline immunization Cost profile – 2012

When the expenditure is analysed by type of service delivery, fixed delivery accounts for nearly 60% and outreach activities account for nearly 40% (inclusive of shared costs). As can be expected from a low population density country, the outreach costs are significantly higher since more personnel time and transportation costs are required to reach geographically spread out areas.

7.2 Sources of current immunization financing

The pie diagram below indicates the major sources of financing of immunization expenditure in 2012.

Figure 5: Immunization financing profile – 2012



7.3 Partner involvement in EPI financing

WHO and UNICEF are key partners in delivering immunization services (as opposed to vaccine procurement supported by other donors) to the mothers and children of Bhutan. Their support to the EPI program is mainly in the areas of consultancies and short-term human resource development focusing on updating knowledge and skills in vaccine delivery and cold chain management. Vaccines & injection equipment are procured through JCV, GAVI and ACCF support. However, there is no agreement signed between JCV and Ministry of Health specifying the period of support for immunization service. JCV provides support on request through UNICEF, mainly for the procurement of traditional vaccines. Support for cold chain equipment procurement rendered for almost ten years by JICA was terminated in 2012.The following has been the trend of immunization funding in past:

GAVI has awarded funds for the introduction of Pentavalent vaccine (DTP-Hep B-Hib) and corresponding injection safety supplies for 2011 to 2015. This includes roughly $130K annually, of which GAVI pays ever decreasing (by 20% each year) co-payment amount with 2015 being the last year of GAVI support when GAVI will pay 20% of the mentioned amount (i.e. approximately $26K, the balance being shouldered by the Bhutan Health Trust Fund (BHTF). As long-term partners, WHO, UNICEF and JCV are expected to continue to support EPI activities, although the Government is readying itself to the contingency of JCV support termination.

The Government of Bhutan remains the major contributor to immunization with 76% of total expenditure. The other major donor account for: GAVI – 6%,JCV – 7%, WHO – 3%, UNICEF – 1,5%. It may, however, be noted that the Government meets the bulk of personnel costs whereas donors fund other program costs. The government funding is included in shared costs since the staff delivers package of MCH services, including immunization.

8. Future program financing, sources and funding gap analysis

8.1 Future requirements

As discussed earlier, Bhutan intends to introduce PCV and Rotavirus vaccines (in 2016 and 2017 respectively) as well as to switch from OPV to IPV vaccine starting from 2015. All of these endeavours will be financed exclusively from the national financial sources, taking into account the country graduation from the GAVI support programs.

Table 10: Total recurrent (no capital and shared) costs for immunization during 2014 -2018

Year	Total recurrent cost $
Baseline year-2012	984,957
2014	1,164,854
2015	1,274,906
2016	1,555,640
2017	1,857,527
2018	1,849,257

Substantial increases in routine immunization costs throughout the new cMYP period have to do with introduction of new vaccines in 2015-2018: switching from MR to MMR in 2015, switching from OPV to IPV in 2015, introducing PCV in 2016 and Rota in 2017. The projected figures assume substantial reduction in vaccine wastage rates due to transition to smaller (one and two) dose vaccine presentations. The new vaccines – due to their substantial packaging volume - will require additional delivery costs and cold chain storage costs. Also the first year/ introduction year cost is inflated by the inclusion of a 25% buffer stock for each vaccine.

8.2 Future funding sources

The tables below give the details of sources of funding, describe secure and total (secure and probable) funding, and gaps in funding. The Royal Government of Bhutan is committed to the EPI program and will provide secure funds to finance in the future not only personnel costs but also ever increasing share of vaccine procurement – through the Bhutan Health Trust Fund; no gap of funding is expected.

Table 11: Secure funding for 2014 – 2018

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	$54,000	$52,000	0	0	0
UNICEF	0	0	0	0	0
WHO	0	0	0	0	0
JCV (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

Table 12: Probable funding for 2014 – 2018

Probable Funding	2014	2015	2016	2017	2018
Government	0	0	0	0	0
GAVI - Vaccine Fund	$60,000	$65,000	0	0	0
UNICEF	0	0	0	0	0
WHO	0	0	0	0	0
JCV (UNICEF)	$130,000	$135,000	$140,000	$145,000	$150,000
ACCF	$145,000	$150,000	0	0	0
BHTF (Trust fund)	$391,500	$411,075	$431,628	$453,209	$475,869
Total probable funding	$726,500	$761,075	$571,628	$598,209	$625,869

The probable funding from the government from the 11th Five Year Plan is equally distributed over the five years as detailed financial allocations are not worked out yet. It is evident that if these funds are used as and when the need arises over the five years there will not be any funding gap, if the probable funds are realized.

