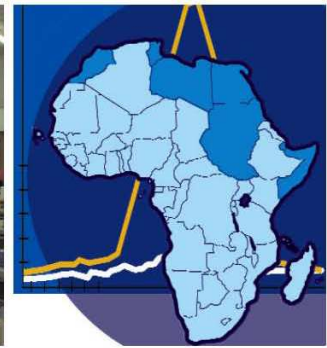


Guide for National Public Health Laboratory Networking to Strengthen INTEGRATED DISEASE SURVEILLANCE AND RESPONSE (IDSR)



World Health Organization Regional Office for Africa (AFRO)
Communicable Disease Surveillance and Response (CSR)
Brazzaville, Republic of Congo

Test Version 1.0 - September 2008

Guide for National Public Health Laboratory
Networking
To
Strengthen
Integrated Disease Surveillance and Response
(IDSR)

Test Version 1.0
September 2008

Table of contents

Acknowledgements.....	vi
1.0 Background.....	9
Introduction.....	9
Purpose of the guideline.....	11
Target audience.....	11
Application of the guideline.....	12
2.0 Situation analysis	12
3.0 Justification.....	16
4.0 Essential public health laboratory functions.....	17
5.0 Establishing National Public Health Laboratory Network	19
5.1 Definition of a National Public Health Laboratory Network.....	19
5.2 Goal of a National Public Health Laboratory Network	19
5.3 Establishing a National Public Health Laboratory Network.....	20
5.4 Policy and procedures	20
5.5 Membership of NPHLN.....	21
5.6 Coordination of the NPHLN.....	21
5.7 Administration and management of NPHLN	22
5.8 Structure of NPHLN	22
5.9 Functions of the NPHL	24
5.10 Laboratory specimens	25
5.10.1 Priority diseases requiring laboratory confirmation	25
5.10.2 Types of lab specimens and tests at different levels.....	26
5.10.3 Where to send specimens for laboratory testing.....	27
5.10.4 Transportation of infectious material.....	27
5.11 Standard operating procedures.....	30
5.12 Bio-safety and bio-security	30
5.13 Training of laboratory personnel	31
5.13.1 Target groups for training	32
5.13.2 Training approaches.....	32
5.14 Supervision	34
5.15 Feedback	34
5.16 Laboratory resource requirements	35
5.16.1 Physical structure.....	35
5.16.2 Equipment requirement for network laboratories	35

5.16.3 Human resources.....	36
5.17 Quality assurance including quality control	37
5.18 Laboratory data management, information sharing, and communication ...	37
5.18.1 Laboratory data within the network.....	38
5.18.2 Sharing of data with WHO	38
5.19 Network communications	40
5.19.1 What information should be communicated.....	40
5.19.2 To whom should the laboratory communicate.....	40
5.19.3 How often should the network communicate	40
5.19.4 What methods should be used.....	40
5.20 Laboratory functions related to IHR.....	41
5.21 Resource mobilization and coordination of partners	41
6.0 Steps for establishing an NPHL network.....	41
6.1 Prepare to assess existing national laboratory system	42
6.2 Assess and describe the current practices and identify gaps.....	43
6.3 Define the desired future NPHL network.....	43
6.4 Develop national strategic plan to implement NPHL network.....	44
6.5 Obtain approval for the plan from MoH officials.....	44
6.6 Launch NPHLN and implement plan	44
6.7 Monitor, evaluate and improve implementation.....	44
7.0 Linkage of NPHLN with WHO regional and sub-regional PHL network.....	41
7.1 WHO actions to strengthen NPHL Network	45
7.2 WHO regional and sub-regional PHL Network.....	46
7.3 Coordination of WHO/AFRO laboratory networks.....	47
7.4 Antimicrobial resistance network	48
8.0 Monitoring and evaluation.....	49
9.0 References.....	50
10.0 Annexes.....	50
Annex 1: Terms of reference for NPHLN	53
Annex 2: Terms of reference for an IDSR Laboratory Technical Committee	54
Annex 3: Terms of reference for the laboratory focal person.....	60
Annex 4: Public health laboratory network functions	64
Annex 5: WHO/AFRO IDSR priority diseases	65
Annex 6: List of core IDSR laboratory tests for confirming outbreaks	66
Annex 7: Laboratory line list of bacteriological specimen and pathogens isolated for surveillance	68

Annex 8: Recommended laboratory equipment for each level.....	69
Annex 9: Recommended supplies for outbreak investigation	71
Annex 10: Sample form for reporting laboratory results.....	72
Annex 11: Proposed laboratory indicators for monitoring and evaluating the implementation of a laboratory network.....	73
Annex 12: Requirements of the national laboratories in the context of IHR – core capacity checklist.....	75
Annex 13: Specimens for priority diseases to confirm at district level	76

Acknowledgements

This document was developed by the World Health Organization for Africa (WHO/AFRO) in collaboration with the U.S. Centers for Disease Control and Prevention (CDC). The contents are based on recommendations in the *Technical Guidelines for Integrated Disease Surveillance and Response in the African Region*. This document intends to support policy makers and national public health authorities in carrying out activities for improving laboratory support to the Integrated Disease Surveillance strategy. Funding for the development and production of this document was provided by the United States Agency for International Development (USAID Africa Bureau).

Authors:

Dr. Jean Bosco Ndiokubwayo
Programme Manager, Health Technologies and
Laboratories
Division of Health Systems and Services
Development
World Health Organization
Regional Office for Africa
Brazzaville, Republic of Congo

Dr. Wondimagegnehu Alemu
Integrated Disease Surveillance, CSR Unit
World Health Organization
Regional Office for Africa
Brazzaville, Republic of Congo

Dr. Senait Kebede, Consultant to CDC

Cover and layout design

Ms. Helen Perry
CDC-NCPDCID-DEISS
IDSR Coordinator
Atlanta, GA

Diane Speight
Graphic Communications Specialist
CDC-Atlanta, GA

World Health Organization Regional Office for Africa (AFRO) IDSR Laboratory Network Working Group:

Dr. Yada Adamou Alzouma, EPR /AFRO
Dr. Tshioko Kweteminga Florimond, CDS/AFRO
Dr. Ali Ahmed Yahaya, LAB/CDS/EPR/AFRO
Dr. Thomas Aisu, LAB/CDS/EPR/IST Eastern &
South/AFRO
Prof. Bréhima Koumaré, LAB/CDS/EPR
/IST/West/AFRO

Dr. Pierre Rugimbanya, NRL, Rwanda
Dr. James C.L. Mwansa, UTH, Microbiology,
Zambia
Dr. Emmanuel Ekow Otu Biney, NRL, Ghana
Dr. Kariuki Njenga, CDC-KEMRI/Kenya

We recognize the significant contributions to earlier versions of this document from:

Ms. Kathy Cavallaro, CDC-NCIRD (Atlanta)
Dr. Sambe Duale, Africa 2010
Dr. Stella Chungong, WHO/HQ
Dr. Louis Koyange Delysogo, INRB, DRC
Dr. Phillippe Dubois, WHO/Lyon
Mr. John Baptiste Gatabazi, NRL, Rwanda
Ms. Mary Harvey, USAID/Africa Bureau

Dr. Margaret Lamunu, WHO/HQ
Dr. Kerrigan McCarthy, NICD, South Africa
Dr. Bekithemba Raymond Mhlanga, WHO/AFRO
Dr Vital Mondonge, Ministry of Health,
Democratic Republic of Congo
Dr. Ahmad Iyane Sow, RNL, Senegal

Abbreviations

AFP	Acute Flaccid Paralysis
AFRO	Regional Office for Africa (WHO, Brazzaville)
AFR/RC	African Regional Committee
AIDS	Acquired Immune Deficiency Syndrome
AI	Avian Influenza
BSL	Bio-safety level
BSC	Biological Safety Cabinet
CDC	Centres for Disease Control and Prevention (USA)
CDS	Communicable Diseases Surveillance
EQA	External Quality Assessment
EPR	Epidemic and Pandemic Alert and Response
FA	Field Assistants
HIV	Human immunodeficiency virus
IATA	International Air Transport Association
IST	Inter-Country Support Team
IDS	Integrated Disease Surveillance
IDSR	Integrated Disease Surveillance and Response
IHR	International Health Regulations
ITD	Intra-Typic Differentiation
M&E	Monitoring and evaluation
MoH	Ministry of health
MDR	Multi-drug resistant
NGO	Non Governmental Organization
NPHLN	National Public Health Laboratory Network
NPHRL	National Public Health Reference Laboratories
NRL	National Reference Laboratory
PHL	Public Health Laboratory
PHLN	Public Health Laboratory Network
RRL	Regional Reference Laboratory
SEARO	South-East Asia Regional Office (WHO, India)

SOP	Standard Operating Procedures
TB	Tuberculosis
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
WHO	World Health Organization
XDR	Extensively drug resistant

1.0 Background

Introduction

A well functioning disease surveillance system is critical for providing evidence-based information to use in planning, implementing, monitoring and evaluating public health intervention programmes. Recognizing the need to coordinate disease surveillance resources and strengthening the role of surveillance in the control of communicable diseases, the World Health Organization African Regional Office (WHO/AFRO) developed an integrated approach to streamline approaches to disease surveillance and response.^{1,2} Since its adoption in 1998, the Integrated Disease Surveillance (IDS) strategy has been implemented with encouraging success in many countries in the African Region.^{3,4}

The specific goals of Integrated Disease Surveillance and Response (IDSR) are to strengthen district-level surveillance and response for priority diseases, to integrate surveillance with laboratory support, and to translate information generated from surveillance and laboratory data into specific public health actions.^{5,6}

The successful detection, characterization and tracing of disease transmission that is essential for the prevention and control of public health events requires an efficient public health laboratory (PHL) system. As a result, WHO-AFRO's Regional Committee adopted resolution AFR/RC43/R7 that urged Member States to develop well-staffed and properly equipped laboratory support that can contribute to the strengthening of the disease surveillance system at the national level.⁷

1 World Health Organization, Regional Office for Africa. Integrated Disease Surveillance in the African Region, a regional strategy for communicable diseases 1999-2003.

2 World Health Organization, Regional office for Africa, Centres for Disease Control and Prevention Technical Guidelines for IDSR in the African Region Atlanta, Georgia. Public Health Service, Centres for Disease Control and Prevention/Epidemiology Program Office, Division of International Health; National Centre for Infectious Diseases, Division of Bacterial and Mycotic Diseases. July 2001:10-11. Detect and respond to Priority Diseases (http://www.cdc.gov/idsr/IDSR_resources/detection/detect_respond_eng.pdf)

3 World Health Organization, Regional Office for Africa. Regional Committee Resolution AFR/RC 48 /R2, 1998

4 World Health Organization, Regional Office for Africa. Documentation of IDSR implementation in the WH WHO African Region: Summary of the Synthesis Report, CDER, May 2003

⁵ Perry HP, McDonnell SM, Alemu W, Nsubuga P, Chungong S, Otten MW Jr, Lusamba-dikassa P and Thacker SB. Planning an integrated disease surveillance and response system: a matrix of skills and activities. BMC Medicine 2007, 5:24 available from <http://www.biomedcentral.com/1741-7015/5/24>

⁶ McNabb S JN, Chungong S, Ryan M, Wuhib T, Nsubuga P, Alemu W, Carandekulis V and Rodier G: Conceptual framework of public health surveillance and action and its implication in health sector reform. BMC Public Health 2002 ,2:2

⁷ World Health Organization: Regional Office for Africa .Regional Committee Resolution AFR/RC 43 /R7, 1993

A public health laboratory network in a country may involve disease-specific and clinical investigations performed in Ministry of Health and other national institute laboratories. Support to the laboratories may come through a single disease program or a collection of diseases. The purpose of the public health laboratory network is to improve the performance of laboratories in support of disease surveillance and response. The network functions include provision of training, supplies, equipment and quality assurance so that tests can be performed and laboratory data linked to surveillance activities. The result is the availability of timely laboratory data on confirmation of suspected pathogens during outbreaks. The laboratory data set the stage for an evidence based investigation and implementation of appropriate control interventions. Monitoring of laboratory data for existing, emerging and re-emerging pathogens, as well as for drug resistance of pathogens that cause epidemics can provide early warning of public health events. The laboratory data can provide evidence for introduction of new vaccines, updating of existing vaccine composition, and guidelines on treatment and prevention policies and protocols at both national and regional levels. Building laboratory capacity including networking at national and regional levels is therefore essential for successful implementation of the IDSR strategy.

The WHO Regional Office for Africa in collaboration with the Centers for Disease Control and Prevention (CDC), USA and other partners is developing a regional strategy to strengthen national public health laboratories (NPHL). The laboratory-strengthening strategy focuses on public health laboratory diagnostics for selected priority diseases and contributes to sustainable implementation of integrated, multi-disease surveillance and response activities. The laboratory strengthening strategy covers three broad areas, namely:

- Collecting, analyzing, and reporting laboratory data and using this information for public health action.
- Establishing appropriate, accurate, and sustainable diagnostic practice
- Linking public health laboratory diagnostics with National and Regional surveillance activities

For greater efficiency, public health laboratories need to be organized within a national public health laboratory network (NPHLN) through appropriate links to sub-regional, regional and international laboratory networks. Initial efforts in many countries have aimed to provide data through organized networks for high priority epidemic-prone bacterial diseases including cholera, dysentery, meningococcal meningitis, and plague. With the growing concern of emerging and re-emerging diseases, network activities may now include avian influenza (AI), tuberculosis (TB), malaria and HIV/AIDS. As laboratory network activities mature, other etiologic agents specific to local, regional and or international public health threats should be included.

Purpose of the guideline

While this guideline presents recommendations that can be applied to multi-disease laboratory networks, a particular emphasis is placed on providing laboratory data for high priority bacterial diseases including cholera, dysentery, meningitis and plague.

The purpose of this guideline is to:

- Define the purpose of a public health laboratory network
- Define the components of a public health laboratory network
- Describe the coordination of a laboratory network
- Provide general guidance for establishing and strengthening a national laboratory network, and
- Promote linkages with WHO collaborating centres, other international laboratories and specific disease program partners.
- Facilitate the development of national laboratory network policy

Target audience

This guide is intended for the national ministry of health (MoH) laboratory focal point or chief officer who oversees all the laboratories in the country, the coordinator of the NPHLN, and the laboratory personnel. Other users of this guide may include IDSR focal persons at all levels, training officers, curriculum developers, and Ministries of Health and their partners.

Application of the guideline

The laboratory focal person or chief medical officer can use this guide to develop a plan to establish or strengthen a NPHLN. This guideline can be used to advocate for political commitment and funding at national levels in support of laboratory strengthening to improve detection, confirmation, response, and prevention of priority infectious diseases. The guideline is also useful for laboratory personnel so they know and comply with its objectives and content.

2. Situation analysis

Access to reliable diagnostic testing facilities is among the major challenges in Africa contributing to the delay or lack of appropriate and timely response to outbreaks and quality patient care. Despite the growing threat from emerging and re-emerging pathogens including HIV, TB and malaria as well as Avian Influenza (AI), the majority of an estimated 12 million annual deaths in Sub-Saharan Africa remain uninvestigated. Laboratory investigations continue to be undervalued as evidenced by lack of skilled manpower for quality-control and reproducible laboratory testing. This contributes to the widespread use of empiric patient care in Africa which would not be tolerated in other countries.^{8,9}

Other major barriers for laboratory capacity in Africa include: lack of funds, weak health infrastructure, lack of basic essential equipment and laboratory consumables, scarcity of educators and training programs, inadequate logistical support, insufficient monitoring of test quality, de-emphasis of laboratory testing and inadequate representation of laboratory personnel in health policy development and implementation of public health interventions. This situation calls for a major investment to building capacity for epidemiological surveillance and public health laboratories in Africa.

⁸ Bates I and Maitland K. Are laboratory services coming of age in Sub-Saharan Africa? Editorial Commentary. CID 2006;42(1February) 383-384

⁹ Martin R, Hearn T, Ridderhof J, and Demby A. Implementation of a quality systems approach for laboratory practice in resource-constrained countries. AIDS (2005). 19 (supplement 2), S59-S65.

Despite the above challenges, exemplary achievements have been documented in the region. For example, polio surveillance activities take place even in countries with difficult terrain and security risks. This finding suggests that given appropriate resources and commitment similar achievements can be obtained in improving laboratory support to strengthen implementation of IDSR.

Example of polio laboratory network

The polio activities in many countries are successfully supported by multiple partners including WHO, UNICEF, NGOs and bilateral agencies. The activity is well organized and includes active surveillance visits by field assistants (FA) covering a large portion of the countries. Case notification and arrangement for stool specimen collection and transportation are communicated immediately through radio and email. Stool specimens are frozen and shipped to the central laboratories from where they are transferred to the polio reference laboratory in the country or to the designated laboratory in the sub-region for viral isolation. Subsequently, isolates requiring Intra-Typic Differentiation (ITD) are sent to the WHO/AFRO Regional Reference Laboratory (RRL) in South Africa.

