Impact of Laboratory Accreditation on Patient Care and the Health System

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Abstract

Accreditation is emerging as a preferred framework for building quality medical laboratory systems in resource-limited settings. Despite the low numbers of laboratories accredited to date, accreditation has the potential to improve the quality of health care for patients through the reduction of testing errors and attendant decreases in inappropriate treatment. Accredited laboratories can become more accountable and less dependent on external support. Efforts made to achieve accreditation may also lead to improvements in the management of laboratory networks by focusing attention on areas of greatest need and accelerating improvement in areas such as supply chain, training, and instrument maintenance. Laboratory accreditation may also have a positive influence on performance in other areas of health care systems by allowing laboratories to demonstrate high standards of service delivery. Accreditation may, thus, provide an effective mechanism for health system improvement yielding long-term benefits in the quality, cost-effectiveness, and sustainability of public health programs. Further studies are needed to strengthen the evidence on the benefits of accreditation and to justify the resources needed to implement accreditation programs aimed at improving the performance of laboratory systems.

Recent years have seen unparalleled investment in expanding and improving health care for major diseases in the developing world. Countries, with support from the United Nations’ Global Fund to Fight HIV, Tuberculosis and Malaria, the US President’s Emergency Fund for AIDS Relief, The World Bank, The Gates Foundation, and other donors, have invested in expanding and strengthening public health services to save lives, reduce morbidity, and improve patients’ quality of life.1,2

These efforts have partnered with public health services in many developing countries to expand basic coverage of HIV, tuberculosis (TB), and malaria treatment and prevention services. For example, while more than 3 million people have gained access to HIV antiretroviral treatment during the past decade, an estimated 6 million people remain in need of life-saving treatment today.3 However, as efforts to expand services continue, increased attention is being given to ensuring that the efficiency, cost-effectiveness, and quality of delivered services are high. Bolstering the quality and competence of current services will likely improve the sustainability of large-scale public health initiatives and lead to improved outcomes for individual patients and programs. The trend with these strengthening efforts is to target health systems rather than specific disease areas. The intention is that, even if the entry point is HIV, TB, or malaria, there are spillover benefits for the delivery of health care for other important diseases, such as diarrhea, upper respiratory tract infections, parasitic infections, and a range of noncommunicable conditions such as diabetes and heart disease.

Laboratory testing is an essential component of improved health care for patients in resource-limited settings.4 Accurate and rapid diagnostic tests are required to diagnose illness,
identify causative factors, monitor the effectiveness of treatment, and perform surveillance for key diseases. Reliable and actionable test results are often a prerequisite to the delivery of high-quality patient care. Historically, laboratories in developing settings have been underresourced and marked by poor performance. This has fostered distrust in laboratory data among clinicians and helped to reinforce cycles of underinvestment in laboratory systems. Nevertheless, the demand for diagnostics in developing settings has increased substantially in recent years to meet the needs of expanded treatment and prevention programs for HIV and other major diseases, and there has been significant recent investment in improving access to testing.\(^5\)\(^6\) Expanded test menus are now available at even the lowest level of health care facility.\(^9\)

However, it is not enough to invest in the expansion of diagnostic access. Simultaneous improvements in the quality of laboratory testing are needed to ensure clinician and patient confidence in test results. Accreditation is widely used in developed countries to encourage or enforce improvements in the quality and reliability of laboratories. With significant investment beginning to be channeled into recently launched laboratory accreditation initiatives in resource-limited settings,\(^10\) it is worthwhile evaluating the impact that accreditation can have on patient care and health systems.

**Value of Laboratory Testing in Patient Care**

Laboratory results are required for making a large proportion of medical decisions. In developed countries, an estimated 60% to 80% of patient management decisions are based on laboratory data.\(^11\)\(^-\)\(^13\) Laboratory investigations are often more sensitive and specific than clinical decision criteria alone.\(^14\)\(^,\)\(^15\) Diagnostics and clinical patient management have an interdependent relationship; laboratory data provide justification for clinical decision making, while clinical signs or the clinical management protocol often prompt laboratory testing. For example, during the management of HIV infection, poor performance of tests at any stage of the care and treatment continuum (ie, diagnosis, disease staging, treatment initiation, the monitoring of drug efficacy and toxic effects) can reduce the effectiveness of treatment and deny appropriate care to patients in need by impeding the path of patients along the continuum.\(^\text{Figure I}\) Without a reliable diagnosis, patients will not receive most HIV-related services for treatment or prevention. Without an accurate CD4 cell count, many patients cannot have their disease correctly staged, which could prevent them from accessing lifesaving antiretroviral drugs before the onset of serious illness. Once a patient is receiving therapy, ongoing CD4, clinical chemistry, hematology, and, in some settings, viral load tests provide clinicians with necessary information on the safety and efficacy of the drugs. If these tests are not available or are inaccurate, treatment outcomes for patients are likely to be poorer, with higher mortality and more frequent illness.\(^16\)\(^,\)\(^17\) Reliable laboratory testing is needed, or the scale-up of treatment programs may be retarded and their long-term effectiveness and sustainability reduced.

