CHAPTER 47

Laboratory services and medical supplies

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SUMMARY

The management of medical and laboratory supplies and equipment shares many similarities with the management of pharmaceuticals and is just as important in providing effective health services. Although the value of supplies and equipment may equal a substantial proportion of what governments spend on pharmaceuticals, such items are rarely given enough attention. Each country's ministry of health is responsible for ensuring that commodity management standards are set and followed by instituting quality assurance mechanisms and monitoring evaluation and reporting systems.

Problems associated with supplies and equipment include lack of policies, absence of dedicated government budgets, and lack of standardization. Countries should develop a national list of medical and laboratory supplies and equipment, based on expected types of tests, treatments, and interventions to be delivered at different levels of health care. Such a national list is useful to—

- Define priority items and help ensure that the most essential items are available where needed
- Promote cost-effective use of scarce financial resources
- Reduce the number of items through standardization
- Serve as the basis for training staff and technicians

The four main criteria in selecting equipment are (1) local possibilities for servicing and spare parts; (2) local availability of essential supplies (such as chemicals and filters); (3) a well-established brand name and a simple and sturdy design; and (4) local possibilities for training staff in equipment use and maintenance.

Finding good data on the consumption and cost of medical supplies is a challenge, especially on individual items. The number of different items and brands is much larger than the average number of essential medicines, and the specifications are much less standardized. Another problem comes from the records used to compile data: Are different sizes of X-ray films or all sizes of syringes regarded as one item? In some countries, medicines and other medical supplies and laboratory supplies come under different management structures or different budgets, which makes intercountry comparisons difficult.

Before procuring medical and laboratory supplies and equipment, specifications should be defined in close collaboration with technical staff. These specifications are needed for the procurement department and for claims in case of faulty products.

Donations of commodities and equipment to laboratories and health facilities must be handled carefully, including the assurance that donations are based on need expressed by the recipient country. When donors provide medical and laboratory supplies and equipment, problems related to the lack of standardization and to maintenance may arise.

47.1 Introduction

Clinical laboratory services are a critical, yet often neglected component of essential health systems in resource-limited countries. Laboratories play a central role in public health, in disease control and surveillance, and in individual patient diagnosis and care, yet many millions of people still do not have access to reliable, basic, diagnostic laboratory services (Petti et al. 2006).

Effective laboratory leadership and management are often lacking—many countries still do not have a national laboratory policy, a strategic plan, or a dedicated budget for laboratories. Fundamental weaknesses in the overall management of laboratory services, together with a lack of human and financial resources and poor infrastructure, prevent the efficient operation and delivery of accessible, quality-assured laboratory services to support national public health programs, including malaria and tuberculosis (TB) control and treatment and the delivery of antiretroviral therapy (ART). A greater realization of the laboratory's role combined with advocacy from global health initiatives such as the U.S. President's Emergency Plan for AIDS Relief to build capacity for laboratory systems has resulted in encouraging signs that suggest a gradual increase in focus. Country Study 47-1 describes a successful program to build leadership in laboratories in Uganda.

If laboratory services are to support health care effectively, they need to provide reliable, valid, and timely results. Functioning, good-quality equipment and uninterrupted supplies of test kits, reagents, and other consumables are mandatory. Yet many countries have given little attention to the particular needs of laboratories and what is required to create an effective commodity management system. Governments and donors responsible for procuring and managing laboratory equipment and other commodities often lack updated standard international guidance. Consequently, stockouts occur when large quantities of materials that are inadequate, inappropriate, or of poor quality are procured, and resources are wasted.

Like laboratory services and commodities, medical supplies and equipment are rarely given enough attention. Recognizing the important role of this category of products, the World Health Assembly adopted a resolution in 2007 that covers the need to establish priorities in the selection and management of health technologies, specifically medical devices. The World Health Organization (WHO) defines a *medical device* as "an article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose" (WHO/EHT 2011b, 4). The term *equipment* refers to a medical device that requires calibration, maintenance, repair, user training, and decommissioning. According to WHO's definition, medical equipment excludes implantable, disposable, or single-use medical devices (WHO/EHT 2011b). Items that have traditionally been categorized as "supplies," including bandages and gloves, are considered devices under WHO's taxonomy. This chapter and the rest of the book recognize the new definition of *device* but continue to refer to such nonpharmaceutical items as supplies and commodities to reflect common understanding and usage.

As a result of the 2007 World Health Assembly resolution, WHO launched the Global Initiative on Health Technologies to make core health technologies available at an affordable price, particularly to resource-limited communities. Through the initiative, WHO and its partners have developed a series of reference documents for countries,

Country Study 47-1
Strengthening laboratories to expedite the countrywide scale-up of the ART program in Uganda

With funding from the U.S. President's Emergency Plan for AIDS Relief, Management Sciences for Health (MSH) partnered with the Joint Clinical Research Centre (JCRC) and the Ugandan Ministry of Health (MOH) to design and implement the Laboratory Performance Improvement Program for laboratory management teams from selected MOH regional referral hospitals that support the national ART rollout program. Traditionally, laboratory support has focused on providing equipment and supplies and training staff in test methods but has ignored underlying management issues. Before this program, many regional hospital laboratories in Uganda were unable to provide quality-assured basic services to manage treatment of those infected with HIV/AIDS and TB.

MSH helped bring together multidisciplinary laboratory management teams, comprising the medical superintendent, the hospital administrator, a doctor, a nurse, laboratory staff, and local staff from the JCRC-TREAT Program (Uganda's national ART program). As part of the program process, each team took responsibility for improving laboratory performance at its own hospital by managing the resources and developing effective work processes to produce quality laboratory test results. During the program, the teams received support from a central JCRC-TREAT-MOH team of experts, including the principal technologist at the central public health laboratory.

Through a series of five workshops spread over one year, the teams learned leadership and management skills and how to work together more effectively. They learned how to apply the performance improvement process to narrow the gap between the specific results they wanted to achieve and their actual results, created a vision of how well their laboratory could operate in the future, and then committed themselves to realizing this vision by developing and implementing an action plan. Critical to their progress were the activities that each team implemented between workshops to use existing resources to improve laboratory performance. These efforts led to the first hospital monthly budget allocation for laboratory supplies, additional space for key laboratory functions, improved laboratory staff morale, and increased productivity resulting in more essential tests being performed in a timely manner. Early in the program, MSH worked with the teams to develop a laboratory performance monitoring tool that was appropriate for their local needs. Teams used the tool at the beginning of the program and again at the end of the program to review their progress and pinpoint remaining challenges.

At the end of the program, the executive director of JCRC stressed what the Laboratory Performance Improvement Program had demonstrated—

> The laboratories are critical for the quality and safety of the TREAT Program . . . There is such a huge need because the [Laboratory Performance Improvement] Program started almost from scratch as far as up-country laboratories were concerned. Only a tiny group of leaders and professionals were involved, and they almost unanimously expressed great appreciation for the importance of laboratory training, especially in management. It has exposed a big gap.

Source: MSH n.d.

covering areas such as policy, regulations, management, and innovation. The document series and other information can be found at WHO's website on medical devices: http://www.who.int/medical_devices/en.

With the increased emphasis on the importance of effective laboratory services to a country's public health, this chapter focuses particularly on issues related to laboratories. It provides guidance for procuring and managing equipment and other supplies that health facilities and laboratories use.

