National Public Health Laboratory Strategy for Infectious Diseases

Institute of Epidemiology, Disease Control & Research (IEDCR)
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of the People's Republic of Bangladesh

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National Laboratory Strategy
Applicable for all public health laboratories in Bangladesh

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Abbreviations

BCSIR-Bangladesh Council of Scientific and Industrial Research
BFRI – Bangladesh Fisheries Research Institute
BIRDEM-Bangladesh Institute of Research and Rehabilitation in Diabetes
BITID- Bangladesh Institute of Tropical and Infectious Diseases
BLRI-Bangladesh Livestock Research Institute
BMDC-Bangladesh Medical and Dental Council
BSL-Biosafety Level
BSMMU-Bangabandhu Sheikh Mujib Medical University

CDC-Center for Disease Control and Prevention
CDIL-Central Disease Investigation Laboratory
CLSI-Clinical Laboratory Standards Institute
CMBT-Center for Medical Biotechnology
CMU-Chattogram Medical University
CPHL-Central Public Health Laboratory
CQI-Continuous Quality Improvement
CRP-Centre for Rehabilitation of the Paralyzed

DGHS-Director General of Health Services
DLS- Department of Livestock Services
DNA- Deoxyribonucleic Acid

EID-Emerging Infectious Disease
EQA-External Quality Assurance
EQAS-External Quality Assurance Scheme
EQAP-External Quality Assurance Programme

FDIL-Field Disease Investigation Laboratory
FIQC- Fish Inspection and Quality Control

GDD- Global Disease Detection
GHSA-Global Health Security Agenda
GoB-Government of Bangladesh

HBV-Hepatitis B Virus
HIMS-Health Information Management System
HIV-Human Immunodeficiency Virus

icddr,b-International Centre for Diarrhoeal Disease Research in Bangladesh
ICT-Immunochromatographic Test
IDH-Infectious Disease Hospital
IEDCR-Institute of Epidemiology, Disease Control and Research
IPH-Institute of Public Health
IPHN-Institute of Public Health Nutrition
IQC-Internal Quality Control
ISO-International Organization for Standardization
IVD-In vitro Diagnostics

JE-Japanese Encephalitis
JEE-Joint External Evaluation

KPI- Key Performance Indicator

LIMS-Laboratory Information Management System

LRI-Livestock Research Institute
LQMS-Laboratory Quality Management System
LQS-Laboratory Quality System

M&E-Monitoring and Evaluation
MIS-Management Information System
MoEF-Ministry of Environment and Forestry
MOH- Ministry of Home
MOHFW- Ministry of Health and Family Welfare
MoLSF -Ministry of livestock and fisheries
MT-Medical Technologist

NGO-Non-government Organization
NIC-National Influenza Centre
NICVD-National Institute of Cardiovascular Diseases
NIKDU-National Institute of Kidney Diseases & Urology
NILM&RC-National Institute of Laboratory Medicine and Referral Center
NIPSOM-National Institute of Preventive and Social Medicine
NLSC – National Laboratory Strategic Committee
NPHL-National Public Health Laboratory
NPHLN-National Public Health Laboratory Network
NICRH-National Institute of Cancer Research & Hospital
NIDCH-National Institute of Diseases of the Chest and Hospital
NIMH-National Institute of Mental Health
NIO-National Institute of Ophthalmology
NINS-National Institute of Neurosciences & Hospital
NITOR-National Institute of Traumatology & Orthopedic Rehabilitation
NIENT-National Institute of Ear, Nose and Throat,
NTC-National Technical Committee
NTRL-National Tuberculosis Reference Laboratory

PCR-Polymerase Chain Reaction
PEP-Post-exposure Prophylaxis
PHL-Public Health Laboratory
POC-Point of Care
POCT- Point of Care Testing
PPP- Public Private Partnership
PRTC-Poultry Research and Training Centre

QA-Quality assurance
QC-Quality Control
QMS- Quality Management System

RDT-Rapid Diagnostic Test
RMU-Rajshahi Medical University
RTRL-Regional Tuberculosis Referral laboratory

SMU-Sylhet Medical University
SOP-Standard Operating Procedure

TB-Tuberculosis
ToR-Terms of Reference

VDRL-Venereal Disease Research Laboratory
VPHL-Veterinary Public Health Laboratory

WHO-World Health Organization

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Introduction

Laboratories are often the first sites for the detection of disease outbreaks and also serves as a major source for health information. They produce critical and relevant information for epidemiology surveillance and disease management. Laboratory diagnostic Information provided by the medical laboratory supports the practice of modern medicine. This information also helps by defining the incidence and prevalence of disease. Strong laboratory facilities are therefore essential to health as well as to the national well-being and maintenance of health and economic development.

Over the years, the Ministry of Health and Family Welfare (MoHFW), Bangladesh has the commitment to improve the institutional capacity of the health sector to be able to respond in an adequate and timely manner to the public health care needs of the country within a resource constrained environment. Bangladesh has no specific strategy for laboratory services. All laboratories are currently run by an ordinance of 1984. A national laboratory strategy is essential to run the laboratory services properly in the country. A joint external evaluation (JEE) in May 2016 also highlighted the absence of national laboratory policy and strategy. WHO/ GHSA suggested to develop capacity to detect priority pathogen at regional level and develop a national strategy. Institute of Epidemiology, Disease Control & Research (IEDCR) is trying to identify pathogens (known/unknown) of public health concerns by improving laboratory capacity of not only at IEDCR but also at national and sub-national level. IEDCR will build capacity of seven laboratories as regional laboratory to detect priority pathogens.