While cost and infrastructure development are notable challenges to providing laboratory testing services, policymakers have to weigh the benefits of diagnostics against the opportunity to invest in other areas of the health care system. Unfortunately, while the benefits of laboratory tests may seem obvious, there are few studies in resource-limited settings that quantify the usefulness and cost-effectiveness of diagnostics in terms of patient lives or life-years saved. One recent study demonstrated that patients receiving HIV antiretroviral treatment over 5 years without laboratory test results had approximately one third increased risk of death,\(^16\) while another study found a significantly increased risk of death in patients continuing an undiagnosed, failing HIV drug regimen.\(^17\)
Owing to long-term underinvestment in laboratory networks, there is considerable unmet need for reliable diagnostics services in many developing countries. Representative data show that more than two thirds of pediatric febrile illnesses in Africa are not malarial and that accurate diagnosis could drastically reduce the unnecessary use of expensive combination-drug antimalaria therapy and help ensure that patients receive the correct treatment. The World Health Organization (WHO) estimates that fewer than 10% of malaria cases in Africa are properly diagnosed by using microscopy or rapid tests. It is further estimated that more than 95% of patients with multidrug resistant TB globally are not treated with appropriate second-line drugs, in large part owing to lack of access to diagnostics. These examples highlight how reliable and timely testing services could benefit patients with malaria and TB and reduce the risk of disease spread into their communities.

**Laboratory Errors and Patient Care**

Diagnostic testing today typically involves multistep processes subject to multiple sources of error. Many tests in small to medium-sized laboratories are manual or automated and subject to inaccuracy associated with lack of operator competence or failure to adhere to standard test procedures. There are also other sources of error, such as incorrect reagent storage or expiration and instrument inaccuracy. Even the simplest tests have multiple stages at which errors could be introduced. Commonly used tests (eg, rapid test strips, TB sputum smear microscopy, semiautomated chemistry analysis, and HIV nucleic acid testing) each have up to 45 steps that are susceptible to error. Manual assays are particularly prone to inaccurate pipetting, cross-contamination, or the mixup of samples. Automated assays are subject to instrument errors due to miscalibration or other instrument malfunction. Improper storage or the expiration of test reagents can also lead to inaccurate results. Errors can also be introduced during sample collection, labeling and transportation, registration at the laboratory, or the transcription and delivery of results. Combined, these errors can lead to significant variance in the accuracy of the reported result, potentially leading, in some cases, to incorrect diagnosis, inappropriate treatment, or withholding of lifesaving therapy.

Studiersthe the United States and Europe have demonstrated that errors occur throughout the testing process, including the preanalytical stage (sample collection, labeling, and transport); analytical stage (testing in the laboratory); and postanalytical stage (data management and reporting results). The majority of errors occur outside of the laboratory in the preanalytical (46%-68%) and postanalytical stages (18%-47%). This does not include clinic-based errors that occur in deciding which tests to order and in the interpretation of test results, both areas of high error risk. The frequency of errors during the analytical stage is lower but remains significant, estimated to be between 7% and 12%, despite years of quality management regulation. In the United States, it is estimated that 6% to 12% of laboratory errors put patients at risk of inappropriate care and potentially of adverse events, whereas 26% to 30% of errors have a negative impact on other aspects of patient care.

The magnitude of laboratory errors in resource-limited settings is not well documented. It is likely that error rates and their impact on clinical decision making and patient outcomes are greater in resource-rich settings, but studies to evaluate this are needed.

