Oxygen Delivery Toolkit
Resources to plan and scale medical oxygen

Reference Pricing Guide

Assisting stakeholders in incorporating use of reference pricing in their procurement processes to help increase their budget efficiencies

For use by:

Decision-makers

Implementers

June 2021

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.

Acknowledgments

The **Oxygen Delivery Toolkit: Resources to plan and scale medical oxygen** was developed by PATH, in collaboration with international and national maternal, newborn, and child health and industry partners, as well as the ministries of health in India, Indonesia, Kenya, Malawi, and Senegal. The authors are grateful to each contributor for their insightful feedback and support on the development of the toolkit components.

Oxygen Delivery Toolkit disclaimer

Contents

Introduction

Medical devices differ from essential medicines, vaccines, and diagnostics in that they are used across disease areas, can be single use (e.g., disposable syringe) or for repeated use (e.g., anesthesia machine), and have different training and maintenance requirements. Durable medical devices are those that are used for multiple patients and are intended to last for months to years, providing health systems with a compounded value over time. For example, a single dose of medicine is priced per unit and delivers a cure or treatment per unit, while a device such as a handheld pulse oximeter can be used for multiple patients over some time, with the replacement of accessories such as probes, making it difficult to calculate costs and value per patient.

Low- and middle-income countries (LMICs) face the double burden of communicable and noncommunicable diseases, which requires increased government expenditures on medical products and the need to improve the efficiency of procurement processes. Despite the general availability of medical equipment worldwide, public health facilities in LMICs are often deficient when it comes to durable medical devices.[1] Research also indicates that governments in many of these countries often pay disparate prices. For example, manufacturers' prices and overall suppliers' prices for pulse oximeters and oxygen concentrators have been found to vary considerably across LMICs in Asia and Africa.[2,3] Given the price sensitivity of national procurement agencies in these countries, opportunities to realize the best value for money in medical device procurement are of great importance.

One way to lower costs for medical products is by procuring drugs and medical devices at competitive prices. **Reference pricing**—a process that compares the selling prices of a given product within a country/region or at the international level and calculates a benchmark for negotiating the final purchase price—is a powerful tool for reducing price disparities of medical devices across countries and regions and making public procurement of essential medical products more sustainable for growing health care needs.

Purpose of this guide

The Reference Pricing Guide is intended for both decision-makers and implementers, including ministry of health and ministry of finance officials, subnational health leaders, and district health committee members, as well as health facility managers and procurement teams. It may also be of interest to policymakers in their role to increase transparency for the purpose of negotiating prices for publicly procured health equipment.

The guide provides an overview of steps to determine reference prices for durable medical devices using examples of products related to respiratory care. It includes a methodology for using domestic (internal) or international (external) reference pricing while describing factors that influence the prices of products. The guide considers reference pricing of durable medical devices used across many levels of health systems, from primary health care, general wards, and emergency transport, to intensive care units and specialized hospitals,[4] and does not include single-use devices such as syringes or medical devices unable to withstand repeated use.

Reference pricing for medical devices

Definition of reference pricing

According to the World Health Organization/Health Action International Project on Medicine Prices and Availability, reference pricing refers to "the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country."[5] The first step in reference pricing is to identify the source(s) from which medical device prices will be obtained. The next step is to create a database of the prices and use those prices for comparison. After comparisons have been made, the benchmark figure can be calculated as decided by the purchaser; for example, by using the mean or median of the prices. Types of calculations chosen to determine reference prices may vary across products, depending on the information available.

Reference pricing is most effective when there is considerable variation in the prices of goods or services across vendors or countries. It aims to stimulate competition to secure reasonable prices without driving manufacturers out of the market.[2,3] Reference pricing can provide an incentive to a manufacturer to set prices closer to the benchmark, thus reducing total procurement costs for the payer, such as a ministry of health. Reference pricing is gaining momentum in public purchasing of medical devices due to the wide variation in prices found within countries and across regions.

