The Need for Standardization in Laboratory Networks

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Abstract

Expanding health care services for HIV, tuberculosis, and malaria has increased the demand for affordable and reliable laboratory diagnostics in resource-limited countries. Many countries are responding by upgrading their public laboratories and introducing new technology to provide expanded testing services into more regions. This expansion carries the risk of increasing the diversity of an already highly diverse technology and testing platform landscape, making it more difficult to manage laboratory networks across different levels of the health care system. To prevent this trend, countries are recommended to implement policies and guidelines that standardize test menus, technology, platforms, and commodities across multiple laboratories. The benefits of standardization include rational prioritization of resources for capacity development and more efficient supply chain management through volume-based price discounts for reagents and instrument service. Procurement procedures, including specification, prequalification, and contract negotiation, need to align with the standardization policies for maximum benefit. Standardization should be adhered to irrespective of whether procurement is centralized or decentralized or whether carried out by national bodies or development partners.

International public health efforts to control HIV, tuberculosis, and malaria in resource-limited settings have led to the rapid expansion of prevention, care, and treatment programs in recent years. In many regions of Africa, Asia, Latin America, and the Caribbean, growing national and international expenditure on these programs has led to a substantial investment during the past 5 years in health services infrastructure in resource-limited settings with benefits that spill over to general health care. Laboratory tests are increasingly being used in these programs and are recognized as essential for surveillance, patient management, and programmatic decision making. Governments are faced with the challenge of managing the scale-up of laboratory testing and the introduction of new technology while ensuring cost-effectiveness and long-term sustainability.

In recent years, significant effort and resources have been applied toward laboratory-strengthening programs in resource-limited settings. This has included the upgrade of the physical infrastructure and water and electrical supplies, pre-service and in-service training of technical staff and clinicians, and the strengthening of operational systems such as quality management, logistics, and supply chain management. Besides these investments, even greater resources are required for laboratory commodities (test reagents and consumables). In the case of HIV antiretroviral treatment in some settings, up to one quarter of recurrent expenditure is spent on diagnostic equipment and commodities, representing the second highest expenditure after antiretroviral drug purchases Figure 11.

Mechanisms are required to manage and reduce these costs where possible, without compromising the quality of patient care. Approaches include volume-based discounts and improved supply chain management. However, despite
increased budgets for diagnostic supplies and higher commodity procurement volumes in many countries, economies of scale and efforts to reduce cost are often not realized owing to disaggregated and poorly organized procurement and supply chain systems. The market for laboratory equipment and test commodities remains highly fragmented in many countries, which leads to logistic problems such as unpredictable order specifications, quantities, and delivery schedules. These factors result in supply inefficiencies that affect the cost of manufacturing, distribution, and after-sales support, which, in turn, lead to higher costs for consumables and instrument service, more frequent testing stoppages, expensive emergency orders, and overstock wastage. This can have a negative impact on the operation and scale-up of large public health initiatives.

A number of approaches can be taken to address these challenges. One of the most important interventions is standardization and harmonization across the laboratory network, including the establishment of standard test menus and the use of common testing technology, instruments, and test devices (platforms) and consumables. Policies and guidelines that promote standardization can improve the operation and efficiency of laboratory networks. These policies achieve maximum benefit when they are consistently implemented across all laboratories providing public testing services. The benefits, drawbacks, and challenges to standardization are outlined in this article, as are recommendations for implementing standardization policies that can be used by policy-makers and managers of laboratory networks.

**Standardization in Laboratory Networks**

Public medical laboratories often form a tiered network of testing facilities operating under common principles and procedures with a rational distribution of testing capacity. The networks may include government-run and private units that are commonly integrated with hospitals and clinics. Typical networks consist of 3 to 5 levels or tiers, depending on whether testing is conducted in health center facilities and whether the network includes reference laboratories. Table II. Laboratory networks require a degree of central management and direction setting through national laboratory policies and regulatory oversight and coordination of operational functions such as procurement, quality assurance, and logistics to ensure more efficient operation and collective benefits across all laboratories. The establishment of policies and guidelines on the standardization of test menus, service delivery, and technology across the network promotes more efficient and cost-effective operation and management of the network, and the policies and guidelines are implemented through strategic and operational plans for laboratory strengthening that define the priorities, timelines, and resources needed.

