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[ROADMAP FOR PREPARING NATIONAL PUBLIC HEALTH LABORATORY SERVICES FRAMEWORK]

27 April 2010

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1 BACKGROUND

Infectious diseases continue to be a significant cause of morbidity, mortality and socio-economic loss in developing countries. While the endemic infections are far from being conquered, newer pathogens have been emerging almost every year alongside known pathogens that have resurfaced in more devastating forms. Early identification, detection, characterization, prevention and control of these agents require a laboratory support as an integral part of disease surveillance systems. Several attempts have been made to strengthen public health laboratory structure in India under vertical disease control programs as well disease surveillance projects with varying degrees of success. However, these have not taken the shape of concerted national health laboratory framework, the need for which has been voiced for some time now. With the Asia Pacific strategy for health laboratory strengthening in place and some of the recent disease events like the H5N1 outbreaks and H1N1 pandemic reiterating the critical role of laboratories in disease prevention and control, the topic has gained momentum. To translate this need into a concrete national strategic plan, a national level consultation of major stakeholders is being convened by the Ministry of Health & Family Welfare, Government of India in collaboration with WHO India Country Office in New Delhi on 12-13th May 2010. The objectives of this all important consultation are:

- To build consensus on a strategic framework for strengthening public health laboratories services in India in order to make their contribution to infectious disease prevention and control more effective
- To propose a roadmap for the systematic implementation of current and future efforts

The Public Health Foundation of India has been commissioned to develop a framework for this roadmap. In close collaboration with the WHO India, this is an attempt to seek strategic inputs from the expert consultation for further refinement before being submitted to the Ministry of Health for uptake in the proposed National Public Health Laboratory Policy.

2 CONTEXT/ SITUATION ANALYSIS

The diverse role that public health laboratories play in disease prevention and control cannot be overstated. Their functions range from: 1) disease prevention, control, and surveillance; 2) integrated data management; 3) reference and specialized testing; 4) environmental health and protection; 5) food safety; 6) laboratory improvement/regulation; 7) policy development; 8) emergency response; 9) public health related research; 10) training and education; to 11) partnerships and communication. The following section traces back the evolution of health laboratory networks in India and how have these come together to perform the various functions expected from such a networks.

2.1 EVOLUTION OF HEALTH LABORATORY SERVICES IN INDIA

To begin with, like other places the concept of health laboratory in India was that of a clinical diagnostic laboratory. With the advent of vertical disease control programs such as malaria, the concept of public health laboratories started evolving. A major impetus to PHLs was seen after the reinvigoration of tuberculosis control program in India which went all out to detect and treat pulmonary TB cases under the RNTCP. In some of their recent reforms, the RNTCP systematically analyzed human resource required to serve the public health functions under the program and filled the gaps accordingly.

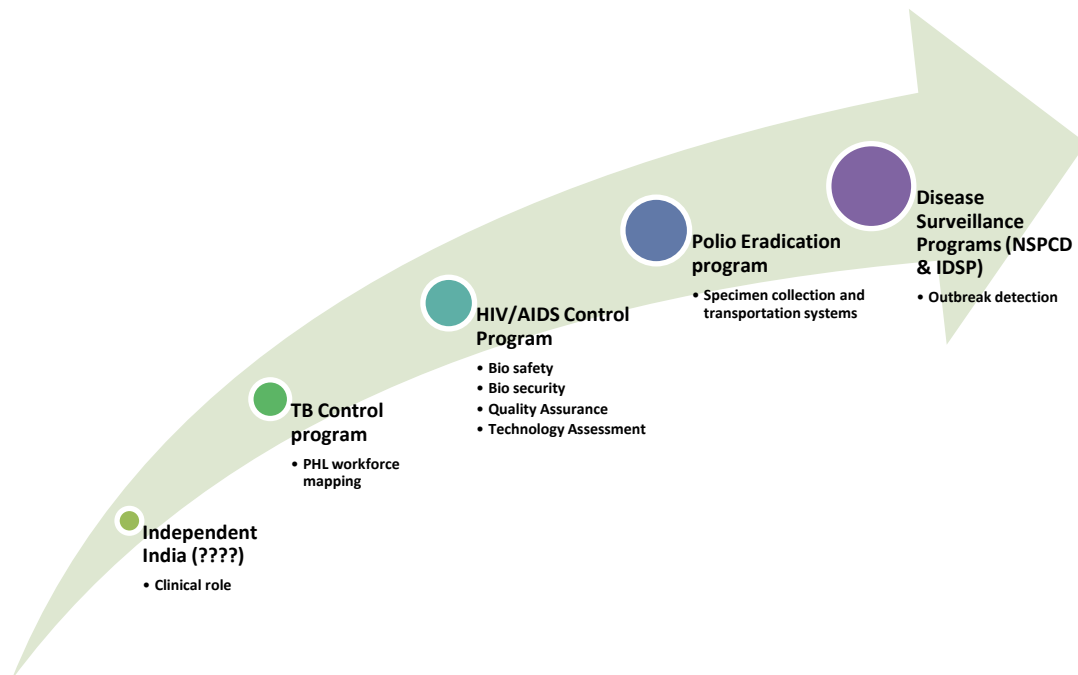


Figure 1: Evolution of Public Health Laboratory services in India

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The emergence of HIV/AIDS brought the concept of universal precautions and laboratory bio-safety in big way to Indian PHLs. Quality assurance in laboratory testing received a major boost with the introduction of panel testing of HIV serology by laboratories in the network. Given the social significance attached to HIV diagnosis, attention was also drawn towards systematic technology assessment in the form of kits/diagnostics evaluation before their introduction into the markets for patient testing.

Proper specimen collection, storage, packaging and transportation is central to the successful outcome of any microbiological investigation. This was best exemplified by the efficient specimen transportation systems put in place under national polio eradication program which has become a role model for other programs.

As the network of PHLs was growing under the vertical disease control programs, need was being felt for building a decentralized disease surveillance and response capacity for other epidemic prone diseases. Accordingly, following the recommendations of the National Apical Advisory Committee (1994), disease surveillance laboratories were strengthened under the NSPCD in 101 districts beginning 1997. Successes of NSPCD were then scaled up under the IDSP, a nation-wide decentralized disease surveillance project with a strong component of laboratory strengthening and networking.

Following the lessons learnt from SARS and H5N1 outbreaks and their pandemic potential, the International Health Regulations (2005) drew further attention towards laboratory capacity strengthening in member countries. IHR (2005) requires that all countries have the capacity to assess, detect, notify and report public health events to the World Health Organization and to respond to public health risks and emergencies of international concern, supported by accurate and reliable laboratory results, to ensure a timely and effective response. Annex 1 of IHR (2005) specifically identifies the capacity to provide "laboratory analysis of samples ..." as a core need. IDSP was thus made the backbone for strengthening disease surveillance and response capacity under IHR (2005).

The emergence of H5N1 outbreaks in 2006 was a cornerstone in the history of PHLs in India. The outbreaks not only highlighted the issues around specimen transportation but also safe handling of specimen in laboratory facilities thus giving tremendous impetus to the concept of bio-safety, bio-security and bio-containment. BSL 3 laboratories were established both in the human and veterinary sectors and capacity building was done to ensure safe collection, transportation and processing of biological material from the field to the testing laboratories. All these efforts were made to develop the surge capacity for specimen testing as well as preparation for the unknown and dangerous pathogens as and when they emerge, including pathogens for intentional use. These came handy during the H1N1 pandemic. The issue of testing the human and animal specimens in same laboratory facility however, remains unresolved with scientists trying to find out the most practical protocols.

Even after being repeatedly challenged by diverse range of pathogens (SARS, H5N1, H1N1, chikungunya) and agreements for international exchange of biological material being in place in India (Global influenza

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network, Global Polio Eradication Initiative), while India sought to benefit from international expertise (diagnostics, reagents, training and capacity building), a consensus on policy for biological material transfer has not evolved.

The following section describes the current structural and functional configuration of health laboratory services in India. In doing so, the description also highlights the key strengths and gaps in the networks.

2.2 STRUCTURAL CONFIGURATION OF LABORATORY SERVICES IN INDIA

From a structural point of view, the PHL structure in India is divided into laboratories under the vertical disease control programs and those that have been strengthened under the disease surveillance projects, mainly NSPCD and IDSP.

