Ministry of NHSR &C

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National Laboratory Policy

Islamic Republic of Pakistan

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Government of Pakistan

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National Laboratory Strategic Framework

Islamic Republic of Pakistan

Message

Federal Minister

The implementation of International Health Regulations (IHR) (2005) is an important concern for the Government of Pakistan. We are well aware of health security issues and cognizant to strengthen the core capacities under IHR (2005) and Global Health Security Agenda (GHSA). Laboratory services are also included in the IHR (2005) framework as a core public health capacity. Therefore, a comprehensive approach to strengthening laboratories across Pakistan is required to harmonize efforts to implement communicable disease prevention and control strategies in the country.

Realizing the importance of the laboratory services, the Ministry is focused on One Health methodology towards strengthening the laboratory system in Pakistan through a systematic approach. We consider cross-sectoral collaboration for system strengthening as vital and thus a National Laboratory Working Group (NLWG) was established to spearhead the policy, strategic and operational planning for the laboratory system in Pakistan. The NLWG, comprising relevant experts and stakeholders from different Ministries and sectors of health and provincial authorities, provided valuable input through a series of consultations for the finalization of the National Laboratory Strategic Framework in Pakistan. The consultative process ensured national ownership for the Strategic Framework as well as the commitment of all relevant stakeholders.

I believe that this important framework document will lay the foundation for building a sound laboratory system in the country. It is the responsibility of the Ministry of National Health Services, Regulations & Coordination to provide leadership through regulation, policy and collaboration as well as direct service provision to assure that within resource limitations the most appropriate mix of laboratory services - diagnostic, surveillance and outbreak response - is developed to achieve the best outcomes in health for all.

Saira Afzal Tarar
Federal Minister
National Health Services, Regulations & Coordination
Government of Pakistan

Message

Federal Secretary

Health laboratory systems can be strengthened by developing national policies, strategies and standards, supported by sustainable pre-service and in-service training programs for laboratory staff at the managerial and technical level. Ministry of National Health Services, Regulations and Coordination truly understands the responsibility in this regard and has always been striving hard to provide the best medical facilities to the masses. The present policy has been accomplished through a sternuous process and is meant for providing better and quality assured laboratory diagnostic services to the people of Pakistan

We would like to commend the hard work and commitment of the National Laboratory Working Group in preparing this policy. We also appreciate the assistance extended by technical advisors from WHO and the support of the European Union.

The Ministry of National Health Services, Regulations & Coordination shall remain committed to implement the GHSA, provide technical assistance, advocacy and resource mobilization for the building IHR 2005 core capacities in the country.

Naveed Kamran Baloch
Federal Secretary
National Health Services, Regulations & Coordination
Government of Pakistan

Preface

Accurate and reliable diagnosis is the cornerstone of disease management and prevention. Well-functioning, sustainable laboratory services, operating according to international principles of quality and safety, are an essential part of strong health systems and are crucial to improving health care. The analyses that laboratories provide offer a reliable foundation for evidence-based control of disease outbreaks, robust surveillance of adverse events associated with pharmaceutical or vaccine use and early and correct treatment of both acute and chronic diseases. Furthermore, laboratory services should operate according to the core capacity requirements of the International Health Regulations (IHR) (2005), a legally-binding agreement which provides a framework for the coordination of the management of events that may constitute a public health emergency of international concern. It intends to improve the capacity of all countries to detect, assess, notify and respond to public health threats. Furthermore we also have to strengthen our capabilities under One Health and Global Health Security Agenda.

The development of greater laboratory capacity in resource constrained countries is an urgent need, as defined in the Maputo Declaration on Strengthening of Laboratory Systems of 2008 and the Freetown Declaration of 2015. Pakistan, with its population of over 200 million people, is the sixth populous country in the world, and, as many countries, is constrained in resources. Where the unmet needs for health services are most prominent, the application of the cost effective interventions should be of the highest priority.

Well-functioning health laboratory services require coordination and supervision of laboratory services at the national and provincial levels, as well as the implementation of and adherence to laboratory quality standards.

The development of a National Laboratory Policy covering all laboratories is a step towards strengthening the laboratory services. The Pakistan National Laboratory Policy is designed to guide best choices in achieving health.

Prof Brigadier Aamer Ikram, SI(M)
Executive Director
National Institute of Health

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Contents

Contents

Foreword

Laboratories play an essential role under the International Health Regulations (2005) and are a key building block of a properly functioning health system. Accurate and reliable diagnosis is the cornerstone of disease management and prevention. Poor laboratory services are costly in terms of high wastage of scarce public resources and private out-of-pocket expenditures on ineffective treatments, loss of economic productivity of the population due to (chronic) illness and loss of life of humans and animals alike.

Recent independent assessments by WHO have shown that our laboratory sector needs improvement. The development of a National Laboratory Policy covering all laboratories involved in health under the One Health concept is a crucial first step in addressing the needs of the laboratory system as a whole. It provides direction to laboratory strengthening efforts and ensures efficient use of public funds and donor investments as well as the development of a sustainable system of laboratory services.

This document reflects the strong commitment of the Ministry of National Health Services Regulations & Coordination and other ministries for improvement of the laboratory sector in the country. It is the first essential step towards strategic and operational plans to drive actions that are carried out in an integrated manner at a pace that is in-line with the country's managerial and financial resources.

This Policy is the result of an established methodology, as described in the facilitators' guide of WHO for National Laboratory Policy development. The implementation of these policy recommendations aims to overcome the current challenges to improve the laboratory performance in the country. Therefore, all actors are strongly encouraged to contribute to realization of these policy statements.

Acronyms

AFIP	Armed Forces Institute of Pathology
AJK	Azad Jammu & Kashmir
ASM	American Society for Microbiology
BCLRA	Baluchistan Clinical Laboratory Registration Authority
BSC	Biosafety Cabinet
BSL	Biosafety Level
CAP	College of American Pathologists
CCHF	Congo-Crimean Hemorrhagic Fever
CDC	Centers for Disease Control (Atlanta, GA)
CME	Continuous Medical Education
CPSP	College of Physicians and Surgeons Pakistan
EPA	Environmental Protection Agency
EQA(S)	External Quality Assurance (Services)
FAO	Food & Agriculture Organization
FDA	Food & Drug Administration
FELTP	Field Epidemiology & Laboratory Training Program
GB	Gilgit Baltistan
GF	Global Fund
GHSA	Global Health Security Agenda
GLI	Global Laboratory Initiative
HIV	Human Immunodeficiency Virus
IATA	International Air Transport Association
IHR	International Health Regulations 2005
ISO	International Organization for Standardization
IT	Information Technology
JICA	Japan International Cooperation Agency
JCI	Joint Commission International
KfW	German Development Bank (Kreditanstalt für Wiederaufbau)
KIT	Royal Tropical Institute (Koninklijk Instituut voor de Tropen), Netherlands

Acronyms

KP	Khyber-Pakhtunkhwa
LAT	Laboratory Assessment Tool
LIMS	Laboratory Information Management System
LIS	Laboratory Information System
LQMS	Laboratory Quality Management System
LQSI	Laboratory Quality Stepwise Implementation (tool)
MNHSR&C	Ministry of National Health Services Regulation & Coordination
NIH	National Institute of Health, Pakistan
NLWG	National Laboratory Working Group
OIE	World Organization for Animal Health
PNAC	Pakistan National Accreditation Council
PPM	Public-Private Mix
PPP	Public-Private Partnership
PT	Proficiency testing
QC	Quality Control
RIQAS	Randox International Quality Assessment Scheme
SOP	Standard Operating Procedure
SWOT	Strengths, Weaknesses, Opportunities & Threats
TB	Tuberculosis
WHO	World Health Organization
WHO EMRO	World Health Organization Eastern Mediterranean Regional Office

Background

The Government of the Islamic Republic of Pakistan recognizes the significance imparted to diagnostic laboratories under the IHR (2005) and One Health agenda. Laboratories remain a key building block of an appropriately functioning health system. Recent independent assessments in the country denoted improvement in the laboratory sector.