**Laboratory Accreditation**

The variability of test results and the frequency of errors can be reduced by implementing and monitoring a comprehensive laboratory quality management system. In developed country settings, this has included participation in regular proficiency testing (PT) and enrollment in accreditation programs. Accreditation provides verification that laboratories are adhering to established quality and competence standards deemed necessary for accurate and reliable patient testing and the safety of staff and the environment.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Error-Susceptible Steps in the Testing Process for Common Clinical Diagnostic Tests and Number of Essential Consumables Required for Each Test</th>
<th>No. of Error-Susceptible Steps</th>
<th>Consumables Needed to Perform Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid test (malaria, HIV, syphilis)</td>
<td>11</td>
<td>4-5</td>
<td></td>
</tr>
<tr>
<td>Hemoglobin (manual/semiautomated)</td>
<td>9</td>
<td>5-9</td>
<td></td>
</tr>
<tr>
<td>CD4 testing (automated BD FACSCount, BD Biosciences, San Jose, CA)</td>
<td>13</td>
<td>9-11</td>
<td></td>
</tr>
<tr>
<td>Tuberculosis sputum smear (microscopy)</td>
<td>20</td>
<td>10-12</td>
<td></td>
</tr>
<tr>
<td>Clinical chemistry (automated)</td>
<td>12</td>
<td>12-15</td>
<td></td>
</tr>
<tr>
<td>HIV DNA polymerase chain reaction (Roche Molecular Diagnostics, Pleasanton, CA)</td>
<td>45</td>
<td>22-25</td>
<td></td>
</tr>
</tbody>
</table>
Laboratories that achieve accreditation are recognized for superior test reliability, operational performance, quality management, and competence. A functional national laboratory accreditation initiative within a country requires at least 3 elements: a laboratory policy framework that makes accreditation a requirement for laboratories, designated quality standards against which laboratories can be assessed, and accrediting bodies (local or international) authorized to assess laboratories and certify their performance against the designated quality standards.

Accreditation is most effective when it is rooted in a policy framework for evaluating laboratory quality and patient safety. In some countries, accreditation is a mandatory requirement for testing operations, while in other countries, accreditation is voluntary and driven by market incentives. Governments may stipulate that laboratories functioning below the accreditation standard be required to submit detailed improvement plans and take timely action to demonstrate compliance, with continued failure to comply resulting in penalties, service limitations, and prohibitions against further testing. To set up a national laboratory policy in-country may require new laws or an update of existing legislation. For example, in the United States, the Clinical Laboratory Improvement Amendments (CLIA) provide an example of legislative action to regulate laboratories and improve the quality of testing services.28-31 The amendments stipulate that all laboratories conducting non-research testing on humans observe certain minimum quality standards, participate in PT, and submit to biannual inspections. Laboratories can fulfill this inspection requirement by subscribing to the accreditation program of one of several government-endorsed accreditation providers.

International and/or national quality standards are the backbone of accreditation. Standards provide the guiding framework within which laboratory performance is evaluated. ISO 15189, a laboratory standard from the International Standards Organization (ISO), specifies quality management system and competency requirements for medical testing. Based on ISO/IEC 17025 and ISO 9001, it has gained widespread recognition as a reference standard for accrediting clinical laboratories. For example, the recently launched WHO Regional Office for Africa (AFRO) Laboratory Accreditation Program has harmonized its assessment tools to ISO 15189, and laboratories working through the program will progressively develop compliance with this standard.

While accreditation is common throughout the developed world, most laboratories in resource-limited settings are not accredited. For example, in a review of College of American Pathologists (CAP), Joint Commission International (JCI), South African National Accreditation Services (SANAS), United Kingdom Accreditation Services (UKAS), Clinical Pathology Accreditation (CPA), and National Association of Testing Authorities (NATA) online registers for accredited laboratories in sub-Saharan Africa, we found there were only 3 International Laboratory Accreditation Cooperation-affiliated national accrediting bodies and fewer than 30 laboratories outside of South Africa that have been formally accredited, primarily in the private sector. For countries in which national accrediting bodies are not yet established, regional organizations and providers with international experience are sometimes used. The Southern African Development Community (SADC) has recently established the SADC Accreditation Service (SADCAS) to serve its member states. International accreditation services for clinical laboratories can be contracted through CAP, JCI, UKAS, CPA, NATA, and SANAS, among others.32 The WHO-AFRO laboratory accreditation program will soon begin to provide services across a number of African countries. Therefore, an increasing range of resources exists that can be accessed by countries and laboratories seeking accreditation.

