

The Role and Impact of Reference Laboratories in the Primary Health Care System

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Abstract

Laboratory tests give us information on the presence of disease, the activity of inflammatory disorders, the presence of some bacteria and viruses, the functions of the organ systems, the success of therapy and the changes in it after therapy, as well as the side effects of therapy. A reference laboratory is a medical laboratory with procedures followed in a specified environment and particular conditions for the purpose of preparing reference materials, reagents, or kits to be used in laboratory tests or for providing quality control materials in results of measurements or conformity assessments made in laboratories or by organizations. It is necessary to mention that throughout these processes while preparing reference materials, reagents, or kits from the envelope till the process is finished certified products must have been done with recommended quality norms. Reference laboratories are mainly established for a significant role in health services, and they have primary designations to develop a high level of service quality in the health care system.

Keywords: Reference Laboratories, Primary Health Care, Disease Diagnosis, Collaboration, Economic Benefits, Primary Health Care

1. Introduction

Medical laboratories are essential building blocks of the health care system. Laboratory results inform most of the clinical decision making and are a cornerstone for monitoring, evaluating, and controlling health priorities. Ensuring the provision of quality laboratory services and strengthening existing laboratory networks is crucial for ensuring quality-assured laboratory reports and ultimately achieving better patient outcomes. In many health systems around the world, 2005 was seen as a turning point in the increasing availability of advanced medical laboratory tests, which created the need for a more targeted test ordering by clinicians. The number of different tests has been continuously increasing for many reasons: such as needs for early accurate differential diagnostics, the growing age of the population, the appearance of different sub-categories of the population with previously unknown risk factors due to environmental changes and personal lifestyle, the increasing occurrence of non-communicable diseases, the growing number of chronic patients and with it linked croplands of microbiological, biochemical and serological tests by monitoring the activity of rounds.

1.1. Background and Significance

Laboratory Medicine plays a role in managing migrant health problems globally by contributing to the

health rights of international migrants. Collaboration with medical and social services, policy makers, nongovernmental organisations, and migrant communities with cultural sensitivity is required to achieve these new goals. Salient action themes are planned for educational institutions to align with the result of this literature review and interdisciplinary analysis, which can help migrant health and thus contribute positively to the resident's health. Laboratories must therefore be organized in such a way as to ensure continuous methodological and technological development, to reduce the rate of technical errors and improve the training of staff, to introduce efficient information systems for sample tracking and accounting of results, and to implement a system of methodological certification. Homogenous and accurate measurement of analytes is an unconditional requirement for further comparability between results obtained in different centres. Accurate, traceable, and comparable measurements are constraints imposed by progress of medicine and by international health policies, and can be applied to clinical research, chemical safety and security monitoring, food safety and environmental control activities, and to pharmaceutical industry monitoring.

Laboratory services in clinical and public health care systems have been credited with huge contributions to patient care, public health systems, and the health sector's overall economy [1]. One of the major roles of reference laboratories in public health care is their vital function in detection of pathogens before they become the cause of epidemics and pandemics. Surveillance of new pathogens in cases of immune deficiency diseases, warning of bioterrorism threats and selecting suitable antibiotics are strategies for prevention and control of such events. The reference laboratories should also provide instructions to enhance capacity building for diagnosis, so that as soon as a new disease is identified, the technology to detect it can be transferred. Reference laboratories play a vital role in maintaining a functional, efficient, and cost-effective laboratory system for effective disease diagnosis in rural environments, which cannot establish or maintain their own diagnostic and surveillance facilities.

2. Understanding Reference Laboratories

Post-conflict and resurging among the worst affected small countries, the so-called Small Low-Income Countries (SLICs), often present health care facilities that are dilapidated and lack competent human resources. Blood analyses are the most common second diagnostic tool in primary care facilities after the clinical examination, if presumed that minimal clinical competence has already voted clinical probability of the patients to be tested beforehand. The entire meaningfulness of any subsequent diagnosis, treatment or public health decision always presupposes optimal laboratory performance [2]. Therefore, involvement and support of those who are dedicated to the performance and quality of medical laboratories is urgent and of outstanding relevance. For setting the priorities and reaching out strategic alliances prerequisite for needs assessment is a survey addressing concerns and expectations those who purposely contribute to and use laboratory generated medical data.