A national strategy will help MOH&FW in better understanding of the laboratory services in the country. The national laboratory strategy is developed with particular focus to infectious diseases. This national strategy will include mapping of the laboratories at the divisional level, laboratories having disease specific detection facilities, national laboratory quality system (LQS), disease specific reference laboratories (NTRL, IPH, IEDCR, icddr,b etc.) and laboratory networking.

Challenges to establish a network:

- Limited laboratory policy and strategy for networking;
- Lack of adequate funding and logistics;
- Laboratory personnel are not adequately trained/ oriented with networking.

Situational Analysis:

Public health laboratory resources include laboratories at all medical universities, medical colleges, district hospitals, upazilla health complex and specialized institutes including the Institute of Epidemiology and Disease Control Research (IEDCR)/NIC, NILMRC, Institute of Public Health (IPH), National Institute Of Neurosciences & Hospital (NINS), National Institute of Traumatology & Orthopedic Rehabilitation (NITOR), National Institute of Kidney Diseases & Urology (NIKDU), National Institute of Ophthalmology (NIO), Bangladesh Institute of Tropical and Infectious Diseases (BITID), and the National TB Reference Laboratory (NTRL), plus major laboratory resources at icddr,b, etc. which can be drawn upon by the public health system.

The countrywide public health laboratories are either public or private. The major contributions are from government of Bangladesh. The public health laboratory facilities can further be categorized at different tiers;

- Primary: Upazilla Health complex laboratories with limited laboratory capacity supporting sample collection, preparation and rapid testing.
- Secondary: district level laboratories at the District Hospitals or at the specialized hospitals (TB and/or other infectious diseases).
- Tertiary: specialized laboratories working under the departments of Microbiology, Virology, Biochemistry, Hematology, Histopathology, Immunology, Molecular Biology and Laboratory Medicine/Clinical Pathology at different Medical Colleges & Hospitals. These laboratories are equipped with standard instruments for testing of body fluids, tissues and other biological specimens.
- Laboratories of different specialized facilities, e.g. NILMRC, IEDCR, IPH, IPHN, NIPSOM, NTRL, NICVD, NIKDU, NIMH, NIRCH, NIO, NINS, NITOR, NIENT,NICRH, NIDCH, Sheikh Russel Gastro liver Institute, IDH, BITID, CMBT, NTRL and others. Some of these laboratories are equipped with advanced instruments and capable of conducting high level biochemical, immunological, microbiological and molecular analysis of the clinical/biological specimens.

Besides there are some laboratories under the autonomous authorities of BSMMU, Dhaka Shishu Hospital, BIRDEM and other universities that have the infrastructural facilities to conduct research level analysis of the biological specimens. There are also 4,458 laboratories in the private health sector – some of these laboratories that are attached to large private hospitals are contributing significantly in healthcare services. Moreover, there are some other inter-ministerial laboratories that further contribute and strengthen the countrywide laboratory facilities and capacity in case of any national crisis. Animal health laboratories are under MoLSF include LRI, BLRI, CDIL, FIQC, PRTC, BFRI, VPHL and FDILs. Besides a number of other ministerial laboratories e.g.; food, water, organic and antimicrobial testing laboratories of Ministry of Local Government; drug testing, forensic and DNA laboratories of Ministry of Home Affairs; BSTI laboratories of Ministry of Industries; BCSIR, National Institute of Biotechnology laboratories of MoST, public health related laboratories at different Universities; BARI, BRRI, SRDI research laboratories of MoA; National food safety lab under the Ministry of Food etc. are the prospective laboratories with wider range of technical capacities in case of any public health crisis/issues.

Bangladesh has huge laboratory work force at the national level, with advanced testing capacities at IEDCR and icddr,b laboratories for human health, BLRI and CDIL for animal health, BFRI and FIQC for aquatic health. Regarding core tests coverage as per the International Health Regulations mandatory diseases, Bangladesh has SOPs.

Having been considering the above mentioned laboratory facilities, following is the glimpse of their activities:

- Routine clinical testing for outbreak investigation, surveillance and advanced research .such as:
  - IEDCR works as NIC,GDD Centre
  - BLRI works as reference laboratory for avian influenza
  - IEDCR works as reference laboratory for AMR, Nipah, JE
  - National Polio Lab/IPH works as virus culture for poliovirus
  - IEDCR and icddr,b for Influenza and Chikungunya virus culture
  - IEDCR/BSMMU/ icddr,b /Designated Labs at medical colleges for Sero-Immunology
  - District Hospitals/Medical College Hospitals/NTRL/RTRL/icddr,b for microscopy of mycobacterium tuberculosis
  - District Hospitals/Malaria Laboratory for Rapid diagnostic testing of plasmodium spp.
  - Medical Colleges/IEDCR/icddr,b,/BSMMU/CDIL/FDIL/NILMRC for bacterial culture for disease surveillance and AMR.
  - All tertiary level hospitals are equipped for PCR
  - IEDCR and icddr,b has facilities for sequencing, next generation sequencing
- Collaboration with US CDC/WHO reference laboratory, ASM etc. to ensure further testing and technical supports are available if necessary
- Ministry of Defense has laboratories for serving armed forces, they can provide emergency laboratory support if needed.

