National Immunization Policy and Strategic Guidelines

Vaccine Preventable Disease Program
Department of Public Health
Ministry of Health
2011

Contents

List of tables and figures

FOREWORD

Vaccination was first introduced in Bhutan during the global drive to eradicate small box. In 1976, DPT, OPV and BCG vaccines were introduced in few districts. The Expanded Programme on Immunization (EPI) was launched in 1979 and the national Plan of action for the acceleration of EPI made in 1987. In February, 1988, the 66th National Assembly passed a resolution calling from all children and pregnant mothers to have access to immunization services and to be fully vaccinated. The health system responded effectively and achieved Universal Child Immunization (UCI) in 1991.

The "Zero" polio status is being maintained since 1986. Since 1994, only one case of Neonatal tetanus was reported in 2006. The nationwide MR Vaccination campaign was conducted in 2006 with 98% coverage. Similarly, nationwide HPV vaccination campaign was conducted in 2010 for 12-18years girls with 98% coverage and its incorporation into the routine immunization schedule from 2011. These results indicate that immunization programme has been a very successful public health intervention. These successes place Bhutan firmly on the track toward the global goals of vaccine preventable diseases prevention, control, elimination and eradication. As we reach closer to these goals, it has become critical to align our strategies and policies to focus on improving quality immunization services and standards.

Encouraged by the success of the programme, the availability of newer vaccines and newer combinations and also safer vaccination technologies, government has taken a decision to add newer vaccines into the child immunization schedule and to adopt safer techniques. This requires an understanding of agreed policy and operational norms among service providers and beneficiaries. An agreed policy will help to consolidate the gains to take up emerging challenges, to give strategic directions to the programme and to maintain high quality of services. The need to have such a policy was articulated very strongly in the last EPI programme review.

This edition of the "National Immunization Policy and Strategic guidelines" incorporated the changes in policy and strategies of immunization services in Bhutan since the introduction of 1st edition in 2004. I am confident that this document will go a long way in helping policy makers, planners, supervisors, implementers and beneficiaries of immunization services in the kingdom of Bhutan.

Tashi Delek

(Dr. Gado Tshering)
SECRETARY
Ministry of Health

ACKNOWLEDGEMENT

The Department of Public Health, Ministry of Health, Royal Government of Bhutan would like to acknowledge UNICEF for the financial and technical support in developing this document. The Department of Public Health also would like to acknowledge the valuable comments and inputs from members of National Committee for Immunization Practice (NCIP) and WHO experts.

Department of Public Health would like to thank Dr. Dhrupthob Sonam, Medical Superintendent, JDWNRH, Dr. H.P. Chhetri, Paediatrician, RBA Hospital, Lungtenphu, Dr. K.C. Buragohain, Sr. Medical Officer, Chukha BHU and all other officials and individuals who have extended their assistance and support in developing this document.

1. BHUTAN EPI POLICY

1.1 Introduction

With the launch of the First Five Year Plan in 1961, a modern health care delivery infrastructure has been gradually expanded throughout Bhutan. Bhutan signed the Alma Ata Declaration in 1978 and adopted primary health care (PHC) approach to health delivery in 1979. Currently, the health care is provided free of cost to all the people in the country through a network of 30 hospitals, 181 Basic Health Units (BHUs) and 518 outreach clinics (ORCs) spread throughout the country. The consistent and systematic expansion of the health services with a focus on primary health care, education and safe water supply has had major impact on the overall health and wellbeing of the people.

The first National Immunisation Policy and Strategic Guidelines were formulated in the year 2004 for terms of planning, new vaccine introduction, surveillance and immunization safety. Recent EPI programme review and EPI survey[1] has also indicated the need for emphasis on the quality of immunization services in addition to the focus in maintaining high levels of coverage. This policy reflects recent programmatic changes and seeks to streamline existing protocols and guidelines based on local needs and feasibility. The policy aligns itself with global policy recommendations such as GIVS, the current 5-year plan, C-MYP, earlier EPI policies and recommendations of previous program reviews. The document also provides strategic guidelines on program components such as increasing immunization coverage, injection safety, vaccine standards and specifications, and Adverse Events Following Immunization (AEFIs). In addition, strengthening of cold chain system, vaccine management, supervisory skills & advocacy and social mobilization are also incorporated. This document is expected to guide the programme in the provision of an effective and sustainable immunization service in the country.

1.2 Goal

Reduce Morbidity, disability and Mortality related to VPDs to a level where they cease to become a Public Health hazard.

1.3 Guiding Principles

1.2.1 Universal reach: Achieve 100% immunisation coverage of all Target Population.

1.2.2 Equity: Provide all target population in Bhutan Complete Immunisation irrespective of residency or nationality.

1.2.3 Quality & Safety: Follow" first do no harm" principle comply with global and local safety practices.

1.2.4 Sustainability: Achieve Self Financing and move away from donor dependency.

1.2.5 Management Excellence: Follow result based principles and evidence based practices.

1.4 National Immunization Policy Statement

1.4.1 Universal reach/Access

- All children living in Bhutan shall be fully immunized in line with the approved national Immunization schedule.
- Royal Government shall maintain above 90% immunization coverage at all times

1.4.2 Schedule policy and contra-indication

- Immunization Schedule shall be updated periodically based on major programmatic shift recommended by global and local research, introduction of new vaccine or when new epidemiological pattern emerges.
- The immunization schedule for children living with HIV/AIDS including immune compromised children is in accordance with current immunization schedule.
- Children with symptom of AIDS will be given routine immunization except BCG.
- The mother and child health (MCH) hand book, as proof of full immunization, shall be essential for all school admission at the primary level.
- All women during their pregnancy shall be immunized with tetanus toxoid in line with national immunization schedule.

1.4.3 Vaccine quality & safety

- All vaccines that are procured for the immunization services in the country shall be Pre qualified by WHO and registered with the Drug Regulatory Authority and have valid market Authorization, Product Registration.
- All health staff shall monitor, report, investigate and manage Adverse Events Following Immunization (AEFI) appropriately.
- Adverse Events Following Immunization (AEFI) shall be communicated to the parents and general public after proper investigation.

1.4.4 Introduction of New vaccines

- Introduction of new and underutilized vaccines shall be done upon the recommendation of the National Committee on Immunization Practice (NCIP) and regulatory approval of the Drug Regulatory Authority (DRA).
- General public shall be informed prior to the introduction of new vaccines.

1.4.5 Pandemic and Epidemic vaccination

- Vaccination shall be provided for the cohort population/high risk population as collaborative global and regional effort to control and prevent epidemic or pandemic.

1.4.6 Cold Chain and vaccine management

- All cold chain equipments shall be Chloro-Fluoro-Carbon (CFC) free Cold chain equipments for vaccine storage/transport shall be used only for vaccines at all levels of health system.
- All the vaccines which are imported must be accompanied by cold chain monitoring devices.

1.4.7 Vaccine Wastage

- As policy, practice of one child one vial shall be followed; however every health workers shall put in place all efforts to reduce wastage of vaccines with proper scheduling of immunization time and day.
- Multi-dose vials of OPV, Td, DTP+Hepatitis B vaccine shall be used in subsequent Immunization session for up to maximum of 28 days in static clinics.
- Reconstituted vaccine shall be used within 6 hours of opening/reconstitution.

1.4.8 Suspension/ withdrawal of vaccines from use

- Vaccines shall be suspended or withdrawn from use by Drug Regulatory Authority (DRA) based on the technical recommendation of the National Committee on Immunization Practice (NCIP) or World Health Organization (WHO).

1.4.9 Replacement Policy

- All cold chain equipments shall be replaced after ten *years,* however if the equipments is optimally functioning properly after completing 10

years, the health facility shall be advised to continue using it after proper technical evaluation.

1.4.10 Safety of Injection

- All the immunization must be safe. Every injection must be given with auto-disable syringes, which is then safely disposed after use as per existing guideline.

1.4.11 Vaccine Preventable Disease (VPDs) Surveillance

- Bhutan shall commit to the achievements and maintenance of global & regional control, elimination and eradication targets
- VPD-Surveillance shall be strengthened at all level.

1.4.12 Program Supervision, monitoring and evaluation

- The program shall be reviewed and evaluated once during each of the FYP period
- The immunization coverage, AEFI incidences and dropout rates shall be amongst the indicators to monitor the performance of the immunization services in all health facilities
- The cold chain and vaccine management shall be assessed regularly to ensure the safety and efficacy of the vaccines and shall be in compliance with the regulatory requirements of the DRA.

1.4.13 Research in Immunization

- Disease burden studies shall be mandatory for introduction of any vaccines.
- Operational research shall be utilized for informed decision-making relating to immunization services.

1.4.14 Sustainability

- The RGoB shall finance the cost of procuring all traditional vaccines (BCG, OPV, DT, TT, MR) and new vaccines being introduced in the national immunization schedule
- Ministry of Health shall play a key role in advocacy, social mobilization and program communication for immunization.

