



NATIONAL IMMUNIZATION POLICY

20th November 2013

Draft version

DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH AND FAMILY WELFARE

Table of Contents

PREAMBLE.....	2
INTRODUCTION.....	3
SECTION 1 NATIONAL IMMUNIZATION POLICY STATEMENT.....	5
A Policy Goal.....	5
Policy Guiding Principles.....	5
SECTION 2 NATIONAL IMMUNIZATION DIRECTIONS.....	6
1 IMMUNIZATION REPORTING, SURVEILLANCE AND RESEARCH.....	6
1.1 Routine Reporting of Vaccination.....	6
1.2 Surveillance of Vaccine Preventable Disease.....	6
1.3 Immunization Data Quality.....	6
1.4 Immunization and Vaccine Research.....	7
2 REGULATION AND COORDINATION.....	7
2.1 Agency Roles in Regulation and Coordination.....	7
2.2 Immunization Human Resources.....	8
2.3 Cold Chain and Vaccine Management Policy.....	8
2.4 Adverse Events Following Immunization.....	9
2.5 Safe Injection and Waste Management.....	9
2.6 Private Sector Immunization.....	9
2.7 Regulation and Procurement of Vaccines.....	10
3. VACCINES POLICY.....	11
3.1 Changing the Immunization Schedule.....	11
3.2 Contraindications for Vaccination.....	11
3.3 Decision Making on Introduction of New Vaccines.....	11
4 VACCINE SECURITY.....	12
4.1 Sustainability of Financing of Vaccines.....	12
4.2 Security of Vaccine Supply.....	12
5. IMMUNIZATION SERVICE DELIVERY POLICY.....	13
5.1 Rural Immunization Services.....	13
5.2 Urban Immunization Services.....	13
5.3 Immunization Services for High Risk or Vulnerable Groups.....	13
5.4 Immunization Campaigns.....	14
5.5 Immunization in Educational Institutions.....	14
5.6 Hospital/Health Facility Based Immunization Services.....	14
5.7 Advocacy, Communication, Demand Creation and Client Rights.....	14
5.8 Policy on Gender and Immunization.....	15
5.9 Policy on User Fees for Immunization.....	15
Conclusion.....	15

PREAMBLE

The goal of the national Immunization Policy is to ensure the reduction in vaccine preventable diseases for all age groups through provision of quality, effective and safe immunization services through public, private and NGO sectors. The achievement of this goal will be critical for achieving our broader health and development goals as outlined in the National Health Policy.

Immunization has been a great success story for Bangladesh. Millions of children and women have been protected from vaccine preventable diseases, and we have also commenced in recent years to protect our population from additional diseases using the latest new vaccines and medical technologies.

But in reality, despite these successes, we face important challenges and opportunities in the coming years. The economy is growing, society is urbanizing, and there has been a steady expansion of private medical sector and NGO service providers providing vaccination services. There are now opportunities to expand immunization to older age groups including school children and travelers, and those who are particularly at risk including the aged and those with chronic diseases.

There is increasing commercial importation of vaccines into the country, and there remain opportunities for development of our own local vaccine production capacity. We also confronted by the challenge of reaching all of the population, including the poorest and those living in the remotest areas.

All of these factors establish the need for a National Immunization Policy in order to guide decision making and regulation to ensure the highest quality and safety standards, and to take advantage of these new opportunities to protect all of our population from vaccine preventable diseases.

The policy document is intended to guide not only the Ministry of Health and Family Welfare, but also its implementing and collaborating departments and partners including the Ministry of Education, Ministry of Primary and Mass Education, Ministry of Local Government Rural Development & Cooperatives (LGRD&C), Ministry of Religious Affairs and Ministry of Women and Children Affairs, and Ministry of Social Welfare.

I would like to request colleagues at the Ministry of Health and Family Welfare, health managers and providers at all levels of the health system (including private sector and NGO service providers) to carefully work within the framework of this policy, and develop strategies, guidelines and planning actions that help us to realize our goals for protection of the population from vaccine preventable diseases.

INTRODUCTION

Policy Background

Following the launch of the National Immunization Program in 1979, immunization in Bangladesh progressed through several stages of development from its early beginnings in the 1980s, to consolidation of the program in the 1990s, and more recently through introduction of new vaccines and medical technologies in the 2000s. There have been substantial disease prevention and control achievements in this time. Immunization coverage for the EPI program have expanded to over 95% for Diphtheria Pertussis and Tetanus (DPT) vaccine by 2011. Bangladesh has remain polio free since importation of the wild polio virus in 2006, although the last indigenous case of polio was in August 2000. Elimination of neonatal and maternal tetanus was certified by WHO in 2008. The National Program introduced Hepatitis B vaccine in 2003 and Haemophilus Influenzae Type B (in the form of pentavalent vaccine) in 2009, and measles second dose and measles and rubella (MR) vaccine in 2012. It is also planned to introduce pneumococcal vaccine in 2014 for prevention of some forms of childhood pneumonia and meningitis. Additional vaccine options in the coming years include vaccines for prevention of cervical cancer (Human Papilloma Virus) and vaccine to prevent rotavirus diarrhea, typhoid and cholera, hepatitis B (birth dose), inactivated polio vaccine (IPV) and other new and underutilized vaccines.