Efficient laboratory services operating at high quality are an urgent need in primary health centers. Many of them, especially in post-conflict and underserved countries, often lack information about reference intervals and confounded interpretations. The overall aim of this study was to elaborate the first steps that could support laboratorians in their meaningful alignment to the WHO List of Essential In Vitro Diagnostics within poorly developed health care systems [3].

2.1. Definition and Functions

According to the Recommendation of the Committee of Ministers to Member States on Biomedical Research (Rec 4, 2006) of the Council of Europe, "medical biochemistry laboratories provide vital

support for diagnostics, treatment and follow-up care in the healthcare system” [4, 5]. In the Laboratory Recommendation for the Diagnosis of Synthetic Function of the Liver publication we read: “The main tasks of medical diagnostic laboratories are to assess patient health status rapidly and accurately, the control of drug treatment and monitoring of the progression of the patient’s disease. Results of laboratory tests help doctors to initiate or continue appropriate treatment, select drugs, and appropriate doses, to monitor the development of diseases, to detect relapses of diseases at the earliest possible stage, and to identify risk factors and conditions related to the appearance and maintenance of disease symptoms”. Screening laboratory tests are used to detect disease and risk factors. Exploratory laboratory tests are used in following and diagnosing acquired and congenital diseases in patients predicted with one illness [3, 4]. The objectives of the follow-up testing are: “confirmation of the diagnosis of the disease, confirmation of the severity, prognosis, determination of the effectiveness of the therapy, recognition of the appearance of the side effects of the medical treatment”, the collection of the follow-up data for patients with known disease, the monitoring or the effectiveness of the treatment.6The fundamental purpose of the laboratory tests is to obtain data that will constitute a pool of results to be verified subsequently and will generate feedback to clinicians and other professionals. During such activity, it is important to optimize public spending by addressing over-analysis issues. The results of examinations in laboratories are requested by all doctors, regardless of their specialization, so the number of tests for diagnosis, therapy, and observation is increasing. Ordering tests is the first diagnosis of a disease. A patient may have a lot of clinical symptoms, but none of them could be attributed to the illness or disease. All laboratory procedures ordered for the diagnosis “I do not know but I want to know” are also called “exploratory” laboratory procedures. This way can be used in patients with clinical symptoms that neither explained the patients’ psychological and physical conditions nor is typical for any disease. It means something unusual at the first glance. Either those symptoms cannot be easily explained and there are possibilities of being confused with one another. Those clinical situations like fatigue, weight loss, chronic diarrhea, or hepatomegaly or jaundice, for example, should be examined separately for dyspepsia, cough, acute diarrhea, anemia, pancytopenia, dysphagia, fever, axillary lymphadenopathy, arthritis, cellulitis in each patient. This approach should be applied to every clinic. Recommending tests is an important part of the medical duties of the laboratory and it is also worrisome. We must explain this problem with possible reasons, and we must create a manageable system strategy for this problem. An important part of our study was to reveal the laboratory diagnosis-oriented tests. Since there are no test recommendation programs for this purpose. In parallel with the studies mentioned before, a more repetitive program of similar scale, suitable for use in an anticipated laboratory information system of districts, was prepared and the performance of this program was validated. It was shown that the designed laboratory biochemistry test recommendation system performs well, and the data was evaluated. This test can be given to biochemists from different countries at different times and the result was not affected by the country or year.

2.2. Types of Reference Laboratories

At the intermediate level, mainly inside regional, secondary referral hospitals, a range of special references are performable, usually related to the fields of haematology, microbiology, and some chemistry investigations. The role of the broader spectrum laboratories is to cover all areas of laboratory medicine and provide diagnostic supporting expertise for clinicians and general practitioners (e.g. by interpretation of the laboratory results). Moreover, they are general referral centers with laboratory networks [1]. The concept of reference laboratories was established with the main aim to offer such

laboratory services that are not generally provided elsewhere in the country. These laboratories have a special responsibility for ensuring the harmonization and standardization of laboratory measurements and methods, research, serving additional expertise complementation, education, quality assurance of the laboratory practice, and providing consulting services, especially with the respect to disinfection and decontamination and remediation concepts.