The first step toward standardization in laboratory networks is the establishment of common test menus within each level of the health care hierarchy. These menus should be harmonized between different levels and based on the minimum package of health care services, tests required for locally

**Table II**

**Recommended Four-Tier Structure for Public Medical Laboratories**

<table>
<thead>
<tr>
<th>Laboratory Level</th>
<th>General Description</th>
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<tbody>
<tr>
<td>I, primary</td>
<td>Health post and health center laboratories that primarily serve outpatients</td>
</tr>
<tr>
<td>II, secondary</td>
<td>Laboratories in intermediate referral facilities for health centers (e.g., district hospitals)</td>
</tr>
<tr>
<td>III, tertiary</td>
<td>Laboratories in a regional/provincial referral hospital that may be part of a regional or provincial health administration</td>
</tr>
<tr>
<td>IV, national/multicountry reference laboratory</td>
<td>Reference laboratories for ≥1 countries</td>
</tr>
</tbody>
</table>

*Based on Maputo Harmonization 2008. In some countries additional tiers may exist.*
prevailent conditions, and the available capacity and infrastructure (laboratory space, water and electricity, personnel), degree of remoteness, and the size of the population served. Owing to constraints in infrastructure, human resources, and other factors, it is neither feasible nor practical to establish similar laboratory capacity at all levels of health care delivery from central to remote areas. In addition, fewer diagnostic tests may be required at clinics at lower levels in the network with a more limited range of health care services. To ensure universal access to all essential tests, robust linkages between clinics and laboratories at different levels are required. At lower levels in the network, a more limited range of tests is conducted on site, while others require referral of samples to higher level laboratories.

The next step toward standardization is the selection of common technology and testing platforms to be used across multiple laboratories, eg, flow cytometry for CD4 cell counts or lateral flow rapid tests for malaria diagnosis. This often entails the selection of preferred instruments or other test devices, as well as reagents and consumables, that meet required technical performance criteria. These are often produced by specific suppliers. There are a number of benefits from restricting testing across the network to a limited range of platforms and laboratory supplies, as described in the following section.

Benefits of Standardization

Planning and Resource Allocation

One of the principal values of standardization is the clear definition of test menus and diagnostic supplies required at each level of the laboratory network. This makes it easier to project resource needs from year to year and also simplifies forecasting and budgeting for reagents and consumables, as well as planning for infrastructure and capacity development. Standardization can, therefore, improve the organization and management of laboratory networks, potentially leading to improvements in the quality of testing and patient care.

Procurement and Supply Chain

Standardization can help improve the efficiency of procurement and supply chain management across laboratory networks and help ensure that the correct testing supplies are available when needed. Networks that implement common test menus, technology platforms, and supplies across multiple laboratories can aggregate testing volumes across these laboratories to more easily negotiate bulk discounts for reagents, consumables, and related laboratory services than if the volumes are split among a larger range of suppliers. By limiting the number of order transactions and/or improving the predictability and forecast accuracy of orders, the procurement process becomes more efficient.

Consolidating volumes from multiple laboratories into negotiations with the vendor, or pooled procurement, requires some degree of central coordination of procurement or contract negotiation. This may not always be easy if the network laboratories are independently managed and if procurement is normally decentralized. However, if the laboratories are standardized, the benefits of pooled procurement are significant enough to justify the establishment of mechanisms for coordinating procurement, or at least contract negotiation, from a central point. This can be done irrespective of whether orders are placed and payments made in a centralized or decentralized manner Table 2.

