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BUILDING A STANDARD LABORATORY EQUIPMENT LIST

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I. INTRODUCTION

Laboratory services are a cornerstone of programs that provide successful HIV and AIDS testing and treatment services. Since comprehensive HIV and AIDS services require many laboratory tests, strategies to streamline the provision of those tests can improve the efficiency, quality, and affordability of testing for the service provider. One strategy is to reduce the number of testing platforms used for each test and move toward a laboratory system that makes use of standard equipment across comparable facilities or levels in the system (i.e., district or regional facilities).

Broadly, standardization of laboratory procedures and equipment—and thus, supplies—can help countries and/or programs to better allocate limited resources available for laboratory services as well as provide the basis for an external quality assurance scheme. Standardization involves definition of test menus, techniques, operating procedures, and equipment for each type of test, for each level of the system, to be applied across all laboratories.

This document is a tool to aid country laboratory program decisionmakers in one aspect of standardization: identifying, documenting, and evaluating criteria to select laboratory equipment to appear on the country's standard equipment list. For HIV and AIDS programs, this typically includes equipment to perform hematology tests (full blood count), chemistry tests (liver and kidney function), and immunology tests (CD4 count and viral load).

This paper is divided into two sections. The first section represents a wide array of criteria for evaluating laboratory equipment to meet a country's current and future programmatic needs. Although the criteria are interrelated and are not meant to be evaluated individually, they are presented and defined separately. Considerations are divided into three broad categories: program, equipment, and supply chain. These criteria, when organized and defined, can help to determine how well the equipment being evaluated meets or matches the needs of the program or level/facility that would operate it.

The second section outlines the application of the methodology; specifically, how to use the criteria to select a standard laboratory equipment list. It is advisable for each country program to review the list, select the relevant items according to the context, and prioritize these criteria to help guide the selection process. Answering the questions that follow each program, equipment, and supply chain consideration can help decisionmakers to define the current landscape and to agree on criteria for appropriate equipment to meet program needs. Programs may consider constructing a matrix that categorizes and lists the parameters under consideration.

II. CRITERIA TO CONSIDER WHEN SELECTING LABORATORY EQUIPMENT TO SUPPORT HIV TESTING AND TREATMENT PROGRAMS

A. Program Considerations

Program considerations describe the current state and expected changes of HIV and AIDS programs in a particular country. Program considerations not only allow programs to select equipment based on the current context and requirements, but also define a future state for which equipment will be required. Because HIV and AIDS programs are dynamic and continue to scale up in many contexts, it is important to define what the program requirements will be in the future in order to select equipment that will not only be appropriate for the current environment but also will meet future needs.

PROGRAM EXPANSION

Many HIV and AIDS programs are rapidly expanding, and equipment standardization can help programs reach expansion goals while rationalizing resource allocation. Laboratories can prepare for a planned increase in services if expansion plans are taken into account in the equipment selection process. Thus, decisionmakers must consider the current program situation and its plans for the future to determine whether (and which) laboratory equipment can fill program gaps. In addition, the skill and capacity of laboratory staff, and the physical infrastructure of the laboratories where they work, may affect decisions about equipment selection.

- What are the program targets for HIV testing? And for patients on antiretroviral therapy (ART)?
- Is a particular population (e.g., military, pediatrics) being targeted? Different target groups may require different types of equipment platforms (military may have a large test volume, while pediatrics will likely be a smaller sample that may need more specialized testing, such as the ability to report CD4 percentage in addition to total CD4 count).
- Are the numbers of ART sites increasing? Will this expansion include laboratories for monitoring patients? What laboratory levels will be included in this expansion?
- What are the laboratory requirements to support the expansion plans? Are there HIV and AIDS laboratory guidelines/protocols (e.g., when starting on ART, CD4 counts should be conducted every month for the first three months and then every three months until stable)?
- What laboratory tests are required in the ART guidelines/protocols?
- What levels in the laboratory system require automated equipment?

SPECIMEN REFERRAL

Some resource-limited countries are opting to create a specimen referral system whereby specimens are transported to a central location with a high-throughput machine and appropriately skilled laboratory staff. In addition to a reliable transportation system and a sound information management system, the referral site must have appropriate, functional equipment. Plans for specimen referral will dictate the type and capacity of the equipment needed at the referral sites.

- Do future program plans envision a specimen referral/centralized testing location?
- How many referral testing locations will be included in the system?
- What tests will be included in the specimen referral system?