47.2 Using national policies to guide equipment and supply management

Sound national policies on laboratories and medical equipment with lists of related essential supplies can simplify supply issues, reduce costs, and promote efficient provision of health care and rehabilitation; however, only 33 percent of low-income countries in a 2010 survey had national policies covering health technologies (WHO/EHT 2011b). Policies should specify which medical equipment and supplies should be used in which types of medical tests, interventions, and operations. Because different medical procedures are carried out at different levels of health care, and different tests are performed at different levels of laboratory service, the policies define the sets of supplies and equipment that will be needed at each of these levels.

National laboratory policy, strategic plan, and budget

A national laboratory policy provides a framework for ensuring that health laboratory services adequately support the efficient delivery of a country's health care package. National laboratory policies usually support regional and global health goals and priorities; for example, the 2008 Maputo Declaration on Strengthening of Laboratory Systems in Africa recognizes the challenges and limitations of scaling up services for TB, malaria, and HIV/AIDS and calls on national governments, donors, and partners to integrate support to improve laboratory systems (WHO/AFRO 2008b). In addition, achieving the three millennium development goals of reducing child mortality; improving maternal health; and fighting HIV/AIDS, malaria, and other diseases requires efficient national laboratory systems.

Implementation of a national laboratory policy requires a strategic plan that provides clear guidance on the actions needed to improve laboratory systems as well as insight into implementation and budget implications for translating policy into practice. The plan and budget guide the mobilization of needed resources and help the government and stakeholders identify areas to target.

Aligning laboratory services with packages of health care

A national laboratory policy usually contains objectives to ensure the availability of appropriate functional equipment and adequate supplies of test kits, reagents, and consumables for laboratories at all levels. It may also outline strategies for ensuring an effective supply chain, national standardization of equipment and supplies, registration by the appropriate regulatory authority, equipment maintenance and servicing, management of donations, and safe disposal of obsolete equipment and expired supplies. However, neither the laboratory policy nor the strategic plan usually specifies the actual list of equipment and other laboratory commodities because these may change with technology development and innovation.

National policies and decisions on public health priorities and health care should indicate which essential laboratory tests and services each level of health care will provide and which resources the laboratory needs to deliver these services. This approach stems from the "basic package" health care concept that was developed to increase the efficient allocation and use of limited resources (World Bank 1993). A basic (or essential) package of health care includes limited and proven cost-effective interventions that focus on health conditions and service gaps that disproportionately affect the poor and address a country's major causes of morbidity and mortality. The elements of a country's basic package of care provide a foundation for determining which types of clinical and public health services, treatments, and medicines will be provided at each health care level and the rationale for referrals to the next level of care. This information is critical for compiling the essential list of laboratory tests and services required to implement the interventions, and it contributes to the management of each target disease or condition.

Developing a national list of essential laboratory supplies and equipment

Once the ministry of health has established a list of essential laboratory tests and services that each level of health care will provide, the next step is to nationally adopt the methods or technologies needed to provide each test and service, including the most appropriate types and makes of equipment. All of these steps need to be completed before compiling the lists of essential equipment and the test kits, reagents, and commodities needed to run the equipment or perform tests. Many central medical stores do not have a national laboratory supplies list, and staff members do not know which items or how much of a particular item is required to carry out essential laboratory tests. As a result, many products may not be stocked or even available in the country. Therefore, the develop-

Box 47-1
Steps for preparing a national list of essential laboratory equipment and supplies

- Review national health plans and policies on priorities for service provision and essential health care packages to identify target diseases and conditions.
- Review standard treatment and diagnostic protocols for each disease or condition for each health care level to identify where laboratory support is required.
- For each level of health care provision, make a list of all the priority disease areas and conditions in the health care package.
- Next to each disease area, list the essential tests required at that level of health care. (Note that some tests will appear against several conditions.)
- Use this information to summarize the list of laboratory tests and services to be provided at each level.
- Obtain a consensus on the technologies and test methods to be used at each level of health care.
- Identify and come to an agreement on the capital equipment items best suited to deliver these technologies and test methods.
- Write technical specifications for each item of capital equipment.
- Identify manufacturers or vendors to supply the capital equipment.
- Prepare a capital equipment list, specifying make, model number, and so on for the national catalog.
- Identify all proprietary consumables, test kits, and reagents required to operate and perform quality control for the equipment.
- Identify all nonproprietary consumables, test kits, reagents, and minor equipment items required to deliver essential laboratory tests and services.
- Compile a capital equipment list.
- Compile a list of laboratory consumables and supplies, disaggregating proprietary and nonproprietary items.
- Come to consensus with national medical stores on VEN/ABC classification for all laboratory items in the national stores catalog.
- Prepare guidelines for administrative and laboratory staff on how to use the catalog for ordering, including explanation of VEN/ABC classification.
- Print and distribute catalogs, or where feasible, maintain an online catalog.
- Update lists annually.

ment of a standardized list is essential for laboratories to function properly.

A national committee of experts should combine the lists for each level of care into one national list of essential laboratory supplies and equipment. Similar to the list of essential medicines, this list should form the basis for standardizing procurement and distribution of supplies and equipment, as well as for training. Box 47-1 summarizes the steps to prepare such a list.

The list of essential laboratory supplies and equipment should contain a complete and clear description of each item, including stock number, type, standard pack size, and the most recent unit price. With more laboratories improving availability and use of automated analyzers for hematology, clinical chemistry, and immunology, combining the complete list of all proprietary items needed to operate each analyzer is useful because the items need to be procured and supplied to each laboratory as a complete package. Nonproprietary items should be grouped either by laboratory specialty (for example, microbiology, hematology, blood transfusion, chemistry, and immunology) or by category (for example, chemicals, culture media, test kits, antibiotics, glassware, minor equipment, safety items, and disposables), and use the stock or catalog number to identify the category.

Standardization of equipment and devices

The absence of equipment policy guidelines and lack of standardization of supplies can lead to wasteful overstocking. In many supply organizations, the number of different items of equipment and other commodities can be greater than the number of essential medicines. Although equipment is not generally subject to expiration, many examples are available of accumulating stocks of outmoded analyzers, instruments, and spare parts that have been ordered but that are no longer required or are not compatible with newer types of equipment.

The world is still not harmonized in several important areas, such as electrical and measurement systems. There are at least four different types of electrical plugs; two voltage systems, with 110 or 220 volts and 50 or 60 cycles per second; three different weight and volume measurement systems; and instructions in dozens of languages. In addition, for equipment such as gauges on gas containers, different companies may use different internal standards. These variations create immense problems for countries that have not managed to standardize their equipment or that receive equipment from a number of different donors.

The obvious strategy for tackling this problem is to standardize equipment and devices as much as possible. When

the standard types and brands have been chosen, a list of standard equipment with specifications should be prepared to serve as a guideline for the procurement department and for donations.

Countries without an equipment standardization policy will often have several brands of the same piece of equipment on hand, which creates difficulties in procuring spare parts, arranging for service contracts, or providing training for staff to use the equipment. For example, a survey of laboratories in Malawi identified ninety microscopes from sixteen different manufacturers, 63 percent of which had been procured by donors (Mundy, Kahenya, and Vrakking 2006). Although 50 percent of the microscopes in use were reported to be in good condition, none had ever received professional service or repair, and in fact, were ineffectual because of mechanical faults and fungal growth on the lenses, although unsupervised staff used them for malaria microscopy.

