NATIONAL STRATEGY FOR INTEGRATING POST-VACCINATION VIGILANCE 2025 (NSIPV 2025)

Directorate General of Drug Administration (DGDA)
Mohakhali, Dhaka - 1212

Health Services Division
Ministry of Health and Family Welfare
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PREFACE

The enhancement of healthcare systems, particularly in the domains of immunization and vaccine safety, remains a fundamental priority in the pursuit of national public health advancement. Within this framework, the National Strategy for Integrating Post Vaccination Vigilance-2025 represents a pivotal initiative aimed at safeguarding the health and well-being of the population during the critical post-vaccination period.

This strategic document is anchored in two core principles: integration and vigilance. These concepts constitute the foundation of a contemporary, responsive, and sustainable safety surveillance system. Integration highlights the imperative for coordinated action among all stakeholders, ensuring the alignment of data, resources, and expertise across sectors. Vigilance emphasizes the necessity of continuous, proactive monitoring to promptly identify, evaluate, and respond to adverse events following immunization (AEFIs).

The relevance of an integrated post-vaccination vigilance system has been increasingly recognized at both global and national levels, particularly in the wake of recent public health emergencies. A robust safety surveillance infrastructure not only serves to protect public health but also plays a crucial role in maintaining public trust in immunization programs.

The National Strategy delineates a structured, phased approach to institutionalizing vigilance within all tiers of the health system. It promotes active collaboration among national regulatory authorities, immunization programs, healthcare providers, academic institutions, and community stakeholders. Furthermore, it underscores the critical role of technology and data-driven methodologies in strengthening the early detection, reporting, and management of vaccine safety concerns.

Acknowledgment is due to the diverse group of partners, subject matter experts, and stakeholders whose invaluable contributions have shaped the development of this strategy. Their collective expertise and commitment ensure that this document is not merely a procedural guideline but a catalyst for fostering a safer, more resilient vaccination ecosystem.

As the Director General of the Directorate General of Drug Administration, it is with great honor that I present this strategy. I urge all stakeholders to join in its implementation with unwavering commitment. Through the principles of vigilance, integration, and collective action, we shall continue to uphold and advance the highest standards of vaccine safety for the benefit of all.

Major General Md. Shameem Haidar
Director General
Directorate General of Drug Administration (DGDA)
Ministry of Health and Family Welfare
Government of the People's Republic of Bangladesh

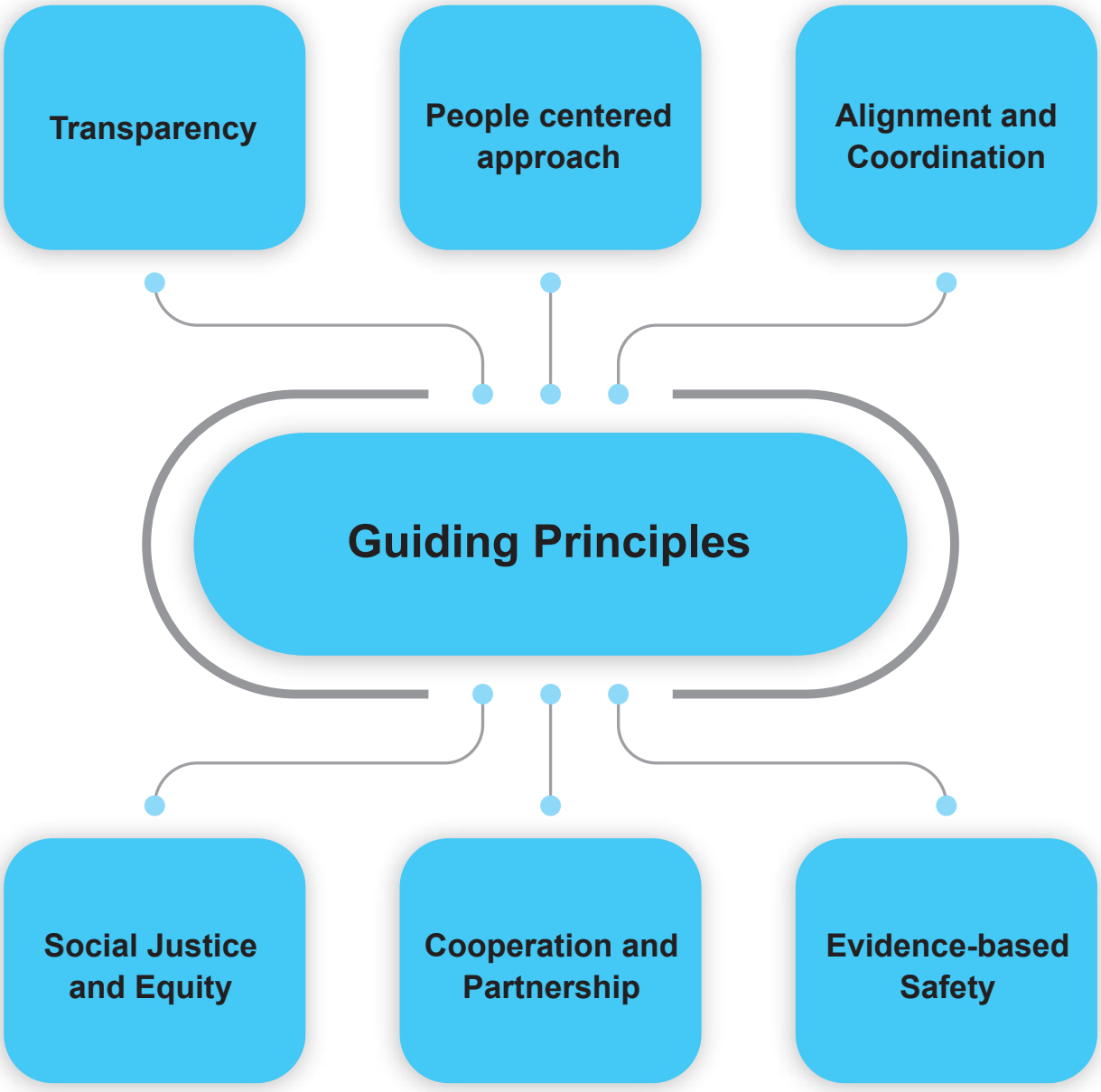
LIST OF ABBREVIATIONS

ADE	Adverse Drug Event
ADR	Adverse Drug Reaction
ADRAC	Adverse Drug Reaction Advisory Committee
ADRM	Adverse Drug Reaction Monitoring
AEFI	Adverse Event Following Immunization
AEFI-NEPIV	Adverse Event Following Immunization-Non EPI Vaccines
APR	Annual Program Review
BCG	Bacillus Calmette-Guerin
BCDS	Bangladesh Chemist and Druggist Samity
BDHS	Bangladesh Demographic & Health Survey
BHFS	Bangladesh Health Facility Survey
BHP	BRAC Health Programme
BMET	Bureau of Manpower, Employment and Training
BRAC	Bangladesh Rural Advancement Committee
CA	Causality Assessment
CDC	Communicable Disease Control
CEO	Chief Executive Officer
CPH	Central Police Hospital
CRM	Cross-Reacting Material
DGDA	Directorate General of Drug Administration
DGFP	Directorate General of Family Planning
DGHS	Directorate General of Health Services
DGME	Directorate General of Medical Education
DGMS	Directorate General of Medical Services
DGNM	Directorate General of Nursing and Midwifery
DHIS2	District Health Information Software 2
DNA	Deoxyribonucleic Acid
DNCC	Dhaka North City Corporation
DSCC	Dhaka South City Corporation
DPT	Diphtheria- Pertussis- Tetanus
EPI	Expanded Programme on Immunization

GAVI	Global Alliance for Vaccines and Immunization
GBT	Global Benchmarking Tool
GxP	Good x Practice
HIV	Human Immunodeficiency Virus
HPNSPs	Health, Population and Nutrition Sector Programs
HPV	Human Papilloma Virus
HR	Human Resources
HRH	Human Resources for Health
HWF	Health Workforce
ICT	Information and Communication Technology
ICSR	Individual Case Safety Reports
IPV	Inactivated Polio Vaccine
KPI	Key Performance Indicator
LGRD	Local Government and Rural Development
LoI	Letters of Intent
MIS	Management Information Systems
MMR	Measles-Mumps-Rubella Vaccine
MNC&AH	Maternal Neonatal Child and Adolescent Health
MOHFW	Ministry of Health & Family Welfare
MoU	Memorandam of Understanding
MoV	Means of Verification
MR	Measles-Rubella Vaccine
MSB	Marie Stopes Bangladesh
MTR	Mid-Term Review
NEPIVs	Non-EPI Vaccines
NEPIV-AEFI	Non EPI Vaccines - Adverse Event Following Immunization
NEPIV-SSS	Non-EPI Vaccines Safety Surveillance Strategy
NGO	Non-Government Organization
NIP	National Immunization Program
NIPORT	National Institute of Population Research and Training
NPC	National Pharmacovigilance Centre
NSIPV	National Strategy for Integrating Post-Vaccination Vigilance
OPs	Operational Plans
OPV	Oral Polio Vaccine

PA	Protective Antigen
PAP	Priority Action Plan
PCV	Pneumococcal Conjugate Vaccine
PIDM	Programme for International Drug Monitoring
PV	Pharmacovigilance
PVV	Post-Vaccination Vigilance
Q&A	Question and Answer
RABIVAX	Rabies Vaccine
rDNA	Recombinant DNA
ROTATEQ	Rotavirus Vaccine
SDG	Sustainable Development Goal
SEARN	South-East Asia Regulatory Network
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
SOP	Standard Operating Procedure
TG3	Technical Group 3
TTVax	Tetanus Toxoid Vaccine
UHC	Universal Health Coverage
UMC	Uppsala Monitoring Centre
USAID	United States Agency for International Development
WG3	Working Group 3
WHA	World Health Assembly
WHO	World Health Organization
WHO-CCs	WHO Collaborating Centres

GUIDING PRINCIPLES



GOAL

To promote a stronger public health system through integration of the post-immunization vigilance-related initiatives on vaccine safety as undertaken by relevant stakeholders in bangladesh

STRATEGIC ACTIONS

Strategic Action 1: **Address the systemic issues through revisiting and aligning policies, rules and regulatory frameworks relevant to post-vaccination vigilance issues and improve/create the environment for optimum coordination.**

- Review the legislative and regulatory frameworks of the regulatory agencies and other Stakeholders as relevant to the safety vigilance after immunization.
- Suggest, if necessary, the modification of existing legislative and regulatory measures to improve safety vigilance after immunization.
- Suggest, if necessary, the introduction of new legislative and/or regulatory measures to improve safety vigilance after immunization.
- Take steps for the modification of the existing or introduction of new legislative and/or regulatory measures and administrative steps, as appropriate.
- Enhance the implementation of the relevant acts by framing the rules and regulations as related to safety vigilance after immunization.
- Improve/create a comprehensive policy environment for optimum coordination.

Strategic Action 2: **Develop the normative aspects such as shared values, culture and vision across organizations, professional groups and individuals regarding post-immunization safety surveillance issues.**

- Sensitize relevant policy makers, Planners, and Senior Administrators through advocacy initiatives.
- Initiate large-scale awareness campaigns, involving service users and the wider community, using mass media, social media and community-oriented activities.
- Generate awareness and motivation among service Providers (like Physicians, Nurses, Pharmacists, and Community Health Workers) and using effective tools and channels.
- Generate awareness and motivation regarding post-vaccination vigilance integration among Manufacturers, Importers, Distributors and Retailers.
- Develop common integration goals among the stakeholders.
- Identify and address communication gaps among stakeholders.
- Build immunization service relationships and trust through local events.
- Involve service users and the wider community.

Strategic Action 3: **Coordinate structures, governance systems and relationships across stakeholders.**

- Develop formal and informal contractual or cooperative service commissioning arrangements among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.
- Develop formal and informal contractual or cooperative arrangements among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.
- Develop umbrella organizational structures such as federations or local partnerships for post-immunization safety surveillance reporting.

Strategic Action 4: **Address administrative issues through the alignment of methodology and tools, back-office functions, budgets and financial systems across integrating units.**

- Develop shared information systems among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.
- Develop shared accountability mechanisms among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.
- Develop shared funding processes among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

Strategic Action 5: **Generate and improve the methodology and tools related to AEFI reporting of vaccines.**

- Review the existing reporting Forms with input from the various stakeholders.
- Redesign, if necessary, the Forms with special reference to user-friendliness.
- Design, if necessary, new Forms with special reference to user-friendliness.
- Design short and simple Forms, as much as possible, without compromising the quality.
- Use (as much as feasible in the Bangladesh context) the digital channels (eg. Apps in mobile phones) for the integration of post-immunization vigilance.
- Create databases for cumulating the AEFI reports at various levels.

Strategic Action 6: **Incorporate integrated post-vaccination vigilance related contents in the course-curricula and syllabi of the relevant professional education/training programs.**

- Create content and educational materials related to post-immunization vaccine vigilance for providing education and training to students from relevant levels and disciplines.
- Take organized initiatives to incorporate post-immunization vaccine vigilance-related contents in the course curricula and syllabi of the educational and training programs.
- Review the impact of education and training-related reforms on post-immunization vaccine vigilance.

Strategic Action 7: **Strengthen research activities on post-immunization vaccine vigilance.**

- Identify priority areas and projects for research activities on consultation with various stakeholders.
- Develop coordinated mechanisms to promote research in the prioritized fields.
- Create a pool fund to support research in the selected areas.