Meanwhile, the Department for Communicable Disease control implements immunization programs for rabies control as well as provides opportunities for vaccination for travelers, and has been influential in coordinating pandemic influenza disease prevention and control responses. Additionally, there is an emerging private medical sector and an active NGO sector which provides additional opportunities for provision of immunization services to the population.

Policy directions up until this time have focused successfully on the protection of women and children from vaccine preventable diseases. This has been an internationally recognized public health success story. Nevertheless, the context for immunization services is rapidly changing both globally and in Bangladesh. In this “Decade of Vaccines”, there are expanding opportunities to introduce new vaccines and medical technologies, as well as opportunities to extend the immunization schedule to cover additional population age groups. In addition to the expanding opportunities, there is also increased complexity in service provision with a range of agencies both public and private providing immunization services, as well as an increasing diversity in production and importation of vaccines. This increased diversity and complexity of immunization in an urbanizing, globalizing and economically developing society, presents significant policy and regulatory challenges for the Ministry of Health and Family Welfare.

This document will provide a policy framework for decision makers, managers and service providers, in order that services are in conformance with the highest national and international safety and quality standards, and which meet the health needs of the population of Bangladesh. This policy statement will build on national health policy, the sixth five year plan, and existing national immunization strategy and guidelines, as well as realigning with the above mentioned new policy challenges and the changing social, epidemiological and technological context.

Policy Scope and Directions

Based on the above rationale, the direction of the National Immunization Policy is as follows:

1. Scaling up immunization coverage further by reducing immunization inequities
2. Expanding immunization services to other population age groups
3. Improving the quality and safety of immunization services in public, private and NGO sectors
4. Introducing new vaccines and medical technologies

Given these directions, the scope of immunization policy will be widened to include older age groups, public and private sectors, and service provision through multiple departments of the Ministry of

Health and Family Welfare, and through the multi sector support of the education and local government sectors in particular.

Policy Outcomes

The expected outcomes of policy implementation will be reduced mortality and morbidity from vaccine preventable diseases, wider and more equitable access of the population to the latest vaccines and medical technologies, and consistency in safety and quality of vaccination whether these services are delivered through public, private or NGO service providers.

