

Oxygen Delivery Toolkit

Resources to plan and scale
medical oxygen

Health Facility Standards Guide

Assisting stakeholders in creating
or improving high-quality,
country-specific resources that
outline health facility infrastructure
and medical device standards

For use by:



Decision-makers



Implementers



Advocates

August 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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Abbreviations

GMDN	Global Medical Devices Nomenclature System
LPM	liters per minute
MOH	ministry of health
MoHCDGEC	Ministry of Health, Community Development, Gender, Elderly and Children
TWG	technical working group
UMDNS	Universal Medical Devices Nomenclature System
WHO	World Health Organization

Background

Overview of health facility standards

National health facility infrastructure and medical device standards (also referred to as health facility standards) are a set of guidelines on infrastructure and medical device specifications recommended in each health facility level in a country. These documents may include the location of facilities, infrastructure details, staffing requirements, wards and health services provided, and recommended lists of medical devices. In some cases, these exist as a single document per country, covering all levels of the health system, while in other cases these are presented as a package of separate documents, one for each level of the health system. They are often designed to help ministry of health (MOH) and hospital officials understand what each level of health facility should look like in a country, and can be used when opening new health facilities, certifying existing health facilities, or comparing facilities to a set standard.

Medical devices are an important component of a health facility's needs, and requirements for medical devices are often included in these documents. Understanding the service requirements at each level of the health system can help clarify medical device needs. From there, medical device guidance formally establishes the expectation for the types of devices, number of devices, location of devices within a facility, maintenance/service for devices, or personnel required to use these devices. These details can be used by health care workers and planners within a facility to understand the types of medical devices to procure, how many of each are needed, and where to place them within a facility. Additionally, by establishing clear expectations, they can be used as a reference point for facility accreditation or budget allocation for new device purchases. An added benefit of establishing clear medical device guidelines is that it can help medical device manufacturers understand the potential market size in a country by showing the number of devices required in each facility type.

Current state of country-level resources for health facility standards

In 2011, the World Health Organization (WHO) released suggested lists of medical equipment that should be present in different levels of health facilities¹—equipment that is essential for facilities to provide health services. However, these are not requisite lists. WHO stated in a disclaimer that these are “working documents and are only a current snapshot of ongoing work being conducted at WHO.” Additionally, “the information here has not been reviewed by a committee of clinical experts and must be adapted to the specific conditions or settings where they will be applied.”

Without international benchmarks, the availability and content of health facility standards vary widely across countries. According to WHO, which conducted a survey of these documents for its Global Atlas of Medical Devices (2017), 59 percent of 158 countries have national standards or recommended lists of medical devices for different types of health care facilities² (27 percent for different health care facilities and 32 percent for different health care facilities and specific procedures). An additional five percent of countries have national standards or recommended lists of medical devices for specific procedures (but not for different health care facilities). In comparison, 70 percent of 195 countries³ were identified as having essential medicines lists in 2017. While essential lists for medicines/drugs and, more recently, diagnostics have become more common at the global and country levels, this is less common for medical devices.

This work can be used as a starting point for countries looking to create their own national health facility standards.

RESEARCH METHODOLOGY

To better understand the availability and content of health facility standards across countries, PATH conducted research to review existing standards documents from select countries. The team began by identifying all countries that reported having either national standards for medical devices or lists that recommend health technologies for high-burden diseases as part of the WHO Global Health Observatory.⁴ Of the 157 countries included in the WHO Global Health Observatory data repository, approximately 50 were selected for further research, based on income status (with a focus mostly on low- and lower-middle-income countries) and population (mostly targeting countries with a population of over 10 million). Attempts were made to locate these documents by leveraging connections with local ministries of health, emailing WHO medical device points of contact for each country, and conducting secondary research online. This led to the resulting 16 countries used as the basis for key learnings and best practices in this guide.

From each of these documents, PATH extracted data on a variety of indicators, with the goal of compiling similarities, differences, and best practices from across the countries. These indicators covered general information about the documents (e.g., who published them, where they can be found, who provided technical or financial support, the purpose of the documents), information on health facility infrastructure (e.g., recommended number of beds, health care providers, wards, health services, and facility requirements by facility type), information on medical devices (e.g., whether factors such as the number, type, location, maintenance, service, or safety of devices were discussed), and specific details on oxygen devices as a case study.

Purpose of this guide

This guide provides recommendations on how to create or improve high-quality, country-specific resources that outline health facility infrastructure and medical device requirements across different levels of the health system. It uses oxygen delivery and pulse oximetry devices as specific case studies when discussing medical devices. Evaluating a country's existing health facility standards alongside this guide may lead to improvements in equipment availability, ultimately helping to increase access to medical oxygen and pulse oximetry (as well as other medical devices) across all levels of the health system. This guide:

- Compiles best practices from a review of health facility standards from countries across income levels and world regions.
- Offers suggestions for developing or improving health facility standards, including specific recommendations on each section of the document.
- Provides case study examples, using oxygen delivery sources and pulse oximetry devices, to highlight current country standards that meet the outlined best practices.

Limitations of this guide

- This research was conducted by reviewing national-level health facility infrastructure and medical device

standards, when available. Documents such as health sector strategic plans, clinical treatment guidelines, and guidelines with a narrow focus on a specific part of the health system were not included. In some cases, when complete documents were not available, medical device lists were reviewed.

