The Access and Delivery Partnership (ADP) works with low- and middle-income countries to ensure life-saving medicines and health technologies reach the people who need them. We support countries to strengthen and harmonize policies and systems, and we build the capacities of key people and institutions to drive the necessary reforms for sustainable, country-led progress towards universal health coverage. ADP is supported by the Government of Japan and led by the United Nations Development Programme, in collaboration with the World Health Organization, the Special Programme for Research and Training in Tropical Diseases, and PATH.
Procuring medical equipment presents unique challenges that are not encountered when procuring medicines. For example, when procuring medical equipment, it is necessary to consider:

- Performance and functional requirements
- Installation site characteristics
- Power availability and quality
- End-user and technician skills
- Spare part availability and funding
- Consumables planning, funding, and supply
- Total costs of equipment ownership

Unfortunately, these operational needs and constraints are often inadequately considered during medical equipment planning and procurement processes. It is estimated that between 40% to 70% of medical equipment in low- and middle-income countries is broken, unused, or unfit for purpose. This high rate of equipment failure impacts patient outcomes, health system efficiency, and the workload of health care providers.

Value-based procurement (VBP) is the practice of evaluating potential new products, services, and solutions to maximize overall value for money (VFM), rather than focusing only on the lowest purchase price. In the context of medical equipment procurement, VBP approaches require that procurement teams work as part of a health technology management (HTM) system to fully evaluate medical equipment, services, or alternative solutions, aiming to maximize VFM.

Working on a multidisciplinary HTM team, procurement staff can collect input from facility staff, clinicians, biomedical engineers, program managers, financing experts, and other stakeholders. This expert input enables procurement teams to better analyze options, estimate costs, and identify equipment, services, and/or appropriate solutions that can meet health needs in the long term.

This guide is intended to support public sector procurement teams in resource-constrained health systems to implement a VBP approach when planning for and procuring new medical equipment. This guide provides information in seven sections:

1. Implementing value-based procurement
2. Leveraging health technology management systems
3. Documenting medical equipment requirements and specifications
4. Estimating, comparing, and planning for total costs of ownership
5. Considering alternative procurement models
6. Preparing for medical equipment installation, commissioning and training
7. Managing Medical Equipment Donations

Accomplishing VBP of medical equipment will require procurement teams to coordinate support and input from government leaders, finance systems, donors, technical agencies, regulators, manufacturers, suppliers, and other partners.

Medical equipment is defined by the World Health Organization (WHO) as a medical device requiring calibration, maintenance, repair, user training, and decommissioning—activities typically managed by biomedical engineers.

Examples of medical equipment include:

- Laboratory equipment, X-ray machines, and magnetic resonance imaging (MRI) scanners (diagnosis)
- Surgical instruments and radiology equipment (treatment)
- Electrocardiogram (ECG) machines and pulse oximeters (monitoring)
- Infant incubators, blood-gas analyzers, and ventilators (critical care)
- Oxygen therapy systems (community-based care)
- Defibrillators (emergency services)
- Pharmaceutical and vaccine refrigerators, refrigerated vehicles, transport carriers, and temperature-monitoring equipment (supply chain)
Implementing Value-Based Procurement

Value-based procurement (VBP) is the practice of evaluating potential products, services, and solutions to maximize overall value for money (VFM), rather than focusing only on the lowest purchase price.

As illustrated in Figure 1, a VBP approach will identify and consider not only the core health outcome and costs factors during planning and procurement processes—but also the potential benefits to patients, providers, and national health and HTM systems. As part of VBP, a VFM analysis framework can be applied to support decision-making that looks at broader benefits and long-term equipment and management costs.

How is value for money evaluated?

A VFM evaluation framework can be subjective and difficult to standardize; however, it typically considers five key elements: economy, effectiveness, efficiency, equity, and sustainability.

**Economy**

Does the equipment provide required health services at the lowest total cost of ownership (TCO)?

Questions to consider when evaluating the economy element of VFM include:

- Will the equipment/service support national strategic plans?
- Will the equipment/service support multiple health program targets?
- What is the total cost of ownership of the different equipment/service options?
- Is it feasible to correctly install, maintain, and operate equipment over its full life cycle?
- Will consumables and associated equipment (e.g., cold chain for reagents) be available?
- Do health technology assessment (HTA) reports support this type of medical equipment?

**Effectiveness**

Can the equipment effectively contribute to better health outcomes?

Questions to consider when evaluating the effectiveness element of VFM include:

- Will the equipment/service model meet the needs of clinicians and patients?
- Will the equipment/service model align with existing guidance from technical partners or HTA reports?
- Will the equipment/service model facilitate health care services?
- Will the equipment/service model maximize health outcomes over other options/investments?

**Efficiency**

Does the equipment/service model maximize patient, clinician, or health system benefits relative to equipment or service alternatives?

Questions to consider when evaluating the efficiency element of VFM include:

- Will the equipment/service model benefit multiple health programs?
- Will less complex equipment models meet health and end-user needs?
- Are adequate resources allocated to management systems and TCO?
- Will the equipment/service model facilitate health care services?
- Will the equipment/service model increase the efficiency of the health system?
- Will the equipment/service model minimize risks?
Equity

Does the equipment support the health needs of all populations?

Questions to consider when evaluating the equity element of VFM include:

• Will the equipment/service model benefit all populations with high disease burdens, rates of new infections, or difficulty accessing health care?
• Will the equipment/service model reduce financial, human rights, or gender-related barriers to health care?

Sustainability

Can a health facility, program, or system maintain the equipment/service model long-term?

Questions to consider when evaluating the sustainability element of VFM include:

• Are adequate resources allocated to build and sustain health service access?
• Is there a strategy to maintain competitive prices and access?

VFM should consider all five of the above elements during the evaluation process. When available, health technology assessment (HTA) reports can often provide valuable information for a VFM analysis. VFM criteria to include in bid evaluations include quality and safety standards and indicators of supplier capabilities.

The amount of detail and level of complexity applied to a VFM evaluation should reflect the complexity and cost of the medical equipment being procured.

Challenges include:

• VFM is subjective and difficult to formalize in a single framework.
• VFM evaluation requires input from diverse stakeholders.
• Managers may be unwilling to change the practice of making decisions based on lowest bid price.

It is critical for procurement teams to promote value-based procurement during conversations around equipment planning, procurement decision-making, and overall system management.

Global Fund VFM Recommendations

Following a multi-country analysis and pilot testing of a proposed VFM framework, the Global Fund has shared the following recommendations for new investments in national HIV, tuberculosis, and malaria laboratory systems:

1. Use a reagent rental or all-inclusive business model for service delivery instead of capital purchase of new laboratory equipment.
2. Include and monitor key performance indicators for suppliers, end users, and equipment.
3. Prioritize multi-disease diagnostic platforms over single-disease equipment, so that costs of maintenance and consumables can be shared across programs.
4. Standardize a minimum package of supplies, tests, and equipment needed at each level of a tiered laboratory system.
5. Implement laboratory network assessments and optimization activities prior to purchase or rental of new equipment.
Leveraging Health Technology Management Systems

Medical equipment planning and procurement are conducted as part of a national health technology management (HTM) system. As defined by WHO, the proper management and use of health care technologies begins with a strong understanding of the needs of the country, region, community, and facility, and ends with final equipment decommissioning and disposal.

HTM includes planning and procurement, appropriate donation solicitation and provision, effective equipment delivery and installation, asset inventory management, maintenance, and end-user training on correct operation. HTM is conducted alongside health technology assessments (HTAs) and health technology regulatory and performance compliance.\(^9\)

Recognizing the important role of health technologies, the 60th World Health Assembly reinforced the need to establish priorities in the selection and management of health technologies in resolution WHA60.29.\(^10\) This resolution recommends that to reduce wasted resources, ministries of health develop national strategies to support HTM, including the development of systems to assess, plan, procure, and manage health technologies.

HTM systems will vary by country and health system level. Some countries will need to invest in additional advocacy and analysis activities to underscore for decision-makers the important role that HTM plays in an efficient health system.

Figure 2 illustrates some of the links of HTM to policy, regulation, financing, and public health research processes, and shows the various stakeholders that contribute to and benefit from an HTM system.

Figure 2. HTM linkages to a national health system

Ministries of health will need to work with stakeholders to identify practical and feasible HTM indicators to monitor and use for performance management systems. Procurement teams can incorporate these HTM indicators into contracts and service level agreements as appropriate.

**HTM processes and activities**

Medical equipment planning and procurement are HTM processes in the acquisition stage. The acquisition stage is followed by the utilization stage of HTM. Examples of activities that occur during the acquisition and utilization stages of HTM are shown in Table 1. This guide focuses on the equipment acquisition stage of HTM.