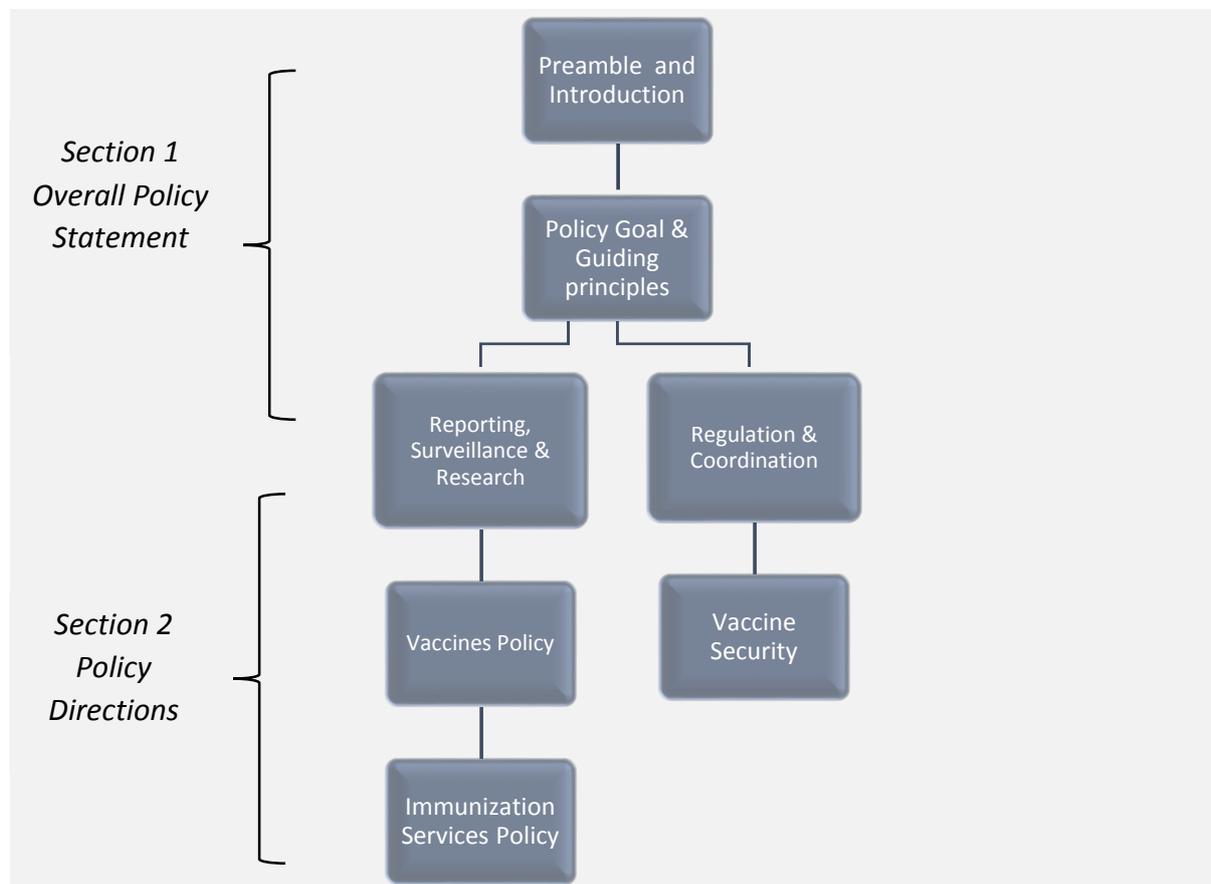
Policy Process and Framework

This policy document has been developed in the following manner:

1. A literature review was conducted of immunization data, the grey literature on immunization in Bangladesh, peer reviewed literature, as well as of immunization policies from other countries
2. Consultations were held with directors and managers under the Ministry of Health and Family Welfare to identify main policy priorities and content areas, as well as the scope of the policy
3. A series of consultations were also held with expert panels on immunization in Bangladesh including the National Committee on Immunization Practice, as well as with the National Regulatory Authority (Directorate-General of Drug Administration).
4. A National Immunization Policy Consultation conducted on the 2nd November achieved consensus on a draft policy framework. This was achieved with the participation of the Ministry of Health and Family Welfare and other line ministries, immunization specialists, regulatory authorities, international agencies, professional bodies, private sector and NGO actors.

This policy document is divided into two sections, the first of which details the main policy goals and guiding principles, with the second section detailing the specific clauses for each policy area.

Policy Framework National Immunization Policy Bangladesh



SECTION 1 NATIONAL IMMUNIZATION POLICY STATEMENT

A Policy Goal

The goal of the National Immunization Policy is to ensure the reduction in vaccine preventable diseases for all age groups through provision of quality, effective and safe immunization services through public, private and NGO sectors.

The policy objectives will be to:

1. Improve effective coverage for immunization services to traditional target groups including women of reproductive age and children under the age of five, including expanding immunization coverage for adolescents and adults and high risk population groups.
2. Achieve disease elimination and eradication objectives for vaccine preventable diseases.
3. Expand protection for the population from diseases protected by new and underutilized vaccines for diseases including meningitis, pneumonia, diarrhea and cervical cancer and rabies and for other vaccine preventable diseases that would be available in the future.
4. Ensure the quality and safety of immunization services through standardization of cold chain, safe injection and surveillance, monitoring and evaluation standards and procedures for all agencies (public, private and NGO) providing immunization services in Bangladesh
5. Ensure consistency in the regulatory, technical advisory and decision making processes to ensure that the immunization schedule and vaccine procurement is based on sound scientific evidence and technical expert recommendations, and responds to the population health needs of Bangladesh
6. Ensure that a human resource management system is in place to ensure the provision of a consistent standard of immunization and surveillance practice across public, private and NGO sectors
7. Promote research on health systems, service delivery and effectiveness of immunization to determine best practices and contribute towards an evidence base and research on vaccine development
8. Promote sustainability of the immunization program and security of vaccine supply through the increased government and international commitment to financing of vaccine procurement and program operational costs

Policy Guiding Principles

Policy development and implementation will be guided by the following principles.

1. *Equity and Social Justice:* Ensure the constitutional rights of every citizen of Bangladesh, irrespective of caste, creed, religion, group, income and gender, and particularly that of the children and women of all areas regarding his/her access to immunization services in the light of social justice and equality (as per National Health Policy)
2. *Immunization Safety:* The safety of immunization services should be maintained through consistent implementation and monitoring and evaluation of the highest safety standards for immunization services in public, private and NGO sectors
3. *Immunization Services Quality:* The quality of the program will be maintained through detailed regulatory mechanisms to ensure the quality of vaccines, and human resource management practices that ensure a consistent standard and quality of service provider.
4. *Coordination and Alignment:* Create opportunity and provide assistance to the coordination between all public and private and NGO agencies with an aim to ensure effective immunization services for all in the context of alignment with the National Health Policy

5. *Evidence based Decision Making:* Decision making for the immunization schedule and new vaccines will be guided by scientific evidence on vaccine efficacy and safety.
6. *Sustainability:* Continuously increase government allocation for immunization considering health as a main subject for socio-economic development of the country (as per National Health Policy), and promote institutional and community sustainability through strengthening of health systems and demand generation

SECTION 2 NATIONAL IMMUNIZATION DIRECTIONS

1 IMMUNIZATION REPORTING, SURVEILLANCE AND RESEARCH

1.1 Routine Reporting of Vaccination

- 1.1.1 All health facilities (public, private, NGO) will maintain a uniform vaccination register outlined by MoHFW for the target population in the catchment area of the health facility, and if feasible, will link immunization registration to birth registration processes
- 1.1.2 All health facilities (public, private, NGO) will record immunization provided on an immunization card, with the immunization card providing as a minimum standard the contents of the routine public sector immunization schedule.
- 1.1.3 All health facilities (public, private, NGO) should report monthly on numbers of population vaccinated as per approved schedule to the relevant local health authority and ultimately to the MoHFW