47.3 Laboratory and medical commodity management systems

Efficient laboratory and medical commodity management ensures that appropriate commodities of adequate quality are reliably available, so technicians can perform laboratory tests for individual patient care and health care staff can treat patients appropriately. Managing commodities in any setting (public or private sector) and at any level (local, regional, provincial, or national) requires appropriate—

- Selection
- Quantification
- Procurement
- Quality assurance
- Distribution
- Inventory management
- Disposal

The following section deals with the practical aspects of managing these components, which, although similar in many ways to how pharmaceuticals are managed, have distinct differences.

Selecting diagnostics and supplies

As indicated in Section 47.2, ensuring availability of essential commodities requires that health managers and policy makers seek input from users (health care providers and laboratory staff) and review current information on national health policies and plans and budgetary constraints. The

Box 47-2
Developing guidelines for diagnosing HIV

Standard guidelines or algorithms for HIV testing must be developed and periodically updated at the national level. HIV testing guidelines should address the range of service delivery models to be used and the settings in which they are to be deployed.

Diagnosing HIV infection involves two different types of tests—both based on detecting HIV antibodies in the blood: (a) screening or initial tests and (b) confirmatory or supplemental tests. Initial tests identify antibody-positive specimens, whereas supplemental tests confirm whether specimens found reactive with a particular screening test contain antibodies specific to HIV. A variety of simple, instrument-free initial tests are now available. The test kits contain testing devices and all other supplies needed to perform the test. Specimens and reagents are often added by means of a dropper to the test device. The results are read visually. Most of these tests can be performed in less than twenty minutes and are therefore called rapid assays. In general, these tests are most suitable for use in testing and counseling centers and laboratories that have limited facilities and process low numbers of specimens daily.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) and WHO recommend three testing strategies to maximize accuracy while minimizing cost. The choice of the most effective strategy depends on the prevalence of HIV in the sample population; the sensitivity and specificity of the test; and the objectives for performing the test—surveillance, diagnosis, or blood screening purposes.

One of two testing algorithms is part of the strategy. In a *parallel* testing algorithm, blood samples are simultaneously tested using two assays. In the *serial* algorithm, all specimens are tested by a first test that is highly sensitive. If the result is negative, the specimen is considered a true negative. Positive specimens are retested with a second assay that has a high specificity. If the second assay is also positive, the sample is considered a true positive. In both algorithms, discordant samples are retested immediately using the same tests to rule out error. If they remain discordant, the client is advised to come back in two weeks for another test to rule out HIV infection.

Sources: CDC/UNAIDS/WHO 2009; Walkowiak and Gabra 2008; WHO 2010a; WHO/EHT and UNAIDS 2009.

selection process involves reviewing the health problems or conditions to be prevented, tested for, and treated at facilities in line with the country's basic health care package; developing a list of commodities by level of health care; choosing appropriate packaging or unit sizes; and basing the selection process on relevance, proven efficacy and safety, performance in a variety of settings, quality, cost-benefit ratio, previous experience, location of manufacturer, and capacity of laboratory or facility staff.

WHO is creating model lists of devices and equipment for different levels of health facilities, from health posts to specialized hospitals, (http://www.who.int/medical_devices/innovation/health_care_facility/en/index1.html).

Diagnostics. Standard guidelines for disease testing must be developed at the national level, and national and local guidelines should be developed or updated in accordance with international recommendations. The responsible coordinating body (for example, the national AIDS control committee in the case of HIV diagnosis) may need to work with the national essential medicines committee to update the existing national essential medicines list, formulary, or both to include the diagnostic needs for a public health program. Box 47-2 describes different strategies for approaching HIV testing.

Selecting a limited range and type of diagnostic commodity can lead to better availability, better staff knowledge (from buying reagents that staff are familiar with), more appropriate use, and lower costs. As with pharmaceutical selection (Chapter 16), sensible commodity and equipment selection is one of the most effective ways to save costs because it has both clinical and economic implications. The WHO Prequalification of Diagnostics Programme's recommendations should be followed to ensure that laboratories purchase affordable diagnostic commodities of assured quality that are appropriate for use in resource-limited settings (WHO/DLT 2011).

Ensuring safe and effective use of diagnostic services and commodities entails a range of interventions, including incorporating laboratory testing into diagnostic and treatment guidelines, developing and implementing standard operating procedures, and using job aids and other appropriate behavior-change interventions targeted at clinicians, diagnostic service providers, and care-seekers in the community.

Box 47-3 highlights the high cost of using an unapproved diagnostic test for TB.

Disposable and reusable items. The national policy on the use of disposable or reusable items may differ from one country to another. Table 47-1 lists important factors to consider in making a choice. If reusable products are chosen, buying products that can be autoclaved is essential. When buying disposable components for special equipment, ensuring that what is purchased will actually fit the equipment is important. Some equipment uses standard disposables; other equipment requires product-specific supplies.

In countries with limited funds for medical supplies, challenges with using disposable syringes and needles have been expensive and have caused stockouts. As a result, facilities sometimes sterilize disposable supplies and reuse them, which creates two problems: first, disposables are not meant to be sterilized, and the practice can result in air leakage and compromised performance; second, the method of sterilization is often inadequate. It is common to see a few "disposable" needles and syringes floating in a pan of water, with or without a lid, which may or may not have been boiling for some time. Boiling only disinfects; it does *not* sterilize. The same applies for soaking disposables in a disinfectant solution. Where stockouts are a problem, every health facility should probably keep a few reusable syringes and needles in reserve. This implies that a national policy for using only disposable or only reusable materials is not always practical.

The United Nations Children's Fund (UNICEF) and WHO tackled the problem of disposable reuse by creating "auto-disable" disposable syringes, which are made so

Box 47-3
WHO urges a ban on inaccurate blood tests for tuberculosis

In 2011, in an unprecedented move, WHO issued an explicit "negative" policy recommendation against a widely used diagnostic practice and is urging countries to ban the use of commercial blood tests to diagnose active TB. These tests, which are manufactured in North America and Europe, have not been approved by any regulatory authorities yet are widely used in developing countries. Expert analysis shows that the tests produce either false-positive or false-negative results at least half the time, which obviously puts individual patients at great risk and negatively affects public health overall.

WHO estimates that more than a million of these inaccurate blood tests are carried out every year to diagnose active TB, especially in India and China. The tests are costly for patients, who can pay up to 30 U.S. dollars for them. "Blood tests for TB are often targeted at countries with weak regulatory mechanisms for diagnostics, where questionable marketing incentives can override the welfare of patients," said Dr. Karin Weyer, coordinator of TB diagnostics and laboratory strengthening for the WHO Stop TB Department. "It's a multimillion-dollar business centered on selling substandard tests with unreliable results."

Source: WHO 2011.