**HTM requirements**

Identifying, analyzing, and planning to address the life cycle requirements of medical equipment not only helps procurement teams maximize VFM and patient outcomes, but also informs accurate technical specifications that represent national, subnational, and facility-level needs.

Public procurement teams must have active participation from a multidisciplinary team of HTM stakeholders, including health facility staff, clinical and laboratory experts, biomedical engineers, health program managers, health system strategists, health financing agencies, and—in some cases—patients to fully understand equipment requirements. Some of the required inputs from HTM representatives are listed in Table 2.

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**Table 1. Examples of stages, processes, and activities for HTM acquisition and utilization**

<table>
<thead>
<tr>
<th><strong>MEDICAL EQUIPMENT ACQUISITION STAGE</strong></th>
<th><strong>Activity examples</strong></th>
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<td><strong>Equipment planning</strong></td>
<td>Needs assessment</td>
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<td>Health technology assessments</td>
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<td>Health system strengthening</td>
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<td>Budgeting/financing for TCO</td>
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<td>Feasibility appraisal</td>
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<td>Value for money appraisal</td>
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<tr>
<td></td>
<td>Market analysis</td>
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<td><strong>Equipment procurement</strong></td>
<td>Procurement specifications</td>
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<tr>
<td></td>
<td>Tender/purchase/lease</td>
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<td></td>
<td>Delivery and installation</td>
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<td>Commissioning and acceptance</td>
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<td></td>
<td>Initial training of users and technicians</td>
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</table>

<table>
<thead>
<tr>
<th><strong>MEDICAL EQUIPMENT UTILIZATION STAGE</strong></th>
<th><strong>Activity examples</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Process</strong></td>
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<tr>
<td><strong>Equipment management</strong></td>
<td>Contact management</td>
</tr>
<tr>
<td></td>
<td>Supplier management</td>
</tr>
<tr>
<td></td>
<td>Equipment inventory/audits</td>
</tr>
<tr>
<td></td>
<td>Performance monitoring</td>
</tr>
<tr>
<td></td>
<td>Maintenance/spare part tracking</td>
</tr>
<tr>
<td></td>
<td>Routine training of users and technicians</td>
</tr>
<tr>
<td></td>
<td>Evidence-based replacement planning</td>
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<tr>
<td></td>
<td>Decommissioning and disposal</td>
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<tr>
<td><strong>Risk management</strong></td>
<td>Post-market surveillance</td>
</tr>
<tr>
<td></td>
<td>Inspection and calibration</td>
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<td></td>
<td>Adverse event monitoring</td>
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</tbody>
</table>
HTM regulations and standards

HTM should be supported at the national, sub-national, and facility levels with regulations, standards, and funding.

HTM regulations or standards must outline:

- Roles and responsibilities for medical device (including medical equipment) management.
- Importance of HTM that includes selection, acquisition, acceptance, maintenance, repair, monitoring, and disposal of equipment.

Examples of existing HTM policies or standards include:

**UK Health and Social Care Act (Regulated Activities) Regulations 2014: Regulation 15**

This UK Government regulation includes the requirement that medical equipment used to deliver care and treatment must be clean, suitable for the intended purpose, maintained, stored securely, and used properly.


### Table 2. Stakeholder inputs to equipment planning and procurement HTM processes

<table>
<thead>
<tr>
<th>Health facility personnel</th>
<th>Clinicians and laboratory managers</th>
<th>Biomedical engineers</th>
<th>Policy and financial personnel</th>
<th>Procurement staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health need characterization</td>
<td>Health need characterization</td>
<td>Maintenance requirements</td>
<td>Relevant strategic initiatives</td>
<td>Bidding documents</td>
</tr>
<tr>
<td>Usability criteria</td>
<td>Usability criteria</td>
<td>Quality standards</td>
<td>Legal requirements</td>
<td>Contract documents</td>
</tr>
<tr>
<td>Background on past equipment performance</td>
<td>Patient needs</td>
<td>Power quality and availability</td>
<td>Budgets for maintenance</td>
<td>Contract management</td>
</tr>
<tr>
<td>Past local supplier performance</td>
<td>Consumables</td>
<td>Environmental factors</td>
<td>Budgets for operation and disposal</td>
<td>Supplier performance monitoring</td>
</tr>
<tr>
<td>Facility accessibility</td>
<td>Existing annual or multi-year facility plans</td>
<td>Water and waste systems</td>
<td>Timeline and constraints</td>
<td></td>
</tr>
<tr>
<td>Infrastructure status</td>
<td>Training needs</td>
<td>Transport</td>
<td>Partnership management</td>
<td></td>
</tr>
<tr>
<td>Power quantity and quality</td>
<td>Assessments</td>
<td>Installation</td>
<td>Donor management</td>
<td></td>
</tr>
<tr>
<td>Training needs</td>
<td>Existing HTA outputs</td>
<td>Maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TCO input data</td>
<td>TCO input data</td>
<td>Spare part management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Risk identification</td>
<td></td>
<td>Inspection</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Calibration</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TCO input data</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Requirements for risk management, including adverse incident reporting.
- Training requirements and access to the manufacturer’s instructions.
- Record keeping, including asset inventories and maintenance tracking requirements.
- Conditions for outsourcing of maintenance.
- Standard protocols for equipment deployment, tracking, and utilization.
- Equipment acquisition and utilization financing.
- Decontamination requirements, when needed.
In 2017, the Zambian Ministry of Health requested that the Tropical Health and Education Trust (THET) study the impact of biomedical engineering technologists (BMETs) on medical equipment performance in reference hospitals.

At the conclusion of the Medical Equipment Uptime Project, a systematic approach to procurement of new medical equipment was recommended to diminish the large differences in equipment availability at various hospitals. This approach would also make access to health care throughout Zambia more equitable and would support the goal of universal health coverage.

Financial analysis at the end of the project concluded that medical equipment procurement without an equipment maintenance plan is wasteful. Analysis also indicated that:

- Cost of Service Ratio (COSR), defined as the yearly cost of providing maintenance divided by the initial procurement cost of the equipment, was estimated as 2.8% for “in-house” maintenance.
- COSR of 5% should be budgeted for outsourced maintenance contracts.
- Maintenance budgets should not be assumed to be available.
- Equipment lifetime will be reduced by a factor of 2 if maintenance costs are not addressed.
- Priorities of the health departments did not correspond with equipment procured centrally.
- Standard Equipment Lists (SEL) focused primarily on needs of higher-level hospitals.
- New equipment procurement often replaced available equipment that could instead be repaired.
- Procurement of spare parts was needed in 30% of repair cases; however, procurement of spare parts from international suppliers was not successful in the project timeframe.

Adapted from: THET, Medical Equipment Uptime Project Final Report. Photo: PATH/Gabe Bienczycki.
HTM RESOURCES

WHO publications on medical devices
Available at https://www.who.int/medical_devices/publications/.

“How to Manage” Series for Healthcare Technology
This series is designed to contribute to improved health care technology management (HTM).
The series includes:
• Guide 1: How to Organise a System of Healthcare Technology Management
• Guide 2: How to Plan and Budget for your Healthcare Technology
• Guide 3: How to Procure and Commission your Healthcare Technology
• Guide 4: How to Operate your Healthcare Technology Effectively and Safely
• Guide 5: How to Organise the Maintenance of your Healthcare Technology
• Guide 6: How to Manage the Finances of your Healthcare Technology Management Teams

Managing the Lifecycle of Medical Equipment

International Federation for Medical and Biological Engineering (IFMBE) website
The IFMBE supports the United Nations and WHO to promote information on biomedical and clinical engineering and advancing safe and effective medical technology design, deployment, and management programs.

EBME website
This medical engineering portal operated in the United Kingdom includes many articles and aggregates standards and guidelines for medical equipment management and maintenance.

HTM support materials
The Biomedical Equipment Management and Maintenance Program of the National Health Systems Resource Centre, Ministry of Health and Family Welfare, Government of India, has produced the following:
Documenting Medical Equipment Requirements

Medical equipment requirements document the functions, performance, and features necessary to meet the end user’s needs and deliver the desired health outcomes at the facility in which equipment will be utilized and maintained. Requirements should communicate what is needed over the complete equipment life cycle, from installation to the operational and decommissioning stages.

Incomplete or inaccurate medical equipment requirements will result in equipment that:

• Does not meet a health need.
• Cannot be correctly installed or commissioned.
• Will not have access to the required quantity or quality of energy.
• Will be broken by untrained users or technicians.
• Cannot be calibrated or maintained according to manufacturer’s recommendations.
• Is not sustainable for operation in the facility’s existing budget.
• Will not be decommissioned or disposed of properly at the end of its economically viable lifetime.

Requirements should be written in simple, precise, and brand-agnostic language to support active, fair, and transparent competition in the tendering process. Requirement documentation should be a collaborative activity that engages all relevant HTM members.