To implement pooled procurement, a central body, eg, the ministry of health or central medical store, establishes an umbrella agreement on pricing, terms, and services with the vendor. The terms of this agreement can be accessed by all laboratories in the network, irrespective of whether the order is placed and paid for by the central body or whether each laboratory procures directly, provided the terms of the umbrella agreement are adhered to by the vendor for all eligible purchasing laboratories. There are certain responsibilities for the central body to conduct on behalf of all laboratories in the network, including the following:

- Technology selection and standardization
- Forecasting demand and negotiating contracts
- Monitoring supplier performance and product quality
- Overseeing reagent distribution

<p>| Table 2 |
| Characteristics of Centralized and Decentralized Procurement Approaches in Laboratory Networks |</p>
<table>
<thead>
<tr>
<th>Procurement Approach</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decentralized</td>
<td>Each individual laboratory or hospital manages the entire procurement cycle from planning to tendering and ordering. Minimal central involvement may involve approving budget allocations or monitoring adherence to regulations, policies, or guidelines.</td>
</tr>
<tr>
<td>Centralized</td>
<td>A single organization has an aggregate understanding of the country’s laboratory network, testing needs, and funding sources and uses its information to manage the system, including forecasting, tendering, supplier selection, contract negotiation, and ordering.</td>
</tr>
</tbody>
</table>
• Aggregating site information to manage the system
• Working with prequalified vendors to ensure product consistency and lower prices

Different stages of the procurement cycle are easier to manage when a standard range of products is routinely ordered, including forecasting, specification, warehousing, inventory management, distribution, and consumption tracking. This also allows manufacturers to synchronize their production and supply chains with demand. Vendors may have greater incentive to support distribution and after-sales service, eg, distribution systems or the provision of in-country engineers for service and maintenance and stocking of spare parts. These benefits cannot be realized if test menus and testing platforms are not standardized.

Standardization may also make it easier to bundle the procurement of certain products, including products that are commonly used or that have specialized use. For example, all consumables related to sample collection or the conduct of a particular diagnostic assay can be procured together, rather than from a number of different suppliers, to ensure homogeneous quality from one round of procurement to another. Bundled procurement, or procurement in lots, can simplify the range of suppliers that procurement departments have to deal with and can focus procurement on suppliers and products of established performance and quality. The rules of competitive tendering can still be applied in the case of bundled procurement, provided they allow for consideration of quality and technical performance.

Instrument Service

Standardization and pooled procurement provide opportunities to improve the design of service and maintenance agreements and to lower response times and reduce cost. For example, if the network standardizes CD4 cell counting with 1 or 2 models of flow cytometer for multiple laboratories, the service arrangements for these instruments can be combined into a single agreement, providing an opportunity to spread certain fixed costs, eg, engineer travel and spare parts, across multiple instruments in a network. In addition, a group service agreement for multiple instruments may allow a renegotiated number of repair visits per machine to be pooled and used as needed for instrument breakdowns across the network, instead of limiting each instrument to a fixed number of repairs. Problematic instruments may require more repair visits, while stable instruments require fewer. Annual service costs for multiple instruments can also be pooled and then bundled into the pricing of reagents to eliminate the need for separate service contracts, which are often neglected. With this approach, there may be fewer testing stoppages owing to lapsed or absent maintenance contracts on individual instruments or an exceeded number of repair visits.

Technology Selection

Standardization requires that laboratory instruments, reagents, and consumables are selected based on specific criteria such as quality, performance (based on licenses or evaluations), existing installed base, and technical recommendations. This can help limit the diversity of platforms and ensure that only products of the required standard are used at each health care level. Establishing such standards is important because successful laboratory testing often requires products with specific qualities. For example, a specific type of sample collection tube, calibration reagent, filter paper, polymerase chain reaction machine, or growth medium may be preferred or required, based on proven performance or optimization with a diagnostic test or the test manufacturer’s recommendations. Hence, technical preferences exist and are exercised for specific products based on their performance or other distinctive features. These may be available only from select suppliers. Unlike drug procurement, many laboratory equipment, reagents, and consumables are not typical commodities, ie, products from different suppliers may not be easily interchangeable owing to differences in specifications that have an impact on test performance. This may limit the range of suitable suppliers. This is particularly true of newer technologies, some of which are being implemented in expanded HIV, tuberculosis, and malaria programs in resource-limited settings.