A data manager for Acute Flaccid Paralysis (AFP) receives hard copies of the AFP initial and detailed case investigation forms from the field and laboratory results from central laboratories. In collaboration with the program coordinator, data is cleaned and edited, while data entry and analysis are centralized under the technical officers in the sub-region or region. Zero reports and work plans are submitted monthly. Most countries in the region have achieved the polio certification level surveillance targets for all indicators since 2002 and have maintained it since then. The lessons learned from polio have been useful for measles surveillance systems which were integrated into AFP surveillance in a number of countries.^{10, 11}

10 World Health Organization. Strengthening surveillance and response for epidemic-prone and vaccine-preventable diseases in selected African and Eastern Mediterranean countries (WHO/CDS/CSR/LYO/2005.23)

11 The Global Polio Laboratory Network: A Model for Good Laboratory Practice
<http://www.qaproject.org/pubs/pubstechreports.html#globalpolionetworks>

WHO/AFRO and national public health laboratories

WHO/AFRO in collaboration with partners has conducted various activities designed to strengthen public health laboratory (PHL) capacity in countries. These include establishment of sub-regional and regional reference laboratories, organization of annual meetings for directors of National Public Health Reference Laboratories (NPHRL), assessment and documentation of national reference laboratories' (NRL) capacity, and training of laboratory scientists on standard laboratory methods and procedures.¹²

WHO/AFRO in collaboration with WHO/Lyon has also organized a two year training program, alternating between course time spent in WHO laboratory training centers in Lyon, France and Ouagadougou, Burkina Faso and application of the training in the trainees' own countries. The purpose of the training is to encourage good public health laboratory practice, encourage better management of national laboratory services and narrow the gap between field epidemiology and diagnostic laboratory services.

The AFRO public health laboratory network (see Figure 1) includes national reference centers, sub-regional and regional reference laboratories for specific diseases and a WHO Collaborating Centers for plague. These laboratories have adopted the WHO recommended standard materials, methods and operating procedures for cholera, bacillary dysentery, bacterial meningitis and plague. They have been provided with essential reagents and antigens to enable rapid investigation and confirmation of outbreaks. They have also been supplied with computers, fax machines and e-mail connection to enhance fast transmission of information.

Among the seventeen countries in the West Epidemiological Bloc, 14 (82%) of the countries regularly send laboratory data on meningitis and diarrhoeal diseases on a weekly basis to WHO. Laboratory-based surveillance of meningitis epidemics has played a significant role in the timely outbreak response. Countries in the meningitis belt regularly provide laboratory data on a weekly basis. Feedback on this data is given to all

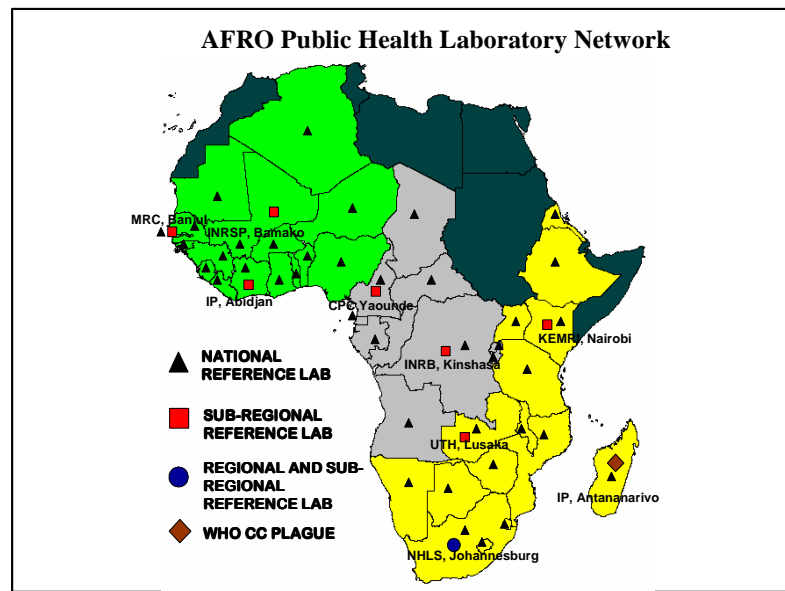
¹² Centres for Disease Control and prevention-USA. IDS Update Bulletin. IDSR links with other surveillance programs. Update Bulletin, Vol 2, Fall 2001

contributing laboratories. A monthly bulletin on epidemiological and laboratory data is also issued and shared with countries and partners. The regular analysis of laboratory data allows countries to predict the circulating meningitis serotype and thus the appropriate selection of a vaccine.

WHO/AFRO External Quality Assessment Programme

The WHO/NICD microbiology External Quality Assessment (EQA) programme was started in May 2002. Presently, over 72 laboratories in 45 African countries participate in this programme. Globally, the EQA programme assesses the laboratory capacity to detect the epidemic prone disease, specifically meningitis caused by *Neisseria meningitidis*, *Streptococcus pneumoniae* and *Haemophilus influenzae*; enteric disease caused by *Salmonella*, *Shigella*, *Vibrio cholerae*, enteropathogenic *E. coli* and plague caused by *Y. pestis*. In addition, this programme assesses the laboratory capacity to diagnose malaria and tuberculosis. Since October 2005, 63 Laboratories in 45 countries are involved in an EQA scheme for malaria microscopy. Tuberculosis smears were added to the existing WHO/NICD EQA programme in October 2005 and currently, 62 laboratories now participate.^{13, 14}

Fig 1: WHO/AFRO Public Health Laboratory Network



13. Centres for Disease Control and Prevention-USA. IDS Update Bulletin. Documentation of IDSR implementation in the African & Eastern Mediterranean Regions. Update Bulletin, issue 4, 2003
 14 World Health Organization, Country office in collaboration with Great Lakes Epidemiologic Bloc. IDS/Health Information Bulletin Integrated Disease Surveillance & Response
www.cdc.gov/idsr/files/CSR_Bulletin_Dec_02_Volume_7/CSR_Bulletin_Dec_02_Volume_7.htm#lab

3.0 Justification

During the past decades, over 30 new pathogens were detected globally, and many of them were responsible for serious outbreaks. Furthermore, there is a growing problem of antibiotic resistance. Seventy percent of bacteria that cause hospital infections in many countries are resistant to at least one of the drugs most commonly used to treat infections¹⁵. In order to deal with these challenges, a well-functioning laboratory is critical for confirmation of clinical diagnosis and the conduct of reliable infectious disease surveillance.

The PHLs generate information that is essential for guiding responses to infectious disease outbreaks by public health practitioners, epidemiologists and clinicians. The information is also essential for the establishment of national health policy and epidemic preparedness. They also serve as a repository for confirmatory tests and diagnostic tests for rarely encountered pathogens such as Ebola and Marburg hemorrhagic viruses, *Yersinia pestis*, *Rickettsia prowazekii*, and *Bartonella quintana*.

To address the weak diagnostic capacity for supporting effective surveillance of epidemic-causing infectious diseases, emerging pathogens, and the emergence of resistance to anti-microbial agents in the African region, the 43rd session of the WHO Regional Committee for Africa adopted Resolution AFR/RC43/R7 in 1993, declaring a five-year period for preventing and combating epidemics of communicable diseases through improved epidemiological surveillance at the district level. The Resolution, further considered that “the frequent occurrence in the African Region of epidemics such as cholera, plague, yellow fever, malaria, cerebrospinal meningitis (CSM) brings untold human suffering and loss of lives”, and therefore urged Member States to “develop well-staffed and properly equipped laboratory services”.

15 World Health Organization, Regional Office for South-East Asia New Delhi. Laboratory Support to Emerging Diseases. www.whoindia.org/LinkFiles/Public_Health_Laboratory_Networking_SEARO_recommendations_on_networking_of_PHL.pdf

In 1996, Ministers of Health and Ministers of Interior from 16 West Africa countries, joined by Chad and Algeria, met in Ouagadougou to consider ways and means of preventing future epidemics. Similarly, their counterparts from countries of the Great Lakes met in Kigali in 1997 to deliberate on the unabated epidemics of infectious diseases. At the conclusion of these meetings, the Ministers “... *acknowledged that the unduly long delay in identifying and confirming the causal agents of these epidemics, retard the initiation of action likely to contain epidemics, resulting in catastrophic loss of lives*” and called for a systematic evaluation of the state of laboratories in their respective countries, and resolved to strengthen laboratory diagnostic capability in Member States. Protocols for co-operation in the prevention and control of epidemics have been signed by Ministers of Interior and Health in all 5 blocs - West Africa (1996), Great Lakes (1997), Horn of Africa (1998), Central Africa (1998) and Southern Africa and Indian Ocean (1999) blocs.

The NPHLs, regardless of their location, are important sentinel sites for surveillance of infectious diseases of international concern such as viral influenza infections, and should be an integral part of the global network of laboratories. It is therefore important that they 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.

4. Essential public health laboratory functions

In many Ministry of Health laboratories, there is an overlap of clinical and public health testing. Results for clinical diagnostics may take place in the same laboratory where public health laboratory tests are conducted to provide information for decision makers to enact appropriate disease control measures. The focus of the clinical diagnostic testing is the individual patient care. In contrast, the concern of public health laboratory testing is the community at large. Data generated from both services are essential for surveillance activities.

The functions of a public health laboratory include provision of the following:

- Timely laboratory confirmation of disease pathogens for surveillance, including epidemic alert, response and prevention, and monitoring microbiological safety of food and water.
- Policy, standards, and advocacy for public and private laboratory services.
- Training and continuing education for laboratory personnel on laboratory techniques, use of equipment, and appropriate and safe collection, storage and transportation of specimens.
- Strengthened rapid response to outbreaks through timely testing of specimens and identification of the causative agents and ensuring the capacity to process a large volume of specimens in an emergency situation.
- Laboratory support during outbreak investigation in order to determine the source of infection; identify carriers and reservoirs of infection in the environment; monitor epidemiologic trends to detect epidemiologic shifts; and assure rapid analysis and dissemination of laboratory information.
- Specialized tests (or access to such testing facilities, e.g., WHO Collaborating Centers) for unusual events and emerging infections, and for monitoring antimicrobial resistance.
- Testing to meet specific needs of public health agencies
- Coordination and promotion of quality assurance programs for clinical and environmental laboratories including training, consultation, certification and proficiency testing.
- Scientific and managerial leadership in development of public health policy.
- Research and development capacities by sponsoring researchers and creating a forum for sharing research findings.

In order to deliver these essential functions, it is of paramount importance that the people holding leadership positions in the national public health laboratory service have the appropriate education background including the relevant qualifications and

skills as well as attitudes to effectively coordinate and build a team. Ensuring that critical factors are in place such as political commitment at the highest level, adequate budget and appropriate organizational and functional structure is the key for a sustainable high standard of delivery of services.

5. Establishing National Public Health Laboratory Network

5.1 Definition of a National Public Health Laboratory Network

A national public health laboratory network (NPHLN) is composed of laboratories at each level of the health system (health centre, district, regional/provincial, national) committed to the proper diagnosis of priority infectious diseases for public health decision making. The laboratories in a functional laboratory network have established communication channels for routine communication, exchange of information, and interaction in specified ways with each other, and with epidemiology departments at the level of the national IDSR 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.

A template of the terms of reference (TOR) for a national public health laboratory network (NPHLN) is available in Annex 1 of this document.

5.2 Goal of a National Public Health Laboratory Network

The goal of a national public health laboratory network is to provide high quality, accurate and timely laboratory-based information. This information can be used for public health decisions directed at effective control and prevention of priority diseases in the country and potential public health emergencies of international concern.

5.3 Ensuring a successful National Public Health Laboratory Network

When establishing a national public health laboratory network, the following guiding principles need to be observed.

- *National ownership and leadership:* Provide national ownership and leadership for the NPHLN to ensure sustainable and effective implementation of IDSR. The NPHLN should be linked with the national multi-disciplinary surveillance coordinating body established to coordinate the implementation of IDSR such as a task force or steering committee.
- *National policy on laboratory services:* Establish national public health and clinical laboratory policy that clearly defines roles of laboratories for the different levels.
- *Resource management:* The need for long-term sustained efforts to ensure the budget flow, supply skilled human resources, supply and maintain essential laboratory equipment, reagents and supplies and develop infrastructure development for NPHLN.
- *Partnership:* Expanded partnership with clear definition of roles and contributions of each partner at national, intermediate and district levels. Through the NPHLN, establish contact with similar networks at sub-regional, regional and international levels.
- *Access to quality laboratory services:* Equitable access to quality public health laboratory services with greater attention to the district level especially in rural, semi-urban and underserved areas.
- *Standardization:* Building on acceptable international standards and norms for quality laboratory tests adapted to suit the local epidemiological context and overall guidance of WHO recommendations in selecting cost effective methods.

5.4 Policy and procedures

The NPHLN provides technical leadership in public health laboratory services for disease surveillance, prevention and control and for guiding public health policy development. This could be achieved through provision of scientific and technical leadership; establishing contacts with scientific and technical regional and international networks to forge partnerships for surveillance, outbreak alertness and response and

facilitating establishment of national laboratory policy that clearly defines roles of laboratories at all levels.

The network could also play critical role in promoting integration of high quality laboratory science into public health practice; supporting development of laboratory standard operating procedures (SOP), documentation of experiences and assisting the development of level-specific guidelines as well as advocating the need to strengthen national laboratory systems amongst decision-makers, partners and the public.

5.5 Membership in the NPHLN

Network membership should have as its focus the NPHL, or its functional equivalent (for example, the NRL). Network members include teaching or tertiary level hospital laboratories, laboratories of disease specific programs, major private medical laboratories, and provincial/regional and district reference hospital laboratories.

5.6 Coordination of the NPHLN

The MoH should officially establish the NPHLN and designate an Advisory Committee (technical committee) to guide coordination and management of the network. Members of the Advisory Committee may vary from country to country but, as a minimum, should include senior microbiologists (or medical laboratory specialists), virologists, clinicians (infectious disease specialists) and an epidemiologist or public health specialist. As an example, terms of reference for a technical committee in Uganda is included as Annex 2 of this document.

The NPHL or the designated NRL is responsible for coordination of the laboratory network at the national level. In order to effectively coordinate the functioning of the NPHLN, the leadership should have the appropriate technical, interpersonal and managerial competencies. These individuals must also have the necessary authority and accountability for managing their laboratories, and be able to communicate with the appropriate levels of the public health system.

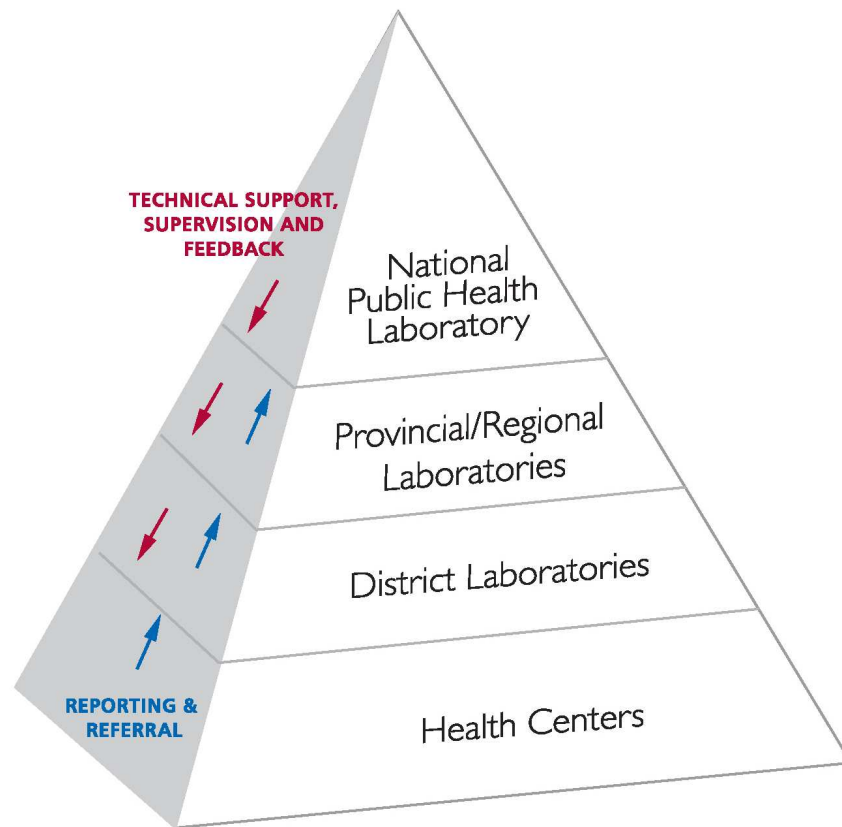
5.7 Administration and management of NPHLN

The Ministry of Health laboratory focal point and the director of designated reference laboratory will be the responsible administrative focal person for the effective functioning of the network in the country. To ensure proper functioning of the network, regular meetings should be held at the national level at least once a year with participation of representatives from all levels of the NPHLN. Participants of the meetings should share their experiences, achievements, challenges and discuss ways of strengthening performance of the network to support and actively participate in the national disease surveillance and response. An example of one country's terms of reference for the Laboratory Focal Point for Epidemic Prone Diseases is available in Annex 3 of this document.

5.8 Structure of NPHLN

The NPHLN should be based on a pyramidal structure with the NPHL or the designated reference laboratory at the top of the pyramid followed by provincial or regional, district and peripheral and health centre laboratories (please see Figure 2). The laboratory activities should be defined for each level and address a common list of priority activities for all health centre laboratories. A complementary package for district and provincial/regional laboratories along with specification of specialized tests for central referral laboratories should also be designated. The laboratories should also be provided with the standard operating procedures relevant to the functions appropriate for their level.