Rationale:

A national laboratory strategy is essential to run the laboratory services properly in the country. An ordinance of 1984 is available for laboratories of Bangladesh. A joint external evaluation (JEE) in May 2016 highlighted the need of policy and WHO/ GHSA suggested to develop a national strategy for public health laboratories. Therefore the national laboratory strategy is being developed.

Vision:

- Strengthening of national public health laboratory services.

Mission of the Laboratory Services:

- Improving services at different tiers of public health laboratories in Bangladesh.
- Establishment of laboratory networking.
- Development of human resources.
- Building up integrated response capacity to address public health threats.
- Strengthening collaboration between in-country and regional stakeholders / partners.

Objectives:

- To establish standard and sustainable laboratory services to combat public health threats;
- To establish system of monitoring and evaluation of public health laboratory services;
- To develop skilled laboratory personnel by training and education;
- To establish laboratory networking;
- To improve Laboratory Quality Management (LQM) System;
- To provide technical supports for research;
- To facilitate accreditation of public health laboratories according to IS0 15189: 2012;

Scope:

This guide is intended for the policy makers as well as persons involved in management of public health laboratories and the coordinator of the NPHLN. Other users of this guide may include laboratory personals at all levels, training officers, curriculum developers, and Ministry of Health and their partners.

CHAPTER 1

Public Health Laboratory Services

Introduction:

Laboratory services are an integral part of clinical decision making and contribute to various aspects of health services, including diagnostic and therapeutic decisions for patients, disease surveillance, monitoring, prevention and research. Well-functioning and sustainable laboratory services are essential for strong health systems and crucial for improving public health.

The National Public Health Laboratory Services plays a pivotal role in response to an effective health care delivery. As many emerging and re-emerging diseases are connected with environmental and animal health, PHL services should run following one health networking approach. The laboratory serves as a key component to achieve both quality clinical care and meaningful public health interventions.

Accurate and reliable diagnosis is the cornerstone of disease management and prevention. As such, public health laboratories are indispensable as they provide the diagnostic services that are critical to individual case management but also to disease surveillance, control, education and research.

The laboratories perform core public health and environmental activities, including public health reference tests, disease prevention, control and surveillance, population-based interventions, and communication with healthcare providers on appropriate patient care, and emergency response efforts.

Goal:

- To achieve quality laboratory services at different tiers of country's health care system in an integrated way keeping pace with one health approach.

Objectives:

- To improve and strengthen the existing PHL for ensuring quality laboratory services;
- To support disease surveillance, emergency response, planning and policy development;
- To establish an effective referral system and networking among laboratories of different tiers;
- To strengthen laboratory data management system at local level as well as integrate communication with central data management system;
- To ensure incorporation of private diagnostic laboratories within PHL networking;
- To ensure at least biosafety level II in all tiers of PHL;
- To establish effective networking of PHL with other concern bodies dealing with animal and environmental health;
- To secure allocation of adequate budget in operation plan/revenue;
- To encourage Public Private Partnership(PPP) in PHL services;
- To ensure involvement of stakeholders in development, management and maintenance of PHL;

Components of Public Health Laboratory Services

- **Laboratory organization and structure**

  There should be a clear organizational structure with appropriate authority to coordinate and manage comprehensive health laboratory services at all levels in the country.

- **Laboratory network tiers and networking** (see chapter 3)

- **Laboratory equipment and supplies**

The strategy must ensure that laboratories are adequately and appropriately equipped and ensured with adequate supplies.

- **Infrastructure**

It must be ensured that all laboratories meet the minimum infrastructural requirements as defined by National Biosafety and Biosecurity Guidelines for Medical Laboratories.

• Research and development

The strategy should promote research and development relevant to health priorities of the country.

• Financing Laboratory services

It is to ensure adequate budget allocation in operational plan for implementation and support of laboratory services.

• Laboratory governance

Laboratory governance is necessary to optimize standard laboratory function, comprehensive laboratory management and laboratory quality assurance.

Activities:

- Strengthening of existing laboratory capacity by
    - o Renovation of infrastructure where required
    - o Provision of adequate human resource (laboratory specialist, Medical Technologist (MT) and other supporting staffs)
    - o Forecasting and planning for supplying equipment, logistics and reagents
    - o Provision of maintenance of equipment
    - o Allocation of budget to maintain the above mentioned activities
- Improvement of laboratory service at upazilla, district, divisional, regional and national level by:
    - o Early detection of public health threats to plan timely intervention
    - o Provide information to the stakeholders appropriately against potential threats.
    - o Provision of point of care (POC) testing facilities for emergency services
    - o Monitor notifiable and reportable conditions in a comprehensive way
- Introduction of an effective referral system and networking among laboratories of different tiers (chapter 4)
- Development of digital data management system in all tiers of PHL
- Integration of laboratory data with existing central data management and communication system
- Incorporate private diagnostic laboratories within PHL networking
- Establish at least biosafety level II in all tiers of PHL
- Allocate adequate budget in operation plan
- Establish Public Private Partnership (PPP) in PHL services
- Involve stakeholders in development, management and maintenance of PHL
- Periodic comprehensive evaluation of National Public Health Strategic Plan so that modifications can be made against new threat in health service delivery
- Create a standing PHL Advisory Committee (appendix 5)
- Ensure routine laboratory diagnostics test at all level.
- Provision for inclusion of newly introduced laboratory tests at all level

CHAPTER 2

Human Resources

Introduction:

Health workforce is still a major bottleneck for the appropriate provision of health services, with challenges in adequacy of numbers and skills, motivation, retention, and performance challenges. Medical technologists play a vital role in laboratory services. Although adequate numbers of qualified medical technologists are available in the country, the recruitment in public sector has been suspended for many years that made a huge challenge to ensure quality services. There is no occupational health strategy and provision of remuneration program in place now. Harmonization of different curriculum for the same discipline is also important for better outcome. A strategic timeline with monitoring and evaluation framework is critical to achieve the goal for human resource development.