Structure and function of constituent laboratories of networks under vertical disease control programs is unique to each of them, depending upon the disease agent and the nature and type of testing required. Nevertheless, in general the vertical programs have laboratories at peripheral level (PHCs and CHCs) that perform basic investigations such as malaria microscopy and sputum for AFB. Next level of PHLs is located at district levels, with essentially similar functions except that laboratories at district level also perform monitoring, supervision and quality assurance support to peripheral laboratories. District level PHLs of vertical programs also perform serology based investigations (HIV, HBV, HCV) in addition to supporting transportation and storage for specimens tested at state and national level. State level PHLs perform function similar to district laboratories but for the district laboratories. Intermediate level laboratories or regional reference laboratories have been strengthened to perform the next level of function under these programs such as bacterial cultures (RNTCP), drug sensitivity testing (RNTCP), quality assurance (RNTCP, NACO, Polio), virus isolation (Polio). National referral laboratories undertake specialized tasks for the vertical disease control programs.

The regional and national reference laboratories under vertical disease control programs have been located within the centers of excellence under the state governments (BJMC Ahmadabad, SGPGI Lucknow), medical research and training institutions (AIIMS, PGIMER, JIPMER) as well as institutes of Indian Council of Medical Research (ERC Mumbai, TRC Chennai, NTI Bangalore, NIV Pune) and DGHS (NCDC Delhi). In fact, the evolution and development of some of these centers of excellence has been planned to provide specialized function for disease prevention and control as their major mandates.

IDSP, to begin with, envisaged a 5-tier laboratory structure (L1 to L5) with extensive networking with vertical disease control laboratories, both at peripheral (L1,L2,L3) as well as regional reference (L4) and national levels (L5). IDSP was also entrusted with integration of disease control programs, at least in terms of information sharing and database management. As the project evolved, it was also envisaged that resources at the district level under different vertical programs would also be pooled for more efficient laboratory services and better collation of disease information. At the end of 5 years of project period,

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mechanisms for networking with regional and national reference laboratories are yet to be clearly defined. With the exception of reporting of malaria microscopy results as part of IDSP laboratory reporting formats, not much progress has been made in the direction of integration. In addition, attempts have been made under IDSP to involve laboratories under infectious disease hospitals and medical colleges into surveillance efforts with variable success.

Health laboratory networks outside of the central and state ministries of health exist in other sectors. Notable amongst these are the laboratories under AFMS, railways, CGHS and ESI dispensary (do we have any figures or estimates here?). In addition, microbiology departments of over 192 recognized medical colleges are also a valuable resource that provides infectious disease diagnostic services.

Diagnostic facilities are also available under the private sector. These include small laboratories to medium and large sized chains of laboratories (do we have any figures or estimates here?).

Centers of excellence also exist in sectors outside of the health sector. These include basic sciences and research laboratories under DST, DBT and CSIR that work on infectious diseases (do we have any figures or estimates here?).

Similarly, public health engineering, water testing, food safety and regional and national referral laboratories under other ministries/sectors indirectly contribute to health sector's functioning (do we have any figures or estimates here?).

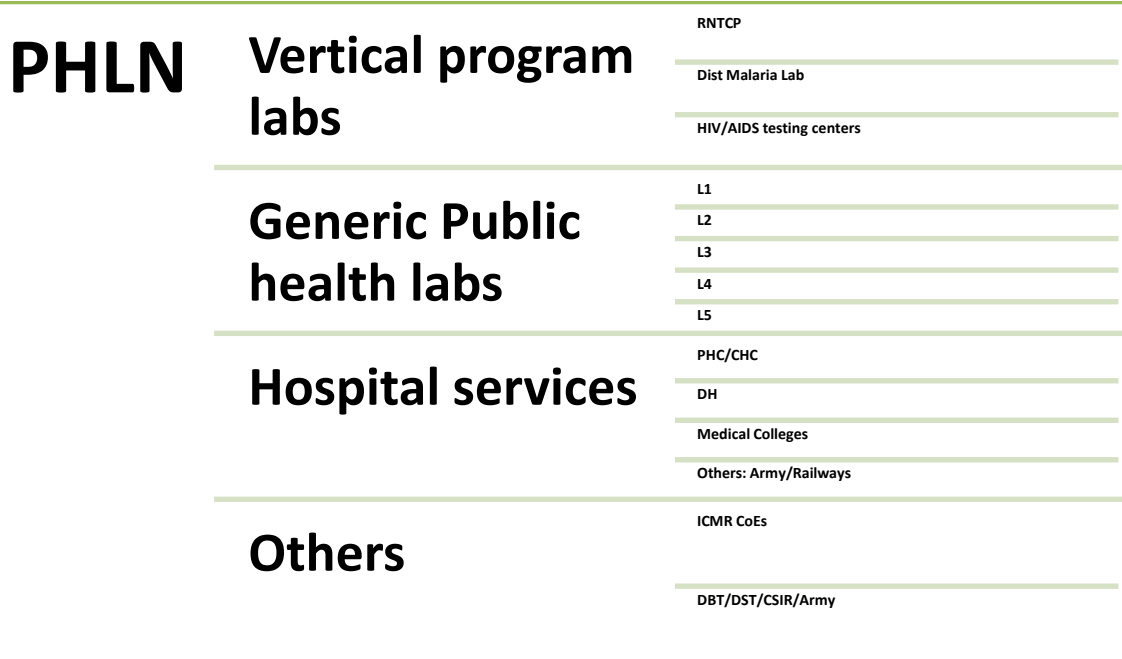


Figure 2: Structural components of public health lab network

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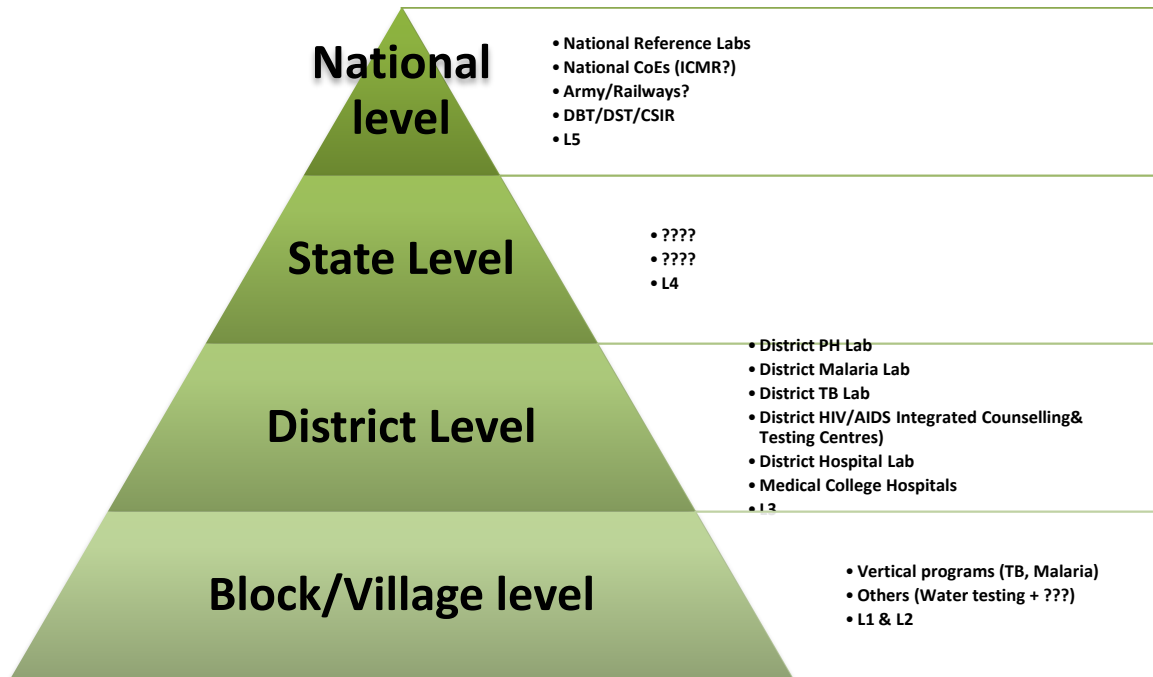


Figure 3: Alternate Structural components of public health lab network

2.3 FUNCTIONAL CONFIGURATION OF LABORATORY SERVICES:

2.3.1 TYPE OF MANDATES

From a functional stand point, laboratories working on infectious diseases perform can be broad classified into three categories: clinical diagnostic laboratories, PHLs and research laboratories. Within the health sectors, there is considerable overlap in these three functions. However, laboratories outside of the health sector generally focus on advanced level basic, applied and translational research and development involving infectious disease and are thus a valuable resource of high end expertise in the country.