Figure 2: Structure of national public health laboratory network



The NPHLN is placed under the responsibility of the NRL as designated by the MoH. In order to develop a vision and to guide policy for public health laboratories, the MoH should ensure adequate representation for the laboratories by creating a division of laboratories at central level. This directorate should be headed by a laboratory expert.

The position of Director of NPHL should be at the level of Deputy Director of Medical Services or equivalent and at the same level with other heads of divisions at the MoH and reporting directly to director of Medical Services. It is further recommended that the Directorate of NPHL be separated from other major assignments such as Pharmacy, Diagnostic Imaging and Blood Transfusions Services in order to enhance his or her commitment in management and advocacy for the Public Health Laboratories.

5.9 Functions of the NPHL

National Public Health Laboratories (NPHL) should act as the first line of defense for the rapid recognition of priority communicable diseases and contribute to preventing their spread. The NPHL plays a role in strengthening these activities through enhancing communications between the different levels and facilitating access for laboratory activities particularly for:

- Development of policy and enforcement of standards
- Referral of specimen/isolates to a Regional Reference Laboratory (RRL) for confirmation and specialized testing as necessary
- Training of laboratory technicians/technologists in diagnostic techniques & bio safety procedures
- Training of intermediate, district and peripheral health care facility staff in specimen collection, safe handling, storage and shipment to the referral laboratory
- Monitoring of anti-microbial resistance of priority diseases including *S. dysenteriae type 1*, and multi-drug resistant TB (MDR XDR -TB).
- Establishment of internal and external quality assessment and quality control systems.
- Making available a national strain bank for epidemic prone diseases permitted for the level of laboratory
- Following up the implementation of regular appropriate upkeep and maintenance of laboratory equipment
- Collecting, compiling, analyzing and sharing laboratory data with network laboratories, MoH, WHO and other partners
- Publishing feedback bulletins and dissemination (electronic and print newsletters, issue briefs, training materials, survey reports, conference proceedings and other resources) to all concerned.

The recommended actions for the PHLN at the different levels are summarized in Annex 4 of this document.

5.10 Laboratory specimens

5.10.1 Priority diseases requiring laboratory confirmation

The priority diseases that are the leading causes of illness, death and disability in the African region are listed in Annex 5 of this guideline. These diseases are divided into three groups: epidemic-prone diseases, diseases targeted for eradication or elimination, and other diseases of public health importance. The list of priority diseases varies from country to country and may be updated from time to time.¹⁶ *Note: As of 2008, WHO AFRO IDSR guidelines are undergoing a major revision and additional diseases are being added. Those current diseases requiring laboratory confirmation are listed in the table below.* The priority diseases are a combination of communicable and non-communicable diseases, and not all of them require laboratory testing for confirmation. In some cases, the disease control program such as the Expanded Programme on Immunization may already support laboratory networks to detect and confirm polio and measles.

The following priority diseases require laboratory confirmation. Please note that the causative agent for the first four epidemic-prone diseases are bacterial pathogens addressed in this guide.

Epidemic-prone diseases	<ul style="list-style-type: none">• Cholera• Diarrhoea with blood (<i>S. dysenteriae</i>, type 1)• Meningococcal meningitis• Plague• Viral hemorrhagic fevers• Yellow fever• Avian influenza
Diseases targeted for eradication or elimination	<ul style="list-style-type: none">• Poliomyelitis (AFP)• Measles
Endemic epidemics	<ul style="list-style-type: none">• Malaria• Tuberculosis• HIV

¹⁶ World Health Organization, Regional Office for Africa and Centres for Disease Control and Prevention. Technical Guideline for Integrated Disease Surveillance and Response in the African Region, May 2002

5.10.2 Types of lab specimens and tests at different levels

The proposed list of specimens to be collected for each priority infectious disease caused by a bacterial agent with the relevant laboratory test to be conducted at each is shown in Table 2. At the district level, specimens are inoculated onto an appropriate transport media for safe shipment to the referral laboratory. Reference laboratories may perform additional testing such as confirmation of strains, verification of some sensitivity testing for unusual resistance or sensitivity to an antibiotic. Some laboratories may also be able to perform PCR to confirm a pathogen.

Table 2: Recommended types of tests by disease and levels

Levels	Diseases	Types of tests
District	Cholera:	<ul style="list-style-type: none"> • Macroscopic examination • Microscopic examination for “shooting star” pattern for <i>V.cholerae</i> • Inoculation of transport media (Cary Blair, APW) • Rapid test if available
	Meningitis:	<ul style="list-style-type: none"> • Macroscopic and microscopic examination (direct & after Gram staining on sediment from centrifugation) • Latex agglutination test for <i>N. meningitidis</i>, <i>S.pneumoniae</i> and Hib (if possible) • Inoculation of media transport (Trans-Isolate bottle)
	Plague:	<ul style="list-style-type: none"> • Microscopic examination after Gram staining bubo aspiration or sputum • Dipstick testing on bubo aspiration or sputum • Inoculation of transport media (Cary Blair) • Collect and ship blood sample to the reference laboratory for serology testing
	Diarrhea with blood	<ul style="list-style-type: none"> • Macroscopic examination • Inoculation of transport media (Cary Blair)
	Tuberculosis:	<ul style="list-style-type: none"> • Acid fast bacilli (AFB) staining technique for TB (at TB centers)
	Gonococcus	<ul style="list-style-type: none"> • Microscopic examination after Gram stain on urethral pus
Provincial	Cholera	<ul style="list-style-type: none"> • <i>Vibrio cholerae</i> isolation from stool specimens and antimicrobial resistance testing
	Diarrhea with blood	<ul style="list-style-type: none"> • isolation of <i>S. dysenteriae</i> type 1 from stool specimens and antimicrobial resistance testing
	Meningitis	<ul style="list-style-type: none"> • Macroscopic and microscopic examination (direct & after Gram staining on sediment from centrifugation) • Latex agglutination test for <i>N. meningitidis</i>, <i>S.pneumoniae</i> and Hib • Culture, identification and antimicrobial resistance testing if possible
	Tuberculosis:	<ul style="list-style-type: none"> • Acid fast bacilli (AFB) staining technique for TB (at TB centers)
	Gonococcus	<ul style="list-style-type: none"> • Microscopic examination after Gram stain on urethral pus

Central	Diarrhea with blood	<ul style="list-style-type: none"> • Isolation of <i>S. dysenteriae</i> type 1 from stool specimens & antimicrobial resistance testing
	Cholera	<ul style="list-style-type: none"> • Isolation of <i>Vibrio cholerae</i> O1 from stool specimens specimens & antimicrobial resistance testing
	Meningitis	<ul style="list-style-type: none"> • Microscopic examination (direct & after Gram staining on sediment from centrifugation)) • Latex agglutination test for <i>N. meningitidis</i>, <i>S.pneumoniae</i> and Hib • Culture, identification and antimicrobial resistance testing • PCR(if possible)
	Plague	<ul style="list-style-type: none"> • <i>Yersinia pestis</i> isolation from bubo or sputum and antimicrobial resistance testing
	Tuberculosis	<ul style="list-style-type: none"> • Culture, identification and Antimicrobial resistance testing
	Gonococcus	<ul style="list-style-type: none"> • Isolation of <i>N gonorrhoeae</i> from urethral pus and Antimicrobial resistance testing

5.10.3 Where to send specimens for laboratory testing

The IDSR focal persons at each level of the health system should maintain an updated list of the laboratories that have the capacity to perform the required laboratory testing and widely circulate it to all health care facility staff (Annexes 6 & 7). The transport mechanism must be clear and supported for sending samples from the peripheral level to the district and then the provincial/regional and central levels. Similarly, the process for sending the feedback to health centre, district and region/province has to be clearly defined and supported.

5.10.4 Transportation of infectious material

Packaging and shipping of infectious material must follow the International Air Transport Association (IATA) guidelines. According to IATA, diagnostic material is any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue fluids being shipped for the purpose of diagnosis, excluding live infected animals.

Triple packaging of infectious material is required. This includes the primary container with the specimen (e.g. freeze dried/slab culture) is packed into a water tight, leak proof container surrounded with absorbent material around. The secondary container should also be water tight and leak proof. This

should contain labels that are UN approved. The sender is responsible for: arranging with receiver and carrier, and notifying receiver. The carrier is responsible for preparing shipping documentation, and notifying the sender about packaging and transportation route, delays (e.g. in custom) and eventual receipt. The receiver is responsible for obtaining import papers, acknowledging receipt to sender.

Triple Packaging Requirements:

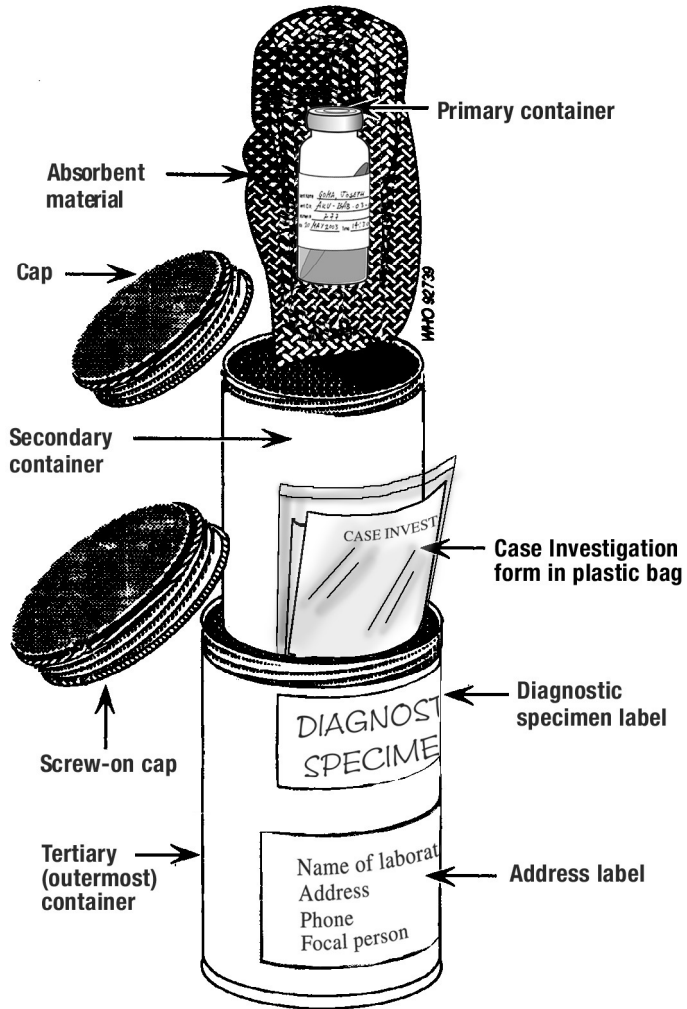
Primary container: The primary packaging which contains the specimen must be watertight. Example: Vacutainer with adhesive tape around screw cap. Use screw-cap conical test tubes or cryovials. Do not use Eppendorf tubes, with tape or parafilm around cap.

Secondary Container: The secondary packaging may contain several primary containers. The secondary packaging must also be watertight. Examples of watertight secondary containers include Ziplock plastic bags, a conical 50ml test tube, and screw-cap containers. Absorbent material: must be placed between the primary and secondary container. The quantity should be sufficient to absorb all liquid in the shipment. Examples would include paper towels, cotton balls, filter paper, etc.

If dry ice is needed to keep samples frozen, it should be put between the secondary and tertiary packaging. Styrofoam and cardboard both allow dry ice vapor to escape, so dry ice must be placed only OUTSIDE the secondary packaging. Packaging dry ice inside impermeable, screw cap containers may cause your shipment to explode.

Outer Shipping Container: The tertiary packaging (outside) must protect the inside packaging to avoid breakage or perforation under normal transport conditions. Corrugated cardboard is the usual choice. Remember that Styrofoam boxes, plastic bags, or paper envelopes are unacceptable outer containers for shipping biological materials.

Figure 3: Triple Packaging System



5.11 Standard operating procedures

To ensure consistency in performing laboratory activities, it is essential to develop and make available standard operating procedures (SOP) for the different laboratories at all levels. Their use should be mandatory by all laboratory staff members every time they perform an activity. In addition, accreditation and licensing procedures should require compulsory use of SOP to ensure quality. The NPHL and the technical advisory committee will be responsible for the development of SOPs while MoH will monitor the process.

5.12 Bio-safety and bio-security

There is a risk of laboratory-acquired infections for those working with infectious microbiological agents. It is, therefore, essential that laboratory personnel are aware of potential hazards. They must be trained and proficient in the practices and techniques of handling such materials safely. Bio-safety or operations manuals that identify the hazards that will or may be encountered, and that specifies practices and procedures designed to minimize or eliminate exposures must be adopted and made available.

Laboratory personnel safety practices and techniques must be supplemented by recommended immunizations (Hepatitis B virus, yellow fever and so on), and appropriate facility design and features, safety equipment, and management practices. Safety equipment includes biological safety cabinets (BSCs), a device used to provide containment of infectious splashes or aerosols. One important primary barrier is the centrifuge cap, an enclosed container designed to prevent aerosols from being released during centrifugation. Also to be provided are items for personal protection, such as gloves, coats, gowns, shoe covers, boots, masks, respirators, face shields, safety glasses, or goggles. For details regarding relations of laboratory tests to bio-safety levels, practices and equipment, please refer to WHO bio-safety manual. Further details are also available in the guidelines for transport of infectious substances^{17 18}.

¹⁷ World Health Organization, Geneva 2004. Laboratory bio safety manual.

¹⁸ World Health Organization, Guidelines for safe transport of infectious substances and diagnostic specimens WHO/EMC/97.3. <http://www.who.int/emc>

The term “bio-security” refers to the protection of microbial agents from loss, theft, diversion or intentional misuse. This is accomplished by limiting access to facilities, research materials and information. Laboratory bio-security activities should be established with clear and consistent policies and guidance. Training and familiarization concerning the objectives and requirements of laboratory bio-security activities should be ongoing. Further details are available in the *WHO Guideline Laboratory Bio-security Guidance, September 2006* available from http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

5.13 Training of laboratory personnel

To achieve the NPHLN organizational objectives and deliver quality service, laboratories require a workforce equipped with the necessary technical and managerial skills. Therefore, training and development of laboratory personnel is indispensable in improving the quality of laboratory services.

As new technologies are introduced constantly, new pathogens recognized, and information about known pathogens expanded, NPHLs should have the capacity to assist personnel to acquire and maintain new and existing skills and knowledge. This will enable them to perform their duties optimally, develop their leadership skills and remain motivated as valuable members of the public health workforce.

National Public Health Laboratories should support human resource development by:

- Establishing clear statements of the work required and standards to be met, for laboratorians in each organizational level
- Providing or facilitating training courses and workshops for laboratory staff
- Providing access to continuing education in management and leadership for those charged with administrative roles
- Facilitating access to information on new technologies and

technology transfer.

- Promoting the training and retention of higher cadre laboratory scientists in the personnel services schemes.
- Establishment or revisions of the national laboratory policy to accord PHL appropriate parity of leadership and clear link with the MoH and epidemiologists

The national laboratory training plan should include managerial and inter-laboratory meetings, national bench training and attachments to reference laboratories. The NPHL Network could also benefit from the inter-country and regional meetings co-organised by WHO and partners.

5.13.1 Target groups for training

The National Public Health Laboratory Network should have a systematic and regular method of assessing training needs and skills development of staff. The aim of the training needs assessment should be to:

- Identify the skills and levels of proficiency required for specific laboratory activities at each level of the network
- Determine the current level of proficiency;
- Assess the gap (i.e., the skills deficiency) between these two criteria and thus determine the training needs.

This process requires systematically reviewing the need for improving performance of the laboratory workforce, utilizing such methods as performance outcome data; performance management review; individual employee issues and concerns regarding development; and changes in mission, functions, or processes. In addition, feedback from Q& A programs should also inform training needs.

5.13.2 Training approaches

Pre-service laboratory training

Laboratory training may be the responsibility of the designated laboratory training institutions or universities at national level. The NPHL may support the pre-service training through participating in the teaching and taking part

in development of curriculum and training materials. Training should include not only laboratory topics but also skills and knowledge for public health surveillance and epidemiology.

In-service laboratory training

The NPHL should regularly conduct short-term courses, workshops and refresher training for laboratory personnel. Once training needs are assessed and gaps identified, appropriate training approaches should be selected. Consideration must be given to availability of funds and level of expertise of individuals providing the training. Whenever appropriate, consultation with training experts at local level and in collaboration with WHO and partners will provide more opportunities for guiding relevant training program. The emphasis of a training activity should be on demonstrable skills and should focus on measurable competencies. Competency-based or skills-based training for public health laboratory professionals should preferably use adult learning methods.

Depending on the cost, content, and the instructional expertise required, managers should use various innovative training methods such as on-the-job training, classroom work, bench training, WHO/partner-supported training, and distance learning activities including video conferences, computer-based training, internet and video/audio tapes.

National workshops for staff of health care facilities involved in collecting, storing and transporting specimens to the laboratory should be held at the National Laboratory in collaboration with Disease Surveillance Officers and other health personnel.

Attachments to reference laboratories

Laboratory personnel, microbiologists or technologists from the National Public Health Laboratory may be selected to undergo training in new techniques or re-training in basic techniques as required at the Regional Reference Laboratory or other WHO collaborating centre. Such training programmes could be arranged by the NPHL using its own contacts or through WHO or other partner agencies.