Requirements are specified in three documents which will be developed sequentially and are detailed here.

How are medical equipment requirements documented?

There are three different documents used to communicate medical equipment requirements:

1. Procurement product profiles
2. Technical specifications
3. Procurement specifications (also known as bidding or tender documents)

These documents will be used for different purposes and with varying levels of detail, as described in Table 3.

These three documents—the procurement product profiles, technical specifications, and procurement specifications—are developed sequentially, as shown in Figure 3 on the next page.

Table 3. Description, purpose, and key contributors to medical equipment requirement documents

<table>
<thead>
<tr>
<th>Document type</th>
<th>Purpose</th>
<th>Contributors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procurement product profile</td>
<td>Preliminary documentation that provides a high-level description of what is needed, including accurate information from a facility perspective. This document also highlights urgent constraints that must be addressed in the technical specifications document.</td>
<td>End users, Program staff, Biomedical engineers, Technical experts</td>
</tr>
<tr>
<td>Technical specifications</td>
<td>The technical specifications document is a common format that specifies functional, performance, and design requirements for medical equipment. It also outlines what will be needed for delivery, installation, commissioning, and acceptance of equipment.</td>
<td>Biomedical engineers, Technical experts</td>
</tr>
<tr>
<td>Procurement specifications</td>
<td>Also known as bidding or tender documents, procurement specifications will include technical specifications and information on the procurement process, dates of bid submission and opening, evaluation criteria and methods, and contract terms and conditions.</td>
<td>Procurement staff, Technical experts</td>
</tr>
</tbody>
</table>
1. Procurement product profile

The procurement product profile is a high-level description of basic medical equipment requirements, specifically focused on meeting the needs of patients and end users, recognizing what is appropriate for a specific facility context, and planning for how the equipment will need to be supported by the health technology management system.

The procurement product profile will be developed and coordinated by the procurement team, with input from facility managers, intended equipment end users, clinical and laboratory experts, biomedical engineers, and other members of the HTM team.

Table 4 lists examples of procurement product profile content from facilities that characterize the health, user, and facility needs.

Clinical, laboratory, biomedical engineering, and other technical experts will review the facility and end-user information to help procurement teams draft functional, performance, and design requirements. They will also assist with other considerations, such as requirements to conform with recognized quality standards, or provision of reference materials and training activities in local languages.
<table>
<thead>
<tr>
<th>Profile sections</th>
<th>Potential questions</th>
</tr>
</thead>
</table>
| **Intended use** | • What will be the main application for this medical equipment (description and purpose)?  
| | • What health care tasks will be supported (name, goal, frequency, flexibility, dependencies, inputs, outputs)?  
| | • Which patient population or health program will benefit from this equipment, and what is the timing within the treatment or care continuum?  
| | • How many patients will need this equipment in a given time period (or alternative metric to assess equipment need)? |
| **System fit** | • How will this equipment fit into a clinical system/process/package of care?  
| | • Will this equipment benefit multiple health programs/needs?  
| | • Do existing clinical guidelines address use of the equipment?  
| | • Is other equipment required for proper use of equipment (e.g., cold chain for reagents, patient trolleys, networked computers)?  
| | • Will this equipment increase access to care of underserved or at-risk populations? |
| **Current practice** | • What equipment is currently used to meet the health need, and what are the costs of operation?  
| | • How does the facility finance medical equipment maintenance?  
| | • Are there alternative equipment, services, or solutions that have been used in the past?  
| | • Are patients referred to other facilities to access health services requiring this medical equipment, and if yes, where is this facility? |
| **User profiles** | • Who will be the users, and what is the designation and number of staff required for use?  
| | • Who will be responsible for maintenance, inspection, and repair?  
| | • What will be the number of users and technicians, and what are their current skills?  
| | • What are the anticipated benefits to users of the new medical equipment?  
| | • What is the current practice for on-boarding new staff and on-the-job training? |
| **Environment** | • Is there a secure area with sufficient dimensions for access and installation?  
| | • What are the expected ambient conditions (e.g., temperature, humidity, elevation, dust, saltwater, flooding, winds, etc.)?  
| | • How accessible is the facility, and will it be difficult to transport and service the equipment?  
| | • What is the availability and quality of electricity at this facility? (Indicate any seasonal differences, use of a generator, problems with maintaining electrical equipment, access to automatic voltage stabilizers/regulators, etc.)  
| | • Are there solar-powered systems on the premises?  
| | • Does this facility have potable water? (Indicate seasonal differences.)  
| | • Does this facility have a health care waste management system? (If yes, describe.) |
Table 5. Functional, performance, and design requirements in procurement product profile

<table>
<thead>
<tr>
<th>Profile sections</th>
<th>Potential questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Functional</strong></td>
<td>• What tests are needed from what specimens (e.g., from laboratory equipment)?&lt;br&gt;• Is an audio or SMS alarm needed when out of range (e.g., controlled temperature range)?&lt;br&gt;• Are there display requirements for the equipment?&lt;br&gt;• What are the requirements for periphery devices or consumables?</td>
</tr>
<tr>
<td><strong>Performance</strong></td>
<td>• What is the level of required throughput, cold chain storage capacity, or other performance specification?&lt;br&gt;• What is the level of accuracy required of outputs?</td>
</tr>
<tr>
<td><strong>Design</strong></td>
<td>• What is the need for device mobility?&lt;br&gt;• Are there size limitations for the device?&lt;br&gt;• Does the device require electricity or other utilities?&lt;br&gt;• Will automatic voltage stabilizers be required to protect electronic components?&lt;br&gt;• What is the need for calibration, repair, and maintenance?&lt;br&gt;• Will data be exchanged with other devices or systems?</td>
</tr>
<tr>
<td><strong>Accommodations</strong></td>
<td>• What level of quality assurance is required?&lt;br&gt;• Based on asset inventory and maintenance data, what is the likely operational life of the device?&lt;br&gt;• What are the language requirements for reference materials provided with equipment and for manufacturer training?&lt;br&gt;• What is the availability of spare parts, and how will international orders for spare parts be managed?&lt;br&gt;• How will service agreements and warranties be managed?</td>
</tr>
</tbody>
</table>

Table 5 lists content that will be drafted by these experts based in part on the facility-level information.

The HTM team should review and finalize the procurement product profile information and clarify which requirements and risks must be considered and prioritized when selecting the medical equipment.

The procurement product profile will subsequently be used to help write medical equipment technical specifications.

2. Technical specifications

A technical specification communicates to potential medical equipment suppliers the specific requirements the equipment must meet (e.g., performance, functional, design, physical, utility, accessory, environmental, training, warranty, and other requirements).

Biomedical engineers and technical experts will review the product profile information and convert it into technical specifications to ensure that the procured equipment is aligned with industry standards and norms, can be installed and operated at the intended installation sites, and will be clearly understood by potential suppliers.
The technical specifications development process includes finding and reviewing available reference material, including:

1. Procurement product profile information on health need, facility environment, usability, and accommodation, alongside draft functional, performance, and technical specifications.

2. National or global technical specifications of similar medical equipment.

3. Technical specification templates, including national templates or the WHO Technical Specifications for Medical Devices template.\(^{12}\)

4. Relevant local, regional, or global HTA reports.

5. Market analysis reports.

Biomedical engineers, clinical and laboratory experts, and specialists will help procurement teams ensure that the technical specifications include all accessories and consumables required to support the operational performance of the medical equipment being procured.

Biomedical engineering teams will also include detailed information on installation, calibration, training, and maintenance requirements in the technical specifications as needed. These requirements are often defined in the technical specifications and expanded upon in more detail in the special conditions of the contract in the procurement specifications. Installation, calibration, training, and maintenance requirements are described in the “Preparing for Medical Equipment Installation, Commissioning, and Training” section.

Information from a technology landscape can also be used to help inform development of the technical specifications. This information can include:

- Identifying and assessing potential suppliers and the medical equipment they offer.
- Degree of competition in the market.
- Availability of alternative or substitute products and services.
- Rate of technological developments in the market.
- Supplier risks.

The extent of the technology landscape necessary will depend on the medical equipment, the complexity of the equipment requirements, the total value of the equipment life cycle costs, and the level of risk to the health program.

Methods for gathering technology landscape information include:

- Issue a request for information (ROI) to obtain information from potential suppliers on specifications and price indications.\(^*\)
- Consult with in-country and neighboring country procurement or clinical colleagues who have experience within the specific area and who can help define what is required.
- Consult existing brochures and catalogues.
- Consult with suppliers or manufacturers specializing in this type of product.
- Access baseline supply chain assessment reports to identify gaps in practices, people, or equipment.\(^\dagger\)

\(^*\) ROIs are often used in the sourcing process, but can support drafting of specifications, terms of reference, or scopes of work. Procurement policies outline how contact with potential suppliers should be conducted to ensure transparent and fair procurement practices.