Strategic Action 8: **Build the capacity of the relevant stakeholders in the area of post-immunization vaccine vigilance.**

- Strengthen the PV Cell of DGDA with relevant inputs on physical infrastructure and human resources.
- Explore the existing potential infrastructure/facilities for their probable incorporation in post-immunization vaccine vigilance.
- Encourage suppliers to take ownership of their capacity building efforts.
- Develop training programs with customized course-curricula and training materials for specific groups of professionals from the relevant stakeholders.
- Arrange regularly the Fresher as well as follow-up training programs for the relevant professionals.
- Enhance the ICT infrastructure to use the digital tools and channels for conducting relevant activities like advocacy/awareness, reporting, education, training, and research.

1. BACKGROUND

A strategic approach towards integrated safety surveillance during post-vaccination periods revolves around two basic concepts namely integration and vigilance, which are now widely discussed issues in discussions related to health system development.

1.1 INTEGRATION

There is not yet any universally agreed definition of health system integration. Usually, 'Integration' is used as a term interconnected with 'integrated care' which, in the healthcare sector, means that planners and providers of services must 'impose the patient perspective as the organizing principle of service delivery' (Lloyd and Wait, 2005). Integration is the processes, methods and tools of integration that facilitate integrated care. Integration involves connecting the health care system (acute, community and primary medical) with other service systems (such as long-term care, education, or housing services) (Leutz, 1999). A focus on integrated care can help policy-makers, managers and practitioners decide on the model of care they wish to develop. They can draw upon a combination of processes and mechanisms that enable integrated care to develop. The term 'integrative processes' provides a link between the concept of integrated care (in terms of the ambition to deliver services across providers with minimal duplication and disruption, and with high-quality outcomes and patient experience) and the concept of integration (in terms of the methods and approaches used to align goals across professional groups, teams and organizations).

Five main types of integration are typically found in literature:

i. ***Systemic:*** This integration involves the coordination and alignment of policies, rules and regulatory frameworks;

ii. ***Normative:*** The normative integration involves the development of shared values, culture and vision across organizations, professional groups and individuals;

iii. ***Organizational:*** This signifies the coordination of structures, governance systems and relationships across organizations;

iv. ***Administrative:*** This integration involves the alignment of back-office functions, budgets and financial systems across integrating units; and

v. ***Clinical:*** The clinical integration includes the coordination of information and services and the integration of patient care within a single process.

Horizontal and vertical integration: Horizontal integration focuses on competing or collaborating organizations, networks or groups in the health economy and might involve, for instance, grouping outpatient clinics within a geographic network of providers. Vertical integration focuses on networks and groups at different stages of care within the health economy (what some commentators refer to as the supply chain

or care pathway) and might involve, for instance, the drawing together of a hospital with local community services.

1.2 VIGILANCE

1.2.1 Vigilance and surveillance: The understanding, detection, assessment, and prevention of adverse effects or any other possible medical product-related problems require a scientific approach leading to appropriate actions. The term 'Vigilance' (or more specifically 'Pharmacovigilance') refers to both the science and activities relating to this approach. The task of vigilance does not end at this point. Ventilation of authoritative information, regarding the safety of medical products, to general people and relevant stakeholders, is also part of an effective vigilance system. Two closely related concepts are also referred to by WHO in this regard: Market surveillance and Post-market surveillance.

Market surveillance: The Regulatory Authorities (or Competent Authorities) carry out certain activities and undertake some measures to check and ensure that a medical product (such as drug, vaccine, device, and in vitro diagnostics) complies with the requirements set out in the relevant legislation and does not endanger health, safety or any other aspect of public interest protection. These activities and measures, together, are termed market surveillance. The objective of market surveillance (and hence control function) is to ensure compliance of the products placed on the market with pre-set criteria for quality, safety and efficacy (i.e., verify compliance with marketing authorization and GXP guidelines). Accordingly, market surveillance and control functions play a crucial role in assuring medical products consumer safety. There are four major themes in market surveillance and control function activities: (1) control of import activities, (2) prevention and detection of and response to substandard and falsified medical products, (3) market surveillance program for monitoring the quality of medical products throughout the supply chain, and (4) control of promotional, marketing and advertising activities. The aforementioned activities may or may not be undertaken by a single entity (e.g., organization, division, or department) (WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products, Revision VI).

Post market surveillance: After the marketing of a medical product, the Manufacturer or its downward Agencies (such as Importer and Authorized Distributor) systemically collect and analyze the experience gained from these products. This systemic process is termed as the Post Market Surveillance.

1.2.2 Stakeholders in vigilance: As stated above, vigilance is closely related to surveillance systems which involve complex sets of actors, settings, and processes. The actors include regulators, program managers, healthcare professionals, experts, patients and manufacturers. The development of vigilance has often been associated with public health programs in the SEARN region where the member countries include Bangladesh, Bhutan, the Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Sri Lanka, Nepal, Thailand and Timor-Leste. Under this context, a Stakeholder is defined as an individual, group or organization that has an interest in the

organization and delivery of health care (WHO Global Benchmarking Tool (GBT) for Evaluation of National Regulatory System of Medical Products, Revision VI).

SEARN has acknowledged the diversity of vigilance regulatory systems within and between the Member States and it has also acknowledged that there may be variations in the number, type, and responsibilities of the different stakeholders. With an understanding of these limitations, it has identified the main Stakeholders of the Vigilance of Regulatory Systems. Based on the scope and objectives of vigilance integration, the Actors have been classified as follows: i. Critical stakeholders for vigilance integration; ii. Regional and national vigilance centers; iii. National regulatory authorities; iv. Public health programmes (e.g. Tuberculosis, Malaria, HIV, etc.) and immunization programmes at all geographic levels; v. Manufacturers, marketing authorization holders, other economic operators (e.g. importers, wholesalers, authorized representatives, etc.); and vi. National Control laboratory. Among the group of critical stakeholders the following names have been mentioned: National Regulatory authorities, National and regional vigilance centers, Public health programmes (e.g. Tuberculosis, Malaria, HIV, etc.) and immunization programmes at all geographic levels, Manufacturers, marketing authorization holders, other economic operators (e.g. importers, wholesalers, authorized representatives, etc.), National control laboratory, and other important stakeholders (Patients, caretakers, users, healthcare professionals, allied professions, and Media).

SEARN has also identified some other stakeholders that may be considered for vigilance integration (opportunity). Those are as follows: Clinical centers of excellence, clinical research organizations, universities, other departments of the Ministry of Health, Center for traditional medicine, Hospital safety committees, Poison control centers, Patients and consumer associations, Professional associations (e.g. medical doctors, pharmacists, nurses, etc.), Relevant Non-Governmental Organizations, and Donors.

One group of important actors in vigilance integration are the international stakeholders. It is usually assumed that the safety concerns observed in one population may happen in other populations unless demonstrated otherwise. This assumption is the driver of international and regional vigilance integration. The power of pharmacovigilance is greatly enhanced by a larger population achieved through inter-country collaboration. Accordingly, multi-country aggregation of data is a useful tool to increase the chances of detecting issues relevant to all countries. The effective risk minimization measures and other relevant steps in one country may greatly benefit from the experience of other countries.

The WHO Programme for International Drug Monitoring (PIDM) is the global vigilance platform to share the vision of safer use of medicinal products. Through sharing ICSR for medicinal products into the WHO global database of reported adverse events (VigiBase), this platform (and some other similar platforms) aims for international integration of vigilance. Following a data access policy, the PIDM Members, WHO and the WHO Collaborating Centres (WHO-CCs) may access the shared ICSRs. The dissemination of the analysis outputs may be done through different channels such as the periodic WHO Pharmaceutical Newsletters. The WHO Collaborating Centre for

International Drug Monitoring (UMC) supports the analysis. Regional networks, such as SEARN, may also offer a platform for the integration of vigilance.

1.2.3 Vigilance integration: As mentioned previously there is no widely accepted definition of health system integration (and no definition of vigilance integration). It generally intends to put the needs of the patient or the population at the center ((Lloyd and Wait, 2005; Dawda, 2019). This principle opposes fragmentation and aims at creating coherence, cooperation, coordination, and information sharing.

With the large number of stakeholders involved in vigilance activities, it is obvious that an integration process is central to the coordinated functioning of these multiple stakeholders. Coordination in this context means the act of making all the people involved in a plan or activity work together in an organized way.

1.2.4 Benefits of integration: Through the process of vigilance integration the Stakeholders are benefitted in many ways. Accessing required information, avoidance of redundancy, and optimization of the decision-making process are greatly facilitated by integrated vigilance. An important outcome is the facilitation of safety signal detection and an increase in the probability of detecting rare adverse reactions from larger data. Isolated collection and analysis of safety information within each stakeholder may limit the detection of safety signals of medicines and vaccines due to an insufficient quantity of data. Collaborating and gathering information by the stakeholders in a coordinated manner greatly facilitates signal detection. Also, some of the stakeholders may have limited capacity to perform core vigilance activities. They may take advantage of vigilance integration. Examples of such collaboration include human resources, financial support, and training.

1.2.5 Initiatives by SEARN: SEARN fully acknowledges the importance of vigilance integration as well as the need for customization of such integration based on individual country's perspectives. Accordingly, on 8 June 2022, the Assembly of SEARN adopted the SEARN Work Plan 2022-2023 (SEARN, 2022). In that Work Plan, Action point 11 [led by Working Group 3 (WG3)] recommends the following on the issue of Vigilance: ‘Draft a strategy to support integration of vigilance’. Accordingly, every member country should develop Vigilance Strategies in the relevant areas of Pharmacovigilance. In the context of the great public health concern regarding vaccination, the development of post-immunization vigilance strategy is an important task for the health sector.

In Action Point 11, certain challenges to integration were identified and some practical solutions were suggested. The challenges at the subnational level were lack of time or motivation of staff, lack of awareness and information, and inadequate tools. The practical solutions at this level included advocacy and training; inclusion in Guidelines, SOPs, templates, and KPIs; regular meetings and feedback; and convergence and/or development of tools, or facilitation of mutual access to existing tools and communication platforms. At the national level, the challenges include organization mandate (e.g. another department/ministry/organization), differences in culture/ practice, legal concerns on confidentiality of the data, concern about the perception from the public, and lack of awareness and information. The practical solutions are suggested as advocacy, meetings, MoU or decision from a higher authority after agreement between the organizations;

mutual information through communication; participation in respective committees/ working groups, engagement in revised documents/policies, regular or thematic meetings; long-term work towards convergence; reviewing the legal responsibilities of the different actors; requesting clarification from the relevant legal department as needed; informing data holders regarding how their data may be used; if applicable, considering a change in legal provisions; communication: e.g. explain why integration is important to protect public health on the website, develop a Q & A, etc; advocacy and training; and inclusion in Guidelines, SOPs, templates, and KPIs Regular meetings and feedback. The Action Point also identified two challenges at the regional/international levels which are as follows: differences in culture/practice, lack of information, and legal uncertainty. The practical solutions at these levels were suggested as mutual information through communication, participation in regional/international committees/working groups, engagement in revised documents/policies; long-term work toward convergence; requesting clarification from the relevant legal department as needed; consider an MoU; and if applicable, consider a change in legal provisions.

2. IMMUNIZATION AND PHARMACOVIGILANCE: THE BANGLADESH CONTEXT

2.1 SUCCESS STORY OF IMMUNIZATION IN BANGLADESH

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 the introduction of new vaccines and medical technologies in the 2000s. Since the introduction of EPI, the country made outstanding progress in implementing the program and it became one of the first countries to eradicate smallpox and polio. Presently, 10 vaccines are provided through the program with universal free access (Table 1). A few of these vaccines are also available as non-EPI vaccines, both in the public sector and private sector facilities. There are other non-EPI vaccines (Table 2 and Table 3) that are delivered by both public and private sectors. Meanwhile, the Department for Communicable Disease Control (CDC), under the Directorate General of Health Services (DGHS) implements immunization programs for rabies control as well as provides opportunities for vaccination for travelers. The Department has also played a central role in coordinating pandemic influenza disease prevention and control responses. Other public sector agencies under the Ministry of Local Government and Rural Development (LGRD). Ministry of Defense and Ministry of Home Affairs are also contributing in the immunization initiatives substantially. Additionally, there is an emerging private medical sector and an active NGO sector which provides additional opportunities for the provision of immunization services to the population.

2.2 FUTURE DIRECTIONS IN IMMUNIZATION

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 'Era 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 (MoHFW).

2.3 PHARMACOVIGILANCE IN BANGLADESH

In Bangladesh, Pharmacovigilance (PV) was introduced in 1999 with the formation of an Adverse Drug Reaction (ADR) Monitoring Cell by the then Directorate of Drug Administration. An ADR reporting form which was distributed to approximately 8 medical college hospitals. Seminars and workshops were also organized. Because of a shortage of

manpower and required funds and also the unwillingness of the healthcare professionals, the ADRM cell and its program became dormant in the following years. Realizing the importance of drug safety, the activities of the ADRM Cell was revitalized with technical assistance from the USAID-funded SIAPS Program. The MoHFW declared the DGDA as the National Pharmacovigilance Centre (NPC) for Bangladesh, with the ADRM cell overseeing the center's activities. The MoHFW also revived the Adverse Drug Reaction Advisory Committee (ADRAC) to work in conjunction with the ADRM cell to provide technical guidance for implementing PV activities; evaluate Adverse Drug Event (ADE) reports; and make recommendations for regulatory decisions to the DGDA, the country's licensing authority for drugs [3]. For operationalizing the system, the National Guideline on the Pharmacovigilance System in Bangladesh, 2023 deliver a basic agenda for the responsibilities and activities of the Cell. The collection, assessment, understanding and reporting of the safety data of the pharmaceutical products are detailed in the Guidelines which help in the prevention of medication-related problems. The guidelines are expected to ensure uniformity in the execution of safety and effectiveness monitoring activities of pharmaceuticals and other health products in Bangladesh.

