



The Forgotten Factors Affecting the Expansion of Medical Laboratory Services to cope up the Rising Health Demands in Sri Lanka

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EXECUTIVE SUMMARY

Introduction: The government of Sri Lanka identifies health laboratory service as an essential component in the health care service and is committed to providing quality essential laboratory services to healthcare seekers. Ministry of Health, Sri Lanka is responsible for the establishment and enactment of relevant legislation, and for providing technical and managerial guidelines for the maintenance of laboratories which comply with nationally and internationally accepted standards. Epidemiological and demographic transitions in Sri Lanka have compelled it to focus its attention to combat noncommunicable diseases, which are accounting for an estimated 80% of the annual deaths in the country. Improvement of diagnostics was identified as a priority in Health Master Plan 2016-2025 and by Primary Health Care System Strengthening Project.

Methodology and results: Qualitative methods such as key informant interviews, attending meetings and desk reviews were used to collect the factors affecting the expansion of laboratory services and the most crucial factors were identified by using the 80:20 rule. Issues related to the implementation of the National Laboratory Policy, laboratory financing, human resource issues, accreditation, and lack of making sense of data were found to be the most crucial factors that need to be addressed strategically to successfully expand laboratory services across healthcare institutions.

Conclusions: It is essential to improve the competencies and capabilities of the Policy Analysis and Development Unit of the Ministry of Health to facilitate policy analysis, reviews, and preparation of groundwork for National Policy enactment. Lack of accredited health laboratories and a plan to accredit may reflect adversely on the technical competence. Widespread unavailability and compartmentalization of information management systems have led to underutilization of laboratory-related data and this has resulted in a lack of a viable plan for evidence-based laboratory finance allocation and human resource development.

KEYWORDS: Expansion, Factors, Laboratory Services, Sri Lanka.

INTRODUCTION

Sri Lanka as a developing country should consider the health of the population as the foundation of its development. Sri Lanka has achieved remarkable health indicators among the region's countries, such as increased life expectancy for both genders, and low maternal, child and infant mortality levels. Further, Sri Lanka was awarded WHO certificates for eliminating malaria, measles, lymphatic filariasis, mother-to-child transmission of HIV and syphilis [1]. These improvements have been achieved relatively at a low cost, due to strategic health interventions on health education and promotion, disease prevention and access to health care. Sustaining these interventions is paramount to protecting the already achieved levels of health outcomes.

However, the population of Sri Lanka is now facing a set of new health challenges due to its demographic and epidemiological transitions. Among the major challenges, Sri Lanka needs to pay attention to combat chronic and non-communicable diseases (NCDs), which account for an estimated 80% of deaths in the country to date [2]. Further, the threat of growing future epidemics of known, emerging or unknown diseases cannot be ruled out. In 2016, the Ministry of Health Sri Lanka (MoHSL) published the Health Master Plan 2016-2025, which provides a strategic framework for improving and strengthening the health sector over the next ten years [3]. Prevention and early detection of chronic diseases are one of the main targets of the plan. Further, in 2018 the World Bank launched a USD 4419 million worth of "Primary Health Care System Strengthening Project" in Sri Lanka to improve the quality and utilization of primary health care in terms of detecting and managing noncommunicable diseases among high-risk groups of the population [4]. WHO included diagnostic tools in one of six building blocks of the health system and WHO Noncommunicable Disease Global Action Plan comprises actions for the improvement of diagnostics across the world for combating these diseases [5]. To improve the diagnostic services amidst the epidemiological and demographic transitions the following mission



statement was included in the Health Master Plan of Sri Lanka “to improve the health status of Sri Lanka through the provision of quality services by advancing the capabilities of all laboratories in laboratory technology, related public health disciplines, training, research and well-motivated staff.”

Medical Laboratory services in Sri Lanka

Medical laboratory service in Sri Lanka is provided by both the public and private sectors. The public sector has an extensive laboratory network across the country and caters its services to most of the Sri Lankan population. Depending on the primary purpose medical laboratories can be broadly divided into clinical and public health laboratories. Clinical Laboratories are primarily used for the diagnosis and case management of infectious and noncommunicable diseases and public health laboratories provide results for disease control and prevention. However, both types of laboratories are being used for the purpose of controlling diseases in both public and curative sectors.