1.2 Surveillance of Vaccine Preventable Disease

- 1.2.1 All Vaccine Preventable Diseases should be reported from all static health facilities (including primary, secondary and tertiary hospitals, private facilities and NGOs) on a weekly basis to the relevant health authority according to the case definitions, procedures and guidelines of the Directorate General of Health Services of the Ministry of Health and Family Welfare.
- 1.2.2 All Divisions, Districts, City Corporations, Upazila Health Complexes, Municipalities and Hospitals (public and private) will appoint a trained and designated surveillance focal person to conduct active and passive surveillance for vaccine preventable diseases, and report and respond to disease events according to the guidelines and procedures of the Ministry of Health and Family Welfare.
- 1.2.3 All fixed health facilities will implement the required surveillance, vaccination and case management responses to vaccine preventable disease outbreaks according to the standards and procedures of the Ministry of Health Family Welfare.
- 1.2.4 The MoFHW, in collaboration with technical partners and research institutes, will develop the laboratory capacity of the country in order to introduce case based laboratory surveillance for all vaccine preventable diseases (for laboratory confirmation of diagnosis, tracking epidemiology of diseases, and for evaluating vaccine efficacy and program effectiveness) and will monitor quality of vaccines as assessed by appropriately equipped and staffed National Control Laboratory (NCL).

1.3 Immunization Data Quality

- 1.3.1 Annual assessments or self-assessments should be undertaken of the quality of vaccination data by Health Authorities within their own jurisdiction, in accordance with the guidelines and procedures of the National Programme on Immunization, under the Directorate General of Health Services of the Ministry of Health and family Welfare.

1.4 Immunization and Vaccine Research

- 1.4.1 A national population based coverage survey will be conducted regularly in Bangladesh in order to evaluate the impact of the program in terms of quantity and quality
- 1.4.2 A post introduction evaluation will be conducted following the introduction of any new vaccine or medical technology.
- 1.4.3 Burden of disease assessments should be undertaken on a periodic basis to provide an evidence base for introduction of new vaccines, to assess the efficacy of vaccines, and to measure the impact of immunization programs on vaccine preventable disease burden.
- 1.4.4 Post marketing research and evidence from vaccine trials should be undertaken on a regular basis to monitor the safety and efficacy of vaccines in the context of Bangladesh
- 1.4.5 Periodic social research will be undertaken in order to assess population barriers to immunization access, particularly for vulnerable, high risk or unreached population groups
- 1.4.6 Vaccine or impact assessments should be conducted by the relevant implementing agency in collaboration with MoHFW
- 1.4.7 All research should conform to the ethical standards for research as reviewed by the Bangladesh Medical Research Council (BMRC)

2 REGULATION AND COORDINATION

2.1 Agency Roles in Regulation and Coordination

- 2.1.1 The principal agency for making technical recommendations on the immunization schedule, immunization practices, and new vaccines and technologies will be the National Committee for Immunization Practice (NCIP). The NCIP will appoint sub committees for immunization related programs for disease prevention and control, elimination, eradication and safety.
- 2.1.2 The principal agency for regulation and licensing of vaccines in Bangladesh will be the Directorate General of Drug Administration (DGDA). It is the policy commitment of the MOHFW that all licensing and registration of vaccine production and marketing should come under the single regulatory umbrella of the DGDA
- 2.1.3 It is the policy commitment of the Ministry of Health and Family Welfare to upgrade and maintain the capacity of the DGDA to undertake the six core regulatory functions of (i) a published set of requirements for licensing, (ii) surveillance of vaccine field performance, (iii) introduction of systems of lot release, (iv) use of laboratory when needed, (v) regular inspections for good manufacturing performance and (vi) evaluation of clinical performance.
- 2.1.4 As part of its licensing and registration function, the Directorate General of Drug Administration (DGDA) will aim to regulate the price of vaccines in Bangladesh
- 2.1.5 The DGDA will take the primary responsibility for post marketing pharmacovigilance
- 2.1.6 The principal mechanisms for coordination of national and international resources for immunization will be the Inter Agency Coordination Committee (ICC), or any other sector coordination agency appointed by the Government.
- 2.1.7 The principal agency responsible for ensuring the quality and safety of implementation of the routine public immunization schedule and immunization campaigns is the National Immunization Program, Directorate-General of Health Services, Ministry of Health and Family Welfare.