Within the PHL networks, including those under vertical disease control programs, orientation is more clinical at peripheral levels. State, regional and national referral labs, on the other hand, have a largely public health focus, in addition to providing marginal diagnostic support on a referral basis. Diagnostic versus PH focus is also determined by the location of the health laboratories. Health laboratories located in medical colleges, district hospital and other patient care facilities such as CGHS and ESI dispensaries tend to have clinical diagnostic focus, with biochemical and hematological investigations constituting major load.

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As mentioned in the earlier section, within the tiered system of PHLs, the cumulative PH functions continue to be more basic at the peripheries and include disease detection and reporting, specimen collection and transport. These become more advanced at higher level of PHLs and include pathogen characterization, standards setting including QA protocols, integrated data management including strain repository maintenance and management, policy development, public health related research, training and education and partnerships and communication. It is also notable that with time, its only the variety of investigations that have been added to district level laboratories, the hub of public health activity. Laboratory strengthening efforts have not generally translated into greater capability and sophistication of district laboratories with the exception of HIV/AIDS laboratories and blood banking services that have introduced ELISA based investigations in a big way at this level.

2.3.2 QUALITY SYSTEMS

Laboratory services are cardinal to evidence based decision making. This is possible only when laboratory functioning is quality assured and results from laboratories are reliable. QA in health laboratories has generally been limited to vertical programs (Polio, RNTCP, Malaria, HIV/AIDS) (**Insert Box: List of QA procedures under different vertical disease control programs**).

QA in laboratory services outside of vertical programs has not gained roots firmly though. In India, EQAS in microbiology was started as a voluntary participation program in 1997. The participation has progressed slowly. There are two main EQAS networks: 1. Christian Medical College, Vellore (at the behest of Indian Association of Medical Microbiologists) EQAS in clinical microbiology. This network began with 22 laboratories in 2001; the number has risen to 52 (**updated figures?**). Notably, participation is mainly voluntary and a few private laboratories also participate; 2. Another EQAS provider, the Department of Pathology, BHU, Varanasi, started EQAS for microscopy in clinical microbiology in 1998. This scheme is also purely voluntary.

Several attempts have also been made under NSPCD and IDSP by NCDC/WHO and some other partners to develop a prototype model for district public health laboratories. These have, however, not met with any substantial success.

2.3.3 LABORATORY ACCREDITATION

Accreditation of laboratories is a natural extension of quality assurance. Accreditation of clinical laboratories has been started by the Department of Biotechnology, Government of India in 1999 through the NABL. This is largely voluntary and mostly private laboratories have come forward for accreditation. So far 22 (**?updated figure**) private laboratories have been accredited.

2.3.4 LABORATORY BIO-SAFETY AND BIO-SECURITY

Bio-safety and bio-security in laboratories continues to be strong component of HIV/AIDS testing VCTCs and regional and national referral laboratories under RNTCP. Recent disease developments have lead to

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attempts being made under the IDSP to ensure their implementation in peripheral to state levels laboratories. Similarly, RNTCP is also working towards strengthening these procedures as the program rolls out culture and drug sensitivity testing in several facilities. Clinical diagnostic laboratories, however, continue to largely follow universal precautions and waste management protocols laid down by the NACP.

2.3.5 TECHNOLOGY EVALUATION

Unlike the stringent procedures (pre-marketing as well as post-marketing) in place for drugs and biologicals, there is no systematic mechanism for technology assessment and diagnostics evaluation in India. Limited centralized evaluation for programmatic decision making is done for critical diagnostics like HIV/AIDS, HBV, HCV serology (by NIB, NOIDA) and malaria RDTs (by NIMR). Rest of the evaluations are small scale studies conducted in house by organizations having the capacity. These seldom find their way into published literature and even when they are published, are not in a position to guide public health decision making. In the absence of a national regulatory agency, standard protocols for evaluation of diagnostics also not thus available.

2.3.6 LABORATORY RESEARCH

Recent research shows that of the overall quality adjusted health research output in India, public health research constitutes less than 5%. Health systems related research is part of public health research and therefore an even smaller fraction. It is then expected that research to understand the system related issues on public health laboratories would be even miniscule.

2.4 PRIVATE DIAGNOSTIC CENTERS COMING OF AGE

A surge in lifestyle diseases, changing demographics, growth in medical outsourcing as also medical tourism and increased penetration of medical insurance has contributed to a frenetic expansion of organized path labs that operate on the 'hub and spoke' concept - an internationally proven model that has a super/ multi-specialty hub surrounded by advanced secondary care spokes aided by primary health care centres. This was touted as the model of choice for early-birds in Indian healthcare and has today spawned widely variant growth models in the diagnostic space.

The market however continues to be highly fragmented. There are labs existing within hospitals and there are independent labs of all shapes and sizes. There are automated, semi-automated and manual labs besides reference labs that act as regional hubs, usually in large metros. Collection centres are located in hospitals, nursing homes, pathology labs and doctors clinics. As organised players grow, small and independent labs are becoming franchises in the hub and spoke model; partnering large chains on referral basis and getting acquired by them. Thus a market driven private diagnostics industry has resulted in 3 major diagnostic laboratory chains which include Lal Path Labs, Super Religare, Metroplis Laboratories and Piramal Diagnostics.

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One of the oldest path lab service providers in the country, Lals' have been in existence for 60 years. The chain has 40 labs in India, 50 upgraded patient service centres, 650 collection centres, 2500 pickup points which includes blood centres like Apollo hospitals.

Super Religare Laboratories (formerly SRL Ranbaxy Ltd) came up 12 years ago and has seen bulk of its growth in the last two years. From 19 labs and 500 collection centres they currently service 4000 hospitals/path labs and over 50,000 doctors, performing 34,000 tests a day and catering to 6 million patients a year.

Metropolis laboratories process over 10 million tests a year, catering to more than 10,000 labs, hospitals, nursing homes and 20,000 consultants. Their services include Clinical Laboratory Medicine, Radiology & Imaging Services, Hospital Laboratory Management, Central Laboratory Services for Clinical Trials, Site Management Services, Home Health Services, Preventive Health Checkups and Remote Pathology Testing Services and they also do a wide range of checkups within the home.

Piramal Diagnostics (formerly known as Wellspring), a large chain with 124 clinical diagnostic centres in 85 cities and over 400 collection centres is visited by more than 9900 patients a day. They perform over 4 million pathology and radiology tests every year with a wide test menu offering a comprehensive range of tests in pathology covering Biochemistry, Immunology, Hematology, Histopathology and Immunohistochemistry, Microbiology, Molecular Biology, Cytogenetics and Flow Cytometry. They also offer a comprehensive range of tests in Radiology spanning X-ray, Ultrasound, Color Dopplers, Mammography, Bone Densitometry, Orthopantomography (OPG), CT scan and MRI. They are one of the few diagnostic centre chains that offer pathology and radiology under one roof on such a scale.

In spite of the enormity of scale of operations and outreach, there is no regulatory framework to monitor the performance of either large chains or smaller units of diagnostic laboratories. Quality assurance and laboratory accreditation (ISO, NABL or TUV) in these laboratories is voluntary and largely culture driven. A reflection of this was the inability of a large number of these laboratories unable to meet the standards of testing required for H1N1 testing at the peak of pandemic. There are 50,000 private labs in India, of which only 200 meet NABL accreditation.

2.5 GAPS

Status of public health laboratory function in India has been typically polarised. While on one side the country has some of the finest global and regional centers of excellence in infectious disease diagnosis and research, laboratory support at state, district and sub-district levels has been far from adequate. After several attempts made by center and states through vertical programs as well as disease surveillance projects, there remain gaps in their ability to perform both clinical diagnostic and public health functions with acceptable levels of quality and safety. Even at the national level, gaps in coordination between centers and their functions has not allowed dovetailing of evidence from laboratories to allow disease burden estimation and evidence based decision making, at least outside of the disease control programs.