- While standards documents hold utility for all medical devices, this guide was created as part of a project specifically focused on oxygen delivery sources and pulse oximetry devices. As a result, product-specific examples and case studies focus solely on those products.
- While this guide provides suggestions on the type of content that should be included in these standards, it does not include information on how to determine the exact content. For example, it may recommend including the number of medical devices for each type by ward, but it will not consider how to arrive at those numbers and types. See the "[Helpful resources](#)" section at the end of this guide for other resources that can be consulted further while building these standards.
- Research was not done to determine whether and to what extent creating more detailed standards documents will lead to improved health outcomes. However, it operates on the working assumption that improved clarity in policy guidance will improve access to medical devices, thus positively impacting health outcomes.

Guide to create or improve health facility standards

The recommendations listed below are based on PATH's research and review of country-level health facility infrastructure and medical device standards documents (health facility standards) from 16 low- and lower-middle-income countries;^a these are supported by PATH's knowledge and experience from a long history of working on issues related to medical device access. The recommendations are based on a comparison of these documents across countries, with useful examples highlighted as case studies. The guide is organized in four sections: 1) how to create effective health facility standards, 2) what general facility standards content to include, 3) what medical device standards content to include, and 4) how to enforce health facility standards.

1. How to create effective health facility standards

The process to create effective health facility standards can be very resource intensive in terms of time and cost. Therefore, in order to create a high-quality document, it is important to adopt a data-driven approach with effective leadership and buy-in from relevant stakeholders. This section outlines best practices for creating health facility standards.

Publishing body

Health facility standards are typically created and owned by the MOH in an individual country. It is recommended to have the MOH own this document process, as it already oversees most aspects of the health system and is accustomed to publishing similar types of guidelines and policy documents. Many guidelines list lead departments within the MOH that are responsible for document creation, such as departments overseeing health quality assurance, estate management, logistics of medicine and related products, or the medical equipment committee. The specific department may vary by country, but the department leading the effort should be named in the document for increased transparency. Much the same as clinical guidelines, essential medicines lists, or other health policies that facilities may follow (especially in the public sector), oversight and endorsement of standards by the MOH facilitates effective implementation.

Technical support

Soliciting technical support from a broad variety of groups, both at the country and global levels, is key to developing high-quality standards.

Country-level support

- Government officials, including elected officials and parliamentarians.
- Public workers, including members of the MOH, other government ministries (such as finance or procurement), and administrative authorities.
- Technical experts, including medical device experts and academics.
- End users, including physician groups, health workers, and members of the private health sector.
- Nongovernmental health organizations.

Global-level support

- Multilateral organizations (e.g., WHO)
- Governmental agencies (e.g., Deutsche Gesellschaft für Technische Zusammenarbeit [German Agency for Technical Cooperation], European Union, Japan International Cooperation Agency, the United Kingdom's Department for International Development)
- International global health organizations (e.g., Clinton Health Access Initiative)

Financial support

Along with technical support, financial support is important in order to prioritize the development of health facility standards. While adherence to these standards requires a longer-term strategy and investment, the actual development step is a one-time investment, with smaller incremental costs over time to update or revise. Domestic financing, or a combination of domestic financing and donor aid, is often leveraged to support the development of these guidelines. Funders that have provided such financial support to countries in the past include the Clinton Health Access Initiative, Japan International Cooperation Agency, United Kingdom Department for International Development, US Agency for International Development, and WHO. It is important to specify the funder of the work (whether it is self-funded by the MOH or funded from external support), as this provides more transparency and can highlight potential conflicts of interest.

^a Democratic Republic of the Congo, Ghana, Guatemala, India, Indonesia, Kenya, Malawi, Nicaragua, Senegal, Sri Lanka, Tanzania, Tunisia, Uganda, Ukraine, Vietnam, Zambia.

Creation process

An effective way to create the standards document is to establish an interdisciplinary technical working group (TWG) under the MOH to lead the process. TWGs can include a variety of different expertise and roles, including many mentioned above in the “[Technical support](#)” section. This diversity of perspectives will ensure the document is well-researched and, ultimately, useful. This creation process could take up to one to two years, so sufficient time and budget should be planned for. The process should be iterative in nature, with the MOH continually reviewing drafts from the TWG to ensure buy-in. Including a clear description of how the standards document was created and who was involved will add credibility and transparency.

Timeline

While the structure and types of content in health facility standards may not change from year to year, components of the content may need to be updated on a regular basis in order to ensure the standards are up to date with the

current technologies, global guidelines, clinical practices, and other relevant health care guidance. Publication dates and the frequency of revisions to country standards can vary considerably across countries (PATH’s review of country standards found that the publication dates of current versions varied from 1994 to 2017). It is recommended that once a detailed document with the desired content is compiled, an update to the document is conducted at a minimum of every five years, or sooner as circumstances require. This ensures sufficient time for the documents to stay relevant without becoming costly to update. Scheduled revisions may also minimize confusion for users in determining whether the current document is the most recent. In addition, they would alert advocacy groups to supply the MOH or responsible entity with recommendations or edits in a timely manner for the next version.

Accessibility

Ensuring that health facility standards are accessible to their intended audience is as important as creating an effective document. Many documents identified through

CASE STUDY: Tanzania

The Tanzanian Ministry of Health, Community Development, Gender, Elderly and Children’s (MoHCDGEC’s) 2017 *Basic Standards for Health Facilities* series of documents includes an extensive list of all organizations and individuals that the MoHCDGEC engaged in the development of the standards. The document states:

Development of the standards is a product of an extensive consultation that started in 2011 with coordination of the Health Quality Assurance Division – through the Health Services Inspectorate and Quality Assurance Section, and the Curative Services Division – through the Hospital Reforms Unit and the Coordinator of Palliative and Rehabilitation Services in the Non Communicable Diseases and Substance Abuse Section. The Standards for Rehabilitation Medicine Services involved extensive consultations with the Experts in Physiotherapy, Prosthetics and Orthotics, Occupational Therapy, and Speech and Language Therapy from the following organisations – Association of Prosthetists and Orthotists in Tanzania (APOT), Association of Physiotherapists in Tanzania (APTA), Tanzania Occupational Therapists Association (TOTA), Muhimbili National Hospital (MNH), Kairuki Hospital, Muhimbili Orthopaedic Institute (MOI), Mwananyamala Regional Referral Hospital, and London Health Centre. The tireless coordination efforts facilitated experts from various organizations and within the MoHCDGEC to provide inputs that have culminated in printing of the standards. The MoHCDGEC would like to acknowledge the contributions of experts from the following organizations: . . . [This is followed by a list of 36 specific organizations that assisted with the development of the standards.]