STAFF CAPACITY

The level of expertise and skill required to operate and maintain a laboratory instrument can dictate how appropriate it is (if at all) for a given facility or level of the system. Since the demand for skilled laboratory staff is often inadequate in resource-limited settings, when defining standard instruments, decisionmakers must consider the available staff capacity, time, and skill level required to run and interpret the tests.

- Does the program have staff with the proper skills and experience at the level for which the equipment is destined?
- Are there plans to scale up the number of qualified staff to accommodate program expansion?
- How long does it take (or how many people are required) to prepare a sample, perform a test, and interpret the results?

B. Equipment Considerations

Equipment considerations outline all the parameters, requirements, and questions that will help users identify equipment that best meets a program's needs. Different equipment has distinct strengths and limitations. The goal of reviewing equipment considerations is to match the context with the equipment that has the greatest number of complementary strengths and the least number of associated limitations.

EXISTING EQUIPMENT

Another facet of the current program situation involves the equipment already used in the system. If one brand of machine is most widely used, it should be subject to the same decision criteria as the other possibilities. If all else is equal, decisionmakers may choose to include the existing instrument on the standard list because of the

capital that has already been invested. However, care should be taken, as monopolies can be introduced, resulting in counterproductive results.

- What equipment is currently being used in-country?
- How many of each instrument does the country or program already own?
- Is this equipment functional? How much longer is it expected to be functional?
- Are staff members trained to use the existing equipment?
- Do staff or program managers prefer one instrument over another for the same test? If so, why?

TESTING PARAMETERS AND CAPACITY

As mentioned above, the key to simplifying the management of laboratory equipment and supplies is to standardize the test menus and techniques by level in the system. Based on this standardization, the equipment to be selected should have the capacity to conduct the required tests. For example, some chemistry tests are critical at the lower levels to orient the diagnosis (e.g., ALT and creatinine), while other tests required for more sophisticated diagnosis are important but can be referred to the higher level (e.g., amylase, electrolytes, magnesium). This level of detail will guide choices of instrumentation by level. A complex, multiple-parameter chemistry machine would be inappropriate at the lower level, where only ALT and creatinine testing are performed.

Additionally, the number of tests performed (testing volume) will differ by level; thus, equipment at high-, medium-, and low-volume facilities should be selected accordingly. A high-throughput machine will be inappropriate, underutilized, and could lack quality at a low-volume testing site. The testing capacity parameters by type of facility should be defined prior to selection (e.g., high testing volume $\geq$ 1,000 tests/day; medium $>$ 300 and $<$ 1,000 tests/day; and low $\leq$ 300).

- What are the testing parameters required by level for each type of equipment?
- What are the testing capacity parameters by level?
- What equipment types are appropriate for each testing capacity parameter?

INFRASTRUCTURAL REQUIREMENTS

Different equipment types have specific infrastructural requirements, including stable electricity or reliable generators, tap or distilled water, large space requirements, and/or temperature control. At the health center level, using battery-powered photometers and sunlight-powered microscopes may be appropriate if the facilities do not have access to consistent power. It is important to consider the physical conditions of the facility to install appropriate equipment.

- What are the infrastructure realities at the different levels of facilities?

- What are the infrastructure requirements of the equipment being reviewed? Which equipment would be appropriate for each level?

MAINTENANCE AND SUPPORT

Laboratory equipment, particularly sophisticated equipment, requires regular preventive maintenance to ensure reliability of the test results and to avoid interruption of services owing to equipment malfunction.

- Is there a reliable distributor or agent locally or regionally?
- Does the vendor have a reputation for reliable customer service?
- Is there a maintenance engineer locally? Regionally? Internationally?
- What is the warranty period of the equipment?
- Is on-site training included in the procurement contract?
- Does the vendor offer continued on-site training?
- Does the vendor warehouse durable parts in country or regionally?

EQUIPMENT DISPOSAL

The disposal of laboratory equipment is complex and should be considered during the selection process. Laboratory equipment can range from very small, basic equipment to large, complex machines, and as a result disposal procedures will have to take into account the variations among equipment. If national guidelines for the disposal of equipment exist, they should be implemented. However, if national guidelines do not exist, some considerations should guide the disposal process. Because used laboratory equipment poses a biomedical hazard, it will need to be decontaminated before decommissioning and handing over to nonlaboratory personnel. If there are chemical hazards, these should be removed as well. In addition, some equipment will emit electromagnetic radiation, and may still pose a risk of radiation even after decontamination. Therefore, care should be taken to dispose of this equipment in accordance with national regulations on the disposal of radioactive materials. Once the safe disposal of equipment has been completed, the accounting procedures for the disposal of equipment should be followed.

