Oxygen Delivery Toolkit Resources to plan and scale medical oxygen

Asset Management Guide

Assisting stakeholders in the pragmatic design, implementation, maintenance, and market application of asset management systems for medical devices

For use by:



Decision-makers



Implementers

May 2020

This resource is part of the **Oxygen Delivery Toolkit: Resources to plan and scale medical oxygen**. The materials provided within the toolkit can be used together or separately, as needed. The complete Oxygen Delivery Toolkit includes the following resources:

- Oxygen is Essential: A Policy and Advocacy Primer
- Health Facility Standards Guide
- Baseline Assessment Manual
- Consumption Tracking Tool
- Procurement Guide
- Quantification and Costing Tools
- Reference Pricing Guide
- Electricity Planning Guide
- Asset Management Guide
- Global Financing Facility Medical Oxygen Investment Guide

The toolkit is available at www.path.org/oxygen-delivery-toolkit.

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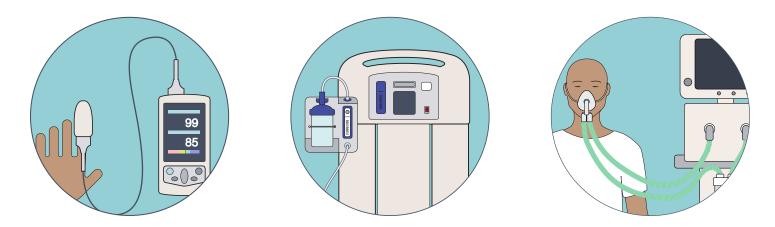
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Abbreviations

ASPAK Aplikasi Sarana, Prasarana & Peralatan Kesehatan NHSRC National Health Systems Resource Centre

Summary



The importance of medical devices

Medical devices save lives. They can provide many people with effective health care and increase treatment capabilities of health facilities. They are also highly costeffective, providing care and value for years beyond their procurement initial costs.

An example of the lifesaving power of medical devices is in providing safe and reliable medical oxygen for treatment and diagnosis of hypoxemia. Caused by severely low levels of oxygen in the blood, hypoxemia is tied to many medical conditions and is a major risk factor for preventable death. These deaths are occurring in cases of childhood pneumonia and obstetric emergencies such as eclampsia, hemorrhage, and pulmonary embolism.

• Childhood pneumonia is the leading cause of infectious death of children under 5 years old. With administration of oxygen therapy, along with supportive care, the lives of nearly 400,000 babies could be saved each year.

 15 percent of all women develop an emergency obstetric complication, yet a disproportionate
 99 percent of maternal deaths occur in low- and middle-income countries. Less than half of hospitals in these areas can supply reliable oxygen, and only half can provide functional pulse oximeters for diagnosis of hypoxemia.¹

Deaths from these conditions represent a huge burden of disease and disproportionately afflict vulnerable populations, such as women and children in low- and middle-income countries. Medical devices such as pulse oximeters and oxygen delivery devices can help with early diagnosis and treatment of hypoxemia regardless of the underlying cause. The diversified utility of such medical devices makes them particularly valuable health care assets when managed effectively.

Lack of access to medical devices

Poor access to medical devices can result from a variety of factors. For example, countries with many different device models may struggle to reliably stock model-specific spare parts or consumables. Further, negotiation and management of contracting terms with a variety of device manufacturers and distributors can be complex and time consuming. Table 1 below outlines five areas by which to evaluate challenges in device management: awareness, availability, affordability, assured quality, and appropriate design.² Issues in each area can pose unique challenges to the effective use of medical devices, so an assessment that considers these factors can elucidate areas to improve management practices.

For more discussion on best practices and a country case study addressing management challenges for medical oxygen access in The Gambia, see Appendix 1.

Awareness	 Are health care workers trained in proper use and clinical applications of medical devices? Have health facility staff roles been appropriately clarified to ensure the level of required maintenance is feasible?
Availability	 How many devices are needed and are they placed in wards within facilities to meet this need? How many spare parts and consumable pieces are required to use the device?
	 Are reliable contracts and/or plans in place for routine maintenance of devices and coordinating the supply of spare parts and consumables?
Affordability	How much does it cost to procure the medical device?
	 Is there competition among suppliers in the market?
	Have prices changed over time? Why?
	 Are contracts already in place with the medical device suppliers?
	What is the budget available for medical device purchases?
	Who is the primary customer and what is their willingness to pay?
Assured quality	Is the medical device or medical device manufacturer independently verified by a notified body?
	 Has the medical device been through country-specific quality assurance testing and/or regulatory oversight?
	 Are there health facility staff available and trained to maintain medical devices? Are there enough technicians or trained personnel to install, use, and maintain the device?
	 Is there a process in place for initial installation and routine calibration of devices?
Appropriate design	 Is the procured device appropriate for the health system requirements? Does donated equipment align with health facility infrastructure, come with instructions, and have adequately trained technicians available?
	Will environmental conditions impact the ability of your device to reliably function?
	Does the device mandate reliable power?

Table 1. The 5 A's for assessing challenges in device management.

Asset management systems can increase reliable access to medical devices

Lack of access to medical devices can pose significant risks to health care services. Routine management of the devices is multifaceted and often complex.

Throughout this guide, asset management refers to the activities performed over the duration of a medical device's life span—from procurement to disposal—to keep medical devices in working condition. Asset management systems organize and track data associated with medical devices and asset management activities. They assist in maintaining medical devices and maximizing their operating efficiency and life span. Data collected through asset management systems can be shared between health facilities and analyzed in aggregate to inform procurement, installation, training, use, maintenance, and disposal. For example, data collected in an asset management system can inform future procurement by providing real-time estimates of gaps in device availability, records of device failures, total life span for specific device models, and supplier performance when contracted for maintenance. When this information is shared, procurers may be better positioned to purchase an accurate number of high-quality devices from suppliers with a track record of providing timely maintenance and consumable resupply.

How to use this guide

Within this guide are key considerations in asset management system development, including:

- Types of information that can be collected.
- Considerations for implementation based on existing health infrastructure.
- How to structure routine data collection and system maintenance.
- How data can be analyzed and applied for improved market engagement.

While other guides may individually highlight aspects of medical device management, like device maintenance, this guide is distinct because it combines insights from multiple reference texts (see References) to cover asset management system design, implementation, maintenance, and use in a comprehensive text. Figure 1 shows how this content is organized to provide a pathway to action for the reader. Each arrow in the pathway refers to the sections within this guide that will help the reader understand (summary), design (sections 1 and 2), maintain (3), and use (4 and 5) asset management systems.