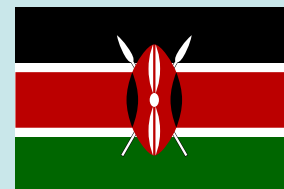
Working with a variety of organizations ensures that perspectives and inputs of a broad set of stakeholders are considered, resulting in a robust document. Additionally, listing each of these stakeholders and thanking them individually add credibility and transparency to the document by highlighting this collaboration between a variety of technical experts.

Source: Ministry of Health, Community, Development, Gender, Elderly and Children (MoHCDGEC), The United Republic of Tanzania. Basic Standards for Health Facilities. Volume 3: Hospitals at Level I & II and Stand Alone Facilities at Level I & II. Dar es Salaam: MoHCDGEC; 2017.



CASE STUDY: Kenya

The Kenyan Ministry of Health's 2017 *Health Infrastructure Norms and Standards*, has a clearly outlined section in the report titled "Methodology." This section details the development process, principles for development, and development steps. Including this level of detail signals that the document was created in a clearly designed and thorough manner, and can help readers understand the process that was undertaken. In the development process section, the document states:



The development of these Infrastructure Norms and Standards was based on a revision from Norms and Standards for Health Service Delivery (2006). A stakeholders' workshop was held in November 2014 in Naivasha during which a decision was taken to separate the human resources for health norms and standards from that of infrastructure norms to incorporate the managed equipment services status report, which a rapid assessment was being done. Subsequently a Technical Working Group (TWG) was selected from amongst the stakeholders to refine the draft. The TWG held several meetings culminating in the final draft which was subjected to review from various stakeholders and experts. Inputs from reviewers were consolidated to enrich the draft and produce the final document. The outputs were then reviewed by Ministry of Health heads of departments to further contextualize the desired health infrastructure norms and standards.

Source: Ministry of Health (MOH), Republic of Kenya. Health Infrastructure Norms and Standards. Nairobi: MOH; 2017.

PATH's research were only accessible via in-person visits to MOH offices or via extensive online research. Documents that only exist as paper copies, or that are difficult to find online and are only accessible by direct links, are difficult to access for health facilities and others looking to consult them. In order for the standards to be as useful as possible, it is recommended that online versions are posted to

central document storage locations within MOH websites and that a notice is sent to health facilities each time a new version is published. Additionally, these documents can be cross-referenced within other relevant standards (such as clinical treatment guidelines) or within other health facility planning reference documents (such as accreditation forms or budget allocations forms; see [Section 4](#) below).

Key takeaways

1. Identify a specific directorate or group within the ministry of health to lead the document development process in order to ensure accountability.
 2. Establish and document a transparent development process and ensure a cross-disciplinary technical working group is engaged in the standards development and revision.
 3. Investigate potential sources of funding for development of the first set of standards, including internal (within country) and external groups.
 4. Revise standards on a regular schedule, at a minimum every five years or sooner, and communicate to end users when new versions are available.
 5. Ensure standards are easily accessible online through the ministry of health website.
-

2. What general facility standards content to include

Within each health facility standards document, much of the content focuses on general facility infrastructure standards. This includes details such as wards, health services, beds, population served, health care providers, location, utility requirements, or others. This section describes best practices for the type of content to include on general facility standards.

Wards and health services

Setting an expectation for the wards and/or health services that ought to be present and offered at each level of the health system is a clear way to show differences between each level of care. For example, clearly outlining the level of preventative and curative care that should exist at each facility level will make it clear to facilities what services they are expected to offer. Lower-level health posts and health centers may only offer outpatient preventative services and basic curative services, whereas hospitals may offer inpatient stays and complex curative services. Within the description of wards and services, it is recommended to keep the language as clear, concise, and consistent as possible. Wards and health services are strongly

correlated; thus, outlining the wards that should be present and the services that these wards may provide is a strong way to organize this content and make it easy for facilities. Similar language should be used throughout the document anytime wards are discussed.

Beds and population served

Clearly establishing the population that each level of the health system is expected to serve ensures that the beds, wards, health services, providers, medical devices, and other requirements are proportionate to the actual need. It is recommended that the standards document outlines a clear number or range of population served, since good understanding of the surrounding population that a health facility is expected to serve (its catchment area) will influence what is needed at a facility. Country guidelines typically include a number or range of beds that should be available at facilities at each level of the health system, though some lower-level health posts may not have inpatient beds to report. Bed counts by ward are an additional level of detail that can be helpful to health facility managers. To ensure consistency, if ward-level details are used throughout the document, it is recommended to include an approximate number of beds by ward, so that this ward-level detail can correlate to other requirements in the facility.

CASE STUDY: Malawi

The Malawian Ministry of Health's 2009 Standard Equipment List for Typical District and Community



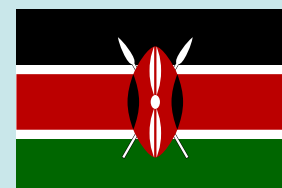
Hospital and Health Centre With Generic Specifications for Some Common and General Equipment is an example of a document that clearly outlines the wards that are expected to be present at each level of the health system. By comparing these wards across levels, it becomes clear what services are available at each level. This also is a source for information on how many medical devices are needed per ward (included in [Section 3](#) of this guide).