1.4.15 Partnership in immunization

- UN agencies, bilateral, multi-sectoral Agencies and relevant stakeholders shall play a vital role in ensuring and sustaining universal coverage

2. BHUTAN NATIONAL IMMUNIZATION STRATEGIC GUIDELINE

The Department of Public Health, Ministry of Health has come up with the following strategic guideline to make effective use of the National Immunization Policy. This guideline shall be revised as and when deemed necessary.

2.1 Immunization schedule, dosage and route of administration

- The immunization schedule, dosage and route of administration shall be updated by the Vaccines Preventable Disease Program, NCIP in coordination with DRA periodically based on;
  - WHO vaccine position paper or local research,
  - New epidemiological patterns and disease burden
  - Introduction of new vaccines
  - Market Authorization/ Registration

- HIV Infected children: The vaccine will be administered to HIV positive children and children born from HIV positive mothers according to the standard national immunization schedule. However, Measles vaccine will be administered in three doses (at 6 months, 9 months and 24 months to HIV positive children.
- The Programme shall specify contraindications to immunization, particularly for immune-compromised children (including children living with AIDS) as well as ensure that special needs of immune-compromised children (including children living with AIDS) are addressed as the new vaccines are introduced into the national immunization schedule.

2.2 Contraindications for vaccinations

All infants shall be immunized except in these five rare situations:

i. Anaphylaxis or a severe hypersensitivity reaction to previous doses of a vaccine.
ii. Persons with a known allergy to a vaccine component.
iii. BCG vaccine to an infant who exhibits the signs and symptoms of AIDS.
iv. Subsequent dose of DTP following convulsion after the previous dose.
v. A sick infant whose parents refuse for the immunization. The parents shall be instructed to come back when the infant gets well.

Table 1: Recommended Routine Immunization

Antigen	No. of dose	Children/ Age	Adolescents	Adults	Considerations
BCG- OPV0	**1 each**	**At birth**			
Hepatitis B (monovalent)	**1**	**At birth (within 24 hours)**			
OPV	**3**	**6 wks, 10 wks, 14 wks**			
DPT-HepB– Hib	**3**	**6 wks, 10 wks, 14 wks**			
***MR 1st dose**	**1**	**9 months**			
MR 2nd dose	**1**	**24 months**			
DTP	**1**	**24 months**			
Td	**1**	**6 years**			
Td	**5**			**One dose at 1st pregnancy**	
Td	**1**		**12 yrs**		
HPV	**3**	**0, 2 and 6 months (12 yrs girls only)**			
Vitamin A	**10**	**1 dose every 6 months beginning 6 months of age up to the age of 5 years**			**100,000 IU in age 6-11 months AND 200,000 IU after the age of 1year**
Hepatitis B (monovalent)	**3**	**0, 1 and 2 months**			**High Risk and Health Worker**

*Source: Bhutan Immunization schedule + recommendations from the * WHO Position papers (MR 1st dose at 12 ms, DT & MR 2nd dose at 5 yrs, NB: If Tetanus immunization in infancy and adolescent is not documented, 2 doses in 1st pregnancy and 1 dose in subsequent pregnancies for total of 5 doses*

- *Hepatitis B booster dose is not recommended* Note: Serious non fatal AEFIs with combination vaccine shall be continued with Td and Monovalent Hepatitis B

Table 2: Td Vaccination Schedule for Adult including pregnant women (with out documentation of Childhood Immunization) VPD Program

Vaccine	Schedule	Dosage	Route/site
Td1	1st contact or as early as possible in pregnancy	0.5 ml	Intramuscular
Td2	At least after 4 weeks of Td1	0.5 Ml	Intramuscular
Td3	6 months after 2nd dose or one dose in subsequent pregnancy	0.5 ML	Intramuscular
Td4	1 year after 3rd dose or one dose in subsequent pregnancy	0.5 ML	Intramuscular
Td5	1year after 4th dose or one	0.5 ML	Intramuscular

	dose in subsequent pregnancy		

Table 3: Td Vaccination Schedule for Adult including pregnant women with documentation of Childhood Immunization

No.	Category	No. of doses required	Schedule
1	With documentary evidence of primary series	3 doses	2 dose at least 1 month apart 3rd dose during next pregnancy
2	With documentary evidence of 3rd dose DTP booster at 6 years and 12 years of TT/ Td vaccination	2 doses	1 dose on 1st contact 2nd dose after 6 months or during next pregnancy
3	With documentary evidence of primary series, booster dose at 6 years and TT/Td vaccination at 12 years	1 dose	1 dose on 1st contact or 1st pregnancy

2.2.1 Eligible Target Groups

- The target group is defined as Infants (0-12 months), children (12-24 months), adolescent (12 years), Pre-school children (6 years) and women of child bearing age.

  The programme shall ensure that vaccines and immunization services are provided according to the national immunization schedule free to all eligible populations[2] living in Bhutan, irrespective of their residency or nationality status.

- The immunization status of every child shall be checked at all level of health system at each contact (including hospital outpatient departments) and immunized if needed.

- *Other at-risk groups especially in out-break situations and those travelling to endemic areas.*
- *International travellers*

No eligible person shall be denied immunization unless there are medical contraindications as stated in the standard of practice.

- Children who have never been vaccinated and brought to a health centre at a later age shall be vaccinated according to the EPI manual for Health workers

2.3 Expansion of vaccination beyond the eligible target group

With the objective of providing long immunity against tetanus to all primary school graduates, sustaining of MNT elimination, the school-based immunization strategy shall be used to target at the age of 12 years with Td.

2.4 Determination of denominators and the size of the target population

- The building block of planning for routine immunization is the district micro-plans, which is compiled at BHUs and further completed at the district level. One of the components of district or BHU micro-plan is estimation of target population where health worker shall regularly conduct head counts in their BHU catchment area and then estimate the annual target for infants (0-12 months), children (13 – 24 months), pre-school children (4-7 years), adolescents (12-15 years) and pregnant women.

- DHOs shall be trained to use the Data Quality Self-assessment (DQS) tool to assess the denominator, especially in districts that are poorly performing or having problem of over-reporting or under-reporting.

- The combination of approaches may be used to reach eligible target groups.

2.5 Reaching the un-reached people in every district at least 4 times a year

- Reaching Every District (RED) strategy shall be implemented in every district to reach all children & pregnant women particularly the population living in areas that are geographically difficult to reach, remote areas without access to health facilities and migrants. All districts and BHUs shall develop micro-plans using a national standardized format and shall draw maps for their catchment areas indicating locations with hard to reach population. RED approach shall be used to ensure that all children under five are reached and defaulters are followed-up and vaccinated.

- The managerial and supervisory skills of the DHOs shall be strengthened by training, specifically on supportive supervision and regular district quarterly review meetings.

2.6 Quality Assurance of Immunization Programme

2.6.1 Cold Chain and logistics

- Every health centres providing immunization services shall be equipped with refrigerators
- Local Power Authority shall be sensitized on the importance of cold chain management and provision of un-interrupted power supplies

- All vaccines cold stores and health centres shall have Standard Operating Procedures (SOPs) for storage and distribution of vaccines.
- The cold store and health centres shall have adequate storage space when new vaccines are being introduced and bundle distribution system shall be practiced.
- All cold chain equipments declared unfit for use by inventory shall be surrendered to the Ministry of Finance (MOF) and replaced by new ones. The programme shall be informed accordingly.
- During the interim period of cold chain break down, a health centre shall utilize cold chain facilities of the nearest health centre.
- In case of non-functional cold chain equipment declared, interim measures as per the current EPI manual for Health workers shall be implemented.
- The list of all hospitals & BHUs without functioning refrigerators/ freezers because of damage or being old (costly to repair) shall be made available to the programme, DHOs and EPI Technicians (for identifying an interim solution) until the equipments are being replaced by new one.
- National health staff shall use VVM present on the vaccine vial or container to help select or discard vaccines. Vaccine with a VVM indicating excessive heat exposure shall be discarded. The quantities of vaccine discarded shall be noted on the stock inventory form and the reasons for discarding shall be noted. This information shall be reported to the DHO, Regional Cold Store and the Programme and wastage rates by cause shall be reported quarterly from the districts.
- Open multi-dose vials of liquid vaccines shall be used in the next immunization session in fixed clinics only, if all the conditions as outlined in the EPI manual are met.The logistics of immunization will require adequate and well-functioning transportation and communication systems, for optimal use of resources and shall be useful to move towards coordinated and sector-wide financing and management for transportation and communication.
- Regular training on Cold chain management shall be conducted to update the knowledge of EPI Technicians on installation, repair, and maintenance,
- The relevant DVED staff and EPI Technicians shall be updated regularly on the pre-shipment and arrival procedures.
- Health Workers shall be updated regularly on cold chain maintenance and handling
- National/Dzongkhag Health Officers and decision-makers shall be trained to use the EVM Self-assessment guidelines to assess the performance of the EPI Central and Regional Vaccine Stores periodically.