- 2.1.8 The Department of Communicable Disease Control, Directorate-General of Health Services, Ministry of Health and Family Welfare, has the primary responsibility for implementation of vaccination programs for rabies prevention, traveler's vaccination (including Haj Pilgrims) and seasonal influenza vaccination and for other emerging infectious diseases.
- 2.1.9 Key managerial positions in the National and sub national health system should have full accountability for the management arrangements for better leadership in improving immunization services
- 2.1.10 NGOs supplying immunization services through City Corporations or Municipalities will provide immunization services that conform to public sector immunization policies and standards in relation to cold chain and vaccine management, safe injection practices, and routine surveillance and immunization reporting and other immunization standard operating procedures.
- 2.1.11 It is the policy of the Ministry of Health and Family Welfare that City Corporations and Municipalities identify and mobilize immunization human resource numbers and operational costs that meet the standard and procedures for management of the public sector immunization services elsewhere in the country.

2.2 Immunization Human Resources

- 2.2.1 All vaccinations provided in Bangladesh should be provided by a service provider with the required skills and competencies in vaccination and inter personal communication. The minimum qualifications, competencies and training requirements for an immunization service provider (in public, private and NGO sectors) will be specified in the guidelines and procedures of the Directorate-General of Health Services of the Ministry of Health and Family Welfare.
- 2.2.2 The MoHFW will commit to resourcing the training of service providers on immunization related topics, and particularly in the areas of adverse events following immunization and cold chain management.
- 2.2.3 Vaccination at rural wards will be designated by the MOHFW, and will include the Health Assistant and the Family Welfare Assistant (FWA).
- 2.2.4 Vaccination in urban wards is the primary responsibility of Local Government through their appointed service provider of the City Corporation, Municipalities or NGOs.

2.3 Cold Chain and Vaccine Management Policy

- 2.3.1 All health facilities and providers (public and private and NGO) must conform to Ministry of Health and Family Welfare guidelines and procedures on maintenance of the cold chain with respect to vaccine arrival procedure, temperature monitoring, storage and transport of vaccines, maintenance of cold chain equipment, stock management and distribution and vaccine management. The purpose of this policy is to ensure consistent safety, quality and efficacy of vaccine in both public and private sectors.
- 2.3.2 It is the responsibility of local health authorities in Districts, Upazila, City Corporations and Municipalities to ensure that all fixed health facilities store and distribute vaccines according to a consistent national standard as specified in the guidelines of the National Expanded Programme on Immunization, Directorate General of Health Services, Ministry of Health and Family Welfare.
- 2.3.3 Vaccine arrival inspections, storage and transport for public and private sectors (including importation of vaccines and monitoring of cold chain implementation) will be conducted by the DGDA (or a competent authority appointed by the DGDA to do so)

2.4 Adverse Events Following Immunization

- 2.4.1 An adverse event following immunization is defined as any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavorable or unintended sign, abnormal laboratory findings, symptom or disease.
- 2.4.2 In order to ensure the quality and safety of immunization in Bangladesh, all community, health facilities, hospitals, NGOs and private clinics in rural and urban areas should report adverse events to the relevant disease surveillance focal points according to the procedures and guidelines of the Ministry of Health and Family Welfare.
- 2.4.3 Any serious AEFI (death, hospitalization, and significant community concern or cluster event) must be investigated in both rural and urban areas by designated AEFI committee, and a report should be submitted by the AEFI investigation team to the relevant health authority as early as possible.
- 2.4.4 A national AEFI Expert Review committee will review the existing reports, confirm causality assessments and make recommendations to the National Committee on Immunization Practice and National Regulatory Authority (DGDA).
- 2.4.5 In all health facilities there should be a contingency plan for post vaccination emergency including maintaining an emergency response kit as per AEFI guidelines

2.5 Safe Injection and Waste Management

- 2.5.1 Poor injection practices put service recipients and service providers at risk of infection and/or blood-borne diseases including HIV, Hepatitis B and C. Poor sharps waste management is a risk for the general public and may also provide opportunities for unsafe reprocessing and repackaging of used disposable injection equipment.
- 2.5.2 Every health facility manager in public, private and NGO sector is responsible for ensuring safe and appropriate disposal of syringes, sharps and all injection related waste.
- 2.5.3 For immunization services, promotion of single-use injection equipment in public and private sectors will be promoted to ensure sterility and to improve the safety of injections.
- 2.5.4 Public, private and NGO health care services that provide injections have a responsibility to manage sharps waste in a way that is safe and environmentally friendly, using final disposal options that comply with environmental regulations.
- 2.5.5 Determination of the most appropriate method for the final disposal of syringes and sharps waste in a given health care facility or area will aligned the National Injection Safety Policy
- 2.5.6 The Ministry of Health and Family Welfare commits to resourcing the supply of quality safety injection and waste management equipment, and to implementing communication strategies for service providers and recipients in order to promote safe injection practices.