Ideally, the equipment manufacturer should provide guidelines for its disposal. Upon the purchase of laboratory equipment, the disposal of such equipment should be included in the contract; complex equipment may have to be returned to the manufacturer for final disposal.

- Do national guidelines exist for the disposal of equipment?
- What are the disposal considerations for each type of equipment?
- Does the manufacturer provide guidance for disposal of the equipment?
- Is disposal of equipment included in the manufacturer's contract?

- Does the manufacturer accept complex equipment for final disposal?

MANUFACTURER

The reliability of the equipment manufacturer should also be a serious consideration. All manufacturers considered should have a proven record of reliability and continuing support.

- Does the manufacturer have a reputation for reliability?
- Is the supplier able to provide spare equipment/parts, training, and upgrades quickly and reliably?
- Does the manufacturer show evidence of continuous research and development?
- Is the manufacturer putting effort into product development by getting constant feedback from users?
- Has the manufacturer's equipment been used elsewhere, or it is being used for the first time?

COST

When determining how equipment rates in terms of its "affordability" for the program, recurring costs (e.g., costs of reagents, consumables, and maintenance) should be considered in addition to the one-time cost of the instrument. Given rapidly changing technology, the cost of disposing of equipment must be considered as well.

- What is the initial equipment cost?
- What items are included in the initial cost?
- What items are required to use the equipment that are not included in the initial cost?
- What is the cost of reagents and consumables, per test?
- How much are anticipated maintenance costs, including spare parts?
- What other costs might be related to introducing this instrument into the system/program/facility (e.g., training, other equipment required, storage, distribution)?
- What is the cost of disposing of the equipment?

CLOSED AND OPEN SYSTEMS

Closed systems are laboratory equipment that require a specific brand of reagents. The closed systems generally (but not always) cost more and can be of much higher quality because of manufacturing practices, but are dependent on a single source for procurement. Open systems are laboratory instruments that do

not require a specific brand of reagents. Open systems can use reagents from any manufacturer that develops the specifications needed for the test, which are usually procured competitively. However, although sourcing reagents from a number of suppliers may yield competitive prices, it will require a good validation mechanism and continuous reagent quality assurance process, since various suppliers will provide reagents of varying quality. When troubleshooting in a situation where reagents and supplies come from multiple sources, it may be difficult to pinpoint the problems quickly, and this may affect program service delivery. When selecting equipment, it is important to review the benefits and limitations of both types of systems.

- Which equipment being considered are open systems and which are closed systems?
- What are the benefits and limitations of the closed systems?
- What are the benefits and limitations of the open systems?
- Which benefits and limitations affect the equipment selection for this country?

VALIDATION AND EXTERNAL QUALITY ASSURANCE

Validation refers to a process or analytical method that documents the ability of an instrument to produce a consistent result of consistent quality. International organizations such as the World Health Organization (WHO) are beginning to validate certain testing platforms. But, unlike pharmaceuticals, this process is not yet done consistently for all platforms. Validation of the equipment is often done in-country or regionally by an external entity.

Instruments will behave differently in different environments. Therefore, it is necessary to ascertain whether the subject equipment performs to expectation in a particular environment. This is usually done against a gold standard, or a method accepted generally as the reference method. The validation process is often limited to the performance of equipment in the laboratory. However, other aspects such as cost and national policy will need to be included in the validation processes. A robust validation protocol can help shift from accepting marketing claims made on a product to understanding its true functionality.

External quality assurance (EQA) is a program that allows testing sites to assess the quality of their performance by comparing their results with those of other laboratories using the same equipment and/or testing technique (known as a peer group). Ideally, EQA processes should already exist or be developed. Therefore, the following criteria should be reviewed on a country-by-country basis, possibly as the initial step to limit the number equipment being evaluated, where applicable.

- Is the equipment being considered qualified by agreed-upon international agencies (e.g., WHO or U.S. Food and Drug Administration)? Is this validation adequate, or does the equipment need in-country or regional validation?