Goal:

- Adequate availability of the laboratory personnel with the appropriate skills and competencies to support the delivery of a comprehensive laboratory services at each level of health care.

Objectives:

- To ensure development and availability of skilled laboratory personnel;
- To strengthen a digital platform for human resource development;
- To establish an occupational health program for laboratory personnel;

Activities:

- Harmonization of different curriculum for the same disciple in both government and private institutions..
- Strengthening accreditation process for different institutions responsible for developing human resources of laboratory services.
- Develop career plan for laboratory personnel.
- Create job facilities for different levels of laboratory services.
- Update term of references (ToR) at different levels of laboratory services.
- Provide regular training.
- Assessment of competency.
- Conduct human resources audits periodically to determine staffing gaps within laboratories.
- Establish human resource database for e-governance / digital platform.
- Establish an occupational health program for laboratory personnel.
- Conduct pre- recruitment and periodic screening of occupational hazards.
- Formation of national laboratory strategic committee (NLSC).

CHAPTER 3

Laboratory Networking

Introduction:

A national public health laboratory network (NPHLN) is composed of laboratories at each level of the health system (national, divisional, district, upazilla) committed to the proper diagnosis of priority infectious diseases for public health decision making. A functional laboratory network establishes channels for routine communication, exchange of information, and interaction in specified ways with each other at the level of the national integrated disease surveillance program. The national public health laboratory may also communicate and interact as necessary with sub-regional and regional WHO networks and with international collaborating centres. The aim of the functional network is to provide strategic advice and share expertise to strengthen national capacity for laboratory services to support disease surveillance and control and share knowledge during disease.

A good disease surveillance system needs disease detection by laboratory investigation. Capacity and type of every laboratory is not the same. Sample collection for surveillance may be from any place in Bangladesh. Laboratory at upazilla is of BSL-1, and can carry out limited number of investigations. At the next higher level, laboratories at district level can conduct investigations at a higher level. Most of the Microbiology/Virology laboratories at Medical Colleges are of BSL-2 level. A BSL-2 laboratory at IEDCR is the reference laboratory for Influenza ,Nipah and AMR.

Most of the emerging diseases are of zoonotic origin, including currently ongoing COVID-19. Laboratories at livestock sector conduct investigations for animal disease surveillance. For an effective surveillance and response to zoonotic emerging diseases, close collaboration between laboratories of human and animal health is necessary in consistence with one health approach.

The National Public health laboratories (NPHLs) are usually included as sentinel sites for surveillance of infectious diseases of national and international concern and should be an integral part of the global network of laboratories. It is, therefore, important that they should be linked into an effective national communication network. Network formation can assist members in a variety of ways and facilitates the timely and effective use of PHL information to guide the selection of appropriate interventions.

The laboratory networking strategy covers three broad areas, namely:

- Collecting, analyzing, and reporting laboratory data and using this information for public health action.
- Strengthening appropriate, standard and sustainable diagnostic practice
- Linking public health laboratory diagnostics with national and regional surveillance activities.
- Establishment of intra and inter laboratory referral system for sharing of knowledge, information and practices although IEDCR by its various surveillance activities throughout the country is maintaining networking with the sentinel sites of the surveillance.

Currently, there is no formal networking among PHLs in Bangladesh. Yet Laboratory personnel working in charge of the laboratories, often share experiences informally at different levels of healthcare settings. In the event of public health emergency for zoonotic, food-borne chemical, environmental, and radiation hazards, a multi sectoral collaboration using One Health Approach between PHLs is warranted.

Goal:

- To achieve high quality, accurate and time demanding laboratory-based information for policy making and public health decisions.

Objectives:

- To ensure functional and sustainable networking among different tiers of PHLs;
- To strengthen intra and inter sectoral regional and international networks for surveillance, outbreak alertness and response;
- To promote integration of high quality rapid and reliable laboratory information;
- To strengthen scientific and technical collaboration between the PHLs;

Activities:

- **Establishment of NPHLN:** The MoHFW will officially establish an Advisory Committee (National Technical Committee- NTC) to guide coordination & management of a functional network. Secretarial support will be provided by focal institute.
- **Coordination of the laboratory network :** The NTC will assign the national public health reference laboratories (NPHRL) for coordination of the laboratory network at the national level.
- **Formation of NPHLN coordinating body:** Will be formed with persons from multiple relevant ministries and should be in action through appropriate links with the NPHLN.
- **Development of National policy on laboratory services:** Establish national public health and clinical laboratory policy that clearly defines roles of laboratories at different levels.
- **Establish contact with other networks:** Network will be established at regional and international levels through the NPHLN,
- **Strengthens collaboration:** Collaboration with laboratories of animal health, chemical, radiation. environment, food and similar other sectors will be strengthened.
- **Standardization of laboratory tests through regional and international cooperation:** Laboratory tests will be standardized through regional and international cooperation .
- **Sharing of test results:** Disease-specific information such as COVID 19, anthrax, influenza, Dengue, Chikungunya or other emerging or re-emerging diseases will be provided at any time with any or all of the network members.