Realizing the importance, the Ministry of National Health Services, Regulations & Coordination (MNHSR&C) notified a National Laboratory Working Group (NLWG) to guide and develop a draft laboratory policy and strategic plan. The National Laboratory Policy was developed in a series of interactive, facilitated workshops involving primary stakeholders (Annex IV - list of members) and two external facilitators from WHO Country Office and the WHO Collaborating Centre for Laboratory Strengthening at the Royal Tropical Institute (KIT) in Amsterdam, The Netherlands. The process of policy development and the methodology followed is detailed in Annex I. There was a consensus from all laboratory stakeholders to have a clear vision for a national policy as a crucial activity for laboratory strengthening. Primarily, the National Laboratory Policy needed to be integrated with already existing health policies and strategies and at the same time incorporate current international best practice in laboratory systems strengthening. In order to ensure wider national ownership as well as the commitment of all relevant parties, a post-workshop policy dialogue phase and consultations with all stakeholders was performed.

Vision 2025

Pakistan shall have well-organized, sustainable system of quality laboratory services under the One Health concept that are accessible and affordable to all. This system is governed and monitored through implemented and regularly updated policies, plans, rules and regulations. Laboratories are organized in networks and use paperless information and communication systems according to international standards and a state-of-the-art referral and sample transportation system, thus ensuring optimal patient care and robust surveillance for public health events.

Up to date pre-service and in-service training programs generate well-trained, qualified staff that is dedicated and well-paid. Trained laboratory managers are competent to manage and lead processes in the laboratory. At all levels of the laboratory networks, technical staff performs evidence based quality assured laboratory tests using quality equipment and consumables, standardized methodologies and ethical practices. Where appropriate, procedures are automated to allow for high volume testing.

All laboratories are registered and licensed based on defined minimum standards and EQA programs are widely established. Laboratories are encouraged to pursue accreditation. Proper biorisk management, infection control and waste disposal systems are implemented in all laboratories.

Policy Objective

The objective of the National Laboratory Policy is to give direction to laboratory strengthening efforts for all laboratories involved in human, animal, agricultural, food safety and environmental care under the concept of “One Health” and to ensure the development of a sustainable system of laboratory services in-line with international standards and able to meet the need of the population, while safeguarding efficient use of Government funds and donor investments.

Definitions

Biorisk management: overarching term that includes both biosafety and biosecurity management.

Biosafety management: Coordinated activities to prevent accidental or unintentional personal, laboratory and environmental exposure to potentially infectious agents.

Biosecurity management: Coordinated activities to prevent malicious or intentional personal, laboratory and environmental exposure to potentially infectious agents.

Continuing education: All training and retraining received after a person has started working. This can be on the job training as well as formal courses.

Inter-sectoral: referring to overarching activities that involve multiple sectors of the laboratory services under the One Health concept, such as human health, veterinary, agricultural, food safety and environmental laboratory services.

LIMS: software-based laboratory information management system with features that support a modern laboratory's operations and management.

LIS: software-based information management system with features that support data exchange and management as a part of Laboratories network.

Metrology: measurement, embracing both experimental and theoretical determinations at any level of uncertainty in any field of science and technology

One Health: the One Health concepts aims to improve health and well-being through the prevention of risks and the mitigation of effects of crises that originate at the interface between humans, animals, agricultural, food safety and the environment (www.onehealthglobal.net).

Policy: a deliberate system of principles to guide decisions and achieve rational outcomes. A policy applies to a certain field (in this case Laboratory Services) and guides the future activities in this particular field. It describes the direction in which the country wants to proceed (concentrating on "what" and "why").

Pre-service training: all training performed at universities, colleges and similar that aim to develop competencies that are relevant for the field of work in which a person will start his/her career.

Provincial/provinces/interprovincial: pertaining to all provinces and Federal Administered Territories

Quality assurance: activities aimed at the prevention of nonconformities in laboratory testing as per international standards.

Quality control: activities aimed at the detection of nonconformities during and after laboratory testing.

Quality management: a coordinated set of activities needed to control, assure and manage the quality of the laboratory's processes with the aim to provide consistent and reliable results in an efficient way.

Sustainable: Ability to maintain certain capacities or use a resource so that the resource is not depleted or permanently damaged

Tiered Laboratories System: A system of laboratories arranged at different levels (National/Regional or Provincial, District/Tehsil and Community)

Policy Statements

Component 1: Regulatory and legal framework

Legislation

Outcome: Continuous, consistent laboratory policies, laws, rules and regulations that are fully implemented, monitored and enforced.

1. Federal and Provincial legislation on laboratory services shall be harmonized with the National Laboratory Policy and Strategic Plan and be in line with international recommendations.
2. All laboratory policies shall take the One Health concept into account.
3. Trained and competent laboratory experts from all relevant sectors shall be involved in the development of laboratory-related policies, laws and regulations.
4. Legislation shall specifically include biosafety and biosecurity requirements including safe standard transport/shipment of specimens.
5. There shall be a mechanism to regularly review and update all laboratory-related policies, plans, laws, and regulations to ensure that they are in line with the latest developments in the field of laboratory services.
6. There shall be a mechanism to enforce implementation of policies and legislation.
7. Implementation of laws and regulations shall be monitored and evaluated to ensure compliance and identify points for improvement.
8. The list of notifiable diseases as well as the notification mechanism(s) shall be regularly updated in line with national and international requirements.

Licensing

Outcome: ***All laboratories and laboratory workers in Pakistan are registered and licensed.***

9. There shall be a licensing body at federal and/or provincial level for licensing laboratories as well as laboratory workers.
10. All laboratories and laboratory workers (public and private) shall be licensed according to the national standards to ensure quality of services.
11. The laboratory license shall be periodically renewed after re-inspection to ensure continued compliance with the standard.
12. The laboratory worker's license shall be periodically renewed based on a defined set of criteria.

Policy Statements

Component 2: Coordination and networking

Structured networks

Outcome: Functional laboratory network system(s) with a defined harmonized package of services and effective communication, collaboration and coordination.

1. There shall be a Federal coordinating and advisory mechanism, whereas the Provinces shall have the implementing arm for the Laboratory strategic framework.
2. Sustainable, accessible and rationally designed tiered laboratory networks under the One Health concept shall support disease management, surveillance, prevention and control.
3. Vertical program laboratory networks shall as far as possible be integrated into the general laboratory network.
4. The best practices of the vertical program laboratory networks shall be taken into account in the design of the tiered laboratory networks.
5. Standardized Terms of Reference with clear and distinct roles and responsibilities shall be prepared for each tier of the laboratory network to ensure harmonized laboratory activities.
6. There shall be a robust laboratory-based surveillance system for diseases of public or animal health importance.
7. All public and private laboratories shall be part of or report to relevant human and animal health surveillance networks.
8. There shall be a national laboratory database for all laboratories indicating the scope of service delivery.

Referral systems

Outcome: Standardized safe and secure handling, packaging, storage and transport of sample and data including appropriate communication within the facility, across the country and abroad.

9. A national system for efficient, reliable, timely and safe sample referral and reporting system shall be designed and implemented to ensure standardized and traceable sample referral.
10. National sample/patient referral guidelines shall be based on international guidelines.
11. Institutes shall implement and familiarize the staff for safe handling storage, packaging and transport including accidents such as leakage and spills of biological materials.
12. Local courier services should be authorized by National Biosafety Committee and guided for proper and safe transport of such specimens.

13. A system of international sample referral shall be in place and regularly tested to ensure safe and secure transportation of samples in compliance with international regulations, including IATA rules.

14. The laboratory budget shall have a separate earmarked allocation for sample referral.

Coordination

Outcome: Efficient and effective coordination between all stakeholders in the laboratory sector.

15. Relevant Federal and Provincial Ministries shall have a dedicated laboratory policy and planning unit to ensure the availability of relevant expertise at Government level.

16. Expertise, knowledge and capacities exchange mechanisms among different laboratory sectors shall be in place to ensure efficient use of resources, information and data sharing.

17. There shall be a coordination mechanism for laboratory based surveillance for notifiable diseases.

18. The Federal Government shall promote and strengthen effective communication, collaboration and coordination between Federal and Provincial authorities to ensure harmonization of activities.

19. Expertise, knowledge and capacities exchange mechanisms between professional organizations shall be in place to ensure efficient use of resources, information and data sharing.

20. There shall be appropriate and effective linkages among public laboratories and between public and private laboratories to ensure coordination of activities.