2.4 PHARMACOVIGILANCE OF VACCINES IN BANGLADESH

There is no dedicated special Unit for PV of vaccines within the ADRM cell in the DGDA. Specific officials and staff within the ADRM cell are assigned with the duties of collecting and analyzing adverse events following immunization (AEFI) data from the field and keeping the records as well as passing the observations to the relevant authorities. The officials/ staff in the divisional/ district levels also work with such a mixed responsibility. There is a specified Form for this purpose and the reports are still physically collected and maintained. Analyzed reports are transmitted by email and also manually.

The principal source of data for AEFI reporting is EPI operating under DGHS-MOHFW. The program has its own AEFI reporting arrangements and an expert committee is responsible for evaluating the reports. Apart from the vaccines reserved for EPI itself, the program deals with some additional vaccines (like tetanus) which are also available through other public or private sector providers. These are termed as non-EPI vaccines and the AEFI reports are processed by EPI in the same manner. The ADRM-DGDA receives a cumulated version of the EPI report. The list of vaccines presently provided by EPI is provided in Table 1.

Table 1: Vaccines included in the EPI Program of Bangladesh

Vaccine	Disease
BCG	Tuberculosis
Pentavalent	Diphtheria, Pertussis, Tetanus, Hepatitis B, Haemophilus influenza type-B
PCV	Pneumococcal Pneumonia
OPV, IPV	Poliomyelitis
MR	Measles-Rubella
Td	Tetanus, Diphtheria
HPV	Cervical cancer

Another important source of the reports is the Communicable Disease Control (CDC) which also operates under the DGHS. The Centre is responsible for the Rabies vaccine as well as vaccines for travelers and emergency situations.

Apart from the EPI vaccines, there is a growing number of non-EPI vaccines which are offered by a number of public and private (for-profit as well as not-for-profit) providers. The list of the non-EPI vaccines presently manufactured in Bangladesh are given in Table 2 and the list of the imported non-EPI vaccines is provided in Table 3. So far, the AEFI reporting system for these vaccines has remained at a preliminary stage. There are only a scarce number of reports and a diversity of sources is almost absent.

The major players (DGDA, DGHS, EPI and CDC) are under the Ministry of Health and Family Welfare (MOHFW). Few other agencies/organizations in the public sector, outside the MoHFW, are involved in delivering immunization services in various ways and on diverse scales. One of the major vaccination providers in urban areas of the country are the City corporations and Municipalities which are under the Ministry of Local Government and Rural Development (LGRD). These organizations operate the immunization program (mainly based on EPI) through the Urban Primary Healthcare Project (at the Urban Health Centres) with support from the Development Partners and the actual services are usually contracted out to selected Non-Government Organizations (NGOs). Among the direct providers of immunization services (both EPI and non-EPI), the Ministry of Defense is an important one that operates through its fairly large chain of hospitals and clinics. Presently, the chain is providing EPI services in selected facilities with supply and support from the City Corporations. Apart from EPI, only booster dose of Td is provided in those facilities. Potentially, these chain of facilities may be utilized for both EPI and Non-EPI vaccination programs on a larger scale and thus their role in post-vaccination vigilance may be increased. The Police Hospital/Clinic Chain (under the Ministry of Home Affairs) are also providers of these services. Again, the services are mostly limited to EPI vaccines; however, the hidden capacity may be utilized to expand the services further in both EPI and Non-EPI areas as well as in post-vaccination vigilance. Major Railway Hospitals (under the Ministry of Railway) provided EPI vaccination services earlier. Presently, these hospitals are not providing vaccination services due to HR limitations; however, with quite large physical infrastructures, they may be potential partners in future.

Apart from the public sector agencies and organizations, private sector players are playing an increasing role in the delivery of immunization services. The non-profit organizations (many of those registered as NGOs) have so far played a major role in this area; gradually for-profit organizations are becoming important providers of vaccination, especially for non-EPI vaccines. The chain of Marie-Stopes Clinics is one of the most potential Partners in this respect. Another highly potential collaborating partner in the integration plan is the BRAC health program, The program is not directly involved as a provider of vaccination (except during the COVID-19 pandemic), but they have a large community healthcare network in Bangladesh which is actively involved in disease surveillance and patient as well as community awareness activities. The expertise, experience and capacity of the program may be utilized to enhance AEFI reporting as well as in the integrating process of the post-vaccination vigilance.

A suggested List of the Stakeholders for post-vaccination vigilance integration is provided in Table 1. More comprehensive stakeholder-wise elaborations, along with the present status and future potential of integration, are provided in Annexure 1.

Table 2: Locally produced/registered Non -EPI Vaccines in Bangladesh

Sl	Manufacturer	Trade Name	Generic Name
1	Incepta Pharmaceuticals Ltd	Vaxphoid Vaccine	Typhoid Polysaccharide Vaccine
2		Hepa-B Vaccine (For Adult)	Hepatitis B Vaccine (rDNA)
3		Hepa-B Vaccine (For Paediatric)	Hepatitis B Vaccine (rDNA)
4		Vaxitet Vaccine	Adsorbed Tetanus Vaccine
5		Ingovax ACWY Vaccine (0.5ml)	Meningococcal Polysaccharide Vaccine
6		Rabix – VC Vaccine	Rabies vaccine (Human)
7		Influvax Vaccine.	Inactivated Influenza Vaccine
8		Rubavax M Vaccine	Measles and Rubella vaccine
9		Ingovax ACWY Vaccine 5ML	Meningococcal Polysaccharide Vaccine
10		PrevaHAV Vaccine (For Adult)	Inactivated Hepatitis A Vaccine
11		PrevaHAV Vaccine (For Pediatric)	Inactivated Hepatitis A Vaccine
12		Varizost Vaccine	Varicella vaccine (Live, attenuated)
13		Cholvax Vaccine	Inactivated Oral Cholera Vaccine
14		Influvax Tetra Vaccine	Inactivated Influenza Vaccine (Quadrivalent)
15		Papilovax Vaccine	Human 1nfluenza1irus bi valent
16		Prenovax 23 Vaccine	Pneumococcal Polysaccharide vaccine 23 serotype
17		Evimar 13 Vaccine	Pneumococcal Polysaccharide conjugate vaccine (13 serotypes: 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F)
18	Popular Pharmaceuticals Ltd	TTVax Injection	Tetanus Toxoid Vaccine
19		Hepavax-B Injection	Hepatitis B Vaccine (r DNA)
20		Hepavax-B Injection	Hepatitis B Vaccine (r DNA)
21		RABIVAX injection	Rabies Vaccine (Purified Vero cell Rabies vaccine as Inactivated & Purified Rabies Antigen Concentrate)
22		HPVax Injection	Recombinant Human Papillomavirus Vaccine (Types 16, 18)

Sl	Manufacturer	Trade Name	Generic Name
23	Healthcare Pharmaceuticals Ltd.	Mvax ACYW Injection	Meningococcal Polysaccharide Vaccine
24		Teta-fix 0.5 ml vaccine	Adsorbed Tetanus Toxoid
25		HB-fix 10 Vaccine	Hepatitis B Vaccine (rDNA)
26		HB-fix 20 Vaccine	Hepatitis B Vaccine (rDNA)

Table 3: Imported Non-EPI Vaccines Registered in Bangladesh

Sl No	Importer	Trade Name	Generic Name
1	Synovia Pharma PLC	Avaxim 80U Pediatric	Inactivated Hepatitis A vaccine
2		Hexaxim	Diphtheria, tetanus, pertussis (acellular component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus 2nfluenza type b conjugate vaccine
3		Menactra	Meningococcal (Groups A, C, Y, W-135) polysaccharide diphtheria toxoid conjugate vaccine
4		Tetraxim	Diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentous haemagglutinin, poliomyelitis virus (inactivated)
5		Typhim VI	Vi capsular polysaccharide typhoid vaccine
6		VaxigripTetra	Quadrivalent inactivated influenza Vaccine
7		Verorab	Purified inactivated rabies vaccine, prepared on Vero cells
8		Stamaril	Attenuated yellow fever vaccine
9		Vaxigrip	Inactivated Influenza vaccine
10	Janata Traders	Prevanar 13 Suspension for Injection	Pneumococcal Polysaccharide serotype 1, 3, 4, 5, 6A, 6B, 7F, 9V,18C, 19A, 10F,23F conjugate to CRM 197 Carrier Protein and adsorbed on aluminum phosphate
11		Typhibev Typhoid Conjugate Vaccine	Typhoid Vi Polysaccharide Vaccine conjugate to 16mcg to 100 mcg of CRM 197
12		MMR Vaccine (Measles, Mumps and Rubella Vaccine Live) Attenuated	Measles Virus Mumps Virus Rubella Virus
13		Diphtheria and Tetanus Vaccine Adsorbed for Adults and Adolescents	Diphtheria toxoid Tetanus toxoid
14		Rotasiil- Liquid	Rotavirus Vaccine, Live Attenuated (Oral) (Liquid), 2ml-1 dose

Sl No	Importer	Trade Name	Generic Name
15	Healthcare Pharmaceuticals Ltd.	GARDASIL	Quadrivalent Human Papillomavirus
16		ROTATEQ	ROTAVIRUS VACCINE, LIVE, ORAI,, PENTAVALENT
17		PNEUMOVAX 23	PNEUMOCOCCAL VACCINE POLYVALENT
18		VARIVAX	Oka/Merck Varicella Virus

3. POST-VACCINATION VIGILANCE INTEGRATION IN BANGLADESH

3.1 NEED FOR INTEGRATION TO UPGRADATION OF BANGLADESH TO GBT LEVEL 3

WHO has developed a Global Benchmarking Tool (GBT) to evaluate national regulatory systems using this maturity level concept (WHO, 2021a). Countries and WHO can identify the gaps and challenges to drive the improvement of the system, based on the maturity level of the national regulatory system, which can then be used to establish a solid framework for public health interventions.

Bangladesh is striving to upgrade itself to WHO GBT maturity level 3 which (as per the target of WHA resolution 67.20) requires a stable formal system approach with a stable, well-functioning and integrated regulatory system (WHO, 2021b). The diversity of involvement in vaccination programs and the multiplicity of stakeholders in the post-vaccination AEFI reporting (Sections 2.4 and 3.1) raises the necessity for integration of the activities undertaken by the stakeholders.

3.2 KEY STAKEHOLDERS IN POST-VACCINATION AEFI REPORTING IN BANGLADESH

In line with the information as provided in Section 1.3.2, the major stakeholders may be identified and their levels of involvement in the integration process (adaptation from the SEARN recommendation, but contextualized in the Bangladesh perspective) may be indicated (Table 4). It should be noted that some Ministries/Agencies and other stakeholders are not direct providers of services; however, from the literature as well as from the discussion with regulatory agency officials/experts, some of these stakeholders have been suggested to be included as critical stakeholders in the integration process.

Table 4. Key stakeholders for integration (Adapted from action point 11-SEARN)

Critical stakeholders	Strategic stakeholders (opportunity)
• Regional and national vigilance centers • National Regulatory Authorities: DGDA, DGHS (specially EPI, CDC, Director of Hospitals, and MIS) • Public health programmes (e.g. Tuberculosis, Malaria, HIV, etc.) and immunization programmes • Manufacturers, marketing authorization holders, other economic operators (e.g. importers, wholesalers, authorized representatives, etc.) • National Control Laboratory • Other important stakeholders (Patients, caretakers, users, healthcare professionals and allied professions) • Media	• Clinical centers of excellence, clinical research organisations, universities • Hospital Safety Committees • Patients and Consumer Associations • Professional Associations (e.g. medical doctors, pharmacists, nurses, etc.) • Relevant Non-Governmental Organizations • Development Partners/ Donors

3.3 PRESENT STATUS OF INTEGRATION AEFI REPORTING IN BANGLADESH

3.3.1 Policies and regulations regarding integration of AEFI reporting: Although a separate integration-related document has not been developed, few direct or indicative suggestions are available in the already existing documents. One of the 4 policy statements of the National Immunization Policy 2013 (DGHS, 2013), is as follows: Improving the quality and safety of immunization services in public, private and NGO sectors. The statement implies a coordination between these players regarding the safety aspects of vaccination. As one of its objectives, the policy further emphasizes this point: 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. An entire section (Section 2) in the policy has been dedicated to regulation and coordination and, under subsection 2.1 (Agency Roles in Regulation and Coordination), the coordinating role of the DGDA has been explicitly mentioned (subsection 2.1.5: The DGDA will take the primary responsibility for post-marketing pharmacovigilance). Subsection 2.4.4 elaborates on the issue further: 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).

As per the AEFI Surveillance and Response Guideline 2021 (DGDA, 2021), direct coordination of relevant information channels exists through the DHIS 2 platform (Tracker Capture App) which facilitates collection, collation, transmission, analysis and feedback of the country's vaccine safety-related data (AEFI data). The information flow diagrams from the community to higher levels of health facilities have been shown for both rural and urban areas. The timings for individual case reports and aggregate reports have been mentioned and also for immediate reporting, in applicable cases, have been emphasized. As the urban areas are included in the Guideline, the City Corporations and Municipalities (which are under the Ministry of LGRD), inter-ministry information exchange and collaboration have been assumed in the Guideline.