Deputy Director General Laboratory Services (DDGLS) is the National Laboratory Focal Point and responsible for policy implementation, improvement, supervision, and coordination of laboratory functions across the country. National Laboratory Technical Advisory Committee (NLTAC) has the responsibility of advising the Ministry of Health on national health laboratory policies, and relevant medical and technical developments related to laboratory services. On average 189 types of laboratory investigations perform within the state sector laboratories and these medical investigations are full-fledged to meet the needs of the routine laboratory test requirements of both curative and public health sectors of the country. However, the types of investigations performed by a medical laboratory depend on the level of care provided by a healthcare institution. Apart from the types of investigations, not all divisional hospitals comprise medical laboratories. Out of all Divisional Hospitals, 41 of 61 Divisional A, 57 of 132 Divisional B hospitals and 12 of 288 Divisional Hospitals provide essential diagnostic facilities. All Primary Health Care Units designated only for day outpatient services do not comprise in-house laboratory services. In addition, there are numerous private medical laboratories across the country which make a significant contribution to full fill the overall needs for laboratory services.

Objectives

- To identify factors affecting the expansion of laboratory services in the light of demographic and epidemiological transition in Sri Lanka.

METHODOLOGY

- Key informant interviews (KII)
- Attendance to the meetings at Directorate of Laboratory Services
- Desk reviews

Key Informant Interviews were conducted with the Director Medical Research Institute, and Heads of Health Care Institutions. Summaries of all meetings and KIIs and meetings were synthesized according to common words and coded into thematic areas. Each thematic area was then converted into information which is listed below.

RESULTS

Factors affecting the expansion of laboratory services

1. Issues related to National Laboratory Policy implementation
2. Lack of making sense of available data
3. Lack of national standards for medical laboratories
4. Lack of accreditation mechanism
5. Human resource issues
6. Quality management system
7. Lack of laboratory information management system
8. Lack of integration of laboratories
9. Lack of proper monitoring and evaluation plan
10. Financing issues

11. Inadequate public private partnership

Problem prioritization

The most influential factors affecting the expansion of medical laboratories were identified using the Pareto Principle and the issues related to policy implementation, laboratory financing, lack of national laboratory standards, human resource issues, and lack of making sense of data are falling within the critical 20% area of the Pareto Chart.

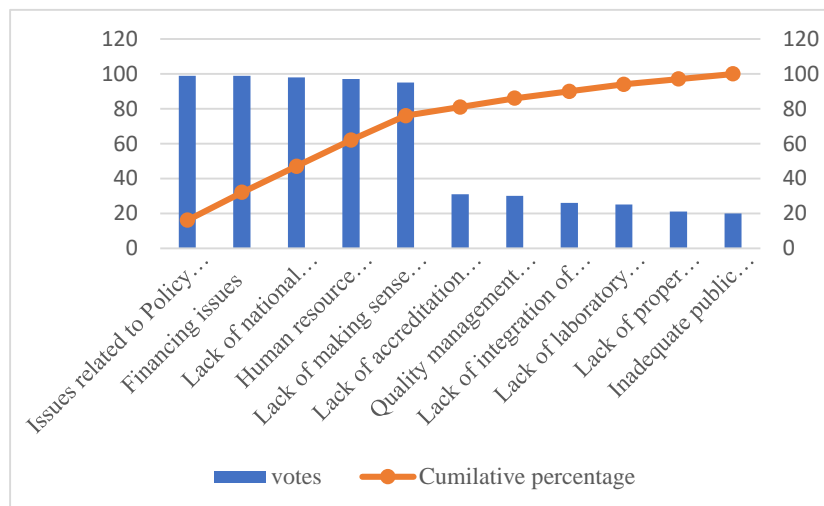


Figure 1: Pareto Chart: Prioritization of factors affecting laboratory expansion

1. Issues related to national laboratory policy implementation

Policy implementation is a series of activities undertaken by the government to establish with an apparent intention to do something or to stop something as articulated in the policy statement. Centre for Disease Control and Prevention of the USA and the Scottish Parliament of the UK reiterate the importance of immediate enactment of a health policy once a policy has been developed if it is to have an impact on the targeted population [6,7]. Further, the WHO reiterates the importance of having a strategic framework for policy implementation, strengthening health laboratory services and guiding activities needed in developing sustainable national health laboratory systems [8].