2.6 Private Sector Immunization

- 2.6.1 The National Immunization Policy aims to promote coordination between the government and private organizations in order to ensure effective, safe and quality immunizations services for all.
- 2.6.2 Vaccination services in the private sector should be provided by a trained service providers who meet the minimum qualifications and training requirements for a

- immunization service provider as specified in the guidelines and procedures of the Directorate-General of Health Services of the Ministry of Health and Family Welfare.
- 2.6.3 All vaccines provided through the private sector should be licensed through the Directorate General Drug Administration (DGDA)
 - 2.6.4 All vaccines for women and children administered within the private sector should be administered according to the Ministry of Health and Family Welfare recommended immunization schedule (age of administration, dosage, interval between doses, contraindications for administration)
 - 2.6.5 Policies and standards for cold chain, cold chain equipment and vaccine storage and safe injection practices (including waste management) in the private sector will conform to the same standards and practices as do apply for the public sector.
 - 2.6.6 Reporting requirements for the routine immunization schedule and for surveillance in the private sector will conform to the public sector policy guidelines for reporting.
 - 2.6.7 Use of vaccines outside the routine immunization schedule are permitted in the private sector, provided these vaccines are licensed and registered through the Directorate General Drug Administration (DGDA) and are administered according to WHO Guidelines.
 - 2.6.8 It is the responsibility of the public sector (through the relevant Local Authority) to ensure that private sector and NGO immunization practices conform to national immunization policy safety and quality standards.

2.7 Regulation and Procurement of Vaccines

- 2.7.1 All vaccines procured for use in Bangladesh for public, private and NGO sectors will be reviewed and recommended by the National Committee for Immunization Practice (NCIP), and will be endorsed by the Ministry of Health and Family Welfare
- 2.7.2 All vaccines procured for use in Bangladesh in both public and private sectors will be licensed and registered through the Directorate General of Drug Administration (DGDA) and will be procured from a manufacturer that is prequalified by the World Health Organization
- 2.7.3 It is the policy commitment of the Ministry of Health and Family Welfare to encourage the local production of vaccines that are licensed and registered through the DGDA and meet national and international standards for good manufacturing practice as assessed by the DGDA and the World Health Organization prequalification procedure. This is aligned with National Health Policy to encourage “local entrepreneurs to produce these items locally, which will help flourish and foster the state of local industry of the country.”
- 2.7.4 In the event of a public health emergency, the DGDA, based on the technical recommendation of the NCIP and the endorsement of the MOHFW, may waive the requirement for registration of a specific vaccine
- 2.7.5 In the case where vaccines have been approved for a clinical trial by the national Institutional Ethics Committee (The BMRC) there would be an exemption for requirement for registration of the vaccine through the DGDA.

3. VACCINES POLICY

3.1 Changing the Immunization Schedule

- 3.1.1 Changes to the routine Immunization schedule are technically reviewed and recommended by the National Committee on Immunization Practice (NCIP) and will be endorsed by the Ministry of Health and Family Welfare.
- 3.1.2 Changes will be based on updated research evidence of disease burden, vaccine efficacy, vaccine safety or program feasibility, as recommended by the National Committee on Immunization Practice (NCIP) and assessed by the Directorate-General of Drug Administration, based on information from the following sources:
 - 3.1.2.1 National vaccine trials, post marketing surveys and program evaluations
 - 3.1.2.2 The latest international evidence as reflected in updated WHO Position papers
- 3.1.3 The NCIP will make recommendations on the routine public sector national immunization schedule (“EPI Vaccines”) but will also consider making recommendations on vaccine schedules for additional vaccines provided through the private sector, NGOs or other departments (“Non-EPI Vaccines.”), with these recommendations based on the latest scientific evidence as indicated in the most recent WHO position papers.

3.2 Contraindications for Vaccination

- 3.2.1 Contraindications for vaccination should follow national immunization program guidelines and evidence from WHO Position Papers

3.3 Decision Making on Introduction of New Vaccines

- 3.3.1 The Process for Decision making on incorporating New Vaccines into the public sector routine immunization schedule will be according to the following systematic steps
 - 3.3.1.1 Assessment of burden of disease (through surveillance data, research study, disease burden estimates)
 - 3.3.1.2 Review of global recommendations and latest international evidence as described in the most recent WHO Position Papers on vaccine efficacy and safety
 - 3.3.1.3 Assessment of system readiness and programmatic feasibility to adopt the new vaccine into the national immunization schedule (cold chain capacity, surveillance capacity and safety requirements)
 - 3.3.1.4 Conducting of vaccine trials to test the efficacy and safety of the proposed new vaccine in the Bangladesh context in cases where there are questions raised concerning either efficacy or safety (as assessed by the NCIP or DGDA)
 - 3.3.1.5 Assessment of costs and financing gaps, and, where possible, economic impacts, including clearance by the Ministry of Finance
 - 3.3.1.6 Preparation of an introduction plan that includes a public communication strategy, preparation of service providers and plan for post marketing surveillance.
 - 3.3.1.7 Review of the above documentation by the National Committee for Immunization Practice (NCIP), DGDA and recommendation to the Ministry of Health and Family Welfare