There is, however, no mention of any formalization of the collaborating arrangements even in the information-sharing areas.

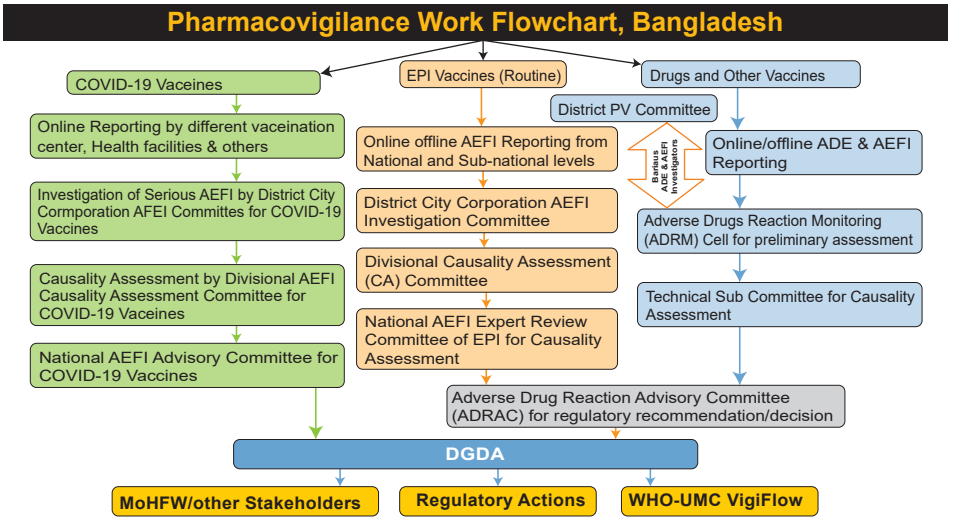


Fig 1: Pharmacovigilance Work Flowchart

In the National Guideline on the Pharmacovigilance System in Bangladesh 2023 the Pharmacovigilance Work Flowchart (Fig 1) depicts the coordinating role of DGDA in AEFI information processing and vigilance activities. As the diagram shows, this includes EPI as well as non-EPI vaccines. The role has been made more binding by the Drugs and Cosmetics Act, 2023 (MOHFW, 2023). In Article 69(1) of the act, the pharmacovigilance component has been mandatory for all manufacturers, importers/distributors, hospitals, clinics, public health programs and all other relevant organizations/stakeholders involved in drug (which includes vaccines)-related activities. In the same Article, sending reports and information to the licensing authority (in this case, DGDA) has also been mandatory as, otherwise, the competent Authority may defer or cancel the relevant license of the particular organization as per Article 66(4). The act further transforms the issue as a dynamic process through article 66(2) where it is mentioned that the relevant organizations must conform to the regulations and guidelines framed from time to time by the licensing authority as well as internationally recognized bodies like WHO.

3.3.2 Present status of integration among the stakeholders: The status of post-vaccination vigilance integration in Bangladesh substantially differs between the EPI and Non-EPI vaccines.

In case of the EPI vaccines, the AEFI reporting system following AEFI Guideline (as mentioned in Section 3.2) operates across all the public, and private (for-profit as well as not-for-profit) stakeholders. Accordingly, at least on principle, a semi formalized system operates which has the potential for post-vaccination vigilance integration. On discussion with individual stakeholders, the reporting levels were found to be variable and dedicated officials with awareness about the importance of integration were found only in a few cases. The follow-up system after reporting and inter-stakeholder discussion as well as interaction were limited mostly among a few public sector stakeholders. Training of the field-level providers, however, were mostly organized by EPI in collaboration with the Development Partners and some social organizations, both in the public and private sectors. This created an indirect avenue for alignment of the AEFI reporting for EPI vaccines and this process served as a vital ingredient for integration, the advantage of which has yet to be fully utilized.

In case of the Non-EPI vaccines, the integration system for post-vaccination vigilance is not yet organized in Bangladesh. Following the same channels, as mentioned for EPI, some reporting are done in the MoHFW-based public sector and this is cumulated in the PV cell of the regulatory authority. However, in case of the non-MoHFW public sector as well as in the private sector (who are also major providers of the Non-EPI vaccines), the post-vaccination vigilance integration is practically non-existent. In most cases, the stakeholders are not aware of the issue and its importance. With rapidly rising scope of these vaccines, this part of the integration as well as EPI & Non-EPI integration deserve special attention.

3.4 MAJOR CHALLENGES FOR POST-VACCINATION VIGILANCE INTEGRATION IN BANGLADESH

Diversity of the immunization service providers (with substantial numbers outside the fold of MoHFW) coupled with low reporting of the AEFIs is the major challenge to effective post-vaccination vigilance integration in Bangladesh. The country is part of the SEARN region and the barriers to AEFI reporting has identified in Action Point 10 (led by the Working Group 3 or WG3) in the SEARN Work Plan 2022-23, also applies to this country. A systemic analysis reveals the challenges related to legislation and regulation, awareness and motivation, methodology and tools, human resource training, professional education, research, and capacity enhancement of the regulators and other stakeholders.

3.4.1 Challenges related to legislation and regulation

The existing legislation in Bangladesh (such as the Drug and Cosmetics Act, 2023) may cover the implementation of the post-vaccination vigilance integration. However, the rules & regulations, stemming from these legislations should be revisited and carefully scrutinized to ascertain that objectives of integration are properly covered by various Articles and Clauses. This is especially important for a Strategy like the present one as it necessarily involves multiple stakeholders from various Ministries, Directorates, Agencies and even individual citizens (Annexure 1). This diversity may lead to the involvement of different legislative and regulatory frameworks and directives which may not be convergent, and may even be contradictory in some cases. Additionally, due to the obvious involvement of private sector Providers, especially in the NEPIV initiatives, there may be extra challenges to design and implement the legislative and regulatory issues regarding the safety surveillance of this subgroup of vaccines. Since, in some cases (like the Drug and Cosmetics Act, 2023) the Rules-Regulations have not yet fully formulated, there are still scopes to take care during their drafting so that the vigilance integration issues are fully covered. In addition, the Health Protection Act is now under the process of approval by the Government; care should be taken so that the new Act becomes further useful in meeting the legislative and regulatory challenges of the post-vaccination vigilance integration.

3.4.2 Challenges related to normative aspects such as shared values, culture and vision across organizations, professional groups and individuals regarding post-immunization safety surveillance issues

In general, organized initiatives to promote awareness and motivation regarding the reporting of AEFI are lacking in both the relevant public and private sectors. This is due to the widespread belief and confidence that vaccines are safe products and noting of post-vaccination adverse effects is a redundant activity. In many cases, even the relevant professionals and highly educated/alert people share this view. Low motivation in this regard is evident among all the stakeholders including the common public (the Consumers), Providers (Physicians, Pharmacists, Nurses, Paramedics etc.), Policy Makers and Suppliers (Manufacturers, Importers, Distributors and Retailers). Under this perspective coordinated initiatives, as required for effective integration of post-vaccination vigilance, becomes more challenging.

3.4.3 Limitations regarding methodology and tools for AEFI reporting

The methodology adopted for AEFI reporting of the EPI vaccines is fairly well-defined and mostly homogenous across all the stakeholders encompassing the public as well as private sectors. However, due to resource and system limitations, the process is still semi-digitized and efficiency is not yet optimal. In the case of NEPIVs, the methodology is not streamlined and implemented yet, especially in the case of the private sector stakeholders. In addition to the methodology, the used Tools are not optimally user-friendly. The Distribution Channels, based on binding regulations and the capacity- and category-specific authorization of the Providing Facilities (especially the private pharmacies) are not yet explicitly evident. Modern information-communication technology (ICT) has yet not been fully incorporated for AEFI reporting of vaccines outside EPI. All these factors play an inhibitory role in post-vaccination vigilance integration.

3.4.4 Inadequacy of well-trained human resources

The concerned immunization service providers, in many cases, have severe limitations regarding the availability of well-trained human resources in a sustainable manner. Accordingly, the field-level human resources may not always be properly trained and motivated in the detection and reporting of AEFI. Programs for The vaccine-and category-specific organized and continued training programs are still not participated by a number of Stakeholders and many of them (as proposed to be engaged in the present Strategy) are not yet invited. Development of human resources among the stakeholders, with training and motivation for proper AEFI reporting, is a major challenge for onward integration of post-vaccination vigilance.

3.4.5 Deficient professional education

The pharmacovigilance issues, in general, are not adequately addressed in the course-curricula of the healthcare professionals (physicians, pharmacists, nurses and paramedics). The contents related to drugs are thought to cover the vaccine issues and, thus the specific points related to vaccines are even more marginalized. Under this situation, it is obvious that AEFI and its integration are hardly mentioned in the existing course-curricula. It is well-recognized that the safety standards of the vaccines are higher as healthy persons are involved and, accordingly, a separate focus should be provided to integrated AEFI during the education of the professionals.

3.4.6 Missing evidence with local relevance

It is highly important to generate context-specific scientific evidence regarding post-vaccination vigilance and its integration among the relevant stakeholders. This is due to the fact that specific racial communities may have different responses to vaccines (like drugs) due to genetic, cultural and lifestyle heterogeneity. Credible evidence and balanced inference are vital to develop conclusions and appropriate actions in this field. Sometimes, the relatively small number of AEFIs may be misleading, the life of even a single person must be considered as extremely valuable. In addition, commercial interest may override public health interest on this issue. Robust and reliable evidence in such cases will be crucial to confront commercial interest in most cases. The culture of generating research-based evidence, specially in this field, is still missing in Bangladesh.

3.4.7 Inadequate capacity among the relevant stakeholders

Post-vaccination vigilance is a complex issue involving multiple Ministries, Directorates, Agencies, Institutions, Programs, Groups and even individuals as stakeholders (Annexure 1). Any coordinating and integrating effort will require a parallel strengthening in the capacity and expertise of the regulatory agency. With the present infrastructure and human resource capacity, it will be difficult for the existing PV Cell of DGDA to implement these activities. In fact, the present capacity is not even adequate for the proper pharmacovigilance of drugs. There is no dedicated subcell for safety surveillance of vaccines in this cell and thus consistent post-vaccination vigilance integration are not done at a national level.

It is obvious that the capacity of the stakeholders are highly important to implement any efficient and sustainable integration plan for post-vaccination vigilance. Presently, the capacity of the other Stakeholders is not uniformly optimum in most cases. The non-MoHFW Stakeholders are mostly unaware about the importance of this issue. Accordingly, the implementation of the Actions in the present strategy will have to address these challenges.

4. NSIPV: GOAL, OBJECTIVES AND STRATEGIC ACTIONS

4.1 STRATEGY DEVELOPMENT PROCESS

A consultative process involving some stakeholders was followed to develop the first draft of the Strategy. The major guiding document in framing the present strategy was the action point 11 of the SEARN Action Plan 2022-23 (formulated by the TG3). The basic challenges for post-vaccination vigilance integration, in the context of Bangladesh, were worked out through an initial round-table meeting with the relevant officials in DGDA. Extensive desk review was made and few of the relevant professionals were consulted. After getting feedback, the present conceptual zero draft will be ventilated on a larger scale and it will be further refined with input from the policy makers, other experts and stakeholders.

4.2 GOAL AND OBJECTIVES OF NSIPV

GOAL

To promote a stronger public health system through integration of the post-immunization vigilance-related initiatives on vaccine safety as undertaken by relevant stakeholders in Bangladesh.

OBJECTIVES

The objectives of NSIPV are to:

- Coordinate and align policies, rules and regulatory frameworks relevant to vaccine safety issues in the context of Bangladesh;
- Develop shared values, culture and vision across organizations, professional groups and individuals regarding vaccine safety issues;
- Coordinate structures, governance systems and relationships across relevant organizations;
- Align administrative functions, and budgets/ financial systems (in applicable cases) across integrating units;
- Generate or improve the methodology and tools related to the integration of the post-immunization safety vigilance as practiced (or to be practiced) by the stakeholders;
- Incorporate items on coordinated post-immunization safety vigilance in the course-curricula and syllabi of the education programs of the relevant stakeholders;
- Stimulate research activities in vaccine safety vigilance areas;
- Enhance the capacity of the relevant stakeholders in alignment to their role in implementing the strategic objectives.

4.3 STRATEGIC ACTIONS

Strategic Action-1	Address the systemic issues through revisiting and aligning policies, rules and regulatory frameworks relevant to post-vaccination vigilance issues and improve/ create the environment for optimum coordination

The diversity of the Agencies, organizations and institutions' engagement in the delivery of immunization services in Bangladesh leads to the consequent involvement of multiple stakeholders in post-vaccination safety-surveillance initiatives. Apart from the immunization service providers, important players like the consumers; authorities responsible for school education, information, and women and children affairs; and mass media should be included as stakeholders (in some cases, critical ones). For the stakeholders within the fold of MoHFW, some degree of collaboration exists; however, those should be further formalized with appropriate regulatory and administrative steps. As obvious, many of these stakeholders are from outside MoHFW and there is inadequate information exchange and coordination of the PV regulatory authority with these stakeholders. Accordingly, attention is required to the systemic issues related to the policies, rules and regulations as relevant to vaccine safety surveillance. Aligning these systemic issues among the stakeholders will greatly help in improving/creating an optimum environment for proper integration.

1.1 Review the legislative and regulatory frameworks of the regulatory agencies and other stakeholders as relevant to the safety vigilance after immunization.