21. Communication and information technology developments shall be harnessed to facilitate transmission among laboratories and laboratory networks.

22. There shall be an intersectoral body of national representatives comprising of laboratory-, quality and biosafety- and biosecurity experts endorsed at Federal and Provincial levels.

Policy Statements

Component 3: Equitable accessibility

Outcome: Equitable and accessible laboratory services for all.

1. Network design criteria shall include geographical distribution and operating hours to ensure equitable accessibility of laboratory services.
2. In places where laboratory services are not available, a system of sample collection and referral stations shall be set up to ensure equitable access.
3. Advocacy activities shall be undertaken to raise the awareness and augment the trust of the general population and the professional community in existing laboratory services.
4. A Code of Ethical Conduct shall be developed that will guide all laboratory personnel and services.
5. Laboratory staff shall treat all clients with respect and shall safeguard confidentiality and privacy.

Component 4: Infrastructure

Outcome: Well-maintained, standardized, functional, safe and secure laboratory facilities.

1. National minimum standards and guidelines for laboratory construction and design according to function and tier requirements shall be developed. These shall include safety guidelines based on assessed risks of biological hazard and threat and uninterrupted supply of basic utilities.
2. A mechanism and approved budget shall be in place for skilled construction and continuous maintenance of laboratory premises.
3. Licensing requirements shall include compliance of laboratories to these national standards and guidelines to ensure continuous and high quality laboratories services.

Policy Statements

Component 5: Finance

Outcome: Adequate and sustainable funding and financing mechanisms for laboratory services at all levels.

Budget and budgeting

1. Each province shall have a secure-targeted budget for laboratory services as a whole based on need assessments. Consequently, each public laboratory shall receive a dedicated budget to cover actual expenditures.
2. The laboratory budget shall cover laboratory operating, management, maintenance and capital costs.
3. A transparent and regular independent auditing system shall be in place to ensure programmatic and financial accountability of the laboratory services.
4. There shall be a secure-targeted budget for emergency testing in case of public health emergencies.
5. Laboratory activities related to disease surveillance shall receive sustainable public funding.
6. There shall be dedicated training programs for laboratory managers and auditors in laboratory budgeting to ensure transparent and correct handling of budgets.

Income generation

7. There shall be a rationalized costing formula including direct as well as indirect costs for establishing and regularly updating the justifiable prices of testing.
8. There shall be a regularly updated list of laboratory services that are provided free of charge through public funding by public and public-private partnerships laboratories.
9. All public laboratories shall be allowed to charge for their services and a fixed percentage of the funds thus generated will be earmarked for that laboratory.
10. Appropriate financial support shall be extended to private laboratory facilities for laboratory services provided as part of Public Private Partnerships.
11. There shall be public-private partnerships for outsourcing of auxiliary services to ensure high quality and cost-efficient services.
12. Laboratory tests that are included into health insurance schemes shall be reimbursed for both outpatient and inpatient testing.
13. There shall be a coordination mechanism between the Government and donors to ensure efficient and effective use of financial resources in line with the National Laboratory Policy and its implementation plans.

Policy Statements

Component 6: Human Resource Management

Outcome: Availability of well-trained, competent and motivated staff in adequate numbers capable of providing quality laboratory services.

Organizational structure

1. The staff/workload ratio for each laboratory shall be determined and regularly reviewed in an evidence-based way to ensure an appropriate workload.
2. The laboratory at each tier of the network shall be staffed by the recommended number of competent and appropriately trained personnel to ensure quality laboratory services in line with its defined terms.
3. All laboratories shall have an organizational chart clearly indicating the lines of authority.
4. All laboratories shall have an adequately trained laboratory manager to ensure both technical and managerial leadership.

HRM

5. Job descriptions with defined tasks and responsibilities as well as requisite qualifications, competencies, skills and attitudes shall be developed for each position in the laboratory.
6. A transparent service regulatory policy regarding hiring, career development and service termination shall be implemented. Background checks shall be performed before hiring staff where applicable like sensitive tasks, working in BSL3 or BSL4. Laboratories, etc.
7. All laboratory staff shall adhere to the Code of Conduct to protect patients/clients against exploitation and harm.
8. A mandatory orientation program shall be in place for all newly hired staff regarding laboratory environment and their tasks before commencement of work to ensure the quality of their work.
9. Personnel files in accordance with international requirements shall be available for each laboratory worker.
10. There shall be an intersectoral national database of laboratory personnel working in both in both the private and the public sector.
11. A system of career development and financial and non-financial incentives for high-performing staff shall be designed to increase staff motivation and retention.
12. The salary structure of the different levels of laboratory workers in all sectors shall be regularly reviewed to ensure that they are competitive with similar professional categories to ensure retention of staff.
13. All laboratory staff shall have a regularly renewed license to practice.

Policy Statements

Pre-service training

14. Minimum relevant educational qualifications shall be defined for each staff level to ensure adequately qualified staff.
15. Laboratory training curricula shall be competency-based and include theoretical knowledge and practical skills development as well as mandatory internship.
16. Existing laboratory training curricula shall be reviewed and, where necessary, updated and harmonized to ensure that they are in line with the requirements of modern day laboratories.
17. All training Institution/training programs shall be accredited.
18. Sustained funding support to both pre-service and continuing education trainings as well as Training of Trainers shall be identified to ensure sustainable in-country capacity.

Continuing education

19. There shall be a system of continuing education and training for laboratory personnel to improve their working skills, knowledge and ethics to ensure staff motivation and quality laboratory services.
20. There shall be an effective continuing education program for laboratory professionals in coordination with universities, vocational training institutes and other relevant stakeholders.
21. Continuing education and/or re-training shall be part of the laboratory workers' licensing requirements.
22. A dedicated budget for continuing education activities shall be available at institutional level.
23. It shall be the responsibility of the employer to provide opportunities for all laboratory personnel to participate in appropriate continuing education activities.
24. There shall be periodic trainings including competency assessment for biosafety and security.
25. There shall be specialized education programs for laboratory quality management systems.
26. There shall be a specialized education programs for laboratory managers on laboratory leadership and management.
27. Participation in national and international training programs shall be encouraged to ensure experience and expertise exchange.

Policy Statements

Component 7: Equipment and consumables

Outcome: A steady supply of quality reagents and consumables and well maintained, high quality equipment are available at all laboratories.

Procurement

1. Procurement shall be based on the specifications provided by the end users with guidance of a laboratory procurement specialist if required.
2. A transparent system of tendering shall be followed taking both quality and price into consideration.
3. The public procurement procedure shall be uniform, streamlined, monitored and regularly reviewed to ensure the continued timely procurement of quality materials for all tiers of the laboratory network.
4. There shall be procedures in place for emergency procurements.
5. Laboratory supplies and equipment shall only be purchased from qualified and certified companies taking the recommendations of end-users into account.
6. Each laboratory budget shall have an approved budget line for procurement of laboratory equipment and supplies.
7. Training in supply management shall be promoted at all tiers of the laboratory network to ensure steady supplies.
8. There shall be a proper documentation system to support supply management (electronic and/or paper based).
9. All donations of equipment and supplies shall be accounted for on mutually agreed terms and conditions and shall be needs-based.

Equipment maintenance

10. Equipment contracts shall include installation, initial validation, training and after-sales services including maintenance.
11. Each laboratory shall have an annual maintenance plan and an approved budget line for equipment maintenance, calibration and validation to ensure optimal functioning of its equipment.
12. Each laboratory shall have access to biomedical engineering services for equipment maintenance and metrology.
13. There shall be a body to license agencies to certify biosafety cabinets in accordance with accepted international standards.
14. There shall be a system for safe de-commissioning and disposal of obsolete laboratory equipment.

Policy Statements

Component 8: Information and data management

Information and communication technology

Outcome: An efficient and effective information and communication system with adequately trained staff structured to the needs of the users and beneficiaries.

1. All laboratories shall have access to information technology with proper data storage and backup facilities for communication and staff trained in the use of these facilities.
2. All databases and data exchange mechanisms shall be designed to ensure data security and patient/client data confidentiality.
3. A system shall be set up to ensure direct communication and data exchange within the laboratory network, including remote areas. Direct communication for consultation shall be made available 24/7.
4. A system shall be set up to inform and advise professionals about the available tests and the interpretation of test results to ensure informed decision making.