5.14 Supervision

Supportive supervisory visits are essential for effective follow-up of trained personnel and on-the-job performance of the staff. This will enhance the improvement of performance in a given area. Supportive supervision also contributes significantly to an employee's application of new skills and principles. Most skill-based performance problems are correctable with appropriate training, improved on-the-job communications, and mentoring. When participants are not able to apply new skills and information, they can become demoralized, and training can lose its credibility.

Regular supervision should be conducted in accordance with the structure of the NPHLN with district laboratories being in charge of supervision of health centres in their catchments area. Appropriate logistic support including transport and other necessary tools should be made available to facilitate regular supervision at all levels and at different stages of development. For example laboratories for new testing sites may require more frequent supervision during establishment and capacity development phase. Determination of the level of performance should be based on observation and documentation using a checklist applicable for the different levels of laboratories.

5.15 Feedback

Following completion of supervision visits, feedback should be in the form of a written report or an on-site discussion as appropriate. In addition, the laboratory staff may be called to attend refresher training, or other corrective action whenever necessary.

Another forum for feedback is through sharing of information on laboratory and personnel performance at monthly district meetings. It is also essential to support and encourage the regular publication and wide distribution of epidemiological bulletins to enhance performance and share experience between the laboratories.

5.16 Laboratory resource requirements

5.16.1 Physical structure

The construction of laboratory facilities requires standard designs that facilitate function, protect laboratory workers and provide barriers to ensure the safety of people outside the laboratory. The laboratory management is responsible for ensuring that facilities are built and maintained with appropriate standards commensurate with the laboratory's function and the recommended bio-safety measures.

5.16.2 Equipment requirement for network laboratories

The NPHLN should adopt a list of minimum laboratory equipment for the different levels. A minimum recommended list that could be adapted to local situations is presented in Annex 8. A list of supplies for laboratory participation in outbreak investigations is provided in Annex 9. Laboratory equipment should be assessed on a regular basis to ensure maintenance, availability, and quality.

Countries are encouraged to mobilize resources to adequately support laboratory capacity for confirmation of causative agents of priority infectious diseases. This ensures the ability to deal with emergencies and to deliver quality surveillance activities. The WHO/AFRO will support the procurement of reagents for network laboratories, from established WHO accredited laboratories for confirmation of epidemic-causing infectious diseases and for External Quality Assessment (EQA) scheme.

Funds should be sourced for needed essential reagents and supplies identified for surveillance of diarrhoeal diseases, bacterial meningitis, plague and other essential laboratory-based surveillance activities. The requirements of each laboratory will vary according to its level and related activities. The head of national laboratory services at the MoH will submit annually laboratory needs (at all levels), including the required budget for training, maintenance, replacement of laboratory equipment, reagents, and media.

5.16.3 Human resources

The projections for manpower should ensure that the different categories of laboratory staff are produced in adequate numbers to fill vacant positions and to provide for attrition of staff, retirement, and potential for future expansion.

The following should be considered when projecting future needs for laboratory staffing:

- The total number of laboratories;
- Staffing patterns in existing laboratories;
- Workload
- Future developments and expansion of laboratories; and
- Loss due to retirement or other reasons

It is also essential to ensure development of appropriate cadres of service providers and distribute them according to workload as well as geographical access and equity.¹⁹ Using the method proposed in reference 19, Table 3 gives an example of staff requirements for average sized laboratories.

Table 3: Types and number of personnel by levels

Level of laboratory	Types and number of personnel
District	3 Laboratory technicians
Provincial /Regional	5 Laboratory technicians 2 Technologists* 2 Microbiologists
Central level	10 Laboratory technicians 4 Technologists 3 Microbiologists
Reference level	15 Laboratory technicians 5 Technologists 5 Microbiologists

¹⁹ World Health Organization Regional Publication, South-East Asia Series No.24, 2nd Edition, 1999 (ISBN 92 9022 1674)

5.17 Quality assurance including quality control

The NPHLN member laboratories should participate in a national external quality assurance and control programme (EQAP). The NPHL should be responsible for running and supporting the EQAP; overseeing the reliability, reproducibility, and relevance of results from the public health laboratories at all levels of the health system. The NPHL should:

- Adopt norms, standards and indicators to measure performance,
- Supervise the implementation of quality systems (including quality assurance programs, auditing and monitoring) or working in partnership with the agency that has this responsibility,
- Evaluate results, and provide feedback and support to participant laboratories,
- Participate in international quality assurance schemes where feasible and relevant and
- Prepare an annual report on the performance of the laboratories grading them accordingly with recommendations to improve quality.

5.18 Laboratory data management, information sharing, and communication

Modern information and communication technologies have the potential to significantly improve data-sharing even in the most remote areas of developing countries. Such technologies should be available to NPHL network member laboratories and each should have access to personal computers and its own institutional E-mail account. This will go a long way in enhancing epidemic alert and response by:

- Capturing and analyzing essential laboratory data; maintaining and sharing the data in standardized formats
- Developing regular exchanges of information and surveillance data with other laboratories within the country and other countries
- Supporting a national network capable of receipt, storage, retrieval and analysis of laboratory surveillance data.
- Facilitating regular reporting of laboratory-confirmed notifiable diseases
- Enabling timely flow of information between different levels and different professional groups within the health system

- Having established means to communicate rapidly with national authorities in relation to potential public health emergencies
- Providing collated data to inform policy and decision-making authorities

5.18.1 Laboratory data within the network

All participating laboratories should maintain standard records with date of specimen receipt, patient/case information, specimen condition, test result and date when results were reported out. (Please see Annex 10 for a sample specimen transmittal and reporting form). A system of immediate and regular reporting of district laboratory information to the provincial and to the national levels would be expected.

The NPHLN has to be open to epidemiologists and should have access to the laboratory database for public health use. There should be two types of reporting to the national epidemiologists, immediate and routine. Immediate reports should go directly to the unit in charge of action. In general, a positive culture for *Vibrio cholerae*, *Neisseria meningitidis*, *Shigella dysenteriae* type 1 or *Yersinia pestis* should be reported immediately to the district and the national epidemiologists. For routine reporting of laboratory data to the national epidemiologists (including positive, negative and pending results), a database with all specimens year-to date should be shared every month to the national level.

5.18.2 Sharing of data with WHO

The NPHL should share selected laboratory data with the WHO. This could be done immediately, weekly or monthly as part of the routine reporting system. An immediate notification should be made by E-mail for diseases, conditions or events described in the International Health regulation (IHR) or other previously agreed-on reporting requirements²⁰ such as a positive serology for plague, positive culture of *Shigella dysenteriae* type 1, *V. cholerae*, *N. meningitidis*, or *Y. pestis*.

²⁰ World Health Organization, Geneva 2006. International Health Regulations (2005) <http://www.who.int/csr/ihr/en/>

Regarding routine reporting, a database of laboratory results should be shared with WHO weekly and monthly. Experiences and lessons learned from the WHO polio laboratory network shows that sharing data with WHO is very important as it allows WHO to:

- Participate in the quality assurance process,
- advocate for more funds for laboratory strengthening
- Provide feedback to funding partners on the impact of the contribution of partners,
- Identify areas where case detection and specimen collection are inadequate to take corrective measures
- Identify locations of outbreaks to alert neighbouring countries,
- Respond to outbreaks, and
- Mobilize resources for outbreak response and outbreak prevention.

Table 4. Screen shot from WHO/AFRO bacteriology database

INTEGRATED BACTERIOLOGY LABORATORY DATABASE, TZ EPIWEEK

Country: Laboratory name: Biosafety Level:

EPID No. (CCC-PPP-DDD-YY-NNN): Source: Name of patient or source:

Age (years): Sex: District: Suspected Disease:

Specimen type: Date spec. collected: Transport medium:

LAB PROCESSING INFORMATION

Lab ID No.: Date of receipt in lab:

Direct examination

Condition of specimen: Macroscopic Appearance: Leucocytes (n per mm³):

Red blood cells: Parasites: Yeast:

Giemsa

Polymorphs %: Lymphocytes %:

Gram stain **India Ink** **Ziehl Neelsen**

Latex agglutination result:

Identification Antimicrobial Susceptibility test done?

Antimicrobial Susceptibility test method: Standard used:

Date results to the District: Date specimen sent to the Reference Lab:

Remarks:

Responsible Officer:

Repeat Last

Antibiotic	mm_mic	Interpretation

5.19 Network communications

5.19.1 What information should be communicated

Regular and informal information may be shared in the network. Regular reports provide disease-specific information requested as part of the reporting requirements of the network. Initial efforts should aim at providing data for high priority epidemic-prone bacterial diseases. These diseases include cholera, dysentery, meningococcal meningitis, and plague. As network activities mature, other etiologic agents should be included in the report. Additional information may be shared at any time with any or all of the network members at the discretion of each reporting authority.

5.19.2 To whom should the laboratory communicate

Regular monthly communications within a country should be organized by the NPHL. NPHLs should communicate directly with the WHO Country Office and through them to the WHO Inter-Country Support Team (IST). Each Inter-country Team will compile the reports from all Member States in their sub-region and will communicate with the point of contact at the WHO Regional Office for Africa. National (internal) networks are encouraged to establish their own reporting framework that best suits their situations. Informal communication may be directed to any or all of the network members at any time.

5.19.3 How often should the network communicate

Reports from the laboratories in the network should be submitted monthly, arriving at the national level no later than the 10th day of the month. Summary information should be for the previous month or for the preceding period for which information is available.

5.19.4 What methods should be used

All national level laboratories should have their own computer and email for communication. Other laboratories in the network should communicate using the most rapid and reliable means available to them, which may include email, fax, telephone, radio and surface mail.

5.20 Laboratory functions related to IHR (2005)

The nature of International Health Regulations (IHR) 2005 implies that laboratory work should be carried out according to internationally recognized quality standards, in order to rely on trusted data. Every member state should be able to provide reliable and timely laboratory identification of infectious agents likely to cause public health emergencies of international concern. This will help to minimize international traffic of specimens and preserve national sovereignty.

As very few countries have a comprehensive laboratory capacity, the organization of laboratory diagnostics should be based on a reliable sample collection and transport system, domestic diagnostic capacity for the priority events and the use of outside capacity when needed. Each member state should determine the structure of their laboratory capacity system and assess its proficiency in order to reach the requirements mentioned for IHR.²¹ (Annex 12)

5.21 Resource mobilization and coordination of partners

Funds for the development and continuity of laboratory services will be derived from both the governments' and partners' support and collaboration.

²¹ Core capacity requirements for surveillance and response- IHR
http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf

6. Steps for establishing an NPHL network

Steps for establishing and implementing NPHL Network

1. Prepare to assess existing national laboratory system
2. Assess and describe the current practices and identify gaps
3. Define the desired *future* NPHL network
4. Develop national strategic plan to implement NPHL network
5. Get the national strategic plan & Policy approved
6. Launch the NPHL Network and implement the approved plan
7. Monitor, evaluate and improve implementation.

6.1 Prepare to assess existing national laboratory system

Establish a working group

The process of establishing a viable NPHLN requires a systematic approach and demanding preparation by concerned national authorities and other stakeholders. The process starts with establishment of a working group (technical committee) to coordinate and oversee the establishment of the NPHL network. The working group should comprise five to seven members and should be designated by the appropriate authority of the MoH.

Ideally, it should include but not limited to:

- Director or chief officer in charge of the laboratories at the ministry of health ,
- Chief epidemiologist in the ministry of health,
- A representative from private or non-governmental laboratories and,
- A representative of one of the university laboratories (medical school or the teaching hospital) and
- A representative of the regional/provincial reference laboratories, and
- Stakeholders in disease specific programs, funding partners and so on.

This working group should provide leadership in defining the desired future NPHLN, the assessment and preparation of current conditions, practices and needs, and preparation of multi-year plan for strengthening the NPHLN.

Develop a plan to assess the existing national laboratory network

The working group should develop/adapt a plan with detailed timetable, tool and logistics requirement for the assessment and eventually establishment of the network. The working group should also accomplish the following.

- Identify and agree on the tasks for completing each of the steps,
- Identify the responsibilities and tasks of each group member, and
- Set timetables for completing the tasks.
- Prepare /adapt the generic WHO assessment tools
- Identify resources (human, finance and material)

6.2 Assess and describe the current practices and identify gaps

In this step, the working group develops a thorough description of the current practices and functions of the laboratory system. The assessment should address laboratory infrastructure, equipment, staffing profile, type of tests performed at each level, quality assurance systems, reporting, supervision and sources of funding. Efforts spent in documenting these practices, included what worked well or not well in each of the assessment domains will ensure a systematic approach to improving gap areas and building a solid foundation for a national public health laboratory network. WHO has prepared a generic assessment tool offering suggestions that may help the working describe current practices and infrastructure so that priority actions can be identified.²²

6.3 Define the desired future NPHL network

Define the vision and overall direction of the NPHLN in the country. The vision should build on what is working and rectify what is not working within the means that are affordable for the country. It is important to

²² World Health Organization Regional Office for Africa. Protocol for assessment of national communicable disease surveillance and epidemic preparedness and response systems (February 2000). AFR/IDS/01.1

involve all stakeholders in defining the vision, goals, scope, objectives and strategies of the NPHLN.

6.4 Develop national strategic plan to implement NPHL network

Determine priorities for strengthening NPHL Network system and develop vision, goals, objectives, expected results and strategies to achieve the desired results. Prepare a detailed budget that forecasts funding needed each year for at least the first 3 years. Using the available resources and partners' support finalise the policy and plan with assigned budget and time frame.

6.5 Obtain approval for the plan from MoH officials

The working group should present the finalised strategic plan to the MoH policy makers and planning authorities for approval. If approved this plan should be incorporated in the health sector plan. Launch the NPHL Network and implement the plan

6.6 Launch NPHLN and implement plan

Following the approval of the strategic plan, obtaining essential resources and preparation of the operational guide or a well formulated constitution for establishing a laboratory network, a formational meeting should be organised. This meeting should be attended by all "would be" member laboratories, surveillance officers and representatives of local, bilateral and international partners. The meeting can serve as an impetus to kick-start the long but doable journey of forming and maintaining a viable NPHLN.

6.7 Monitor, evaluate and improve implementation

The implementation of the plan should be monitored to track if the planned activities are indeed being implemented. The National IDSR program should participate in the monitoring process and should support in finding solutions to some of the outstanding issues including helping in mobilization of resources for supporting critical and strategic activities of the network.

Regular tracking of implementation should be supplemented with a periodic assessment of the overall effectiveness and outcome/impact of the NPHLN using appropriate laboratory indicators. The generic laboratory indicators

developed by WHO in close collaboration with technical partners (CDC – USA) could be adapted to the national context and applied and selected by Member States. (Annex 11).

7. Linkage of NPHLN with WHO regional and sub-regional PHL Network

Network formation beyond the national level will assist member states in a variety of ways and facilitate the timely and effective use of information and sharing of technical, material and financial resources to strengthen laboratory capacity. The recent trend of African laboratories liaising with laboratories in the West including development of work plans and creating linkages for shared activities is timely for enhancing surveillance to detect and respond to the increased threat of global epidemics.

7.1 WHO actions to strengthen NPHL Network

The first priority for the WHO Regional Office is to support establishment of a National Public Health Laboratory in all Member States of the WHO African Region to ensure successful implementation of IDSR and International Health Regulations (IHR-2005).

The establishment of an NPHLN could be a phased approach beginning with a few laboratories equipped with appropriately trained staff, essential equipment and maintenance facilities and reliable supply of reagents. These laboratories could be supported to be part of the regional external quality assurance and control program and provisions could be made for laboratory-based data management. With experience and availability of more resources, the network could be expanded to the provincial and district reference laboratories as well as private laboratories.

7.2 WHO regional and sub-regional PHL Network

The WHO Regional Laboratory Coordinator and WHO inter-country laboratory experts will provide technical support to ensure proper functioning of the NPHLN. The Regional Office will also encourage and promote appropriate and effective use of laboratories to support implementation of the national integrated disease surveillance and response activities. In addition, the Regional Office will also deploy short term consultants and experts to support the NPHLs selected as sub-regional and regional laboratory networks.

Regional reference laboratories

There is at least one regional reference laboratory in each epidemiological block. These laboratories are able to diagnose rare pathogens referred by national and sub-regional reference laboratories. The functions of these laboratories are to:

- Confirm results of national and sub-regional referral laboratories, when necessary
- Establish a strain bank of unusual organisms
- Conduct molecular and genetic characterization of isolates
- Refer selected isolates to international collaborating laboratories
- Prepare and distribute to sub-regional referral laboratories, non-commercial reference and diagnostic reagents
- Train staff of national and sub-regional referral laboratories
- Perform quality control and monitoring of performance standards of national laboratories via sub-regional referral laboratories and through the management of proficiency tests.
- Monitor anti-microbial resistance of targeted diseases

Sub-regional reference laboratories

There are at least two sub-regional reference laboratories in each of the three WHO sub-regions which are duly supported by the inter-country laboratory expert. The selection was made after assessment by the regional and inter-country laboratory experts. The functions of these sub-regional laboratories are to:

- Confirm results of national laboratories, when necessary
- Train staff of national laboratories at sub-regional level of the bloc
- Support national laboratories in terms of equipment and reagents and assist in case of outbreak confirmation
- Collaborate with the Regional Reference Laboratory in the regional EQC/QA scheme designed for NPHL
- Support developing national EQA schemes and participate in corrective actions based on the results of the regional EQA program.