International or external reference pricing

External reference pricing (ERP) depends on a seller-supplied price and broadly refers to the use of the ex-manufacturer price (or other common price point) of a product in other countries to create a benchmark that can inform the negotiations for the price of the product in the country in question. The marketer can generate a price that is most favorable for the seller by using a specific product advertisement, a product price tag, and/or reference prices for a similar product(s). By doing so, the marketer is generating a product price based on the information the marketer gathered about the specific product over time. By using the marketer's own ERP guide, the generated product price set by the marketer can now be used as a starting point for price negotiation between the marketer and the potential buyer.

Domestic or internal reference pricing

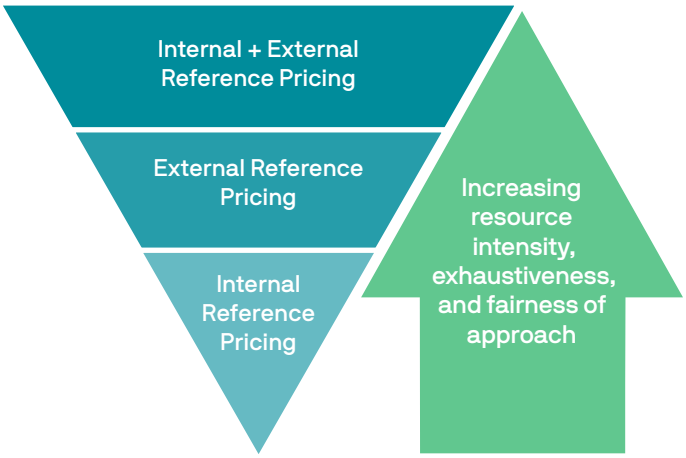
Internal reference pricing (IRP) is the practice of using prices from regions within a country to derive a benchmark price to set or negotiate the price of a product. Public procurement teams often use previous purchase prices to compare and negotiate prices, or they directly use tendering to purchase medical devices.[6]

Approaches to reference pricing

There are three main challenges in using reference pricing: (1) accessing true negotiated prices and collecting manufacturer price information from different sources can be difficult, (2) comparing identical or very similar products can be complex for medical devices with variable feature sets, and (3) the process is resource intensive. Significant time and effort are required to establish a reference price database for medical devices; however, once the database is functioning, subsequent inputs are easier and substantial benefits will follow.

Available time and resources of a procurement team will heavily guide the approach taken to build a reference price database. The most exhaustive process includes determining both ERP and IRP for each device (Figure 1). Many countries use some form of IRP for medicines and some health products, while often omitting information for ERP because of the time and cost required to establish it.

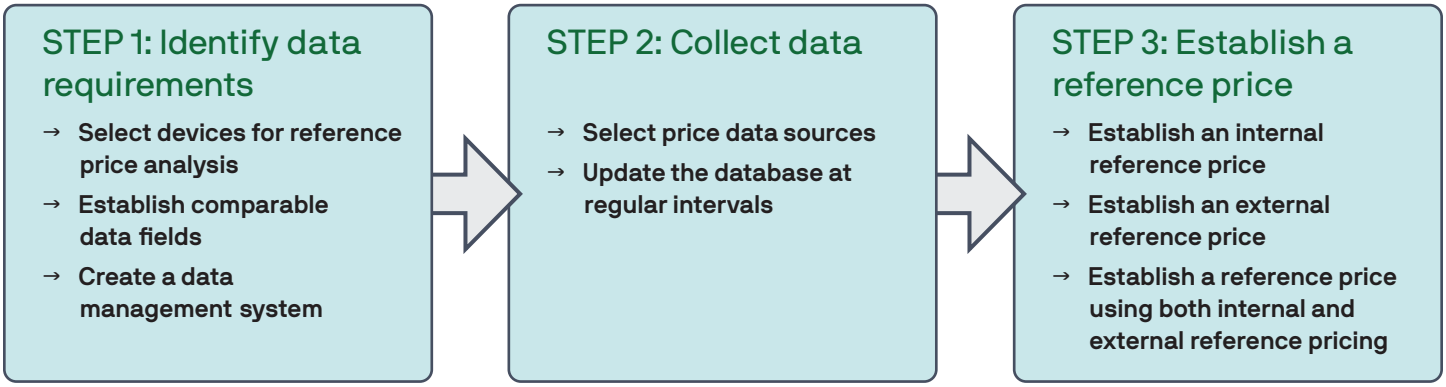
Figure 1. Approaches to reference pricing in order of resource intensity and thoroughness.