Existing legislative and regulation frameworks, related to the duties and obligations of the stakeholders, will have to be critically reviewed with support and input from legal experts. The promoting factors and barriers to integration of the post-vaccination vigilance-related activities of stakeholders will need to be especially scrutinized during this review. It should also assess whether the regulations have been formulated to implement the specific Act. Particular attention will be required for the legislations under process (such as the Health Protection Act) as there is still some scope for improvisation in these Acts.

1.2 Suggest, if necessary, the modification of existing legislative and regulatory measures to improve safety vigilance after immunization.

If felt necessary after the review, suggestions regarding probable amendments will need to be generated with a view to enhanced integration of the post-vaccination vigilance activities. The necessary regulatory and administrative steps should also be suggested.

1.3 Suggest, if necessary, the introduction of new legislative and/ or regulatory measures to improve safety vigilance after immunization.

Through the review process, suggestions for new legislation should also be generated, if necessary. Steps to expedite the enactment of the legislation(s) already under process will need to be taken. The chain of documents, from legislation to administrative orders will need to be available and any missing link should be rectified.

1.4 Take steps for the modification of the existing or introduction of new legislative and/or regulatory measures and administrative steps, as appropriate.

To ensure effective post-vaccination safety surveillance in Bangladesh, it is crucial to revisit and modify existing legislation, regulatory measures, and administrative processes. Based on the findings and suggestions from thorough reviews, necessary adjustments should be made to current frameworks to address gaps or inefficiencies. Where applicable, entirely new legislation, regulations, or administrative steps should be introduced to strengthen coordination among stakeholders and enhance vaccine safety. These efforts will help create a more robust and responsive system for post-vaccination vigilance.

1.5 Enhance the implementation of the relevant Acts by framing the rules and regulations as related to safety vigilance after immunization.

The Drug and Cosmetics Act, 2023 may be utilized in creating a partnership environment for all the stakeholders; however, the Rules-Regulations of the Act need to be formulated and implemented as soon as possible.

1.6 Improve/create a comprehensive policy environment for optimum coordination.

To enhance post-vaccination safety surveillance in Bangladesh, it is essential to align policies, rules, and regulations among diverse stakeholders, including immunization providers, consumers, educational authorities, and the media. While some collaboration exists within MoHFW stakeholders, further formalization through regulatory and administrative steps is required. However, for stakeholders outside MoHFW, there is insufficient information exchange and coordination with the Pharmacovigilance Regulatory Authority. Improved coordination through regulatory and administrative adjustments will create an optimal environment for effective integration and comprehensive vaccine safety surveillance.

Strategic Action 2:	Develop the normative aspects such as shared values, culture and vision across organizations, professional groups and individuals regarding post-immunization safety surveillance issues

Even with appropriate legislative and regulatory frameworks, optimum integration for post-vaccination safety-surveillance will not be achieved unless the normative aspects of the stakeholders are parallel developed. Since a large number of individuals, institutions and organizations (from diverse sources) will need to be involved in the integration initiatives, it will be mandatory to develop certain alignment in the attitude and value systems of the stakeholders. Creating awareness and motivation, using appropriate tools of communication, will be central in the creation of common cultures. The communication tools should be customized for individual groups with proper attention to the sociodemographic, economic, cultural and religious context.

2.1 Sensitize relevant policy makers, planners, and senior administrators through advocacy initiatives.

Creation of awareness and motivation among the policy makers, planners and senior administrators are mandatory for effective implementation of the strategic activities and focused advocacy, targeted to individuals and groups, will need to be arranged for this purpose. Leading professionals from the providers should also be included in this group. Properly planned well-designed advocacy materials will be required to approach and convince these groups as they are among the central change makers.

2.2 Initiate large-scale awareness campaigns, involving service users and the wider community, using mass media, social media and community-oriented activities.

As post-vaccination vigilance integration requires a number of stakeholders (including nonmedical professionals and general people), the awareness and participation of the stakeholders are of crucial importance. Using appropriate channels (such as print and digital mass media, social media platforms, and community-oriented activities), mass campaigns will need to be conducted.

2.3 Generate awareness and motivation among service providers (like physicians, nurses, pharmacists, and community health workers) and using effective tools and channels.

Designed for specific groups, targeted awareness and motivation programs, will need to be conducted among these professionals. Effective implementation of these programs should be ensured with appropriate tools and channels.

2.4 Generate awareness and motivation regarding post-vaccination vigilance integration among manufacturers, importers, distributors and retailers.

The awareness and motivation programs will need to be targeted to specific professional groups and subgroups. Using appropriate channels and tools, the messages should include the stimulation of AEFI reporting as well as the coordination and integration of such reporting among the stakeholders.

2.5 Develop common integration goals among the stakeholders.

To achieve optimal integration of post-vaccination safety surveillance, it is crucial to align the values, culture, and vision of diverse stakeholders. While appropriate legislative frameworks may exist, full integration cannot be achieved without fostering shared attitudes and goals. Given the involvement of numerous organizations and individuals from various sectors, awareness and motivation must be cultivated through tailored communication strategies. A governance framework with clear decision-making structures should be established to guide collaboration, ensuring open communication and transparency. These strategies should be sensitive to the sociodemographic, economic, cultural, and religious contexts of each stakeholder group, ensuring alignment towards common integration goals.

2.6 Identify and address communication gaps among stakeholders.

Effective integration requires seamless communication and coordination among a diverse group of stakeholders, including healthcare providers, regulatory agencies, consumers, and international partners. Communication gaps can hinder the flow of crucial information, delay adverse event reporting, and perpetuate misconceptions about vaccine safety, leading to underreporting of adverse events following immunization (AEFI). Stakeholder mapping and assessing current communication methods are essential to identifying barriers such as technological limitations, language differences, unclear reporting protocols, or cultural factors. Gathering feedback through structured surveys, interviews, and focus groups helps to highlight these gaps, which can then be categorized and prioritized based on their impact on vaccine surveillance. Tailored communication strategies-such as standardized protocols and the use of shared digital platforms-should be developed to streamline data sharing and ensure transparency. Capacity-building efforts, including communication training and collaborative workshops, can improve engagement, while regular communication reviews and feedback mechanisms ensure ongoing improvement. Monitoring communication efficiency through Key Performance Indicators (KPIs) such as response times, reporting accuracy, or stakeholder engagement levels allows for continuous refinement, fostering effective stakeholder collaboration in post-vaccine vigilance efforts.

2.7 Build immunization service relationships and trust through local events.

To ensure the effective integration of post-vaccination safety surveillance in Bangladesh, it is crucial to build and strengthen relationships and trust within immunization services through local events. This involves organizing and participating in community-based activities that foster direct engagement between healthcare providers, regulatory agencies, and the community. By creating opportunities for face-to-face interactions and open dialogue, these local events can bridge communication gaps, address misconceptions, and reinforce the shared values and goals of all stakeholders. Emphasizing trust-building and collaboration at the local level will enhance collective motivation and commitment to vaccine safety, aligning normative aspects and promoting a unified approach to post-immunization vigilance.

2.8 Involve service users and the wider community.

Despite having robust legislative and regulatory frameworks, the success of post-vaccination safety surveillance depends on aligning the normative aspects of all stakeholders. Engaging service users and community members helps in fostering shared values, attitudes, and understanding towards vaccine safety. By actively including service users, their feedback, concerns, and experiences, fostering a more inclusive and effective approach. Tailoring communication tools to address the diverse socio-demographic, economic, cultural, and religious contexts will be essential for building a unified approach to post-immunization vigilance. This involvement enhances trust, improves awareness, and ensures that the surveillance system is responsive and effective, ultimately strengthening the overall post-vaccination vigilance framework.

Strategic Action 3:	Coordinate structures, governance systems and relationships across stakeholders

Shared values, culture and vision (as mentioned in Strategic Action 2) under the optimum systemic environment (as mentioned in Strategic Action 3) will facilitate the development and implementation of the coordinated structures and governance systems as related to post-vaccination vigilance. Such relationship may spread within a large spectrum starting from informal partnership and coordination to formal binding agreements. For optimum integration, a formal arrangement (even in the form of a Memorandum of Understanding or Letter of Intent) is desirable. The initiative may have a ballooning effect leading to larger organizations based on partnership. Suggestions for such formalization have been provided in Annexure 1.

3.1 Develop formal and informal contractual or cooperative service commissioning arrangements among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

To ensure a cohesive and structured approach to integrating post-vaccination vigilance in Bangladesh, it is essential to establish clear roles and responsibilities through both formal and informal service commissioning arrangements among stakeholders, including regulatory bodies, healthcare providers, and regional and international partners. Formal agreements, such as Memoranda of Understanding (MoUs) or Letters of Intent (LoIs), will align stakeholders with shared values and objectives, while informal partnerships will foster flexibility and adaptive collaboration. These formal agreements should clearly define the scope of services, performance standards, and financial commitments to ensure alignment with strategic objectives. Informal arrangements, facilitated through regular meetings and collaborative initiatives, help build trust and enhance communication. Effective communication channels, continuous monitoring, and regular evaluations are crucial to ensuring that these arrangements meet their objectives and adapt to evolving needs. This approach strengthens governance structures and ensures a coordinated, efficient, and responsive post-immunization vigilance system, creating a robust framework for vaccine safety.

3.2 Develop formal and informal contractual or cooperative arrangements among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

Effective post-vaccination surveillance requires sustained financial resources for data collection, reporting, analysis, and stakeholder coordination. Establishing formal and informal cooperative arrangements among regulatory agencies and other stakeholders is crucial for maintaining and enhancing vaccine safety surveillance. Steps should be taken to develop formal and informal contractual or cooperative pool funding arrangements among the relevant stakeholders.

3.3 Develop umbrella organizational structures such as federations or local partnerships for post-immunization safety surveillance reporting.

For building an integrated framework in post-vaccination surveillance, umbrella structures serve as centralized, organized platforms where diverse stakeholders - such as regulatory agencies, public health institutions, healthcare providers, research bodies, pharmaceutical companies, civil society organizations, and other relevant partners-can collaborate within a unified system. By formalizing federations or partnerships at local and national levels and establishing a governance framework with clear decision-making processes, the strategy enhances efficiency in data collection, reporting, and monitoring of Adverse Events Following Immunization (AEFI). Leveraging existing networks, resources, and infrastructure while fostering collaboration through capacity building and the exchange of best practices across partners improves reporting quality and efficiency. This organizational model clearly defines responsibilities and promotes resource sharing, resulting in better coordination across sectors and regions. Additionally, these structures not only strengthen national oversight but also enhance alignment with international vaccine safety protocols, creating a more robust and integrated vigilance system.

Strategic Action 4:

Address administrative issues through the alignment of methodology and tools, back-office functions, budgets and financial systems across integrating units

The actual delivery of the post-vaccination vigilance-related integrated services will require the alignment of the methodology and tools rooted in the shared goals and objectives. Such alignment will benefit from a substantially lowered effort in terms of human resources. This, consequently, may lead to a cost-sharing and cost-saving approach. In addition to the economic benefit of this coordinated initiative, there is a social benefit generated from the feelings of partnership and togetherness.

4.1 Develop shared information systems among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

Developing shared information systems among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting reduce duplication of efforts, lessen the burden on human resources, and foster a sense of partnership, leading to improved national and international coordination in vaccine safety. This approach requires establishing common goals, standardizing data collection and reporting protocols, and implementing interoperable technology platforms that allow seamless, real-time data sharing. A centralized data repository will ensure that all stakeholders have access to accurate, up-to-date information on Adverse Events Following Immunization (AEFI). To support this system, stakeholders must receive proper training on using the technology and reporting processes. Regular communication, feedback, and audits will help maintain the system's effectiveness and ensure it aligns with the objectives of vaccine safety surveillance, fostering transparency, efficiency, and collaboration.

4.2 Develop shared accountability mechanisms among regulatory agencies and other Stakeholders for post-immunization safety surveillance reporting.

Shared accountability fosters cooperation, transparency, and alignment of goals among stakeholders, reducing inefficiencies and minimizing duplication of effort. Developing formal agreements, such as Memoranda of Understanding (MoUs) or Letters of Intent (LoIs), alongside clearly defined roles and responsibilities, will enable the implementation of a unified reporting framework. Furthermore, establishing measurable performance indicators, real-time data sharing, promoting progress reports, and conducting regular audits will help identify gaps and opportunities for improvement. These steps will ensure that shared accountability mechanisms support a coordinated, efficient, and responsive post-vaccination safety surveillance system.

4.3 Develop shared funding processes among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

Developing shared funding processes among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting involves creating a collaborative financial framework that ensures sustained support for surveillance activities. This can be achieved by establishing formal agreements, such as Memoranda of Understanding (MoUs) or Letters of Intent (LoIs), that outline the financial commitments of each stakeholder. A pooled funding mechanism, where resources from different stakeholders (Public-private partnerships, Government grants, International funding, Donor engagement) are combined and managed by a governing body or a neutral third party, ensures a more resilient and scalable system. Stakeholders can contribute based on their capacity, with clearly defined roles in terms of financial responsibilities. Transparency in financial management is key, with regular audits, progress reports, and performance evaluations to ensure funds are being allocated and used effectively. By linking funding to measurable outcomes and shared goals, this approach promotes accountability and aligns financial resources with the strategic objectives of the post-immunization safety surveillance system.