Standardization policies can also provide the justification for prequalified or single-source procurement. For example, often the installed base of equipment requires specific test reagents and consumables, which may be available from a limited range of suppliers or a sole source. If a country uses a certain brand of CD4 count machine, then it is generally not possible to exchange the installed base of instruments annually with each round of reagent procurement. In many cases, the reagents for automated analyzers have to be procured from the manufacturer of the instrument in each procurement cycle until the equipment changes. Policies on standardization can help establish standard product lists and specifications and provide justification for the use of prequalified technologies and platforms or sole-source procurement for specific products. While open procurement promotes competition among commodity suppliers and is generally considered good practice (eg, as a safeguard against corruption), it may not always produce the best outcomes for laboratories. Prequalification allows competition to continue among high-performing suppliers of the same technology while limiting the risk of low-quality or incorrect products being procured. Standardization policies provide justification for prequalification criteria and help ensure that price is not the primary factor driving procurement decisions by including technical criteria in the decision-making process.
Standardization may help resolve challenges resulting from the use of “open” analyzers and generic reagents. Many models of instruments require laboratories to use proprietary and often expensive reagents. This has promoted a preference for open instruments that are able to use generic reagents. For example, this preference is common with low- and intermediate-volume chemistry machines. Reagent stock-outs have been a perennial problem in many resource-limited settings, and procurement bodies have tried to ensure alternative reagent sources. As a result, open systems are today highly valued, and the ability to run generic reagents is often specified in instrument tenders. Although the use of open platforms helps ensure easier access to low-cost reagents, when there are multiple competing suppliers, procurement decisions may be driven more by competitive pricing than proven performance. Poor-quality or frequently changed reagents can affect testing reliability. For example, many open chemistry instruments require recalibration if a reagent from a different manufacturer is used, and some laboratories may fail to do this. Restricting procurement to one or a limited number of reliable reagent brands with a known track record of performance can help resolve these problems. Laboratory personnel can be trained to use and calibrate their instruments appropriately with the commonly used reagents. By prequalifying suppliers of the selected reagent brand, it may be possible to negotiate competitive prices in return for regular orders. If the reagent supplier also services the instruments, this may provide additional incentive for the supplier to ensure the instruments are kept operational.

**Quality**

The implementation of multilaboratory quality assurance programs is simpler with a smaller range of instrument types because this allows more statistically meaningful comparison of internal and external quality assurance results among peer platforms. Networks also have to validate and track postmarket performance on fewer platforms, making management of the instrument network less challenging. Standardization also enables laboratories to collaborate on testing by sharing testing reagents or sample loads, thereby preventing problems with the interpretation of test results from different instruments in cases in which they differ.

**Training**

Standardization reduces the need for continuing education of in-service technicians. Owing to high staff turnover, skill sets to run less common instruments may be lost, and it can be costly and difficult to maintain adequate numbers of laboratory staff proficient on testing platforms if these change frequently. For example, many countries have standardized certain brands of rapid tests; in those countries, introduction of a new set of tests may require retraining of many health care workers. Moreover, with fewer types of testing systems in use, there is greater opportunity for technicians to be able to share experiences and problem-solving tips.

### Challenges to Standardization

#### Existing Diversity

The medical diagnostic market is highly diverse, with multiple test platforms and sometimes multiple sources for reagents and consumables for each test platform. An intermediate-sized laboratory can be required to procure and track 200 to 400 distinct products, each of which may have multiple manufacturers and distributors. A survey in 2007 of clinical chemistry, hematology, and CD4 instruments and malaria rapid tests in use within public laboratories in 15 countries in Africa and the Caribbean found 90 different manufacturers and more than 300 products (unpublished data)Table 3. The survey also found high intracountry variability in diagnostic products. This diversity is suggestive of a historic lack of standardization that may influence the deployment of new technologies. It is difficult to standardize across a network with a high variety of platforms in current use. Few laboratories like to retire instruments that are otherwise operational, and training on new platforms can be costly and unpopular.