The following section tries to identify some of these gaps and factors that have contributed to the less than optimal public health laboratory capacity in India:

2.5.1 GAPS IN PUBLIC HEALTH LABORATORY FUNCTION

2.5.1.1 Competing priorities of non-public health laboratories

At every administrative level, there are a variety of laboratory facilities. Some of them are in research domain (including basic and applied research), while others perform purely diagnostic functions. Some of the states such as Maharashtra, also have a network of state and district public health laboratories which perform the function of food and water testing in addition to some other infectious disease diagnoses. Water testing and food testing in most other states is performed primarily by public health engineering department and PFA laboratories. To a small environmental monitoring is also done in public health laboratories (testing for microbiological quality of water both during outbreak investigation and on a regular basis). At district level, often the public health laboratory function is entrusted with the district hospital laboratory or less frequently inside the microbiology department of medical colleges.

Such a variety of structure often leads to confusion in defining the public health function of the laboratories at all levels, especially when this does not align with the major mandates of the laboratories and institutions e.g. as in the case of district hospital laboratories, disease specific reference laboratories with largely research focus being requested to provide diagnostic support for other infectious diseases.

In general, the roles and functions have been better defined under vertical disease control programs, especially when they have dedicated laboratory units e.g. microscopy centres under RNTCP, regional reference laboratories for polio virus isolation and typing, operational research on anti-malaria drug regimens in drug resistance belts in India etc. These programs, however, also have demonstrable best practices and success stories that could be adapted by disease control projects e.g. QA networks of RNTCP and NACO, laboratory bio-safety programs under NACO, specimen transportation system under NPSP.

2.5.1.2 Essential public health function of laboratories less clearly defined

Essential public health functions of laboratories have not been defined at various levels of functioning and mandates. While the inventory of investigations and infrastructural support needed to perform these functions is dynamic and contingent upon changing technology and emerging disease epidemiology, core values and essential functions of public health laboratories are expected to change much less rapidly.

2.5.1.3 Absence of national policy and strategic planning mechanism

A comprehensive national public health laboratory policy outlining the stakeholders, resources, processes and functions has not been developed so far.

Strategic planning for public health laboratory strengthening as a policy has largely been restricted to vertical disease control programs. Similarly, financial outlays for laboratory infrastructure outside of

vertical programs have largely been reflection of support for demand and supply cycle of day to day functioning of laboratories.

2.5.1.4 Ineffective laboratory networking

While the need for 'networking' or 'functional networking' of laboratories resources and expertise has often been voiced, careful planning and clear description of the functions of the network and roles/responsibilities of the partners in these networks has not been evident. Effort has largely been focused on infrastructural strengthening with no clear definition/ indicators of minimum laboratory functional output as an outcome from the networks. Most of the networks are the outcomes of recent developments in infectious diseases landscape e.g. the influenza surveillance networks of NCDC and ICMR in the aftermath of H5N1 outbreaks in India. A consistent policy on networking and sharing of information and biological material with centers outside of the country is also absent, except under some traditional international mechanisms such as the National Influenza Centers.

2.5.1.5 Limited inter-sectoral collaboration:

Immense resources (expertise, diagnostic capacity, manpower, infrastructural support) lie both within and outside of the traditional public health sector. These include medical colleges, veterinary sector, basic research laboratories (under DST, DBT, CSIR), armed forces (both training and non-training facilities), food testing laboratories, water quality standard setting and monitoring agencies. A clear plan has neither been laid down nor facilitated at all various levels. Given this, collaboration with private sector should be a distant dream.

2.5.1.6 Quality assured testing and accredited laboratories - an elusive dream

For a laboratory network to contribute effectively and reliably to clinical diagnosis or public health laboratory support, an important attribute is the quality of testing. Except for quality assurance mechanisms under vertical programs, QA networks in armed forces laboratories and some other independent networks with voluntary subscription (e.g. CMC Vellore network of government and private diagnostic laboratories), the culture of quality testing has not percolated in the public health laboratory network in the country. Several attempts made by WHO and NCDC as pilot projects under the NSPCD and IDSP could also not see light of the day. Even at the level of national referral laboratories quality of testing has been an issue and needs urgent attention.

Box 1: Example of issues with quality of testing in National Referral Laboratories in India

Example of issues with quality of testing in National Referral Laboratories in India

A recent assessment of the NRLs under NACP conducted jointly by CDC, WHO and NACO has shown that only 2/13 NRLs scored the threshold score of 80% (internationally accepted standard level of QA). The assessors made a special note of the fact that while some laboratories scored relatively high, the real driver of this high score was the perfect score in their equipment QSE. There were significantly lower scoring issues in the personnel area for these laboratories. Similarly, other, especially hospital-based NRLs scored much lower in the equipment and space (crowded) categories which drove their total score down in spite of better qualified and trained personnel. Although not part of the checklist per se, a significant observation was the fact that only two of 13 NRLs had documented HIV rapid testing procedures and reporting forms that were consistent with NACO guidance.

Source: Source: Report of External Assessment of HIV Testing Quality of the National Reference Laboratories (NRLs), India, 2008

2.5.1.7 Issues with compliance to and enforcement of bio-safety and bio-security guidelines

Except for the recent emphasis on laboratory bio-safety & bio-security and its implementation at national referral laboratories, specialized laboratories with BSL 3 facilities and laboratories under veterinary sector dealing with exotic pathogens, general concepts and practices of bio-safety and bio-security have been weak in Indian public health and diagnostic laboratories ([any references here?](#))

2.5.1.8 Lack of regulatory mechanisms for validation of diagnostics before and after marketing

A number of diagnostics and technology products required and related to infectious disease diagnosis, manufactured either in India or abroad, find their way into the Indian market on regular basis. Except for a handful of diagnostics such as HIV, HBV, HCV and malaria diagnostics, a quality assurance system similar to that of DCGI for manufacture and marketing of pharmaceuticals is not in place. Once marketed, no agency or institution has been entrusted with the mandate to assess the performance characteristics of these products. As a result the usage of these products at various levels, institutions and purposes results in generation of evidence that may not be comparable between institutions or different parts of the country and hence to the effect on quality and reliability of surveillance data. At the same time certain situations such as clinical diagnosis, incorrect results result in adverse outcomes and potentially affect the reputation of laboratories.

2.5.1.9 Limited scope of laboratory based research

Research in laboratories has largely had a microbiological and technological focus. Operational research and research into system issues related to laboratory strengthening have lagged behind. In the absence of such a research focus, most of the laboratory strengthening, efforts outside of vertical disease control programs have been informed by sound evidence to a lesser extent.

2.5.2 GAPS IN PUBLIC HEALTH LABORATORY STRUCTURE

Vertical disease control programs as well as disease surveillance projects have both contributed to the strengthening existing public health laboratory capacity. However, as opposed to the former,

strengthening has been fragmented and ineffective in the case of latter. This is reflected in the quest for 'model public health laboratory' under the IDSP after over 5 years of implementation of the project. Some of gaps and factors leading to ineffective strengthening are:

2.5.2.1 Absence of a strategic planning body and consequent lack of political will and administrative stewardship

At the national level, there is no government body responsible for strategic planning for systematic public health laboratory capacity strengthening. Lack of leadership and administrative stewardship is further reflected by the absence of a National Focal Point for laboratories. State level structure also follows a similar pattern of deficiency.

2.5.2.2 Issues of monitoring and supervision due to ineffective decentralization

While considerable administrative decentralization has occurred under vertical disease control programs, similar provisions have not been made under disease surveillance projects. Direct supervision and monitoring from the national level has not been able to cater to the needs of a vast and varied public health laboratory function in India which has unique and ever changing requirement. Regional laboratories have been identified under the IDSP to function as disease specific laboratories with a rather loose additional mandate allocated to them to contribute to laboratory network. These have however not been promoted as regional hubs that could in addition to providing reference facilities, facilitate networking, act as bridges between national and between national and sub-national laboratories, or simply act as conveners.

2.5.2.3 Over-ambitious planning and over expectation from peripheral laboratories

The quest for a model public health laboratory function often lead to ambitious expectations from the laboratories, especially at the state and district levels. Nature and type of investigations proposed (and often followed by infrastructural strengthening and training) traditionally has been decided more on judgment rather than prioritization based on evidence of disease epidemiology. Laboratories are thus expected to start with a long list of investigations rather than a small beginning, consolidation and incremental introduction. This has resulted in either non-performance due to an unsustainable strategy or output that lacks quality, reliability and safety.