The National Laboratory Policy of Sri Lanka was approved by the Cabinet of Ministers of Sri Lanka in 2006 and the National Health Laboratory Services Act was prepared accordingly. However, neither enactment of the act nor the development of a national strategic plan for the effective implementation of laboratory policy has not materialized since then.

2. Laboratory financing

Checklist based assessment conducted to find out the status and challenges with human resources, Information Systems, drugs, and laboratory services under the primary health care system strengthening project in Sri Lanka reports that only 43% of the essential laboratory investigations are available in 50% of primary medical care institutions. Insufficient reagents and consumables which have a direct link with financial uncertainty are understood as one of the crucial factors affecting the smooth functioning of these laboratories [9]. The total cost incurred for laboratory services from 2014 to 2018 did not exceed 5% of the current health expenditure (3.6% of GDP) of Sri Lanka [10]. Research evidence proves that financial uncertainty has a direct impact on themes such as human resources and infrastructure development [9]. Hence adequate and sustainable financing of laboratory services must be a realistic theme of the annual health budget for the achievement of the intended goals.

3. Lack of conformity with national laboratory standards

The focus on the patient safety movement was intensified in 1999 after publishing the report "To Err is Human" by the Institute of Medicine (IOM) of the USA. IOM estimated 60% to 70% of total deaths (n = 98,000) due to medical errors are accounted for by decisions related to diagnosing or treatment which involves laboratory services. Laboratory tests along with accepted validity and reliability are considered the cornerstone of diagnosing diseases [11]. The improvement of validity and reliability of laboratory results could be improved by introducing quality management systems to health laboratory services. Quality management systems



involve benchmarking processes by which the quality of one laboratory is compared and improved to match that of others. The Sri Lanka Accreditation Board (SLAB) is an independent body who provide accreditation services for conformity assessments of services of medical laboratories. SLAB uses ISO 15189 standards to assess the quality and reliability of medical laboratories. However, no public sector medical laboratory except the Clinical Bacteriology Laboratory of Medical Research Institute has been awarded an accreditation certificate from SLAB [12]. Hence there is an immense challenge of developing infrastructure, technology, human recourse, and information technology of the government medical laboratories to conform with international ISO standards.

4. Human resource issues

An adequate number of qualified laboratory staff are needed to implement the national medical laboratory policy. Checklist based assessment conducted to find out the status and challenges with human resources, Information Systems, drugs, and laboratory services under the primary health care system strengthening project in Sri Lanka found that around 33% of laboratory technician (MLT) posts were vacant in primary health care institutions [9]. The total number of MLTs across healthcare institutions in Sri Lanka was 1724 (2017). Even though the increment of MLTs during 2006-2017 was around 82%, the increment is grossly irregular across the healthcare institutions and type of cadre [13]. Hence, the number and types (carder) of laboratory health workers required for the optimum function of the laboratories need to be defined. Further, there should be designated additional training centres to accommodate trainees in laboratory medicine and technology. The development of a comprehensive national human resource and capital development plan in coordination with the Ministry of Higher Education is indispensable to meet the projected requirements for medical laboratory services.

5. Lack of making sense of data

Data is for action. Proper management of data is important for laboratories for correct analysis, recording and verification of tests. Further, data need to be stored securely to assure confidentiality, accuracy, and for evaluation to plan quality medical laboratory services for the future. Medical laboratories have two information management systems namely Laboratory Information Management System (LIMS) and Laboratory Information System (LIS). The LIMS is an integrated information system designed to capture, analyze, report and view data across all the laboratories of the country. LIS is designed to manage all the aspects of laboratory operations within the health care institution. However, LIS as a system is not available for many hospital laboratories in Sri Lanka and LIMS is not in a state to collect laboratory related data across all healthcare institutions. Further, to develop a comprehensive laboratory expansion plan, it is essential to compare laboratory data along with the national morbidity and mortality and other essential hospital data. This aim could be achieved by extension of LIMS and LIS to all healthcare laboratories and by linking national LIMS to the national health information management system (HIMS) and the hospital information system [14].