Best practices for asset management systems in low- and middle-income countries, specifically their applications for oxygen delivery devices and pulse oximeters, are referenced throughout the guide. These real-life examples should help readers conceptualize asset management systems, as well as promote immediate application of the guide. Detailed descriptions of asset management systems in other countries and supporting resources are included within the appendices.

Figure 1. Pathway to action for asset management systems.

Understand	 Medical devices are important. Many factors contribute to lack of access to medical devices. Asset management systems can increase reliable access to medical devices.
Design (1-2)	 Many types of information and data can be collected to assess health system capabilities and limitations. Baseline data can be used to build an asset management system. Key considerations for asset management system design involve implementation, platforms for system management, how to plan for system upkeep, and potential costs.
Maintain (3)	 Collecting medical device performance data helps maintain systems. Asset management systems and other health information systems can be linked. Routine system maintenance is necessary.
Use (4-5)	 There are many types of performance measures and analysis of asset management system data. Data can be leveraged to improve market engagement and opportunity. Asset management systems can help evaluate health impacts, improve patient care, and increase access to medical devices.

1. Data collection

Why collect data?

To understand the importance of collecting asset data, the distinction must be clear between assets and consumable inventory. Consumable inventory fulfills its value upon use and typically requires little to no maintenance. The value of assets, however, is contingent on how well the asset is maintained over time. For instance, an oxygen cylinder is valuable for providing health care until depleted, whereas an oxygen concentrator is valuable as long as it can safely and reliably produce medical oxygen. Optimization of cylinder usage revolves around inventory management and the ability to reliably replenish stock. Optimization of oxygen concentrator usage depends on a whole host of management activities, such as procurement of appropriate device models, correct installation, calibration, and routine maintenance. These management tasks are informed by collecting and tracking data regarding the asset, which can be achieved through an asset management system. Overall, this guide is concerned with asset management systems to optimize the operating efficiency, life span, and value of long-standing assets like medical devices—and data are critical to achieving this goal.

What types of data can be collected?

Table 2 demonstrates how general medical device management activities link to data inputs for asset management systems. The table is organized by stage of medical device life span. How to collect and organize data is discussed in further detail within the corresponding sections of this guide. There are a number of resources available to assist data collection. Appendix 1 provides a list of resources with specific relevance to data collection for asset management systems.

2. How to implement an asset management system

The following section discusses activities that can be done prior to medical device acquisition; these activities help develop asset management systems and may impact the effectiveness of device management. Activities include adapting baseline assessment tools for routine data collection and tracking, choosing a suitable system for asset management, delegating roles and responsibilities to decrease the burden on health care workers, and determining how to incentivize system upkeep and manage costs.

Data and asset management systems

Collecting baseline data is important for both procurement and development of an asset management system. This section discusses how baseline data can be inputs for an asset management system and how baseline collection tools can be adapted for routine data collection instead of for a single cross section in time.

Baseline data collection can be difficult. Indonesia's Aplikasi Sarana, Prasarana & Peralatan Kesehatan (ASPAK) system for asset management serves as a good example for how to navigate challenges, such as data organization, and incentivize accurate and routine data collection. The ASPAK platform for asset management collects device, electricity, and water availability information across health facilities. This information was initially used as means to accredit health facilities that meet national standards; thereafter, it was used to decide allocation of finances for medical device procurement.

The ASPAK system raises a key consideration: Who is paying for medical devices? Depending on where procurement

Table 2. How asset management systems connect to medical device management activities.³⁻⁷

Guide organization	Stage	Activities	System inputs
Section 1: Data collection	Pre- procurement	 Evaluation of challenges (5 A's). Collection of health infrastructure data. Use of resource guides to assist in planning for procurement (needs assessment, inventory assessment, procurement and implementation guides, etc.). 	 Inventory of existing and working medical devices. Infrastructure capabilities/baseline assessment (water, electricity, power source type, etc.).
Section 2: How to implement an asset management system	Procurement	 Identification of standards and norms for health facility requirements (number of devices needed to meet policy requirements). Market research and market sizing. Procurement process consideration (who holds procurement decision- making authority). Planning for maintenance (through contracting or assigning roles and responsibilities to existing staff). 	 Medical device information and identifiers (ID #, device type, model, etc.). Numbers of manufacturers, distributors, device variants, costs, etc.
	Installation	 Contracting for distribution to facility. Installation and calibration. Storage of associated parts, consumables, manuals, and technical specifications. 	 Location of device (ward, etc.). Date of installation and by whom. Parameters of calibration and dates. Location of associated manuals, technical specifications for devices, spare parts, and consumables associated with device.
	Training	• Training of clinical staff to correctly use device.	 Who is trained, when, and on what devices (update over time).
Section 3: Routine data collection and maintenance of asset management systems	Standard operation and maintenance	 Device operation. Maintenance contracting (preventative and corrective maintenance). Collection of performance data. 	 Metrics of performance data. Dates of maintenance activities, records of what was done and by whom. Stock reorders of parts and consumables. Power usage. Recalibration events. Safety incidences.
	Disposal	 Contracting for disposal activities (removal, decontamination, etc.). Use of technical specifications and performance data to predict device life span and forecast reordering. 	Device life span.Record event of disposal.
Section 4: The utility of asset management system data	Data evaluation	 Use of data collection platforms to organize and analyze data. Submission of data to entities such as procurement agencies that use data for allocation of funding. 	Data are used to assist future procurement, reduce costs, avoid supply chain disruptions, and improve access to care.

Aplikasi Sarana, Prasarana & Peralatan Kesehatan as a model for baseline data organization.

Aplikasi Sarana, Prasarana & Peralatan Kesehatan (ASPAK) collects device inventory information from health facilities in Indonesia. Linking ASPAK data to the allocation of funding from the Ministry of Health incentivizes data collection, which would otherwise be difficult to achieve in Indonesia's decentralized government. The platform provides a model for how baseline assessment tools can be translated into systems for routine management of devices. Users can search and compare data within ASPAK with filters such as device type, health facility location, facility name, and numbers of facilities with and without devices.



funding comes from, there may be expectations, requirements, or performance metrics set by the paying entity. In some countries, health facilities must appeal for funding and support their appeal with baseline data. After

Implementation: Theory to practice

This section discusses additional considerations for implementation of an asset management system, including platforms for management systems, who is involved in system management, and potential costs.