2.5.2.4 Overlapping and wastage of precious resources due to absence of clear roadmap for effective integration under IDSP

IDSP sought to integrate laboratory resources across disease control programs at the state, district and sub-district levels. However, in the absence of clear plan and roadmap and too frequent changes in strategic inputs, this complex task has practically been elusive.

2.5.2.5 Non-availability of national laboratory database

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Finally, fragmentation of the public health laboratory support to disease prevention and control is also reflected in the absence of national data base of laboratories (and facilities available), disease information, strain repository, standards, protocols etc.

2.5.2.6 Absence of a well-organized specimen transportation plan

Specimen referral plan is not available outside of vertical disease control program often leading to compromise of laboratory diagnosis due to specimens either not being collected at all or being referred only to NCDC which at times might be overwhelmed.

3 WAY FORWARD / ROAD MAP

Laboratory services are essential to health care delivery. They address both preventive and curative activities, i.e. patient diagnosis, and the selection of drugs for treatment. They are also an indispensable tool in the surveillance and control of diseases, since improved disease recognition will improve the accuracy of statistical reporting, and thus effective national health planning. In countries with limited resources, even rural health facilities can manage the most common diseases and those with outbreak potential by carrying out simple laboratory tests.

Several attempts and large investments have been made in India over the years to develop laboratory capacity for infectious disease diagnosis. Important outcomes of these efforts have been the following:

1. At national level the country has developed state of the art capacity to deal with existing as well as emerging pathogens
2. Laboratory strengthening under the vertical disease control programs as well as disease surveillance projects have provided a nationwide framework over which future systematic attempts can be made.
3. Best practices models exist both within and outside of vertical disease control programs that can guide laboratory strengthening e.g. specimen transportation, bio-safety, quality assurance, networking and operational research
4. Laboratory capacity continues to be polarized: national and regional capacity have made major strides in developing their capacity with evolving disease epidemiology but an effective peripheral laboratories network, especially district public health laboratories remains an elusive dream

Yet, major challenges exist in making health laboratories less than effective. These include weak nationwide systems, disjointed procurement and supply systems, disparity between urban and rural areas, lack of infrastructure and human resources, the variable quality of laboratory performance, and equipment/supplies/diagnostics that is either inappropriate or ill-maintained. In addition, scarce resources are often used to buy "high-tech" laboratory equipment that is never used, either because staff are unable to operate it, or due to lack of affordable reagents or spare parts or scant after sales support. Conversely, obsolete and less reliable techniques can still be seen, resulting in substandard patient care.

At a time when recent developments have aroused renewed interest in importance of laboratories in disease prevention and control and with the IDSP receiving an extension for 2 years, it is an opportune time to convene national stakeholders and lay out a roadmap for systematic strengthening of health laboratory services in India in the next 5 years. The guiding principles of such a framework are:

- Laboratory and diagnostic services rooted in national health laboratory policy with a clear roadmap for planning, implementation and evaluation

- Laboratory service standardized and validated through quality systems and bio-safety standards
- Equitable access to high quality diagnostic and laboratory procedures through use of local products, technology transfer and delivered by skilled manpower

3.1 PHASED APPROACH

Situational analyses of the structural and functional organization of public health laboratory services for infectious disease diagnoses highlight a number of challenges to their strengthening. While issues at peripheral levels relate to workforce capacity and capability and absence of quality testing and lack of transportation systems, the problems at referral levels relate more to lack of coordination and duplication of effort and absence of ownership and mechanisms for oversight by these labs on the peripheral labs. The absence of a cohesive leadership mechanism at the national level further adds to the inertia.

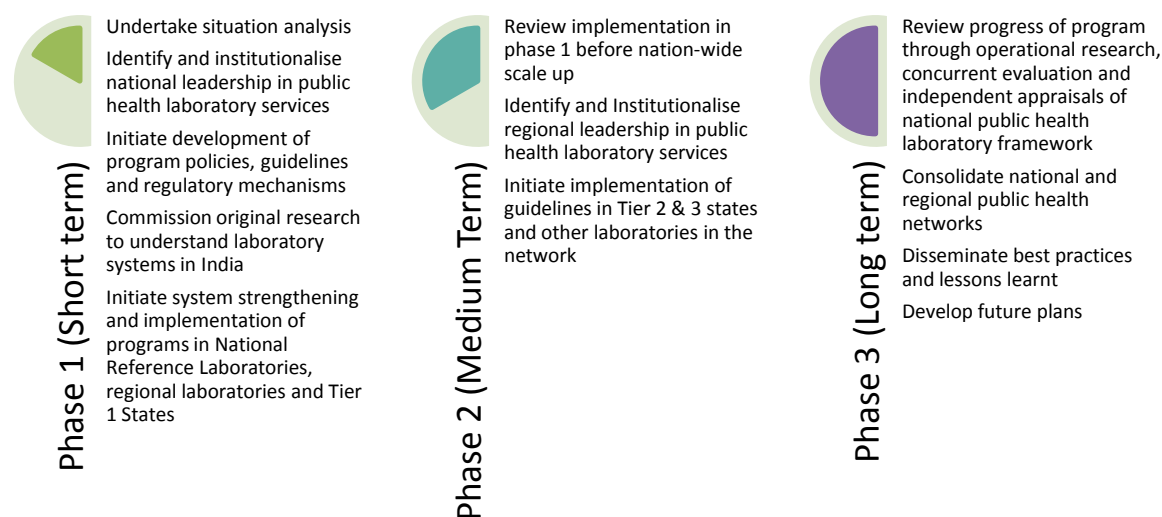


Figure 4: Goals of Each Phase of National Public Health Laboratory Roadmap

Accordingly, it is prudent that a phased approach is adopted for the preparation and implementation of a national public health laboratory framework. This will facilitate the generation of sufficient evidence and identification of a national and regional leadership. The identified leadership can subsequently use the information generated for evolving a consensus among all stakeholders and formulating a nuanced lab policy that is based on evidence and carries the endorsement of principle stakeholders.

An initial intensive phase of 2-3 years for initial groundwork will be needed in terms of evidence generation, leadership identification, establishing regulatory mechanisms and advocacy to ensure smooth scale up. In addition to implementation of activities at national and regional levels, this phase will involve

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extending laboratory strengthening to select states (Tier 1 states) which have a favorable baseline for such activities. This would generate evidence and a proof of concept to guide the scale in phase 2.

Phase 2 will involve review of findings of phase 1, any mid-course corrections and scale up of implementation to tier 2 & 3 states. Phase 3 would then review the progress of national laboratory framework and its various components. This would be done by commissioning evaluations, independent reviews and appraisals followed by future planning in light of the findings and prevailing public health needs of the country.

The categorisation of the possible activities into different phases is merely indicative and to be used as a reference for the drawing up of final timelines that will be drawn by experts in the national consultation. Therefore, it is possible that some level of merging of activities take place in the final plan so that activities placed in one phase are combined with another.

Box 2: Mechanisms of rolling out interventions

Mechanisms of rolling out interventions

It is suggested that the phase wise implementation of public health laboratory services framework is preceded by a mapping of current laboratory resources and accompanied with concurrent evaluation.

It is proposed that states be categorised into Tier 1, 2 & 3 classes depending upon the availability of public health laboratory services. The more developed states can be selected for implementation of the public health laboratory services framework initially. This will facilitate the pilot testing of strategies and the accumulation of evidence allowing replication and scaling up in the relatively poorer functioning states.

The implementation can be phased out in the following manner:

1. Tier 1 States
2. Tier 2 States + Tier 3 States
3. Review and future strategic plan

3.2 STRATEGIES

3.2.1 LEADERSHIP CREATION AND STEWARDSHIP BUILDING

The WHO Asia Pacific Strategy recommends a multi-layered leadership structure for governing national and sub-national public health laboratory strategies. A National Steering Committee is proposed which will act as a 'body of elders' who can provide the larger vision to the national focal point. The national focal point can be an individual officer or even a division dedicated to implementing the national public health laboratory policies.