Steps to establish reference pricing

This section outlines the three primary steps to (Figure 2), considerations for, and challenges of establishing reference pricing for medical devices, whether using ERP, IRP, or both.

Figure 2. Steps to establish reference pricing for medical devices.



STEP 1: Identify data requirements

Whether a reference price database is being created for multiple devices or a few devices will determine the fields of data, the amount of information, and the number of sources needed.

Select devices for reference price analysis

There are more than 10,000 types of medical devices found in the health industry and more than 90,000 variations.[1] As such, an important consideration for decision-makers is which medical device(s) should be included in the reference price database. The primary devices to consider are those used at all or most levels of the health system and, therefore, are purchased in large volumes, as well as devices for which prices vary greatly. Collaborating with a multidisciplinary team of procurement managers, medical personnel, and biomedical engineers can help in determining the priority equipment. Well-functioning inventory and asset management systems can provide a baseline of available medical devices that may benefit from pricing analysis when replaced.

Resources that can provide information for selection of baseline medical devices for a health system are the World Health Organization's *Lists of Priority Medical Devices*, the World Health Organization's *Core Medical Equipment* resource guide, and national essential medical device lists.

Establish comparable data fields

A major challenge of reference pricing is ensuring that similar devices are being compared during the negotiation process. For instance, prices collected for the same model may not include the same components, such as essential accessories. Some suppliers may quote ex-factory prices, while others might quote retail or wholesale prices. Some prices may refer to the base device model, while others may include advanced features. Using the cost categories of the total cost of ownership can help to ensure that all hidden costs are disaggregated clearly, and prices are mapped to the correct components. The total cost of ownership is typically the aggregate of costs by capital expenditures and operating expenditures. Once disaggregated, ex-works prices (transport and shipping costs paid by the buyer and not bundled with the price of the device) or capital expenditures should be used for reference price comparisons, as operating costs and other overhead (such as local taxes) bundled in the total cost of ownership may be misleading due to differences in national and/or regional conditions.[7] Furthermore, the prices of additional items (e.g., generators, batteries, and probes) should be indicated separately when using reference pricing.

Create a data management system

Based on available resources and current systems used by procurement teams, a reference price database can be developed using simple digital tools, such as spreadsheets. It can also be outsourced to a service provider that creates computerized databases. The latter can perform sophisticated functions, such as providing device price or currency rate updates from different countries and calculating reference pricing based on a defined process.[a]

- **Digital applications or database:** This approach can be used for a database containing a few devices but is not ideal for a centralized database of hundreds of devices, diagnostics, and medicines that requires regular updates.
- **Government- or privately owned database:** This approach is most appropriate for a large database that requires automatic price updates, exchange rate updates, and price calculations. Combined with digital asset management systems, a computerized reference price database can be managed and used across the country and can include e-tendering and other digital procurement platforms.

STEP 2: Collect data

This section highlights important aspects of collecting data for creating a reference price database. While recommendations are outlined below, data sources and the cadence for updating inputs may evolve with time. It is recommended to draw upon as many data sources as is feasible for the endeavor and be mindful of past purchase data price points where available. Most of the cost of developing a reference price database lies in establishing the system and conducting the initial research. After this step is complete, the database requires only maintenance and updating, and will provide significant savings in the long run.