Data management

Outcome: Adequate and efficient data management contributing to evidence-based decision making.

5. All laboratories shall have access to (electronic) databases relevant to their Terms of Reference and staff trained in the use of these databases.

LIMS

6. There shall be dedicated LIMS units at national and provincial levels.
7. There shall be a mechanism in place for regular compilation, exchange and analysis of laboratory management data to improve planning and decision making at Federal and Provincial levels.

LIS

8. There shall be a laboratory sample and data management program to ensure efficient sample and data handling.
9. There shall be a uniform national coding system for national and provincial laboratory databases.
10. There shall be effective and efficient, standardized and harmonized reporting systems at different tiers of the laboratory networks.

11. There shall be unified guidelines for laboratory-based disease surveillance and data analysis to ensure timely decision making for disease control and outbreak response.
12. There shall be a systematic inter-sectoral data and information exchange mechanism in place to allow coordinated and rapid responses when needed.

Component 9: Quality management systems

Outcome: Efficient, high quality laboratory services providing accurate, reliable and timely results.

Quality assurance

1. All laboratory testing shall include appropriate controls and quality assurance to ensure reliable results.
2. There shall be a regularly updated list of approved tests and testing algorithms for each tier of the public laboratory network.
3. There shall be designated entities that provide EQA services for all laboratories within the country.
4. Approved external quality assurance schemes shall be expanded to all critical tests to ensure quality results.
5. There shall be sets of quality indicators for the different tiers of the laboratory network to objectively assess the quality of the services provided by the laboratory.
6. Laboratory licensing criteria shall include use of quality indicators and participation in selected EQA programs.
7. Reference laboratories shall be encouraged to participate in international quality assurance programs.

Quality management

8. Regularly reviewed and updated national quality standards for each laboratory tier shall be developed on the basis of international standards to improve quality of laboratory services.
9. Each laboratory shall conform to the national quality standards as part of its licensing requirements to ensure quality of services.
10. A trained quality focal person shall be available at each laboratory to ensure sufficient attention to quality aspects of the work.
11. Awareness and sensitization programs on the importance of quality shall be developed for laboratory staff, managers and other stakeholders..

Certification and accreditation

12. All reference laboratories shall be encouraged to obtain accreditation according to international standards.
13. There shall be auditing systems for licensing of laboratories and laboratory workers to ensure compliance to national quality standards.
14. There shall be incentives to ensure motivation of laboratories to reach certification or accreditation.

Component 10: Occupational health

Outcome: Laboratory staff is well protected from occupational health hazards.

Occupational health

1. There shall be a comprehensive occupational health program for all laboratory workers including medical check-ups, vaccinations, accident management, ergonomics and risk-group management (for example pregnant women, immune compromised or disabled persons).
2. Sufficient and appropriate personal protective equipment shall be available at all laboratory facilities.
3. There shall be a system in place for incident reporting and corrective and preventive measures.

Component 11: Biorisk management and waste management

Outcome: Laboratory services that are safe to staff, clients, the community and the environment.

Waste management

1. All institutions dealing with biological materials shall have an effective waste management program that incorporates waste segregation at the time of waste generation, waste minimization, waste disposal and documented traceability of the disposed material.
2. All institutes/laboratories shall provide proper training of staff in waste handling.
3. In case of third party involvement for the waste disposal, the institute shall assess this third party's capacity and capability (EPA approved or similar).

Biorisk management

4. Each laboratory shall have a laboratory safety focal person.
5. There shall be a National Biosafety Committee comprising of experts in laboratory biosafety and biosecurity from all sectors and endorsed at Federal and Provincial levels. This Committee shall be responsible for overall implementation and monitoring of biosafety and biosecurity legislation and guidelines.
6. All safety guidelines will be regularly reviewed, updated and communicated to laboratory personnel and administration.
7. Each laboratory dealing with biological materials shall have an institutional biosafety/biosecurity committee.
8. All laboratories shall have emergency management plans in place.
9. Each laboratory dealing with biological materials shall have an approved annual budget to implement its biosafety and biosecurity program.

Component 12: Research

Outcome: A research culture is fostered in the country that is compatible with international standards.

1. The existing Codes of Conduct for Researchers shall be reviewed, harmonized and universally implemented. Review shall include concerns related to dual-use of research (biosecurity).
2. All research proposals involving living organisms shall be approved by the institutional ethical review board.
3. The Government shall mobilize resources for research activities from public funds, private sector alliance, donors and external universities and institutes.
4. A mechanism for inter-institutional infrastructure and knowledge sharing shall be set up to ensure efficient use of resources for high quality research.
5. A dedicated budget shall be available for research to strengthen infrastructure, personnel, equipment and training.
6. There shall be a system of continuing education for research personnel to improve their research skills including research methodology, proposal writing and ethics.
7. An approval mechanism shall be designed to use research outcomes for routine testing after validation, trials and standardization.

Policy Statements

8. Research forums shall be established to ensure communication of research results with stakeholders.
9. Research activities shall be promoted at all levels and shall conform to national goals and priorities, while reflecting local needs.

Policy Implementation

The development and approval of a National Laboratory Policy needs to be followed by the development of Federal and Provincial Laboratory Strategic and Operational Plans that ensure that the Policy statements are translated into actions that are carried out in an integrated manner at a pace that is in-line with the country's and provinces' managerial and financial resources.

Development of strategic and operational plans again requires the support of many sectors of society and government. It will be of utmost importance that all actors involved in the planning process have realistic and accurate expectations and will operate in an effective, coordinated and timely way. The strategic plans must be living documents, implemented through continual annual operational plans that are linked back to the plans' goals and objectives and updated as needed to reflect successes and lessons learned. The operational plans focus on specific technical and managerial areas, should have clear objectives, indicators identified and activities spelled out.

An intersectoral core leadership team including representatives from the provincial governments as well as laboratory experts, guided by the Ministry of National Health Services Regulation & Coordination, should move forward at an administrative and political level; it will act as the driver of the overall process, will give management oversight and vision to the entire program, including specialist task groups, as required. Relevant Ministries and departments will be responsible for implementation of the National Laboratory Policy.

Annex I

The process of Policy development

The development of the National Laboratory Policy followed WHO guidelines and was divided into three phases:

Phase 1: Preparatory activities

The NLWG was officially established and essential information on the country's laboratory system was collected. For the collection of this information the system questionnaire of the Laboratory Assessment Tool (LAT) developed by World Health Organization (WHO) was used (http://www.who.int/ihr/publications/laboratory_tool/en/). Information on the laboratory system was gathered and analyzed before and during the first workshop (see Annex II).

Phase 2: Workshops and activities for the development of a National Laboratory Policy

This phase involved 3 facilitated workshops of 3 days each, the first of which was conducted during a broader assessment visit. During these workshops participants of the NLWG worked together on the development of the National Laboratory Policy using an established methodology, as described in the facilitators guide of WHO for Policy development. The first Policy development workshop was held in Islamabad on 4-6 February 2015, the second workshop on 6-8 October 2015 and the final workshop on 9-11 November 2015 under the guidance of the Ministry of National Health Services Regulation & Coordination and WHO Regional and Country Office. Dr. Linda Oskam of the WHO Collaborating Centre for Laboratory Strengthening at KIT (Royal Tropical Institute), Amsterdam, the Netherlands and Dr. Musa Rahim of the WHO Country Office in Pakistan served as facilitators for these workshops.

During these workshops the foundation for a National Laboratory Policy was build, through development of Vision 2025, performance of SWOT analysis (Annex III) and formulation of Policy components and their sub components.

Phase 3: Policy dialogue and final draft preparation

After the third workshop a Policy dialogue process was set in motion to discuss the draft National Laboratory Policy before endorsement. This ensured national ownership as well as the commitment of all the relevant stakeholders.

Annex II

Outcomes of the LAT system assessment

The summary outcomes of the assessment and the gap analysis are given in Figures 1 and 2. The outcomes were verified and discussed during the meeting on 4-6 February and formed the basis for subsequent discussions.

Limitations

Because of the short time frame in which the LAT tool had to be completed, it was not possible to collect all the documentation or perform extensive interviews with a large group of experts. However, the questionnaires were filled in by a group of three experts and the overall outcomes were verified by and discussed during a meeting with a large group of experts on 4-6 February 2015.