National steering group	Advises the national focal point in preparing the strategic plan
	Facilitates mobilization of political and material resources
	Provides accreditation to local public health laboratory networks
National regulatory agency	licenses providers
	Sets minimum standards for human resources, materials, kits, machines & methodologies
	Monitors & enforces standards
National Focal Point	Advises national authorities
	Guides all laboratory initiatives in line with national policies & plans
	Responsive to rapid changes
National public health laboratory network	Provides referral lab testing services to affiliate laboratories (service network)
	Transmits test results information to central database for epidemiological analysis (information network)
	Brings together practitioners to facilitate storing, sharing and adoption of their 'tacit' and 'explicit' knowledge (knowledge management network)

Figure 5: ToRs for National Leadership Framework (adapted from Asia Pacific Strategy)

The activities of the abovementioned bodies will be complemented by the establishment of an autonomous regulatory agency that can lay down appropriate guidelines and carry out oversight functions.

Given the lack of evidence base, a limited understanding of the public health laboratory functions and a compartmentalised approach to laboratory services in the country, it is proposed to establish a national public health network that can link institutions and practitioners together and fill in these gaps. More description follows in the next section.

3.2.2 NETWORKING

It is proposed that all the major institutions providing some aspect of public health laboratory services be linked together across different levels, regions and disciplines. This will allow sharing of information, operationalization of a referral services, and generation of a central database for advanced epidemiologic analysis and program prioritization.

More importantly perhaps, it will help in linking together practitioners and institutions, allow the sharing of practical experiences and fostering innovative practices in laboratory research and management.

Smaller and more focussed networks can later arise out of the larger network having regional or thematic focus.

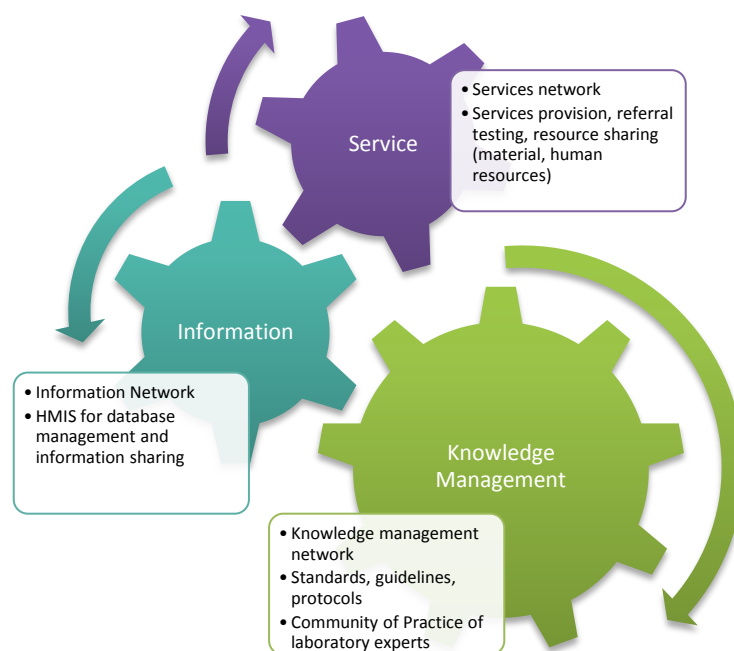


Figure 6: Different aspects of Networking

3.2.3 ACCOUNTABILITY

As described in the situation analysis there is limited discussion on the importance of a national laboratory focal point and the functions of a national public health lab network. Given the complexity and multi-layered nature of the proposed national roadmap, it is essential that its implementation is accompanied with the institution of strong regulatory mechanisms.

The proposed national regulatory authority can prepare guidelines and protocols, identify and monitor indicators of program performance, undertake quality testing and accreditation of laboratories and ensure ethical testing and delivery of services.

3.2.4 RESEARCH FOR EVIDENCE BASED PLANNING

As highlighted in the previous sections, situation analysis is going to play an important role towards increasing the current understanding about the functional status public health labs in India. A range of issues relating to research will need to be explored by the national steering group including operational research to understand systemic issues, encouragement to existing research on microbiological aspects of public health labs; technology research to guide evidenced based planning; mechanism creation for uptake and dissemination of findings.

The nature of research questions will possibly change over the years as more stakeholders get involved in the national public health laboratory network. As a more refined understanding of the functioning of public health labs develops, the nature of research themes will shift from situation analysis and stakeholder analysis to preparing workplans and resource allocation issues, and subsequently to more

specific and practical research themes that can facilitate in the process of consolidation of the Public health lab networks.

The role of research doesn't stop with the initial documentation; rather it will be an ongoing activity that can facilitate the national group in making informed decisions. For evidence based policy decisions, it is important to ensure that the process of research and evidence generation should accompany policy formulation and implementation. Ideally the implementation should be accompanied with concurrent evaluation which should produce further evidence for monitoring and revising the policy implementation.

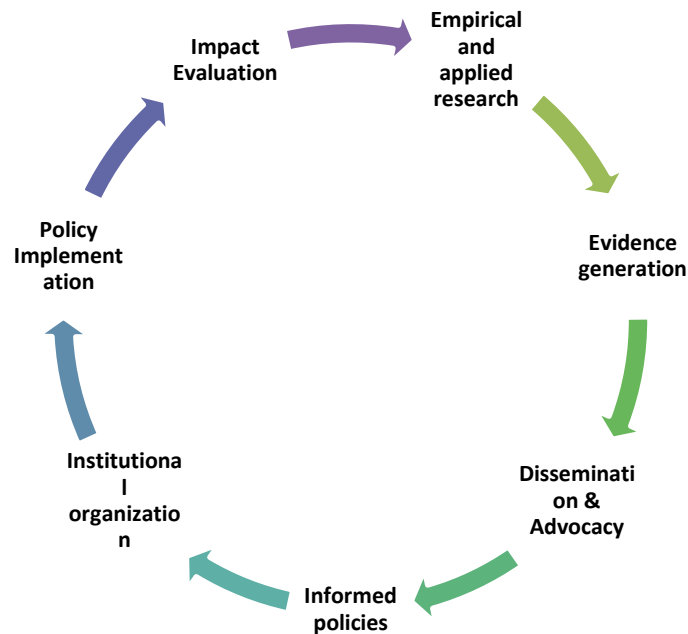


Figure 7: Evidence - Policy - Implementation Cycle

3.2.5 ADVOCACY

The process from evidence generation to policy information and implementation is necessarily an extended one and requires a systematic and sustained advocacy. Informed policy-making also entails disseminating knowledge and facilitating the process of generating awareness and discussion among different stakeholders.

Given the lack of awareness regarding the importance of public health laboratory functions and policies, one of the core activities under the roadmap will be to disseminate latest scientific evidence regarding the importance of the functions of public health lab network and disseminates best practices among different stakeholders.

Advocacy will also be required for creation of a national leadership which can advocate role of laboratories in different networks, mobilize resources and promotion of rational use of laboratory services

4 CHARTER OF ACTIVITIES FOR NATIONAL PUBLIC HEALTH LABORATORY SERVICES STRENGTHENING

We propose the following activities towards the preparation and uptake of a national public health lab policy:

4.1 STRUCTURE STRENGTHENING

Phase 1 Strategic Planning, System strengthening and initial implementation	Phase 2 Review and scale up	Phase 3 Consolidation, review, dissemination and future planning
1. Establish a coherent national framework for laboratory services		
1.1. Establish oversight mechanisms at national, regional and state levels		
1.1.1 Establish steering groups		
<ul style="list-style-type: none"> ▪ Prepare ToRs for national steering group on PH lab services ▪ Identify membership and coordinating agency for housing national steering group on PH Lab services (NCDC/ICMR) ▪ Establish regional chapters of national steering group in Tier 1 states 	<ul style="list-style-type: none"> ▪ Establish regional chapters of national steering group in Tier 2 & 3 states ▪ Establish state chapters of Tier 1 states 	<ul style="list-style-type: none"> ▪ Review TORs and progress made
1.1.2 Designate focal points		
<ul style="list-style-type: none"> ▪ Selection of national focal point with clear ToRs and infrastructural support ▪ Identification regional focal points and state focal points in Tier 1 States 	<ul style="list-style-type: none"> ▪ Identification of state PH lab focal points in Tier 2 and 3 states 	<ul style="list-style-type: none"> ▪ Review TORs and progress made
1.2. Evidence-based national laboratory planning and financing		
1.2.1 Outline a national public health laboratory policy		
<ul style="list-style-type: none"> ▪ Prepare national policy for consultation ▪ Prepare regional / state PH lab policies ▪ Adopt policy with endorsement 	<ul style="list-style-type: none"> ▪ Revise policy based upon feedback and evidence generated 	<ul style="list-style-type: none"> ▪ Revise policy based upon feedback and evidence generated