Source: This table is adapted from Ministry of Health (MOH), Republic of Malawi. Standard Equipment List for Typical District and Community Hospital and Health Centre With Generic Specifications for Some Common and General Equipment. Lilongwe: MOH; 2009.

Wards	Health center	Urban health center	Community hospital	District hospital
Outpatient	X	X	X	X
Maternity	X	X	X	X
Laboratory		X	X	X
X-Ray		X	X	X
Blood bank			X	X
Dental			X	X
Operating theater			X	X
Inpatient			X	X
Pharmacy			X	X
Mortuary			X	X
Physiotherapy				X
Ophthalmology				X
Burn unit				X
Orthopedic				X

CASE STUDY: Kenya

The Kenyan Ministry of Health's 2017 *Health Infrastructure Norms and Standards* document clearly outlines the number of beds, by ward, that should be available for inpatients at each level of the health facility. This level of detail helps for planning, and makes it explicitly clear what is expected at each level. The table below outlines the recommended number of beds by ward and facility level.



Wards	KEPH level 1: Community health services	KEPH level 2: Basic primary health care center	KEPH level 3: Comprehensive primary health care center	KEPH level 4: Primary care hospital	KEPH level 5: Secondary care hospital	KEPH level 6: Comprehensive teaching and referral hospital; specialized and tertiary hospital
General medicine	-	4 male; 4 female	6 male; 6 female	30 male; 30 female	30 male; 30 female	30 male; 30 female
Surgery	-	-	-	-	30 male; 30 female	30 male; 30 female
Orthopedics	-	-	-	-	30 male; 30 female	30 male; 30 female
Burn unit	-	-	-	-	30 male; 30 female	30 male; 30 female
Isolation	-	-	-	-	30 male; 30 female	30 male; 30 female
Pediatric	-	4	6	30	30 under 5 years old; 30 aged 5–12 years; 30 pediatric burns	30 under 5 years old; 30 aged 5–12 years; 30 pediatric burns
Maternity	-	4	6	-	30 gynecology	30 gynecology
Antenatal	-	-	-	30	30	30
Postnatal	-	-	-	30	30 beds; 20 newborn cots	30 beds; 20 newborn cots
Intensive care unit	-	-	-	-	12	24
High dependency unit	-	-	-	-	12	24
Occupational therapy	-	-	-	-	7	7
Total	0 beds	16 beds	24 beds	150 beds	511 beds + 20 cots	535 beds + 20 cots

Note: KEPH, Kenya Essential Package for Health.

Note: "-" indicates no beds are recommended in this ward.

Source: This table is adapted from Ministry of Health (MOH), Republic of Kenya. Health Infrastructure Norms and Standards. Nairobi: MOH; 2017.

CASE STUDY: Tanzania

The Tanzanian Ministry of Health, Community, Development, Gender, Elderly and Children's 2017 *Basic Standards for Health Facilities* series of documents uses ranges of population served and number of beds to highlight the requirements for each level of health facility. This allows the country to adapt to the needs of a specific community where the health facility is based. While this information on bed count and catchment areas is routinely available in most countries, including this detail within a health facility standards document will help contextualize other requirements, such as wards and medical devices.



	Health center	Level I hospital	Level II hospital	Level III hospital	Level IV hospital
Population served	Unknown	10,000–50,000	200,000–500,000	1,000,000–3,000,000	3,000,000–5,000,000
Number of beds	Unknown	24–60	61–150	120–400	401–600

Source: This table is adapted from Ministry of Health, Community, Development, Gender, Elderly and Children (MoHCDGEC), The United Republic of Tanzania. Basic Standards for Health Facilities. Volume 3: Hospitals at Level I & II and Stand Alone Facilities at Level I & II. Dar es Salaam: MoHCDGEC; 2017.

Health care providers

In addition to the health services and number of beds, outlining the number of health care providers that should be present at each level of the health facility ensures that these services can be provided. Some health care services or medical devices require operation by a trained health care professional; thus, including the types of health care providers that should be present in a facility will help ensure an additional level of alignment between wards, health services, providers, and medical devices. While some countries may choose to have a separate document outlining the detailed human resource requirements of health facilities, it is recommended to include a high-level summary within these health facility standards as well to ensure this consistency.

Miscellaneous

It may be helpful to include other guidelines for facilities as part of the general facility infrastructure—this may influence what is available at those facilities. For example, information about location requirements, such as proximity to roads or distance from disaster-prone areas, may influence whether or not frequent deliveries of devices like oxygen cylinders may be feasible or not. Additionally, information about water and electricity requirements may dictate what types of medical devices may be useful. Devices such as oxygen concentrators rely on electricity (either through mains power or a generator), so it is recommended to specify that a facility must have constant access to electricity with a backup source in place before saying that devices requiring electricity should be present.

CASE STUDY: India, District Hospitals

The Indian Ministry of Health and Family Welfare's 2012 Indian Public Health Standards (IPHS): Guidelines for District Hospitals (101 to 500 Bedded) lays out detailed guidance on the recommended health care providers that should be present at each health facility level. It breaks the staff down into medical staff and nursing/paramedical staff and includes recommendations that are flexible based on number of beds. The table below outlines the recommended number of medical staff at district hospitals, based on bed size and medical specialty.