CONCLUSIONS

The government of Sri Lanka identifies health laboratory service as an indispensable component in the health care service and is committed to providing essential laboratory services to customers. According to the National Health Policy of Sri Lanka (2017 – 2025), the MoHSL is responsible for the provision of accessible, reliable, and readily available high-quality laboratory services for patients who are seeking public health care. Further, the Policy Analysis and Development Unit of MoHSL was established to collect, analyze, interpret, and provision of evidence for policy formation and preparation of groundworks for policy enactment. Hence in collaboration with the Directorate of Laboratory Services, the preparation of relevant legislation, and provision of technical and managerial strategies needed for the implementation of the National Laboratory Policy should be a vested responsibility of the Policy Analysis and Development Unit. However, Policy Analysis and Unit does not have an adequate number of competent trained staff to lay out the groundwork necessary for the achievement of the aims stated by the National Laboratory Policy.

Health financing is considered a core function of health systems that will enable improving most health aspects such as coverage and, the effectiveness of care. Globally, the percentage of health financing as a fraction of GDP has an upward trend and laboratory services absorb a considerable share of the healthcare expenditure. Even though epidemiological and demographic transitions indicate that the percentage of finance allocation for medical laboratory services in Sri Lanka should be increased, the exact amount of the additional finance allocation needed will have to decide after conducting a proper situation analysis. As health expenditure largely depends on the income of the country this situation analysis will contribute to identifying the right percentage that needs



additionally and prioritize the areas really in need. Despite having awash of data across the healthcare institutions there is no designated unit or central data repository within the Ministry of Health to analyze and closely monitor these changing needs.

Accreditation of laboratories improves patient safety by reducing risks and costs and improving trust. The assessment domains of ISO 15189 used for laboratory conformity assessment by SLAB comprise personnel qualifications and competence, equipment, reagents and supplies, quality assurance, and pre-analytical, analytical, and post-analytical factors. However, apart from the institutional quality assurance programmes, no viable national accreditation plan was developed to accredit health laboratories of hospitals.

The right number of staff with the right skills in the right place is essential to the smooth functioning of laboratory services. The inadequate number of MLTs is one of the unresolved issues in the health system of Sri Lanka that affect the laboratory expansion process. Training of MLTs is carried out by both the Ministry of Health and the Ministry of Higher Education. However, the annual intake of MLTs for the training institution is not enough to fill the vacancies available in healthcare institutions. Hence it is a vital need to prepare a long-term plan in collaboration with the Ministry of Higher Education to train an adequate number of MLTs needed to fill the vacancies available in healthcare institutions. Public-private partnership is another timely opportunity to be considered by the MoHSL in the training of human resources.

An awash number of laboratory-related data is being collected in different healthcare institutions. Lack of interoperability and a central data platform that links these various systems together has resulted in duplication of collecting data and limited usage of data for decision making. LIMS and LIS are the two information management systems developed years ago to manage and store laboratory data and generate information needed for the improvement of laboratory services. However, the intended purpose has been difficult to achieve due to the nonavailability of these information management systems across all healthcare institutions. Further, no effort has been made to evaluate these systems by reviewing their intended use, capabilities, outputs, and interoperability.

RECOMMENDATIONS

1. Development of competencies and capabilities of the Policy Analysis and Development Unit of the Ministry of Health for its intended use.
2. Preparation of a strategic framework for the expansion of laboratory services, including human resource training and development, accreditation, and information management
3. Development of sustainable human resource training plan with the collaboration of Ministry of Higher Education and by improving private-public partnerships
4. Development of policies to guide health information management and creation of a central data repository linking all health information systems
5. Establishment of a central data repository along with a health data analyzing cell in the MoHSL to identify health priorities which facilitate evidence-based finance and other resource allocation.

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Cite this Article: Krishanth, M. D. A., Rajakaruna, I. M. S. M., Jayathilake, K. A. R. P. (2023). The Forgotten Factors Affecting the Expansion of Medical Laboratory Services to cope up the Rising Health Demands in Sri Lanka. International Journal of Current Science Research and Review, 6(2), 986-991