What is required

An important consideration for asset management systems is the platform used for data organization. Organization can be achieved in many ways; it is important to choose a method that is suitable for the health care infrastructure. The most common platforms are computer based.

Computer-based management systems: If managing many assets at the facility level, a computerized management system can organize inventory, service history, maintenance information, and medical device metrics in an easy-to-access and manipulatable format. Computerized systems may also facilitate the linking of health information systems and sharing of data across levels of health infrastructure and between facilities.⁸

Computerized maintenance management systems can be limited by internet connection quality. The quality and

review of these data, paying entities will allocate funding. An asset management system may be designed with this consideration in mind and be set up to collect baseline data for procurement purposes.

availability of devices needed to log information, such as tablets and computers, can also be limiting. Paper-based systems may be used when these limitations exist, although they are less reliable and increasingly time intensive as the scale of management systems increase. Paper-based systems may work for small-scale asset management systems or be useful in a hybrid management system. Such a hybrid approach may involve recording device metrics periodically on paper, and then a biomedical engineer uploading this device information into a computerized system upon maintenance.

The structure of an asset management system also depends on scale—if it is intended for use with a single asset or applied to a collection of assets. Ideally, all medical devices in a health facility would be included in an asset management system, but this can be resource and time intensive. In scenarios with limited resources, phased introduction may work well, where all new devices are added to an asset management system upon procurement, and existing devices are added in over time. Additionally, a management structure that can manage assets across disease areas can reduce duplication of effort and lessefficient use of resources.

Additional tools for baseline assessment

Baseline Assessment Manual⁹ provides resources to carry out the training of those involved in conducting a baseline assessment survey, including guidelines that the trained personnel can reference in their field work.

Asset management systems can also help collect and track other types of information that are associated with medical device procurement and installation. Anticipating how this information will be collected in or linked to an asset management system prior to device acquisition will impact the effectiveness of asset management downstream.^{10,11} For example, a record of the total cost of ownership of a medical device can be linked to an asset management system and used to track all expenses that are incurred from device operation and management.

More details on tools for baseline assessment and cost tracking for devices are provided in Appendix 2.

Who is involved

One of the biggest challenges regarding asset management system implementation is incentivizing data collection. This section will discuss how data collection can be attached to existing roles and performed in parallel to general asset management practices in order to reduce labor and costs.

Various roles within general device management practices can help support an asset management system. These roles may be assigned while awarding contracts for new medical devices and accomplished through insourcing or outsourcing of labor. India's biomedical maintenance program is a helpful example of a system where maintenance is outsourced to decrease the workload of health facility staff and clinicians.

Facility staff may participate in system maintenance through routine logging of device data and events of device use and maintenance. One such example could be recording who is trained to use specific devices and updating this record as staff turnover occurs or new devices are acquired. Examples of training data that may be tracked in an asset management system and how to structure data collection are discussed in more detail in Appendix 2.

Additionally, consider if proposed roles and responsibilities for asset management system maintenance will require radical behavior changes or result in the overburdening of staff. Also, assess the attitude concerning changes. Does the health care staff understand current issues with medical device management and have a desire to improve conditions? Often, if the reasons for implementing a new system are unclear, there will be limited desire to make effort to facilitate the system.

Sometimes asset management systems are available through a private firm. This contracted labor can help manage health care technology. However, before pursuing this route, the scope and benefits of the service should be evaluated. For instance:

- How comprehensive is the service? (Does the firm deal with particular asset management activities or manage a collection of assets from acquisition to disposal?)
- Can the private system connect to other health information systems? How are these systems set up in facilities?
- Is there training included? What would the beginning stages of use and development look like? What is the cost of contracting a service provider? Can the cost of this service be covered by any branch of a governing body?

System management in India¹²

In 2015, the Ministry of Health and Family Welfare of the Government of India launched the Biomedical Equipment Management and Maintenance Program. The program uses biomedical engineers, who perform medical device maintenance, to survey the availability and operational status of devices in health facilities across the Indian states. India's National Health Systems Resource Centre (NHSRC) assists with the mobilization of technical assistance to the states in order to strengthen the Biomedical Equipment Management and Maintenance Program and build the capacity of the Ministry of Health and Family Welfare. Overall, the surveying is intended to assist biomedical engineers in performing maintenance, but it also demonstrates how collection of device data in an asset management system could be done through outsourcing the labor or combining it with routine management practices.

The NHSRC website offers a complete database of medical devices from the Indian states as well as a library of technical specifications for devices. Additionally, the NHSRC offers resources on biomedical equipment mapping, standards for medical device certification, and instructional videos for managing key medical devices such as oxygen concentrators. The above questions about who will supply labor for maintaining an asset management system, and how, are important for getting at the potential costs involved. The above questions are not exhaustive, but they provide a good starting point for beginning this cost assessment. For additional ideas about how device data collection and system upkeep can be structured, see Appendix 2.

When will it be achieved

It is important to set realistic, time-oriented goals for implementation. Goals can be informed by the scale of the

system, human resources available for asset management system upkeep, the scale of system implementation, and financing ability. Overall, capabilities of the health facility and availability of resources will impact the cost and success of implementation.

As part of implementation, also consider the transition period between the previous system and the upcoming system. Are there changes within this transition that could disrupt normal operations? For instance, if device data must be collected during this transition period, how will these data be collected or accounted for?

3. Routine data collection and maintenance of asset management systems

In order to keep asset management systems running smoothly, routine updates are needed on the performance of medical devices and associated tools for system management. This section will discuss types of medical device performance data, how to collect them, and how asset management systems can link with other health information systems. Additionally, this section discusses how routine maintenance of asset management systems informs asset management practices.

Data collection

A variety of information and metrics can be collected from medical devices. Diligent collection and organization of this information into an asset management system make it available for future use in measuring device performance and managing maintenance, evaluating supplier performance, and informing future procurement decisions. Some of these measures are listed in Table 3.

Notice that some information is collected once procurement is complete whereas other metrics are collected on a routine basis. Identifier information should be used to make sure routinely collected information is linked to the correct device. The length of time between data collection can depend on various factors, including resources available, anticipated maintenance schedule, or performance-based contracting terms. Ease of logging data into the system affects how effectively it is employed. Some methods of data collection, such as recording data on a personal phone and then uploading to a shared server may reduce the burden on health care workers.¹³ Data platforms that automatically update to a most recently edited version or have data validation checks to flag mis-entered information will also save time and effort.