7.3 Coordination of WHO/AFRO laboratory networks

WHO/AFRO maintains a network of national reference laboratories through the sub-regional and regional reference laboratories for bacteriology (*Vibrio cholerae*, *Shigella dysenteriae* type 1, *Neisseria meningitis*, *Streptococcus pneumoniae*, *Haemophilus influenzae* b, and *Yersinia pestis* for plague endemic countries only). The WHO bacteriology laboratory network has mechanisms for quality assessment and laboratory data recording and reporting. The network members have agreed to participate in the EQA as well as in regularly submitting laboratory specimens to the network. The network would follow the WHO polio network model.

Managerial meetings

Directors of Referral Regional and Sub-Regional Laboratories and NPHNL should participate in the joint laboratory and epidemiologists meetings at regional and sub-regional levels. The laboratory directors should share their experiences, problems and achievements and discuss with program managers the implementation of regional, sub-regional and national work plans. Similar meetings should be held regularly at the national level. In addition, every year a regional meeting will be organised for the directors of all NPHLs to discuss strategic issues and make recommendations to chart the way forward.

Technical workshops

Professional staff of Regional and Sub-Regional Reference Laboratories should attend all WHO workshops organized for training in advanced techniques. Depending on the availability of resources, training courses on WHO recommended diagnostic methods for targeted diseases should be held at Regional Reference Laboratory for staff that requires additional training.

National workshops for health care facility staff involved in collecting, storing and transporting specimens to reference laboratories should be held at the NPHL in collaboration with the national epidemiological surveillance unit of the MoH.

Attachments to reference laboratories

Microbiologists or Technologists from Regional, Sub-Regional Referral Laboratories or National Laboratories may be required to undergo training in new techniques or re-training in basic techniques as recommended by WHO consultants.

Remedial training

Should proficiency test results or analysis of reported laboratory data reveal sub-standard performance by staff at a network laboratory of any level, a consultant may be assigned to investigate the source of the problem and propose solutions including conducting training, as appropriate.

7.4 Antimicrobial resistance network

The laboratories in the African region with already established research activities on anti-microbial resistance will be reference laboratories for the network. Anti-microbial testing for *V. cholerae*, *S. dysenteriae* type 1, and *N. meningitidis*, including bacterial pathogens causing STDs and opportunistic infections in patients with HIV/AIDS is already being done by some national laboratories. Therefore, Regional and Sub-regional Reference

Laboratories for anti-microbial resistance will coordinate data collection and further advanced testing of isolates of these three pathogens.

For other organisms (*Neisseria gonorrhoeae* and opportunistic bacteria such as *Salmonella*, *Escherichia coli*, *Pseudomonas*, and *Staphylococcus*), the reference laboratories will conduct anti-microbial resistance monitoring and possibly work with other network laboratories to extend the monitoring.

WHO/AFRO will continue to organize training of personnel from NPHL and/or referral laboratories in order to standardize AMR susceptibility testing. WHO/AFRO will also provide national reference laboratories with reference strains to allow them to perform QC for their AMR testing.

At WHO/AFRO, staff of the sub-regional and regional network form part of the global laboratory network that includes collaborating centres at the international level. The collaborating centres are the designated reference centres for specific diseases such as meningococcal meningitis, influenza, Ebola or Marburg disease. These collaborating centres will provide technical and material support to laboratories at the regional, sub-regional and country levels. Each country's NPHL is the focal point for contacts with the collaborating centres.

8. Monitoring and evaluation

Laboratory performance and staff competence, as well as activities in relation to enhancement of disease surveillance and control, will be monitored regularly through the use of standard performance indicators, proficiency panel testing, on spot assessment, and discussion with surveillance and health officials. EQA will regularly be used at all NPHLs by Regional and Sub-Regional Reference laboratories. The core laboratory indicators will be used to measure the progress. In addition, evaluation of laboratory performance is encouraged each time an epidemic occurs in the respective service area. Please Annex 11 for a list of the IDSR Core Laboratory Indicators.

9.0 References

1. World Health Organization, Regional Office for Africa. Integrated Disease Surveillance in the African Region, a regional strategy for communicable diseases 1999-2003.
2. World Health Organization, Regional office for Africa, Centres for Disease Control and Prevention. Technical Guidelines for IDSR in the African Region, Atlanta, Georgia. Public Health Service, Centres for Disease Control and Prevention/Epidemiology Program Office, Division of International Health; National Centre for Infectious Diseases, Division of Bacterial and Mycotic Diseases. July 2001:10-11. Detect and respond to priority diseases, (http://www.cdc.gov/idsr/IDSR_resources/detection/detect_respond_eng.pdf)
3. World Health Organization, Regional Office for Africa. Regional Committee Resolution AFR/RC 48 /R2, 1998
4. World Health Organization, Regional Office for Africa. Documentation of IDSR implementation in the WHO African Region: Summary of the Synthesis Report . CDER, May 2003
5. Perry HP, McDonnell SM, Alemu W, Nsubuga P, Chungong S, Otten MW Jr, Lusamba-dikassa P and Thacker SB. Planning an integrated disease surveillance and response system: a matrix of skills and activities. BMC Medicine 2007, 5:24 available from <http://www.biomedcentral.com/1741-7015/5/24>
6. McNabb S JN, Chungong S, Ryan M, Wuhib T, Nsubuga P, Alemu W, Carandekulis V and Rodier G. Conceptual framework of public health surveillance and action and its implication in health sector reform. BMC Public Health 2002, 2:2
7. World Health Organization, Regional Office for Africa. Regional Committee Resolution AFR/RC 43 /R7, 1993
8. Bates I and Maitland K. Are laboratory services coming of age in Sub-Saharan Africa? Editorial Commentary. CID 2006:42(1February) 383-384
9. Martin R, Hearn T, Ridderhof, J. and Demby A. Implementation of a quality systems approach for laboratory practice in resource-constrained countries. AIDS 2005, 19(suppl 2):S59-S65
10. World Health Organization. Strengthening surveillance and response for epidemic-prone and vaccine-preventable diseases in selected African and Eastern Mediterranean countries 2005 (WHO/CDS/CSR/LYO/2005.23)

11. The Global Polio Laboratory Network: A Model for Good Laboratory Practice
<http://www.qaproject.org/pubs/pubstechreports.html#globalpolionetwork>
12. Centres for Disease Control and Prevention-USA. IDS Update Bulletin. IDSR links with other surveillance programs. Update Bulletin, Vol 2, Fall 2001
13. Centres for Disease Control and Prevention-USA. IDS Update Bulletin. Documentation of IDSR implementation in the African & Eastern Mediterranean Regions. Update Bulletin, issue 4 , 2003
14. World Health Organization Country office in collaboration with Great Lakes Epidemiologic Bloc. IDS/Health Information Bulletin Integrated Disease Surveillance & Response
www.cdc.gov/idsr/files/CSR_Bulletin_Dec_02_Volume_7/CSR_Bulletin_Dec_02_Volume_7.htm#lab
15. World Health Organization, Laboratory Support to Emerging Diseases. World Health Organization Regional Office for South-East Asia New Delhi,
www.whoindia.org/LinkFiles/Public_Health_Laboratory_Networking_SEARO_recommendations_on_networking_of_PHL.pdf
16. World Health Organization, Regional Office for Africa and Centres for Disease Control and Prevention. Technical Guideline for Integrated Disease Surveillance and Response in the African Region, May 2002
17. World Health Organization, Geneva 2004. Laboratory bio safety manual.
<http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf>.
18. World Health Organization, Guidelines for safe transport of infectious substances and diagnostic specimens. WHO/EMC/97.3.
http://libdoc.who.int/hq/1997/WHO_EM_97.3.pdf
19. World Health Organization Regional Publication, South-East Asia Series No.24, 2nd Edition, 1999 (ISBN 92 9022 1674)
20. World Health Organization, Geneva 2006. International Health Regulations (2005)
<http://www.who.int/csr/ihr/en/>
21. Core capacity requirements for surveillance and response- IHR
http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf
22. World Health Organization, Protocol for assessment of national communicable disease surveillance and epidemic preparedness and response systems (Feb 2000 Version). WHO Regional Office for Africa, AFR/IDS/01.1

10. Annexes

- Annex 1: Terms of reference for NPHLN
- Annex 2: Terms of reference for an IDSR Laboratory Technical Committee (Working group)
- Annex 3: Terms of reference for the laboratory focal person
- Annex 4: Public health laboratory network functions
- Annex 5: WHO/AFRO IDSR priority diseases
- Annex 6: Core bacteriology laboratory tests for IDSR in an outbreak
- Annex 7: Laboratory line list of bacteriological specimen & pathogens isolated for surveillance
- Annex 8: Recommended laboratory equipment for each level
- Annex 9: Recommended supplies for outbreak investigation
- Annex 10: Sample form for reporting laboratory results
- Annex 11: Proposed laboratory indicators for monitoring and evaluating the implementation of a laboratory network
- Annex 12: Requirements of the national laboratories in the context of IHR – core capacity checklist
- Annex 13: Specimens for laboratory confirmation for priority diseases at the district level

Annex 1: Terms of Reference for a National Public Health Laboratory Network

1. Establish, maintain and expand collaborative links between laboratories (including veterinary laboratories) that have functions related to public health impact at the various levels in the country.
2. Promote best practices in all disciplines of public health laboratory services including setting standards, establishing and promoting internal and external quality assurance mechanisms.
3. Improve nationwide access to quality public health laboratory services for confirmation and characterization of causative agents for effective control of communicable diseases.
4. Work collaboratively with the national IDSR focal person/team, WHO and partners to ensure optimal use of public health laboratory resources for communicable diseases surveillance including outbreak investigations.
5. Build on existing laboratory capacity to respond to existing and newly emerging infectious diseases.
6. Respond to matters relating to public health microbiology including resistance monitoring, as referred by national programs.
7. Accreditation of laboratories at national level.

Annex 2: Terms of Reference for the National Public Health Laboratory Technical Committee (working group) in Uganda

This is an example of the terms of reference developed for a national public health laboratory working group formed in Uganda and reflects the Ugandan national priorities and context.

Mandate

The Laboratory Technical Committee (LTC), on behalf of the Ministry of Health, will provide technical and professional guidance and support in all aspects of laboratory work to institutions and organizations, both government and non-governmental, working in the health and allied sectors for effective and efficient performance of health laboratory services.

Terms of reference

House-Keeping:

Propose 'Terms of Reference' (TOR) for the LTC to the Ministry of Health (MOH) for endorsement by the Director General of Health Services (DGHS); review annually and modify TOR periodically in response to changing needs and new developments.

Propose terms and conditions for the operation of the LTC including; number of members (21), their period of service (3 years) and rules for replacement for non-performance (non-attendance at 4 consecutive meetings), ministries, organizations, institutions and NGOs to have representation on the Committee, appointment of officers to specific positions (Chair-Person, Secretary and their deputies) and their rotation, minimum number of members necessary to conduct business (quorum of 7), standing sub-committees, *ad hoc* committees and task forces and their officers, frequency and location of regular meetings and annual review meeting.

Establish lines of reporting to relevant divisions within the MOH, currently Epidemiology and Surveillance, National Disease Control and the Division of Community and Clinical Services.

Identify potential funding sources for LTC Secretariat and for travel reimbursement for meeting attendance of members.

Central Level Activities:

Advocate for structural changes within the MOH to establish a Health Laboratory Services Division, headed by a senior health laboratory professional with appropriate staffing to represent the laboratory sector on the Health Sector Strategic Planning Committee and to coordinate rehabilitation and management of the health laboratory services in the country; the LTC will report to this Division once it is established.

Develop a consultancy to draft national health laboratory services policy for legislative action and a five-year strategic-plan.

Act as a forum for ministries, institutions, donor agencies and NGOs to exchange ideas and plans and provide direction and coordination of resources to under-funded activities.

National level activities:

Working with the Central Public Health Laboratory, set standards for laboratory requirements at Health Centre III and IV and district and regional hospitals in terms of;

- Physical infrastructure and equipment maintenance,
- Staffing levels, certification and support supervision,
- Minimal essential diagnostic tests, equipment, Standard Operating Procedures (SOP) including quality control (QC), commodity stock levels and quality assurance (QA),
- Commodities management,
- Infection control, safety and waste disposal policies,
- Networks,
- Laboratory information management system and reporting,
- Laboratory management.

Establish standing sub-committees (LTC members plus co-opted members from relevant organizations/institutions) to work with stakeholders and partners to fund and conduct needs assessment surveys, design and implement interventions and monitor progress as follows;

Infrastructure:

Coordinate donor funding to rehabilitate and develop physical infrastructure and provide and maintain essential equipment.

Coordinate the development of new technologies and the evaluation of new instruments, diagnostic kits, testing algorithms and protocols and publish findings.

Promote the establishment of networks within districts/regions based on public, private and NGO health facilities for effective referral of patients/specimens.

Staffing:

Advise MOH on appropriate staffing norms at different facility levels; advocate for the filling of vacant laboratory staff positions in district health facilities.

Provide support to the Allied Health Professionals Council (AHPC) in the regulation of health laboratory services through certification and registration of health laboratory professionals and accreditation and performance evaluation of health laboratories.

Identify requirements for in-service training of laboratory staff and assist institutions and organizations in identifying funding to develop and conduct training courses.

Work with donor agencies to develop scholarship programmes to increase the numbers of laboratory professionals in the country and provide short training courses in laboratory management and other relevant laboratory disciplines.

Source funds to expand capacity at laboratory training schools and university medical laboratory departments to include course revisions to strengthen laboratory management components.

Liaise and guide the professional laboratory associations in the promotion of continuing professional development programmes.

Support supervision:

Assist partners in identifying funding to strengthen capacity of Regional Laboratory

Coordinators (RLC) and District Laboratory Focal Persons (DLFP) to monitor laboratory performance including;

Setting of process indicators (to include staff attendance and specimen reporting time) and outcome indicators

Development of performance evaluation tools

Identification of constraints to improved performance; design and implementation of corrective measures and re-evaluation

Scheduling of regular support supervision visits and reporting

Establishment of individual health facility laboratory management teams.

Encourage health facilities to assess laboratory performance in the context of the overall health facility performance by conducting exit polls and making suggestion boxes available.

Work with laboratory professional associations to develop and pilot mechanisms to register and evaluate user (general public and health facility staff) complaints concerning laboratory performance.

Institute a rewards scheme to recognize outstanding individual and laboratory performance.

Establish a joint laboratory monitoring team to evaluate national laboratories (CPHL, Nakasero Blood Bank [NBB], Uganda Virus Research Institute [UVRI] and the National TB Laboratory [NTBL]) and offer this service to other reference and research laboratories.

Plan for regional level support supervision.

Commodities management:

Set standards for commodities management (stock items, levels, and storage and re-order thresholds) through a national consensus workshop.

Conduct regular needs assessment surveys to identify shortfalls and, together with national (National Medical Stores; NMS) and district authorities, plan and implement corrective interventions in the commodities supply chain, to include a

distribution system down to the health facility level.

Train laboratory managers in commodities management and procurement procedures, sensitize laboratory management teams and set progress indicators.

Foster linkages between MOH, WHO, NMS, Joint Medical Stores (JMS), District authorities and development partners (USAID, Deliver, AMREF and CDC) to monitor progress in laboratory strengthening.

Quality assurance:

Ensure SOPs, appropriate to each health facility level, are distributed to all health facilities offering laboratory services.

Designate, and identify funding to support, a specific HC III, HC IV and District Hospital as model facilities within which to develop detailed guidelines for integrated quality assurance activities including process and outcome indicators.

Develop a tool to assess each component of a quality assurance scheme, train RLC/DLFP in its use and organize a national consensus workshop as part of the National Health Laboratory Quality Assurance Scheme.

Assist the HIV Reference and Quality Assurance Laboratory (HRL) at the Uganda Virus Research Institute (UVRI) to develop and implement a national quality assurance (QA) programme for HIV serological testing to include test kit and algorithm evaluation, proficiency testing and quality control (QC) testing.

Identify funding to supplement existing QC activities at NTBL (proficiency testing panels and a referral system for QC testing at NTBL) and strengthen the capacity of NTBL to perform the functions of a TB reference laboratory.

Assist CPHL in responding to funding opportunities to develop its own laboratory space and, to expand and re-define the National Health Laboratory Quality Assurance Scheme (NEQAS) as the overall authority for national laboratory QA.

Establish networks within and between districts for referral and QC activities.

Strengthen existing medical equipment maintenance units in the country.

Commission a needs assessment survey of current practice in requesting, recording and reporting laboratory testing at the different health facility levels; design a national laboratory information management system (LIMS); conduct a national consensus workshop; implement and monitor progress.

Annex 3: Example: Terms of reference for the laboratory focal point for epidemic prone diseases (IDSR)

The focus of these terms of reference for the national laboratory focal point for IDSR is on four bacterial pathogens.

Background

The IDSR Laboratory Focal Point should be designated by the Ministry of Health (preferably Epidemiology/Surveillance Unit). This person should be stationed at the National Reference Laboratory for Bacteriology or the National Public Health Laboratory and be responsible for coordinating the National Public Health Laboratory Network. In addition this person should be a laboratory specialist and have a competency in Public Health and he/she should be a member of the national epidemiologic surveillance team as well as the national Epidemic Response Team.