In general, 3 different levels of laboratory services can be distinguished: basic, intermediate, and reference. The first two levels are usually located at the primary health care (PHC) level, while the latter is generally organized at the tertiary care level, for example in university hospitals [7]. At the basic level, the laboratory provides a limited number of tests, usually the most frequently occurring ones, while on the upper levels, a wide variety of specialties and intricate, time-consuming, and even high-cost tests can be performed. Furthermore, PHC laboratories conduct tests for use at the local level in-house. However, in more specialized and centralized, mainly university-affiliated and academic, tertiary laboratories (parts of reference centers), tests are not generally performed for local patient care in-house, but they serve a much wider catchment area, which may even expand to the whole country by being the reference laboratory for other laboratories.

3. Integration of Reference Laboratories in Primary Health Care

The shaping of separate competencies must be based on joining-up processes. Many practices are devoted to managing resources, educating physicians, and addressing the appropriate health and safety considerations. However, few studies have been devoted to the actual process of exchange between the laboratory and the health care facility. Laboratories should establish a relationship with the treating physician, so they are well positioned to provide the best possible diagnostic service. The laboratory must therefore evolve with the new paradigm and make themselves more open, more flexible, and technologically advanced. For further cooperation, the laboratory should engage in promoting a growth strategy for the overall health care system.

This article wants to suggest strategies for strengthening the role of laboratories in primary health care. According to the World Health Organization, diagnostics play a vital role in patient management, disease surveillance, outbreak control, early warning systems, and quality control in drug resistance. The WHO organized a consultation to identify strategic opportunities for making better use of integration for stronger laboratory systems. Based on this consultation and their experience, the authors suggest some strategies for strengthening the ways in which laboratories in reference laboratories integrate into primary health care services, which they believe would also be relevant for strengthening the role of laboratories in general lab systems. Laboratories in interconnected health care systems should receive samples and treatment requests from a “transmitter-agent” that includes additional clinical information. In turn, the laboratory must provide the “receiver-searcher” with interpretative comment of the highest quality.

3.1. Challenges and Solutions

Basic network of health care supplies using primary health care, municipal and district health care; administrative, territorial, and professional and functional organization of institutions, services, and organizations. In primary health care, the provision and method to get samples was not well organized and the laboratory services were not well established in all Primary Health Care Units. There is no real regional system for laboratory services in Primary Health Care in Montenegro. There are quality problems for all Pre-Analytical, Analytical, Post-Analytical phases and a quality management system

does not exist in Montenegro. The social, economic, and political level to favor a laboratory system in Primary Health Care is essentially lacking. Laboratory network strategy and systematic federal functions are essential for development and improvement of diagnostic capacities in Primary Health Care.

Primary health care represents a basic level of health care, which should be oriented towards the first contact with the patient, which should resolve most health problems and provide continuity of health care. Primary health care is characterized by teamwork, keeping of medical records, evidence-based approach to work, preventive and health-educational activities. Laboratory diagnostics as a research health care activity is always placed in the integral approach to diagnosis and treatment and is essential to the primary health care system due to the increased number of chronic patients. Stress is put on the economics and organisation of laboratory tests, and on the possibilities for improving the quality of laboratory diagnostics and the associated patient treatment.

4. Role of Reference Laboratories in Disease Diagnosis

Complete knowledge of molecular patterns in malignant melanoma (MM) patients is mandatory to better define the personalized therapeutic approach of these patients [6]. Many molecular and genetics mutated genes are the object of translational research from the Western world beside their randomized controlled phase III trial which have shown their pharmacological efficacy. However, except for diagnostic test and therapeutic molecules in medical oncology—for which validated (nutraceutical) or repurposing (oligotherapeutic and antibiotic molecules) knowledge are still far to have reached the phase III clinical trial—a therapeutic approach is still unknown of several MM-affected patient's molecular networks. In translational research various downstream messenger RNA levels are influenced positively and/or negatively to the molecular signals. therapy as hypothesis of integrated targeted the present narrative is focused on MM driver genes in the frontiers. Analyzing the molecular networks could be personalized future therapeutic approach and to design russian arm phase II studies for repurposing the new and old molecularly validated molecules.