Table 47-1 Advantages and disadvantages of disposable and reusable items

Disposables	Reusables
Advantages • No sterilizer or running costs • No labor cost • Safer; less risk of disease transmission (if not reused)	**Advantages** • Cheaper to purchase • Need less storage space • Less waste
Disadvantages • Usually more expensive • Bulky • Waste problem • Unsafe if reused (cannot be sterilized)	**Disadvantages** • Need sterilizing equipment, running costs, and continuous supply of bags, autoclave control tape, and glove powder • Time-consuming to sterilize • Less safe; risk of transmitting disease if not cleaned and sterilized properly

they can be used only once. Although originally more expensive than ordinary disposables, auto-disable disposable syringes are now produced in such large numbers that the price difference has disappeared. The carton in which they are supplied serves as a safe disposal box, with an inner lining that can be burned easily. The plastic melts all needles and syringes into one block, which can be safely discarded. The WHO–UNICEF–United Nations Population Fund policy on injection safety states that all countries should use only auto-disable syringes for immunization (WHO 2006a).

Kits. Pharmaceutical and supply kits contain selected medicines and medical supplies in predefined quantities (Chapter 26). The quantity, range, and purpose of kits vary according to situation. Some comprise essential medicines and supplies targeting health care delivery at various levels. Others comprise special products to meet specific program needs or emergency situations. UNICEF offers a number of different supply and equipment kits, including surgical instruments and basic sterilization and resuscitation equipment. For example, the UNICEF obstetric surgery kit for health facilities to handle 100 deliveries includes instruments and equipment for fifty deliveries with complications and surgery and a midwifery kit that contains basic medicines, renewable medical supplies, medical equipment, and basic sterilization and resuscitation equipment. UNICEF considers its basic surgery set as the minimum investment for a health facility performing basic surgical activities such as simple appendectomies. Box 47-4 contains the list of medical supply items in the basic surgery set.

Diagnostic kits are also available; for example, the Global Drug Facility (GDF) supplies diagnostic TB test kits to facilitate and promote DOTS expansion in countries with a high TB burden. In many of these countries, much of the rural population has limited access to reliable microscopy services; therefore, the kits were designed specifically to meet the needs of lower-level laboratories at the periphery of the health system. Such laboratories often do not have reliable electricity or water supplies or the expertise, equipment, and materials required to prepare good-quality stains. Receiving all the supplies required for performing TB microscopy in one box facilitates easier ordering and distribution and ensures the availability of a complete set of standardized, high-quality commodities. Box 47-5 has more information about the GDF TB test kit.

WHO has starter kits for laboratories that want to introduce CD4+ or viral load testing technology that include equipment, reagents, controls, installation, training, and a maintenance contract. WHO also sells reagents and control kits to laboratories with existing CD4+ or viral load equipment.

Box 47-4
Contents of UNICEF's Basic Surgical Instruments Supply Kit

4 Clamp, towel, Backhaus, 130 mm

2 Forceps, tissue, Allis, 150 mm

6 Forceps, artery, Halst-Mosq, 125 mm, cvd

1 Forceps, artery, Kocher, 140 mm, str

1 Forceps, dressing, standard, 155 mm, str

1 Forceps, tissue, Collin, 160 mm

1 Forceps, tissue, standard, 145 mm, str

1 Forceps, dressing, Cheron, 250 mm

1 Needle holder, Mayo-Hegar, 180 mm, str

1 Probe, double-ended, 145 mm

1 Retractor, Farabeuf, d-e, 120 mm, pair

1 Scalpel handle, no. 4

1 Scissors, Metzembaum, 140 mm, cvd, b/b

1 Scissors, Mayo, 140 mm, cvd, b/b

1 Bowl, stainless steel, 180 mL

Source: UNICEF 2011.

Quantification

Both stockouts and expired items occur because of poor monitoring and quantification nationally and at the facility level. Regular monitoring of the consumption of supplies and equipment is necessary to plan for future requirements, allocate supplies, identify facilities that have higher-than-expected consumption of particular items, and avoid stockouts of other items.

Effective quantification helps—

- Avoid stockouts and ensure continuous availability of essential supplies
- Avoid waste caused by overstocking
- Make the best use of scarce resources and budget within the laboratory's means
- Facilitate central bulk purchasing
- Increase the effectiveness of an existing laboratory supply program budget
- Prepare and justify a budget
- Plan for new or expanding programs and policies
- Calculate emergency needs
- Resupply an existing supply network that has become depleted of supplies
- Estimate how much space, including refrigerated space, might be needed in the future

Three primary methods exist for quantifying how much to order—consumption, adjusted consumption, and morbidity (Chapter 20). The *consumption method* employs historical data on use that should be readily available in both the central medical store and individual laboratories. This method can be applied only to products that have been used in the past or to their direct replacements (for example, one test kit being replaced by an equivalent). In the *adjusted consumption method,* data from a laboratory service with a similar workload and numbers of patients is used as the basis of the quantification. The *morbidity method* is useful when reliable

Box 47-5
Global Drug Facility TB diagnostic kits

Although medicines are essential to TB prevention and cure, their proper use depends on the availability of reliable, quality-assured laboratory diagnosis of TB. Sputum-smear microscopy for TB diagnosis, an integral component of the DOTS strategy, is a relatively simple laboratory procedure but is often hampered by the lack of appropriate diagnostic equipment and sustainable supplies of high-quality laboratory consumables. Supplying kits to low-income countries, those undergoing health-sector reforms, or those in postconflict situations could facilitate procurement and control of laboratory supplies for TB microscopy. As a result of this initiative, the kits are now regularly available through the StopTB Partnership's GDF.

The GDF designed and field-tested four kits—

Consumables kit. Each kit contains 5 × 1 liters of methylene blue plus other consumables, such as slides, filter paper, immersion oil, and lens-cleaning tissue, sufficient to process and stain 1,000 sputum specimens.

Sputum collection containers. Each pack contains 1,000 screw-capped, leak-proof, disposable sputum collection containers. The kit is distinct from the laboratory consumables to permit independent ordering and direct distribution to health facilities for collection of sputum specimens. Specimens are then forwarded to the nearest microscopy center.

Equipment starter kit. The equipment starter kit is for setting up new microscopy sites or for equipping existing sites that do not have the basic requirements. Each kit contains minor equipment items (for example, slide storage boxes, a staining rack, forceps, spirit lamp, slide drying rack) required to process and stain sputum specimens for acid-fast bacilli. This kit plus the consumables kit provides a sufficient set of materials to set up a new microscopy center.

Microscope kit. Many countries have unreliable or intermittent power supplies. Therefore, the microscope kit contains one binocular microscope suitable for use both with a country's main electricity supply and with a mirror and external light source. Accessories in the kit include a 12-volt battery, a battery charger, a mirror unit, an external lamp for use with the battery and mirror unit, a surge protector, and spare bulbs. The battery can be charged either from the main electricity supply or from a solar panel.

The consumables kit is packed in two boxes compatible with the safety regulations for the different classes of chemical reagents. The other three kits are each packed in a single box, which facilitates easy handling, storage, and transport because the total volume of each kit is less than the collective volumes if all the items were purchased individually.

Source: Mundy, Kahenya, and Vrakking 2006.

laboratory data on workload and consumption are not available. A modification of the morbidity method can be used to calculate the quantity of laboratory supplies required for TB microscopy. This method helps national TB programs accurately forecast requirements for laboratory consumables based on simple TB case data that the program already collects.