CHAPTER 4

Laboratory Quality Management System

Introduction:

Quality laboratory report is critical for patient management. International Organization for Standardization (ISO) and Clinical and Laboratory Standards Institute (CLSI) defined Laboratory Quality Management System (QMS) as "coordinated activities to direct and control an organization with regard to quality". In a quality management system, all aspects of the laboratory operation, including the organizational structure, processes and procedures, need to be addressed to assure quality.

Goal:

- To establish laboratory quality management system at all tiers of National Public Health Laboratories.

Objectives:

- To ensure sustainable, comprehensive and quality management systems at all tiers of National Public Health Laboratories ;
- To achieve national and /or international accreditation ;

Activities:

- Development of NPHL guideline.
- Establishment of laboratory quality assurance team.
- Development and implementation of effective quality management system across all levels of PHL.
- Establishment of coordination among stakeholder for implementation of laboratory Quality Management Systems.
- Development of IQA and EQA programs.
- Identification of gap that need to be improved for quality laboratory report.
- Strengthen the quality of point of care testing (POCT).
- Strengthening and implementation of quality management system for laboratory accreditation.
- Conduct periodic audits (internal and external) to evaluate the quality performance of the laboratories.

Monitoring and Evaluation

Introduction:

Implementation of the National Laboratory Strategy for diseases diagnosis requires regular and careful monitoring. It is important to ensure that the activities are properly implemented and financial expenditures are optimum. It is also necessary to put in place appropriate mechanisms to monitor and evaluate the delivery of laboratory services in general. There is a need to develop a comprehensive and effective monitoring and evaluation system to assess the laboratory system's performance also.

Goal:

- To establish a functional and sustainable laboratory M&E system

Objective:

- Establish and strengthen the platforms for Monitoring and Evaluation (M&E) of laboratory services;

Activities:

- To develop M&E framework for laboratory services.
- To establish a position for laboratory monitoring and evaluation coordinator.
- To develop monitoring and evaluation tools to assess laboratory services
- To develop an M&E training program.
- To conduct periodic audits, both internal and external, to evaluate performance and activities, based on the essential elements.

CHAPTER 5

Research Strategy for Laboratory Service

Introduction:

Research acts as a baseline platform to provide information for national policy, improve the functions and quality of the public health laboratory system addressing emerging health challenges.

The potential of public health laboratories in undertaking quality research to improve public health services cannot be denied. It is yet to be effectively explored in developing countries like Bangladesh.

It is an erroneous belief that research can be conducted only in highly sophisticated and modern laboratories. Research relating to public health can be undertaken even in the most peripheral areas of the country to solve public health issues faced by the local population. The major gaps and limitations for research are motivation and prioritization, appropriate planning and policy, adequate funding etc. If these are addressed properly, even a peripheral facility like upazilla health complex laboratory can provide substantial support in improving the health of the people by undertaking research and providing solutions that are acceptable and applicable in that context.

Goal:

- Promote research and innovation relevant to the public health priorities of the country in every tier of public health laboratories.

Objectives:

- To utilize laboratory tests for more effective disease surveillance;
- To introduce newly designed diagnostic methods and find out their impact in country perspective;
- To facilitate new diagnostic technique and testing in country perspective;
- To collaborate with national and international organizations in facilitating research activities;

Activities:

- Organize training and refreshers training for laboratory personnel.
- Conduct regular training in research methodology.
- Develop and disseminate research agenda / priorities for laboratory services.
- Develop a mentorship program on operational research.
- Conduct research that responds to priority areas.
- Recommend research implementations.
- Organize annual laboratory research day.
- Find out and apply newly designed diagnostic methods suitable for public health purpose.
- Signing memorandum of understanding with national and international organization for research collaboration.

CHAPTER 6

Biosafety and Biosecurity

Introduction:

Laboratory biosafety and biosecurity protect the personnel and the environment, keep valuable biological materials safe and secured inside the areas where they are used and stored. Good laboratory biosafety practices strengthen laboratory biosecurity systems. An extensive biosafety culture translates into the routine application of safe practices, procedures, actions and habits that protect the personnel working with biological materials. Significant levels of biosafety may be acquired through carefully designed and implemented work practices, even in resource limited facilities.

Goal:

- Implementation of the national guideline to ensure biosafety and biosecurity at different levels of public health laboratories.