2.6.2 *Vaccine quality & safety*

- All vaccines used in the country shall be registered with Drug Regulatory Authority (DRA). The programme shall as far as possible procure vaccines and devices to maintain cold chain which are WHO/UN pre-qualified.

- All vaccines shall be subjected to LOT release procedure by DRA at the time of arrival

- The programme shall strengthen the capacity for effective vaccine management through training, supervision and the development of information systems in order to ensure the safety and potency of vaccines.

- The use of cold chain monitors such as Vaccine Vial Monitors (VVM), multi dose vial policy and proper quantification in immunization micro planning shall be improved in all health facilities to reduce the vaccines wastage. The Ministry of Health shall explore the possibility of procuring single dose vial for traditional and new vaccines. Periodic cost analysis studies shall be done to effectively reduce wastage cost by determining the vial size.

2.6.3 *Injection safety & safe disposal of immunization wastes*

- The programme shall sustain and monitor safe injection practices including the use of auto-disable syringes and other safe methods of vaccine administration according to the EPI manual for Health Workers.

- The principle of Bundling[3] shall be applied *so* that vaccines and safe-injection equipment (diluents, auto-disable (AD) syringes, mixing syringes and safety boxes) are always available together in corresponding quantities at each level of the supply chain.

- Waste generated out of immunization shall be discarded in the safety box provided for the purpose. Safety boxes & immunization waste generated from the outreach session shall be brought back to the BHUs or hospital and disposed as per the guideline specified in the current “Infection Control and Health Care Waste Management in Health Facilities”.

- Pre-service and periodic in-service training shall be provided to health workers and medical officers in the practice of injection safety and safe

[3] WHO-UNICEF-UNFPA joint statement* on the use of auto-disable syringes in immunization, WHO/V&B/99.25

disposal of immunization waste. Health workers shall be trained to inform their clients of the need for injection safety and the consequences of unsafe injections.

- Appropriate easy-to-understand pictorial job aids and other training materials such as booklets and films on injection safety practices and safe disposal of immunization waste shall be developed.

2.7 Adverse Events Following Immunization (AEFIs)

- The existing AEFI management shall be strengthened for case based surveillance and investigation for AEFI using standard protocols. All immunization staff shall monitor AEFI and report in the forms prescribed for it including zero reporting.
- The Ministry of Health shall ensure that the national AEFI Committee is functional and actively involved in investigating serious adverse events and recommend measures for management.
- The Ministry of health shall liaise with the media to inform the general public in case of reports that are of concern to the program and the general public.
- The programme shall convene meetings of AEFI committees whenever the serious AEFI cases are reported
- The AEFI committee shall review and revise current reporting and investigation formats, particularly in light of new vaccines introduced.
- All AEFI cases shall be managed by the health workers as per the guidelines specified in the current EPI manual for health workers.
- AEFIs cases shall be investigated using standard protocols to increase public confidence in immunization. Testing laboratories at PHL and regional referral hospital laboratories shall be strengthened with necessary trained human resources.
- AEFI reports shall be sent to the National Pharmaco-vigilance centre (DRA) for regulatory actions.
- Regular training shall be conducted to update the health workers on definition of AEFI, types, frequency of minor reaction & rare and serous AEFIs.
- All heath staff shall be trained on AEFI identification, reporting, investigating and management.
- With introduction of new vaccines, all relevant health workers at all level shall be trained on updated AEFI guideline.

2.8 Integrate and Strengthen Vaccine Preventable Diseases Surveillance and Outbreak Response

- Existing VPDs surveillance guidelines and manuals shall be updated periodically particularly in light of new vaccines introduction.

- Update surveillance protocols to include distinctions between clinically diagnosed disease and laboratory confirmed diagnosis.
- All existing and new vaccines preventable diseases targeted by the immunization schedule shall be included in the list of notifiable diseases.
- Clear guidelines outlining the functions of the PHL and regional referral laboratories and the relationships between them in VPDs surveillance shall be framed.
- Regular trainings for health workers shall be conducted on VPDs surveillance and outbreaks investigation.
- Laboratory staff shall be trained and updated on testing techniques for VPDs.
- Routine and active surveillance, investigation and outbreak response shall be conducted according to the surveillance field guide
- Zero reporting shall be undertaken from all health facilities for AFP, suspect maternal and neonatal tetanus (MNT), measles, rubella, CRS and other VPDs on a monthly basis using prescribed reporting forms.
- Community surveillance of VPDs shall be encouraged through training and awareness of Village Health Workers, relevant local government bodies and NGOs.
- Strengthen coordination between VPDP, DHO/MO and BHMIS for:

  -Verification and cross-checking of VPDs reports published by BHMIS
  -Automatic receipt of monthly VPDs surveillance reports from BHMIS
  -Easily accessible web reports for all levels of the program.
- The epidemiology unit shall be strengthened with adequate human and other resources to undertake VPDs surveillance.
- The testing laboratories at the regional referral hospital laboratories and PHL shall be strengthened with necessary trained human resources and testing kits (including virology tests) for all VPDs.
- The PHL shall be involved in the surveillance for AFP.
- Reporting of VPDs shall be included as a benchmark in supportive supervision checklists
- Assessment of VPDs surveillance and outbreak response shall be included in periodic programmatic reviews to identify gaps and solutions.

2.9 Accelerated Disease Control; Elimination and Eradication

Achieve and maintain global and regional VPDs control, collaborate and participate in the global and regional programme on elimination and eradication of targeted vaccine preventable diseases.

2.9.1 *Polio Eradication*

Progress toward certification shall be documented by the National Certification Committee for Polio Eradication (NCCPE).

- To meet certification standards, an Acute Flaccid Paralysis (AFP) surveillance

system is a must each year to:-

- Detect at least two non-polio AFP case per 100,000 persons aged <15 years,
- Collect two adequate stool specimens from ≥80% of persons with AFP, and
- Test all stool specimens for poliovirus at a WHO-accredited laboratory.

- The VPDP shall regularly update the NCCPE by providing AFP surveillance data to assess and verify data critically. MoH shall seek from WHO technical guidance regarding OPV cessation and future options to maintain population immunity against polio including the possibility of IPV use and its cost implications for national programmes. The Global Certification Commission (GCC) will declare the world free of WPV transmission when no WPVs have been found by certification-standard surveillance for 3 consecutive years and all laboratories with WPV-containing materials have adopted appropriate containment measures
- Conduct regular training for health workers to update their knowledge on AFP surveillance, standard case definition, surveillance procedure, case investigation & outbreak response, stool sample collection and AFP surveillance indicators.
- All cases of AFP must be investigated within 48 hours and reported to the next higher centre
- AFP surveillance officers designated by the DoPH will carry out the surveillance activity on monthly and quarterly basis.
- Reports from the surveillance officers must be submitted to the VPD program not later than the following month after every quarter
- All hospitals and BHUs shall conduct routine and active surveillance investigation and outbreak response according to the field guide for AFP surveillance.
- All health centers shall submit a monthly integrated report for AFP, Measles, Rubella, MNT, CRS (including “zero” report) to the DHO. DHO will then send the report to the program according to the latest Surveillance guideline.

2.9.2 Measles and Rubella Elimination

- The field guide for measles & rubella surveillance shall be updated based on the new development on the global and regional measles and rubella strategic plans, surveillance and outbreak response guidelines. These guidelines should be made available to all the health centers.
- Regular training for health workers on measles & rubella surveillance shall be conducted to update their knowledge on case definition/classification, measles & rubella surveillance procedures, case investigation and outbreak response and surveillance indicators.

- District staff shall be trained on identifying and preventing measles and rubella. Health workers shall be trained on the measles & rubella case managements during outbreaks
- Measles & rubella case-based surveillance shall be conducted for any suspected case of measles & rubella and shall be reported immediately.
- All hospitals and BHUs shall conduct routine and active surveillance, investigation and outbreak response according to the field guide for measles surveillance.
- All health centers shall submit a monthly integrated report for AFP, Measles, Rubella, MNT, CRS (including "zero" report) to the DHO. DHO will then send the report to the program according to the latest Surveillance guideline.
- Acute Rash-Fever surveillance shall be extended to the community.
- Clinicians and others involved on measles surveillance shall be monitored for regular reporting by providing feedback and assurance that data are being analysed and used.
- An operational definition for measles elimination in Bhutan shall be developed. The initial indicators for measles elimination shall be:

  a) achieved low incidence
  b) quality surveillance
  c) high two dose vaccine coverage
  d) outbreaks following importation of the measles virus are self-limiting and Contained
  e) absence of an endemic genotype
  f) high population immunity

- All suspected measles & rubella cases shall be investigated using standard protocols to strengthen the immunization system.
- Testing laboratories at the regional referral hospital laboratories shall be provided with necessary trained human resources and testing kits to test measles.
- Guidelines on management of uncomplicated and complicated cases of measles & rubella shall be in place at all level of Health Facility.
- Reporting of suspected measles cases (timeliness of the case investigation, completeness of the case investigation form, cases with adequate specimen, timeliness of lab result & district monthly reporting) – shall be included as a benchmark in supportive supervision checklists. Assessment of measles surveillance and outbreak response shall be included in quarterly district review meetings to identify gaps and propose solutions.