Over time, use indicators can be developed along the lines of those that exist for medicines. An example of a use indicator would be the number of milliliters of stain needed for 100 TB sputum-smear tests or the number of rolls of cotton per month per 100 medical admissions. Such an indicator becomes a useful tool for comparing consumption among laboratories or facilities and for planning future requirements.

Procurement

Procurement of laboratory and medical supplies is not substantially different from procurement of pharmaceuticals (see Chapters 18–21). Good procurement practices depend on reliable and accurate quantification of needs, transparency in selection of suppliers and in management of bids or contracting, and quality assurance of commodities. For example, bidders should have sufficient knowledge of equipment maintenance, rather than being mere equipment traders. Equipment installation and maintenance training in addition to user training should be a condition of the sales contract.

Health managers often set priorities for the selection, procurement, distribution, and use of pharmaceuticals to analyze and control costs (see Chapter 40). A limited number of items are usually responsible for a large proportion of the budget, and these can be identified by ABC analysis. These "A" items should be procured through tender, and as with medicines, the tender should be restricted to prequalified suppliers to ensure quality. The same classifications used for pharmaceuticals can be adapted and applied to laboratory and medical supplies, not only to control costs, but also as a means to ensure that all vital items are supplied in a timely manner to minimize avoidable stockouts and service disruption. VEN categories (vital, essential, nonessential) are also useful for identifying those items that should never be allowed to run out of stock. Classifying items appropriately requires a detailed analysis. Uganda, for example, is developing the country's first lists of essential laboratory and medical supplies, which include level of health care categories and VEN classification to facilitate ordering and procurement (Table 47-2).

Table 47-3 gives examples of how cost analysis tools for pharmaceuticals can be adapted for laboratory consumables and reagents.

For several items, such as cotton and dressing materials, local procurement may be more attractive than importation. For example, both of these items are easy to manufacture and bulky to transport. In addition, they take up enough storage space to make frequent deliveries cost-effective; local producers can provide such deliveries more easily and cheaply. However, capital equipment for laboratories is specialized and invariably has to be imported from an industrialized country—purchasing inexpensive local alternatives is *not* advisable. Service contracts should be arranged at the time of purchase and their cost included in the total procurement cost—an important point because many ministries of health do not have funds available to service equipment.

In addition to the few items that are needed in large quantities, other items are needed in small quantities only. Many of these have to be imported, but neither their cost nor their volume makes putting them through the tender process worthwhile. In those cases, buying these items through international nonprofit suppliers such as the IDA Foundation and UNICEF is usually much more cost-effective.

Requests will always come to procure items that are not on the national list of essential supplies and equipment. For these items or for new items that have not yet been included on the list, or for new items with an expected low turnover, the procurement manager should ask the following questions before placing an order—

- Is the item really necessary? Can and will it be used in the place for which it is being ordered?
- Is a feasible, local alternative available?
- Are spare parts or a way to maintain the item consistently available?

Quality assurance

The quality specifications of pharmaceuticals and laboratory reagents are usually available in pharmacopoeias or from WHO. Unfortunately, such standardization rarely exists for supplies and equipment, making the preparation of detailed specifications for each item important. Many medical supplies (for example, gloves, catheters, and sutures) come in various sizes and materials. One of the most difficult aspects of managing supplies is to ensure that the specifications for the items (size, material, pack size) are all correct.

A national quality assurance system should ensure that products meet international quality and safety standards and technical specifications. In addition to a catalog or list of essential items, a separate set of technical specifications for the items must be developed. Technically qualified personnel must prepare these specifications, which must be as accurate and precise as possible. Accurate specifications are essential for the procurement department or tender board to be able to ensure the quality of the items. Without them, issuing the tender, evaluating bids, and claiming any damages in case of faulty products are difficult. Box 47-6 gives an example of technical specifications for one item.

Table 47-2 Example from the Ugandan Ministry of Health's Essential Health Supplies List

Item code	Description	Specification	Unit	Level of care	VEN
S3	**Bandages and dressings**				
S3.1	Adhesive tape	2.5 cm × 5 m	1	HC2	N
S3.2	Bandage, cotton W.O.W. hydrophilic	75 mm × 4 m	1	HC3	N
S3.3	Bandage, P.O.P	100 mm × 2.75 m	1	H	E
S3.4	Bandage, P.O.P	150 mm × 2.75 m	1	H	E
S3.5	Bandage, triangular cotton	136 × 96 × 96 cm	1	HC3	N
S3.6	Bandage, crepe, stretched	100 mm × 4.5 m	1	HC2	E
S3.7	Gauze, absorbent, ribbon	25 mm × 12 m	1	HC4	E
S3.8	Gauze bandage	7.5 cm × 3.65–4 m	12	HC4	E
S3.9	Gauze bandage	10 cm × 3–4 m	12	HC4	N
S3.10	Gauze pads, nonsterile	10 × 10 cm	100	HC4	N
S3.11	Gauze pads, sterile	10 × 10 cm	45	HC4	N
S3.12	Gauze pads, sterile	10 × 10 cm	100	HC4	N
S3.13	Gauze pads, sterile	10 × 10 cm	1	HC4	N
S3.14	Gauze swabs, abdominal	30 × 50 cm, nonsterile	10	HC4	V
S3.15	Gauze, hydrophilic	90 cm × 50 m, X-ray detectable	1	HC4	E
S3.16	Gauze, paraffin	10 × 10 cm	36	HC4	E
S3.17	Gauze, paraffin, medicated	10 × 10 cm	10	HC4	E
S3.18	Gauze, W.O.W, hydrophilic	90 cm × 50 m	1	HC2	V
S3.19	Plaster, adhesive elastic	100 mm × 4.5 m	1	HC4	N
S3.20	Plaster, adhesive elastic	75 mm × 4.5 m	1	HC4	E
S3.21	Plaster, adhesive, zinc oxide	75 mm × 5 m	1	HC2	V
S3.22	Wool, cotton	500 g	1	HC2	V
S3.23	Wool, cotton	200 g	1	HC2	N

HC = health center; H = hospital; V = vital; E = essential; N = nonessential; P.O.P. = plaster of paris; W.O.W. = woven without edges.

Regulatory agencies in resource-constrained countries often lack the capacity to conduct dossier evaluation of diagnostics, and many countries recognize efficacy and safety evaluations by another drug regulatory authority as "proxy evaluations," particularly countries participating in the International Conference on Harmonization. To help resource-limited countries make decisions related to procuring diagnostic supplies, WHO evaluates the quality and operational characteristics of diagnostics for HIV/AIDS, malaria, and hepatitis B and C (WHO/DLT 2011). Manufacturers of acceptable assays are then eligible to tender for procurement through UN programs. This scheme makes quality-assured diagnostic-related reagents, consumables, and laboratory equipment, such as microscopes, available to purchasers in member countries at reasonable prices.

Countries are also using resources from the Global Fund to Fight AIDS, Tuberculosis and Malaria to purchase diagnostic and laboratory supplies and equipment to support the control of the three diseases (GFATM 2009). In addition, organizations can use AIDS Medicines and Diagnostics Services, which is based at WHO, as a source of information and assistance related to procurement and supply management for HIV-related medicines and diagnostics, including HIV antibody test, CD4 cell count, and HIV viral load count. WHO also maintains a list of prequalified health equipment (http://www.who.int/medical_devices/innovation/en).