The number of laboratory analyses ordered by general practitioners significantly impacted the laboratory's operations [4]. Since unnecessary laboratory analyses waste time and resources, as well as increase patient anxiety, the need to minimize their number in family medicine centers is clear. Local recommendations on laboratory utilization should be developed for primary health caregivers, to harmonize interdisciplinary collaboration following the standards established by the World Health Organization. The WHO emphasizes the importance of health personnel education and interdisciplinary collaboration for assessing medical laboratory technology within the 64 items of the World Health Assembly Resolution WHA64.7 in 2011. However, members of the primary health care team often differ substantially in their judgment on the necessity of laboratory analyses. Poor planning of laboratory analyses in family medicine centers leads to changes in the timeline of sample collection, as well as requiring the need for repeat patient visits. Coagulation studies are good examples, needing the urgent collection of the second sample from patient Pirates.

4.1. Key Testing Areas

They communicate with the entire network, mainly hospitals and outpatient practices including the local health authorities. In summary, the role of national and international reference laboratories is to provide the best possible specialist diagnostic service and to act as central contact points for medical and regulatory aspects. The implementation and improvement of this service should therefore be based on a comprehensive business continuity plan considering the patients in Germany and all neighboring

countries [8]. Key diagnostics for the cooperation are rapid detection of infection organisms including resistance strains and new agents, early diagnosis and therapy monitoring of patients with immune dysfunction, inherited and acquired coagulation disorders, genetic metabolic diseases, neurological disorders, and the main epidemic related and emerging important infections. New diagnostic tools for early diagnosis in cancer genetics must be implemented as fast as possible. Educational and data protection aspects are also important. Consequently, reference laboratories must be seen as an integral part of the health care system which provides analysis services characterized by the highest level of quality in their specific field.

First- and second-line diagnostic tests are an important part of every health care system and must be regarded critically [9]. Since laboratory investigations are a significant part of diagnostics, it is necessary to provide a good interpretation of results and advice for further diagnostic procedures. As an essential part of further decision-making, reference laboratories are responsible for the communication on how to interpret these test results and, when necessary, to indicate further investigations. Reference laboratories are designed to operate at the level of the patient data centre.

5. Quality Assurance and Accreditation in Reference Laboratories

Under accreditation, the laboratory becomes a part of a “network” and can have easier access to findings and resolutions. A laboratory can be regarded as a trustable center with accreditation, as audits and inspections are processed by third parties that are approved by the ministry of health. 10 Increased customer satisfaction and empowerment makes it easier to expand services. The goal of reference laboratories must be to minimize the total testing process error by contributing to the overall accuracy and reliability of laboratory testing and reducing patient risks. This can be achieved through standardization of laboratory processes, appropriate staff training, and careful selection and maintenance of equipment, following standard operating procedures. Therefore, internal, and external quality assurance and accreditation systems must be implemented, and this review aimed to provide detailed information on these systems for reference laboratories.

Laboratory testing is an important part of routine medical practices, and contributes to the prevention, diagnosis, and treatment of diseases. As a diagnostic pathway that informs 70% of clinical decisions related to the management of patients, appropriate and trusted results, robust quality management systems, and high-performing laboratories are considered necessary to end-users. 2 Reference laboratories have a key role in the prevention, diagnosis, and treatment of diseases, and their role and impact in contributing to the overall operation of health systems have been emphasized several times. Accreditation processes exist to confirm that the quality of the laboratory is good enough. Accredited laboratories ensure that both the staff and the management have knowledge, are well trained, and can deliver high-quality laboratory results. In addition, it shows that the laboratory runs with the quality management system approach. 11 Furthermore, ensuring the quality of all laboratory tests and services is mandatory and must be fulfilled for patient safety.

5.1. Importance and Standards

The private sector laboratories typically store most data in the laboratory information system (LIS) or hospital information system, and their laboratories typically have very strong quality controls in place. These programs have been in place for a long time [3]. There may be variations in the reports being generated. The way in which the standard operating procedures (SOPs) are generated in the private and public sectors are quite different—the scores are high in the private sector. It is vital to have SOPs to

standardize laboratory procedures and reporting methods. During the accreditation visits, these were areas that ‘interviewees’ refer, in general, biomarker 183 discussed with the assessors [10].