2.9.3 Congenital Rubella Syndrome (CRS) Prevention

- The field guide for rubella and congenital rubella syndrome (CRS)

surveillance shall be updated periodically

- Regular trainings shall be conducted to update the health workers on CRS case definition (suspected, clinically or laboratory confirmed CRS cases and Congenital Rubella Infection)
- In the CRS prevention stage, the disease surveillance shall be focused on detecting cases of CRS[4].
- If Rubella outbreaks are detected as a part of measles outbreak investigations the program shall follow up outcomes of pregnancies during the period of the outbreak to determine the magnitude of CRS in the affected areas to determine the program response.
- All hospitals and BHUs shall conduct routine and active surveillance, investigation and outbreak response according to the field guide for measles and rubella surveillance.
- All health centers shall submit a monthly integrated report for AFP, Measles, Rubella, MNT, CRS (including "zero" report).
- Infants with CRS are likely to be seen at specialty facilities that do not normally participate in the immunization service or the routine communicable disease surveillance system, e.g. ophthalmology, ENT & cardiac units
- All suspected CRS cases shall be investigated using the national standard protocols to strengthen the immunization system
- Reporting of CRS cases – shall be included as a benchmark in supportive supervision checklists & during district quarterly review meetings.

2.9.4 *Maternal and Neonatal Tetanus Elimination (MNTE)*

Maintaining elimination status shall require further strengthening of the Routine Immunization activities for Pregnant Women and children, NNT surveillance, implementing a school-based immunization strategy, and increasing access to clean delivery practices.

- A childhood tetanus[5] immunization schedule of 5 doses is recommended. The primary series of 3 doses of DTP shall be given in infancy (age <1 year), a booster dose of DT shall be given at the age of 6 years and another booster dose of TT in adolescence, at the age of 12 years.

- In addition to the childhood vaccination programme, an extra TT dose to adults (e.g. first pregnancy) shall provide additional assurance of long-lasting, possibly lifelong protection. Therefore, a sixth dose shall be recommended for adults, e.g. at the time of the first pregnancy. To improve the coverage of TT in pregnant women the program shall develop IEC material to increase awareness in the general population.

[4] SEARO Measles Rubella Surveillance Guide, Final Draft, August 2008

[5] WHO Position Paper for Tetanus

- A high percentage of children, including girls, attend school in Bhutan, a school-based immunization programmes shall be used to deliver the booster doses. A different strategy shall be developed to reach non school attendees.

- Bhutan shall sustain its MNT elimination status; by continuing to rely on immunization in pregnancy. Bhutan has a clean delivery rate of only around 50%, so TT immunization shall be the main way to prevent MNT

- Regular training shall be conducted to update the knowledge of the health workers on the MNT surveillance (clinical case definition, case classification), case investigation and response & surveillance indicators. The VPDP shall collaborate with the MCH unit to ensure and promote institutional delivery to achieve the goal of MNT elimination.

- A case-based surveillance shall be conducted for any suspected case of MNT using the standard protocol and shall be reported immediately.

- All hospitals and BHUs shall conduct routine and active surveillance and investigation according to the field guide for MNT surveillance. All hospital shall review medical records annually (audit), for unreported MNT cases.

- All health centers shall submit a monthly integrated report for AFP, Measles, Rubella, MNT, CRS (including “zero” report).
- NNT is a silent killer – most of the time families do not report a death of a baby few days old, therefore, health workers shall be trained to conduct verbal autopsy (neonatal death reporting) by visiting household in remote communities during ORCs to ask for babies died recently within one month of age with NNT signs & symptoms.

- WHO and UNICEF also recommend community-based surveillance, where feasible, in which the BHU staff identify at least one person in every village to report suspected NT cases to a health worker.

2.10 Introducing New Vaccines and Technologies

- To include newer vaccines in the national immunization schedule, if indicated by disease burden and sustainability, Local decision-makers (VPDP, NCIP, DRA, MoF) shall assess local disease burden, consult WHO position paper, regional technical position, and SAGE recommendations before deciding on NUV Introduction.
- Financial payment mechanism shall be planned in coordination with the MOF when introducing vaccine with donor support**.**
- Long term and sustained financial cost shall be committed and made available by the RGoB/BHTF and supporting partners prior to the introduction of new vaccines. All stakeholders involved in the immunization shall be supported with adequate resources for acquiring knowledge, expertise and training on the new vaccines that has been planned for introduction.

- To Ensure effective and sustainable introduction of new vaccines and technologies;
  - New vaccines shall be integrated in the country cMYP with costing
  - workers shall be trained, required logistic shall be prepared and the Health reporting system shall be updated
  - Appropriate IEC materials developed to inform and educate the public about the benefit of the new vaccines.
  - High coverage shall be achieved within five-years of the NVI as other vaccines given at the same time.
  - Surveillance of diseases that can be prevented by new vaccines, shall be included/expanded and the PHL capacity shall be strengthen to monitor the impact of these new vaccines on disease patterns and program operations
- Clear guidelines shall be developed for conditions during which mono-valent vaccines[6]may be administered.

2.11 Build technical capacities and resource to effectively deliver immunization services

- The MOH shall ensure availability of trained EPI managers at all times, for smooth functioning of the program.
- Immunization-related roles and responsibilities of program managers and staff at all levels (VPDP staff at national levels, MO, DHO, EPI Technicians, BHU staff) shall be clearly defined
- Training need assessment shall be conducted and long term training plan shall be developed for all categories of staff involved in VPDP based on their immunization-related roles and responsibilities
- Immunization materials and methods shall be reviewed and updated periodically to reflect programmatic and technological changes in VPDP, and adapt global and regional technical guidelines and materials. Evidence-based decision-making and management skills shall be included as part of the training curriculum.
- The Royal Institute of Health Sciences (RIHS) shall be strengthened to work as the nodal institute for conducting immunization training. Immunization training curriculum shall be updated in the pre-service training at the RIHS accordingly.
- A pool of dedicated immunization trainers shall be identified at all levels of the health system and capacities of these trainers shall be built in training delivery methods and immunization technical content.
- The technical capacity of the NCIP to guide the VPDP shall be strengthened through appropriate training and attachment.
- A critical essential mass of trained mid-level managers (MO/DHO), technicians[7] and health workers shall be developed through pre-service and

[6] e.g. Hepatitis B, Tetanus and Rubella

[7] in cold chain installation, repair and maintenance and vaccine management.

periodic in-service competency-based training on immunization.

- Skills and knowledge acquired shall be re-enforced with post-training supervisory support

2.12 Management and Review

- Assessment of health worker's knowledge and skills shall be included as a benchmark in supportive supervision checklists.
- Assessment of training progress, skills and knowledge gaps shall be included in periodic programmatic reviews.
- EPI Manager shall have a basic training in Vaccinology.
- The MOH shall ensure availability of pool of national resource persons on assessment and evaluation of the program.

2.13 Program Supervision; Monitoring and Evaluation

- EPI program shall have updated supportive supervisory checklists covering all aspects of the program.
- All Health centres shall have Standardized coverage monitoring charts which shall be updated and analysed to take corrective actions.
- Time-bound plans for monitoring and supervision shall be prepared, using standard checklists with clearly outlined periodicity and sites. Time, budget and human resources shall be allocated to carry out supervision activities.(see Table 4a,4b and 4c)
-

Table 4(a): National level EPI Implementation monitoring

Programme area	Key actions	Monitoring Indicator	Monitoring frequency
Planning & coordination	Develop multi-year plans, including safety plan	MYPOA	Every 5years
	Develop annual plans	Annual action Plan	Annually
	Quarterly ICC meeting	Minutes of ICC meeting	Annually
	Annual EPI review	EPI in agenda of annual health conference	Annually
Assessment	Periodic programme review	EPI review report	3-5 years
	Periodic coverage evaluation	Cluster evaluation survey report	3-5-years
	Periodic cold chain	Cold Chain evaluation report	3-5 years

	assessment		
	Annual evaluation of EPI performance by district	EPI performance report in annual health bulletin	Annually
	Quality of routine data	Data quality assessment report	Every 5 years
Resources mobilisation and financing	Financial sustainability	Financial sustainability plan	Every 5 years
		Gap between total costs estimated in the MYPOA and the expected national expenditure	Every 5 years
		Multi-year financial plan agreed to by the ICC showing the funding need and the source of funding	Every 5years
	Increasing RGoB funding	Percentage of estimated resource gap filled by donor funding pledges	Every 5 years
		Percentage expenditure of funds pledged by donor in the MYPOA	Every 5 years
		Percentage expenditure of the total cost estimated in the MYPOA	Every 5 years
		Percentage expenditure of health budget allocated to EPI	Every 5 years
		Percentage EPI-specific recurrent expenditure paid for with national resources	Every 5 years
		Percentage EPI-specific capital expenditure paid for with national resources	Every 5 years
	HTF returns put into vaccine financing	Percentage of HTF return put into vaccine financing	Every 5 years
Vaccine and cold chain	Vaccine needs planning	Vaccine forecast	Annually