This person is expected to be in contact with the following:

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

He should have at regional and district level a focal person with the same duties.

General mission

The functional laboratory networks are an essential component of the WHO-AFRO Integrated Disease Surveillance and Response (IDSR) strategy. The IDSR Laboratory Focal Point has the general mission to:

- 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 (public and private) a focal point for the epidemic preparation and response
- Submit to the authorities an official text for the creation of the National Network Laboratories, if it is not yet implemented in that country
- Define and adopt a coherent circuit of data transmission
- Organize national meetings with the personnel of the national or public health laboratories, periphery laboratories and intermediate 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 epidemic prone diseases
- 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 epidemic prone diseases (*Shigella*, *Vibrio cholerae*, bacterial meningitis, etc)
- Send regular monthly reports directly to the national office in charge of surveillance and prevention for public health interventions
- Send regular laboratory reports of data to the WHO/AFRO and the IST/CDS + EPR

- Analyze the data and feed-back results to the laboratories (province/region and district) and to personnel in charge of the epidemiologic surveillance
- Make available the reports of epidemic prone pathogens and antimicrobial resistance surveillance
- Send positive results to the district and central epidemiologist unit, according to the IDSR guideline
- 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 bacteriologic diagnosis of cholera, bacillary dysentery, bacterial meningitis, plague and other priority epidemic prone diseases
- 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

Epidemics 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.
- 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 cholera, dysentery, bacterial meningitis, plague and other priority epidemic prone diseases and also standard methods of antimicrobial resistance detection
- Organize national workshop in collaboration with the heads of epidemic prone diseases surveillance, for the personal working in sanitary structure involved in collecting, packaging, storing and shipping of the samples
- Training/refresh training the personal 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 *Vibrio cholerae*, *Shigella dysenteriae*, bacterial meningitis, and *Yersinia pestis* and other micro-organisms
- 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 IDSR Laboratory Focal Point must 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 National Focal Point in IDSR should maintain good scientific linkages with the other laboratories for the specific program and the national institutes for the research.

Monitor and assess regularly the laboratories performance, the personal skill and all the activities for the surveillance and prevention with those responsible for health services, by using the standards indicators IDSR.

Annex 4: Laboratory network functions in the diagnosis of priority diseases

	1.0 Collect	2.0 Confirm	3.0 Report
<p>Patients, Providers <i>(Community, Health Facilities)</i></p>	<ul style="list-style-type: none"> • 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 • Transport specimens to First Contact Laboratory and Referral Laboratory within approved guidelines 	<ul style="list-style-type: none"> • Use standardized case definitions to initiate confirmation process as part of an outbreak investigation • Handle specimens within approved guidelines 	<ul style="list-style-type: none"> • Record collection of specimens
<p>First Contact Laboratory <i>(District, Province)</i></p>	<ul style="list-style-type: none"> • Communicate collection policies and procedures to providers • Request additional specimen collection by laboratory or providers, as needed • Store specimens within approved conditions pending transport or additional studies • Direct additional collection as needed based on outbreak investigation 	<ul style="list-style-type: none"> • Perform laboratory studies for presumptive diagnosis as appropriate: microscopy, staining, microscopy, RDT • Store representative slides from the outbreak as needed • Observe changes in trends during routine analysis of laboratory results 	<ul style="list-style-type: none"> • Record laboratory results • Provide results to clinical staff and patients • Report results to local epidemiology offices • Report observed changes in trends during routine analysis of laboratory results • Use summary information in response to out breaks
<p>Referral Laboratory <i>(National)</i> some laboratories may function as First Contact and as Referral Laboratories</p>	<ul style="list-style-type: none"> • Set collection policies and procedures with national epidemiology office and national reference laboratories • Distribute specimen collection kits for special surveillance activities • Request additional specimen collection by laboratory or providers, as needed • Store specimens within approved conditions pending transport or additional studies 	<ul style="list-style-type: none"> • Set confirmation policies and procedures with national epidemiology office and national reference laboratories • Perform laboratories studies for confirmation as appropriate: culture, isolation, serogroup identification, antimicrobial susceptibility, serology • Store representative isolates from the outbreak as needed • Observe changes in trends during routine analysis of laboratory results 	<ul style="list-style-type: none"> • Report results and summary data to national epidemiology office • Report laboratory results from screening sentinel populations at target sites
<p>International Reference Labs</p>	<ul style="list-style-type: none"> • Request additional specimen collection by laboratory or providers, as needed • Direct additional collection as needed based on outbreak investigation 	<ul style="list-style-type: none"> • Perform additional laboratory studies as appropriate 	<ul style="list-style-type: none"> • Report laboratory results to appropriate epidemiology offices • Use summary information in response to outbreaks

Annex 5: WHO/AFRO IDSR priority diseases

NOTE: This is a revised list of the WHO/AFRO IDSR Priority Diseases, conditions and events updated as of May 2008 to reflect inclusion of non-communicable diseases and those infectious diseases targeted by the International Health Regulations (2005). The emphasis in this guide is on the provision of laboratory services for cholera, diarrhoea with blood, bacterial meningitis, and plague.

Epidemic-Prone and IHR recommended Diseases, conditions and events	
<ol style="list-style-type: none"> 1. Cholera 2. Diarrhoea with blood (Shigella) 3. Meningitis 4. Plague 5. Viral hemorrhagic fevers (Ebola, Marburg, Rift valley fever,) 6. Human influenza caused by a new Subtype 7. Yellow Fever 	<ol style="list-style-type: none"> 8. SARS 9. Smallpox 10. Dengue 11. Trachoma 12. Chikungunya 13. Anthrax 14. Typhoid fever 15. Hepatitis –B 16. Severe Acute Respiratory Infection (SARI)
Diseases Targeted for Eradication and Elimination	
<ol style="list-style-type: none"> 1. Poliomyelitis 2. Dracunculiasis 3. Leprosy 	<ol style="list-style-type: none"> 4. Neonatal tetanus 5. Noma 6. Measles
Other Diseases of Public Health Importance	
<ol style="list-style-type: none"> 1. Diarrhoea in children less than 5 years of age 2. Pneumonia in children less than 5 years of age 3. HIV/AIDS 4. Malaria 5. Onchocerciasis 6. Sexually transmitted infections (STIs) 7. Trypanosomiasis 	<ol style="list-style-type: none"> 8. Tuberculosis 9. Filariasis 10. Buruli ulcer 11. Asthma 12. Diabetes mellitus 13. Epilepsy 14. High blood pressure 15. Sickle cell disease 16. Malnutrition

Annex 6: List of core IDSR laboratory tests for confirming outbreaks

Disease	Specimen	When to collect	Where to send specimen	Type of test	Comments
Diarrhea with blood (Dysentery)	Stool	On each suspected case. If the outbreak has crossed the threshold, collect 1 sample each on the first 10 suspected cases and later on 10 cases	National Reference Lab	<ol style="list-style-type: none"> 1. Stool culture 2. Identification by chemical test (note that <i>S.dysenteriae</i> 1 is always catalase negative) and 3. Agglutination with specific antisera 	For antibiotic sensitivity, test: Nalidixic acid, ampicillin, ciprofloxacin, cotrimoxazole, chloremphenicol and tetracycline
Cholera	Stool	On each suspected case. If the outbreak has crossed the threshold, collect stool specimens on the first 10 suspected cases later on 10 cases	National Reference Lab	<ol style="list-style-type: none"> 1. Stool culture 2. Identification by chemical tests 3. Serotyping by specific antisera agglutination (polyvalent O1, Ogawa, Inaba) antisera anti <i>V.cholerae</i> O139) 	For antibiotic sensitivity, test: erythromycin, tetracycline, nalidixic acid, cotrimoxazole
Meningitis	CSF for culture	On each suspected case (even during non-outbreak season).	National Reference Lab	CSF culture with grouping	For antibiotic sensitivity, test: , oxacillin, chloremphenicol, cotrimoxazole, ceftriaxone
	CSF for latex agglutination		Provincial Reference Lab and/or District Lab	Latex agglutination	Send to Reference Lab for confirmation and antibiotic sensitivity
	CSF for cytology and Gram stain	On each suspected case (even during non-outbreak season).	District Lab Provincial and/or District Lab	Gram stain Cytology on CSF	Send to Reference Lab for confirmation and antibiotic sensitivity
Plague	Serum (Blood)	On each suspected case	Designated National and/or Reference Labs	ELISA test Dipstick test	Send to national reference laboratory or to regional/regional

Disease	Specimen	When to collect	Where to send specimen	Type of test	Comments
	Bubo aspiration and/or Sputum	On 10 first cases	Designated National and/or Reference Lab	Culture from bubo or sputum	regional for confirmation and ATB sensitivity
TB	Sputum	On each suspected case	Designated National and/or reference lab	Microscopy Culture from sputum	ATB sensitivity testing
STD	Urethral pus Blood	On each suspected case	District, Provincial National	Gram stain Serology Culture, Sensitivity	
Malaria	Thick blood smear	On the first 20 cases	Designated National and/or reference lab	MGG stain	
VHF	Blood samples	On the first 10 cases	Designated regional/international reference laboratories	ELISA/PCR	Send to regional or international reference laboratories

Annex 8:

List of recommended lab equipment for each level

	level 1 (district)		level 2 (intermediate)		level 3 (referral)	
	optimum	minimum	optimum	minimum	optimum	minimum
Autoclave	2	1	3	2	4	3
Basic scale	1	0	1	1	2	1
Binocular microscope	3	1	6	3	10	8
Candle jar	2	1	2	2	3	3
Clothes washing machine	0	0	0	0	1	0
CO2 incubator	0	0	1	0	2	1
Computer + printer	1	0	2	1	6	2
Centrifuge	1	1	2	1	3	2
Dryer	1	0	2	1	2	2
Electrophoresis equipment	1	0	2	1	2	2
ELISA equipment (W/I/R)	1	0	2	1	2	2
Emergency power supply	1	1	1	1	1	1
Fluorescence microscope	0	0	2	1	2	1
Freezer-20°	1	0	2	1	2	2
Freezer-70°	0	0	1	0	2	1
Fridge	2	1	3	2	6	3
Gel pulse electrophoresis	0	0	0	0	1	1
Glassware kit	2	1	3	2	4	3
Heated magnetic agitator	1	0	2	1	2	1
Incubator, large sized	1	0	2	1	3	2
Incubator, small sized	1	1	2	1	3	2
Internet connection	1	1	1	1	1	1
manipulation box	1	0	1	0	1	0
McFarland photometer	0	0	1	0	1	1
Media dispenser	0	0	0	0	1	0
Oven	1	0	2	1	2	2
Photographic equipment	0	0	1	0	1	0
pH meter	1	0	1	1	2	2
Pipettes automatic	3	1	4	3	12	8

	level 1 (district)		level 2 (intermediate)		level 3 (referral)	
	optimum	minimum	optimum	minimum	optimum	minimum
Plexiglas screen	1	1	2	1	4	2
Precision scale	1	0	1	1	2	1
Rotative agitator	1	0	2	1	2	2
Safety cabinet class II	0	0	1	0	2	1
Safety cabinet class III	0	0	0	0	2	1
Slide dryer	1	0	2	1	2	1
Thermocycler	0	0	0	0	2	1
Vortex	1	0	3	1	3	2
Washing machine	0	0	1	0	1	1
Water distiller	1	1	2	1	2	1
Water bath	2	1	3	2	4	2

Annex 9: List of supplies for outbreak investigation

Note: Kits for use during rapid response activities should be assembled in advance to ensure correct supplies are available to correctly and safely collect the necessary specimens.

District level:

- Transport media (TI bottles, Cary-Blair and, APW: 25 each)
- Latex agglutination test (15 samples of CSF)
- Dipstick *N. meningitidis* A,C,Y, W135
- Plague dipstix (25 samples)
- Gram stain kit
- MGG (May Grūmwald Giemsa) Kit
- Tuberculosis stain kit
- Triple package boxes for appropriate transport/reference of biological Samples*

*This laboratory supply is needed at all levels

Provincial/Regional Level:

- Transport media (100 TI bottles, 100 Cary-Blair)
- Culture media for enteric (XLD agar, SS media, McConkey agar, Hektoen enteric agar) and meningitis pathogens (chocolate agar, blood agar)
- Plague dipsticks
- Sensitivity test discs
- Antimicrobial susceptibility testing media: Mueller Hinton Agar
- General media
- Latex agglutination test *N. meningitidis*, *S. pneumoniae*, *Hib*
- Dipstick *N.meningitidis* A,C,Y, W135
- Antisera: Anti-*Shigella* polyvalent and anti *S.dysenteriae* 1
 - Anti-*Vibrio cholerae* O1 polyvalent
 - Anti-*Neisseria meningitidis* A, C, W135

Central/Reference level:

- Anti-sera anti *Shigella flexneri*, *boydii*, *sonnei*
- Anti-sera anti *Neisseria meningitidis* serotypes (W135, A, B, C, X, Y)
- Anti-sera anti *Vibrio cholerae* *O Inaba* and *Ogawa*
- Anti-sera anti-*Vibrio* O139
- AMR susceptibility testing: E-test media, IMC media

Annex 10: Sample form for reporting laboratory results

For Health Facility: If lab specimen is collected, complete the following information and send a copy of this form to the lab with the specimen.

Date of specimen collection:

Circle specimen source: Stool Blood CSF Other: _____

____/____/____

Date Specimen sent to lab:

____/____/____

For the Lab: Complete this section and return the form to district team and clinician

Date lab received specimen: ____/____/____ Circle specimen condition: Adequate Not adequate

Disease/ Condition	Type of test	Results (P=pending)	Disease / Condition	Type of test	Results
Cholera	Culture	+ - P	Yellow Fever	IgM	+ - P
	Direct Exam	+ - P	Measles	IgM	+ - P
Meningitis		Exam	Rubella	IgM	+ - P Virus Detection
N. meningitidis	Culture	+ - P	RVF	IgM	+ - P + - P
S. pneumonia	Culture	+ - P	Ebola	IgM	+ - P + - P
H. influenza	Culture	+ - P	CCHF	IgM	+ - P + - P
N. meningitidis	Latex	+ - P	Lassa	IgM	+ - P + - P
S. pneumonia	Latex	+ - P	Marburg	IgM	+ - P + - P
H. influenza	Latex	+ - P			
Shigella Dysenteriae	Culture	SD type 1 Other shig No shig			
Plague	Culture	+ - P			
	IFA>1: 64	+ - P			

Other disease/condition (specify): _____

Types of test and results: _____

Date lab sent results to district: ____/____/____

Name of lab sending results: _____

Other pending tests: _____

Date district received lab results: ____/____/____

Date lab results sent to clinician by district: ____/____/____

NOTE: District is responsible for ensuring lab results get to clinicians. Failure to do so will undermine cooperation with clinicians on reporting of cases in the future

Annex 11:

Revised Proposed Laboratory Indicators for Measuring Progress with the Lab Component of IDSR --REVISED 030906

The diseases/pathogens of concern for this evaluation are: _____

Time period to be covered by this evaluation is: FROM _____ TO _____

Number	Indicators	Denominator	Numerator	Source of information	What it measures	Interpretation	Frequency of analysis
1	Proportion of district laboratories reporting lab data on selected priority pathogen confirmed in specimens collected in the district to higher level for the month	Total number of district labs	Number of district labs that submitted monthly data to higher level	National log book of reports received	Functional reporting system	If districts are collecting and reporting lab data to higher level	quarterly or semi-annually
2	Proportion of district laboratories that have transported adequate diagnostic specimens to provincial labs (Record responses separately for each disease or pathogen included in the evaluation)	Total number of district labs <i>AND the number</i> expected to refer specimens	Number of district labs from which adequate specimens were received	Provincial log of routine reports received	Collection, storage, transportation of specimens	Awareness of referral of priority specimens, and availability of needed logistics	quarterly or semi-annually
3	Proportion of district laboratories that received at least one supervisory visit with written feedback by provincial/national level	Total number of district laboratories	Number of district laboratories that received at least one supervision activity	Reports of the District Lab Focal Person -this may require field visits	Capacity of higher levels to supervise district labs	Is district lab receiving support supervision to help to solve problems	annually
4	Proportion of provincial laboratories reporting analysed lab data to the national lab	Total number of provincial laboratories	Number of provincial laboratories analysing and reporting to NPHL monthly	NPHL	Functional lab-based surveillance system	If provincial levels analyse district laboratory data	quarterly

5	Proportion of provincial (regional in some countries) laboratories reporting culture results for designated pathogens (Record responses separately for each disease or pathogen included in the evaluation)	Total number of provincial (regional in some countries) laboratories	Number of provincial (regional in some countries) laboratories reporting culture results	NPHL	Technical competence; presence of a network; availability of reagents & supplies	If provincial (regional in some countries) labs are able to perform confirmatory testing for designated pathogens	quarterly
6	Proportion of provincial laboratories that received at least one supervisory visit with written feedback by central level	Total number of provincial laboratories	Number of provincial laboratories supervised by NPHL at least once, with written report	NPHL, MoH	Capacity of central levels to supervise provincial labs	Are provincial labs receiving supervision to support them as frontline centers for diagnosis of priority IDSR diseases	annually
7	Proportion of outbreaks with timely laboratory investigation (Record responses separately for each disease or pathogen included in the evaluation)	Total number of outbreaks	Number of outbreaks with lab investigation within prescribed time-frame	NPHL and MoH	Link between Epi and Public Health Lab	Are labs participating timely in outbreak investigation	Post-epidemic analysis

Annex 12: Requirements of national laboratories in the context of IHR- core capacity checklist

- Guidelines, including measures related to biosafety and the cold chain, are available
- An operational system for collection, packaging and transport of samples to and from laboratories is in place.
- High quality outside collaborating centers are identified to allow laboratory identification of epidemic-prone diseases and public health risks when there is no corresponding quality controlled domestic capacity available.
- An inventory of country laboratory capacity for alert and response is available and a list of laboratories designated by the Ministry of Health as part of the national system for alert and response has been established according to the public health priority threats.
- The role and responsibilities of each laboratory within the laboratory system is established, as well as the functional rules of the laboratory system within the national alert and response system.
- All laboratories that are part of the alert and response system are engaged in a credential quality assurance programme based on national quality standards and regularly tested through exercises
- Protocol are preestablished for the participation of laboratories in investigation
- Mechanisms are set to better link laboratories and epidemiology teams
- All laboratories that are part of the alert and response system participate successfully in interlaboratory comparison programmes (i.e. external quality assessment schemes through proficiency testing or rechecking).
- When feasible, an IHR national laboratory coordinator is designated to ensure the coordination of the laboratory system.
- When feasible, the NRL (or acting reference laboratories) part of the alert and response system are accredited to the internationally recognized standards, (WHO, ISO or equivalent).
- When feasible, digital Laboratory Information Systems suited to surveillance and response requirements are in place to track and monitor relevant laboratory data.