\(^\dagger\) Supply chain assessments include the USAID National Supply Chain Assessment (NSCA) and the WHO/UNICEF Effective Vaccine Management Assessment.

After the technical specification is drafted, requirements can be compared with the stated performance and functional capacity of comparable medical equipment on the market to ensure that the technical specification will encourage competition for the medical equipment.

### 3. Procurement specifications

The procurement specification, sometimes known as the bidding or tendering document, is the package of assembled information on the medical equipment requirements that will be shared with potential suppliers.

The procurement specification:

- Provides clear instructions to suppliers on what to submit and how to submit their bids.
- Prevents errors in suppliers’ bids, which can create problems during bid evaluation and contract award.
- Protects against acquiring substandard and poor-quality medical equipment.
- Establishes the rules and expectations for any supplier performance requirements under the contract.
Table 6. Standard categories of content for a technical specification for medical equipment

<table>
<thead>
<tr>
<th>Category</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>A simple and broad description of the specified equipment or service.</td>
</tr>
</tbody>
</table>
| **Background information** | • Introduction to support bid invitations and inform potential suppliers about the health needs and local conditions.  
• This document should define what equipment or service level agreement (SLA) will be considered “fit for purpose.”*  

* Examples of equipment that UNICEF considers fit-for-purpose and VFM are shown at [https://www.unicef.org/innovation/productinnovation](https://www.unicef.org/innovation/productinnovation). |
| **Standards** | • Use international safety and performance standards.  
• When anticipating national competition, national standards might be the appropriate solution.  
• If a specific standard is not mandatory, indicate “or equivalent standards.”  

* Examples of equipment that UNICEF considers fit-for-purpose and VFM are shown at [https://www.unicef.org/innovation/productinnovation](https://www.unicef.org/innovation/productinnovation). |
| **Specific constraints and limitations** | Examples of specific constraints and limitations are:  
• Operating conditions (e.g., maximum and minimum temperatures, noise, pressure, humidity, wind velocity, altitude, dust, etc.).  
• Physical space available for installing equipment.  
• Compatibility with existing equipment, systems, etc.  
• Availability of power supply.  
• Servicing or maintenance requirements or limitations. |
| **Requirements** | • Describe the equipment, service, or work requirement in detail, including functional, performance, and technical specifications.  
• The requirement is typically a combination of the three types of specifications: functional, performance, and technical.  

* Examples of equipment that UNICEF considers fit-for-purpose and VFM are shown at [https://www.unicef.org/innovation/productinnovation](https://www.unicef.org/innovation/productinnovation). |
| **Marking** | Possible marking requirements include:  
• Identification marking  
• Manufacturer’s name  
• Model number  
• Manufacturing standard  
• Warnings (e.g., if fragile equipment) |
| **Packing** | To protect equipment from damage during shipment and storage, it may be necessary to:  
• Use special packing.  
• Limit the size or condition of the container.  
• Plan for what will happen with containers, pallets, or other packing materials after installation. |
| **Packaging** | Some goods associated with equipment installation, commissioning, training, and operation may be available with different packaging options that need to be specified. |
| **Quality** | Specifying quality requirements reduces risks associated with the goods. For example, “only goods produced by suppliers adhering to the ISO 9000 quality system are acceptable.” |
| **Testing** | Acceptance testing of medical equipment might be required by national or donor policy:  
• By the supplier (the buyer should specify the test requirements).  
• By a third-party organization.  
• If testing is specified, the provision of test results should be specified as well. |
All national governments have existing standard bidding document components that are used by procurement personnel when requesting bids from suppliers. Key components of standard bidding documents are briefly discussed below.

**Instructions to suppliers/bidders**

Identifies all requirements, procedures, and other information deemed necessary to aid bidders in submitting their bids, such as how, where, and when to submit the bid; the validity period required for the bid; when the bid will be opened; whether a performance security is required; and any other documentation needed to support the bid. This information is prepared by procurement personnel.

**Technical specifications**

Technical specifications have been completed at this point in the procurement planning process and are included in the bidding document package.

**Schedule of requirements**

Identifies the quantity of each medical device required. Also identifies the requested delivery date for the medical device(s) and the final delivery destination for the device(s). This information is completed by procurement personnel.

**Supplier qualification criteria**

Identifies the documentation that the supplier should submit to verify that the required qualification criteria are met. Criteria can include:

- The supplier has verifiable business and financial stability.
- The supplier has adequate production/supply capacity.
- The supplier has verified capacity (qualified staff, supplies, and equipment) to provide in-country technical support.
- The supplier has a verifiable history of successful performance.

This information is assembled by procurement staff.

**Bid evaluation and award criteria, including weighting and methodology**

Identifies the criteria against which a supplier's bid will be evaluated and a contract award decision made. In public sector procurement, the traditional bid evaluation components are:

- Preliminary examination: reviews suppliers' compliance with the general administrative requirements of the bidding documents.
- Technical evaluation: reviews the medical equipment's compliance with the technical specifications.
- Financial evaluation: reviews the total cost of ownership for the medical equipment and other costs in the supplier's bid to determine best value for money.
- Evaluation of supplier qualifications: reviews supplier's documentation to confirm it meets the identified qualification criteria.

Information on the bid evaluation process and award criteria is assembled by the procurement personnel.

**General conditions of the contract**

These are standard contract terms and conditions that include warranty. General terms and conditions are not changed from contract to contract and are included in the bidding document package by the procurement personnel.

**Special conditions of the contract**

Special conditions of the contract provide the opportunity to add more detailed information on requirements that may appear in the technical specification, such as installation, training, and maintenance requirements. Planning for these requirements will be further discussed in the “Preparing for Medical Equipment Installation, Commissioning, and Training” section.

---

**TECHNICAL SPECIFICATIONS RESOURCES**

**WHO website: Technical specifications for medical devices**


Available resources include a WHO recommended format for technical specifications (2014), applied to 61 devices, and a list of related services to potentially tender, depending on the type of medical device and local condition.

**WHO-UNICEF Technical Specifications and Guidance for Oxygen Therapy Devices**


**National Health Systems Resource Centre website: Technical specifications**


This WHO collaborating center for priority medical devices and health technology policy provides resources such as technical specifications for multiple health care technologies.
The concept of total cost of ownership (TCO) for medical equipment recognizes the importance of planning, preparing, monitoring, managing, and funding the complete equipment life cycle. Planning for TCO supports reliable access to functional medical equipment and will ultimately provide important patient benefits.

TCO estimations sum the costs to purchase, install, operate, maintain, and dispose of the equipment over the complete life cycle, and then subtract any end-of-life resale value or other potential financial benefits received, such as tax reductions.

The TCO includes both direct and indirect costs of medical equipment ownership. Unfortunately, medical equipment planning and procurement decisions often consider only the easily identifiable and centrally funded direct costs such as the purchase price and cost of delivery, as illustrated in Figure 4.

Indirect costs can be more difficult to identify, quantify, predict, and control. Indirect costs are often invisible to central planners and, as illustrated in Figure 4, are represented as the underwater portion of a large iceberg. If central planners or donors use only the purchase price and delivery costs to make purchasing and funding decisions, new medical equipment is unlikely to achieve maximum value for money. To maximize benefits to patients and health systems, equipment purchasing decisions must also evaluate and plan for the indirect costs of ownership, such as regular maintenance, repairs, spare parts, energy costs, and supportive management systems.

The benefits of using a TCO approach when planning and budgeting for medical equipment include:

- Supporting sustainable use of the medical equipment.
- Improving budgeting processes for the medical equipment.
- Planning for proper installation, use, and maintenance of the medical equipment.
- Successful decommissioning, removal, and safe disposal of medical equipment.

Opportunities to apply TCO estimates to value-based procurement decision-making include:

**Procurement planning**

- Compare the TCO of different equipment types, models, or ownership models.
- Support health system strengthening strategies with TCO data for equipment planning and prioritization.
- Evaluate and compare costs of in-house and third-party equipment maintenance solutions.
Procurement implementation

- Use TCO estimates and data provided by suppliers to make VFM determinations.
- If procurement policy allows, use TCO to support selection of medical equipment that offers a lower TCO than other equipment that may offer a lower initial purchase price, but has a high TCO over the anticipated lifespan of the equipment.

Performance monitoring

- Track TCO costs and monitor these costs against expected budget.
- Use TCO data to inform future medical equipment decisions, including potential standardization of equipment models.
- Use TCO data and performance indicators to justify investments in health technology management systems.

How to estimate TCO

There is no standard formula for TCO calculations. The costs that need to be considered will depend on the specific procurement activity, including the type of medical equipment being procured. Figure 5 illustrates a simple TCO formula.