Linking asset management systems and health information

When asset information is divided across health facilities and data collection platforms, the effectiveness of asset management systems decreases; managing multiple databases is time consuming and makes it difficult to keep information updated. Linking asset and health information systems across facilities and departments can collate data in one place and elucidate areas of poor management that can help target specific management practices for improvement. A consideration, therefore, when choosing software for asset management systems is how well the system can be synchronized to other systems (for example, see Table 4). Also, consider the level of data integrity and security the chosen system provides.

Table 3. Device data and routine collection¹⁴

	Collection	time point
Measure	Upon installation	Routinely
Equipment ID #/Unique identifier	Х	
Installation date of medical device	Х	
Warranty expiration date	Х	
Predicted life span of device	Х	
Manufacturer	Х	
Maintenance service provider	Х	
Purchase supplier	Х	
Purchase date	Х	
Purchase price	Х	
Funding source	Х	
Model/Part/Year	Х	
Serial number/Lot number	Х	
Stock and reorder quantities	Х	Х
Part type reordered		Х
Operation and service requirements	Х	
Power requirements	Х	Х
Preventative maintenance schedule and procedures	Х	
Operation and service history		Х
Device uptime		Х
Device breaks		Х
Operational status	Х	Х
Date of calibration	Х	Х
Results of calibration	Х	Х
Next predicted date of calibration	Х	Х
Device location within facility	Х	Х

Table 4. Data platforms and their capabilities to link with asset management systems.¹⁵⁻¹⁷

Health information system	Capabilities	Link to asset management systems
DHIS2: (District Health Information System 2). A browser-based application for collecting and analyzing health data. The platform can collect data such as individual patient health, health program monitoring, and service availability.	 Enables data quality checks through data validation rules. This will flag mis-entered or concerning data entries outside of preset acceptable ranges. Online data collection updates the platform for all users, allowing for data synchronization across time and facilities. Data can be imported and exported to share with other applications. 	 Mapping service availability and referrals across facilities can link with asset management systems and help discover underlying causes of decreased service availability and poor management practices. Similar data auditing methods could be employed in asset management systems to track high-priority areas for management or confirm management activities have occurred.
Inventory and stock-keeping platforms	• Creates an inventory for devices, spare parts, and consumables at a cross section in time.	• Connecting quantities of parts to rate of replacement through an asset management system that tracks type and frequency of maintenance activities can help with planning maintenance activities.
Procurement and tender data	 Procurement platforms, like an e-catalogue, can track the number of devices, manufacturers, and distributors in a market. Can track cost. 	 Availability and cost of devices help with budgeting and planning for device maintenance and replacement, as well as predicting total cost of ownership.

Considerations for routine maintenance

Routine maintenance

Just as medical devices require routine maintenance, so do asset management systems. System maintenance involves routine inputs and data collection, as well as checking the condition of associated devices that allow data collection. This section discusses considerations for maintenance of these associated devices, as well as demonstrates how routine data inputs in a system enable appropriate planning for device management activities such as disposal. Because asset management systems and data organization are often facilitated by hardware and software, it is important to collect information about the state of these associated devices and capabilities. For example:

- What is the speed and reliability of the server you use?
- What is the condition of firmware—such as tablets,

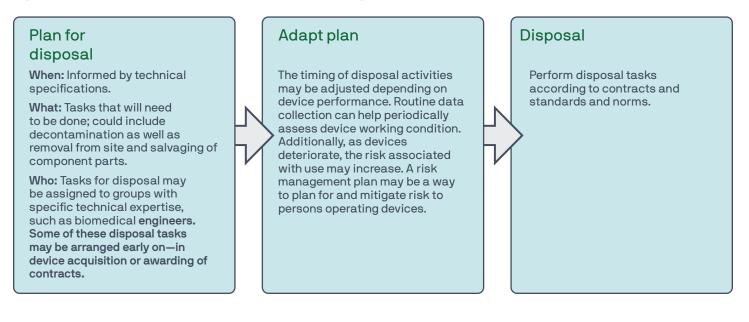
desktop computers, and other physical devices—for data tracking?

• What are the make and model of the software used on these devices, and what are its capabilities and limitations?

How asset management systems inform device management tasks

Maintenance of asset management systems is a particularly important element of timely planning of device management tasks such as disposal. Ideally, disposal is informed by information collected throughout a device's life span, including predicted device life span as suggested by technical specifications, maintenance history, and device performance. Performance and maintenance metrics routinely collected in asset management systems can be evaluated to predict the timeline for disposal and replacement. The flowchart in Figure 2 illustrates how disposal of medical devices can be informed with inputs from an asset management system.

Figure 2. Disposal as an activity informed by the asset management system.



Overall, routine maintenance of asset management systems can help to maximize return on initial investments, increase operating efficiency, minimize overall costs, and accurately monitor and evaluate how well these goals are met through data collection and strategic planning. Additional recommendations for using asset management systems to inform medical device management are provided in Appendix 3.

4. The utility of asset management system data

Up to this point, this guide discussed how to design, implement, and oversee an asset management system for collecting and tracking data. Information collection becomes useful when it is used for improved decisionmaking. One of the greatest benefits of asset management systems comes from leveraging data to optimize device management practices and improve market engagement. Table 5 in the following section focuses on how to use data; it describes what measures of performance can be made, what data can be collected to evaluate these measures, and examples of how the information gathered can improve market engagement. Evaluation of these measures can help ensure appropriate technology is procured from reliable sources, reduce overall costs, and avoid disruptions to supply and patient care.

Using data to improve market engagement

There are many ways data can be analyzed to guide choices in medical device procurement, implementation, and maintenance. A well-constructed asset management system can provide you with tools to increase your market opportunity, decrease costs, and ultimately improve access to medical devices.

Table 5. Leveraging data for market engagement.

Engagement area	Description	How does it help market engagement?	Measures	Data inputs	Example analysis
Supplier performance	Evaluates suppliers on: -Timeliness and consistency of responses to service requests. -Capacity to provide services.	Using suppliers that reliably deliver high-quality products and maintenance services can minimize	Supply landscape	-# of technicians available for maintenance. -Price change over time for services.	Evaluating distribution of suppliers across the market for medical devices can help with anticipating costs and ability of a supplier to fulfill performance requirements.
	 -Cost. -Completeness of orders filled. -Quality of parts and maintenance. -Regulatory compliance. 	services can minimize supply chain interruptions and save costs. d. Data-driven comparison of supplier	an nt,	 Frequency and ease of communication with suppliers. Medical device uptime: Time from making an order to a device being fixed by supplier, time between procurement and installation/ calibration, timeliness of filling supply orders for spare parts/ consumables. Approval ratings for working with suppliers: Annual survey of clinical staff on their satisfaction with supplier. 	 Performance-based contracting is facilitated by data-driven analysis of a supplier's ability to meet set objectives. Such indicators could be: Supplier efficiency: Order quantity received/order quantity submitted = % of order fulfilled. Device uptime: Keep a log of breaks and time a device is out of service. This information can help with evaluating the ability of a supplier to reliably service devices.