Select price data sources

Gaining access to true negotiated prices in other countries or regions within a country is not always possible and may require procurement teams to leverage government relationships in reference countries or to build new ones. Use of multiple sources of data will improve confidence in the downstream reference price. Below is a list of sources from which medical device prices might be obtained.

- **Manufacturer quotes:** The primary sources for ex-works prices for medical devices are manufacturer quotes and published lists of ex-factory prices. Procurement teams across states, districts, or counties within a country can be called upon to assist in obtaining these manufacturer quotes.
- **Wholesaler or retailer prices:** If there are no manufacturer quotes available for a medical device, the wholesale or retail prices may be used by removing mark-ups. For ERP, the mark-ups and taxes in each reference country need to be calculated and subtracted to determine the true ex-works reference pricing.
- **Past purchase data:** IRP may make use of past purchase data for devices, but care must be taken to compare similar costs. The risk in using past purchase data if the previous prices were not negotiated or poorly negotiated is the perpetuation of unsustainable prices for the future.
- **Price-sharing alliances, international databases:** A price-sharing alliance is a collaborative approach to gathering ex-works prices from different countries for comparison with the true negotiated prices in those countries. These alliances usually share databases of medicines, diagnostics, or medical device prices that can be accessed by each of the participating countries, and may align with economic alliances or cooperative arrangements across geographies such as ASEAN, the East African Community, or other international body. They can be used to encourage transparency at low costs of operation and promote regional cooperation for health technology supply chains.[8-10]

[a] There are a number of private firms, such as Inpharmation, that provide pay for service reference price database development, although most focus on this service for pharmaceuticals. Expanded application to medical equipment merits further discussion with existing providers and/or may be an area for new service innovation.

Examples of existing price-sharing alliances are PIEMEDS (Western Pacific countries) and EURIPID (European countries); an example of an international database is the Management Sciences for Health *International Medical Products Price Guide*. Currently, there is no price-sharing alliance or international reference price list for medical devices, but many countries could benefit from a regional or global alliance dedicated to medical devices.

Update the database at regular intervals

A key factor that can affect the reference pricing of a medical device is the frequency at which the database is reviewed and updated. Databases for medical device prices should undergo consistent updates at predetermined times; however, reference countries might update their databases at different times. In this case, the least frequent cadence could be used to set a review period. There is no universally accepted review frequency for reference prices. For example, France updates reference prices for drugs once every five years, whereas the Netherlands reviews its drug reference prices every six months, and Spain applies ERP first at the launch of a drug and periodically thereafter.[11] For medical devices, launch prices when products are first made commercially available may differ from long-term prices. It is crucial to take this into account when deciding on the frequency at which device prices need to be updated.

STEP 3: Establish a reference price

Once all data are gathered—internal, external, or both—reference prices for medical devices can be determined, as detailed here.

Establish an internal reference price

- Ensure that every price is the ex-factory price for the selected medical device by function and feature package.
- Break down costs using standard markups if only the retail or wholesale prices are available.
- Depending on the most current information available during negotiation, the buyer(s) have the option to calculate the median or mean price of a medical device to use as a reference price (see Box 1).
- Use the calculated reference price to negotiate with vendors for each medical device. A reference price can serve as a ceiling price.
- Use these steps for each medical device listed in the reference price database. There will be multiple types of some devices, which may have more than two levels of features or functionality. A database with devices listed by function and feature and a reference price for each category will be required.
- Automating the process could provide greater accuracy if a database of manufacturer prices is available.

Establish an external reference price

- Select a group of countries that might share price information. Many countries can be included, but it may be adequate to use only a subset for a given device. Suggested criteria for choosing the comparison countries are listed in Box 2.
- For each type of device, list the reference prices from different sources within a country, or list the negotiated price from the reference country's government (possibly through a price-sharing network) for each of the countries within the sharing group.
- Compare country reference prices and calculate a final external reference price by calculating a median or mean. Of note, the formula used to calculate the external reference price will be heavily influenced by the reference countries selected. If the countries have purchased high-quality devices and performed multiple quality

BOX 1. Why use median or mean prices?