While different methods and formulas are used to calculate TCO, the formula used to support a value-based procurement process must be:

1. Reviewed and understood by a working group of HTM stakeholders, including procurement, facility, clinical, and biomedical engineering staff members.
2. Applied universally across all suppliers’ bids/tenders and used to differentiate the TCO for each supplier’s bid/tender.

The cost components to include in a TCO analysis will also vary depending on the type of equipment, the procurement model used, and the local context. Examples of costs to consider in a TCO evaluation are shown in Table 7, segmented by purchasing, operating, maintenance, and disposal costs. The table also differentiates between costs that directly relate to the equipment and costs that directly relate to the equipment management processes.

The following steps are recommended to estimate the TCO for medical equipment:

1. Assemble the HTM team with members who can accurately identify and estimate ownership costs and compare benefits.
2. Define and document the TCO estimation process and assumptions, including:
   - Medical equipment/service needs
   - Medical equipment end users
   - Medical equipment maintenance providers
   - Medical equipment monitoring and management systems
   - Anticipated medical equipment lifespan
   - Medical equipment quantity and usage rates
   - TCO formula to be used, including relevant cost categories
   - Process for gathering cost data or estimates

3. Gather available cost data or, when appropriate, estimate representative costs. When using TCO to make comparisons between suppliers or different models of the same equipment type, it may be reasonable to use estimated costs in a TCO formula. The degree to which you can use relative versus absolute cost data should be defined as one of the first assumptions. Potential cost data sources include:
   - National e-catalogues.
   - UNICEF Supply Division catalogue.
   - WHO and UNICEF published technical resources.
   - Online HTA reports or references.
Table 7. Product and management costs of medical equipment ownership

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>Operation</th>
<th>Maintenance</th>
<th>Disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase</td>
<td>• Equipment • Accessories • Personal protective equipment • Furniture • Infrastructure improvements • Delivery costs • Warranties • Licenses • Taxes • Installation costs • Commissioning</td>
<td>• Power • Water • Software upgrades • Consumables • Cleaning supplies • Personal protective equipment • Annual insurance • Extended warranties</td>
<td>• Repair • Planned maintenance • Inspection • Testing • Calibration • Parts and supplies</td>
</tr>
</tbody>
</table>

MANAGEMENT

<table>
<thead>
<tr>
<th>Purchase</th>
<th>Operation</th>
<th>Maintenance</th>
<th>Disposal</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Strategic procurement • User training • Technician training • Integration into existing processes</td>
<td>• Refresher training • Supervision • Inventory tracking • Performance monitoring</td>
<td>• Service request management • Document management • Data management • Workshops • Biomedical engineering units</td>
<td>• Redeployment planning • Disposal and storage systems • Donation</td>
</tr>
</tbody>
</table>

4. Apply the formula and cost data to estimate the TCO.

As mentioned above, there are different methods and formulas that can be used to estimate the TCO for medical equipment. An example of a TCO calculation for medical equipment is shown in Table 8.
Table 8. Example of a TCO worksheet for a generic medical equipment item with an anticipated 10-year life span

<table>
<thead>
<tr>
<th>Initial costs at purchase (one time)</th>
<th>Subtotal cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase price</td>
<td>$80,000.00</td>
</tr>
<tr>
<td>Accessories</td>
<td>$5,000.00</td>
</tr>
<tr>
<td>Duties, taxes</td>
<td>$5,000.00</td>
</tr>
<tr>
<td>Packaging</td>
<td>$3,000.00</td>
</tr>
<tr>
<td>Delivery costs to point of installation</td>
<td>$3,000.00</td>
</tr>
<tr>
<td>Extended warranty</td>
<td>$8,000.00</td>
</tr>
<tr>
<td>Installation, integration, calibration</td>
<td>$4,000.00</td>
</tr>
<tr>
<td>Initial training by international supplier</td>
<td>$8,000.00</td>
</tr>
<tr>
<td>Alterations, electricity upgrades, cabling, communication networks</td>
<td>$2,000.00</td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td><strong>$118,000.00</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of operational costs (per year)</th>
<th>Unit cost</th>
<th># per year</th>
<th>Subtotal cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine staff training</td>
<td>$500.00</td>
<td>2</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>Consumables: supplies</td>
<td>$50.00</td>
<td>12</td>
<td>$600.00</td>
</tr>
<tr>
<td>Consumables: personal protective equipment</td>
<td>$500.00</td>
<td>1</td>
<td>$500.00</td>
</tr>
<tr>
<td>Energy, fuel</td>
<td>$100.00</td>
<td>12</td>
<td>$1,200.00</td>
</tr>
<tr>
<td>Waste disposal</td>
<td>$100.00</td>
<td>6</td>
<td>$600.00</td>
</tr>
<tr>
<td>Preventive maintenance</td>
<td>$200.00</td>
<td>4</td>
<td>$800.00</td>
</tr>
<tr>
<td>Inspection, calibration</td>
<td>$500.00</td>
<td>2</td>
<td>$1,000.00</td>
</tr>
<tr>
<td>Corrective maintenance (repair)</td>
<td>$500.00</td>
<td>1</td>
<td>$500.00</td>
</tr>
<tr>
<td>Spare parts</td>
<td>$300.00</td>
<td>1</td>
<td>$300.00</td>
</tr>
<tr>
<td>Unplanned downtime</td>
<td>$500.00</td>
<td>3</td>
<td>$1,500.00</td>
</tr>
<tr>
<td>Monitoring and supportive management costs</td>
<td>$500.00</td>
<td>6</td>
<td>$3,000.00</td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td><strong>$11,000.00</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disposal costs (one time)</th>
<th>Subtotal cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decommissioning, deconstruction costs</td>
<td>$500.00</td>
</tr>
<tr>
<td>Cost of transportation of equipment from site</td>
<td>$500.00</td>
</tr>
<tr>
<td>Disposal costs (e.g., hazardous items)</td>
<td>$1,000.00</td>
</tr>
<tr>
<td><strong>SUBTOTAL</strong></td>
<td><strong>$2,000.00</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Summary of costs</th>
<th>Amount</th>
<th>% of TCO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Purchase price</td>
<td>$80,000.00</td>
<td>35%</td>
</tr>
<tr>
<td>Total costs at purchase</td>
<td>$118,000.00</td>
<td>51%</td>
</tr>
<tr>
<td>Operational costs per year</td>
<td>$11,000.00</td>
<td>5%</td>
</tr>
<tr>
<td>Operational/disposal costs over 10 years</td>
<td>$112,000.00</td>
<td>49%</td>
</tr>
<tr>
<td><strong>TOTAL COST OF OWNERSHIP</strong></td>
<td><strong>$230,000.00</strong></td>
<td></td>
</tr>
</tbody>
</table>

* This table is an application of the TCO tool available on the New Zealand Government Procurement website, noted in this section’s resources box and presented here for illustrative purposes only.


The outputs from this illustrative TCO calculation highlight that it is likely that the initial purchase costs are much less than the operational costs over the anticipated equipment lifetime.

The TCO example in Table 8 estimates that approximately a third of the TCO is the initial purchase price, with 5% of the TCO estimated as the operating costs per year for consumables, training, energy costs, maintenance, and performance monitoring.
TCO RESOURCES

Total Cost of Ownership (TCO) Calculator [MS Excel file]
This calculator contains a number of categories and sub-categories of costs associated with the life cycle of equipment. Some costs are obvious, like the purchase cost of the item, but some are frequently overlooked, such as costs of unexpected downtime.

Total Cost of Ownership: An Introduction to Whole-of-Life Costing
This guide, intended to accompany the TCO Calculator, provides an overview of TCO, how to calculate it, and additional factors to consider.

Greenhealth Cost of Ownership (GCO) Calculator
This calculator provides a framework to assess the financial costs and hidden costs of equipment ownership to help ensure every equipment purchase delivers the maximum value over the long term. Reference data include representative utility costs by region. Free registration is required to access tool and guide.

Total Cost of Ownership (TCO) for Cold Chain Equipment: Online Calculator
The TCO tool for cold chain equipment is designed to help users understand the costs of purchasing and maintaining cold chain equipment for vaccine storage over time. The tool models capital and operating expenses of prequalified cold chain equipment via interactive worksheets. Users can compare TCO across technology categories and models of equipment.
When complex and expensive medical equipment—such as laboratory and diagnostic imaging equipment—is needed to provide patient care, it may be useful for a health program to consider the different options available for acquiring the medical equipment.

The three basic options offered for acquiring medical equipment are:

1. Buying the medical equipment (often described as a capital asset purchase).
2. Leasing the medical equipment (through a capital lease or an operating lease).
3. Renting the medical equipment.