Table 5. Leveraging data for market engagement (continued).

Engagement area	Description	How does it help market engagement?	Measures	Data inputs	Example analysis
Market structure	Evaluates the number of suppliers in a particular market and the influence this has on price over time.	Informs an understanding of the number of device variants, better product selection, and price negotiation.	Price competition	-Number of manufacturers. -Number of distributors. -Purchase price. -Device make and model.	How many variants of a device exist on the market? For these devices, which have biomedical engineers who are trained in them and who can engage for service contracts?
			Product harmonization	-Number of manufacturers. -Number of distributors. -Device make and model.	More suppliers may result in a segmented market and more difficult device management over time. Consider engaging with suppliers that can service many needs to better consolidate device management tasks.
Demand forecasting	Demand forecasting is a way to accurately predict future needs and is critical to ensuring availability of devices and planning for future costs.	Being able to forecast the demand for medical devices, spare parts, or consumables can help in budgeting for replacement, reducing downtime between replacement, and allowing coordination of bulk procurement	Replacement rate	 -Installation dates. -Forecasted life span from technical specifications. -Routine metrics of power consumption. -Log of which components break the most or need the most replacement. -Usage rate of consumables (inventory). 	Example: There is an increased need for nasal prongs during cold months due to rise in pneumonia. Bulk orders can be planned to ensure availability. -Log breakdowns or times when there are unmet supply needs. Compare against technical specifications to inform replacement rates of spare parts and consumables.
		or advance commitments if applicable. Demand forecasting ultimately decreases expense and lack of access.	Minimum market size	-Inventory (count) of existing equipment. -National standards for equipment available in each health facility level.	Looking at the national guidelines for equipment can help determine the minimum pieces of equipment required in a given market (minimum market size); when compared with the count of equipment that is available and functional, you can determine the remaining gap and immediate demand.

Table 5. Leveraging data for market engagement (continued).

Engagement area	Description	How does it help market engagement?	Measures	Data inputs	Example analysis
Technology suitability	itability is the technology the extent significations affect infrastructure health system limitations affect infrastructure? the usability and This market efficiency of area evaluates technology can suitability by be leveraged limitations for future in resources, procurement finances, decisions. workforce, and environmental areas of conditions.	the extent to which infrastructure limitations affect the usability and efficiency of technology can be leveraged for future procurement decisions. By elucidating	Appropriate selection	 Power requirements. Frequency of outages. Frequency of device use. Number of qualified technicians for installation, maintenance, and general use. Workforce culture and knowledge surrounding the technology. 	 Compare technical specifications and actual electricity use to evaluate expected versus actual power requirements. Collect data on # of hours device is used, voltage fluctuations, watts available, and whether there is back-up supply for electricity.
		Performance tracking	-Replacement rates of spare parts and consumables.	Air filter needed replacement X number of times in the last year compared to forecasted replacement rate. Environmental conditions may be too dusty for an oxygen concentrator versus canisters. -Equipment downtime.	

Data and health

Asset management system data can also be used to evaluate health impacts, such as how well devices fulfill patient load requirements, improve health outcomes, and ensure patient safety. For example, having cost-effective technology can ensure that care requirements are fulfilled at higher rates and with less cost to the hospital and patient. An example analysis to measure health impact could be using total cost of ownership of devices to evaluate relative cost-per-person for using a medical device. Also, data may allow a facility to evaluate the number of people who received care via a medical device type and inform gap analysis for care fulfillment.

Overall, data collected through asset management systems equip health facilities with information to increase their market potential, as well as understand their limitations and capabilities in providing care.

5. Conclusion

Lack of access to medical devices is a major barrier to health in low- and middle-income countries; it arises from a variety of issues, including poor device management. An asset management system can help users collect and track data throughout a device's life span. When these device data are analyzed in the context of health facilities' needs, it may provide insight on how to improve management practices, maximize the operating efficiency of devices, and minimize costs associated with device downtime and premature device failure. The following list of considerations for adoption and implementation of this guide should help stakeholders plan for asset management systems. Included is a list of search terms for the reader hoping to explore additional resources.

Broader considerations for implementation and adoption of this guide

This guide cannot foresee all the needs and technicalities of a specific health system. Table 6 contains key questions stakeholders can ask themselves to assess their unique limitations and barriers to implementing an asset management system or to reading and adopting this guide.

Table 6. Key questions for implementation and adoption of this guide.

Key question	Who might address these questions	
 What are the human resources available within your health system's infrastructure? Is the health care staff overburdened? 	Health facility staff	
 How much does staff turnover occur? What training or retraining occurs and who is responsible? 	or	
 How do health care workers feel about their current system for asset management? What are the preferred methods for logging and organizing information for asset management? What incentives exist to accurately report maintenance information and statistics that may be reported as inputs for an asset management system? 	Health facility manager	
 Do the proposed systems for asset management link, or are they compatible, with current management systems and strategies within the health facility? 		
What interdependencies may exist that would influence the ability to successfully implement an asset management system?		
Will an implementation and adoption checklist be used?		
 Are there any personnel management issues that may hold up or inhibit implementation and coordination of asset management activities? 		
Who would need to take on this work on a routine or semi routine basis to keep up a system for asset management? Who would become the "champions" of the process?		
How many biomedical or clinical engineers are in your country or area?	Ministry of	
What options exist for outsourcing versus insourcing management of medical devices and asset management systems?	health or	
What is the landscape of health policy? What role does the country's local or national government play in implementing health policy and facilitating asset management?	Governing body for health	
 How can documents such as this guide best be distributed, accessed, and used? (Will they be provided as online pdfs or printed and held on-site?) 	systems by district/region/	
Who can listen to feedback and questions concerning implementation of practices from a resource guide?	nation	
How will stakeholder engagement and buy-in be established?		
How will successes and challenges with implementation, dissemination, and adoption be documented?		