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of major stakeholders		
1.2.2 Strategic Planning		
<p>Evidence generation</p> <ul style="list-style-type: none"> ▪ Commission studies on situation analysis & resource mapping ▪ Document best practices Policy research <p>Planning</p> <ul style="list-style-type: none"> ▪ Initiate National Strategic planning ▪ Prepare vision document ▪ Develop model regional and state plan and roll out in Tier 1 states and regions 	<ul style="list-style-type: none"> ▪ Review progress in Tier 1 states and corresponding regions ▪ Roll out strategic plans in Tier 2&3 states and regions ▪ Ongoing review of evidence, preparation of projections, regional assessments and operational research 	<p>Review TORs and progress made</p> <ul style="list-style-type: none"> ▪ Independent evaluation ▪ Dissemination of findings / sharing of best practices ▪ Prioritization exercise ▪ Undertake further research on strengthening laboratory systems
1.2.3 Financial Planning		
<p>Evidence generation</p> <ul style="list-style-type: none"> ▪ Undertake cost effectiveness analysis of pilot projects ▪ Undertake costing studies ▪ Map financing resources and mechanisms ▪ Advocate for financial outlays <p>Planning</p> <ul style="list-style-type: none"> ▪ Prepare financial projections for national and regional plans Design financing strategy for national, regional and state plans ▪ Engage Tier1 states for budget sharing ▪ Roll out financial strategy in Tier 1 states 	<ul style="list-style-type: none"> ▪ Undertake financial planning for Tier 2 & 3 states ▪ Roll out financial strategy in Tier 2&3 states ▪ Review progress in Tier 1 states ▪ Ongoing review of evidence, preparation of projections, regional assessments and operational research 	<p>Review TORs and progress made</p> <ul style="list-style-type: none"> ▪ Independent evaluation ▪ Dissemination of findings / sharing of best practices ▪ Prioritization exercise ▪ Undertake further research on strengthening laboratory systems
1.3. Lay out a National Public Health Laboratory Network		

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- Map resource persons / Institutions at national, regional and state levels including the focal points
- Sub-organize larger network further into
 - core network of health laboratories and need-based/client base linkages with non-health laboratories
 - disease and function based networks
- Develop guidelines/ protocols/ indicators for functioning of these linkages and networks
- Host a national public health laboratory web based portal (secure as well as public domains) to network resource persons and institutions and ensure easy availability of information regarding public health lab functioning and research
- Operationalize the network
- Consolidate existing international networks and explore formation of newer networks
- Review the TORs and progress made with special focus on progress in Tier 1 states
- Continue strengthening of network in Tier 2 & 3 states
- Scale up Network to all regions in India Review TORs and progress made

1.4. Establish national regulatory mechanisms

- Enlist ToRs (Quality assurance, Accreditation, Technology assessment, biosafety/biosecurity, information management, material transfer, rational use of laboratory services)
- Identify institutional arrangements at national,
- Review progress and compliance in Tier 1 states
- Identify institutional arrangements in select Tier 2&3 states
- Roll out in Tier 2&3 states
- Review TORs and progress made

regional and state levels

- Assign roles and responsibilities to regulatory institutions/ stakeholders
- Develop standards and guidelines
- Conduct baseline assessments
- Roll out in Tier 1 states

2. Build capacity for laboratory services

2.1. Physical infrastructure and equipment

- | | | |
|--|--|---|
| <ul style="list-style-type: none"> ▪ Conduct resource mapping / assess and re-assess infrastructure requirements at national, regional, state and district levels in line with stratified essential public health laboratory functions ▪ Establish technical guidelines for design, location of public health laboratories at different levels ▪ Implement guidelines for design, location of public health laboratories at national, regional labs (of Tier 1 states) and in Tier 1 states | <ul style="list-style-type: none"> ▪ Review performance of laboratories through commissioned assessments in national, state, regional (Tier 1 states) and Tier 1 states ▪ Conduct resource mapping / Assess infrastructure requirements in Tier 2 & 3 states | <ul style="list-style-type: none"> ▪ Implement guidelines for design, location of public health laboratories in regional laboratories (Tier 2 & 3 states and Tier 2 & 3 states) ▪ Review progress and future planning |
|--|--|---|

2.2. Human resources

- | | | |
|---|---|---|
| <ul style="list-style-type: none"> ▪ Assess workforce capacity at national, regional and state level in line with essential public health laboratory functions ▪ Prepare and adopt national public health lab workforce policy after consultation with major stakeholders including state governments ▪ Depute/ recruit identified/ created positions for PH lab | <ul style="list-style-type: none"> ▪ Review performance of lab workforce through commissioned assessments in national, state, regional (Tier 1 states) and Tier 1 states ▪ Depute/recruit identified/ created positions for PH lab personnel at regional level (Tier 2&3) and in Tier 2&3 states ▪ Develop and conduct competency based training programs for regional level | <ul style="list-style-type: none"> ▪ Review progress and future planning ▪ Undertake periodic assessments to improve work conditions in PH labs |
|---|---|---|

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personnel at national and regional level and in Tier 1 states

▪ Develop and conduct competency based training programs for national, regional (Tier 1 states) and Tier 1 states; include focus on public health laboratory management; trainings conducted through network of partner institutions identified as part of lab workforce policy

(Tier 2&3) and in Tier 2&3 states; trainings conducted through network of partner institutions identified as part of lab workforce policy

3. Procurement & Supply Chain Management

- Assess procurement & supply chain management systems for lab services at national, state and district levels, including under vertical disease control programs
- Establish a coordinated PSCMS system at national (could be under existing mechanisms such HMSC) levels
- Develop and disseminate model PSCMS frameworks for state and districts in consultation with stakeholder including states
- Establish (refine existing frameworks wherever necessary) PSCMS in Tier 1 states
- Review performance of PSCMS through commissioned assessments in labs at national, regional (Tier 1 states) levels and Tier 1 states
- Establish (refine existing frameworks wherever necessary) PSCMS at regional level (Tier 2&3) and in Tier 2&3 states
- Review progress and future planning
- Undertake periodic assessments to improve PSCMS in PH labs

4. Specimen Transportation System

- Assess specimen transportation systems (STS) and available resources (including private courier services) at national, state and district levels,
- Review performance of STS through commissioned assessments in labs at national, regional (Tier 1 states) levels and Tier 1 states
- Review progress and future planning
- Undertake periodic assessments to improve STS in PH labs

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<p>including under vertical disease control programs</p> <ul style="list-style-type: none"> ▪ Establish (refine, if necessary) STS at national levels ▪ Develop and disseminate model STS framework/guidelines for state and districts in consultation with stakeholder including states ▪ Establish (refine existing frameworks wherever necessary) STS in Tier 1 states 	<ul style="list-style-type: none"> ▪ Establish (refine existing frameworks wherever necessary) STS at regional level (Tier 2&3) and in Tier 2&3 states
<p>5. Information systems and communication</p>	
<ul style="list-style-type: none"> ▪ Develop communication framework for linking all Public Health Networks for information sharing and collaboration ▪ Determine data elements for health and non-health laboratories for information sharing ▪ Develop IT standards for supporting the above framework ▪ Implement IT Standards at national level and in Tier 1 States 	<ul style="list-style-type: none"> ▪ Review performance of IMS ▪ Implement IT Standards in Tier 2 & 3 States
	<ul style="list-style-type: none"> ▪ Review progress and future planning

4.2 FUNCTIONAL STRENGTHENING

1. Define charter of functions for public health laboratories

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- | | | |
|---|---|---|
| <ul style="list-style-type: none"> ▪ Enlist essential public health functions of health and non-health laboratories in consultation with stakeholders ▪ Assign functions according to the level of functioning, mandates and sophistication; identify indicators of success (of function such as number of specimen tested, outbreaks investigated and confirmed, lab QA panels successfully cleared etc.) ▪ Disseminate to regions, states, districts and sub-districts ▪ Ensure structural strengthening in line with essential functions at national, regional (Tier 1 states) levels and in Tier 1 states | <ul style="list-style-type: none"> ▪ Review implementation, feasibility, relevance, deliverability, quality of essential functions at national, regional (Tier 1 states) and in Tier 1 states ▪ Expand to regional labs (in Tier 2&3 states) and in Tier 2&3 states to ensure structural strengthening in line with essential functions | <ul style="list-style-type: none"> ▪ Review progress and future planning |
|---|---|---|