Strategic Action 5:	Generate and improve the methodology and tools related to AEFI reporting of Vaccines

The AEFI reporting channels are relatively organized in the case of MoHFW and, on principle, similar channels should be followed in the case of other providers. In practice, however, such organized systems are absent in the case of many stakeholders. Those should be streamlined under proper regulatory provisions and the methodology for such channels should be clearly defined. With a clear definition of the channels from the periphery to the center, the reporting systems need to be streamlined. It is of central importance to make the tools user-friendly and simple as far as possible. The digital tools need to be optimally used.

5.1 Review the existing reporting forms with input from the various stakeholders.

With input from the relevant stakeholders from all the relevant sources (including general people, as appropriate) and special attention to user-friendliness, the presently used reporting forms should be reviewed. Summaries of the rational feedback should be prepared and maintained.

5.2 Redesign, if necessary, the forms with special reference to user-friendliness.

The reporting forms should be redesigned, if necessary, based on the rational feedback, as mentioned in Section 5.1.

5.3 Design, if necessary, new forms with special reference to user-friendliness.

Based on the rational feedback (as received in Section 5.1) and also on other review points, new reporting forms should be designed, if necessary.

5.4 Design short and simple forms, as much as possible, without compromising the quality.

The issue of simplicity and shared values should be given due consideration during the redesigning/designing of reporting forms, however, quality should not be compromised and the essential elements in the forms must not be missing.

5.5 Use (as much as feasible in the Bangladesh context) the digital channels (e.g. Apps in mobile phones) for the integration of post-immunization vigilance.

For creating awareness and motivation for post-vaccination vigilance integration among the stakeholders, the digital channels will be vital. In Bangladesh context, mobile phones may be extensively used and targeted Apps may be developed for these purposes. However, constraints related to the availability of relevant sets and internet connection should be given due consideration, especially when general people are the targets.

5.6 Create databases for cumulating the AEFI reports at various levels.

For optimum integration, the AEFI reports should be digitalized as much as possible and proper databases should be used to store the information. The connectivity and compatibility with the regional and international databases should be ensured.

Strategic Action 6:

Incorporate integrated post-vaccination vigilance related contents in the course-curricula and syllabi of the relevant professional education/ training programs

Human Resources (HR), with appropriate knowledge and skill, are vital for optimum post-vaccination vigilance integration among the stakeholders. Those groups of HR need to be trained on the safety surveillance issues of vaccines and the training

sessions should also be used as motivating sessions for increased reporting. Professionals (like physicians, pharmacists, nurses, paramedics and community health workers) should get such knowledge and training during their academic life and they should also have refresher training during their service life. The training should be organized with proper planning on course-curricula targeted to specific groups of Providers. The formal acknowledgment of the training programs will create further motivation among the participants. It is important to create customized content targeted to specific professional groups with professional engagement. In addition to the health professionals, policymakers, administrators and media professionals should also be exposed to the post-vaccination vigilance issues with targeted contents and techniques. The relevant regulatory authorities for different professional groups will need to be convinced through targeted advocacy. Appropriate teaching-learning techniques will need to be adopted for the effective education of professionals on safety surveillance issues.

6.1 Create content and educational materials related to post-immunization vaccine vigilance for providing education and training to students from relevant levels and disciplines.

With appropriate professional input, the course-curricula and syllabi of the academic and training programs should be designed for periodic upgrading of the knowledge and skills of relevant stakeholder groups. The content must be informative and practical with emphasis on the local context. At the same time, the content should be target-specific and precise so that the students are not overburdened.

6.2 Take organized initiatives to incorporate post-immunization vaccine vigilance-related contents in the course curricula and syllabi of the educational and training programs.

The inclusion of the post-vaccination vigilance issues into the relevant academic/training programs of the agencies, institutions, and universities requires special efforts, through awareness and advocacy initiatives. These will be required to convince the relevant agencies/ universities/ institutions to include these materials in their regular academic programs.

6.3 Review the impact of education and training-related reforms on post-immunization vaccine vigilance.

Organization of academic/training programs may not yield desired outcomes unless proper evaluation and feedback mechanisms exist. An in-built mechanism for evaluating the impact of the training programs should be designed and the contents and methodology of the program should be adjusted, from time to time, based on rational feedback.

Strategic Action 7:

Strengthen research activities on post-immunization vaccine vigilance

Research, leading to context-specific evidence, is crucially important for vaccines due to their public health importance and, consequently, its central role in health system planning. It is especially important for post-vaccination vigilance integration due to its sensitive nature resulting from multiple stakeholders. Convergence of the views and methods of the diverse stakeholders (some of whom are not even vaccination providers) need data and information from different viewpoint, including the social science ones. Due to racial variations (originating from genetic as well as lifestyle factors) the same vaccines may have some variable effects. An effective safety surveillance program will require continued research on various aspects of post-vaccination and their coordination. Academia-industrial partnership should be fostered to promote research in these areas.

7.1 Identify priority areas and projects for research activities on consultation with various stakeholders.

In the specific context of Bangladesh, priority research areas will need to be identified through interactive mechanisms among the stakeholders and other relevant groups. Some ideas on individual projects may also be generated within the prioritized areas.

7.2 Develop coordinated mechanisms to promote research in the prioritized fields.

Within an umbrella perspective plan, potential in-country researchers and research groups, as well as potential global collaborating partners, should be identified. A comprehensive and coordinated approach to research, involving all probable stakeholders in the public as well as private sectors, should be adopted. The need for academia-industry partnership should be highlighted.

7.3 Create a pool fund to support research in the selected areas.

A pooled fund should be generated to support research on priority areas. Initiatives to mobilize resources for creating the pooled fund will be necessary and support from the Government, NGOs, Industries, and Development Partners will be important in this respect.

Strategic Action 8:

Build capacity of the relevant stakeholders in the area of post-immunization vaccine vigilance

The present strategic actions will be implemented effectively only when a parallel capacity is developed among the stakeholders, especially at the central coordination center. As per the present situation, the PV Cell of the DGDA is the agency coordinating the national, regional and international stakeholders. It now needs to be converted into a department with dedicated cells/units for drugs, vaccines, medical devices, etc. A parallel increase in

infrastructure as well as HR capacity will make it possible to ensure the health of the population through proper safety surveillance of pharmaceutical products. At the same time, the capacity of the other stakeholders, including Suppliers (Manufacturers, Importers, Distributors and Retailers), will need to be enhanced, mainly through planning and supervision by the Regulatory Agency. Investment of own resources by the suppliers, to increase their own capacity, should be encouraged.

8.1 Strengthen the PV Cell of DGDA with relevant inputs on physical infrastructure and human resources.

All strategic actions presuppose the existence of a resourceful and efficient pharmacovigilance functional unit in the regulatory body (i.e. DGDA). The presently functioning PV cell in the DGDA may be upgraded to a full-fledged department with dedicated units for drugs, vaccines, and medical devices. The post-vaccination vigilance activities should be conducted by a dedicated subunit of the vaccine unit of PV cell. For such upgradation, appropriate infrastructure and human resources are mandatory.

8.2 Explore the existing potential infrastructure/facilities for their probable incorporation in post-immunization vaccine vigilance.

Some of the public or private sector agencies, with relevant input, may be potentially used for some of the actions under this strategy as they may have already functioning facilities in these areas.

8.3 Encourage suppliers to take ownership of their capacity building efforts.

The suppliers of the respective vaccines (as manufacturers, importers, distributors etc) should give appropriate attention to developing their capacity in the post-vaccination vigilance integration, with support from the regulatory body and other stakeholders as necessary. Ultimately, ownership of these stakeholder groups is vital to implement the actions of the present strategy.

8.4 Develop training programs with customized course-curricula and training materials for specific groups of professionals from the relevant stakeholders.

With appropriate professional input, the course curricula and syllabi of the training programs should be designed for periodic upgrading of the knowledge and skills of relevant professional groups (like regulators, providers, manufacturers, importers, distributors and retailers). The content must be informative and practical with emphasis on the local context.

8.5 Arrange regularly the fresher as well as follow-up training programs for the relevant professionals.

Fresher as well as follow-up training should be designed separately. Arrangements for periodic training programs should be planned on discussion with the various executing agencies.

8.6 Enhance the ICT infrastructure to use the digital tools and channels for conducting relevant activities like advocacy/awareness, reporting, education, training, and research.

The previously mentioned infrastructure development includes capacity development in ICT areas. However, due to its special importance in almost all strategic actions, this activity is mentioned separately with special prioritization.

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6. Annexures

ANNEXURE 1

Suggested stakeholders for vigilance integration in the Bangladesh context along with the current level of integration and strategy to strengthen integration (adapted from SEARN Action Point11)

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
1	**National Regulatory/ Implementing Authorities:** Directorate General of Drug Administration (DGDA)	Critical	-	Legislative, regulatory and administrative issues are to be critically reviewed and capacity is to be enhanced for playing the effective lead role in integrating the post-vaccination vigilance activities	Director General, DGDA	DGDA is operating under considerable infrastructure and human resource constraints. Effective expansion of its services for post-vaccination vigilance integration will require additional capacity.
2	**National Regulatory/ Implementing Authorities:** Directorate General of Health Services (DGHS)	Critical	-	Legislative, regulatory and administrative issues are to be critically reviewed and capacity is to be enhanced for playing the effective second lead role in integrating the post-vaccination vigilance activities	Director General, DGHS	The facilities/ programs under DGHS are the main providers of vaccines in the public sector (especially through EPI). It also supervises the private-sector vaccine delivery services, Accordingly, the role of DGHS as a regulatory agency is vital for the integration process.
3	**National Regulatory/ Implementing Authorities:** Directorate General of Medical Education (DGME)	Opportunity	No integration	Formalization required with capacity development	Director General, DGME	DGME can contribute by incorporating vaccine safety content into the medical education syllabus, ensuring that future healthcare professionals are well-

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
						trained in integrated action for post-vaccination vigilance.
4	**National Regulatory/ Implementing Authorities:** Directorate General of Family Planning (DGFP)	Critical	For EPI-Formal Non EPI-absent	Further formalization is necessary	Director General, DGFP	There is potential for expansion to Non-EPI as well as EPI services.
5	**National Regulatory/ Implementing Authorities:** Directorate General of Nursing and Midwifery (DGNM)	Opportunity	No integration	Formalization is necessary	Director General, DGNM	DGNM can contribute by incorporating vaccine safety content into the medical education syllabus, ensuring that future healthcare professionals are well-trained in integrated action for post-vaccination vigilance.
6	**Regional/ International Vigilance Center:** Uppsala Monitoring Centre (UMC), World Health Organization (WHO)	Critical	Formal	With the increased workload on implementation of the present integration strategy, the coping mechanism for efficient upward reporting should be designed in time.	Concerned Official, UMC	Presently the AEFI reporting system from DGDA is directly linked to UMC without any regional intermediary.

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
7	**National Vigilance Centers:** PV Cell, DGDA	Critical	For EPI vaccines, mostly formal For the non-EPI vaccines, mostly informal	Formalization, in any acceptable form, will be helpful in administering the integration process and this should be applicable for all the sectors (public and private) as well as for all types of vaccines. This will require added capacity and a dedicated subunit.	Director, PV Cell, DGDA	This is the main executing stakeholder for this strategy and a dynamic subunit under this Unit is a prerequisite for the successful implementation of the strategy.
8	Expanded Programme on Immunization (EPI), DGHS	Critical	Mostly formal for EPI vaccines No integration with Non-EPI vaccine providers	Further formalization with the National Vigilance Center and relevant Stakeholders will be helpful. A coordination mechanism with Non-EPI vaccination services will be useful, especially with a preregistration system all types of vaccines.	Director/ Line Director, MNC&AH (EPI), DGHS	This highly successful program coordinates many other stakeholders from diverse origins. Its experience and capacity should be maximally utilized.
9	Communicable Disease Control (CDC), DGHS	Critical	Non-EPI - partially formal and partially Informal	Further formalization is necessary	Line Director/ Director, CDC, DGHS	Provides Rabies vaccine and also implements the vaccination programs for the people going to Hajj.
10	Management Information System (MIS), DGHS	Critical	For EPI- mostly formal Non EPI- Informal	Further formalization is necessary	Director, MIS, DGHS	AEFI reports are entered into the DHIS2; however, the process needs further

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
						streamlining with added capacity and sustainability plan.
11	National Institute of Population Research and Training (NIPORT)	Critical	No integration	Formalization required with capacity development	Director General, NIPORT	By leveraging its expertise in training NIPORT can help build a highly skilled and knowledgeable workforce by incorporating post-immunization vaccine vigilance content and educational materials into training programs for key professional groups, such as regulators, providers, manufacturers, importers, distributors, and retailers.
12	Public health programmes (e.g. Tuberculosis, Malaria, HIV, etc.)	Critical	EPI-Formal Non EPI-Absent	Further formalization required	The Line Directors of the respective OPs	The issue needs to be incorporated in the program documents.
13	Infectious Diseases Hospital, Mohakhali	Critical	Non EPI-Informal	Further formalization is required with capacity increase for integrated post-vaccination vigilance reporting	Director, IDH	No EPI service. There is potential for expansion to Non-EPI as well as EPI services.
14	Armed Forces Medical Services	Critical	For EPI-Formal Non EPI-limited only to TT boster doses	Further formalization is required with capacity increase for integrated post-vaccination vigilance reporting	Director General, Directorate General of Medical	EPI services are provided with support from Dhaka North City Corporation. There is potential for expansion to Non-EPI as

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
					Services (DGMS)	well as EPI services, throughout the country.
15	Ministry of Local Government, Rural Development and Co-operatives contains	Critical	EPI-Formal Non EPI-Absent	Further formalization is required with capacity increase for integrated post-vaccination vigilance reporting	PD, Urban Primary Health Care Services Delivery Project-II And Chief Health Officers of respective City Corporations/ Municipalities	There is potential for expansion to Non-EPI as well as EPI services, throughout the country.
16	Dhaka South City Corporation (DSCC)	Critical	EPI-Formal Non EPI-Absent	Further formalization is required with capacity increase for integrated post-vaccination vigilance reporting	Chief Health Officer, DSCC	There is potential for expansion to Non-EPI as well as EPI services.
17	Dhaka North City Corporation (DNCC)	Critical	EPI-Formal Non EPI-Absent	Further formalization is required with capacity increase for integrated post-vaccination vigilance reporting	Chief Health Officer, DNCC	There is potential for expansion to Non-EPI as well as EPI services.
18	Central Police Hospital (CPH)	Opportunity	EPI-Formal Non EPI-No integration	Further formalization is required with capacity increase for integrated post-vaccination vigilance reporting	Social Welfare Officer, CPH	There is potential for expansion to Non-EPI as well as EPI services, throughout the country.