Due to the devolved laboratory system, with the responsibility essentially at provincial level, it is difficult to give an overarching picture of the laboratory system situation in Pakistan. From the discussions it became clear that the situation is quite heterogeneous, leading to many "partial" (2) scores in the LAT tool. The system in Punjab is in many aspects further developed than the rest of the country. It would be good to do LAT system assessments at provincial level to get a better insight into this heterogeneity and design locally relevant interventions.

Analysis of the assessment outcomes

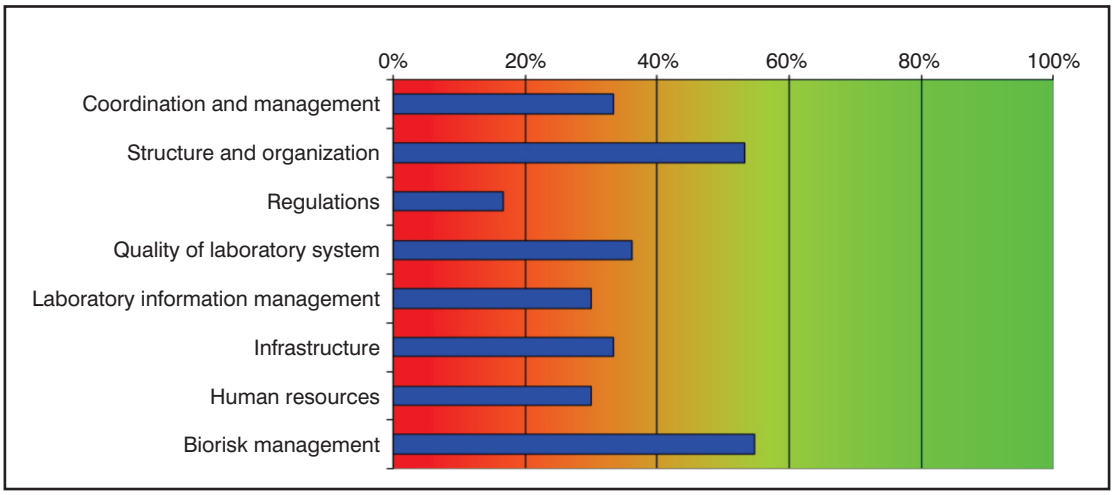

Figure 1: Summary outcome of the laboratory system assessment

Figure 1 shows a typical picture for a system that is at the building up stage. Many activities are being undertaken in Pakistan and many ideas, plans and draft documents are present, but adoption, implementation and enforcement are mostly still in its infancy. This is reflected in the overall score of 36%.

Two topics had medium scores (50-75%): biorisk management and structure and organization.

Biorisk management (55%)

Annex II

There is a high awareness among the experts of biorisk issues, but they felt that the score for this topic was too high. The high score was mainly due to the existence of in-country and international sample transportation systems, even though it was indicated that the compliance of the in-country courier services with biosafety regulations was variable, even though it was improving. Dedicated transportation materials for national sample transportation are available at NIH, but not at all locations. Where it is not available laboratory staff uses alternatives to comply with the rules as good as possible.

The international shipments are carried out according to the IATA regulations and materials and couriers for this are available.

National legislation regarding biosafety measures and requirements has been developed, but this is still in draft.

The absence of national certification bodies for biosafety cabinets (BSCs) was perceived as a large problem: BSCs now have to be certified by international experts (often the manufacturers) and this is costly and it is not always clear to the laboratory managers whether this is done to international standards.

Safety measures for laboratory staff (vaccinations etc.) is only partly in place.

Structure and organization (53%)

The relatively high score of structure and organization is mainly due to the presence of some reference laboratories. However, there are still many shortcomings, the main being that there is no comprehensive list of laboratories in Pakistan. Especially in rural areas there are many very small private laboratories that are run by technicians and the quality of services is unclear. A system of mandatory registration and licensing could give a better insight in the laboratory sector and would assist the design of tiered networks and referral mechanisms.

The remainder of the categories scored low (below 50%).

Quality of laboratory system (36%)

There are no national laboratory quality standards. With the absence of national laboratory registration and licensing system (see above) it would be difficult to implement these, even when they would be present.

The TB program participates in the international proficiency testing organized by the Supranational Laboratory in Antwerp, Belgium. Armed Forces Institute of Pathology (AFIP) has a quarterly proficiency testing EQA program in which civilian laboratories can participate against a nominal fee, but participation from the civilian sector is low. The AFIP EQA program is currently for chemistry, microbiology and haematology and can provide an excellent basis for setting up an all-encompassing EQA system that should include as many laboratories and laboratory topics as possible.

There are few accredited laboratories in Pakistan (8 are ISO-15189 accredited and 24 are ISO-17025 accredited, there are also some laboratories that are JCI and CAP accredited or are in the process of obtaining this accreditation). However, Pakistan National Accreditation Council (PNAC) exists that can perform accreditation services for both ISO-15189 and ISO-17025.

Annex II

Coordination and management (33%)

The low score for this topic is mainly due to the devolved system, with only limited opportunities for the Federal Government to provide overall coordination. There is a central public health laboratory and compliance with IHR regulations is a Federal responsibility. There is no national laboratory policy, but a first step to develop this was set during the current mission.

Funding of services is a mix of government funding, client fees, donor contributions and private insurance payments. A national health insurance for low income groups (living below the poverty line) is envisaged for 2015, but this only covers inpatient services, including laboratory services. This platform provides a basis for future expansion to universal coverage.

Coordination with donors is partial at best.

Infrastructure (33%)

The situation in the country is heterogeneous. A huge concern at the moment is the frequent load shedding throughout the country, which requires the universal presence of generators for the laboratories to ensure uninterrupted electrical supply. Unfortunately, the LAT tool only has 3 questions in this section, making it difficult to interpret the score.

Laboratory information management (30%)

There is a unit at the NIH that collects and analyses data and also provides a seasonal newsletter regarding notifiable and epidemic-prone diseases. However, most laboratories still use paper-based systems that are not standardized and data are provided at the aggregated level.

Human resources (30%)

The quality and number of staff seems to be inadequate, even though pre-service training is improving. However, there are private educational institutes that provide curricula that do not cover the basic needs of the laboratories. So pre-service training seems to be variable. There is no dedicated system of in-service training and as there is also no register or licensing system for laboratory workers, it is difficult to ensure the competencies of the laboratory workers.

Regulations (17%)

There is no regulatory system for public or private laboratories in Pakistan. In the absence of a comprehensive register of laboratories (see above) this would also be difficult to enforce, even though this can be a chicken and egg question which can be solved by only registering laboratories that have a license to operate. This would only work if there are also enforcement mechanisms (financial or punitive) in place.

Legislation is mostly absent. Some document have been developed, but these are mostly still at the draft stage and need to be implemented.