The quality and impact of research generated via a specific pandemic virus might primarily depend on the existence of, and quality of, testing laboratories which define the virus infection. In Malaysia, such detection amplified the role of two laboratories: the Institute for Medical Research (IMR)—a referral laboratory—and the National Public Health Laboratory (NPHL) as the national public health institute. Both these laboratories work in close tandem and by mutual support. IMR is the national centre for research, diagnostics, policy guidance, and capacity building in medical health sciences. Its Diagnostic Virology and Molecular Genetics laboratory is accredited to ISO 15189, and its virologists are well trained in diagnostics, typing, and analysis of the latest molecular and infection dynamics. The IMR also serves as the WHO National Influenza Centre (WHO NIC), supports case confirmation and certification, and is unique in producing antigen and PCR internal controls from isolated viral components by in-house production and training of reference laboratory candidates [12].

6. Technological Advancements in Reference Laboratories

The possibilities in the field of diagnostics have also been transformed by the more frequent use of advanced technologies in clinical chemistry such as liquid chromatography—tandem mass spectrometry and the large-scale application of pre-analytical and post-analytical data for the development of new biomarkers in fantastic settings [13]. However, the demand for diagnostic testing is not only increasing but also becoming more diverse, as testing becomes more accessible in primary care settings and as new biomarkers and testing technologies are established. The latter’s arrogance of diagnostic, prognostic and therapeutic properties of the molecule is reflected in the term “theragnostic parameters” which can help to tailor-treatment strategies to the individual patient needs. Another tendency in the development of technologies in clinical chemistry is the process of centralization of diagnostic tests, including the transformation of tests into measurements that are executed in “reference laboratories” [14]. This is like a process that has already taken place for information technology. However, while the centralization of the IT support in terms of a few gigantic factories is settled, the centralization of the measurement processes is not yet. Affiliating laboratories can perform an immense part of the analytical workload. Clinical chemistry must cope with these technological evolutions. Even within the reference laboratories, it must consider how the delivery of faster and more accurate test results may contribute to patient diagnosis and treatment. In this regard, the development of suitable responses also involves technological advances.

6.1. Impact on Efficiency and Accuracy

These errors can be mitigated by standardizing the laboratory methods and manual operations. The uniform manual and visual operator training will help minimize these errors. The standard and uniform training on operation of the laboratory equipment is also crucial for minimizing the errors during laboratory tests. Refresher training is required for laboratory technicians at regular intervals to maximize the reliability and validity of tests run and the data generated. Proper regular instrument documentation is required for tracking and traceability and thus eliminating mistakes. No unauthorised activities should be allowed in the laboratory room. Properly trained, validated, and certified laboratory technicians should only be allowed to conduct the tests. Thus, the study focused on the requirement of workforce and infrastructure for improved laboratory testing and diagnostics in rural health settings. Only a few

studies could be retrieved, highlighting the importance of the study and further need for setting up and logistics for the laboratory facilities in rural areas [15].

Before introduction of any new laboratory test or instrument into PHC level, three to six months of supervised observation should be conducted to assess requirements, identify operational constraints, and identify corrective action, if possible. The study report showed varied blood collection errors; no strength for pestle instrument was specified for blood collection in the written instructions. Filling of vials over the line required, poor coordination between laboratory workers while handling the blood for vials investigation leads to leakage and break down of tubes. Similarly, for SGOT tests, the sample collected for procedure was not according to standard prescribed [3].

Study on the workforce requirement, logistics and role of referral and hand-held point-of care tests in rural primary healthcare settings reports that there is a need for increasing the number of healthcare workers, such as technicians, and establishment of clinical services for diagnostic tests at various PHCs. Each primary healthcare (PHC) should have haemogram, biochemistry tests (total bilirubin, serum urea, fasting blood sugar, blood grouping and Rh, and rapid tests for malaria and urinary tract infection) performed regularly by well-trained laboratory technicians. In addition, PHCs must have established collection of blood samples for specific tests, routine maintenance, and certification of all equipment and research activities through awareness programs to prevent diagnostic errors introduced by equipment, sample preparation, and/or tracking errors [16].