Specialty	100 beds	200 beds	300 beds	400 beds	500 beds
Medicine	2	2	3	4	5
Surgery	2	2	3	3	4
Obstetrics and gynecology	2	3	4	5	6
Pediatrics	2	3	4	4	5
Anesthesia	2	2	3	3	4
Ophthalmology	1	1	2	2	2
Orthopedics	1	1	2	2	2
Radiology	1	1	2	2	2
Pathology	1	2	3	3	4
Ear, nose, and throat (ENT)	1	1	2	2	2
Dental	1	1	2	3	3
Medical officer	11	13	15	19	23
Dermatology	1*	1*	1	1	1
Psychiatry	1	1	1	1	1
Microbiology	1*	1*	1	1	1
Forensic specialist	1*	1*	1	1	1
AYUSH doctors	1	1	1	2	2
Total	29 + 3	34 + 3	50	58	68

Note: AYUSH, ayurveda, yoga and naturopathy, unani, siddha, and homoeopathy.

*This number is desired but not required.

Source: This table is adapted from Ministry of Health and Family Welfare (MOHFW), Government of India. Indian Public Health Standards (IPHS): Guidelines for District Hospitals (101 to 500 Bedded). New Delhi, MOHFW; 2012.

Key takeaways

1. Include general facility standards up front in the document—such as wards/health services offered, population served, number of beds, and number of health care providers—as a way to frame the rest of the recommendations in the guidelines.
2. Clearly outline the different expectations by level of the health care system in simple tables or other frameworks as a way to clearly differentiate between each level of care.
3. Provide recommendations by ward when appropriate (e.g., number of beds or number of health care providers), ensuring that the types of wards included are consistent across the document.
4. Identify other relevant facility requirements—such as electricity, water, accessibility, or location, when relevant—to ensure that these link to other requirements in the document (including medical device needs).

3. What medical device standards content to include

Content on medical device requirements by health facility level is an important component of a health facility standards document, but the content is often quite variable across countries. The process of developing the standards offers an opportunity for the MOH to outline what devices are expected at each level, with details on the number and type, and can help for planning and procurement purposes. This section provides recommendations on what content to include on medical device requirements.

Types, placement, and number of devices

The most important pieces of information to include when discussing medical devices in health care facilities are the types, placement, and number of each device that should be present at each level of the health system. Including this level of detail can help facilities know what devices they are expected to have, and higher-level procurement officials and budgeting officers understand approximately how many devices will be needed across a district, region, or country. This information should align with the wards, health services, and health care providers at each level of the facility, as detailed above, to ensure that each facility has all of the required guidelines in place.

What medical device requirements content to include

For each level of health facility, it is recommended to have a table of required medical devices. It is preferable to break this down by wards, if this aligns with other parts of the standards, but the most important details to capture for each device include:

- Type of device:** This should include a specific type of device, not the product brand.
Examples: Oxygen concentrator, oxygen cylinder, pulse oximeter.
- Size of device:** This should specify in detail the size or type of a device. Specifications could also differentiate between adult and pediatric devices, handheld and tabletop and floor devices, or other considerations.
Examples: A 10 liters-per-minute oxygen concentrator, an 8 kg oxygen cylinder, a handheld pulse oximeter.
- Number of devices:** This should specify the number of each device, in total and/or by ward. The number of devices may depend on the size of the device; thus, including both the number of devices and the size of each device is important.
- Consumables:** For some devices, specifying the related consumables that must accompany each device may be important. This may be specified by device, instead of by facility.
Examples: Three probes per pulse oximeter, two nasal cannulas per oxygen cylinder.

Standards may also provide additional details on each type of equipment, including a description of the device type, specifications such as size and weight, or power requirements. While these details may not all be necessary

in a health facility standards document, a certain level of detail may increase user comprehension when determining which medical devices to procure.

CASE STUDY: Uganda

The Ugandan Ministry of Health's 2009 *National Medical Equipment Policy* clearly outlines the required medical devices that should be present at each level of the health facility. The guidelines are made up of three volumes, which each contain different components of the standards. In Volume 2 (List of Medical Equipment and Furniture for Each Health Care Level), it lists the device type, size, and number required for each device type, by department. The table below summarizes the recommendations for oxygen devices by health facility level.



Medical devices	Health centre IV	General hospital	Regional referral hospital
Oxygen concentrator	Theater ward: 2 Maternity ward: 1	Theater ward: 2 Delivery room: 3	Theater ward: 6 Delivery room: 5 Outpatient casualty: 2
Oxygen therapy apparatus, including oxygen regulator and one oxygen cylinder (15–50 kg)	Theater ward: 2 General ward: 2 Maternity ward: 2	Outpatient: 6 Outpatient casualty: 1 Delivery rooms: 3 Theaters: 4	Outpatient: 12 Outpatient casualty: 2 Delivery rooms: 5 Theater: 12
Pulse oximeter	Outpatient ward: 2 Maternity ward: 3	Delivery rooms: 3 Theaters: 6	Delivery rooms: 5 Theaters: 24

Note: The total number of oxygen concentrators, oxygen cylinders, and pulse oximeters may vary based on the number of wards. Other forms of oxygen and pulse oximetry (such as oxygen plants, liquid oxygen, and multimodal devices) were not included in the guidelines.

Source: This table is adapted from Ministry of Health (MOH), The Republic of Uganda. National Medical Equipment Policy: Detailed Technical Specification per Health Care Level. General Hospital. Kampala: MOH; 2009.

CASE STUDY: Uganda (continued)

Volume 3 of the guidelines (Detailed Technical Specifications per Health Care Level) provides details on each type of equipment, including a description of the device, specifications, size/type, power requirements, etc. While not all of these details are needed in a general health facility standards document, Uganda clearly links the description and detailed specifications of each device to the recommended list of equipment per health facility level, making it easy for users to compare different documents. Examples of these device descriptions for general hospitals are provided in the table below.