Annex II

Gap analysis

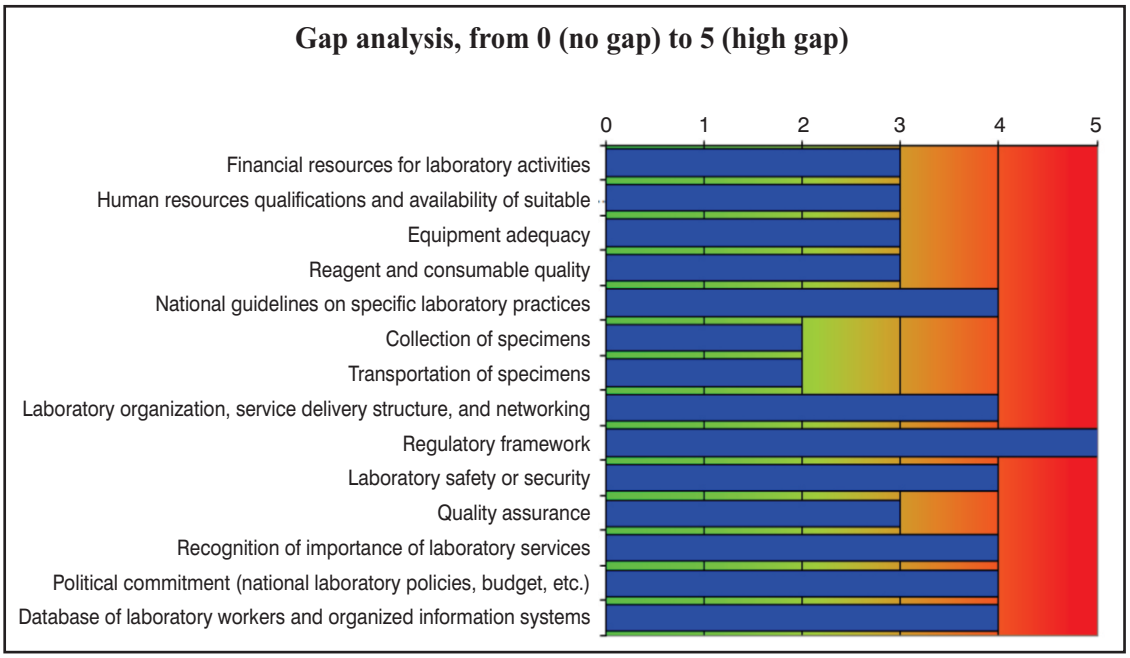

Figure 2: Outcome of the gap analysis

The analysis identified gap in all areas. The main gaps (scores 4 and 5) are due to the weak legislative and regulatory structure that is currently in place in Pakistan and to insufficient advocacy for the importance of laboratory services to clients (patients and doctors) and policy makers.

Additional weaknesses

Two topics were added (both score 4):

- A database of laboratory workers
- Organized information systems

A more detailed identification of weaknesses is given as part of the SWOT analysis (Annex III).

Annex III

Reviewed SWOT analyses for the 11 Policy topics, sub-topics and evidence

Key: F: Fact; O: Opportunity

Topic 1: Regulatory and legal framework

Strengths	Weaknesses
1. Licensing and regulatory mechanisms are in place for blood transfusion laboratories (F) 2. Health care commission regulations in Punjab, KP and Baluchistan for laboratory-related issues (F for human health; Baluchistan Clinical Laboratory Authority Act since 2005; Punjab veterinary health regulations as well) 3. Many universities and institutes have bioethical committees (F) 4. National Biosafety Act (2005) by Environmental Department (F; also important for topic 10) 5. Regulations for Notifiable Diseases (F; list varies per province) 6. Mechanism of notification and list of notifiable diseases (human and zoonotic) is in process (F; expected coming months)	1. No legal framework for laboratories to address One Health issues at regular basis, only **ad hoc** (F) 2. One Health concept is not universally understood at various levels (O) 3. Lack of laboratory policies (F, Punjab and KP have policies) 4. Absence of laboratory regulations in Sindh, AJK, GB, and at Federal level (F) 5. Lack of continuity, consistency, implementation, monitoring and enforcement of policies, rules and regulations between provinces (EO/F, example pre-marital testing for thalassemia) 6. Absence of national regulatory agency for licensing of labs in Pakistan (F) 7. Licensing and registration only for human labs and only has recently started in KP and Punjab (F; Baluchistan has licensing log of BCLRA) 8. Unregulated and unregistered private laboratories, often run by unauthorized staff (F) 9. Unsupervised side laboratories in some public facilities (F)

Annex III

Opportunities	Threats
1. IHR and GHSA force strengthening of the laboratory system (F) 2. Devolution of responsibility for laboratories to the provinces may create local opportunities or threats depending on provincial government (EO) 3. Interest of international organizations (WHO) in policy and legislation development (F) 4. One Health concept recognized for some diseases (F; avian flu, CCHF, dengue, polio in environment) 5. Availability of health legislation other than specific laboratory legislation (F)	1. Devolution of responsibility for laboratories to the provinces may create local opportunities or threats depending on provincial government (EO) 2. Lack of interest regarding One Health concept and laboratory services in general (O) 3. Lack of priority for health issues among politicians (F; based on GDP% spent on health) 4. Weak implementation of legislation in general (F) 5. Weak human resources for health policy making and management (O) 6. Unnecessary political interference in daily management of laboratories (F) 7. Lack of continuity among policy makers/health managers due to frequent turnovers (F)

Subtopics

- Legislation
- Licensing

Annex III

Topic 2: Coordination and networking

Strengths	Weaknesses
1. (Successful) vertical programs and laboratory networks for TB, malaria and HIV (F) 2. TB program has private and public mix of laboratories (F) 3. Some lab-based surveillance systems present and data are shared (F; e.g. TB, dengue, CCHF, Naegleria, Influenza) 4. Formulation and notification of NLWG by the Federal government having representatives from various sectors (F) 5. Professional associations representing medical, veterinarian, and agriculture professionals exist (F) 6. There is collaboration under the One Health concept for some zoonoses.(F; see above) 7. There is reporting for some diseases from districts to higher levels (F; e.g. dengue) 8. National IHR focal point (F; at NIH) 9. Successful program under FELTP funded through international agency (F) 10. Interprovincial coordination mechanism for some vertical programs (F; TB, HIV, polio)	1. Lack of coordination between laboratories; network structure is not well defined (EO) 2. Lack of coordination between human and veterinary public health sectors (F; for most diseases). 3. Lack of tiered laboratory networks (F; after devolution this disappeared except for vertical programs) 4. Lack of standardization of lab services across the country (F) 5. Lack of integration of the laboratory component of vertical programs in the general laboratory system (F; parallel testing facilities) 6. Lack of referral mechanisms for most of the diseases (F) 7. In-country sample transportation system is weak for most diseases due to lack of funding and transport infrastructure (F) 8. International sample referral system is not clear for all situations (F) 9. Lack of integrated diseases surveillance programme backed with a network of Public Health Laboratories (F) 10. Lack of integrated disease surveillance program for emerging infections (F) 11. Weak traveller surveillance at ports of entry (O) 12. Lack of updated list of notifiable diseases at national level (see topic 1) 13. Lack of coordination between different professional associations (F) 14. Lack of linking research labs with routine labs for use of research data for evidence based routine testing (F)

Annex III

Opportunities	Threats
1. Successful vertical programs for TB, malaria, avian influenza and HIV can serve as models for QA tiered lab networks (O) 2. Availability of mobile technologies to strengthen networking and coordination (F) 3. Successful program under FELTP funded through international agency can provide example of intersector coordination (O) 4. Professional associations can be brought together under the roof of One Health to increase communication and networking (O)	1. Devolution of health system makes coordination and networking more challenging (O) 2. Due to security threats access to certain areas is limited (F) 3. Embargo on international travel in case of emergence of communicable disease (outcome of lack of lab services; reason to improve your lab system) 4. Impact of diseases to Pakistan that may become uncontrollable due to lack of surveillance at ports of entry (as previous one)

Subtopics

- Structured networks
- Referral systems
- Coordination

Annex III

Topic 3: Equitable accessibility

Strengths	Weaknesses
1. Basic package of tests available for free in many public health and veterinary labs (F) 2. Specimen transport mechanism in some programs increases accessibility (F) 3. Private health insurance schemes (F)	1. Unequal distribution of laboratory services especially in rural areas (F) 2. Limited trust in laboratory services (O), but it is improving 3. Services not available 24/7 everywhere (F) 4. Limited opening hours for outpatients (F) 5. Majority of insurance schemes only for inpatient care (F)
Opportunities	**Threats**
1. Government health insurance system (F) 2. Government interest in equitable access to quality labs (idem) 3. International interest in health care systems strengthening (F) 4. Vibrant mass media sector (F) 5. Media awareness (O) 6. Sensitization of young population on health issues (F; blood donation day, hepatitis day, school programs, etc.)	1. Low literacy rate (F) 2. Lack of knowledge and awareness among the general public as health is not a separate topic in school/college education (F) 3. Social norms leads to decreased access for some (F) 4. No trained health journalists (F)