7. Research and Innovation in Reference Laboratories

The aging of the population combined with advancing technologies, escalating health care costs, and increasing diagnostic information available for patient care will drive decentralization and expansion of diagnostic testing across the continuum of care long into the future. Private commercial laboratory organizations will be continuously optimized and consolidated at Clinical Chemistry, Hematology, Coagulation, Biology, Endocrinology, Immunology, Electrolyte, Serology, Microbiology, and Anatomic Pathology levels, as for-profit entities. Centralized, area, network, hub and spoken laboratory systems are the future of Reference Laboratories. These will offer a greater number of diagnostic testing services, driven by factors such as chronic disease clinical care, an aging population, new diagnostic technologies, genetics, test preciousness, and personalized medicine. Automation and analytical instrument development across all laboratory disciplines are both driving current innovation as well as future investment. New financial and management alignment and delivery models will be developed. The value of laboratory medicine supports the assertion that the discipline is directly responsible for providing helpful information and knowledge to assist in decision-making in the care, welfare, and health management of populations or individuals. No other medical specialty can directly influence and/or expedite the medical treatment process or directly measure patient care outcomes in a more real time manner.

Laboratory medicine is undergoing a significant transformation globally. The traditional model of pathology testing thrived within hospital-based laboratories. Over the past 60 years, in the U.S., the field of Clinical Laboratory Science transformed into Medical Technology. Approximately 70% of laboratory tests were performed in hospital-based laboratories by the principal health care provider until the mid-80s. Today, over 70% of all laboratory tests are generated by the principal healthcare providers, and less than 30% of laboratory tests are performed in hospital-based laboratories [17]. The laboratory testing space is rapidly changing because the types and numbers of laboratory report outputs are driving most of

the managed care in general, and individual patient medical decision making specifically. Laboratory Medicine is in a process of transformation to a highly service oriented continuum of care asset, especially in the population health space. The effectiveness of laboratory testing increasingly factors into individual physician medical decision-making, and the influence of the clinical laboratory on patient care outcomes will substantially increase, both individually and collectively, over the next decade. With the support and understanding of all clinical laboratory employees, the clinical laboratory profession can learn to embrace the concept of new age Laboratory Medicine and patient care, transforming into Clinical Laboratory 2.0. This will occur primarily because of fostering and inculcating a mind-set of continuous quality excellence, allowing laboratory professionals to collectively develop validated, enhanced diagnostic protocols capable of achieving in the future levels of evidence-based improvement influencing patient care and outcomes, derived from the clinical laboratory [18].

7.1. Collaboration and Partnerships

A small reference laboratory set up by professionals and built on the tested strengths of the colleague—the primary care physician — has immense potential to catalyse the community members realize their wellness potential [7]. Bringing the laboratory in ‘walk-in test centres’ closer to the affected family could be made an integral and essential part of the clinic. The outreach laboratory services may be appropriately organized to make the physicians available for relevant direct face-to-face discussion about the results, from Monday to Sunday. In time, all the involved professionals would feel responsible for the individual test result—with palpable concern for all the elements of test quality—to improve both the patient’s health and the community satisfaction.

Diagnostic performance is largely dependent on the quality and ordering of laboratory tests and the pre-analytical data provided [19]. A mechanism is required to ensure patient samples are both adequately collected and correctly labelled with important patient information such as gender, age, current medication, as well as time of last meal, diagnosis, and test history. The availability of these data is important to guide test decision making, improve the diagnostic process and patient outcome.