From the analysis it can be concluded that Bhutan can sustain the immunization program continuing with traditional vaccines and introduction of new vaccines. However, external support will be helpful in providing smooth transition from donor-assisted EPI provision to full self-sufficiency – i.e. until such time the Bhutan Health Trust Fund becomes fully functional and self-sufficient.

The main effort would lie in making the probable sources secure in the near future, so that there is no uncertainty of funding, even in the enhanced immunization program with newer vaccines. While negotiating for the next round of funding for existing vaccines, introduction of PCV and Rota makes a strong case due to their expected health benefits. Bhutan Health Trust Fund remains an important source for vaccine procurement. EPI will advocate strongly for the secured commitment from BHTF, with the aim of increasing self-sustainability.

The major source of “probable” funding are JCV. The government is also confident of continued support from WHO and UNICEF in the coming years.

The government of Bhutan expects not only co-financing support from GAVI till the end of 2015, but also its support in securing favourable pricing for the new vaccines that the country plans to introduce during next cMYP cycle. Again, introduction of such vaccines is subject to demonstration of disease burden and vaccine efficiency data.

8.3 Reliability of future funding sources

The Policy and Planning Division (PPD), MOH, will advocate for creation of a budget head for immunization service, and pursue the matter with the MOF commencing from the 2014-2015 fiscal year. It is expected that with next stages of Tala Hydel Project being commissioned, the revenue situation of Bhutan will allow further allocation to EPI and sustaining the new vaccines currently supported by GAVI and other donors.

MOH will also advocate with BHTF for a firm commitment for longer-term support to immunization in keeping with fund's mandate.

JCV's support to the immunization program is currently through UNICEF. In order to improve the reliability of its continued support, the program will seek to make JCV's input much more visible in the government and as well as in the communities at large through available media focus. High level advocacy will be carried out in an effort to garner enhanced JCV support for the immunization program.

8.4 Strategies to attain financial sustainability

The c-MYP identifies 'resource mobilization' as one of the program objectives. The various activities have been described in the plan. In summary the following five strategies will be implemented to achieve this:

1. Assure partners' commitment to already planned support for new vaccines
2. Assure accurate EPI needs projections for2014-2018I
3. Negotiate with JCV for another cycle of financial support for traditional vaccines
4. Make BHTF operational to finance traditional vaccines as well as to co-finance new vaccines, after country graduation from donor support
5. Achieve cost minimisation through participation in GAVI-advocated vaccine-pricing initiatives for graduating and middle-income countries
6. Advocate for more government resources for immunization in the future.

Table 16: Planned activities to implement the strategies

Strategy	Activities
Continued GAVI funding for new vaccines	Apply for Pentavalent vaccine support during January 2013 – 2015 Start on surveillance activities to decide on Pneumococcal and rotavirus disease burden.
JCV funding for traditional vaccines	Negotiate and agree with JCV on support for traditional vaccines
BHTF	Plan of action developed by end 2013, starting with agreed sharing of costs for traditional vaccines with JCV. Co-financing for new vaccines to be paid from BHTF
Reduction in vaccine wastage and improved supervision to	Introduction of new vaccines in single dose presentations.

enhance program efficiency	Monitoring of vaccine wastage for Pentavalent and other new vaccine by 6 EPI technicians every month Regular program reviews at district and regional levels Supportive supervision for all health units
Advocacy with new c-MYP	Identify resource gaps and mobilize full funding from Government, BHTF and GAVI

Although this analysis is suggestive of some risk to the financing of immunization services, part of the risk is simply due to the long length of the forward time commitment covered by the analysis. However, it is an accepted fact that fixed costs like personnel, which constitute more than 50% of the total immunization costs, will continue to be entirely supported by the government. It is also rational not to entirely pre-commit the health budget in this way as it allows for some flexibility in being able to divert health funding to emerging crises such as newer disease threats. As such there is no threat of basic funding to immunization services in Bhutan.