Annex III

Topic 4: Infrastructure

Strengths	Weaknesses
1. There are a few high level public and private laboratories (F) 2. Basic laboratory infrastructure is present in most hospitals, research institutes and universities (F) 3. Well-organized infrastructure in vertical programs (F)	1. Majority of private laboratories are not located in designated laboratory buildings (F; many in residential or commercial buildings) 2. Laboratory design and construction for majority of laboratories not at par with international standards (F) 3. Lack of specialized design specialists, architects and engineers for laboratory designing, construction and maintenance (F) 4. Certain specialized construction materials have to be imported (F) 5. Inadequate engineering and financial support for infrastructure maintenance (F) 6. Bidding process for building facilities in public sector is so complicated that good companies do not tender (F) 7. Lack of water storage tanks for regular water supply (F) 8. Lack of generators, gas and petroleum at most facilities (F)
Opportunities	**Threats**
1. Funding sources are available from donors for laboratory renovation and improving infrastructure (F; graduates, alumni, JICA, KfW, GF) 2. Construction consultation on issues such as lab design, BSL3 design and ventilation systems can be taken via electronic communication means (F) 3. Laboratory infrastructure of vertical programs can be used as role model and for integration to support other diagnostic programs (O)	1. Lack of water supply (F) 2. Repeated power failures (F) 3. Poor general infrastructure for commodities such as electricity, water, sewage, etc. (F) 4. Natural disasters such as like floods, earthquakes, etc. (F)

Annex III

Topic 5: Finance

Strengths	Weaknesses
1. Government is recently investing in some laboratories (F, KP, Sindh, Punjab) 2. Some committed funds from the government for public laboratory staffing, some supplies, some equipment, including universities (F) 3. Some public laboratories are generating part of their own budget (F) 4. Availability of Global Fund Grant (F; until December 2017) 5. Allocation of funds in light of IHR and GHSA (F; CDC grant for public health lab network, WHO) 6. Funds available for (international) zoonosis diagnosis and surveillance (One Health) (F; CDC cooperative agreement, Ministry of Food Security and Research) 7. Introduction of PPMs and PPPs in existing public labs (F)	1. Donor dependency (F; but only for vertical programs) 2. Insufficient funds for daily operation of the lab due to lack of proportionate increase (inflation, increased workload) in allocation of funds/resources for most public laboratories (F) 3. Some public laboratories are generating some of their own budget (F) 4. Inadequate budget; and laboratory experts not involved in comprehensive budget planning (F). 5. Laboratory manager not integrally involved and not trained in budget planning (F). 6. Insufficient in-house financial auditing capacity by medical technical auditors (F) 7. Unnecessary or wrong testing by laboratories due to financial perverse incentives (commissions) and/or over-requesting by health workers (F) 8. Unregulated prices in private sector (F)

Annex III

Opportunities	Threats
1. People are prepared to spend for quality services (O) 2. Demand for lab tests for which the client has to pay is increasing (O) 3. Funds generation through charity and donors 4. Geopolitical situation leads to Pakistan being on the international radar for health investments (O) 5. General donor interest in improving the laboratory sector 6. High incidence of zoonosis can attract international funding (O) 7. Social franchising expansion (F) 8. Public and private health insurance systems	1. Economic and geopolitical instability (O) 2. Inappropriate use of funding (O) 3. Lack of sustainability of resources, including donor dependence 4. Large and rapidly growing population (F) 5. Demand for lab tests which have to be provided for free is increasing (O)

Subtopics

- Budget and budgeting
- Income generation

Annex III

Topic 6: Human Resource Management

Strengths	Weaknesses
1. Staff levels are improving because of better training programs (F) 2. Institutes are available that offer laboratory technologist courses and higher specialized degrees (F) 3. Good and structured training for pathologists (F; CPSP, and PhD/M.Phil from universities) 4. Higher Education Commission approves curricula for more than 1 year diplomas and degrees (F) 5. Government and private institutes are offering courses (F) 6. CMEs and training workshops by governmental and non-governmental institutes are increasingly available (F) 7. Service structure (i.e. career structure) for lab technologists and paramedical staff is present, but only in public sector (F). 8. Benefits to working in public sector (F; has to do with work package)	1. Organograms are missing in many laboratories (F) 2. In government system mostly no specific position for phlebotomist in the organogram (F) 3. No job descriptions with defined qualifications, competencies, skills, attitudes (F) 4. Position of laboratory manager does not formally exist in most of the public labs (F; senior most person functions as such) 5. Lack of qualified experienced laboratory managers (F; no training program available) 6. Implementation of hiring, promotion and firing policies is not universally transparent (EO) 7. Lack of trained and duly qualified staff in most public and private laboratories (F) 8. Formal continuing training programs are weak and only mandatory for doctors (F) 9. Scarcity of dedicated laboratory courses for technical staff (F) 10. Staff/workload ratio is not always rationalized, leading to inappropriate workload in most laboratories (F) 11. High turnover rates in private sector (O; want to set up own labs due to lack of regulations or go abroad) 12. Lack of implemented accountability in the public sector (F) 13. Lack of satisfaction due to absence of career structure and work condition and lab environment (O) 14. No competitive remuneration package to improve performance (O)

Annex III

Strengths	Weaknesses
	15. Scarcity of biomedical engineers in Pakistan laboratories due to lack of training opportunities and positions 16. University MSc and BSc curricula lack hands-on experience due to lack of training laboratories and weak internship programs (F) 17. Insufficient capacity in recognized standardized training centres (F)
Opportunities	**Threats**
1. Especially young staff is eager to learn and motivated to look for opportunities (EO) 2. Opportunities for jobs for trained lab professionals (F) 3. International vendors in Pakistan can be used for additional training opportunities in techniques and equipment (F; Roche, Abbott, Siemens etc) 4. Vertical programs organize trainings which can be opened to other staff (O) 5. Additional/external organizations (e.g. WHO, CDC, FAO, ASM, etc) can be approached for additional training opportunities (F) 6. International online courses (F) 7. Telemedicine can be used to explore further training between the centers (F)	1. Brain drain of qualified and trained staff (F)

Subtopics

- Organizational structure
- HRM
- Pre-service training
- Continuing education

Annex III

Topic 7: Equipment and consumables

Strengths	Weaknesses
1. Presence of international companies in Pakistan (F) 2. Some equipment and consumables manufactured locally (F) 3. Rapid diagnostics available for some diseases (F) 4. Some reagents and kits are tax exempted (F) 5. Rental basis procurement of equipment possible (F)	1. Weak equipment maintenance and service contracts (F) 2. Inadequate biomedical engineering support (F; see topic 6) 3. Inadequate system for standardization, calibration and certification of equipment (F; not suitable for accreditation) 4. Standardization of locally produced goods is weak (F; not all companies are ISO9001 certified) 5. Insufficient expertise in writing specifications resulting in procurement of low quality goods (F) 6. Requirements of end users in lower level laboratories are not always taken into account in procurement procedures (O) 7. No laboratory regulatory authority for authorizing quality equipment and consumables (F) 8. Public procurement procedure is time-consuming and lengthy (F; at least 3 months) 9. Low budget for equipment procurement, consumables and maintenance (F) 10. Time lag in receipt of goods due to shipment and customs clearing delays
Opportunities	**Threats**
1. Introduction of new technologies (O) 2. No importation restrictions on the majority of (new) technologies 3. Demand for laboratory technology training programs (topic 6)	1. Fast technological developments leading to established techniques becoming obsolete rapidly asking for new investments (O) 2. New technologies are often expensive (F) 3. Withdrawal of services/vendor from the country (F; due to safety, market, regulatory issues)

Subtopics

- Procurement
- Equipment maintenance

Annex III

Topic 8: Information and data management

Strengths	Weaknesses
1. Partial availability of computerized LIS (F; private, vertical and some public [tertiary, academic] laboratories) 2. Availability of internet services in many higher level laboratories (F) 3. Mobile phone communication used for data exchange and reporting (F) 4. Partial online data exchange system (F; only in private sector and vertical programs) 5. Trained bio-informatics specialists available (F) 6. Government is using IT for information sharing (F) 7. Landlines accessible for almost all laboratories (F) 8. Software available (F)	1. Many laboratories do not have computers and/or internet access (F) 2. Lack of computer proficiency in many laboratories (F) 3. Lack of LIS/LIMS in most laboratories (F) 4. Lack of integration of laboratory data into centralized databases (F) 5. Insufficient data security and confidentiality (F) 6. Lab data are insufficiently used for surveillance and epidemiology (F) 7. Mechanisms for fast data analysis for outbreak detection and control are not fully implemented (F) 8. Hardly inter-sectoral data exchange for One Health (F) 9. Weak data compilation management for paper-based system (F; laborious and not always supervised) 10. No feedback after data analysis (F) 11. Secure data backup facilities are not available (F)
Opportunities	**Threats**
1. Almost universal coverage of mobile networks and internet (F) 2. IT experts and information systems exist throughout the country (F) 3. Local software developers for health management software are available locally (F) 4. International software for health care system and laboratory specific software available (F; for free or for purchase)	1. Online data hacking/data security (i.e. privacy issues) (F) 2. Computer or software crashes (F)