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
19	Bangladesh Chemist and Druggist Samity (BCDS)	Opportunity	No integration	Formalization is required with capacity development	President/ General Secretary, BCDS	There is potential for sensitization of the private (especially small Pharmacy-based) vaccination service Providers (Non-EPI as well as EPI) throughout the country.
20	Manufacturers, marketing authorization holders, other economic operators (e.g. importers, wholesalers, authorized representatives, etc.)	Critical	No effective integration	Formalization is required with capacity development	Director/ CEO of the individual organizations	There is potential for sensitization of the private (especially small Pharmacy-based) vaccination service Providers (Non-EPI as well as EPI) throughout the country.
21	Hospital Safety Committees	Critical	Limited integration with only a few hospitals	More and more hospitals should be engaged with formalized systems	Chair/ Convener of the Respective Committees	Both EPI and Non-EPI vaccines should be included.
22	Marie Stopes Bangladesh (MSB)	Opportunity	For EPI-Formal Non EPI-Informal	Further formalization required	Country Director, Marie Stopes Bangladesh (MSB)	With its large chain of healthcare facilities and the present plans for expanding to non-EPI vaccination fields, the Organization is an ideal Partner to enhance the post-vaccination vigilance activities.

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
23	BRAC Health Programme (BHP)	Opportunity	No integration	Formalization required to conduct large-scale awareness and advocacy programs	Senior Director, BRAC Health Programme (BHP)	The organization, as such, is not a vaccination service provider (except during covid-19 vaccination); however, its country-wide community-based health network may profitably be used to create relevant sensitization among public, providers and policy makers through awareness and advocacy initiatives.
24	Railway Hospitals	Opportunity	No integration	Vaccination services presently discontinued due to HR constraints should be resumed with formalization and capacity development	Chief Medical Officer, Bangladesh Railway	This facility, with its fairly large infrastructure, can be a valuable partner in different parts of the country. Through this partnership, railway workers, their families, and the general public will benefit from better healthcare and easier access to vaccines, which will help improve the integration of post-vaccination vigilance.
25	Directorate of Women Affairs, Ministry of Women and Children Affairs	Opportunity	No integration	Formalization and capacity development required	Director General, Department of Women Affairs	Since the Department conducts large-scale programs for women and children, it can be used as a Partner for creating awareness and motivation regarding post-vaccination safety surveillance.

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
26	Bureau of Manpower, Employment and Training. (BMET), Ministry of Expatriates' Welfare & Overseas Employment	Opportunity	No integration	Vaccination issues are left only to the manpower agencies; the practice should be changed with a control from a dedicated subunit of BMET and integration of the post-vaccination vigilance should be formalized	Director General, BMET	BMET can be a valuable partner in integrating vaccine safety monitoring into the health check-up process for migrant workers. BMET, which regulates emigration clearance, can include post-vaccination monitoring as part of the mandatory health checks required for overseas employment. This ensures that recruited workers are not only vaccinated but also monitored for any adverse events following immunization (AEFI) before and after their departure.
27	Bangladesh Hajj Office, Ministry of Religious Affairs	Opportunity	Through CDC, DGHS, Partially formal	Further formalization is required, e.g. through- - Adding extra module and by giving AEFI form during leaving for Hajj and collecting on return.	Director, Hajj Office, Ministry of Religious Affairs	Formalized attention is required for this vulnerable group.
28	Directorate of Primary Education	Opportunity	No integration	Formalization and capacity development required	Director General, Directorate of	Since the Directorate conducts large-scale programs for school children (who are among

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
					Primary Education	the largest recipients of vaccines), it can be used as a Partner for creating awareness and motivation regarding post-vaccination safety surveillance.
29	Clinical centers of excellence, clinical research organizations, universities	Opportunity	No integration	Formalized integration is required with capacity development of the stakeholder(s)	Director/ CEO of the individual organizations	Customized activities, aligned with the present strategy, will need to be developed based on the objectives, scope and management culture of the individual organizations.
30	Patients and Consumer Associations	Opportunity	No integration	Formalized integration is required with capacity development of the stakeholder(s)	President/ Secretary/ CEO of the individual organizations	Customized activities, aligned with the present Strategy, will need to be developed based on the objectives, scope and management culture of the individual organizations.
31	Professional Associations (e.g. medical doctors, pharmacists, nurses, etc.)	Opportunity	No integration	Formalized integration is required with capacity development of the stakeholder(s)	President/ Secretary/ CEO of the individual organizations	Customized activities, aligned with the present Strategy, will need to be developed based on the objectives, scope and management culture of the individual organizations.
32	Relevant Non-Governmental Organizations	Opportunity	No integration	Formalized integration is required with capacity development of the stakeholder(s)	President/ Secretary/ CEO of the individual organizations	Customized activities, aligned with the present strategy, will need to be developed based on the objectives, scope and management culture of the individual organizations.

Sl No	Identified stakeholders	Type of stakeholder (Critical or Opportunity)	Current level of integration (No integration, Informal, Formal)	Strategy to strengthen integration (with timelines)	Responsible Focal point	Remarks
33	Development Partners/ Donors	Opportunity	Limited integration	Further integration needs to be developed through formalized approaches	Country Director of the individual organizations	Customized activities, aligned with the present strategy, will need to be developed based on the objectives, scope and management culture of the individual organizations.
34	Media: Print, Electronic and Social	Other Important Stakeholder	No integration	Formalized integration is required with capacity development of the stakeholder(s)	President/ Secretary/ CEO of the individual organizations	Customized activities, aligned with the present strategy, will need to be developed based on the objectives, scope and management culture of the individual organizations.
35	Other important stakeholders (Patients, caretakers, users, healthcare professionals and allied professions)	Other Important Stakeholder	No integration	Formalized integration is required with capacity development of the stakeholder(s)	President/ Secretary/ CEO of the individual organizations	Customized activities, aligned with the present strategy, will need to be developed based on the objectives, scope and management culture of the individual organizations.

ANNEXURE 2

Selected Indicators to Monitor Strategic Actions of NSIPV

Strategic Action 1: Address the systemic issues through revisiting and aligning policies, rules, and regulatory frameworks relevant to post-vaccination vigilance issues and improve/ create the environment for optimum coordination

No	Indicator	Description
1	A comprehensive review of legislative and regulatory frameworks, with actionable recommendations on IPV, generated	An in-depth review of existing legislative and regulatory frameworks related to integrating post-vaccination vigilance will be done to identify gaps, inefficiencies, and areas needing improvement. The findings are expected to generate actionable recommendations designed to align national frameworks with international standards. These efforts will enhance the regulatory environment, strengthen the overall strategy for integrating post-vaccination vigilance, and ensure that the regulatory infrastructure supports robust vaccine safety measures, fostering greater coordination and compliance among all relevant stakeholders.
2	Action initiated on implementing relevant legislations and rules-regulations, with special focus on the Drug and Cosmetics Act, 2023	The IPV-related rules-regulations in the Drug and Cosmetics Act, 2023 will be initiated. If necessary, steps will be taken to develop a new Act addressing only for vaccine-related issues. This initiative aims to ensure that the regulatory framework is effectively enforced, prioritizing compliance, enhancing oversight, and reinforcing safety measures, thereby strengthening the overall national strategy for post-vaccination vigilance.

Strategic Action 2: **Develop the normative aspects such as shared values, culture and vision across organizations, professional groups and individuals regarding post-immunization safety surveillance issues**

No	Indicator	Description
3	IPV-centered awareness, advocacy, and motivation campaigns conducted using diverse and effective tools and channels	Organized awareness, advocacy, and motivation campaigns, centered on integrated post-vaccination vigilance, will be conducted with an aim to engage a broad audience using a variety of effective tools and channels. These initiatives seek to educate stakeholders about post-vaccination vigilance, encourage active participation, and emphasize the importance of vaccine safety across all relevant groups. Through diverse communication methods, these campaigns will enhance understanding, foster collaboration, bridge gaps among stakeholders, and drive coordinated efforts to support the national strategy for post-vaccination vigilance.

No	Indicator	Description
4	Broad participation of relevant stakeholder groups in the campaigns and initiatives ensured	Wide-ranging participation of related stakeholder groups (such as policymakers, planners, senior administrators, service providers, suppliers, and the general public) will be actively encouraged in all campaigns and initiatives. This inclusive approach aims to ensure that diverse perspectives are considered, fostering collaboration and strengthening the effectiveness of the national strategy for post-vaccination vigilance. Engaging a wide range of stakeholders will enhance collective understanding, commitment, and integrated action towards vaccine safety.

Strategic Action 3: Coordinate structures, governance systems and relationships across stakeholders

No	Indicator	Description
5	Formal contractual and cooperative arrangements established among Regulatory Agencies and other Stakeholders	Formal contractual and cooperative arrangements will be established as service commissioning and pooled funding agreements among regulatory agencies and other stakeholders for integration of post-immunization safety surveillance reporting. These arrangements will foster shared values, culture, and vision while ensuring the development and implementation of coordinated structures and governance systems. Initially, these relationships may begin as informal partnerships, but formalizing them through Memoranda of Understanding or Letters of Intent will be crucial for optimal integration. This approach will clearly define roles, responsibilities, and collaborative efforts, creating a systemic environment that supports the expansion of partnerships into larger, more robust organizations, ultimately strengthening regulatory oversight and enhancing the national strategy for vaccine safety.
6	Unified multiple partnership entities or frameworks established for post-immunization safety surveillance reporting	The establishment of umbrella organizational structures, such as federations or local partnerships, is crucial for enhancing coordination and governance in post-immunization safety surveillance reporting. These structures will act as centralized hubs, uniting diverse stakeholders under a coordinated system that enables streamlined communication, resource sharing, and collective decision-making. By fostering collaboration at local and national levels, these frameworks will ensure more effective monitoring and reporting of vaccine safety, thereby strengthening the overall strategy for post-vaccination vigilance and promoting a unified effort to maintain high standards of vaccine safety across all regions.

Strategic Action 4: Address administrative issues through the alignment of methodology and tools, back-office functions, budgets and financial systems across integrating units

No	Indicator	Description
7	Administrative functions across regulatory agencies and relevant stakeholders aligned	The effective delivery of integrated post-vaccination vigilance services depends on aligning administrative functions across regulatory agencies and key stakeholders that focuses on harmonizing methodologies, tools, and processes, and this coordination not only enhances efficiency by reducing the need for extensive human resources but also promotes cost-sharing and savings. Key elements of this alignment will include the development of shared information systems, accountability mechanisms, and funding processes for post-immunization safety surveillance. This coordinated effort will streamline operations, optimize resource use, and reinforce the national strategy for vaccine vigilance.

Strategic Action 5: Generate and improve the methodology and tools related to AEFI reporting of Vaccines

No	Indicator	Description
8	Functional inter-stakeholder communication systems established along with User-friendly AEFI reporting forms, digital channels (including Apps) and tools optimized following a review of the existing ones	Enhancing the effectiveness of post-immunization vigilance requires effective communication among the stakeholders and also on the development and optimization of user-friendly AEFI reporting forms, digital channels, and tools. These channels must be streamlined under clear regulatory provisions, with well-defined methodologies guiding reporting from peripheral levels to the center. A comprehensive review of existing reporting forms will gather input from various stakeholders to ensure the tools are both efficient and accessible. If necessary, forms will be redesigned or newly developed, prioritizing simplicity and user experience. Additionally, digital channels, such as user-friendly mobile apps, will be leveraged to optimize reporting and awareness efforts.
9	Upgraded or newly developed digital databases integrated at both national and international levels	Integration of post-vaccination vigilance will be greatly facilitated by shared databases. The development and integration of upgraded or newly created digital databases at both national and international levels are vital for effectively managing IPV. These databases will fully digitalize the reporting process, ensuring streamlined data storage and accessibility across all levels. A key focus will be on compatibility and connectivity with regional and international systems, enabling seamless data sharing and collaboration. This integration will significantly strengthen the post-vaccination vigilance framework, enhancing global efforts to monitor and ensure vaccine safety.