Leasing agreements for medical equipment can also be arranged with varying conditions, such as:

- Bundling the equipment lease with an all-inclusive service agreement.
- Bundling the equipment lease with a “reagent rental” agreement.

Procurement models that offer an alternative to buying the medical equipment directly are becoming more commonly used in public and private laboratories and hospitals in developed countries. However, they are less often used to acquire medical equipment in low- and middle-income countries (LMICs).

These alternative models can support health programs to ensure that all of the services needed to install, operate, and maintain complex and expensive laboratory equipment to manufacturer specifications are provided. Some alternative models incorporate pooled procurement of reagents and test kits as part of a multi-site (and even multi-country) solution, which can reduce operating costs.

These models require investments in planning and health systems. Achieving best value for money (VFM) requires that the laboratory network is optimized and that supplies and information are effectively monitored and managed within a well-integrated health system.  

Recently, alternative procurement and pricing models have been supported by several donors as strategies that both experience and financial analysis suggest may offer optimal VFM. In LMICs, when there is potential for pooled procurement and strong contract monitoring systems and price-sharing, the Global Fund and US President’s Emergency Plan for AIDS Relief (PEPFAR)* are increasingly interested in leveraging an operating lease model, along with strategic pricing structures (“reagent rental” agreements and all-inclusive service contracts) to support national laboratory equipment systems. 

The common leasing and reagent rental models that offer alternatives to buying medical equipment directly (capital asset procurement) are described in Table 9, with their typical applications.

* Per 2019 Country Operating Plan (COP) guidance, PEPFAR no longer supports outright purchase of laboratory instruments and is shifting support to reagent rental pricing models in which the supplier retains ownership of the instruments.
# Table 9. Alternative procurement models

<table>
<thead>
<tr>
<th>Procurement model</th>
<th>Description</th>
<th>Typical application</th>
</tr>
</thead>
</table>
| **Leasing: There are two basic types of leases—capital leases and operating leases** | 1. **A capital lease** is usually long-term and non-cancellable and is used to lease equipment that will be purchased by the lessee at the end of the lease period. In this lease, the lessee is usually responsible for maintaining the asset and paying any insurance and taxes associated with the equipment.  
2. **An operating lease** is usually short-term and may be cancellable before the expiry of the lease period, with penalty. It is commonly used when the equipment will be used for a short period or replaced at the end of the lease. The lessor retains ownership of the equipment and bears the risk of obsolescence. | 1. **Capital leases** are frequently used for large and complex laboratory or diagnostic imaging equipment that need routine maintenance, including calibration and inspection, and are not subject to frequent upgrades.  
2. **Operating leases** are often used for shorter-lifespan equipment that must be replaced in three years or less, either because this equipment will become outdated, is used on a trial basis, or is heavily used.                                                                                                                                                                                    |
| **“Reagent rental” and all-inclusive service agreements**                          | **Reagent rental and all-inclusive service** pricing models transfer the responsibility for equipment installation, maintenance, calibration, training, testing, and removal at the end of the lease to the lessor.  
**“Reagent rental”** arrangements can be priced as cost per test, monthly payment, fair market value lease, $1 buyout lease, or as a simple rental.  
**“Reagent rental”** pricing models bundle the cost of instrument placement, service, training, reagents, and other consumables into one price per test.  
**All-inclusive service** pricing models can be combined with “reagent rental” agreements or used separately. This pricing model will pay a qualified vendor to provide all required equipment services at a fee paid in addition to the operating lease.  
At the end of the term of the agreement, there is no ownership by lessee. | **“Reagent rental”** agreements are often economically advantageous for expensive and complex laboratory and diagnostic equipment that depend on a reliable supply of quality reagents.  
**“Reagent rental”** agreement are usually combined with an all-inclusive service agreement due to the complexity of this equipment and its maintenance requirements.                                                                                                                                                                                                                   |
When to consider alternative procurement models

National HTM systems may not have the necessary policies, personnel, and practices in place to ensure that medical equipment is properly installed, used, and maintained. Financial resources needed to support these requirements may also be limited. In such situations, alternative procurement models may offer an effective mechanism for public sector health programs to address these gaps and ensure that the medical equipment is properly used, maintained, and managed in a manner that effectively supports public health objectives.

Each procurement model (buy, lease, or rent) has its advantages and disadvantages; determining the optimal procurement model requires taking several factors into consideration, including:

- How quickly the technology is changing
- Expected medical equipment lifespan
- Frequency of the medical equipment operation
- Frequency of maintenance, inspection, and calibration services and potential risk of unexpected equipment failures
- TCO of the medical equipment

These factors and their involvement in helping to determine the optimal procurement model (when considering whether to buy, lease, or rent the medical equipment) are summarized in Table 10.

It is important that procurement staff and other HTM stakeholders determine the total cost of ownership for each procurement model and identify risk factors that could impact the implementation of the model.

Table 10. Potential advantages of procurement models based on equipment characteristics

<table>
<thead>
<tr>
<th>Key equipment characteristics</th>
<th>Buy</th>
<th>Lease Capital</th>
<th>Lease Operating*</th>
<th>Rental</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation is improving the equipment technology rapidly:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e.g., some types of diagnostic and laboratory equipment)</td>
<td>X</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>New equipment will meet the health need for more than 3 to 5 years:</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>(e.g., vaccine or blood refrigerators)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment requires specialized consumables and frequent maintenance:</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>(e.g., innovative laboratory and imaging equipment)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Health need for equipment expected for less than one year:</td>
<td></td>
<td>✓</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>(e.g., surge cold chain capacity for immunization campaigns)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TCO of equipment is low and required budgets are available:</td>
<td>✓</td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>(e.g., pulse oximeters and oxygen concentrators)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Operating leases are assumed to be bundled with all-inclusive service contracts.
† Rental options for complex and expensive medical equipment may be limited in LMICs.
‡ Equipment requirements are met only when HTM system and budget are available for long-term and sustainable performance.

Alternative procurement models can use contracting and pricing mechanisms to outsource some or all of the equipment management tasks. These procurement models will require that ministry of health biomedical engineering and health facility management teams are willing and able to accept an active role in vendor and contract management for this equipment. Contract terms and conditions will need to be carefully written, qualified vendors must be selected, and strong contract management systems must be in place for these models to work well for health systems.
An all-inclusive leasing model request for proposals (RFP) was developed by Chemonics in 2019 in support of PEPFAR-funded activities. The RFP was developed for provision of viral load and early infant detection (EID) reagents, consumables, and all-inclusive services. The goals of the procurement model described in this RFP included:

1. Improve pricing and increase price transparency
2. Improve service levels, service commitments, and visibility into performance
3. Transition countries to reagent rental and all-inclusive pricing models
4. Create healthy supply markets in each country
5. Provide benefits for suppliers

As part of this RFP, all-inclusive pricing was required to (at a minimum) cover reagents and consumables, maintenance, ongoing training, connectivity and data reporting, equipment removal or relocation for all new and legacy instruments, and equipment placement. It was preferred that reagent and consumable distribution and vendor-managed inventory be included in the all-inclusive price if these can be cost-effectively provided by the supplier.

The pricing template provided as an RFP annex requested prices for global reagents and consumables, as well as country services pricing for six high-volume focus countries, with costed items including:

- Instrument lease with 3-year minimum term commitment
- Surcharge for no term commitment
- Installation, initial end-user training, and equipment removal
- Currently offered maintenance and ongoing end-user training
- Additional maintenance and ongoing end-user training
- Insurance
- Connectivity-enabled automated reporting and manual reporting
- Freight for reagents and consumables
- Vendor-managed inventory

More information on this RFP and pricing template can be found at:

How to evaluate alternative procurement models and risk factors

Depending upon the complexity of the medical equipment, financing sources, and other circumstances, evaluation of alternative procurement models might include:

1. Conducting a basic cost/benefit analysis of the different procurement models, including comparison of TCO, benefits, and risks.

2. Evaluating potential for medical equipment network optimization, including potential to meet multiple disease or conditions requirements, feasibility of pooling reagent orders, and benefits of combining equipment and all-inclusive services under a single procurement contract.

3. If alternative procurement models are under consideration, meeting with equipment finance companies to evaluate potential financing models, including:
   - Potential tax implications and cash flow requirements, as well as other factors that would impact potential lease or financing contract terms.
   - Costs of agreements, including early-termination fees and additional costs related to insurance, taxes, late payment fees, and other surcharges.
   - Comparison of one or more offers against the cost of buying the equipment directly (capital asset purchase). Prices of consumables and reagents will likely vary based on the type of model offered.

4. If donor support for the medical equipment is an option, working with donors to consider potential lease guarantees that may help to reduce interest rates offered by financial institutions.