Search terms for asset management systems

The following terms might help with finding additional information on asset management systems:

- Health or health care technology management.
- Medical device management.
- Maintenance management systems.
- Clinical engineering.
- Procurement process/guide.
- Implementation guide.
- Asset management "checklist."
- Asset management framework.

Appendix 1. What contributes to lack of access? Country case studies

PATH conducted a review of in-country interventions and existing asset management systems to determine what contributes to lack of access to medical devices. This review was used to define best practices, key considerations, and key questions to evaluate health infrastructure challenges.

Case study 1: Replacing oxygen cylinders with oxygen concentrators in a 42-bed, low-resource hospital in The Gambia

The intervention "Implementation and 8-Year Follow-Up of an Uninterrupted Oxygen Supply System in a Hospital in The Gambia" by Bradley et al. offers an example of how a system for medical technology asset management can be designed, implemented, and evaluated. In this case study, an asset management system was not formally employed, although the methods for collecting and tracking data are comparable to asset management systems as discussed in this guide. Data collected during the study that could be inputs in an asset management system are emphasized in Table A1, in the column "Asset management system data inputs."

Asset management activities	Example from The Gambia case	Asset management system data inputs
Baseline assessment, inventory assessment	 Oxygen cylinders were expensive and logistically challenging. 3 out of 12 hospitals had reliable access to oxygen. Average requirement for oxygen was 5 patients at any given time. Pulse oximeters were available. Hospital had adequate clinical staff. Limitations in maintenance ability. Key issue: Back-up generators were present but the hospital experienced power outages multiple times a week. 	 Costs of cylinders. Refill rates. Available distributors. Inventory assessments across facilities. Gap assessment data. Clinical staff available. Maintenance contractors available. Frequency of power outages and power source type.
Implementation, including installation, delegation of roles, and responsibilities for maintenance	 Oxygen concentrators implemented. Oxygen cylinders stored as back-up supply. Phased approach with purchasing of oxygen concentrators spaced out over time. Initial stock of spare parts was purchased and replacements were ordered as needed over time. All maintenance done in-house (no maintenance contracts). Clinical staff were trained on using the new system. Training was incorporated into the regular training of new staff members. Key solution: Uninterruptable power supply was installed along with new wiring and outlets for plug-in from multiple wards. 	 Inventory assessment and date of assessment. Purchasing costs. Suppliers. Identifiers for devices (unique ID #, type of device, model, manufacturer, etc.). Stock of replacement parts (quantity and type). Personnel responsible for maintenance. Staff training history. Location of technical specifications and user guides.

Table A1. Parallels to asset management system development in an intervention in The Gambia.

Asset management activities	Example from The Gambia case	Asset management system data inputs
Routine management and data collection	 Biomedical engineer department performed routine preventative maintenance. Electronic equipment management database used to log all preventative maintenance tasks. Life span of oxygen concentrators recorded from installation date to retirement. Median duration of operation recorded in hours. Accumulated duration between concentrators. Average number of maintenance checks per year. % of checks requiring corrective maintenance. Average # of parts replaced. Types of parts replaced or broken. Total cost of maintenance and labor. Downtime due to maintenance (as a % of days in service). 	 Service history of maintenance activities. Predicted life span. Installation date. Uptime of device. Downtime. # of maintenance events and type. # of replaced parts and part type. Maintenance costs.
Leveraging data for future decision- making and market engagement	• Maintenance requirements, costs, and user feedback were collected in order to inform an 8-year post-installation audit of the intervention's success: Switching to an oxygen concentrator system saved 51% of oxygen supply costs.	• Evaluation of collected data.

Table A1. Parallels to asset management system development in an intervention in The Gambia (continued).

Other key considerations discussed within The Gambia case include:

- The priorities of the health care staff and stakeholders for improving access to medical oxygen: increase oxygen availability, minimize risks to safety, appropriately train clinical staff, and reduce overall costs.
- In The Gambia case, sockets were implemented for direct plug-in to the uninterruptable power supply from any of the hospital wards. This was a key assurance that

oxygen would be available where it was needed and competition or medical device misplacement between hospital wards and areas of demand was minimized.

- Maintenance support and services were well logged by biomedical engineers over the course of the study. This allowed for effective data analysis on device performance.
- A limitation of the study was a lack of data on improved patient outcomes.

Case study 2: Indonesia's Aplikasi Sarana, Prasarana & Peralatan Kesehatan (ASPAK; Application of Facilities, Infrastructure and Health Equipment) platform and increasing access to medical oxygen

The following section describes how information within an asset management system can be used to perform secondary analysis to target specific health improvement efforts. This case focuses on using Indonesia's ASPAK system to inform improvements and subsequent countrywide efforts to increase access to medical oxygen.¹⁸

The data analysis was conducted in 2017 in partnership with health facilities directorates responsible for initiatives to drive access to medical oxygen in Indonesia. The following filters were used to focus the data analysis:

- Types of oxygen equipment (including oxygen concentrators, oxygen generation systems, oxygen manifold systems, oxygen sets, pulse oximeters, and bedside monitors).
- Data from 34 provinces of Indonesia.
- Data from three types of facilities (hospitals, *puskesmas* [i.e., *pusat kesehatan masyaraket*, community health clinic] with beds, and *puskesmas* without beds).
- Data from four types of power supply (national grid, power generator, solar power, and uninterruptable power supply).

Illustrative data analysis included:

Table A2. Number of functioning oxygen devices of each type across health facilities.

Number of functioning devices in dataset (number not functioning)				
Number of oxygen concentrators	5,246 (2,099)	Number of oxygen sets	1,748 (143)	
Number of oxygen generation systems	627	Number of pulse oximeters	5,248 (1,647)	
Number of oxygen manifold systems	8,295	Number of bedside monitors	15,473 (2,048)	

Figure A1. Percentage of facilities with access to medical oxygen.

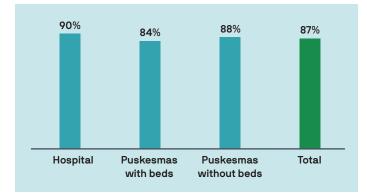


Figure A2. Types of devices used in facilities with access to oxygen.