Strategic Action 6: Incorporate integrated post-vaccination vigilance related contents in the course-curricula and syllabi of the relevant professional education/training programs

No	Indicator	Description
10	Post-vaccination vigilance content and materials developed and integrated into the course- curricula and syllabi and training programs of targeted professional groups	Integrating post-vaccination vigilance content into course-curricula and training programs for targeted professional groups is essential to cultivating a skilled workforce. Tailored educational materials will address the specific needs of professionals such as physicians, pharmacists, nurses, paramedics, and community health workers, as well as policymakers and media professionals. These initiatives will ensure comprehensive training on vaccine safety surveillance during both academic education and ongoing professional development, fostering a deep understanding of safety issues and motivating active participation in post-vaccination vigilance efforts.
11	Assessment conducted on the impact of educational and training reforms on post-immunization vaccine vigilance	A thorough assessment will be conducted to evaluate the impact of educational and training reforms on post-immunization vaccine vigilance. This assessment will measure how effectively these reforms have enhanced vaccine safety awareness and reporting practices among targeted professional groups. Feedback from participants will be systematically collected and analyzed, enabling continuous refinement of educational content and training methods. Regular adjustments based on this feedback will ensure that the vigilance system stays responsive to emerging needs and challenges, ultimately strengthening vaccine safety efforts.

Strategic Action 7: Strengthen research activities on post-immunization vaccine vigilance

No	Indicator	Description
12	Research activities conducted and stimulated on identified priority areas of IPV	Research activities will be initiated and promoted in key priority areas of post-immunization vaccine vigilance focusing on generating context-specific evidence that addresses the diverse effects of vaccines, considering genetic and lifestyle variations. By strengthening safety surveillance programs, the research will provide valuable data that supports the unique needs of the population. Collaboration between academia and industry will be emphasized, ensuring that research efforts are well-coordinated and contribute to more effective health system planning and vaccine safety.

No	Indicator	Description
13	Robust pooled fund established to drive and sustain research initiatives	A robust pooled fund will be established to sustain research in priority areas of post-immunization vaccine vigilance. This fund, created through resource mobilization from the government, NGOs, industries, and development partners, will ensure ongoing research efforts. By pooling resources from diverse stakeholders, the fund will drive innovation and strengthen the national strategy for vaccine safety.

Strategic Action 8: Build capacity of the relevant Stakeholders in the area of post-immunization vaccine vigilance

No	Indicator	Description
14	Physical infrastructure and human resources of regulatory agencies and other stakeholders developed or strengthened, as appropriate.	To effectively implement strategic actions for post-immunization vaccine vigilance, it is crucial to develop and strengthen the physical infrastructure and human resources of regulatory agencies at all levels, from the periphery to the center. This includes upgrading the Pharmacovigilance (PV) Cell of the DGDA into a full-fledged department with dedicated units for drugs, vaccines, and medical devices. At the same time, the capacity development of other stakeholders is crucial for the effective integration of post-vaccination vigilance activities. These enhancements will ensure robust safety surveillance, improved coordination among national, regional, and international stakeholders, and better health outcomes for the population.
15	Integration of existing facilities/ infrastructure into the vaccine vigilance framework	To optimize the vaccine vigilance framework, existing facilities and infrastructure, from both public and private sectors, will be integrated into the system. This involves identifying and leveraging agencies that already have functional capabilities in related areas, ensuring their incorporation into the post-immunization vaccine vigilance efforts. By utilizing these established resources, the strategy will benefit from enhanced efficiency and resource-sharing, ultimately strengthening the overall framework for vaccine safety.
16	Capacity development strengthened through active stakeholder participation	Capacity development for post-immunization vaccine vigilance will be strengthened through the active participation of all relevant stakeholders, including manufacturers, importers, distributors, and retailers. By involving these groups in the process, comprehensive safety surveillance for both EPI and non-EPI vaccines will be ensured. Stakeholders will invest in enhancing their own capabilities, guided by strategic planning and oversight from the regulatory agency, leading to a more robust and collaborative approach to safeguarding public health.

No	Indicator	Description
17	Fresher and follow-up training programs conducted for relevant professional and stakeholder groups	Customized training programs and teaching-learning tools will be developed for specific stakeholder groups, including regulators, providers, manufacturers, and distributors, to enhance their knowledge and skills in vaccine vigilance. These programs will offer practical, context-specific content and will include both initial and follow-up training sessions. Regular training sessions will be organized through planned collaborations, ensuring continuous professional development and effective vaccine safety practices.

Means of Verification (MoV)

For almost all the strategic indicators, the major Means of Verification (MoV) will be the official reports/records from the Ministry of Health and Family Welfare (MoHFW) and/or relevant Ministries/Directorates/Agencies/other Stakeholder organizations. Commissioned Surveys/ Reports like the Annual Program Review (APR)/ Mid-Term Review (MTR) documents, as well as publications [like the Bangladesh Demographic & Health Survey (BDHS) and Bangladesh Health Facility Survey (BHFS)], will also serve as MoVs in some cases. In selected cases, independent studies/ surveys may supplement these initiatives.

The Operational Plans (OPs)/ implementation projects, either through the 5th Health, Population & Nutrition Sector Program (5th HPNSP) or through the other budgetary allocations of the implementing agency, will fix the operational level indicators for individual activities/sub-activities. In reality, those will constitute the Action Plan of the present Strategy (as explained in Annexure 2). In those documents, the OP Indicators and their MoVs will need to be presented under specific log frames.

ANNEXURE 3

Action Plan Schedule for Implementing NSIPV

1. Preamble

Post-vaccination vigilance (PVV) is one of the prerequisites to implement an effective and sustainable immunization program in any community. Awareness and motivation initiatives to receive vaccines constitute only one arm of an immunization program. The continued success of the program also depends on the continued trust and acceptability of the public on the vaccines to a large extent. This, in turn, depends on the efficiency and transparency of the post-vaccination measures undertaken and guaranteed by the concerned program. Involvement of multiple stakeholders Policymakers, Manufacturers, Importers, Distributors, Suppliers, Providers, Consumers, Caregivers and community people in general – makes the post-vaccination vigilance process more complicated than it seems apparently. From these aspects, the task of integration of the post-vaccination vigilance becomes an issue of central importance.

The success story of EPI in Bangladesh is well-recognized all over the world. However, the immunization program in the country is being challenged with the increasing introduction of Non-EPI vaccines for which coordinated plans and programs have not yet been designed and implemented. Also, the involvement of multiple actors in the healthcare sector, who may not be well-prepared to implement the post-vaccination vigilance, creates an additional challenge. Even for the EPI vaccines, increased attention is required for the post-vaccination vigilance issues. These facts lead to the need for a context-specific strategy to integrate the post-vaccination vigilance activities in Bangladesh and the present Strategy is an attempt in that direction.

Bangladesh is going to implement its 5th Health, Population & Nutrition Sector Program (5th HPNSP) in the next 5 years and, incidentally, the implementation of the present NSIPV is going to coincide with the Program. This creates an opportunity to implement various activities under the Strategic Actions through relevant OPs of the 5th HPNSP. This, however, should not undermine the need for increased attention and budgetary allocation in the revenue-based routine activities of DGDA and other concerned Authorities/Organizations. From the Strategy, it is obvious that the non-MoHFW Ministries and Directorates/Agencies have a major role in implementing the conceived Actions. Also, the private (both for profit and not for profit) Actors in the supply as well as the consumer sides have major roles to play in the process of integration. Accordingly, commitment to financial and other relevant resources will be of central importance for the successful implementation of the present strategy.

To facilitate the achievement of these practical ends, a phased approach to the implementation of strategic actions is being proposed in the present schedule. Focusing on immediate priorities and foundational requirements, the Short-Term Activities are proposed to be implemented within the first 2 years of the Sector program. Based on the initial progress and expanding the scope of the foundational initiatives, the mid-term

activities are being proposed to be implemented within 2030. With targets for comprehensive integration of systems and processes and sustained improvement as well as long-lasting impact, the long-term activities are proposed to be implemented at periods extending beyond 2030.

The spreading of the strategic actions over time will facilitate the distribution of work effectively over time, allowing for gradual and consistent advancement toward the overall objectives. With the code number of the activities corresponding to that in the main Strategy, the distribution of activities is shown in section 2 below. It should be mentioned that the distribution is tentative, the actual scheduling (including the incorporation in the Priority Action Plan or PAP of the individual OPs) will need to be done on detailed discussion during the review of the Sector Program.

2. Proposed Scheduling of the Activities under the NSIPV

a. Short Term Activities

Strategic Action 1. *Address the systemic issues through revisiting and aligning policies, rules and regulatory frameworks relevant to post-vaccination vigilance issues and improve/create the environment for optimum coordination.*

1.1 Review the legislative and regulatory frameworks of the Regulatory Agencies and other Stakeholders as relevant to the safety vigilance after immunization.

1.2 Suggest, if necessary, the modification of existing legislative and regulatory measures to improve safety vigilance after immunization.

1.3 Suggest, if necessary, the introduction of new legislative and/or regulatory measures to improve safety vigilance after immunization.

Strategic Action 2. *Develop the normative aspects such as shared values, culture and vision across organizations, professional groups and individuals regarding post-immunization safety surveillance issues.*

2.5 Develop common integration goals among the stakeholders.

2.6 Identify and address communication gaps among Stakeholders.

Strategic Action 5: *Generate and improve the methodology and tools related to AEFI reporting of vaccines.*

5.1 Review the existing Reporting Forms with input from the various stakeholders.

5.2 Redesign, if necessary, the Forms with special reference to user-friendliness.

5.3 Design, if necessary, new Forms with special reference to user-friendliness.

5.4 Design short and simple Forms, as much as possible, without compromising the quality.

Strategic Action 7: *Strengthen research activities on post-immunization vaccine vigilance.*

7.1 Identify priority areas and projects for research activities on consultation with various stakeholders.

Strategic Action 8: *Build capacity of the relevant stakeholders in the area of post-immunization vaccine vigilance.*

8.2 Explore the already existing potential infrastructure/facilities for their probable incorporation in post-immunization vaccine vigilance.

b. Short Term/Mid Term Activities

Strategic Action 2. *Develop the normative aspects such as shared values, culture and vision across organizations, professional groups and individuals regarding post-immunization safety surveillance issues.*

2.1 Sensitize relevant policy makers, planners, and senior administrators through advocacy initiatives.

2.2 Initiate large-scale awareness campaigns, involving service users and the wider community, using mass media, social media and community-oriented activities.

2.3 Generate awareness and motivation among service providers (like Physicians, nurses, pharmacists, and community health workers) and using effective tools and channels.

2.4 Generate awareness and motivation regarding post-vaccination vigilance integration among manufacturers, importers, distributors and retailers.

2.7 Build immunization service relationships and trust through local events.

2.8 Involve service users and the wider community.

Strategic Action 3. *Coordinate structures, governance systems and relationships across stakeholders.*

3.1 Develop formal and informal contractual or cooperative service commissioning arrangements among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

3.2 Develop formal and informal contractual or cooperative arrangements among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

3.3 Develop umbrella organizational structures such as federations or local partnerships for post-immunization safety surveillance reporting.

Strategic Action 6: *Incorporate integrated post-vaccination vigilance related contents in the course-curricula and syllabi of the relevant professional education/training programs.*

6.1 Create content and educational materials related to post-immunization vaccine vigilance for providing education and training to students from relevant levels and disciplines.

6.2 Take organized initiatives to incorporate post-immunization vaccine vigilance-related contents in the course curricula and syllabi of the educational and training programs.

Strategic Action 8: *Build capacity of the relevant stakeholders in the area of post-immunization vaccine vigilance.*

8.4 Develop training programs with customized course-curricula and training materials for specific groups of professionals from the relevant stakeholders.

c. Short Term/Mid-Term/Long Term Activities

Strategic Action 1. *Address the systemic issues through revisiting and aligning policies, rules and regulatory frameworks relevant to post-vaccination vigilance issues and improve/ create the environment for optimum coordination.*

1.4 Take steps for the modification of the existing or introduction of new legislative and/or regulatory measures and administrative steps, as appropriate.

1.5 Enhance the implementation of the relevant acts by framing the rules and regulations as related to safety vigilance after immunization.

1.6 Improve/ create a comprehensive policy environment for optimum coordination.

Strategic Action 4. Address administrative issues through the alignment of methodology and tools, back-office functions, budgets and financial systems across integrating units.

4.1 Develop shared information systems among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

4.2 Develop shared accountability mechanisms among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

4.3 Develop shared funding processes among regulatory agencies and other stakeholders for post-immunization safety surveillance reporting.

Strategic Action 5: *Generate and improve the methodology and tools related to AEFI reporting of Vaccines.*

5.5 Use (as much as feasible in the Bangladesh context) the digital channels (e.g. Apps in mobile phones) for the integration of post-immunization vigilance.

5.6 Create databases for cumulating the AEFI reports at various levels.

Strategic Action 6: *Incorporate integrated post-vaccination vigilance related contents in the course-curricula and syllabi of the relevant professional education/training programs.*

6.3 Review the impact of education and training-related reforms on post-immunization vaccine vigilance.

Strategic Action 7: *Strengthen research activities on post-immunization vaccine vigilance.*

7.2 Develop coordinated mechanisms to promote research in the prioritized fields.

7.3 Create a pool fund to support research in the selected areas.

Strategic Action 8: *Build capacity of the relevant stakeholders in the area of post-immunization vaccine vigilance.*

8.1 Strengthen the PV Cell of DGDA with relevant inputs on physical infrastructure and human resources.

8.3 Encourage suppliers to take ownership of their capacity building efforts.

8.5 Arrange regularly the fresher as well as follow-up training programs for the relevant professionals.

8.6 Enhance the ICT infrastructure to use the digital tools and channels for conducting relevant activities like advocacy/awareness, reporting, education, training, and research.