Device type	Description	Detailed specifications
Concentrator	Oxygen concentrator capable of extracting medical-grade oxygen from atmospheric air using a PSA system. The unit should be mobile on casters and capable of supplying oxygen to two patients at a time. It should incorporate oxygen monitor facility complete with patient tubing.	<ul style="list-style-type: none"> • Performance characteristic. • Dual flow complete with flowmeter. • Flow rate of minimum 2 LPM to maximum 8 LPM, with oxygen purity constant at 95% over this flow range. • Medical-grade oxygen at 95% purity, dry and oil-free oxygen at the rated flow rate. • Safety: Shutdown with power failure, high or low pressure, and high temperature. • Dimensions: About 80 cm (height) x 50 cm (width) x 40 cm (depth) • Main power supply: 240 V, 50 Hz with a suitable surge protector; mains cable length 3 m with 3 pin top plug (United Kingdom) • Standard: ISO 9001:2000 certified or equivalent
Oxygen therapy apparatus	Composition: <ul style="list-style-type: none"> • Oxygen cylinder. • Oxygen regulator. • Adaptor (connector kit) for humidifier bottle. • Humidifier bottle. • Cannula, adult. • Cannula, pediatric. • Carrying case. 	<ul style="list-style-type: none"> • Oxygen cylinder: 15–50 kg. • Oxygen regulator, cylinder mounted, Oxylite: With oxygen flowmeter, metric threads. • Adaptor (connector kit) for humidifier bottle: Should be provided. • Humidifier bottle: Autoclavable PVC, 150 mL capacity or more. • Cannula, oxygen, twin nasal, adult: Should be provided. • Cannula, oxygen, twin nasal, pediatric: Should be provided. • Carrying case 40 cm x 30 cm x 13 cm: Should be provided.
Pulse oximeter	Capable of measuring pulse rate and SpO ₂ using non-invasive method. The unit should be microprocessor based and model on current production.	The following should be available: <ul style="list-style-type: none"> • Large LED screen to display pulse and SpO₂ values. • With reusable sensors. • Accuracy \pm 2%. • With selectable alarm limits. • Other indicators: Pulse strength, low battery, alarm. • Battery backup for at least one hour. • Humidity: 0% to 90%.

Note: ISO, International Organization for Standardization; LPM, liters per minute; PSA, pressure swing adsorption; PVC, polyvinyl chloride; SpO₂, oxygen saturation level.

Source: This table is adapted Ministry of Health (MOH), The Republic of Uganda. National Medical Equipment Policy: Detailed Technical Specification per Health Care Level. General Hospital. Kampala: MOH; 2009.

Caring for devices

Device maintenance and service are very important factors to consider when procuring and managing medical devices; however, these are often overlooked in the development of health facility standards. By only including a list of medical devices with no considerations on maintenance and service, facilities may be left with non-functioning equipment or equipment that cannot be properly maintained. While it is not practical to include device-specific maintenance requirements for every medical device (those would be expected to be found in other documents, such as technical specifications), it is recommended to call out maintenance as a key consideration by including overarching statements that cover routine maintenance, service, device assessments, alternatives, and backups. These can be high level and apply to all devices, acknowledging that detailed guidance should be provided in more technical, device-specific documents.

Use of devices

Considerations on the routine use of medical devices are another type of content that can be included in health facility standards. These could include information on who should be operating various types of medical equipment, how equipment relates to clinical treatment devices, how to dispose safely of medical devices and consumables, and specific safety considerations. If this information is included, it should be linked back to the initial information included on general health facility requirements. For example, if information on what types of health care providers should operate each device is included, it should be linked back to the types of health care providers recommended in the facility. Alternatively, if use of a medical device is linked to specific clinical guidelines, it should be ensured that these types of medical service are actually performed at this level of health facility. While detailed content on these topics does not need to be included in health facility standards, they should be kept in mind while the document is being created.

CASE STUDY: Tanzania

The Tanzanian Ministry of Health, Community, Development, Gender, Elderly and Children's 2017 *Basic Standards for Health Facilities* outlines a high-level device service and maintenance policy that can be applied for all devices. While it does not include details about servicing each individual type of device, it acknowledges the service/maintenance needs that medical devices as a whole will have, which helps to ensure that facilities keep these in mind. The document states:



Planned Preventive Maintenance (PPM) principles should apply to all assets of the facility for example: premises, building medical equipment. . . . Maintenance should be a key factor in the design of any health capital investment project. When planning premises and equipment the following factors should be considered: Materials and items should require a minimum of maintenance, or be maintained by simple means. During planning for procurements of equipment and plant, provisions related to availability of spare parts and service contract should be included. Small workshops and maintenance stores should be provided at all facilities.

Source: Ministry of Health, Community, Development, Gender, Elderly and Children (MoHCDGEC), The United Republic of Tanzania. Basic Standards for Health Facilities. Volume 3: Hospitals at Level I & II and Stand Alone Facilities at Level I & II. Dar es Salaam: MoHCDGEC; 2017.

Key takeaways

1. Include detailed guidance on the number, type, size, and consumables required for each type of medical device needed in the facility.
2. Ensure required devices correspond to the wards and health services provided in that level of facility.
3. Outline broad guidance on medical device maintenance and service that covers all devices to ensure that this is planned for and monitored.

4. How to ensure compliance with health facility standards

Development of national-level health facility standards can be time and resource intensive. In order to reach maximum impact, it is important to ensure the standards are applied across the entire health system, rather than as a stand-alone guidance. This section provides a number of recommendations for ways to prioritize health facility standards.