Annex 13: Specimens for laboratory confirmation for priority diseases at the district level

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Anthrax</p> <p>Reference: WHO Recommended Surveillance Standards WHO/CDS/CSR/ISR/99.2</p> <p>Cutaneous Anthrax: Recommended specimens for Microbiology and Pathology for Diagnosis, CDC</p>	<p>Isolation of <i>Bacillus anthracis</i> from a clinical specimen (e.g. blood, lesions, discharges)</p> <p>Demonstration of <i>B.anthraxis</i> in a clinical specimen by microscopic examination of stained smears (vesicular fluid, blood, cerebrospinal fluid, pleural fluid, stools)</p> <p>Positive serology (ELISA, Western blot, toxin detection, chromatographic assay, fluorescent antibody test)</p>	<p>Cutaneous</p> <ul style="list-style-type: none"> • Vesicular • Eschar <p>Gastro-intestinal</p> <ul style="list-style-type: none"> • Stool • Blood <p>Inhalation</p> <ul style="list-style-type: none"> • Sputum • Blood 	<p>Specimens should be collected from any patient being evaluated for cutaneous <i>Bacillus anthracis</i> infection.</p> <p>It may not be possible to demonstrate <i>B.anthraxis</i> in clinical specimens if the patient has been treated with antimicrobial agents.</p> <p>Organism is best demonstrated in specimen taken at the Vesicular stage</p>	<p>Vesicular stage: collect fluid from intact vesicles on sterile swabs.</p> <p>Eschar stage: without removing eschar, insert swab beneath the edge of eschar, rotate and collect lesion material</p> <ul style="list-style-type: none"> • Store specimen for ≤ 24 h and transport for ≤ 2h at room temperature <p>Stool: collect 5-10 g in a clean sterile leak-proof container. Store for ≤ 24 h at 4°C. Transport ≤ 1h at room temperature.</p> <p>Blood: collect per institution's procedure for routine blood culture. Collect 10 ml of blood in EDTA for PCR. Transport ≤ 2h in room temperature.</p> <p>Sputum: collect expectorated specimen into a sterile leak proof container. Store for ≤ 24 h at 4°C. Transport ≤ 2 h in room temp.</p>	<p>Diagnostic services for Anthrax are not routinely available. Advance arrangements are usually required for Anthrax diagnostic services. Contact the appropriate National authority or WHO.</p>

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Chikungunya</p> <p>Reference:</p> <ul style="list-style-type: none"> Sergon et al. Seroprevalence of Chikungunya Virus (CHIKV) Infection on Lamu Island, Kenya, October 2004. Am J Trop Med Hyg. 2008 Feb;78(2):333-337 Powers et al. Evolutionary relationships and systematics of the alphaviruses. J Virol. 2001 Nov;75(21):10118-31 	<p>Serological tests show a rise in antibody titer to chikungunya virus; the virus may be isolated from the blood of acutely ill patients in newborn mice, mosquitoes or cell culture or detected using IFA or Reverse Transcription Polymerase Chain Reaction (RT-PCR)</p>	<p>Serum</p>	<p>Collect specimen from the first suspected case.</p> <p>If more than one suspected case, collect until specimens have been collected from 5 to 10 suspected cases. If outbreak is confirmed, collect more specimens from cases and also mosquitoes from the affected homes for testing</p> <p>Type of Specimen</p> <ul style="list-style-type: none"> Acute-phase blood (0-10 days after onset) Convalescent-phase blood (7 - 21 days after onset) <p>Time of collection</p> <ul style="list-style-type: none"> When patient presents; collect second sample during convalescence. Between days 7 and 21 after onset. 	<p>Transport of specimens should comply with the WHO guidelines for the safe transport of infectious substances and diagnostic specimens (WHO, 1997).</p> <p>For ELISA:</p> <ul style="list-style-type: none"> Refrigerate at 2° to 8° C serum or clot for testing within 24 hour. If kept for longer store at -80°. <p>For Isolation and RT_PCR</p> <ul style="list-style-type: none"> Store at -80° or transport in fully charged dry shipper. Mosquitoes for testing should be transported in fully charged dry shipper. Focus on Aedes species 	<p>Diagnostic services for Chik are not routinely available. Contact the appropriate National authority or WHO.</p> <ul style="list-style-type: none"> Ministry of Health, Disease Outbreak Management Unit should send samples to WHO reference labs e.g KEMRI Preliminary results are ready within 24 hours after samples arrive in the laboratory. Confirmatory results are ready within a week from sample reception.
<p>Poliomyelitis</p> <p>REFERENCE:</p> <ul style="list-style-type: none"> WHO global action plan for laboratory containment of wild polio viruses. WHO/V&B/99.32, Geneva, 1999 Manual for the virological investigation of polio,WHO/EPI/GEN/97.01, Geneva, 2004 Supplement to the Manual for the virological investigation of Polio-WHO/EPI 2007 	<p>Isolation of polio virus from stool</p>	<p>Stool</p> <p><i>Note: If no specimen is collected, re-evaluate patient after 60 days to confirm clinical diagnosis of polio (AFP).</i></p>	<p>Collect a sample from every suspected AFP case.</p> <p>Collect the first specimen when the case is investigated.</p> <p>Collect a second specimen on the same patient 24 to 48 hours later.</p>	<ul style="list-style-type: none"> Place stool in clean, leak-proof container and label clearly. Immediately place in refrigerator or cold box not used for storing vaccines or other medicines. Transport specimens so they will arrive at designated polio laboratory within 72 hours of collection When there is a delay, and specimen will not be transported within 72 hours, freeze specimen at -20°C or colder. Then transport frozen specimen with dry ice or cold packs also frozen at -20°C or colder. 	<p>Confirmed results are usually available within 21 after receipt of specimen by the laboratory.</p> <p>If wild or vaccine derived polio virus is detected, the national program will plan appropriate response actions</p>

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Cholera</p> <p>REFERENCE: “Laboratory Methods for the Diagnosis of Epidemic Dysentery and Cholera.” CDC/WHO, 1999 CDC, Atlanta, GA, USA</p>	<p>Isolate <i>V. cholerae</i> from stool culture and determine O1 serotype using polyvalent antisera for <i>V. cholerae</i> O1.</p> <p>If desired, confirm identification with Inaba and Ogawa antisera. If specimen is not serotypable, consider, <i>V. cholerae</i> O139 (see note in Results column).</p>	<p>Liquid stool or rectal swab</p>	<p>Collect stool sample from the first suspected cholera case. If more than one suspected case, collect until specimens have been collected from 5 to 10 cases. Collect stool from patients fitting the case definition and:</p> <ul style="list-style-type: none"> onset within last 5 days, and before antibiotics treatment has started <p><i>Do not delay treatment of dehydrated patients.</i> Specimens may be collected after rehydration (ORS or IV therapy) has begun.</p>	<ul style="list-style-type: none"> Place specimen (stool or rectal swab) in a clean, leak proof container and transport to lab within 2 hours. If more than 2- hour delay is expected, place stool-soaked swab into Cary-Blair transport medium. <p>If Cary-Blair transport medium is not available and specimen will not reach the lab within 2 hours:</p> <ul style="list-style-type: none"> Store at 4°C to 8°C Do not allow specimen to dry. Add small amount of 0.85% NaCl if necessary To transport, transport in well marked, leak proof container Transport container in cold box at 4°C to 8°C 	<ul style="list-style-type: none"> Cholera tests may not be routinely performed in all laboratories. Culture results usually take 2 to 4 days after specimen arrives at the laboratory. Cary-Blair transport medium is stable and usually good for at least one year after preparation. It does not require refrigeration if kept sterile and in properly sealed container. If colour changes (medium turns yellow) or shrinks (depressed meniscus), do not use the medium. The O139 serotype has not been reported in Africa and only in a few places in southwest Asia. Serological determination of Ogawa or Inaba is not clinically required. It is also not required if polyvalent antisera results are clearly positive.

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Diarrhoea with blood (<i>Shigella dysenteriae</i> type 1) and other shigellae</p> <p>Note: SD1 infections are epidemic-prone and associated with high levels of antibiotic resistance. SD1 is the most significant of the shigellae due to the high levels of mortality in the young and elderly and due to its association with haemolytic uremic syndrome (HUS).</p> <p>REFERENCE: “Laboratory Methods for the Diagnosis of Epidemic Dysentery and Cholera”. CDC/WHO, 1999 CDC, Atlanta, GA, USA</p>	<p>Isolate <i>Shigella dysenteriae</i> type 1 (SD1) in culture to confirm shigella outbreak.</p> <p>If SD1 is confirmed, perform antibiotic sensitivity tests with appropriate drugs.</p>	<p>Stool or rectal swab.</p>	<p>Collect sample when an outbreak is suspected. Collect stool from 5-10 patients who have bloody diarrhoea and:</p> <ul style="list-style-type: none"> · <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Onset within last 4 days, and · <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Before antibiotic treatment has started. <p>Preferably, collect stool in a clean, dry container. Do not contaminate with urine. Sample stool with a swab, selecting portions of the specimen with blood or mucus.</p> <p>If stool can not be collected, obtain a rectal swab sample with a clean, cotton swab.</p>	<p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Place stool swab or rectal swab in Cary-Blair transport medium. Transport to laboratory refrigerated.</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> If Cary-Blair not available, send sample to lab within 2 hours in a clean, dry container with a tightly-fitting cap. Specimens not preserved in Cary-Blair will have significant reduction of shigellae after 24 hours.</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> If storage is required, hold specimens at 4°C to 8°C, and do not freeze.</p>	<p>Culture results are usually available 2 to 4 days after receipt by the laboratory.</p> <p>SD1 isolates should be characterized by antibiotic susceptibility.</p> <p>After confirmation of an initial 5-10 cases in an outbreak, sample only a small number of cases until the outbreak ends.</p> <p>Refer to disease specific guidelines in Section 8.0 for additional information about the epidemic potential of <i>Shigella dysenteriae</i> 1</p>
<p>Dengue fever</p> <p>Reference: WHO Recommended Surveillance Standards WHO/CDS/CSR/ISR/99.2</p> <p>Dengue: clinical and Public Health Aspects/CDC</p> <p><i>Note: there are several diagnostic techniques available to document an infection by the dengue virus. The IgM ELISA is the basic test for serologic diagnosis.</i></p>	<p>Isolation of the dengue virus from serum, plasma or autopsy samples.</p> <p>Demonstration of a four fold or greater change in reciprocal IgG or IgM antibody titres to one or more dengue virus antigens in paired serum samples.</p> <p>Demonstration of dengue virus antigen in autopsy tissue by immunohistochemistry or immunofluorescence or in serum samples by EIA.</p> <p>Detection of viral genomic sequences in autopsy tissue, serum or CSF samples by PCR.</p>	<p><i>ELISA</i>:: Whole blood, serum or plasma</p> <p><i>PCR</i>: Whole blood or blood clot, serum/ plasma or tissue</p> <p>The samples should be collected for diagnosing a suspected dengue fatality:</p> <p>A blood sample to attempt virus isolation and serology. If an autopsy is performed, blood from the heart should be collected.</p>	<p>Collect specimen from the first suspected case.</p> <p>If more than one suspected case, collect until specimens have been collected from 5 to 10 suspected cases.</p> <p>Type of Specimen</p> <ul style="list-style-type: none"> • Acute-phase blood (0-5 days after onset) • Convalescent-phase blood (≥ 6 days after onset) <p>Time of collection</p> <ul style="list-style-type: none"> • Collect 2nd sample during convalescence. Between days 6 and 21 after onset. • Lab diagnosis of fatal cases is indispensable for understanding the risk factors for severe cases. 	<p>Transport of specimens should comply with the WHO guidelines for the safe transport of infectious substances and diagnostic specimens (WHO, 1997).</p> <p><i>For ELISA or PCR:</i></p> <ul style="list-style-type: none"> • Refrigerate serum or clot • Freeze (-20C or colder) tissue specimens for virus isolation <p>If an autopsy has been performed and no fresh tissues are available, tissues fixed in formalin should be submitted for immunohistochemical studies.</p>	<p>Diagnostic services for DF/DHF are not routinely available. Advance arrangements are usually required for VHF diagnostic services. Contact the appropriate National authority or WHO.</p>
Dracunculiasis	Routine laboratory confirmation for surveillance is not required.				

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Human influenza caused by a new Subtype</p> <p>Reference: Recommended laboratory tests to identify avian influenza virus A in specimens from humans, WHO, revised August 2007.</p> <p>Collecting, preserving and shipping specimens for the diagnosis of avian influenza A(H5N1) virus infection. Guide for field operations, October 2006 WHO/CDS/EPR/ARO/2006.1</p>	<p>Identification of human influenza virus infections by:</p> <ol style="list-style-type: none"> 1) Detection of influenza-specific RNA by reverse transcriptase-polymerase chain reaction 2) Isolation in cell culture (BSL3 lab required for suspected new subtype) 3) Direct antigen detection (low sensitivity) 	<p>A variety of specimens are suitable for the diagnosis:</p> <ul style="list-style-type: none"> • Throat swab • Nasopharyngeal swab • Nasal swab • Nasopharyngeal aspirate • Intubated patients: tracheal swab or bronchial lavage fluid • Blood <p>Specimens should be collected in the following order of priority:</p> <ul style="list-style-type: none"> • Throat swab/Nasopharyngeal aspirate • Acute serum • Convalescent serum 	<p>Obtained specimen within 3 days of the onset of symptoms,</p> <p>Initial specimens (respiratory or blood) should ideally be collected from suspected patients before antiviral therapy is begun but treatment must not be delayed in order to take specimens.</p> <p>Optimally, paired sera (3-5 ml of whole blood), collected first during the acute phase of illness and then 14 days or later after the onset of illness, should be tested simultaneously.</p> <p>Specimens should be collected from deceased patients as soon as possible after death</p>	<p>Respiratory specimens should be transported in virus transport media. Media that could be used for a variety of viruses are commercially available.</p> <p>Specimens in viral transport medium for viral isolation should be kept at 4°C and transported to the laboratory promptly. If specimen is transported within 2 days, it may be kept at 4°C; otherwise should be frozen at or below -70 °C until transported to the laboratory. Repeated freezing and thawing must be avoided to prevent loss of infectivity.</p> <p>Sera may be stored at 4°C for approximately one week, but thereafter should be frozen at -20°C.</p> <p>Transport of specimens should comply with the WHO guidelines for the safe transport of infectious substances and diagnostic specimens</p>	<ul style="list-style-type: none"> • Laboratory results should be confirmed by an approved laboratory. • Any specimen with a positive result for influenza A virus and suspected of avian influenza infection/new subtype should be further tested and verified by a designated WHO CC/WHO H5 Reference Laboratory. Laboratories that lack the capacity to perform specific influenza A subtype identification procedures are requested to: • Forward specimens or virus isolates to a National Influenza Centre or to a WHO CC/WHO H5 Reference Laboratory for further identification or characterisation. • Inform the WHO Office in the country that specimens or virus isolates are being forwarded to other laboratories for further identification or further characterization.