5. To obtain more detail on potential alternative procurement models, the procurement staff can issue a request for information (RFI) to qualified vendors that will provide the following information and requirements:
   - The need addressed by the medical equipment.
   - The medical equipment that is required.
   - Types of procurement models available (option for multiple offers).
   - The anticipated test volumes per year and location.
   - The minimum qualifications of the vendor.
   - The medial equipment specifications (identifying critical and noncritical specification components).
   - The system requirements and accessories (e.g., information technology interface).
   - The supplier responsibilities.
   - The transport requirements.
   - The medical equipment delivery and installation schedule.
   - The inspection requirements for the medical equipment.
   - The after-sales support (warranties, response time, planned preventive and corrective maintenance, uptime guarantees, trainings, recalls, safety standards).
   - A request for consumables details and prices including those needed for installation, commissioning, calibration, and testing of the proposed medical equipment system, as well as expectations for expiry period, stability, and packaging.
   - The bid documentation, including vendor profile.

Collecting additional information and analyzing alternatives to capital asset purchases will help procurement teams make informed decisions on how to achieve the best VFM and ultimately optimize patient outcomes.

Value-based procurement of medical equipment

EQUIPMENT LEASING RESOURCES

Public-Private Partnership to Expand the Reach of Medical Laboratory Services


This brief outlines a suggested process by which laboratory service contracts or other public-private partnership arrangements can be designed and implemented.

Purchased versus rented laboratory instruments, an example of situation analysis on financial aspects in Thailand

Preparing for Medical Equipment Installation, Commissioning, and Training

Common issues leading to nonfunctional medical equipment include failure to adequately prepare, fund, staff, and monitor equipment installation, commissioning, training, and maintenance. Preparation for these activities will save time, resources, and in many cases, lives.

Procurement teams must plan for the safe transport of equipment to the installation site. Damage to medical equipment can occur during long-term storage in hot temperatures (such as in exposed shipping containers) if in-country transport is delayed, or during land transport when export packaging is not designed to protect equipment from the difficult road conditions in many LMIC settings.

Facility management teams must be kept informed about equipment delivery and installation timelines and must have access to the technical information and resources needed to address any necessary construction, electrical, or plumbing gaps.

Once medical equipment arrives at the health facility, technicians, trainers, consumables, tools, manuals, protocols, and supplies must be available to complete, verify, and record the following:

- Installation according to manufacturer recommendations.
- Commissioning results.
- Formal acceptance by facility and entry into its asset inventory.
- Initial end-user and technician training.

At the facility, equipment management responsibilities must be assigned, and budget lines, resources, and monitoring systems must be in place to support:

- Ongoing end-user and technician refresher training programs.
- Delivery of routine equipment maintenance requirements, which can include planned preventive maintenance, calibration, testing, and/or inspection tasks, depending on manufacturer recommendations.

- Continuous performance monitoring that links to responsive and qualified repair services.
- Contingency plans that will meet health needs during unexpected equipment downtime.
- Safe decommissioning and disposal procedures.

Installation, commissioning, training, and maintenance requirements for medical equipment should be identified and addressed during the following stages:

- Initial planning for medical equipment.
- Development of technical specifications.
- Evaluation of offers submitted by suppliers

It is important that all members of the HTM system identify and uphold their responsibilities, and that these members have the resources to manage medical equipment performance requirements over the equipment lifetime.

The following installation, commissioning, and training preparations will need to be adapted based on the complexity of equipment and the health facility conditions.* These preparation lists do not address the project management activities that must be implemented at a central level to manage supplier contacts, monitor arrival and delivery terms and timing, and enforce service agreements and medical device regulation and policy requirements.


Value-based procurement of medical equipment
Installation

Prior to delivery of medical equipment, work with the facility staff and biomedical engineering units to ensure that the facility can receive, install, and operate the equipment.

Ensure facility readiness

Consider the following questions:

- Is there a designated secure, accessible, dry, ventilated space to install the medical equipment?
- Are doors, stairwells, or elevators large enough for equipment delivery?
- Are floors strong enough to support heavy medical equipment?
- Is there an appropriate water supply?
- Is the power supply of acceptable quantity and quality? Is an automatic voltage stabilizer, rewiring of building electrical supply, changes to generator policy, and/or application of alternative electrical supplies (e.g., solar- or wind-generated) required? (Data characterizing common issues with power supplies in LMICs are available in this section’s resources box.)
- Is the required communication equipment, connectivity, and cabling available?
- Who is the point of contact for engineering and installation questions?
- Is there a health care waste management policy or system that can be leveraged, if appropriate?
- If pre-installation preparation does not go as planned and the site is not ready by the planned date, can the equipment be stored at the facility for an extended period without deteriorating?

Prepare the installation site

Ensure that the installation site is ready, including the following preparations:

- Facility management team is notified and ready for equipment arrival.
- All site preparation work (e.g., building, electrical, plumbing) is complete.
- Lifting equipment is available, if necessary.
- Required local supplies (e.g., sand, cement) have been purchased.

Identify biomedical engineering personnel

Ensure that biomedical engineering personnel are identified and available, noting the following:

- At a central and regional level, will a representative from the biomedical engineering unit at the ministry of health provide oversight?
- Will the medical equipment supplier install all equipment or train the biomedical engineering unit to scale up installation if a large number of units are procured?
- If the supplier will transfer responsibility for additional installation and commissioning to alternative agents, such as the national or regional biomedical engineering units, confirm the qualifications of staff, service-level terms, availability of transport and funds, and an independent commissioning procedure.
- Have the names and designations of nominated biomedical engineering managers and technicians who will assist and learn from suppliers at the subnational and facility levels of the HTM system been reviewed by the central-level biomedical engineer providing oversight?
- Have dates, locations, and materials been set for installation and training activities?

Prepare logistics

Logistics preparation should ensure the following:

- Overnight accommodation for the installation team is available.
- Travel and subsistence costs for the installation team (local and non-local staff) can be reimbursed.
- Materials, timing, procedures, and documentation systems are planned for commissioning post-installation.
- Installation teams have access to required tools, parts, consumables, protective equipment, and testing instruments.

Commissioning

Commissioning is necessary to ensure that equipment and systems are installed and are functioning properly. Commissioning also verifies that what was specified in the contract was installed, functions properly, and was successfully turned over to the end user; it is reasonable to assume that performance will be verified, if appropriate.

A documented commissioning plan offers traceable verification and ensures a standard, independent, and systematic approach that minimizes commissioning oversights.

These checklists should not replace the manufacturer’s recommended testing, acceptance, and calibration procedures, or national reporting requirements. Note that checklists may contain items that refer to multiple contractors.
Prior to commissioning

- Request recommended site acceptance testing (SAT) procedures from suppliers, if appropriate. The SAT procedure should provide the majority (if not the entirety) of the commissioning inspection and testing requirements.
- Review design drawings and specifications, if appropriate.
- Obtain copies of the manufacturer's recommended equipment maintenance schedules.
- Check the manufacturer's operating instructions and requirements.
- For some equipment (e.g., radiology equipment), consult with the national regulatory authority as required.
- Work with the biomedical engineering unit to develop and approve a standard equipment commissioning protocol that confirms:
  - Acceptance criteria and specifications
  - Functionality
  - Alarms and safeties
  - Functioning of utilities
  - Maintenance needs
  - Calibration
  - Labeling
  - Delivery of training
  - Turnover of equipment to facility management
- If required, work with the biomedical engineering unit to develop a separate inspection checklist; alternatively, integrate an inspection checklist into the commissioning protocol. Inspection does not include test results and will only visually verify that construction and installation adhere to the specified design, national construction standards, and any relevant regulatory requirements.

During commissioning

During the commissioning process, an independent technician will complete the following:
- Visually inspect the installation and equipment to identify any variations from designs and/or specifications.
- Check individual components for proper position and settings for completeness of installation.
- Review acceptance testing data.
- Review safety testing data, including:
  - Adequate electrical insulation and earth connections.
  - Patient and operator safety.
  - Mechanical safety inspection.
- Review calibration data.
- Complete commissioning documentation.
- Request signature from facility representative if needed for official transfer of ownership.

Providing proper installation, commissioning, training, and maintenance of the medical equipment will help to ensure that the equipment functions according to its performance requirements and supports the health facility in meeting its patients' health care needs.

Initial user and technician training

Improper operation of medical equipment is a frequent cause of equipment failure. Unqualified technicians without proper training, spare parts, tools, and technical reference materials also contribute to high rates of premature equipment failure. It is important that procurement of new medical equipment is combined with contracting of training services and materials, for both end users and technicians.

Routine training mechanisms and content will need to be developed and funded to ensure that skills are refreshed, new staff are trained, and patients and staff are protected.