logistics	Cold chain logistics management cold chain assessment	Vaccine arrival report	Annually
		Vaccine issue notes	Quarterly
		Vaccine physical balance and stock balance report	Monthly
		Cold chain logistics inventory monitoring report	Annually
			Every three years
		Cold chain equipment replacement plan	Every 5 years
		Cold chain equipment distribution order review	Every 5 years
Human and institutional resource strengthening for EPI	EPI staffing need review	Review report	Every 5 years
	Training of EPI managers and health staff	Training need assessment	Every 5 years
		EPI training plan in MYPOA	
		Proportion of training activity recommended by TNA carried out	Every 5 years
		Review of training activity's impact	Every 5 years
		Proportion of DMOs and DHOs trained on MLM in last three years	Annually
		Proportion of health workers trained on immunisation service delivery and cold chain logistics within last three years	Annually
		Proportion of cold chain technicians trained on cold chain maintenance within last three years	Annually
	Updating RIHS training curriculum	Revised curriculum with updated EPI section	As indicated by program matic changes
Advocacy programme	EPI communication	EPI communication strategy	Every 5 years

communication and social mobilization	strategy development		
	Communication strategy implementation	Proportion of action recommended in the communication strategy implemented	Every 5 years
		Communication materials distribution order	Annually
		Reduction in vaccination dropouts	Annually
		Proportion of mothers and caregivers knowledgeable about at least one benefit of immunisation services	Annually
Immunization service	Increasing routine coverage	Coverage stratification by Gewogs	Annually
		Action plan of district to increase coverage	Annually
Delivery	Reducing immunization dropout	Drop-out stratification by Gewogs	Annually
		Action plan of district to reduce dropouts	Annually
	Immunization safety	Immunisation safety plan	Every 5 years
		Resources mobilization for AD syringes	Every 5 years
		Proportion of vaccination injections given using AD syringes	Annually
		AEFI monitoring	Annually
	Immunization coverage reporting	Proportion of health facilities using Immunisation coverage monitoring chart in all immunisation clinics	Annually
		Facility's monthly Immunisation coverage report	Monthly
		Number of fixed outreaches	Annually
		Number of special/mobile/seasonal outreaches	Annually
Vaccine preventable disease	Collect, analyze and disseminate disease	Timelines of integrated vaccine preventable diseases reporting	Annually

surveillance	surveillance reports	Completeness of integrated vaccine preventable diseases reporting	Annually
		Proportion of hospital where active AFP case finding was done	Annually
		AFP rates	Annually
		Proportion of AFP cases whose stool sample collection was done within 2 weeks of AFP occurrence	Annually
		Proportion of AFP cases followed up 60 days	Annually
		Polio compatible and polio cases	Annually
		Measles suspects incidence rate	Annually
		Confirmed measles incidence case	Annually
		Proportion of measles cases confirmed by serology	Annually
		Measles mortality reported	Annually
		Measles mortality rate in cases of outbreaks	Annually
		Maternal and neonatal tetanus suspects reported	Annually
		Confirmed Maternal and neonatal tetanus cases reported	Annually
		Proportion of maternal and neonatal tetanus followed by a supplemental TT immunization response	Annually
		Annual review and dissemination of national vaccine preventable disease surveillance report	Annually

Table 4(b): District level EPI implementation monitoring

Programme area	Key action	Monitoring indicator	Monitoring frequency
Planning and coordination	Develop multi-year plans including injection safety strategy	EPI in 5YP	Every 5years
	Develop annual plans	EPI action plan in annual district plan	Annually
	Quarterly ICC meeting	EPI in agenda of DYT	
	Annual EPI review	EPI in agenda of district health review	
Assessment	Periodic cold chain assessment	Annual cold chain inventory assessment	Annually
Resources mobilization and financing	Annual evaluation of EPI performance by gewogs	Annual stratification of coverage by gewogs in the district annual report	Annually
	Financial sustainability	Five year EPI Budget Annual EPI budget	Annually
Vaccine and cold chain logistics	Vaccine needs planning	Vaccine forecast	Annually
		Vaccine wastage reduction plan	Annually
	Vaccine logistics management	Vaccine arrival reports	Annually
		Vaccine Issue notes	Quarterly
		Vaccine Physical balance and stock balance report	Monthly
	Cold chain logistics management	Cold chain logistics inventory monitoring report	Annually
		Cold chain equipment replacement plan	Every5 years
		Cold chain equipment distribution order review	Every year
Human resource strengthening for EPI	Adequate staffing	EPI staff/BHU staff shortage reported	Annual
Programme	Communicati	Reduction in vaccination	Annually

communication and social mobilization for EPI	on strategy implementation	drop-outs	
		Proportion of mothers and caregiver knowledgeable about at least one benefit of immunisation services	Annually
Immunization service delivery	Increasing routine coverage	Coverage stratification by Gewogs	Annually
		Action plan of districts to increase coverage	Annually
	Reducing immunization dropout	Drop-out stratification by Gewogs	Annually
		Action plan of districts to reduce drop-outs	Annually
	Immunization safety	Immunization safety plan	Annually
		Proportion of vaccination injections given using AD syringes	Annually
		AEFI monitoring	Annually
	Immunization coverage reporting	Proportion of health facilities using immunisation coverage monitoring chart in all immunization clinics	Annually
		Facility's monthly Immunization coverage report	Annually
	Reaching the un-reached	Number of fixed outreaches	Annually
		Number of special/mobile/seasonal outreaches	Annually
Vaccine preventable disease surveillance	Collect, analyze and disseminate disease surveillance reports	Timelines of integrated vaccine preventable diseases reporting form all health centres	Annually
		AFP reported	Annually
		Measles suspects reported	Annually
		Measles mortality rate in cases of outbreaks	Annually
		Maternal and neonatal tetanus suspects reported	Annually

Table 4(c): Facility level EPI implementation monitoring

Programme area	Key action	Monitoring indicator	Monitoring frequency
Planning and coordination vaccine and cold chain logistics	Develop annual plans	EPI action plan in annual district plan	Annually
	Local coordination	EPI in agenda of GYT	Annually
	Vaccine needs planning	Vaccine Forecast	Annually
		Vaccine wastage reduction plan	Annually
	Vaccine logistics management	Vaccine arrival reports	Annually
		Vaccine issue notes	Quarterly
		Vaccine physical balance and balance stock balance report	Monthly
	Cold chain logistics management	Cold chain logistics inventory monitoring report	Annually
		Cold Chain equipment distribution order review	Every year
Programme communication and social mobilisation for EPI	Communication strategy implementation	Reduction in vaccination drop-outs	Annually
		Proportion of mothers and caregivers knowledgeable about at least one benefit of immunization services	Annually during house visits
Immunization service Delivery	Increasing routine coverage	Coverage stratification by Gewogs	Annually
		Action plan of districts to increase	Annually
	Reducing immunisation drop-out	Drop-out stratification by Gewogs	Annually
		Action plan of district to reduce drop-outs.	Annually
	Immunisation safety	Immunization safety plan	Annually
		Proportion of vaccination injections given using AD syringes	Annually

	Immunization coverage reporting	AEFI monitoring	As and when it occurs
		Proportion of health facilities using Immunization coverage monitoring chart in all immunization clinics	Monthly
		Facility's monthly immunization coverage report	Monthly
		Annual stratification of coverage by village in the BHUs annual report to the district	Annually
	Reaching the un-reached	Number of fixed outreaches	Monthly
		Number of special/mobile/seasonal outreaches	Annually

- District level managers and health workers shall be trained in preparing and using coverage monitoring charts to track partially immunized/un-immunized children.
- BHMIS staff and district managers shall be trained to analyze and share coverage reports with the health centres for evidence-based planning.
- National and district managers shall be trained in carrying out effective supportive supervision.
- Systematic monitoring and supervision activities shall be implemented at all levels of the health care system.
- Special attention shall be given for low and poor performing areas in supervision and monitoring
- Assessment of coverage data and reports of supervisory visits shall be included in periodic programmatic reviews.
- Monthly performance of all levels shall be reviewed by analysis of coverage data and reports of supervisory visits.
- Periodic coverage and quality assessments of data shall be conducted every 5 years:
  - national (disaggregated by district) coverage evaluation surveys
  - periodic data quality assessment
  - EPI programme review, including policy implementation monitoring[8]

[8] Monitor dissemination of policy document to the National Assembly members, all ministries and the ICC partners and at the district and BHU levels.

2.14 Immunization in Emergency

The program shall refer to appropriate guidelines available in case of disease outbreak situation.