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
Lymphatic filariasis	<ul style="list-style-type: none"> Night blood smear Filarial antigen test 	<p>Blood smear</p> <p>Blood</p>	<p>Night between 10pm and 2am</p> <p>Any time of the day</p>	<p>Spread three drops of blood on a glass slide and spread across the slide to make three lines. After fixing with heat stain with geimsa stain and examine under microscope</p> <p>Either a rapid ICT card test or by an lab based ELISA test</p>	<p>Positive test is when microfilariae of <i>W.bancrofti</i> is seen under the microscope</p> <p>Positive if filarial antigen is detected</p>
<p>Measles</p> <p>REFERENCE: WHO Guidelines for Epidemic Preparedness and Response to Measles Outbreaks WHO/CDS/CSR/ISR/99.1</p>	<p>Presence of IgM antibodies to measles virus in serum.</p>	<p>Serum</p>	<p>Collect blood samples on 5 suspected measles cases when the number of cases exceeds the measles outbreak threshold (usually more than 5 cases in a district in a month).</p> <p>In countries with an elimination target:</p> <ul style="list-style-type: none"> Collect specimen from every suspected case of measles Collect serum for antibody testing at first opportunity or first visit to the health facility. 	<ul style="list-style-type: none"> For children, collect 1 to 5 ml of venous blood depending on size of child. Collect into a test tube, capillary tube or microtainer. Separate blood cells from serum. Let clot retract for 30 to 60 minutes at room temperature. Centrifuge at 2000 rpm for 10-20 minutes and pour off serum into a clean glass tube. If no centrifuge, put sample in refrigerator overnight (4 to 6 hours) until clot retracts. Pour off serum the next morning. If no centrifuge and no refrigerator, let blood sit at an angle for at least 60 minutes (without shaking or being driven in a vehicle). Pour off serum into a clean tube. Store serum at 4°C. Transport serum samples using appropriate packaging to prevent breaking or leaks during transport. 	<p>The specimen should arrive at the laboratory within 3 days of being collected.</p> <p>Results are usually available after 7 days.</p> <p>If as few as 2 out of 5 suspected measles cases are laboratory confirmed, the outbreak is confirmed.</p> <p>Avoid shaking of specimen before serum has been collected.</p> <p>To prevent bacterial overgrowth, ensure that the serum is poured into a clean glass test tube. The test tube does not need to be sterile, just clean.</p> <p>Transport the serum in an EPI hand vaccine carrier to 4°C to 8°C to prevent bacterial overgrowth (up to 7 days). If not refrigerated, serum stored in a clean tube will be good for at least 3 days.</p>

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
Meningitis REFERENCE: “Laboratory Methods for the Diagnosis of Meningitis Caused by <i>Neisseria meningitidis</i> , <i>Streptococcus pneumoniae</i> and <i>Haemophilus influenzae</i> .” WHO document WHO/CDS/EDC/99.7 WHO, Geneva	Microscopic examination of CSF for Gram negative diplococci Culture and isolation of <i>N. meningitidis</i> from CSF	Cerebral spinal fluid (CSF) Note: CSF is the specimen of choice for culture and microscopic exam. If CSF not available, collect blood (10 ml adults, 1-5 ml for children) for culture.	Collect specimens from 5 to 10 cases once the alert or epidemic threshold (see “Meningitis” in Section 8.0) has been reached.	<ul style="list-style-type: none"> Prepare the patient and aseptically collect CSF into sterile test tubes with tops. Immediately place 1 ml of CSF into a pre-warmed bottle of trans-isolate medium. Incubate at body temperature (36EC to 37EC). Never refrigerate specimens that will be cultured. Keep CSF for microscopic exam and chemistry in the original syringe (replace cap). Refrigerate the capped syringe and send it to the laboratory as soon as possible. 	Isolation of <i>Neisseria meningitidis</i> , a fastidious organism, is expensive, and difficult. It requires excellent techniques for specimen collection and handling and expensive media and antisera. Initial specimens in an outbreak or for singly occurring isolates of <i>N. meningitidis</i> should be serotyped and an antibiogram performed to ensure appropriate treatment. Trans Isolate medium (TI) is stable. If properly stored at temperature (4°C) it can be kept for up to two years after preparation. In the refrigerator, the liquid phase turns gelatinous but reliquifies at room temperature. Unused TI bottles should be kept tightly sealed. If there is any colour change (yellowing or clouding of the liquid medium) or drying or shrinkage of the agar slant, the medium should not be used.
Neonatal tetanus	<i>Laboratory confirmation is not required.</i>				
Onchocerciasis	<i>Routine laboratory confirmation for surveillance is not required.</i>				

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Plague</p> <p>REFERENCE: "Plague Manual: Epidemiology, Distribution, Surveillance and Control". WHO/CDS/EDC/99.2 WHO, Geneva, 1999</p> <p>"Laboratory Manual of Plague Diagnostic tests." CDC/WHO publication, 2000, Atlanta, GA</p>	<p>Isolation of <i>Yersinia pestis</i> from bubo aspirate or from culture of blood, CSF or sputum.</p> <p>Identification of antibodies to the <i>Y. pestis</i> F1 antigen from serum.</p>	<p>Aspirate of buboes, blood, CSF, sputum, tracheal washes or autopsy materials for culture</p> <p>Blood for serological tests</p>	<p>Collect specimen from the first suspected plague case. If more than one suspected case, collect until specimens have been collected on 5 to 10 suspected cases before the administration of antibiotics.</p> <p>With buboes, a small amount of sterile saline (1-2 ml) may be injected into the bubo to obtain an adequate specimen</p> <ul style="list-style-type: none"> If antibiotics have been started, plague can be confirmed by seroconversion (4-fold or greater rise in titer) to the F1 antigen by passive hemagglutination using paired sera. Serum should be drawn within 5 days of onset then again after 2-3 weeks. 	<ul style="list-style-type: none"> Specimens should be collected using aseptic techniques. Materials for culture should be sent to the laboratory in Cary Blair transport media or frozen (preferably with dry ice (frozen CO₂)). Unpreserved specimens should reach the laboratory the same day. Liquid specimens (aspirates) should be absorbed with a sterile cotton swab and placed into Cary-Blair transport medium. Refrigerate. If transport will require 24 or more hours and Cary Blair transport is not available, freeze the specimen and transport it frozen with cool packs. 	<p>Cultures should only be sent to a laboratory with known plague diagnostic capabilities or to a WHO Collaborating Centre for Plague.</p> <p>Plague culture results will take a minimum of 3 to 5 working days from reception in the laboratory.</p> <p>Antibiotic treatment should be initiated before culture results are obtained. Plague patients seroconvert to the F1 <i>Y. pestis</i> antigen 7-10 days after onset.</p>

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Rift Valley disease</p> <p>Reference: Fact sheet N°207 Revised September 2007. Infection Control for VHF in the African Health Care Setting /CDC (Annexes 11-12)</p>	<p>Acute RVF can be diagnosed using several different methods. Serological tests such as ELISA may confirm the presence of specific IgM antibodies to the virus. The virus itself may be detected in blood during the early phase of illness or in post-mortem tissue using a variety of techniques including virus propagation (in cell cultures or inoculated animals), antigen detection tests and RT-PCR.</p>	<p>ELISA (serology)</p> <ul style="list-style-type: none"> • Whole blood • Serum or plasma • PCR • Whole blood or clot • Tissues (fresh frozen) • Serum/plasma • Liver biopsy from fatal cases • Tissue biopsy from fatal cases 	<p>Collect specimen from the first suspected case.</p> <ul style="list-style-type: none"> • If more than one suspected case, collect until specimens have been collected from 5 to 10 suspected cases. 	<p>Laboratory workers are at risk. Samples taken from suspected human cases of RVF for diagnosis should be handled by trained staff and processed in suitably equipped laboratories.</p> <p>ELISA/PCR</p> <ul style="list-style-type: none"> • Preparation and storage (freeze of refrigerate/as cold as possible) • Shipping : frozen on dry ice or ice packs or both <p><i>Note: if dry ice or ice packs are not available, sample may be shipped at room temperature and still provide valid results in most cases.</i></p> <p><i>Immunohistochemistry:</i></p> <ul style="list-style-type: none"> • Preparation and storage :Fix in formalin (can be stored up to 6 wks) • Shipping: Room temperature (do not freeze). 	<p>Diagnostic services for RVF are not routinely available. Advance arrangements are usually required for VHF diagnostic services. Contact the appropriate National authority or WHO.</p>

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>SARS</p> <p>Reference: Use of laboratory methods for SARS diagnosis, WHO</p> <p>WHO Biosafety guidelines for handling of SARS specimens</p> <p>A practical Guide for SARS laboratories: from samples collection to shipment. WHO, 29 Dec 2003.</p>	<p>Confirmed positive PCR for SARS virus:</p> <ul style="list-style-type: none"> At least 2 different clinical specimens (eg nasopharyngeal and stool) OR The same clinical specimen collected on 2 or more days during the course of the illness (eg 2 or more nasopharyngeal aspirates) OR 2 different assays or repeat PCR using the original clinical sample on each occasion of testing <p>Seronconversion by ELISA or IFA:</p> <ul style="list-style-type: none"> Negative antibody test on acute serum followed by positive antibody test on convalescent serum OR Four-fold or greater rise in antibody titre between acute and convalescent phase sera tested in parallel. <p>Virus isolation: Isolation in cell culture of SARS-Cov from any specimen; plus PCR confirmation using a validated method</p>	<p>Nasopharyngeal wash/aspirate specimen of choice for respiratory viruses.</p> <p>Nasopharyngeal swabs or oropharyngeal swabs</p> <p>Stool</p> <p>Serum</p>	<p>The respiratory tract specimen can be collected at any time, but are best taken during the acute phase of illness.</p> <p>The time collection of paired blood samples is very important:</p> <ul style="list-style-type: none"> Collect an acute illness sample at first contact with the patient at days 7, 14, 28 and 90 after onset where possible. Collect blood on discharge if collection of a convalescent sample is unlikely. 	<ul style="list-style-type: none"> SARS specimens should be handled according to appropriate biosafety practices in order to avoid laboratory-related infections and spread of disease to close contacts. Clinical samples from patients should be collected by trained personnel. <p>Nasopharyngeal wash/aspirate: have the patient sit with the head tilted slightly backward. Instill 1.5 ml non-antibiotic sterile saline (Ph 7.0) into one nostril. Flush a plastic catheter or tubing (e.g. mucus trap tubing) with 2-3 ml of saline. Insert the tubing into the nostril parallel to the palate. Aspirate nasopharyngeal secretions. Repeat for the other nostril. Collect aspirates in sterile vial or mucus trap. Remove tubings and discard in plastic bag.</p> <p>Nasopharyngeal or oropharyngeal swabs: use only sterile Dacron or rayon swab with plastic shafts. Place each swab immediately in a tube containing Virus Transport Media (VTM).</p> <p>Serum collection: Collect 5-10 ml of whole blood in a serum separator tube. Allow blood to clot</p> <p>Respiratory / stool / blood/serum specimens: Refrigerate immediately (4°C). If transport/shipping will be international or will occur > 5 days after collection of last specimen, freeze the specimens at -20 °C (serum), -20/-70 °C (respiratory specimens) for planned shipping with dry ice if available. Fixed tissues (formalin fixed) from all major organs. Store and ship fixed tissue at room temperature.</p>	<p>Diagnostic services for SARS are not routinely available. Advance arrangements are usually required for SARS diagnostic services. Contact the appropriate National authority or WHO.</p>
<p>Sexually transmitted infections (STIs)</p>	<p><i>Routine laboratory confirmation for surveillance is not required.</i></p>				

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Smallpox</p> <p>Reference: Specimen selection desase, CDC</p> <p>Smallpox, Potential Bioterrorism agent: category A, Oct 02</p>	<p>Isolation of smallpox (variola) virus from a clinical specimen</p> <p>Or</p> <p>Polymerase chain reaction (PCR) essay identification of variola DNA in a clinical specimen</p> <p>Or</p> <p>Negative stain electron microscopic identification of variola virus in a clinical specimen</p> <p>Note: Level C or D laboratories only.</p>	<p>Biopsy specimens</p> <p>Scabs</p> <p>Vesicular fluid</p> <p>Blood samples</p> <p>Note: blood samples from person where severe, dense rash may be difficult to draw as the skin may slough off. A central line may be needed for access in cases where a peripheral blood draw is difficult.</p>	<p>A suspected case of smallpox is a public health and medical emergency. Collect samples from every suspected case.</p>	<p>Typical practices associated with collection of patient specimens are appropriate for collection of orthopoxvirus lesions as well. These include wearing personal protective equipment, including gloves and sanitizing the site prior to collection. If alcohol is used to prepare the lesion for collection it is important to allow the lesion to dry before it is collected.</p> <p>biopsy specimens: aseptically place two to four portions of tissue into a sterile, leakproof, freezable container. Storage - 20 °C to - 70 °C. Transport ~6h at 4 °C.</p> <p>Note: package non-formalin lesion biopsy for shipping on dry ice, leave formalin fixed biopsy at room temperature. Do not freeze formalin fixed biopsy sample.</p> <p>Scabs: aseptically place scrapings/material into a sterile, leakproof, freezable container. Storage - 20 °C to - 70 °C. Transport ~6h at 4 °C.</p> <p>Vesicular fluid: collect fluid from separate lesions onto separate sterile swabs. Be sure to include cellular material from the based of each respective vesicule. Storage -20 °C to - 70 °C. Transport ~6h at 4 °C.</p> <p>Draw 10 cc of blood into a plastic marble-topped tube, or a plastic yellow-topped serum separator tube.</p> <p>Note: approval must be obtained prior to the shipment of potential smallpox patient clinical specimens to a Reference laboratory.</p>	<p>Diagnostic services for Smallpox are not routinely available. Advance arrangements are usually required for Smallpox diagnostic services. Contact the appropriate National authority or WHO.</p>
<p>Trypanosomiasis</p>	<p><i>Routine laboratory confirmation for surveillance is not required.</i></p>				

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
Smear positive pulmonary Tuberculosis REFERENCE: Laboratory Services in Tuberculosis Control, Parts I, II and III. WHO publications WHO/TB/98.258	Presence of acid fast bacillus (AFB) in Ziehl Neelsen (ZN) stained smears	Deep-chest sputum	Collect sputum (not saliva) for direct smear microscopy and examine at least two stained specimens taken on different days.	Smear should be examined at health facility where the specimen is taken.	TB microscopy is read daily. Quantification of observed mycobacterium are reported using various reporting methods. Refer to the criteria used by the examining laboratory.
Viral hemorrhagic fevers REFERENCES: Infection Control for Viral Hemorrhagic Fevers in the African Health Care Setting WHO/EMC/ESR/98.2 Viral Infections of Humans; Epidemiology and Control. 1989. Evans, A.S. (ed). Plenum Medical Book Company, New York	Presence of IgM antibodies against Ebola, Marburg, CCHF, Lassa or Dengue fever <i>or</i> Presence of Ebola in post-mortem skin necropsy	<i>For ELISA:</i> Whole blood, serum or plasma <i>For PCR:</i> Whole blood or blood clot, serum/plasma or tissue <i>For immunohistochemistry:</i> Skin or tissue specimens from <i>fatal</i> cases.	Collect specimen from the first suspected case. If more than one suspected case, collect until specimens have been collected from 5 to 10 suspected cases.	HANDLE AND TRANSPORT SPECIMENS FROM SUSPECTED VHF PATIENTS WITH EXTREME CAUTION. WEAR PROTECTIVE CLOTHING AND USE BARRIER PRECAUTIONS. <i>For ELISA or PCR:</i> <ul style="list-style-type: none"> Refrigerate serum or clot Freeze (-20C or colder) tissue specimens for virus isolation <i>For Immunohistochemistry:</i> <ul style="list-style-type: none"> Fix skin snip specimen in formalin. Specimen can be stored up to 6 weeks. The specimen is not infectious once it is in formalin. Store at room temperature. Formalin-fixed specimens may be transported at room temperature. 	Diagnostic services for VHF are not routinely available. Advance arrangements are usually required for VHF diagnostic services. Contact the appropriate National authority or WHO.

Suspected disease or condition	Diagnostic test	Specimen	When to collect	How to prepare, store and transport	Results
<p>Yellow fever</p> <p>REFERENCES:</p> <p>District guidelines for Yellow Fever Surveillance, WHO/GPVI/EPI/98.09</p> <p>Yellow Fever. 1998. WHO/EPI/Gen/98.11</p>	<p>ELISA for the presence of yellow fever IgM antibodies</p>	<p>Serum</p>	<p>Collect specimen from the first suspected case of yellow fever. If more than 1 suspected case, collect until specimens have been collected from 5 to 10 suspected cases.</p>	<ul style="list-style-type: none"> • Collect 10 ml of venous blood from adults, 1-5 ml from children. In a standard glass test tube, capillary tube or microtainer. • Separate blood cells from serum: <ul style="list-style-type: none"> – Let clot retract for 30 to 60 minutes at room temperature. Centrifuge at 2000 rpm for 10-20 minutes and pour off serum into a clean glass tube. – If no centrifuge, put sample in refrigerator overnight (4 to 6 hours) until clot retracts. Pour off serum the next morning. – If no centrifuge and no refrigerator, let blood sit at an angle for at least 60 minutes (without shaking or being driven in a vehicle. Pour off serum into a clean tube. • Store serum at 4°C. • Transport serum samples using appropriate packaging to prevent breaking or leaks during transport 	<p>The specimen should arrive at the laboratory within 3 days of being collected.</p> <p>Avoid shaking of specimen before serum has been collected.</p> <p>To prevent bacterial overgrowth, ensure that the serum is poured into a clean glass test tube. The test tube does not need to be sterile – just clean.</p> <p>Transport the serum in an EPI hand vaccine carrier at 4EC-8EC to prevent bacterial overgrowth (up to 7 days). If not refrigerated, serum stored in a clean tube will be good for at least 3 days.</p>