3.3.1.8 Endorsement by the Ministry of Health and Family Welfare based on the NCIP / DGDA recommendation

4 VACCINE SECURITY

4.1 Sustainability of Financing of Vaccines

- 4.1.1 In line with national and international targets, the Ministry of Health and Family Welfare, in collaboration with development partners, will mobilize sufficient resources to extend immunization services to the wider population based on demonstrated public health need.
- 4.1.2 In line with the National Health Policy, this National Immunization Policy commits to increased government allocations for immunization services
- 4.1.3 Every application for new vaccine introduction will be carefully analysed in terms of costs, financing gaps, and government co financing requirements.
- 4.1.4 A decision to proceed with new vaccine introductions will always be accompanied by a clearance from the Ministry of Finance in terms of financial sustainability
- 4.1.5 The steps in this process should be carefully considered to ensure there is no conflict of interest in regard to decision making on new vaccine introduction

4.2 Security of Vaccine Supply

- 4.2.1 It is the policy of the Ministry of Health and Family Welfare to encourage the development of local vaccine production. In order to promote vaccine quality and safety of local production, the following policy directions will be undertaken:
 - 4.2.1.1 Local production of vaccines must meet the regulatory requirements (licensing and registration) of the Directorate General of Drug Administration.
 - 4.2.1.2 It is the policy aim of the Ministry of Health and Family Welfare that steps should be gradually undertaken to ensure that local production standards should meet international standards for good manufacturing practice (GMP) as guided by the WHO prequalification procedure.
 - 4.2.1.3 Unless decided by the MoHFW otherwise prior to vaccine introduction, it is the policy aim that vaccine trials should be conducted to assess the safety and efficacy of the vaccine in the epidemiological and program context of Bangladesh. Post marketing evaluation will also accompany any planned introduction.
 - 4.2.1.4 Vaccines procured for the routine immunization schedule in the public sector will be procured utilizing vaccine from production sources that have been licensed and registered by the DGDA as well as prequalified by the World Health Organization. In a step by step manner, and in order to harmonize the regulatory system, licensing and registration of these products will gradually come under the single regulatory umbrella of the Directorate General of Drug Administration.
 - 4.2.1.5 In certain circumstances, the DGDA may consider registration of vaccine products from manufacturers that are not WHO prequalified. These circumstances include the following (a) procurement of vaccines from a manufacturer in a country with a National Regulatory Authority that is recognized by the WHO as being fully functional (b) procurement of vaccines from a manufacturer in a country with an NRA with an

internationally established record for effective regulation of medical products (e.g. FDA in USA).

- 4.2.2 Please refer to section 2.7 (Regulation and Coordination) for further policy information relating to licensing and registration of local produced vaccine products).

5. IMMUNIZATION SERVICE DELIVERY POLICY

5.1 Rural Immunization Services

- 5.1.1 Vaccination services will be available at fixed facilities on all working days
- 5.1.2 Outreach services will be provided on a monthly basis in rural wards
- 5.1.3 Service providers for vaccination at rural wards will be designated by the MOHFW, and will include the Health Assistant and the Family Welfare Assistant.
- 5.1.4 Immunization contacts will be linked to other feasible service delivery provisions including birth registration, nutrition (screening for acute malnutrition and referral) to leverage the opportunity for delivery of integrated primary care services (this is equally applicable to urban services below)

5.2 Urban Immunization Services

- 5.2.1 Vaccination services will be available at fixed sites on all working days
- 5.2.2 Outreach services will be provided on a weekly basis in urban wards
- 5.2.3 Vaccination at urban wards is the primary responsibility of the Local Government through the appointed service provider of the City Corporation, Municipalities or NGOs.
- 5.2.4 Vaccination services provided through NGO sources will conform to the same cold chain vaccine management and injections safety policies as for the public sector elsewhere
- 5.2.5 NGOs will provide routine immunization reports and surveillance reports to the Ministry of Health and Family Welfare as outlined in Part 1 of this policy
- 5.2.6 It is the responsibility of Local Government (City Corporations and Municipalities) to mobilize human and financial resources to maintain immunizations services to national quality and safety policy and standards for the population within the administrative jurisdiction of the Local Government

5.3 Immunization Services for High Risk or Vulnerable Groups

- 5.3.1 In support of the equity and social justice principle, every Upazila Health complex in rural areas, and City Corporation or Municipality in the urban area, will have an annual immunization micro-plan identifying strategies and actions to reach hard to reach or underserved populations, as well as a system to monitor and take action on immunization drop out. This is aligned with the National Health Policy commitment to ensure a “proper safety net for the poor, vulnerable, and marginalized people.”
- 5.3.2 It is the policy of the Ministry of Health and Family Welfare to implement a system of travelers vaccination check to all Haj Pilgrims
- 5.3.3 It is the policy commitment of the Ministry of Health and Family Welfare to extend the services for travelers vaccinations to all international migrant workers
- 5.3.4 It is the policy commitment of the Ministry of Health and Family Welfare, dependent on the availability of resources, to extend opportunity for seasonal influenza vaccinations and other vaccinations against vaccine preventable diseases for identified high risk population groups, including those with chronic illnesses and older age groups.
- 5.3.5 It is the policy of the Ministry of Health and Family Welfare to implement a system of travelers vaccination check for different vaccine preventable diseases for all Haj Pilgrims, in bound migrants and other target groups at international check posts