2.14.1 Measles control in emergency situations[9]

- The primary reason for high measles morbidity and mortality during complex emergencies is that measles is highly contagious respiratory viral infection. It can be quickly transmitted through air born droplets especially in overcrowded condition when population are displaced and the sanitation situation is poor. Many measles deaths can be prevented by carrying out supplemental immunization activities (SIAs) as rapidly as possible. Well-planned SIAs have proved to be highly successful in complex emergencies[10].
- Measles immunization, together with vitamin A supplementation, is a priority health intervention during and after emergencies. The choice of ages covered will be influenced by local epidemiology and availability of other resources. Measles control programmes in emergency settings has two major components:
  - Measles prevention through routine immunization.
  - Measles outbreak response.

  For all elective and emergency mass campaigns it is recommended that auto-disable syringes and safety boxes be used.

2.14.2 Routine Immunization

Measles immunization programme shall be an early priority of emergency relief programmes with the inclusion of other activities (e.g. nutritional supplementation and vitamin A, treatment of complications), health education and social promotion materials.

- Outbreak response: In the event of a measles outbreak the main strategy shall be to:
  - Ensure proper case management
  - Immunize the population at risk as soon as possible

The presence of several cases of measles in an emergency setting does not preclude a measles immunization campaign. Even among individuals who have already been exposed to, and are incubating the natural virus, measles vaccine, if given within three days of infection, may provide protection or modify the

---

Review all work plans (including MYPOA), technical documents, training materials and communication materials in light of the policy and strategic guidelines.
Using the revised Multi-year Plan of action (MYPOA) monitor the implementation of the National Immunization Policy and strategic guidelines, the annual health conference, with each DMO made responsible for reporting the policy implementation.
Disseminate any update on the policy as an executive directive from the Health Ministry with a reference number linking the directive to the national policy.

[9] Measles mortality reduction and regional elimination, Strategic Plan 2001-2005, WHO-UNICEF, WHO/V&B/01.13 Rev. 1

[10] *WHO/UNICEF Joint Statement on reducing measles mortality in emergencies* (WHO/UNICEF, 2004)

clinical severity of the illness. Isolation is not indicated and children shall not be withdrawn from feeding programmes.

All children aged 6 months (completed) to five years irrespective of their immunization status shall be immunized against measles.

2.14.3 Polio outbreak response guidelines[11]

The occurrence of a case of wild polio in a previously polio free area, whether through importation, laboratory accident, or mutation of vaccine virus (VDPV), shall be considered a public health emergency, that requires a rapid and high quality response as utmost priority.

- The infected and surrounding areas shall be vaccinated in 3 or more house to house campaign rounds and surveillance be boosted.
- Responding to circulating polioviruses in Polio-Free Areas, MOH shall plan to conduct large scale mop up polio campaigns "at least 2 full rounds" after the last virus is detected. The need for further activities will depend on the epidemiology of the outbreak and risk of further importation.

- The surveillance system shall be strengthened to:-
  - detect wild poliovirus circulation
  - detect situations of risk for investigation or action
  - identify high risk areas

- A full investigation and surveillance response shall be initiated within 48 hours of the identification of a suspected outbreak.

2.14.4 Influenza Pandemic[12]

Influenza pandemics are unpredictable but recurring events that can have severe consequences on human health and economic well being worldwide. Advance planning and preparedness are critical to help mitigate the impact of a global pandemic. *National pandemic influenza preparedness guideline* should be referred for detailed plan of action.

2.15 Other Vaccine

- There are several other vaccines available which are used in different countries but are not yet recommended for use worldwide by the EPI. Some vaccines, such as Japanese encephalitis, Meningococcal, Typhoid and Cholera vaccines are against diseases which are prevalent only in limited geographical areas and can be administered in case of outbreak and as MoH take decision when epidemiology necessitates.

[11] Response to a polio outbreak guideline, December 2008, Global Polio Eradication Program, WHO-Geneva
[12] Influenza pandemic preparedness and response, WHO Guidance Document

- Vaccination for travellers: Travellers should make certain that there is enough time (4-6 weeks) to see a health-care provider and obtain any necessary vaccinations before they travel.
- Countries requiring yellow fever vaccination for entry shall adhere to the regulations put forth by WHO as stated in the International Health Regulations.
- The cost and logistic of vaccination for travellers shall be borne by the individual for vaccines which are not in the Essential Drug List.
- Polio vaccination for travellers: All persons travelling to polio endemic area shall be provided with one dose (2 drops) of OPV one month prior to their travel.

2.16 Advocacy; social mobilization and programme communication for immunization

Communication and advocacy must be improved in order to ensure that the public, policy-makers, and health workers understand the vital importance of immunization for the health of both children and adults. Health workers shall be trained to communicate and convey immunization messages to parents, guardians, and communities

- A communication needs research for the immunization program, shall be conducted particularly for newly introduced vaccines.
- A strategic plan on communication channels and materials shall be developed and updated periodically
- Health workers and Village Health Workers shall be trained on providing appropriate IPC messages on immunization[13] to caregivers during sessions.
- Advocacy with health and other relevant ministries and development partners shall be conducted to ensure sustenance of immunization activities.
- Local leaders and NGOs shall be involved at district and sub-district levels in advocating for immunization.
- Enhanced Interpersonal communication (IPC) with mothers during immunization contacts shall be the focus of communication for increasing coverage and reducing drop out rates for immunization.
- Adequate job-aids and IEC materials shall be provided to health workers and village health workers to support IPC.
- Partnership and Inter-sectoral Coordination:
  - In addition to the Partners Coordination Mechanism (PCM), the Ministry of Health shall establish an Inter-agency Coordination Committee (ICC).

[13] Give these 4 Key Messages to the Care-giver:
1. What vaccine was given and what disease it prevents (e.g. BCG for preventing TB);
2. When to come for the next visit;
3. What are the minor side-effects and how to deal with them;
4. To keep the vaccination card safe and to bring it along for the next visit.

- ICC shall comprise of relevant stakeholders such as Ministry of Health, Ministry of Education, UNICEF, WHO, JICA, and other partner agencies.

- The Programme shall develop term of reference for the ICC which shall include
  - Formulation and implementation of immunization strengthening strategies
  - Advocacy about the importance of the immunization program with relevant government departments and stakeholders
  - Securing funding for the immunization program
  - Establishing linkages with appropriate government departments[14]
  - Monitoring and evaluating the implementation of the National Immunization Policy and the multi-year plans of action
  - Establish inter-sectoral cooperation with the Ministry of Education (for school-based immunization program)

2.17 Operational Research in Immunization

- The program shall work with the research unit, Policy and Planning Division (PPD), MoH for operational research which shall be utilized as a tool for informing policy decisions.

- Specific research topics to be addressed include:

  - Assessment of disease burden

  - VPDP review – every 5 years

  - Vaccination Coverage Survey – every 5 years

  - Identification of appropriate incinerators for disposal of immunization wastes

  - Identification of simpler methods of disease monitoring, methods for identifying high-risk areas, and reliable approaches to measuring Td coverage for sustenance of MNT elimination,

  - Evaluation of the cost-effectiveness and impact on routine services of different immunization strategies, particularly in rural areas, including a comparative analysis of fixed sites, regular outreach, mobile clinics and campaigns.

  - Evaluation of cost and programmatic issues with taking Td (and possibly DTP and Hepatitis B vaccine) beyond the cold chain, using local technology to maintain the cold chain for vaccines.

[14] A. Ministry of Home Affairs and the Central Statistical Organization of the Planning Commission (for estimation of immunization targets)
B. Ministry of Education and various NGOs and community based organizations (to promote use of immunization services)
C. Ministry of Environment (for Safe Disposal of Immunization Waste)

- Comparison of different approaches to reach high risk and migrant populations in the country.
- Assessment of the quality of the data provided through administrative reporting and how they compare with survey data.
- Studies on social mobilization and communication strategies to increase community involvement.
- Studies on most effective communication channels for social mobilization for the routine program.
- Research to determine the appropriate strategies for community involvement in immunization.
- A coverage survey to assess the 2nd dose of measles coverage
- School-based immunization strategy

2.18 Policy Implementation Plan

- National EPI policy shall be endorsed by the Ministry of Health.
- The Policy shall be disseminated to all the ICC partners at the national level.
- The Dzongkhag Health Officers and the health staff shall be made responsible for the dissemination of EPI policy information at the community level.
- Relevant area of EPI policy shall be the core of all in country training EPI training programme.
- All future plan of action of EPI shall base on the national policy. The Multi-year plan of action (MYPOA) shall cover all aspect of the National Immunisation Policy and give a framework for operationlizing the policy.
- Any update on the policy shall be disseminated as an executive directive from the Health Ministry with a reference number linking the directive to the national policy.

2.19 Policy implementation monitoring

a. National Immunisation Policy implementation monitoring shall be the responsibility of the Ministry of Health.

b. Implementation of a strategic plan addressing all aspect of policy shall be the major indicator of progress.

c. Policy implementation monitoring shall be done during the annual health conference, with each DMO made responsible for reporting the policy implementation.

d. Policy compliance monitoring shall be done every 3-5 years, as a component of EPI review.