Most countries choose mean prices when setting a reference price, but some use the lowest price found. However, there is a risk of prices converging over time when the lowest price is always selected in a comparison set of countries, especially if those countries are already using a low or the lowest external reference price in their calculations. Hence, a sustainable way of lowering purchase price and keeping markets competitive is to use mean prices, or to use median prices if there are outlying values.

BOX 2. Criteria for selecting countries for external reference price comparisons

1. Level of economic development and purchasing power
2. Willingness to share price information transparently
3. Public health status
4. Political and financial stability

checks, selecting the lowest price may be good practice, but this would not be recommended if countries do not have regulations for quality in place.

Establish a reference price using both internal and external reference pricing

This approach requires the procurement team to determine both an internal and external reference price for a selected medical device and then compare the two. During this step, the mean or median is calculated, or the lower of the two is used. When combining internal and external reference prices, it is important to ensure that the same types of prices are compared; for instance, prices may be listed as with or without taxes or additional supply costs in different countries.

The success of using a reference price for negotiation with suppliers will depend on how aggressive the purchasing ministry of health or facility wants to be and whether this price will be a cap or a starting point for negotiation. Procurement policies should permit flexibility in setting a reference price, rather than forcing the selection of the lowest price, and allow for price negotiations. Procurement teams also need to consider domestic legal frameworks and those in selected reference countries for the successful implementation of reference pricing. Table 1 highlights the trade-offs among the three reference pricing approaches.[5,12-15]

Finally, selection of a reference pricing approach—internal, external, or both—must take into consideration factors such as international health markets, domestic health and procurement policies of the country, and ultimately, device requirements that consider intended health outcomes. The approach taken can have implications for the device market in question. An ERP approach, for example, can accelerate price erosion for a device and catalyze a lower price convergence. An IRP approach can lead to a short-term downward price convergence in-country before this price shift foments a boost in manufacturing and use of local, generic, or price-referenced devices. When the two approaches are taken in unison, a short-term downward price convergence can result, which then transitions to a sustained and normalized price equilibrium for the market. Although the combined approach may yield the greatest benefit for procurers and the market writ large for the long term, this endeavor remains more resource intensive, and considerations should be made based on available resources and health system priorities.

Table 1. Features of the three approaches to reference pricing.

	External reference pricing	Internal reference pricing	Both external and internal reference pricing
Purpose	• Cost containment • Fair price determination • Cost normalization across regions • Most effective for devices that are not manufactured locally	• Balancing and normalization of price variations within a country	• Establishment of a fair reference price that is sustainable for both the demand and supply sides of the market—governments, and manufacturers and suppliers
Data requirements	• Reference country ex-factory device prices • Markups and supply costs in selected countries • Procurement laws of selected countries • Taxation laws and rates for selected countries	• Manufacturer prices within the country from multiple sources • Past purchase data • Markups for wholesalers and retailers	• Combination of data required for external and internal reference pricing
Impact on device prices and markets	• Downward price convergence • Faster price erosion	• Short term: downward price convergence within a country • Increase in manufacturing and use of local and generic devices • Increase in use of referenced devices	• Short term: downward price convergence • Long term: sustainable and normalized device prices in the market
Risks/ Challenges[1]	• Must constantly introduce circular prices due to frequent price revisions in other countries • High risk of using reference prices from a high-income country (in the case of low- and middle-income countries) due to easier access to prices • Resource intensive • Expensive to conduct	• Not applicable if past purchase data are incorrect • Comparison of ex-factory prices to retail prices	• Resource intensive: requires financial, human, and time resources • Lack of access to prices in reference countries • Lack of ex-factory prices within the country • Manufacturers lack interest in dealing with public procurement teams