Prepare trainings

It is important that refresher and on-boarding trainings are also planned, funded, and delivered. Preparation steps include:
- Identifying end users and maintenance technicians requiring training and setting up training schedules well in advance of medical equipment installation.
- Beginning training with a baseline assessment of current knowledge and ensuring that training includes a post-assessment to inform ongoing training needs.
- Ensuring availability of functional equipment, consumables, training materials, and job aids.
- Ensuring that training includes hands-on experience with equipment and practicing correct operation.
Ensuring technician training includes hands-on routine and preventive maintenance tasks.

Ensuring that maintenance instructions:
- Are easy to understand
- List maintenance and troubleshooting procedures
- List all test equipment, spare parts, or consumables required
- List frequency of each preventive maintenance activity
- Illustrate how to replace parts

Identifying local expert trainers to ensure sustainability and continuity of training.

Repeating user and maintenance training as often as needed, based on equipment complexity.

Maintenance and decommissioning

Medical equipment must be routinely maintained and ultimately safely decommissioned. These processes should be costed and included in TCO estimates and must be accounted for in the analysis of VFM of different productions, services, and solutions. Leadership for these processes is likely to fall to the biomedical engineering unit at the ministry of health; procurement teams will need to consult with these experts to ensure that resources are available for equipment management until the point at which medical equipment is safely disposed.

Maintenance systems for health technologies—including medical equipment—are frequently under-resourced. Ample evidence highlights the VFM of investing in these systems, including the findings from the Medical Equipment Uptime Project in Zambia highlighted in the “Leveraging Health Technology Management Systems” section, illustrating that equipment lifetimes may be halved when maintenance services are insufficient. Additional research illustrates the bottleneck caused by weak maintenance systems on laboratory services.

For more information on medical equipment maintenance and decommissioning, review the following sources:

Medical Equipment Maintenance Programme Overview

Decommissioning Medical Devices

Neglect of decommissioning and disposal systems and resources results in health facilities or biomedical engineering workshops storing old and broken medical equipment for years. Plans must be made for disposal of medical equipment in line with health facility building management and sanitation guidelines and national environmental laws. Many types of medical equipment used in hospitals are designated as “special” or “hazardous waste.” Such items contain hazardous components that are restricted from disposal in the usual manner allowed for non-hazardous waste.

Value-based procurement of medical equipment
Managing Medical Equipment Donations

In some countries, nearly 80% of medical equipment is donated or funded by international donors or foreign governments. Medical equipment donations can provide valuable assets that may otherwise be unavailable in low-resource health care settings. This medical equipment may help health care providers save lives.

However, ample evidence illustrates that several challenges limit the benefits of equipment donations, including:

- Donors lack awareness of the health needs and facility requirements.
- Donors and recipients often do not communicate as equal partners.
- Facility managers are not given an opportunity to articulate which equipment is needed.

Because donations are not often made through a value-based equipment planning process, a significant percentage of donated medical equipment found at facilities is uninstalled, unused, or unmaintained, sometimes resulting in loss of life. In Haiti, donor-supplied equipment is frequently not utilized because of insufficient power supplies, with the failure to fully assess and address a facility’s equipment requirements resulting in inoperable pumps, neonatal incubators, lighting, and other essential equipment.

This mismatch between donated equipment and facility needs is immense, with potentially only 10% to 30% of donated equipment becoming operational in developing countries.

Donated equipment may include used equipment from a high-income or private health facility. Alternatively, it may include large amounts of medical equipment provided as part of an emergency humanitarian response; in other cases, it may include solicited equipment funded by donors in response to health system strengthening needs or priority health program funding. Civil service organizations often donate equipment to the local health system to ensure that community health needs are met.

Regardless of the type of donation or donor, it is essential that governments demand that all medical equipment—including that which is donated—is needed, appropriate, and sustainable in the health facilities where it is delivered. As seen in Figure 6, the process of providing donated equipment should be similar to the public sector process of planning and procurement of medical equipment.

**Figure 6.** Donation of medical equipment needs planning and integration into HTM system
Maximizing the value of donated equipment

To maximize the value of donated medical equipment, including improved patient outcomes, WHO suggests that governments:

**Develop a policy**

Develop a policy* for medical equipment donations and a maintenance plan that does the following:

- Maintains a list of medical equipment and associated supplies that are requested or needed, and their quantities. This list should be updated at least annually with input from subnational and facility-level managers to ensure that it represents current health needs and can be installed, operated, and disposed of with available resources.
- Prioritizes the equipment list.
- Requires that donated items comply with appropriate specifications, standardization practices, standard equipment lists, etc.
- Clarifies support needed to ensure proper installation, commissioning, and training.
- Requires that facility-level budgets are available for long-term operational costs.

**Evaluate donors and equipment**

Evaluate donors and donated equipment prior to acceptance, keeping in mind the following considerations:

- Donors can meet delivery and service requests as needed, covering the costs of transport, freight, insurance, import duties, customs clearance, and installation and commissioning costs, if applicable. If not, identify required funds prior to acceptance.
- Proposed equipment must conform to national policy.
- Proposed equipment must be appropriate for the facility environment, health needs, and end users.
- Confirm that maintenance services, spare parts, and consumables are affordable using available budgets and technicians.
- Equipment must come with all relevant accessories, consumables, manuals, and spare parts.
- If the donated goods include reagents or sterile supplies, check whether these will have an adequate expiry date (at least one year in the future, or half of the shelf life if the expiry date is less than one year).
- Check that the equipment on offer conforms to applicable VFM and relevant bid evaluation criteria.
- Determine who will be responsible for the package of inputs required throughout the remaining life of the equipment.

**Implement a standard**

Implement a standard installation acceptance process as applied to new medical equipment purchases, noting the following:

- If pre-installation work is required, prepare the site and personnel for receiving equipment and notify the donor when all preparations are complete.
- Check packaging upon arrival and verify the inclusion of manuals, spare parts, consumables, and accessories. Check expiry dates and labeling of the recurrent supplies.
- After installation, implement commissioning protocol to verify that equipment is functioning according to specifications and includes all components and supplies.
- Confirm receipt of the donated equipment with the donor, including information about the condition, functional status, and sustainability of the equipment.
- If equipment fails to pass commissioning processes, document problems and communicate with the donor on the required response, including removal and disposal of equipment if necessary.
- Keep a record of all donations received.

**Refuse inappropriate donations**

Refuse donations, providing an explanation and maintaining a record of reasons for refusal, including:

- Will not comply with policies and regulations.
- Will not function to manufacturer specifications.
- Is inappropriate or unsustainable for operation in health care facilities.
- Was not solicited by health care facilities or does not align with health system strategies.

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Five WHO criteria for sustainable equipment donations

Evaluate offers to donate medical equipment, keeping in mind the following criteria:*  

**Appropriateness for setting**  
Equipment is appropriate for the setting, based on the following guidelines:  
• Suitable for the facility and service provided.  
• Acceptable to staff and patients.  
• Suitable for operator skills available.  
• Suitable for the local maintenance support capabilities.  
• Compatible with existing equipment and consumable supplies.  
• Compatible with existing utilities and energy supplies.  
• Suited to the local climate, geography, and conditions.  
• Able to operate economically with local resources.

**Quality and safety**  
Equipment is of high quality and is safe, based on the following guidelines:  
• Can meet requirements for a reasonable length of time.  
• Made of durable materials.  
• Can be easily cleaned, disinfected, or sterilized without rusting.  
• Meets internationally recognized safety and performance standards.

• Is suitably packaged and labeled to prevent damage in transit or during storage.

**Affordability and cost-effectiveness**  
Equipment is affordable and cost-effective, based on the following guidelines:  
• Identified as a cost-effective solution to a health need.  
• Affordable based on costs for freight, insurance, import tax, etc.  
• Affordable in terms of installation, commissioning, and training of staff to use and maintain equipment.  
• Affordable to operate (in terms of costs of consumables, accessories, and spare parts over its lifetime).  
• Affordable to maintain and service.  
• Affordable to dispose of safely.  
• Affordable in terms of the procurement process (e.g., the cost of a procurement agent or foreign exchange to source spare parts).  
• Affordable in terms of staffing costs (e.g., costs of additional staff or specialized training required).

• Additional technical assistance is available with service contracts.
• Equipment warranty covers a reasonable length of time, for which the terms are well understood (e.g., does it cover parts, labor, travel, refunds, or replacements?).
• Supply channel exists for equipment-related supplies (e.g., consumables, accessories, spare parts, etc.).

**Conformity with policies, plans, and guidelines**  
Equipment conforms to national policies, plans, and guidelines, including:  
• Procurement, HTM, and donation policies.  
• Medical equipment standardization policies.  
• Standard equipment lists and generic equipment specifications.  
• HTA findings.  
• Conclusions made from end-user feedback and experience with previous purchases and donations.

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* Adapted from WHO, Medical Device Donations: Considerations for Solicitation and Provision. (See this section’s resources box.)
References