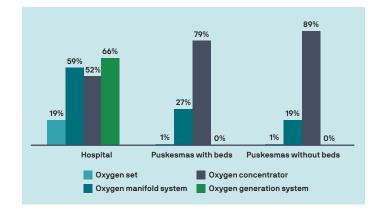
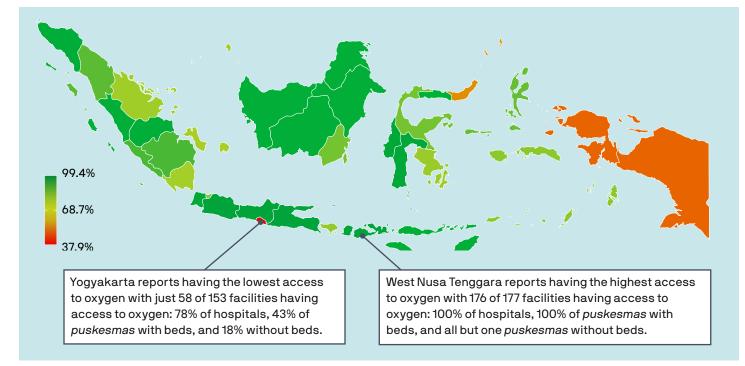


Figure A3. Provinces of Indonesia with the highest and lowest access to medical oxygen.



Overall, many different analyses can be performed with the health facility data of the ASPAK management system. One of the greatest values of these analyses is their ability to quantify gaps in access. Specific quantification of these gaps elucidates factors that contribute most to lack of access; from this specificity, more targeted goals and guidelines to improve access can be created (see Figure A4). For example, the data analysis revealed that puskesmas with beds were only meeting 39 percent of the oxygen need at their level of health facility. Combined with information regarding which types of oxygen technology are used in these facilities, an assessment can be made that puskesmas with beds with cylinderbased manifold systems represent the greatest shortage in oxygen.

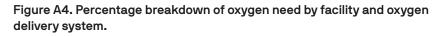
From these data, deficits in care could be specifically targeted and suggestions made for improvement, such as switching to an alternative and/or back-up source of oxygen for *puskesmas* with beds.

Overall, the Indonesian ASPAK

system was designed for data collection and collation of information regarding health facility equipment and infrastructure across the country. If the ASPAK system were adapted from an information and inventory management system into an active asset tracking system, it would more closely resemble asset management systems as described in this guide. The ASPAK system is a useful example from which to begin design of more robust tracking systems.

Case study 3: India's Biomedical Equipment Management and Maintenance Program

India's National Health Systems Resource Centre conducts surveys of medical devices and has compiled databases on medical equipment for the Indian states. These data are collected by medical equipment contractors via biomedical engineers performing medical device maintenance. The biomedical maintenance program required firms to collect information on device availability and operation status in health facilities. Although designed for use by biomedical engineers for medical device maintenance, the program closely resembles an asset management system because of the type of information it tracks and the method of collection through a system. In 2017, PATH worked with the Ministry of Health and Family Welfare to conduct an analysis of publicly available data from 21 Indian states, combined with general statistics from the Ministry of Health and Family Welfare, to evaluate the number of oxygen concentrators and oxygen cylinders at various types of public health facilities. Further gap analyses were also performed using these data, such as evaluation of the quantity of oxygen concentrators that would need to be purchased to close the current equipment gap within the next ten years, according to national guidelines (see Table A3).



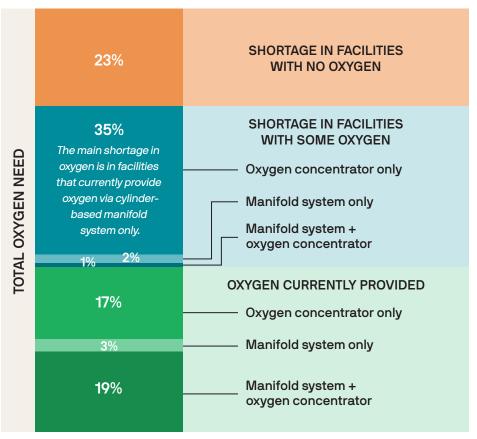


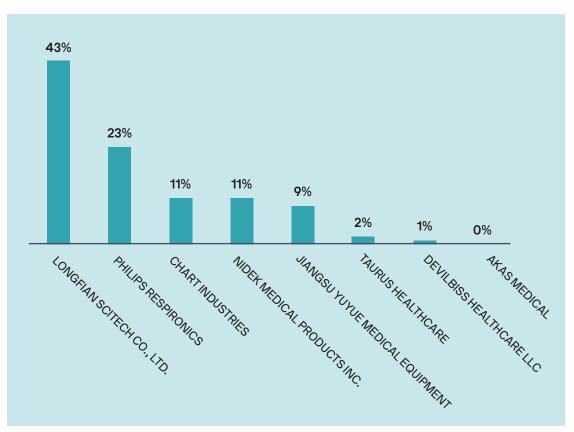
Table A3. Public-sector gap closure for oxygen concentrators: 10-year assumptions.

Facility level	Assumed growth rate	Number of years until gap closed	Average number of devices per year
Primary health centers	25%	10	4,240
Community health centers	17%	10	949
Subdistrict hospitals	17%	10	544
District hospitals	22%	10	2,134

Additional analysis included quantification of the market size and market share by medical device manufacturer (see

Figure A5). This information can be evaluated together over time to forecast medical device demand.





Resources for data collection

There are a number of reference documents and health system and infrastructure guidelines that make recommendations for data collection. While Box A1 is not exhaustive, it provides resources with specific relevance to data collection for asset management systems, as well as resources specific to management of oxygen delivery devices and pulse oximeters.

Box A1. Reference guides for asset management system building.

PATH website. Oxygen Delivery Toolkit: Resources to plan and scale medical oxygen page. <u>www.path.org/oxygen-delivery-toolkit</u>.

- Baseline Assessment Manual: resources to carry out the training of those involved in conducting a baseline assessment survey, including guidelines that the trained personnel can reference in their field work.
- *Reference Pricing Guide*: a guiding framework to create budgets, negotiate price, and ensure the selection of appropriate and sufficient devices.
- *Procurement Guide*: describes the key steps that should be followed when procuring and contracting for an oxygen delivery system.
- Quantification and Costing Tools: an Excel-based tool intended to help procurement decision-makers anticipate cost across oxygen delivery devices based on facility needs, facility conditions, and the marketplace.
- Consumption Tracking Tool: used to track daily oxygen use in facilities in order to inform future procurement planning.

Procurement Process Resource Guide. Geneva: World Health Organization; 2011. WHO Medical Device Technical Series. <u>https://www.who.int/medical_devices/publications/procurement_guide/en/</u>.