CASE STUDY: Pulse oximeters

This section presents a simplified reference pricing exercise using both internal and external reference prices for pulse oximeters. Before gathering and comparing prices, a use case should be defined for the product in question, and specifications established based on that use case. Knowing that some products—such as pulse oximeters—may have different features that support different use cases, it is important to compare similar feature sets, and in some instances, indicators (such as stringent regulatory approval, for example). A single manufacturer may have different models for a single class of product, or products with different regulatory approval, so the process of gathering price data should take these differences and their subsequent influence on price under consideration. This may mean including some prices and omitting others, focusing only on those products that meet the specifications of the desired use case.

Once device specifications and minimum technical requirements for procurement purposes are determined, the procurement team can begin the task of collecting price data. This process may involve speaking directly with representatives of manufacturers, engaging distributors, reviewing publicly available data, sourcing quotes online, or other pathways. Here, the judgment of the procurement team is valuable in categorizing devices by features based on those requirements and available prices for each. After extensive research, data collection, and inclusion of the pertinent products that meet those specifications, a reference price can be determined.

Table 2 shows IRP using three manufacturers and ERP from three countries for three types of pulse oximeters: finger, handheld, and benchtop. In this example, the domestic manufacturer (ex-works) prices were collected for each medical device type to determine internal reference prices. Similarly, to determine external reference prices, the example shows the ex-works prices from manufacturers in each of the reference countries. Even if some data are missing, prices can be compared.

Table 2. Prices for pulse oximeters from different manufacturers in the home country and other countries.

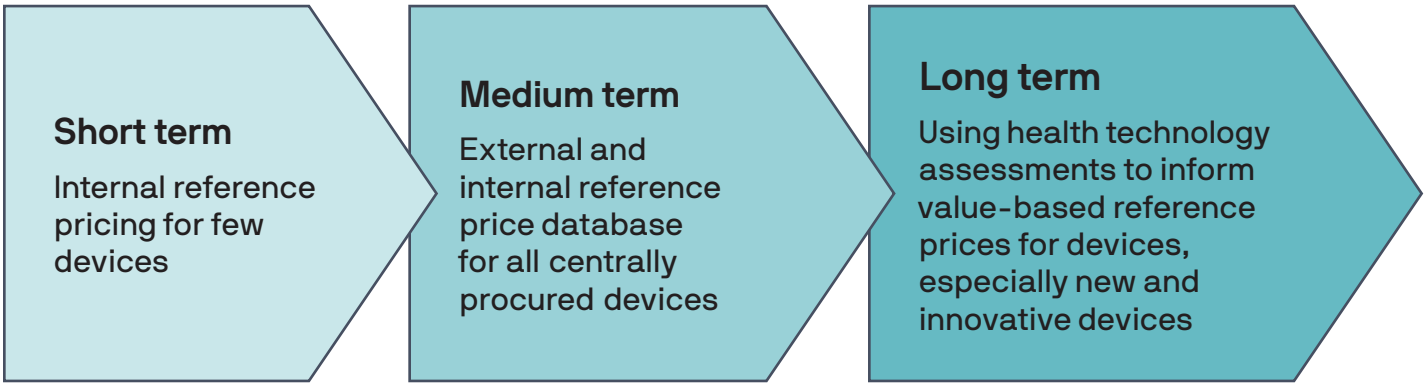
Selected device	Pulse oximeter			
Device category		Finger	Handheld	Benchtop
Internal reference pricing (IRP)	Domestic supplier 1	$17	$130	$240
	Domestic supplier 2	$56	$65, $120	$295
	Domestic supplier 3	$129	$186, $500	$270, $288
	IRP (median)	**$56**	**$130**	**$279**
External reference pricing (ERP)	Country 1 supplier	$15, $102	$220, $372, $425	$350, $409
	Country 2 supplier	$64, $79, $160	$320, $360, $210	$875
	Country 3 supplier	$201, $370	$275, $480	NA
	ERP (median)	**$102**	**$340**	**$409**