#### Fragmented Procurement

The decentralization of government functions such as the procurement of medical supplies can lead to fragmentation of procurement decision making and to the use of a wider range of technologies. For example, where previously a central procurement body made technology choices and paid for instruments and commodities, provinces, districts, and individual laboratories now increasingly procure autonomously with their own funds and make independent technology and vendor choices. In addition, some instruments may bypass existing selection criteria via donations from...
nongovernmental organizations that are passed into government ownership. Sometimes this is done without adequate consultation on the existing equipment standards or installed instrument base.

**Criteria for Technology Selection**

Standardization is simplified when well-recognized performance standards can be used to select quality products. Certain laboratory instruments and reagents used for in vitro diagnosis are licensed or recommended for use by the US Food and Drug Administration (FDA), the European Conformity In Vitro Diagnosis (CE-IVD) licensing, the World Health Organization (WHO), or the Centers for Disease Control and Prevention (CDC). However, many products do not carry this licensing or recommendation, particularly new technologies or technologies designed for resource-limited settings. Furthermore, these standards are not always appropriate for countries outside North America and Europe, and few countries have their own licensing bodies. These countries have to conduct their own evaluations, which is not always possible, or rely on local performance data from other countries. The absence of clear-cut and widely accepted performance data for certain testing platforms hinders the rational selection of technology and testing platforms during standardization. International prequalification systems for diagnostic devices are being developed and will assist; however, in the interim, countries should develop robust selection procedures that will permit platforms to be objectively evaluated by local evaluations or review of performance data from elsewhere.

In many settings, laboratory procurement decisions are made by nontechnical personnel, and appropriate technical specifications may not be represented adequately in the decision-making process. In the absence of standardization policies, ordinary procurement selection criteria may fail to rule out inappropriate or low-quality products and poorly performing vendors. Hence, technology selection needs to be guided by standardization policies based on technical performance to prevent increased platform diversity.

**Risks of Standardization**

**Reduced Competition**

Standardization aims to curtail counterproductive diversity in the range of technologies and platforms in use within laboratory networks. However, concerns may arise that without a high degree of transparency, monitoring, and accountability, standardization favors certain technologies or suppliers while disadvantaging others and, as a result, facilitates anticompetitive and monopolistic practices. Inflexible decisions on technology selection can be counterproductive, and prices may increase if a supplier takes advantage of overdependency on its platform. Serious problems with performance may be overlooked, and switches to alternative technologies may be hindered by inflexible regulations on platform choice or if programs for postmarket surveillance are not in place.

**Restricted Access to New Technologies**

As new technologies are developed and released, vendors may avoid or delay investment in countries that are not open to new diagnostic platforms. New technologies may not have the track record or distribution network of established devices; hence, significant investment may be required from the supplier to gain a foothold in a market dominated by existing platforms. Slowing access to improved or cheaper technology can affect patient care and the laboratory budget.

**Increased Risk of Testing Failure**

By establishing preferred technologies and platforms, unhealthy dependency on certain instruments or suppliers may be created. For example, restriction to one chemistry platform across multiple laboratories increases the risk of testing stoppage or widespread testing errors owing to national or international reagent or consumable shortages, product quality problems or withdrawals, or problems with the financial health or operations of the supplier. If such problems arise, it may be difficult to switch to an alternative platform at short notice owing to the existing installed base.

A set of recommendations is outlined to guide standardization and to help limit the impact of the aforementioned risks.

**Guidelines for Standardization**

For laboratory networks to benefit from standardization, policies are required to guide test distribution, technology choice, and procurement. However, laboratory standardization policies and prequalification procedures do not always exist or may need to be updated. Test menus by health care facility may vary by country, local epidemiology, and available resources. Basic national public health packages often define the diagnostic service offerings at each level of the health care hierarchy. With respect to standardization of technology choice, limited international guidance exists on which instruments and reagents are reliable. FDA, CE-IVD, WHO, or CDC approvals are not always available, especially with emerging diagnostics that are not designed for markets in the United States or Europe. The WHO prequalification system for diagnostics is, however, expanding and promises to be a useful resource.