5.4 Immunization Campaigns

- 5.4.1 In order to support disease eradication and elimination objectives, the Ministry of Health and Family Welfare will implement mass campaigns as indicated as a strategy that is supplementary to routine immunization programme activity (eg. for polio, measles, rubella and tetanus)
- 5.4.2 Measures should be taken to ensure adequate post marketing research is implemented to assess safety and efficacy of vaccines, as well as to confirm campaign coverage rates.
- 5.4.3 The Ministry of Health and Welfare will implement campaign strategies as indicated in the context of pandemic response or in the context of natural disasters

5.5 Immunization in Educational Institutions

- 5.5.1 Immunization Services for educational institutions (both public and private) will be developed in order to extend the benefits of immunization to children of all educational institutions and to protect the population from additional vaccine preventable diseases.
- 5.5.2 Based on coordination with the local health and education sector, each educational institution will check the vaccination card of each child prior to his/her enrollment.
- 5.5.3 The Ministry of Health and Family Welfare will collaborate closely with the Ministry of Education, Ministry of Primary and Mass Education in order to introduce immunization services into Educational Institutions, and provide the necessary information, education and communication materials for teachers, students and parents to support educational institution based immunization activities.
- 5.5.4 Information and education materials for immunization in educational institutions will include information on the immunization schedule, the diseases prevented by immunization and the benefits of immunization. Information will also be provided on adverse events following immunization, including the standard procedures and protocols for responding to such events

5.6 Hospital/Health Facility Based Immunization Services

- 5.6.1 In response to the increased rate of delivery at hospitals/ health facility in recent years, it is now important to consider improvement to the quality and safety of immunization services in hospital/health facility settings to ensure timely administration of vaccines to women and children.
- 5.6.2 Hospitals at primary, secondary and tertiary level (including private sector facilities) will need to consider appointment of a designated trained person for vaccination, and ensure that cold chain, injection safety and reporting and surveillance procedures meet the standards of the Ministry of Health and Family Welfare as outlined elsewhere in this policy document.

5.7 Advocacy, Communication, Demand Creation and Client Rights

- 5.7.1 The Ministry of Health and Family Welfare, through the departments responsible for immunization in Bangladesh and other immunization partners, will develop and implement a public communication strategy to inform clients about vaccine preventable diseases, the benefits of immunization as well as address safety concerns.
- 5.7.2 The Ministry of Health and Family Welfare, through its implementing and collaborating departments and partners including the Ministry of Education, Ministry of Primary and Mass Education, Ministry of Local Government Rural Development & Cooperatives (LGRD&C), Ministry of Religious Affairs and Ministry of Women and Children Affairs, Ministry of Social Welfare and taking into account the significant changes in social and

communications context in Bangladesh, will explore new opportunities for communication about immunization through the educational curriculum and the mass media, for routine immunization and for introduction of new vaccines, and will establish functional inter-ministerial coordination mechanisms to address these issues.

- 5.7.3 All health facilities and partners will develop local area strategies and community based initiatives using different communication for development approaches to increase knowledge of, and demand for, immunization services for unreached or vulnerable groups in rural and urban locations.
- 5.7.4 It is the policy commitment of the MoHFW to engage man folk, religious leaders, local opinion leaders and senior members of family to extend their support for completion of immunization and for reaching the target population
- 5.7.5 Social research will be conducted in order to identify the correct content and marketing strategy for communicating public information about immunization, particularly for high risk or unreached population groups.
- 5.7.6 The Ministry of Health and Welfare will ensure that service providers in public, private and NGO sectors protect and promote client rights through:
 - 5.7.5.1. Ensuring access to immunization regardless of geographic location, gender, income level, religious belief or ethnic background
 - 5.7.5.2. Ensure all clients have been provided information on the benefits of vaccination, the diseases which from vaccination protects, the side effects of vaccination, and when to return for the next vaccination
 - 5.7.5.3. Ensure that verbal consent is obtained for vaccination, including verbal consent from parents or guardians for vaccination of children.

5.8 Policy on Gender and Immunization

- 5.8.1 The gender and immunization policy states that sex disaggregated data should be routinely collected through administrative data collection systems and through annual coverage surveys
- 5.8.2 Gender barriers to Immunization should be researched through programs of social research that identifies the gender based barriers to immunization services for both boys and girls.
- 5.8.3 Relevant program interventions should be designed to address these barriers.

5.9 Policy on User Fees for Immunization

- 5.9.1 Immunization services are provided free of charge in the public sector. This is in support of the overall national health policy direction for universal health coverage
- 5.9.2 In cases where the private sector obtains vaccine from government authorities for implementation of the routine immunization schedule, the recipient should not be charged for the vaccine as well as for the immunization service.
- 5.9.3 As per sub article 2.1.4, the prices of vaccines in the private market will come under the regulatory control of the Directorate-General of Drug Administration.

Conclusion

The National Immunization Policy will be reviewed on a five yearly basis or on an as needs basis by the National Committee on Immunization Practice and the Ministry of Health and Family Welfare and other stakeholders, taking into account developments in social, economic, health systems and epidemiological context nationally, as well as in response to trends in immunization and vaccine development internationally.