The prices used in this case study are actual manufacturer prices; however, prices change over time and these figures should be used only to illustrate how reference prices might be calculated rather than as a preferred price target for each pulse oximeter type. The formula for determining ERP is the median price for each device type/model (e.g., fingertip, handheld, or benchtop). The most important and challenging aspect of determining the reference price for a device is ensuring that the price used is the manufacturer's (ex-works) price, or, if using a retailer or wholesaler price, ensuring that it excludes the average supplier markups and exchange rate costs from the supplier country. Once the internal and external prices for similar types of devices are calculated, procurement teams can use the mean or median as a reference price for negotiation.

Next steps

In the past, reference pricing was primarily used for negotiating prices for medicines.[3] However, expanding the use of reference pricing to negotiate medical device prices has the potential to reduce price disparities while making public procurement of essential medical products more sustainable. It also has the potential to increase the efficiency of procurement processes overall. This *Reference Pricing Guide* can serve as a starting point for procurement teams of governmental entities, individual health facilities, and other health-related institutions. Those interested in building a reference pricing methodology can begin by establishing short-term deliverables, such as developing an external reference price database for only a few medical devices. Depending on the needs of the institution, the resources available, and the quality of experience with reference pricing, institutions can consider gradually expanding to a larger database (Figure 3).

Figure 3. Progression of reference pricing approaches for low- and middle-income countries.



Short term

As mentioned in the "Reference pricing for medical devices" section and outlined in Figure 2, short-term deliverables can include but are not limited to the following: (1) selecting medical devices that will need a reference price analysis, (2) identifying the source(s) from which medical device prices will be obtained, and (3) developing a reference price database for the selected medical devices. By establishing short-term deliverables, ministries of health, procurement agencies, or other responsible institutions can create a high-quality reference price database, which is vital for expanding the database in the future. Short-term deliverables can vary depending on the ministry or agency's needs and resources.

Medium term

Depending on the availability of resources and the quality of experience with reference pricing, the responsible entity can consider developing a larger database over time. After accomplishing short-term deliverables, those actors can progress toward creating medium-term deliverables, including a database for both external and internal reference prices for all centrally procured devices. Building and implementing a schedule for updating the reference price database for all medical devices listed in the whole database should be done in parallel. It is important to note that deliverables may vary from one agency or ministry to another. For further help on how to establish an appropriate medium-term deliverable for specific entity, refer to the "Approaches to reference pricing" section of this guide.

Long term

After meeting both short- and medium-term deliverables, responsible ministries or agencies can gradually create long-term deliverables. These entities can introduce the use of health technology assessments to enhance the quality of retrieving data for medical devices. According to the World Health Organization, health technology assessment "refers to the systematic evaluation of properties, effects, and/or impacts of health technology."[16] It is a "multidisciplinary process to evaluate the social, economic, organizational, and ethical issues of a health intervention or health technology."[17] Ministries or other responsible agencies can use health technology assessment to capture value-based reference prices for medical devices, especially for new and highly complex medical devices.

Conclusion

Achieving greater visibility into the pricing dynamics of the medical device market empowers national procurement agencies and the health systems they support. The financial limitations that burden LMICs and the subsequent price sensitivities to which those procurers are subject, warrant greater clarity on the price of the goods they are charged with procuring. Developing reference prices for products that serve the needs of the health system to the greatest extent feasible will help to rationally inform that procurement decision-making and reduce the shortages of durable medical devices that persist in LMICs. The IRP and ERP approaches discussed are helpful mechanisms to capture necessary data, but the time and resources available may impose limitations on the extent to which these approaches are deployed. Ideally, reference pricing practices should extend beyond individual devices, giving way to a database of all medical devices procured for a health system, maintained on a scheduled basis. These efforts will help to ensure an optimal position from which procurers can secure the life-saving devices necessary to support the health and well-being of the communities they serve.

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