Objectives:

- To ensure compliance of the national biosafety and biosecurity guideline at different levels of public health laboratories;
- To define the biosafety level of the laboratories in accordance with standard guidelines;

Activities:

- Formation of a national biosafety and biosecurity coordination committee (to support and monitor the compliance of the public health laboratories to the National Guideline-ToR).
- Formation of institutional biosafety committee.
- Conduct risk assessment and provide recommendation about the biosafety levels of the laboratory.
- Design / renovate laboratory infrastructure according to the biosafety and biosecurity guideline.
- Develop and maintain facilities for proper storage, safe transport and disposal of potentially hazardous substances from the laboratory.
- To develop an inventory of all chemicals, infectious agents and other harmful materials that have potential health hazard.
- Identify and record the various types of incident and accident which may arise in a laboratory and ensure specific plan of actions against them.
- Conduct induction and on job biosafety and biosecurity training periodically for laboratory personnel.
- Allocate adequate budget for implementation of biosafety and biosecurity

CHAPTER 7

Waste Management

Introduction:

Laboratory activities produce wide variety of wastes which includes general and biohazard wastes.. These may cause significant risk to human health and environment when standard waste management practices is not followed. The laboratory activities needed to be guided by a naturally agreed and approved standard guideline /protocol and presented by all engaged in laboratory work.

Goals:

- Ensure proper treatment ,transport and disposal of waste in accordance with national environmental protection regulation

Objective:

- To ensure segregation and safe management of laboratory wastes for protection of laboratory personnel as well as environment
- To increase awareness on importance of waste management among all public health laboratory stakeholders

Activities:

- Prepare and follow SOPs that include detail procedure for waste minimization and management
- Categorize and segregate laboratory waste in proper container
- Treat waste before leaving the laboratory
- Build a secondary waste storage area in the facility
- Transport and dispose waste according to the national environmental protection regulations
- Conduct orientation and practical on-job training on waste management to all laboratory personnel
- Increase awareness on the importance of waste management among the laboratory personnel
- Orient the laboratory administrative personnel on the importance of waste management
- Provide appropriate PPE and logistics for the staff handling the waste
- Maintain log book for waste disposal
- Monitor the waste management activities periodically

Appendices

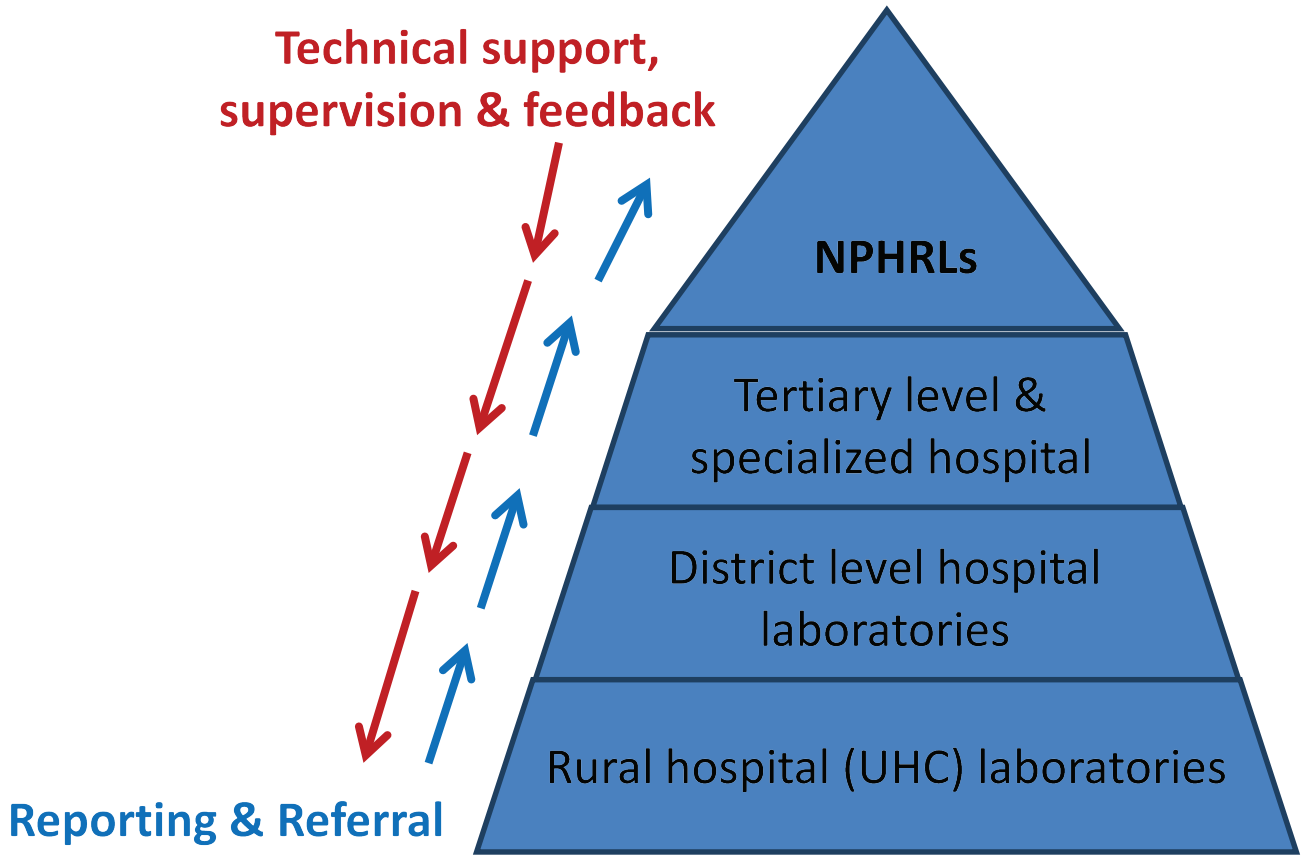
Appendix 1:

STRATEGIC PLAN TIMEFRAME: (Action Plan)

Strategic Plans		Time frame (in years)					Outcomes	Responsible authorities
		1	2	3	4	5		
1.	Conduct need base analysis	√		√		√	Situation analyzed	MOH, DGHS, NLSC
2.	Address requirement and posting of laboratory personnel		√		√		Recruitment	MOH, NLSC,DGHS
3.	Development of human resource skill through training program	√	√	√	√	√	Skill developme nt	MOH, DGHS
4.	Monitoring of the skill development, practice and feedback			√		√	Improve skill	MOH, DGHS
5.	Addressing and implementing pre-service/in-service training	√	√	√	√	√	Resource developme nt	NLSC, DGHS
6.	Conducting internal and external evaluation of training program and laboratory service			√		√	Good laboratory outcome	MOH, DGHS
7.	Developing job criteria and implementing recruitment and promotion	√	√		√		Recruitment	MOH, NLSC, DGHS
8.	Development of human resource database			√	√	√	Optimal use of human resource	MOH, DGHS
9.	Development of intra and inter-departmental co-operation for manpower management through laboratory networking		√	√	√	√	Intra and inter-department al involvement	NLSC, relevant Ministries, NGO's
10.	Formation of national laboratory strategic committee	√					Strategy implements	Relevant ministries, NGO's
11	Registration / enroll before join in a job	√	√	√	√	√		Health & Family welfare Ministry or any authorized body like as BMDC, Nursing council
12	Appropriate carrier plan	√	√	√	√	√		
13	Updated syllabus with appropriate name	√	√	√	√	√		
14	Continuing education /Training	√	√	√	√	√		

Appendix 2:

National Networking Pathway



Appendix 3:

Terms of reference (TOR) of the laboratories at different levels of healthcare facility

Level of laboratory	Activities
National Public Health Reference Laboratory (NPHRL)	• All investigations, including molecular diagnostics; • Compilation of national data bank for the EIDs; • Provide information sought by member laboratories.
Tertiary (Medical college laboratories)	• All investigations, including molecular diagnostics; • Provide information sought by member laboratories; • Regular reporting to NPHRL.
Specialized Hospital laboratories (e.g., National Tuberculosis Reference Laboratory)	• Tests related to specific illness; • Provide information sought by member laboratories; • Regular reporting to NPHRL.
District level hospital laboratories	• Microbiological culture, Microscopy, Serology & RDTs; • Regular reporting to NPHRL.
Primary (UHC)	• Microscopy, selected serology biochemical tests & RDTs; • Regular reporting to NPHRL.

Appendix 4:

Laboratory Network functions in the diagnosis of diseases of public health importance

	Collect	Confirm	Report
Sample providers (patient point of contact, may be first contact laboratory)	• Use standardized case definitions to determine initiation of collection process • Assist first contact laboratory in specimen collection within approved guidelines • Document specimens with patients' complete clinical history and description •(if sample collection in the field) Transport specimens to first contact laboratory and Referral Laboratory within approved guidelines	• Use standardized case definitions to initiate confirmation process as part of an outbreak investigation • Handle specimens within approved guidelines	• Record collection of specimens
District Laboratory/ proposed Divisional Laboratory (may be first contact laboratory)	• Communicate collection policies and procedures to providers • Request additional specimen collection by laboratory or providers, as needed including outbreak investigations • Store specimens within approved conditions pending transport or additional studies	• Perform laboratory studies presumptive for confirmatory diagnosis as appropriate: microbiological culture, staining, biochemical tests, microscopy, RDT • Store representative slides from the outbreak as needed • Observe changes in trends during routine analysis of laboratory results	• Record laboratory results • Provide results to clinical staff and patients • Report results to CS Office of outbreak site (proposed District Epidemiological unit) • Report observed changes in trends during routine analysis of laboratory results • Use summary information in response to outbreaks
Referral Laboratory (National) (may be first contact laboratory)	• Set collection policies and procedures with IEDCR and national reference laboratories • Distribute specimen collection kits for special surveillance activities • Store specimens within approved conditions pending transport or additional studies	• Set confirmation policies and procedures with IEDCR and national reference laboratories • Perform laboratory studies for confirmation as appropriate: microbiological culture, isolation, sero group identification, antimicrobial susceptibility, serology ,molecular diagnostics including genetic sequencing • Store representative isolates from the outbreak as needed • Observe changes in trends during routine analysis of laboratory results	• Report results and summary data to IEDCR • Report laboratory results from screening sentinel populations at target sites
WHO Reference laboratory (may be at National level, e.g., WHO Reference laboratory for Nipah is IEDCR)	• Request additional specimen collection by laboratory or providers, as needed	• Perform additional laboratory studies as appropriate	• Report laboratory results to IEDCR, CS office as appropriate • Use summary information in response to outbreaks

Appendix 5:

Committee Members of National Public Health Laboratory Network

- o Representative from MOH&FW
- o Representative from DGHS
- o Representative from NILMRC
- o Representative from private hospitals
- o Representative from microbiology and virology society
- o Representative from National laboratory System Strengthening committee of IEDCR

Appendix 6:

Terms of reference for National Public Health Laboratory Network

- Establish, maintain and expand collaborative links between laboratories (One Health approach) that have functions related to public health impact at the various levels in the country.
- Promote best practices in all disciplines of public health laboratory services including setting standards, establishing and promoting internal and external quality assurance mechanisms.
- Improve nationwide access to quality public health laboratory services for confirmation and characterization of causative agents for effective control of communicable diseases.
- Work collaboratively with DGHS (IEDCR, Disease Control wing, Hospital wing and other relevant wings) and partners to ensure optimal use of public health laboratory resources for diseases surveillance including outbreak investigations.
- Build on existing laboratory capacity to respond to existing and newly emerging infectious diseases.
- Respond to matters relating to public health microbiology including resistance monitoring, as referred by national programs.
- Accreditation of laboratories at national level

Appendix 7:

Terms of reference for focal institute of NPHL Network

Background

The focal institute for National Public Health Laboratory (NPHL) Network is the epidemiology/ surveillance institute of a country. In Bangladesh, IEDCR is the mandated institute for surveillance and outbreak response. The NPHL Network focal institute should be designated by the Ministry of Health and Family Welfare. It will be responsible for coordinating the NPHL Network activities.

This institute is expected to contact the following:

- WHO Sub-regional Laboratories for epidemic prone diseases
- WHO Regional Reference laboratories for epidemic prone diseases
- Regional WHO Collaborating Centres

It should have at regional and district level a focal institute/point with the same duties.

General mission:

- Ensure the linkage and the interaction of the public health laboratories and the surveillance activities at national and regional levels.
- Implement precise, appropriate and permanent diagnostic practices
- Contribute to the collection, the management, treatment and utilization of laboratory data for public health interventions

Specific mission:

Under the responsibility of the head of the laboratory, he/she has a specific mission as follows:

Structure/ organization/ administration/ legislation:

- Identify in each level of laboratories a focal point for the epidemic preparation and response
- Submit to the authorities an official text for the creation of the National PHL Network
- Define and adopt a coherent circuit of data transmission
- Organize national meetings with the personnel of the national public health laboratories, district laboratories and proposed divisional laboratories to identify needs, to establish consensus and develop working relationships. It will make it easier for the implementation of a professional network for continuous and sharing information
- Improve relations and collaboration between laboratory personnel and epidemiologists
- Ensure exchange of experience within the member countries of the WHO
- Make available a national strain bank for diseases of public health importance (list developed by STAR-IH workshop)
- Advocate for government and partners funds to continue the development of laboratory activities

Follow up the implementation of a maintenance programme for equipment and QA/QC:

Registration/notification/analyze/interpretation/report :

- Standardize the method of the data collected in the laboratories
- Make tools available for collection (form, register) and transmission of data at all levels
- Organize a regular system for the collection and management of data for the laboratories for diseases of public health importance
- Send regular monthly reports directly to IEDCR and DGHS (the national institutions in charge of surveillance and prevention for public health interventions)
- Analyze the data and feed-back results to the laboratories (district) and to personnel in charge of the epidemiologic surveillance
- Make available the reports of epidemic prone pathogens and antimicrobial resistance surveillance
- Send results to the district and IEDCR
- Create a data base for all the analyzed specimens (positive, negative or pending results) and share monthly with persons concerned in surveillance activities

Laboratory confirmation:

- Adopt standard methods for laboratory diagnosis of diseases of public health importance
- Ensure, manage and maintain an adequate stock of reagents and culture media to supply the network laboratories.
- Send some specimens or bacterial/ viral strains, if it is necessary, to reference sub unit regional laboratories/ reference regional laboratories/ regional collaborating centres/ international collaborating centres
- Assess every year all the laboratories in each level and send the report to the regional office of WHO

Public health emergency preparation and response:

- Ensure good management of essential reagents to help the laboratory to investigate epidemics
- Involve laboratory personnel in all levels of outbreak control activities
- Develop the partnership / twinning with public national laboratories/ specialized institutes/ WHO Collaborating Centres for the epidemic prone disease diagnosis
- Report the epidemic/ epidemic potentials
- Monitor and assess the response activated during the outbreaks
- Advocate for funds for rapid shipping of specimens to reference laboratories/ specialized institutes/ WHO Collaborating Centres

Training and supervision:

- Organize training workshops for standard technical, material and methods used for the diagnosis of diseases of public health importance and also standard methods of antimicrobial resistance detection
- Organize national workshop in collaboration with the heads of priority diseases surveillance, for the personal working who are involved in collecting, packaging, storing and shipping of the samples
- Training/refresh training the personnel in charge of public health activities in the field for the collection, packaging, storage and transportation of the samples and also the main steps for laboratories diagnostic
- Training/ refresh training the laboratory technicians in basic epidemiology and data management
- Encourage laboratory participation in regional external quality control and accreditation of reference laboratories program in relevant microorganisms
- Organize a national program for quality assurance for the peripheral laboratories
- Elaborate, adopt and disseminate procedures manual for the laboratory activities and bio security
- Supervise the intermediary and peripheral laboratory technicians

Monitoring and assessment:

- Contribute to the participation of joint meetings with the epidemiologists. The IEDCR to share its experience and its daily constraints to those responsible for the programs, they must prepare and agree on the implementation of the national action plan
- The IEDCR should maintain good scientific linkages with other laboratories and national institutes for specific program and research.
- Monitor and assess regularly the laboratory performance, personal skill and all activities for surveillance and prevention with those responsible for health services, should be monitored and assessed regularly.

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