Chapter 19 includes more information on quality assurance systems.

Distribution

Items are often supplied to laboratories and health facilities because they happen to be in stock rather than because they are actually needed. When stock is adequate, identical quantities of an item may be sent to all laboratories or facilities without considering their particular needs, workload, or past consumption. As a result, some laboratories experience stockouts and cannot provide testing services while others have excess stock, eventually resulting in expired

Table 47-3 Adapted codes for cost analysis of laboratory supplies

Category		Pharmaceuticals	Laboratory consumables, test kits, and reagents
Level-of-use code: Indicates the level of health institution at which the item would normally be permitted for use			
H	Health center level	Items for use through the health system at health center, district hospital, and central hospital levels. For all practical purposes, hospital outpatient departments will be regarded as H level.	Items for use through the health system at health center, district hospital, and referral (regional/central hospitals) levels.
D	District hospital level	Items for use at district hospital and referral hospital levels only.	Items for use at district hospital and referral (regional/central hospitals) levels only.
C	Central hospital level	Items for use at referral hospital level only.	Items for use at referral (regional/central hospitals) levels only.
Therapeutic priority code/diagnostic priority code: Identifies the therapeutic or diagnostic importance of each item using the VEN system			
V	Vital items	The items— • Are potentially *lifesaving*, • Have *significant withdrawal side effects,* making regular supply mandatory • Are of major public health importance (for example, needed by many patients for treatment of serious or contagious diseases, needed to control epidemics, and so on)	The items— • Are required to perform the tests listed in the essential test list to support the implementation of the basic health care package or ART monitoring • Are required to ensure that essential tests are performed in a quality manner (according to agreed standard operating procedures), making regular supply mandatory • Are required for tests used to diagnose, treat, or control diseases of major public health importance (as defined in the basic health care package and national health plan)
E	Essential items	The items— • Are effective against less severe, but nevertheless significant forms of illnesses	The items— • Are normally used to perform essential tests in the basic health care package or ART monitoring; however, absence of the item does not necessarily prevent the test from being performed
N	Nonessential items	The items— • Are used for minor or self-limiting illnesses • Are of questionable efficiency • Have a high cost for a marginal therapeutic advantage	The items— • Are used for additional tests not classified as essential for delivering the basic health care package or ART monitoring • Have a high cost for a marginal therapeutic advantage
Procurement system code: Specifies how items will be procured by national medical stores and by the user units			
A		The items— • Are generally required for large numbers of patients • Will routinely be procured and stocked by national medical stores • Include all H-level medicines Where funds for procurement are insufficient, first priority will be given to the procurement and supply of **V**(ital) **A**-list items. If funds remain after securing such **VA** items, procurement of **E**(ssential) **A**-list items will then be initiated. Thus, ensuring the availability of A-list items is primarily the responsibility of national medical stores.	The items— • Are generally required for large numbers of tests or patients • Will routinely be procured and stocked by national medical stores • Include all H- and D-level laboratory items Where funds for procurement are insufficient, first priority will be given to the procurement and supply of **V**(ital) **A**-list items. If funds remain after securing such **VA** items, procurement of **E**(ssential) **A**-list items will then be initiated. Thus, ensuring the availability of A-list items is primarily the responsibility of national medical stores.
B		The items— • Are generally required for limited numbers of patients • Will not be routinely procured and stocked by national medical stores • Require estimates of annual needs to be made well in advance by the hospitals and submitted as appropriate to national medical stores according to a preagreed time schedule • Require that payment be made in advance before procurement by national medical stores and subsequent supply to the hospitals Thus, procurement of B-list items is primarily the responsibility of the user units.	The items— • Are generally required for limited numbers of tests or patients • Will not be routinely procured and stocked by national medical stores • Require estimates of annual needs to be made well in advance by the hospitals and submitted as appropriate to national medical stores, according to a preagreed time schedule • Require that payment be made in advance before procurement by national medical stores and subsequent supply to the hospitals Thus, procurement of B-list items is primarily the responsibility of the user units.

items and waste. Stockouts of HIV test kits or other essential equipment such as syringes and needles to draw blood may require clients to return another day or go to another clinic. However, many clients who are turned away will not come back, and an opportunity for testing is lost. Country Study 47-2 shows how Zambia dramatically scaled up the distribution of HIV test kits in a few years.

Preprinted standard requisition lists of laboratory and medical supplies organized by service level are useful tools to simplify the distribution of supplies and promote the rational use of limited resources. Such lists indicate to the end user the range of items that are available within the system, with specifications, pack sizes, and stock numbers. The lists can also include current unit prices. In addition, such lists facilitate checking procedures for ensuring that facilities order and supply only approved items. The lists should specify the maximum amounts of all critical items to be kept in the health facility or laboratory. The amount ordered would then be the difference between the stock on hand and this maximum quantity. For facilities with four shipments per year, the maximum amount could reflect three months' use; for hospital wards or departments, a two-week supply is probably reasonable (see Chapter 23).

Putting together a requisition form that is clear to everybody remains a challenge: Should it list single units or packages (for example, one syringe or a box of 100, one bandage or a pack of twelve)? How should the list be organized—strictly alphabetically or by class? Should an alphabetical list

Box 47-6
Sample product specifications

Tricot tubular bandage

- *Elasticity:* Three or four times the original width. Good resistance to lading in both directions. Keeps elasticity after washing or stretching.
- *Components:* Knitted jersey tube, without seam.
- *Material:* 100 percent cotton, unbleached.
- *Size selected:*
- Bandage, tricot, tubular.
- Width: approx. 5 cm.
- Length: approx. 25 m.
- Disposable.
- Nonsterile.

Packaging and labeling:

- Primary packaging: Unit of use.
- One tricot bandage in a plastic bag.
- Labeling on the primary packaging:
- Name and/or trademark of the manufacturer.
- Manufacturer's product reference.
- Type of product and main characteristics. If the packaging is not transparent, it must bear a diagram (preferably actual size) showing the essential parts of the product and indicating the position of the product in the packaging.
- Lot number prefixed by the word "LOT" (or equivalent harmonized symbol) (if applicable).
- Expiry date by year and month, prefixed by the word "EXP" (or equivalent harmonized symbol) (if applicable).
- The words "for single use" (or equivalent harmonized symbol).
- The words "destroy after use" (if space allows).
- Number of units per primary packaging (if applicable).
- Information for particular storage conditions (temperature, pressure, light, humidity, etc.), as appropriate (or equivalent harmonized symbol).
- Manufacturer's instruction for use.
- Alternatively, the instruction for use can be indicated on a separate insert.

Secondary packaging: Protected unit.

- Ten tricot bandages in a plastic bag.
- Labeling on the secondary packaging:
- Labeling to be the same as primary packaging.
- Extra information required:
- Number of units per secondary packaging.

Weight/volume/dimensions:

- Estimated weight: 0.500 kg
- Estimated volume: 2 cdm

Instructions for use:

- Tubular bandage applied under plaster of Paris bandage to protect the skin.
- This dressing should fit the limb snugly but not tightly and without any fold.
- If needed, it can be used as a sterile item in surgery after steam sterilization.
- This size has been chosen as being the most commonly used.
- Provision for hospitals that constantly use this item (see plaster of paris).