The CDC, WHO, and the American Society for Clinical Pathology, in collaboration with country representatives and
other international bodies, have developed a set of guidelines, recommendations, and supporting tools that can be used to help develop or strengthen standardization policy. These documents provide advice on the required laboratory service offering at different levels of infrastructure and the recommended technology protocols. Countries can use these to develop laboratory procurement policies, select appropriate diagnostic platforms and vendors, and direct available resources if laboratory capacity has to be developed or augmented. In customizing these guidelines, general criteria for selection of diagnostic devices can be used, including the following:

- Certified or recommended test method
- Demonstrated accuracy (sensitivity and specificity)
- Test capacity matching volume demand
- Cold-storage requirements matching available cold chain
- Good domestic and international track record of quality and technical support
- Successful under local or international evaluations (eg, FDA, CE-IVD, WHO, or CDC)
- Compatible with quality assurance programs
- Reliable distributor available
- Reliable service and maintenance provider available

Conclusion and Recommendations

Standardization in laboratory diagnostics entails the establishment of uniform test menus appropriate for the health care delivery level and the selection of standard technology platforms, including instruments, reagents, and consumables for each test at each level. Increased standardization in laboratory networks can improve access to essential diagnostics and monitoring tests and the efficiency of procurement and, consequently, the quality of testing affecting patient health. Standardization reduces unnecessary diversity of technology and testing platforms and, through this consolidation, provides a number of benefits in terms of cost savings and ease of management in laboratory networks. The strengthening of policies related to test menus by service delivery level and the procurement of diagnostic instruments and commodities is the first step in the standardization process and an essential prerequisite to improving the supply chain for laboratory networks. Such policies provide access to lower reagent and consumable costs and better organized and more cost-effective after-sales support from laboratory vendors. To implement and benefit from standardization, the following recommendations can be followed:

1. Laboratory policies should be updated to include principles and guidelines for standardization. These policies should be widely adhered to by all laboratories in the network, as well as the government departments and nongovernmental agencies involved in laboratory strengthening and procurement. The policies should ensure a high degree of transparency, accountability, and flexibility in the selection of technologies and platforms.

2. Standardization may not align fully with ordinary public procurement regulations, and adaptation of these regulations may be required to ensure that procurement remains competitive, while still drawing the benefits of standardization policies. To accommodate tendering rules related to ensuring competition, it may be possible to standardize technologies and platforms produced by specific manufacturers on the basis of the aforementioned criteria while maintaining competition among a number of prequalified distributors of these products.

3. Procurement lists should be updated periodically in order for standardization policies to take effect. The specifications and use rates of all supplies should be evaluated to ensure that they are relevant to the present needs and match the standardized test menu distribution and technology or platform selections.

4. All procured products and their suppliers should be subject to routine performance evaluation and postmarket surveillance to ensure that they still qualify for inclusion in the standardized product lists. Serious quality or performance problems should be addressed quickly to allow replacement of the product, if appropriate.

5. Standardization should not restrict the introduction of new technologies and platforms. New promising technologies should always have access to the laboratory supplies market, and the creation of supply monopolies should be avoided. Standardization policies need to be regulated by appropriate and flexible procedures (eg, under the auspices of a technical committee) that would allow for alternative platforms to be quickly, fairly, and transparently reviewed on a routine basis and for adjustments to be made to the array of platforms permitted for use, when appropriate.

6. National strategic and operational plans for laboratory strengthening and national laboratory budgets need to accommodate standardized test menus and technology distribution when planning and budgeting for the renovation of laboratories, purchase of equipment and commodities, the hiring and training of staff, and the establishment of logistics and sample referral systems in order for standardization to reach all levels of the laboratory system.

7. Standardization should be used as an opportunity to establish more effective partnerships with technology suppliers where appropriate, especially with respect...
to training, service, and maintenance and ensuring a continuous supply of testing reagents.

8. International guidelines, recommendations, and prequalification standards can provide relevant advice on standardization that laboratory networks can adapt to locally appropriate policies and standards.

These recommendations can be used as guiding principles when implementing improved standardization across laboratory networks.

Reference

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