Linking to facility accreditation

Linking the standards document to health care facility accreditation, licensing, or permitting procedures creates a strong connection between the two processes. This step would ensure that facilities at each level of the health system are fully equipped and in line with national guidance documents prior to being able to operate legally.

CASE STUDY: Nicaragua

The Nicaraguan Ministry of Health's 2011 *License Approval Manual for Healthcare Facilities* is a national-level guidance document that is imperative to health facility accreditation and licensing. This framing of the document helps ensure that facilities comply with the guidance outlined. The document states:



License approval process evaluates the physical structure, equipment endowment and location, functional medical flow, and human resources appropriate to the services offered by a healthcare facility.

In order to provide or offer healthcare services, facilities must comply with the legal requirements for infrastructure, equipment, and human resources established in this manual. . . . License approval standards will be available on the Ministry of Health website [and] will be reviewed and updated every two years, according to the development of professionals, technicians and technological development of the country. . . . License approval standards are dichotomous: they are met or not met, they are mandatory, they have equal hierarchy and are easily verifiable.

Healthcare facilities with an unsafe infrastructure or incomplete equipment or human resources that do not correspond to the care profile or lack a degree or diploma issued by university higher education institutions shall be immediately closed. . . . Public or private healthcare facilities offering services or performing procedures for which they are not authorized shall be closed immediately. All healthcare facilities that do not have an operating license or do not meet the requirements for licensing, are considered unlicensed. . . . The license approval process starts once the license approval application is submitted and an inspection date is set. During this period, facilities are not allowed to offer or provide services until they are licensed. Facilities that do not meet 100% of licensing standards are not authorized to open.

Additional guidance is also provided on architectural drawings, licensing inspectors, and renovation or construction of a health facility, among other topics.

Source: Ministry of Health (MOH), Nicaragua. License Approval Manual for Healthcare Facilities. Managua: MOH; 2011.

Facility checklists

Providing a checklist or self-assessment form can empower health facilities to meet the criteria outlined in the national-level documents. The checklist could be included as an appendix to the main standards document and would reflect all of the content in the body of the document (including the details mentioned above) in a checklist form. This would give facilities an opportunity to fill out the form on their own and possibly submit it to a district- or national-level body for approval. This step could also be linked to facility accreditation, as described above.

Training health facility personnel

Ensuring that personnel in a health facility are aware of and trained on the current health facility standards document can also help improve compliance. In addition, the document could include specific written instructions on how to conduct an assessment or how to review the standards.

CASE STUDY: Indonesia

The Indonesian Ministry of Health's 2014 *Hospital Classification and Licensing* document states that facilities must complete a self-assessment form in order to receive an operational permit.



This incentivizes facilities to comply with the health facility standards documents and empowers them to complete the assessment on their own. This may be a more feasible method than expecting the Ministry of Health to review each facility each year. The document states:

To get the Operational Permit, the manager submits a written application to the licensing authority according to the classification of the hospital by attaching the following documents: Completed self-assessment instruments according to the Hospital classification that includes services, human resources, equipment, building, and infrastructures.

Examples of the types of information that are needed in the self-assessment form for hospitals (Hospital Operational Permit Self-Assessment Form for Class A Hospital) are shown below. Each of the five broad categories has subcategories (examples shown) and sub-subcategories (examples not shown) that must be reviewed. For each row, the form contains space for the reviewer to write the "current condition" and "notes" next to each line.

Source: Ministry of Health (MOH), Republic of Indonesia. Regulation of the Minister of Health of the Republic of Indonesia on Hospital Classification and Licensing: Number 56 of 2014. Jakarta: MOH; 2014.

- I. Services
 - a. General medical services
 - b. Emergency services
 - c. Basic specialist medical services
 - d. Etc.
- II. Human resources
 - a. Basic medical services
 - b. Basic specialist medical services
 - c. Supporting specialist medical services
 - d. Etc.
- III. Equipment and instruments
 - a. Emergency services
 - b. Internal medicine services
 - c. Etc.
- IV. Facilities and infrastructures
 - a. Emergency building/room
 - b. Outpatient building/room
 - c. Inpatient building/room
 - d. Etc.
- V. Administration and management
 - a. Legal entity status
 - b. Organization structure
 - c. Administration/work procedure/job description
 - d. Etc.

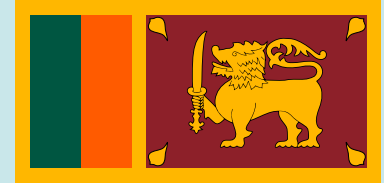
Other

Another potential way to improve compliance is to tie the standards document to budgeting or procurement processes. For example, a district- or national-level procurement teams could base initial procurement and

budgeting decisions on the number and types of medical equipment included in these guidelines. This would require an administrative process to ensure that each facility is getting the proper amount of equipment, which may benefit from an automated tracking system.

CASE STUDY: Sri Lanka

The Sri Lankan Ministry of Health and Women's Affairs' 1994 *Manual on Management of District Hospitals, Peripheral Units and Rural Hospitals* provides some basic step-by-step instructions within their health facility standards to help guarantee that all their health care works are completing their facility evaluations in the same, uniform way. The standards note that the purpose of the evaluation is to (1) maintain the quality of services provided, and (2) identify strengths and weaknesses in the institution. The instructions are shown below.



WHAT TO DO

- You (in consultation with [the] Divisional Director of Health Services [DDHS]) should select the areas/activities that will be used to evaluate the patient care services in your institution.
- Inform your staff regarding the Evaluation Process and the Areas/Activities selected.
- The staff in your institution should be aware of the standards that need to be maintained.
- Conduct the first assessment preferably with the DDHS and use this as the baseline assessment.
- Periodic assessment to be done at regular intervals, eg. Quarterly.
- Assessment reports to be forwarded to DDHS/PHDS [Provisional Director of Health Services].
- You should discuss the results of your evaluation with your staff.