Subtopics

- Information and communication technology
- Data management

Annex III

Topic 9: Quality management systems

Strengths	Weaknesses
1. Quality and accreditation/certification awareness among laboratory staff (O) 2. QC standards and SOPs introduced partially (F) 3. Presence of PNAC for accreditation according to international standards (F) 4. Some laboratories are ISO/JCI accredited (F: public and private; veterinary and human) 5. Good quality private laboratories leading to increased competition (O) 6. System for EQA program available in country through AFIP and vertical programs (F, NEQAPP) 7. Availability of international certified kits (F; CE, FDA)	1. Lack of implemented LQMS in most laboratories (F) 2. Lack of trained QA/LQMS manpower (F) 3. Scarce trainings on aspects of quality management, both pre-service and in-service (F) 4. Quality assurance testing not universally implemented throughout the country because there is no obligation to participate in QA programs (F) 5. Lack of national body for EQA program for One Health (F) 6. No system in place for the local production of QC and standardization materials (F) 7. No dedicated budget available to sustain internal and external QA programs (F) 8. No dedicated budget available to implement and sustain LQMS (F) 9. Lack of accountability for implementing quality measures (F) 10. Reluctance to read and follow SOPs and documents (F) 11. Unnecessary or inappropriate testing because of lack of testing algorithms (F)

Annex III

Opportunities	Threats
1. International EQAS, systems available, but expensive (F; RIQAS NEQAS, CAP) 2. Public demand for quality laboratory services (O) 3. Good quality laboratories can act as role models (O) 4. Certain EQA and PT programs are available and can be used as models to expand (F) 5. Internet availability makes access to international agency information regarding standards possible (F; WHO LQMS, LQSI, GLI tools, FAO and OIE guidance documents)	1. Wrong reporting leading to mismanagement of patients (outcome threat) 2. Low budgets for QA may lead to shortcuts – wrong reporting – undue morbidity (outcome threat)

Subtopics

- Quality assurance
- Quality management
- Certification and accreditation

Annex III

Topic 10: Biorisk management and waste management

Strengths	Weaknesses
1. Biorisk management Policy is under development with input from NLWG (F) 2. Pakistan Biological Safety Association and other associations (F) 3. Private companies are available for collection and disposal of biological waste in some cities (F) 4. There is growing biosafety awareness among lab staff (O) 5. Biosafety and waste management trainings increasingly available (F)	1. Absence of personal protection equipment in most public and private laboratories (F) 2. No occupational health program for laboratory workers (F) 3. No notification of lab acquired infection (F) 4. Proper waste management systems absent in most medical, veterinarian and agricultural laboratories (F) 5. No implementation of governmental regulations for safe disposal of medical waste across the country (F) 6. There is no monitoring of the waste disposal by the private waste disposal companies (F) 7. Incinerators either absent or sometimes installed in non-appropriate locations; majority are non-functional (O/F) 8. Non-existence of biorisk management programs (F) 9. No in-country BSC certification capacity (F)
Opportunities	**Threats**
1. Existence of Environmental Protection Agency at Federal level and in Punjab and KPK, Punjab Healthcare Commission which is governed by a specific act and environmental protection tribunal for safe disposal of waste in Punjab (F) 2. Government is under pressure to take more active initiatives under IHR and GHSA (F) 3. Environmental awareness, fuelled by media (O)	1. Outcome threats: - Pollution of the environment - Fire and chemical hazards - Leakage of pathogens to environment - Reuse of materials such as syringes

Subtopics

- Occupational health
- Waste management
- Biorisk management

Annex III

Topic 11: Research – SWOT analysis

Strengths	Weaknesses
1. Research labs throughout country in universities and research centers (F) 2. International connections with research institutes overseas (F) 3. Researchers are proficient in English (F) 4. National Bioethics Committee in place (F) 5. National and international funding are available for new projects (F) 6. Availability of trained and qualified personnel 7. Courses are taught on Biosafety and security, bioethics and lab management 8. Researchers have access to modern technology (F) 9. Pakistan Health Research Council and other similar institutions in place (F) 10. Researchers are capable of innovative thinking (O) 11. Regular publications in (inter)national, peer-reviewed journals (F)	1. Limited national research grant opportunities (F) 2. Limited experience and training opportunities in grant proposal writing (F) 3. Lack of mechanism for implementation of research finding in routine laboratory services (F) 4. Limited sharing of resources between research institutes due to lack of insight into opportunities available (F) 5. Insufficient core funding for lab research and lab maintenance (F) 6. Institutional bioethics committees not at all research institutes (F) 7. No national oversight mechanism in place (F) 8. Lack of trained mentors (F) 9. Few incentives for researchers (O) 10. Limited integration of academia and industry (O) 11. Lack of awareness and implementation of the Code of Conduct for Researchers (F)
Opportunities	**Threats**
1. National and international collaboration opportunities (F) 2. International funding available (F; research grant opportunities) 3. International exchange programs (F)	1. Lack of encouragement (O) 2. Brain drain due to migration (F) 3. Inappropriate use of research findings and funds (O)

Annex IV

List of laboratory and Public Health Professional participated in the consultative workshops on Development on the National Laboratory Policy in Pakistan

S.No.	Name	DESIGNATION	ORGANIZATION
1.	Aamer Ikram	Professor & Consultant	Armed Forces Institute of Pathology
2.	Aamir Ali Khan	Head of Pathology Department	Nishtar Medical College, Multan
3.	Arshad Mumtaz	Chief Public Health Lab Division	National Institute of Health, Islamabad
4.	Ashok Kumar Tanwani	Professor & Pathologist	PIMS Hospital Islamabad
5.	Attiya Bhatti	Associate Professor ASAB	National University of Science & Technology, Islamabad
6.	Erum Khan	Associate Professor	Aga Khan University Hospital, Karachi
7.	Fauzia Ashraf	Head of Pathology Department	Allama Iqbal Medical College, Lahore
8.	Ghulam Fatima	Senior Pathologist	Civil Hospital, Karachi
9.	Ghulam Sarwar Pirkani	Professor Microbiology	Bolan Medical College, Quetta
10.	Imran Ahmad	Chief Pathologist	Shifa International Hospital, Islamabad
11.	Khalid Naeem Khawaja	Chief Scientific Officer Animal Science Institute	National Agriculture Research Center, Islamabad
12.	Lubna Naseem	Consultant Pathologist	PIMS, Islamabad
13.	Muhammad Kaleem Khan	Pathologist	Ayub Medical College, Abbottabad
14.	Muhammad Salman	Senior Scientific Officer, Public Health Laboratories Division	National Institute of Health, Islamabad
15.	Muhammad Usman	Consultant Pathologist	Shifa International Hospital, Islamabad
16.	Mumtaz Ahmad Khan	Head Pathology Department	Abass Institute of Medical Science, Muzaffarabad
17.	Muhammad Athar Abbas	Senior Scientific Officer NRLPD	National Agriculture Research Center, Islamabad
18.	Musa Rahim	National Professional Officer	WHO Country Office, Islamabad
19.	Naila Siddique	Program Leader	National Agriculture Research Center Islamabad
20.	Obaidullah Qazi	Microbiologist	Institute of Public Health, Lahore
21.	Rani Faryal	Associate Professor	Quaid-e-Azam University, Islamabad
22.	Rumina Hassan	Professor of Pathology & Microbiology	Aga Khan University Hospital , Karachi
23.	Sabira Tahseen	National Advisor TB	National TB Program
24.	Shahtaj Khan	Head of Pathology Department	Hyattabad Medical Complex, Peshawar
25.	Uzma Bashir Amir	Senior Virologist	National Institute of Health, Islamabad

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Pubic Health Laboratories Division,
National Institute of Health, Islamabad