ANNEX 1 : 66TH NATIONAL ASSEMBLY RESOLUTION, 1988

Immunization of Children and Pregnant Mothers, Resolution No. 11 adopted at the 66th Session of the National Assembly of Bhutan dated…26.2.1988.

Having noted high morbidity, mortality and disabilities from vaccine preventable diseases, and cognizant that cost effective measures are available to prevent such morbidities and mortalities, and as a measure to reduce the infant mortality rate

Endorsed the following:

a. All children born in Bhutan should have an access to and must be completely immunized with primary series of vaccination i.e. 1 dose of BCG; 3 doses of DPT; 3 doses of OPV and 1 dose of measles within one year of age against the six vaccine preventable diseases.

b. All pregnant women should be *immunized with two doses of tetanus toxoid vaccine and re-enforced with one booster dose* in subsequent pregnancies.

c. The presentation of a road to health card as proof of full immunization will be an essential pr-requisite for all school admission at the primary level

(Chief Justice Lyonpo Sangay Penjor)

SPEAKER

National Assembly of Bhutan

ANNEX 2

IMMUNIZATION MANAGEMENT RESPONSIBILITIES

National Immunization Program Officer

- Overall program management (technical, financial & administrative)
- Planning
- Work with the national & districts public health officials & partners to develop a National Comprehensive Multi Year Plan (cMYP) for Immunization
- Work with the national/districts public health official & partners to develop detailed national annual work-plans for each succeeding year during the currency of the cMYP (5 year planning cycle)
- Develop a standardized format for district micro-plan & BHU session plan & micro-plan
- Coordinate all immunization program activities with other MOH divisions and local & international partners

GAVI

- Prepare & submit national applications to GAVI for new vaccines introduction support and health system strengthening.
- Ensure that the national ICC (PCM) participated in reviewing the draft application
- Ensure that the MOF & the national ICC (PCM) endorsed the application before is being submitted by the MOH
- Prepare annual progress report (as condition for continuation of support)

External Organisations

- Work with regional, global, multilateral & bilateral organisations
- Prepare regular reports for partners (programmatic, financial & surveillance)

National Immunization Committees (NCCPE & NCIP)

- Provide secretarial support for the NCCPE meetings and provide updates on AFP surveillance data
- Provide Secretariat support for the NCIP meetings & provide program documents & progress reports

Districts review meetings

- Ensure that the DHOs organise quarterly Immunization review meetings for BHUs and participate in meetings of poor performing districts
- Organise regional Immunization quarterly review meetings for DHOs/MOs (5-6 districts) (Central, Western, Easter Regions) and participate in all 4 meetings (one in each quarter).

Vaccines & logistics

- Prepare and submit national annual vaccines, AD syringes & safety boxes requirements.
- Prepare an inventory for all cold chain equipment and submit a cold chain equipment requirements

Vaccine-preventable diseases (VPDs)

- Assist in development of national VPDs surveillance field guides, implementation and monitoring
- Strengthen the AFP surveillance, to achieve all surveillance indicators for certification
- Strengthen the Measles, Rubella & CRS surveillance.
- Program review, assessments, surveys, research, etc. Prepare proposals, identify funding and consultants to assist the MOH in conducting these activities

Training

- Assess training needs of districts & BHUs, using the expertise of the Royal Institute of Health Sciences
- Develop a training plans
- Conduct Training of trainers to assist on training and re-training of health workers

Supportive supervision

- Train DHOs on supportive supervision and in-service training
- Provide quarterly feedback on routine immunization coverage, wastage rate, and surveillance. It should be written in the form of a bulletin.

District Health Officer (DHO)

- Work with the district and BHUs staff to prepare a district micro-plan and BHUs sessions & micro-plans

- Organise quarterly immunization review meetings with BHUs HAs to review the implementations of micro-pans and discuss progress and constrains. A summary report of the meeting should be sent to the national immunization officer.
- Ensure that AFP cases are timely reported, investigated and stool samples collected and sent to the national EPI office.
- Ensure that measles & rubella suspected cases are reported, investigated and blood specimens collected and sent to the PHL
- Submit regular programmatic and surveillance reports timely
- Conduct regular supervisory visits and provide supportive supervision
- Ensure that vaccines, AD syringes and safety boxes requirements are correctly prepare and submitted to the national immunization office.
- Monitor regularly stocks and wastage rate
- Consolidate all BHUs monthly regular reports and submit to the national immunization office

Health Assistant

- Overall BHU management (technical, financial, and administrative)
- Prepare the BHU sessions and micro-plan
- Ensure that adequate stock of vaccines, AD syringes, safety boxes, vaccination cards, immunization register, etc.
- Monitor the performance of the refrigerator on a daily basis by filling the temperature chart.
- Ensure that all ORCs are carried out as scheduled
- Report and investigate suspected cases of measles & rubella, collect blood specimen and send it to higher level, then to the PHL
- Prepare and submit regular monthly reports to the DHO.

ANNEX 3: SOME IMPORTANT HEALTH INDICES

Total Population	6,72,425
Rate of Growth (NI)	1.8 %
Live Births	13,344 (2 % of popn.)
Birth Rate	20.3 per 1000 population
Death Rate	7 per 1,000 population
Neonatal mortality rate	30 per 1000 live births
Infant Mortality Rate	40.1 per 1000 live births

Under-five mortality rate	61.6 per 1000 live births
Maternal mortality Rate	255 per 100,000 live births (2000 health survey)
Children < 1 Year	12,810 (1.9 % of population.)
Children < 5 Years	68,180 (10.3 % of population)
Children < 15 Years	2,10,333 (31.9 % of population)
Pregnant women	13,344 (2 % of Population.)
Women of Child Bearing Age (15-49 yrs)	167,739 (25.5% of population.)

Bhutan's Health Indices *References; Health survey 2000, PHCB 2005*

ANNEX 4:- VACCINE PREVENTABLE DISEASE PROGRAM

Launched in 1979 as the Expanded Programme on Immunization (EPI), strong government commitment and community mobilization has resulted in Bhutan maintaining high immunization coverage at >90%. Bhutan is on track towards achieving the global goal of vaccine preventable diseases, prevention, control, elimination and reduction goals. Immunization has also been realized as a key contributor to achievement of Millennium Development Goals (MDGs).

Milestones:

- Vaccination introduced as part of the global drive to eradicate small pox in 1977
- DPT, OPV and BCG vaccines introduced in selected districts in 1984
- Alma Ata declaration and the Primary health care model for attaining Health For All by the year 2000 adopted
- EPI launched to immunize all children with DPT, OPV, BCG and Measles vaccines in 1979
- EPI expanded to all districts and fully integrated with general health services
- National Institute of Family Health (NIFH) facilitated in-country immunization training of health workers
- Tetanus Toxoid (TT) immunization of pregnant women introduced in 1984

- Last case of compatible polio reported in 1986
- National Plan of Action for the acceleration of EPI formulated
- 66th National Assembly resolution for full vaccination of all children and pregnant women passed in 1988
- Universal Child Immunization (UCI) achieved in 1991
- Global polio eradication programme adopted in 1998
- National and sub national immunization days conducted in 1995-2002
- AFP surveillance protocol instituted in 2002
- Newer vaccines funding to Bhutan approved by GAVI in 2002
- Cold Chain Assessment conducted in 2002
- DTP-HepB combination vaccine introduced nation-wide in 2003
- AD syringes introduced for immunization services in 2003
- National Immunization Policy and Strategic Guidelines for National Immunization Services adopted in 2004
- EPI restructured into Vaccine Preventable Disease Program (VPDP) to include emerging VPDs and newer vaccines in 2005
- Joint WHO/National Review of Surveillance for AFP conducted in 2005.
- Nationwide Measles and Rubella (MR) vaccination campaign conducted in 2006
- MR combination vaccine included in national immunization schedule for children at 9 and 24 months of age in 2006
- Last case of neonatal tetanus reported in 2006
- Comprehensive Multi Year Plan (2009-13) of the immunization program formulated in 2008
- National Immunization Coverage Survey conducted in 2008
- Bhutan received Best Immunization Award for achieving 95% sustained Immunization coverage from GAVI Alliance Partners Forum, Hanoi,Veitnam,19th November,2009
- DTP-HepB-Hib (pentavalent vaccine) introduced on 1st September, 2009
- Nationwide HPV vaccination campaign for 12-18 years girls conducted in 2010
- DTP-HepB-Hib (pentavalent vaccine) re-introduced on 11th June,2011
- Monovalent Hepatitis B introduced in national immunization program in

2011

- Joint National/International EPI/VPD Surveillance Review and Post Introduction Evaluation (PIE) for HPV Vaccine in Bhutan conducted from 18-30 March, 2011

VPDP Service Delivery

Currently, immunization services are fully integrated into the general health services and are provided throughout the country from fixed centres at hospitals/ BHUs and outreach clinics (ORC). The schedule of the ORC is planned in advance which is communicated to the catchment population. The primary health care workers, namely the Health Assistant (HA), Auxiliary Nurse Midwife (ANM) and Basic Health Worker (BHW) are responsible for providing immunization services to the children and pregnant women. A Voluntary Village Health Worker (VVHW) assists the health workers during these ORC visits.