2. Assure the quality of health laboratory services

2.1. Quality assurance of laboratory testing

- | | | |
|---|---|---|
| <ul style="list-style-type: none"> ▪ Develop laboratory quality assurance policy ▪ Develop a National External Quality Assessment Program (NEQAP) ▪ Identify and strengthen institutional network for implementation of NEQAP ▪ Develop guidelines including integrated monitoring and supervisory guidelines ▪ Affiliate national laboratories with international external quality assessment programs, wherever not existing | <ul style="list-style-type: none"> ▪ Implement QA program in Tier 1 states | <ul style="list-style-type: none"> ▪ Review progress in Tier 1 states ▪ Implement QA program in Tier 2&3 states |
|---|---|---|

2.2. Accreditation of health laboratories

- | | | |
|--|---|---|
| <ul style="list-style-type: none"> ▪ Review the current | <ul style="list-style-type: none"> ▪ Complete accreditation of | <ul style="list-style-type: none"> ▪ Complete accreditation of |
|--|---|---|

<p>accreditation systems for their adaptation to public health laboratories, including those under Indian Public Health Standards</p> <ul style="list-style-type: none"> ▪ Develop a public health laboratory accreditation policy ▪ Advocate/promote laboratory accreditation at national and regional levels 	<p>national level laboratories</p>	<p>regional laboratories</p> <ul style="list-style-type: none"> ▪ Review progress ▪ Develop strategic plan for accreditation of state and district labs
<p>3. Improve laboratory safety</p>		
<ul style="list-style-type: none"> ▪ Assess Biosafety standards and needs of labs at different levels in line with essential public health laboratory functions ▪ Develop a public health laboratory biosafety policy in consultation with stakeholders ▪ Define national standards and incorporate them in accreditation policy ▪ Identify institutional networks for implementation of mandatory biosafety standards ▪ Popularize standards nationally ▪ Implement standards in national, regional (in Tier 1 states) and Tier 1 states 	<ul style="list-style-type: none"> ▪ Review progress in Tier 1 states ▪ Implement standards in Tier 2&3 states 	<ul style="list-style-type: none"> ▪ Review progress and future planning
<p>4. Support research and ethics in laboratory settings (operational research, technology assessment and research ethics)</p>		
<p>4.1. Research</p>		
<ul style="list-style-type: none"> ▪ Conduct research prioritization exercise and develop a strategic research agenda ▪ Establish dedicated funds and resources for conducting systems research for laboratory strengthening ▪ Establish mechanism for 	<ul style="list-style-type: none"> ▪ Commission local research ▪ Disseminate through annual meetings/ congress/ bulletins/ policy briefs 	<ul style="list-style-type: none"> ▪ Commission local research ▪ Disseminate through annual meetings/ congress/ bulletins/ policy briefs

dissemination and uptake of research findings into policy
Commission studies in shortlisted areas

4.2. Ethics

- | | | |
|--|--|---------------------------------------|
| ▪ Develop code of ethics | ▪ Establish Institutional review Boards in Tier 2 & 3 States | ▪ Review progress and future planning |
| ▪ Establish Institutional review Boards in NRLs, regional labs and Tier 1 States | | |

5. Promote the rational use of laboratory services

- | | | |
|--|--|---|
| ▪ Formulate strategy for promoting rational use of PH lab services by health service providers and involving community | ▪ Disseminate strategy among program managers
Conduct campaigns among practitioners and community members | ▪ Conduct campaigns among practitioners and community members |
|--|--|---|

ANNEXURE 1: LAB NETWORK OF DISEASE CONTROL PROGRAMS

Brief description of laboratory network under each vertical disease control programs followed by:

- **function (as well as investigations) of labs at different levels and**
- **number of labs at different levels**

	Laboratory network				
	NRLs	Regional reference labs	State labs	District labs	Peripheral lab
NACO					
RNTCP					
Polio					
Malaria					

ANNEXURE 2: LABORATORIES UNDER IDSP

Matrix of laboratories under IDSP

Short description

	Laboratory network				
	L1	L2	L3	L4	L5
IDSP					

ANNEXURE 3: LABORATORIES OUTSIDE OF PUBLIC HEALTH NETWORK

Matrix of laboratories outside of public health network:

Short description

	Laboratory network				
	NRLs	Regional reference labs	State labs	District labs	Peripheral lab
AFMS					
CGHS					
Railways					
ESI					
Medical colleges					
AFMS					

ANNEXURE 4: LABORATORIES UNDER NON HEALTH SECTOR MINISTRIES

Matrix of laboratories under non-health sector ministries

Short description

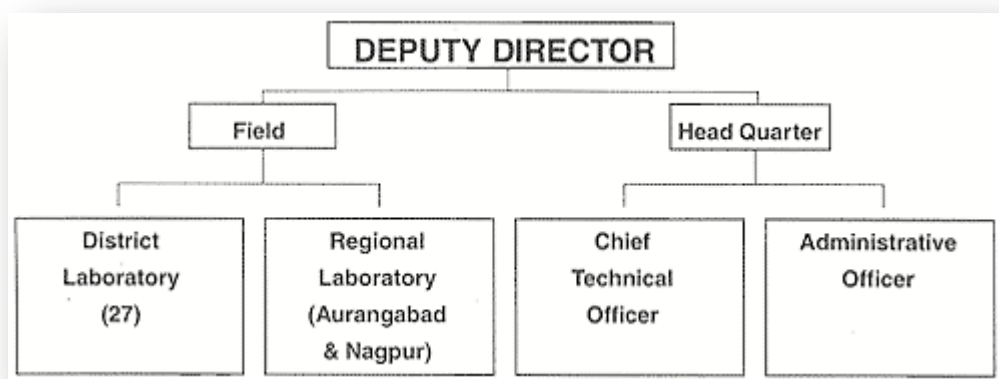
	Laboratory network				
	NRLs	Regional reference labs	State labs	District labs	Peripheral lab
Ministry of agriculture					
Food processing laboratories					
Veterinary laboratories					
Water testing laboratories					

ANNEXURE 5: PUBLIC HEALTH LAB NETWORK- IN MAHARASHTRA

Maharashtra Public Health Laboratory Services

The State has Public Health laboratories situated at State, Regional and District Level. The State Level Laboratory at Pune is also recognized as Central Food Laboratory. The two Regional Laboratories are located at Aurangabad and Nagpur. 27 Districts are having District Public Health Laboratories.

Organizational Structure



Functions:

1. To examine water samples chemically and bacteriologically for potability.
2. To examine samples of blood, stool and vomit for isolation of enteric pathogens.
3. To organize Health Education and Training Activities to create public awareness for detecting adulteration.
4. To carry out analysis of food samples under prevention of food adulteration Act.
5. To analyze samples of sewage, trade waste and effluent for statutory control of environmental pollution.

Activities

A. Monitoring of Bacteriological quality of water

Water quality is regularly monitored in urban and rural areas. The consolidated monthly information of all non-potable water samples in urban and rural areas are sent to the Sec. U.D. & R.D.D.

Urban Area - 22 Municipal councils & 15 Corporations have been given targets for sending water samples on population basis. The samples should be taken, one from the source and four from distribution

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Rural Area - Each Primary Health Center is given target to send minimum 10 samples per month

- B. Chemical examination of water, bleaching powder, alum, waste water and industrial effluents
- C. Control and prevention of epidemic due to water born diseases.
- D. Food adulteration
- E. Investigation of food poisoning cases

Role as Central Food Laboratory

In 1976 , the State Public Health Laboratory, Pune was notified by Govt. of India as Central Food Laboratory and is performing following functions as per PFA Act 1954.

1. To examine statutory samples of food received from various courts and Port Health Officers.
2. To analyze samples of food sent by any Officer or authority authorized by Central Government.
3. To do investigations for purpose of fixation of standards of any article of food.
4. To participate in various investigations and collaborative work with other institutions.
5. To take active participation in various sub committees of central committee of Food Standards.