8. Economic Benefits of Reference Laboratories

A cost-effective laboratory test is any test that, if not done, leads to an increase in patients suffering. When properly implemented, stewardship activities improve patient health by providing clinically appropriate laboratory tests and decreasing the harm associated with unnecessary tests. Small laboratory stewardship practices are great opportunities to increase visibility of the laboratory as a meaningful player in patient care. In the inpatient setting, simple and targeted interventions can have financial benefits as high as four to eightfold. Moreover, inappropriate utilization of laboratory care in the ambulatory setting is associated with poor patient experience and high healthcare costs in primary care. In many underserved communities and among people of color, underutilization of tests for chronic disease management is a serious threat during the COVID-19 pandemic. Critical stewardship strategies under these circumstances involve implementing specific structured practices to ensure that necessary chronic care continues in parallel with preventive and outbreak diagnostic efforts. In American rural settings and tribal communities during the COVID-19 pandemic, fighting both test overutilization and underutilization requires a system of stewardship that engages patients, providers, and laboratory professionals in collaborative decision making.

Strong data from reference laboratory-based evidence assisting physicians could lead to changed practices with a more prudent use of laboratory tests [3]. In the last decade in South Africa, equipping of

laboratories and primary healthcare facilities has been a major focus of government [20]. In resource-poor countries, demand management and test stewardship may also act as effective interventions to reduce waste and misuse of finite resources [21].

8.1. Cost-effectiveness

The operational costs of a primary laboratory for a population of 100,000 vary in the states of Maharashtra and Goa, India. The laboratory services for a similar load will be relatively cheap in Goa as compared with the state of Maharashtra since the economy of the state is better [15]. Other factors such as transportation of supplies and results and salaries of the staff vary from state to state. We have seen from the data provided that the operational cost of a reference facility is higher than that of a primary laboratory. However, on a revenue basis, a reference facility performs better than the primary one. If the general populations and the institutional contributors are the same with increased payments for the services, a primary laboratory can meet only 80% of its operational costs. On the other hand, a reference laboratory will easily surpass the operational costs and start profiting from this basic activity.

The operational cost of a reference laboratory based on the profile of tests it performs, the reagents, the consumables, and the human resources, both technical and administrative, is higher than those of a primary laboratory [22]. However, the tests to be carried out in a reference laboratory are invariably more expensive when we do that in a primary laboratory. So, there will be trade-offs when a primary laboratory takes on additional tests at reference laboratory rates under the pressure of patient load [3]. It is theoretically possible to quantify such trade-offs, but it is difficult. So additionally, the role and impact must also be measured qualitatively and tailored to the local circumstances.

9. Case Studies and Success Stories

Add reference laboratory services to Community Health Centers (CHCs) to impact existing resources and contracts. Evaluate the potential value of implementation of molecular CT/NG point of care tests in clinical practice and compare the results with previous literature. Benefits and challenges must be considered in planning for implementation. Two cases are studied to demonstrate how the involvement of a large teaching hospital-based reference laboratory in the development of and services to CHCs solve the common problems of partnership and become the CHC test center. Enhanced test services help CHCs to improve the independent capability of diagnosing diseases, optimize labor distribution, and improve the patient experience. The management and relationship between the two hospital centers are studied to help CHCs' insufficient technical services. Improved staff training and use of mobile phone APPs help the general practitioner to improve his test level. nearby accredited reference laboratories, like the PCR laboratory, may support testing for rural Alberta's primary care. This case of a public health pathology strategy provides a foundation for transition from the central- ized strategy towards the locally available strategy, which may contribute to enhancing timely health-care delivery in rCHCs and smaller laboratories and to recovering the economy and life. The goal of this study is to contextualize what reference laboratories provide in secondary health-care settings to better understand what services could be recommended for implementation and the information required for laboratories to determine their role in testing for a new clinic [23]. Changes to clinical pathways and additional resources can have significant impacts on CHCs and need to be considered when implementing POC tests. The result of producing bacterial tests in the US compared to Canada is different. Including US values in the cost analysis could be considered in future research due to different healthcare system funding mechanisms.

The improvement in diagnostic rates shows the value in the implementation of a NAAT, although NAAT test costs may offset this.

9.1. Examples of Effective Implementation

BSRI is a nonprofit medical research institute based in metro San Francisco, California, with a staff of 30–35 scientists, data managers, project coordinators, patient-examiners, laboratory personnel, and administrative support staff. BSRI's operation is directly supported by three (NIH) grants and 5 AIDS Clinical Trials Group (ACTG) protocols, the latter of which are indirectly supported through a cooperative agreement between BSRI and the University of California, San Francisco (UCSF) under the umbrella of the AIDS Clinical Trials Group. In addition, we recently have achieved some of the first product placements in campaign resources by population services international (PSI) in Zambia and by sub-Saharan African (SSA) in South Africa [3].