Guide 1: How to organize a system of healthcare technology management. In: 'How to Manage' Series for Health Care Technology. East Sussex, United Kingdom: Health Partners international; 2005. <u>https://www.who.int/management/</u>resources/equipment/How%20to%20Organize%20A%20System%20of%20Healthcare.pdf.

National Health Systems Resource Centre (NHSRC). *Biomedical Equipment Management and Maintenance Program*. New Delhi: Ministry of Health and Family Welfare of the Government of India; 2015. <u>http://nhsrcindia.org/sites/default/files/practice_file/Biomedical%20Equipment%20Revised%20%2810-02-2015%29%282%29.pdf</u>.

Appendix 2. Additional methods and resources for structuring data collection for asset management systems

A record of the total cost of ownership of a medical device can be linked to an asset management system and used to track all expenses incurred from device operation and management. This is separate from a routine health facility budget, as it should record the cost and date of devicespecific expenses. These expenses will include up-front costs from device acquisition (shipping, installation costs) and then routinely updated costs for maintenance activities and replacement parts. This record of device costs can be linked to a larger health facility budget and help to assess the cost of operating and owning devices. This has the potential to help facilities reduce costs in the future.

Table A4 provides a snapshot of the "Template for supplier total cost of ownership costs," an appendix item from the <u>Procurement Guide</u> (part of the Oxygen Delivery Toolkit). Some of the fields in this example could be used to design a system for routine cost tracking or link to an asset management system.

Table A4. Template for supplier total cost of ownership costs.

Expenses		Total cost
Cost category 1	Cost items	Unit cost
All initial costs on purchase (one-off)	Unit price	
	Accessories	
	Packaging	
	Delivery costs	
	Taxes	
	Installation/integration/engineering/calibration costs	
	Training costs	

Other cost categories that may be relevant to collect and track are regular ongoing operational costs, service and maintenance costs, fuel and energy, and disposal costs.

Asset management system maintenance can also be performed by health facility staff—for example, logging training data. Box A2 gives a couple examples of device measures that may be recorded:

Box A2. Examples of training data that may be tracked in an asset management system.

- Date of training.
- Employee trained.
- Training entity.
- Device trained on (unique ID, make, model).
- Training procedure (manuals used, technical specifications).
- Status of device upon training (date of last calibration, date of last maintenance event).

The *Procurement Guide* may also be a helpful resource if looking to log and track training data for medical devices. Annexes J-L of the guide contain sections with examples of many more measures and considerations for collecting and organizing data. Table A5 describes general methods to collect medical device data, and the pros and cons of each method. These methods are particularly conscious of what resource constraints may exist in a health facility or region.

Example method	Pros	Cons
Have a designated workforce that visits facilities in a region, collects data on medical devices, and logs in to a shared system.	 The workforce is trained to collect data. Measures for collection are standardized. Having one specific task reduces distraction for the worker. 	 Time consuming. Labor intensive. May require lots of travel. Not all facilities may have internet or a way to upload data; workers may need devices to track and store data until they can be uploaded.
Have contracted labor collect device data as part of standard asset management (whether this is a service provider who must collect baseline data during installation or calibration or a biomedical engineer who logs device data during routine maintenance).	 Laborer is trained for data collection. Reduces labor for health facility workers. Service providers can be held accountable for device performance data, and this incentivizes data collection. 	 Additional work for the laborer. May not be able to capture all data measures, especially if maintenance is infrequent or the service provider does a poor job.
Have health facility staff collect device data as a standard practice.	 Potential for more routine data tracking. Staff have a closer connection to the importance of device management. 	 Labor intensive. Time consuming. May not be realistic if human resources are constrained within the facility. Staff may not be trained to collect data on devices or use a data-tracking system.

Appendix 3. Using asset management systems to inform medical device management

Asset management systems can help plan timing, prioritization, and budgeting of maintenance activities for medical devices. Performance data from medical devices along with records of maintenance activities, such as preventative or corrective maintenance, should be routinely tracked information that links with an asset management system.

Inspective and preventative maintenance: Planned for based on technical specifications and technician recommendations and performed routinely to minimize damage, inefficient use, and device downtime. May also include calibration.

Corrective maintenance: Used when devices have broken or are working suboptimally.

Routine audits of this information within the asset management system will help with advising proper device

care and management activities, thus allowing for better maintenance prioritization and budgeting of time and money.

If attempting to routinely manage a large collection of medical devices, a strategy for maintenance prioritization may be helpful. The following example demonstrates how maintenance prioritization can be achieved objectively by scoring devices based on their function, associated risk, and maintenance requirements.^{19,20} Capturing risk associated with devices, either by recording the number of safety incidences over time or by using a risk prioritization matrix such as below, can also help to inform future procurement activities.

The total equipment management number was calculated from function points, risk points, and maintenance requirement points, as shown in Table A6.

Score	e Function	Risk	Maintenance requirement
10	Life recovery	_	_
9	Surgical and intensive care	_	_
8	Physical therapy	_	_
7	Surgical and intensive care	_	_
6	Other physiological monitors	_	_
5	Analytical laboratory	Patient death	Very important
4	Laboratory equipment	Patient/staff injury	Moderately important
3	Computers	Wrong diagnosis	Less important
2	Belong to the patients	Treatment delays	The least important
1	Other equipment pieces	Risk not important	Minimally important

Table A6. Total equipment management number, calculated from functional points, risk points, and maintenance requirement points.

Table A7. Length of time between medical device maintenance activities ("test interval") correlated to a range of values for the equipment management number score—example of a pulse oximeter.

Medical device	PVST parameters	Simulator analyzer measurement device	FP	RP	MRP	EMN	Test interval
Pulse oximeter	Oxygen saturation ECG BPM test	SPO2 Analyzer (Fluke Index 2 XLF)	7	3	4	14	12 months

Note: ECG BPM, electrocardiography beats per minute; EMN, equipment management number; FP, function points; MRP, maintenance requirement points; PVST, periodical performance verification and safety testing; RP, risk points.

The correlation between the equipment management number score range and the test interval was informed by biomedical engineer and device technical specifications. A scoring system, such as the example above, could be used to prioritize maintenance of medical devices when building a maintenance plan as part of an asset management system.

Box A3. Reference guides for medical device management

Medical Equipment Maintenance Programme Overview. Geneva: World Health Organization; 2011. WHO Medical Device Technical Series. <u>http://apps.who.int/medicinedocs/documents/s21566en/s21566en.pdf</u>.

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