HOW TO DO

- It is best you carry out the evaluation as a team.
- Team may be comprised of DDHS, Heads of Institution, Registered Medical Practitioner/Assistant Medical Practitioner, Sister/Senior Nurse.
- For each area/activity selected, follow the following steps:
 - Assess the current status.
 - Compare the current status with the standards given for each item.
 - Identify any gaps, shortcomings, or deficiencies.
 - Find out the reasons for items to be identified.
 - Take corrective action.
- Display the findings of each assessment in a chart in your office.
- Discuss the findings with your staff.

Source: Ministry of Health and Women's Affairs, Sri Lanka. Manual on Management of District Hospitals, Peripheral Units and Rural Hospitals. Colombo: Ministry of Health and Women's Affairs; 1994.

Key takeaways

In order for health facility standards to be most effective, it is important to ensure they are effectively used across the health system. Select ways to prioritize compliance with guidelines include the following:

1. Linking health facility standards documents to facility accreditation, licensing, or permitting: In order for a facility to be allowed to operate legally, a governing body would have to confirm that facilities meet the standards outlined in the guidelines.
 2. Providing facilities with self-assessment checklists: This would empower facilities to assess the state of their own compliance with the guidelines, and possibly submit these to a governing body for approval on a regular basis.
 3. Ensuring health facility personnel are properly trained on the guidelines: Making health workers aware of the content of these documents will allow them to understand what is expected at their facility, and may help them conduct self-assessments or perform other tasks to improve compliance.
-

Conclusion

The current availability and content of national health facility infrastructure and medical device standards (health facility standards) vary widely by country. While WHO has drafted working documents that outline suggested lists of medical equipment by facility level, only 59 percent of 158 countries reported having national standards or recommended lists of medical devices for different types of health care facilities in 2017.

Health facility standards should include requirements, by health facility level, on topics such as the location of facilities, staffing requirements, wards and health services provided, other infrastructure requirements, and suggested lists of medical devices. For medical devices specifically, guidance should be included that establishes the expectation for the types, number, and location of devices within a facility, maintenance/service required for devices, and personnel required to use these devices. These guidelines may be used by:

- The MOH and hospital officials to understand the infrastructure requirements for each level of health facility.

- Health care workers and planners within a facility to understand the types of medical devices to procure.
- Medical device manufacturers to understand the potential market size in a country by showing the number of devices required in each facility type.

Overall, it is important for health facility standards to include an appropriate level of detail that may be easily understood and is consistent with related national documents, such as those related to human resource guidelines, medical equipment technical specifications, or others. While this guide contains recommendations and best practices for how to create or improve health facility standards, their application will vary based on country needs. Finally, it is important to understand that once high-quality health facility standards are created, they need to be implemented and integrated into regular facility planning, monitored appropriately, and updated as needed on a regular basis. Clear policy design is only half of the equation; implementation and accountability for doing so are fundamental to realizing policy impact.

Helpful resources

Existing guidelines and resources could be helpful in creating or updating health facility standards, in order to build upon guidance that already exists and make use of existing best practices. Some existing guidelines and resources are listed below.

Service Availability and Readiness Assessment: An Annual Monitoring System for Service Delivery. Reference Manual (WHO)

https://dhsprogram.com/pubs/pdf/SPAQ5/SARA_Reference_Manual_Chapter3.pdf

This document is helpful in determining basic health facility guidance on the number of facilities, beds, health workers, and service utilization. The targets include the following, which are further explained in the source document:

- 2 facilities per 10,000 population.
- 25 inpatient beds per 10,000 population.
- 10 maternity beds per 1,000 pregnant women.
- 23 core health workforce per 10,000 population.
- 5 outpatient visits per person per year.
- 10 hospital discharges per 100 per year.

Medical Devices by Health Care Facility (WHO)

https://www.who.int/medical_devices/innovation/health_care_facility/en/

This document is helpful in determining recommendations for medical devices. The resource includes draft lists of medical equipment recommended for each level of health facility (health post, health center, district hospital, provincial hospital, and specialized hospital). While these lists are working documents and have not been reviewed by clinical experts, they can provide a great starting point to

countries, which can then be adjusted and adapted based on local conditions. Device lists, for each facility level, include the following information:

- Categorization of equipment into the following types (when applicable to each level of health facility): Treatment, diagnostic, inpatient, complementary, outpatient, critical medicine, and chemotherapy equipment.
- Localization of the equipment (including area, unit, and subunit).
- Common name of equipment.
- Two international classification codes for equipment [Global Medical Devices Nomenclature System (GMDN) and Universal Medical Devices Nomenclature System (UMDNS)].

Oxygen Delivery Toolkit (PATH)

The toolkit offers resources to help decision-makers, implementers, and advocates plan, manage, and communicate the value of scaling up oxygen delivery systems and access to oxygen and pulse oximetry. The following toolkit materials could be helpful when considering how to create or improve health facility standards:

- ***Asset Management Guide***: Contains guidance on how an MOH can track medical devices within a health system.
- ***Baseline Assessment Manual***: Helps the user understand what medical devices are currently in the country, which may influence newly formed standards.
- ***Electricity Planning Guide***: Contains helpful information about electricity requirements for medical devices.
- ***Procurement Guide***: Contains information on how to create and work with a multidisciplinary team for different elements of the procurement process.
- ***Quantification and Costing Tools***: Allows the user to calculate the total need for medical devices related to oxygen delivery sources and pulse oximetry devices.

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For more information

www.path.org/oxygen-delivery-toolkit

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