VPDP Coverage and Surveillance

Bhutan has been successful in sustaining high immunization coverage since the UCI declaration in 1991. Both reported and evaluated coverage show >90% coverage for all antigens. Incidence of target EPI diseases also shows a decreasing trend. VPD Surveillance has been integrated to include AFP, Measles, Rubella (CRS), MNT, Diphtheria and Pertussis. Zero reporting, however, exists for AFP measles/Rubella (CRC) and MMT.

ANNEX 5: FUTURE NEW VACCINES

THE ROTAVIRUS VACCINES[15]:

WHO is recommending that all national immunization programs include the oral rotavirus vaccine, which could help prevent deaths and hospitalizations from the disease. WHO recommends that the first dose of either RotaTeq or Rotarix be administered during the period when the infant is aged 6 weeks to 15 weeks. The maximum age for administering the last dose of either vaccine is recommended to be 32 weeks. WHO also recommended that sentinel surveillance for severe rotavirus

[15] http://www.who.int/entity/wer/2009/wer8423/en/index.html WER 5 June 2009, vol. 84, 23 (pp 213–236)

gastroenteritis should be in place to monitor the vaccine's impact. Moreover, post-marketing surveillance systems shall be established to monitor possible adverse events related to the vaccines, including intussusceptions.

Use of the vaccine shall be part of a comprehensive strategy to control diarrhoeal diseases and shall include, among other interventions, improve water quality, improvements in hygiene and sanitation, zinc supplementation, community-based administration of oral rehydration solution and overall improvements in case management.

Pneumococcal conjugate vaccine[16]:

WHO considers that pneumococcal conjugate vaccine should be a priority for inclusion in national childhood immunization programmes.

A 3-dose regimen given in infancy is expected to confer a high level of protection against invasive pneumococcal disease.

MOH shall conduct appropriate surveillance for invasive pneumococcal disease to establish a baseline measure and to monitor the impact of vaccination. This is particularly important for Bhutan that shall be among the first countries to introduce the vaccine into the national programmes.

Japanese encephalitis vaccine;

Japanese B encephalitis occurs in Southeast Asia and the Western Pacific countries (ACIP 1993a; EPI 1994b; Igarashi 1992). In areas where JE is endemic, the annual incidence ranges from 1 - 10 per 10 000. Children younger than 15 years of age are mainly affected. For primary immunization two doses of mouse brain JE vaccine are administered subcutaneously at an interval of 1 - 2 weeks. One additional dose is recommended a month after the primary immunization. A booster dose is recommended every 1 to 4 years. The vaccine has been shown to be highly effective and safe. The vaccine is produced in Japan, Republic of Korea, Taiwan, Thailand, and Vietnam. Purified JE vaccine is also produced and used in India (Rao Bhau 1992). Given the severity of the disease, particularly in young children, and the effectiveness of the available inactivated vaccines, countries where JE is endemic should consider its inclusion in their immunization programmes. There are no data on whether JE vaccine can be given simultaneously with measles or other EPI vaccines. Issues that need to be resolved in further studies include: (1) the earliest age for immunization; (2) the need for booster doses; (3) whether JE vaccine can be given simultaneously with other EPI antigens, and (4) ways to decrease the cost of JE vaccine.

Meningococcal vaccine:

Neisseria meningitiis causes both endemic and epidemic disease, principally meningitis and meningococcaemia (Wright 1989). Case fatality ratios reach 10-20% despite treatment in industrialized countries, and may be higher in developing countries. Most meningococcal diseases are caused by meningococci of serogroups A,

[16] WER 23 MARCH 2007, 82nd YEAR

B and C. Serogroup A is mostly responsible for large epidemics. Safe and effective vaccines composed of monovalent groups A and C, bivalent A + C or quadrivalent A,C, W-135 and Y capsular polysaccharides are currently in use. A single dose of group A polysaccharide given to persons over 2 years of age will protect for 1 to 3 years. For children less than 2 years of age, two doses of group A polysaccharide vaccine are required 3 months apart to achieve protective levels of immunity. The vaccine has a clinical efficacy of 85-95% against serogroup A disease and is of use in controlling epidemics. Group C polysaccharide vaccine is effective in adults, but fails to elicit protective levels of antibodies in children less than two years of age. Currently available meningococcal polysaccharide vaccine is not recommended for routine infant immunization because of the short duration of immunity and the failure to protect against endemic serogroup B infections. However, widespread emergency immunization can control meningococcal A/C disease if implemented early in the course of an epidemic. Therefore, effective meningitis surveillance is needed to detect the emergence of an epidemic in order to institute immunization at the earliest possible time. WHO recommends that meningitis incidence rate of 15 per 100 000 averaged over 2 weeks is a specific and predictive threshold for an epidemic and for initiating emergency immunization (Moore et al. 1990, 1992).

Typhoid vaccine:

Typhoid fever remains an important and underestimated disease in many regions of the world (causing 560,000 deaths every year globally) and it poses a risk for travelers. In most endemic areas the incidence of typhoid fever is highest in children 5 - 19 years of age; hence a vaccine is needed that can establish durable immunity prior to school age (Levine 1990, Levine et al 1991, Editorial 1992, Ivanoff et al. 1994). Existing inactivated, injectable typhoid vaccines prepared from whole cell organisms confer protection after two doses in 51 - 88% of school children, but cause high rates of adverse reactions. Live oral typhoid vaccine contains an attenuated strain of *Salmonella typhi*, Ty21a. The vaccine is safe and its efficacy has been evaluated in field trials in endemic areas. With a liquid formulation, a 67% protective efficacy has been obtained after 7 years of follow up in an endemic area. Purified Vi antigen, a polysaccharide capsule in the surface of *S. typhi*, has been used as a one-dose injectable vaccine in Nepal and South Africa, where the vaccine provided, respectively, 72% protection at 17 months, 64% protection at 21 months and 55% protection after 5 years of follow-up. Both Ty21a and Vi polysaccharide are currently licensed and available, and offer an alternative to the poorly tolerated whole cell typhoid vaccine (Levine 1990). There is, however, insufficient information on the efficacy of these vaccines in children below 2 years to recommend them for use in infant immunization programmes at this time. Because of the current increased resistance against antibiotics, immunization should be considered as an alternative strategy in combating typhoid fever.

Cholera vaccine:

Parenteral immunization with the killed whole-cell vaccine is of no practical value in epidemic control or management of contacts of cases. This vaccine provides only partial protection (50%) of short duration (3 - 6 months), and is not regarded as a useful public health intervention. Attention has instead turned to the development of oral vaccines that could more efficiently stimulate local immunity (Clemens et al. 1990). Both inactivated and live oral cholera vaccines have been developed (Levine and Kaper 1993). Significant progress has been made recently towards the development of a one dose live attenuated cholera vaccine, containing the strain CVD-103 HgR, a *V. cholerae* 01 mutant strain, in which genes encoding cholera toxin have been deleted. In adult volunteers and children over 5 years of age the vaccine is immunogenic.

Figure 1: Coverage Evaluation Survey (%)

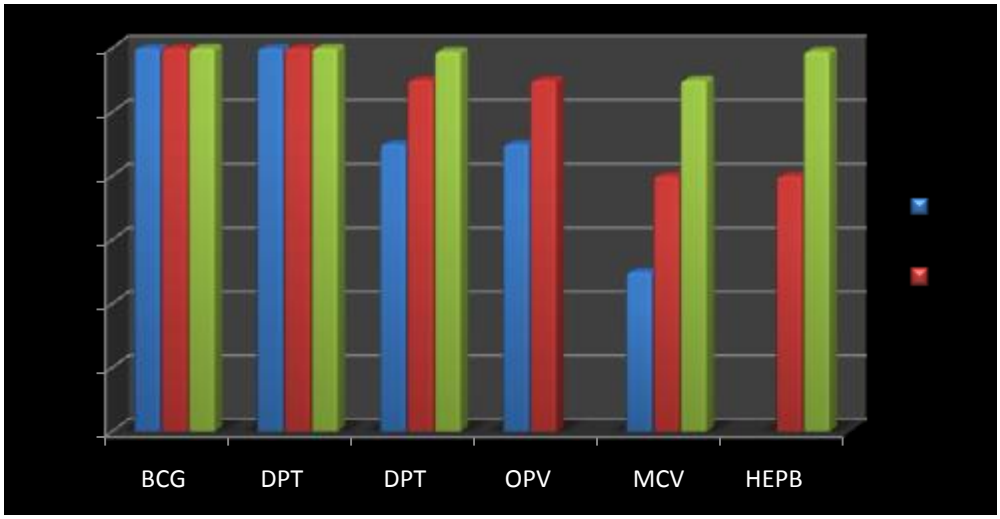

Figure 2: VPD Incidence