Conditions for stock:

- Keep under dry conditions.

Source: UNICEF 2011.

Country Study 47-2
Scaling up HIV testing in Zambia

The objectives of the Zambia Voluntary Counseling and Testing Services (ZVCTS) are to coordinate the implementation of voluntary counseling and testing (VCT) services, train adequate numbers of VCT staff, review and harmonize HIV testing protocols, streamline information systems, improve tracking of specimens sent for testing, and continue research activities with the virology laboratory.

Zambia has scaled up its HIV testing and counseling services substantially since 1999; ZVCTS reports that the number of VCT sites had increased from 22 to 650 by the end of 2006. ZVCTS data show that the number of clients tested increased from 27,348 in 2002 to 337,760 in 2006—representing a twelvefold increase in the number of test kits that needed to be stored and distributed in just four years.

In 2000, six different rapid HIV test kits were used in Zambia because of the lack of harmonization across donors and facilities. Some donated test kits were either not included in the national HIV testing protocol or were inappropriate for the technical capacity and local situation. In 2001, after a literature review and consultation with kit users, stakeholders, and regional laboratory technicians, the country adopted a nationwide testing protocol. In the absence of reliable information, each newly established VCT site estimated how many new kits it needed; these numbers were consolidated and adjusted based on population, epidemiological data, and projected coverage.

ZVCTS and the Ministry of Health recognized early on that building capacity at the district level is essential to support scale-up of HIV testing and counseling services and to sustain programs in the long term. Strategies to transfer technology and skills to the district level and build local ownership began in 2002 and included establishing a pull system for ordering, developing tools as part of the commodity management information system, and training staff to quantify their commodity needs and prepare accurate reports. The information system is actually maintained at the district level; the district officer is responsible not only for aggregating data and generating and forwarding reports to ZVCTS, but also for providing feedback to facilities on a monthly basis. This monthly report compares each site's activities with other similar facilities and aims to motivate staff to maintain or improve their performance.

Facilities no longer need to collect their test kits and supplies from the Medical Stores Limited (the central medical store), because it delivers directly to the HIV counseling and testing sites. A long-established system is used for returning short-dated stock for redistribution. In 2005, mobile HIV testing and counseling units began offering services, and demand for services is reportedly high, with some sites reporting that mobile services are contributing more than 50 percent of the clients tested. Building the commodity management capacity of districts has been key to supporting the rollout of this new service delivery model, because mobile units get their commodities from and report consumption to the district level.

In 2006, stakeholders, including the National AIDS Council, the Zambia HIV/AIDS Prevention, Care and Treatment Partnership, and the Ministry of Health, developed and approved a new national HIV testing algorithm. The new standard test kit does not require refrigeration and is easier to use. The phased implementation of the new algorithm began in 2007 with support for managing the new commodities coming from new forms, standard operating procedures, and training.

Source: Walkowiak and Gabra 2008.

mention *Bandage*, *crepe*, or *Crepe bandage*? If the list is by class, should all plastics be listed together or classed as disposables, nondisposables, or something else?

The best solution for the central store and highest-level health facilities is a full list of items organized in groups and using the common pack size of items as the counting unit. For the lower levels of the health care system or for individual hospital wards, a short alphabetical list and standard order form can be used, with single items as the counting unit. Whatever the system, it needs to be logical, and the form should be tested with some end users.

Inventory management

Good management of storage and inventory involves monitoring expiration dates, inventory levels, unexplained losses (leakage), and storage conditions such as light, temperature, and sanitation, which are particularly critical for test kits and diagnostic reagents (Chapter 44). Computerized or manual records are required to control inventory effectively. These records include basic records such as stock or bin cards, monthly consumption records, inventory control forms, and a list of expired supplies (Chapter 23). The pro-

cess should be supported by an information system for performance monitoring (Chapter 49).

The following conditions need to be considered when storing supplies, especially for the laboratory—

- Restricted access to the laboratory to authorized staff
- Cleanliness of benches and shelves
- Appropriate methods for disposal of waste
- Humidity
- Temperature requirements and monitoring
- Adequate refrigerated space maintained at optimal temperatures (+2 to +6°C)
- Adequate freezer space (at -20°C and -70°C)
- Emergency power supply
- Lighting (for example, store out of direct sunlight)
- Appropriate shelving and cupboards

Safe disposal

The safe disposal of laboratory waste and other contaminated materials is of prime importance.

Although most medical and laboratory waste is similar to domestic waste, 10 to 25 percent is infectious or hazardous. These items represent dangers to both laboratory and health facility staff and the community. In addition, the uncontrolled dumping of solid, liquid, chemical, and biological medical and laboratory waste threatens the environment.

Laboratory and medical waste includes—

- Sharps
- Chemical waste—expired reagents and consumables
- Human anatomical waste
- Blood and body fluids
- Solid waste such as cotton wool, tissue paper, culture plates with used media, used blood-giving sets, empty blood packs, used test tubes, and used glass slides
- Laboratory specimens
- Equipment effluent

Incineration is the most widely used technology to dispose of medical waste, but other methods are available and may be more appropriate depending on the context. WHO has published detailed guidelines on medical waste management (Prüss, Giroult, and Rushbrook 1999) and has a website with information on disposing of hazardous medical and laboratory waste (http://www.healthcarewaste.org/en/115_overview.html).

47.4 Equipment management

Countries should develop an equipment policy that includes a maintenance plan, a budget for equipment maintenance (that is, for repairs and spare parts), and guidance on equipment donations. Laboratory or health facility managers must have technical oversight of equipment management and monitor related activities. They should assign responsibilities and ensure all staff members are trained on basic equipment management requirements.

Criteria for selecting equipment

Managers must select capital laboratory and other equipment based on the proposed use of the equipment, the equipment's fit with the service provided, its performance characteristics, facility and infrastructural requirements, cost, availability of reagents and consumables, ease of operation, and input from users such as health care providers and laboratory staff. In addition to input from users, equipment should be selected in consultation with maintenance staff.

WHO's Regional Office for Africa and partners published a document that provides equipment specifications that may be useful when selecting equipment (WHO/AFRO 2008a). In addition, WHO has published a list with fact sheets of core medical equipment (WHO/EHT 2011a).

Equipment acquisition

Equipment may be acquired through direct purchase, lease, or rental. Expertise is required for the purchase and maintenance of medical equipment. Consulting experts at an early stage of the procurement process may prevent problems later.

Procuring equipment centrally is often best. If many of the same items are required, then bulk procurement may be the most cost-effective and practical approach. Regardless of how the equipment is acquired, laboratories and health facilities must consider the responsibilities of the manufacturer or distributor and the conditions of the sales contract, customer support plan, and maintenance contract.

The manufacturer or distributor must guarantee—

- Provision of all reagents, consumables, and culture materials at an affordable and sustainable price (distributors usually offer reduced prices for high-consumption items, so bulk or central ordering may be an advantage)
- A reasonable expiration date on all reagents and consumables
- Acceptable shipment conditions and assistance with customs logistics to avoid damage to equipment or deterioration of the reagents
- Installation of the equipment, staff training, and ongoing technical support
- Provision of a parts manual and an operator's manual
- A trial period for the equipment, after which it can be returned if it is not deemed suitable

- Ongoing maintenance and repairs, including emergency services

The sales contract must be reviewed carefully before completing the purchase. The contract should clearly stipulate all of the preceding manufacturer or distributor responsibilities, and a customer support plan and maintenance contract should be available for all capital equipment. Maintenance contracts are essential for all automated equipment, such as hematology and chemistry analyzers, CD4 counters, automated blood culture and liquid TB culture systems, such as the Mycobacteria growth indicator tube and Cepheid GeneXpert® TB assay, and biosafety equipment, which should also include maintenance contracts for biological safety cabinets.