Impact of Accreditation

Adherence to such quality standards—and participation in accreditation programs that certify this adherence—can improve operational efficiency and customer service and reduce rates of laboratory errors. While there are limited published data that directly link accreditation to reduced laboratory errors and patient outcomes, studies have clearly shown that participation in PT programs, a key component of accreditation, leads to more accurate test results. For example, participation in just 3 rounds of an external CD4 PT program resulted in a 26% to 38% reduction in errors in the CD4 count among laboratories.33 When PT participation became a standard requirement in the United States, PT failures among laboratories were noted to decrease with successive PT challenges, as has the percentage of laboratories cited for deficiencies during successive inspection cycles.34 In high-resource settings with strongly performing laboratories, the impact of accreditation may be modest. For example, accreditation of cervicovaginal screening laboratories in Singapore led to relatively minor improvements in quality performance.35 It can be assumed that laboratory system strengthening initiatives necessary to accredit developing country public-sector laboratories will yield direct improvements in the quality of testing. It is likely that patients will benefit from improved medical decision making resulting from a reduction in test errors. However, data are limited, and studies of the impact of accreditation on laboratory error, testing quality, and patient outcomes in resource-limited settings are needed.

Emphasis on accreditation is also likely to be beneficial for individual laboratories by providing incentives to consistently achieve the performance levels required to maintain their accredited status. During the accreditation process,
individual laboratories participating in assessments typically identify areas that require attention and focus their improvement efforts in a systematic and strategic manner. This creates a positive feedback loop that helps to accelerate improvements within each laboratory, making the process toward accreditation beneficial even before accredited status is attained. Once accredited, individual laboratories take on greater accountability for their performance. This may reduce the need for supervision and supportive funding, allowing investments in laboratory strengthening to be refocused on other aspects of testing services or other areas of the health system.

Efforts to implement accreditation can also help accelerate improvements in the operational systems supporting large-scale laboratory networks. Many countries are undertaking initiatives to strengthen different aspects of their national public health laboratory systems, eg, laboratory policy updates and long-term strategic planning, improved procurement and supply chain systems, laboratory networking and sample referral, human resources management and training, instrument service maintenance, and data and quality management. Each of these areas will need to be strengthened before laboratories can achieve accreditation. Accreditation can provide a well-defined vision and focus for laboratory system development, guiding continued investment in system strengthening and driving greater coordination and synergies between different strengthening initiatives.

Accreditation provides much needed quality standards for diagnostic services. Drugs are commonly required to meet international quality standards; however, in many countries, clinical laboratory testing is often not held to analogous standards. Testing is a decidedly more complex process than delivering drugs, with greater variability in quality and higher potential for incorrect, misleading outcomes. Ensuring that patients get standardized, high-quality testing meeting international standards should be a universal priority. Accreditation provides a mechanism by which patients, health care organizations, and governments can measure the performance of laboratories against international standards. Accreditation promotes trust in laboratories and confidence among authorities, health care providers, and patients that laboratories and the results they produce are accurate and reliable. Successful laboratories can justify the resources they need to maintain quality. Increased resources, in turn, help improve laboratory capacity and may boost performance. The challenge for many laboratory networks today is to visibly improve their performance to a level at which this type of positive reinforcement begins to take effect.

Accreditation is likely to have spillover effects on the performance of other areas in the health care system. Laboratory-driven improvements can help improve health care management more broadly. For example, improved supply chain requires improved forecasting skills and better inventory management and consumption-tracking systems. The process of upgrading these systems at a national level could also benefit systems for drug supply chain. Furthermore, the example of laboratory accreditation, with its established and structured processes, defined standards, and accrediting bodies, can demonstrate the benefits of systematic performance evaluation and ongoing quality improvement and could catalyze the impetus to improve patient care across the entire health care system.

Conclusions

As governments, donors, and other organizations seek to strengthen access to essential diagnostics in resource-limited settings, simultaneous improvement in the quality of testing should be of high priority. Laboratory accreditation is the internationally accepted framework for increasing test quality and reducing the frequency of laboratory errors. Higher quality laboratory testing associated with accreditation is expected to improve patient care by aiding the timeliness and accuracy of medical decision making. Accreditation programs can help drive improvements in the management of individual laboratories and laboratory networks and may also have positive spillover effects on the performance in other sectors of the health care system. Studies are needed to better define this and the relationship between accreditation and improved patient care. Nevertheless, ministries of health, donors, and other development agencies should start now to make accreditation of public laboratories a high priority and should undertake coordinated efforts to integrate accreditation programs into their policy, planning, and health system strengthening initiatives.

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References