Since its establishment in 1999, nonprofit program Blood Systems Research Institute (BSRI) had been developing expertise primarily around the management and execution of highly successful and sustainable U.S. National Institutes of Health (NIH) R01-type clinical trials in sexually transmitted infections (STIs), specifically the San Francisco Bay Area site of the National Institutes of Health–funded HIV Vaccine Research & Design (HIVRAD) and the HIV vaccine trials network (HVTN). Under the umbrella of these trials, the researchers have created a considerable amount of laboratory infrastructure—e.g., an extensive and well-characterized systemic repository, a successful biorepository, and a controlled storage and shipping protocol—thereby contributing to the HIV vaccine development enterprise. Thus, BSRI had achieved a very high reputation and market visibility in HIV/AIDS vaccine-preventive research.

10. Conclusion and Future Directions

International standards recommend comprehensive laboratory services at primary health care (PHC) level, with referral to reference laboratories (RLs) for specialized, complex, or non-routine testing. In Indonesia, a lower middle-income country, PHC services are provided in over 9000 community health centers (CHCs/rumah sakit bersalin desa) and over 10,000 health clinics (puskesmas) or health centers (rumah sakit umum), covering the vast archipelago with three time zones. The specific aim of the present study is to review KLS—particularly, how their work within healthcare is relevant to the goal to create and treat healthy communities in Indonesia and how they can bridge the gap in the level of service provision between PHC facilities and RLs.

The survey involved structured interviews with senior managers in four successful and two unsuccessful RLs, representing university, government, and private RLs. We conclude that in Indonesia sustainable laboratory services at PHC level require functional RLs; despite human and financial constraints, existing RLs have shown possibilities for growth in this direction. There is an opportunity for active implementation of the key recommendations of Clinical Laboratories 2.0 and collaboration among the stakeholders at national and regional levels [25]

Reference laboratories (RLs) have an essential role in the diagnosis and management of diseases by expert evaluation of patient samples referred from primary health care (PHC) level. This study reviews their role in Indonesia, a lower middle-income country facing a situation common in many countries. It uses Indonesia as a case, applying the Domain of Competences for Professional Practice (DCPP) scheme developed by European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). These

competences reflect internationally recognized practices in clinical chemistry and laboratory medicine, thus allowing generalization of the findings to other countries. 18

10.1. Summary of Key Findings

In a case study on the influence of laboratory services at primary health care centers on overall outpatient department performance, Kadam and Sule found that all three laboratory process indicators were significant predictors of facility cleanliness—where fewer than two laboratory indicators were present, facilities breached minimum hygiene levels [26]. In adjusted analysis, the mean difference was 0.6775 (95% confidence interval 0.0635/1.2915; <0.05), while unadjusted analysis showed minimum detectable levels of 0.7225. In adjusted analysis, in facilities with no laboratory process indicators, the mean patient care score was lower—mean difference 2.061. Nearly 50% of facilities provided some outpatient laboratory services PP, and 80% provided a quarter of facilities provided as high as 44% of services using SL. None of the facilities provided comprehensive laboratory services. In adjusted analysis, pharmacy stock out was associated with laboratory services, decaying moderate antenatal care services PI, and poor outpatient department scores for care and cleanliness. supplies were associated with laboratory service availability.

Medical laboratory technology in primary health care should be evaluated at each stage of the health care delivery process and within interdisciplinary teams to ensure the seamless continuity of care. In the United Kingdom, Wolfuth and Miah 4 evaluated the funding impact of a model for medical biochemistry testing developed and implemented in a GP surgery in Hackney. The researchers aimed to evaluate the success of the MMU in point-of-care testing by comparing the number of patient visits to the GP surgery in Hackney before and after the MMU. They issued new guidelines for the management of diabetes, which have been implemented successfully in primary care. Their multidisciplinary approach to the development and implementation of their novel model was commended. The general conclusion of their study was that the increased use of point-of-care testing both enhanced patient care and allowed the funding body to divert its resources to other areas of need.

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