Before installation, confirm who is responsible for installation and verify that physical requirements have been met, including safety checks of electrical connections, space, ventilation, water supply, and ambient temperature. Upon equipment receipt, verify package contents. The new equipment should not be used before it has been properly installed; the manufacturer should install capital equipment.

Equipment inventory management

The basis for effective inventory management is an up-to-date and complete list of all equipment in a health facility's inventory. The minimum information to be on the list includes the manufacturer, the model, the identification number, the power requirements, and the equipment's physical location in the facility. Other minimum information is listed in WHO's manual on the topic (WHO/EHT 2011c).

After the inventory list has been compiled, it needs to be updated whenever information changes, such as purchase of a new piece of equipment or movement of an existing item. In addition, the facility engineer, or whoever is responsible, should conduct an annual audit to make sure the list is accurate. The inventory list can then be used as a resource to develop budgets, identify human resource and training needs, and manage service contracts, among other activities (WHO/EHT 2011c).

Equipment maintenance and service

After installation, establish an inventory record for the equipment; define the conditions for the equipment's use; develop and implement protocols for calibration, performance verification, and operating procedures; establish a maintenance program; and provide training for all operators. New equipment must be validated and calibrated before use.

Equipment maintenance programs ensure equipment safety, fewer work interruptions, lower repair costs, longer equipment life, and greater confidence in the reliability of test results. Maintenance involves systematic and routine cleaning and adjustment or replacement of instrument and equipment parts. Maintenance should be performed daily, weekly, or monthly, depending on the equipment. Laboratory or facility managers should schedule regular service for all key equipment by the manufacturer or representative. Having all items of the same model (for example, microscopes) serviced at the same time is efficient. Local biomedical service technicians can maintain basic equipment items such as water baths.

If a piece of equipment malfunctions, users should check the manufacturer's instructions, determine the source of the problem—which could be, for example, the sample, the reagent, the equipment, the electrical supply, or the water supply—and make one change at a time to try to diagnose the source of the problem.

Retire equipment when experts indicate the item cannot be repaired or is outmoded and should be replaced with a new model. Updating equipment prevents inaccurate test results, frees up valuable space, and reduces hazards. Any usable parts from the old equipment can be salvaged, taking into account any biohazards. Safety disposal procedures must be followed for any parts that cannot be reused.

47.5 Donations of equipment and other commodities

Donations of commodities and equipment to laboratories and health facilities must be handled carefully, ensuring that donations are based on need expressed by the recipient country. When donors are involved in providing medical supplies and equipment, problems related to the lack of standardization and to maintenance may arise. First, many donors want to buy the equipment, leaving the recipient to solve the problem of paying for installation, maintenance, and recurrent costs. Second, many donors are not sensitive to the recipient's technical requirements. Therefore, storerooms in many countries have equipment that has never been used or has broken down and cannot be repaired because of a lack of spare parts and local service facilities or a lack of instructions in the local language. Third, a donor's policy may differ from the national policy, for example, in relation to the use of disposable syringes. In general, donated equipment contributes to the lack of equipment standardization in developing countries.

All donated capital equipment and diagnostic commodities must comply with the quality standards of both the donor and the recipient country, and insisting that donated diagnostic commodities have a shelf life of at least one year is reasonable. Any instructions should be in English or in the country's national language that is easily understood by

laboratory or facility staff. Whenever possible, the donor agency pays for international and local transport, warehousing, and port clearance as well as a maintenance contract. Adequate supplies of consumables should accompany donations of capital equipment.

Most of the principles of pharmaceutical donations, as presented in Chapter 15, apply equally to supplies and equipment. Nevertheless, a few specific issues regarding equipment donations should be kept in mind (WHO/EHT 2011d). Governments should develop local policy, guidelines, and regulations to govern health care equipment donations, if they do not already exist. The most important issue is the provision for maintenance and spares. As mentioned, it should be the first criterion used in choosing equipment for procurement; it should also be the first argument for acceptance of a proposed donation.

In its guidelines on health care equipment donations, WHO (2000) outlined the four core principles of equipment donations—

- A health care equipment donation should benefit the recipient to the maximum extent possible.
- A donation should respect the wishes and authority of the recipient and conform to existing government policies and administrative arrangements.
- No double standard should exist in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.
- The donor and the recipient should communicate effectively, with all donations resulting from a need expressed by the recipient and following a plan formulated by both parties. ■

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ASSESSMENT GUIDE

Management

- Does a national laboratory policy exist?
- Have national lists of essential medical supplies and equipment been officially adopted and distributed countrywide?
- Is there an official committee whose duties include updating the lists?
- Have the lists been updated and distributed countrywide in the past five years?

Selection

- How many items does the list of essential medical and laboratory supplies and equipment contain? How are the items classified?
- Is the list divided into levels of health care? How many items exist for each level?
- What equipment, testing kits, reagents, consumables, and specimen collection supplies are needed to perform specific diagnostic tests, such as HIV diagnosis, monitoring of HIV treatment, TB diagnosis, identification of drug resistance, and so on?
- Does the laboratory equipment require unique commercial brands of testing reagents or kits?
- Does the equipment need specialized preventive maintenance and repair?
- Are the parts accessible?
- Does a service agreement exist?

Procurement and distribution

- Is procurement in the public sector limited to items on the list?
- What is the ratio of the value of items from the list procured in the public sector to the total value of laboratory supplies and equipment procured in the same sector?
- What mechanisms for procuring laboratory reagents, test kits, and consumables currently exist at the national level, the facility level, or both?
- If no system exists, can procurement be integrated into the existing medicine or laboratory supply system?
- If the procurement of laboratory supplies and diagnostics is to be decentralized to lower levels, do the staff have the skills, finances, managerial support, and information to carry out procurement functions successfully?
- Do equipment and supply donations comply with the national lists?
- Do any of the commodities have special storage requirements? Is the freezer, refrigerated, or cold storage space adequate? Is the electricity supply reliable?
- Is a procedure in place for a cold chain to maintain and monitor special storage temperatures from delivery of the commodity to storage and use? Are supplies to transport heat-sensitive commodities, including cooler boxes and icepacks, adequate? What system is in place to monitor freezer, refrigerator, and storeroom temperatures regularly?
- How much room is needed to store all the commodities between deliveries? Can more storage space be found or more frequent deliveries be scheduled? If scaling up is planned, where will additional commodities be stored?

Human capacity

- Are staff trained to handle specimens, equipment, reagents, test kits, and other consumables safely and appropriately?
- Do they need training updates for new tests or procedures? Are approved, written standard operating procedures available and followed for (1) use and maintenance of each item of equipment, (2) preparation of reagents, (3) procedures for performing each test, and (4) safety practices?
- Are supplies available to safeguard the health and safety of the staff performing HIV testing?

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