- Is an external validation process, by an independent in-country and/or regional evaluation process, available or in place? Can/has the equipment under review be/been validated?
- Is there proven reproducibility of test results in-country and/or regionally as measured by the coefficient of variation (C.V.)[1] of selected tests?
- Is the equipment compatible with the EQA scheme in the country? Will there be enough equipment to form adequate peer groups for this scheme?

REGISTRATION

Local registration of equipment is required in certain nations, while it is not a common practice in others.

- Is the equipment being considered either registered in the country or can it be registered easily and with minimal delays (if applicable)?

C. Supply Chain Considerations

Supply chain considerations include the range of issues that impact the supply chains for laboratory commodities in-country. When it comes to equipment, supply chain considerations are often neglected. It is important to consider the supply chain of the products (reagents and consumables) associated with each piece of equipment. A particular piece of equipment may be appropriate for a certain context, but if the pipeline is too long or does not accommodate cold-storage requirements, programs may not be able to ensure the continuous availability of usable reagents and consumables.

SHELF LIFE OF REAGENTS

Although many laboratory reagents have a long shelf life, certain reagents, especially for automated equipment, have much shorter shelf lives. The shelf life of the reagents associated with closed systems being evaluated should be considered with regard to the supply system. Many laboratory supply systems may have an entire supply chain—from manufacturer to point of use, including all of the storage and transportation links the products must go through—that is longer than the shelf life of the reagents. Most reagents, unless locally manufactured, arrive in-country with at least three months less than the total shelf life. This is an important factor in that there is a great risk of product expiry and faulty test results.

- What are the shelf lives of the required reagents for each instrument? Are they more than 12 months?

[1] The C.V. is a measurement of the precision (or reproducibility) of a laboratory test or process. Modern instruments have a C.V. of 3 to 5 percent. When all other parameters are equal, the lower the C.V., the better the test.

- Does any equipment require reagents with exceptionally short shelf lives?

REAGENT AND CONSUMABLE STORAGE REQUIREMENTS

Some instruments use cold-chain reagents (which require refrigeration), while other equipment used for the same test do not require cold-chain reagents. Considering this criterion during the equipment selection process can significantly reduce cost and enhance product quality during transportation and storage. It is important to remember that products will expire before their stated expiration date if they are not stored in the recommended conditions. Additionally, some of the reagents and consumables are packaged in bulk, which is not appropriate for laboratories at all levels in the system.

- Do the reagents for any equipment require cold storage or refrigeration (2°C to 8°C)?
- Given the storage conditions at and transportation capacity to lower-level facilities, can the reagents be stored at the recommended temperature throughout the pipeline?
- Are the reagents or consumables packaged at appropriate sizes for the target laboratory? If not, can the manufacturer package the supplies in more appropriate sizes?
- Is there adequate storage space at each level for all supplies required for each instrument?

III. APPLICATION OF THE METHODOLOGY

This tool is meant to be used to identify and evaluate criteria to select standard equipment by level in the laboratory system. As mentioned earlier, the questions presented in this tool may not be applicable for every country. However, the program managers can use this tool to identify relevant criteria in determining the country's priorities for selecting the equipment.

It is envisioned that this tool will be used in selecting a standard laboratory equipment list. Typically, this process involves the following steps.

Stage 1: Review the Current and Future Situation (Programmatic Considerations)

Form a small equipment selection committee that includes program managers and representatives from different laboratory levels and other cooperating partners or agencies. The selection committee describes the current situation in the country using the programmatic considerations. If it is agreed that standardization of equipment by level is necessary based on the expected program growth and change, the committee should note the program areas that are most important to the equipment selection

process, include the variables in a criteria list, and proceed to Stage 2. If the country is already standardized, continue to Stage 3.

Stage 2: Select and Apply Criteria

Based on the evaluation of the current and future situation using programmatic considerations, programs should choose the relevant supply chain and equipment criteria. Next, the committee decides which equipment to review. The committee then applies the selected criteria to each piece of equipment and reviews the results. The result is a standard list of equipment by level for automated instrumentation. Once this list is developed, it is presented to key decisionmakers for approval.

Stage 3: Documentation, Dissemination, and Implementation

The approved list is documented and disseminated to all stakeholders in the laboratory system, including program managers, implementers at the laboratory, and cooperating partners or agencies. This list is used for all future equipment and related supply procurements. An implementation plan is developed to map out the transition from the current situation to the agreed standards, including phasing out nonstandard equipment.

For more information, please visit deliver.jsi.com.

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