IMPROVING MEDICAL DEVICE PROCUREMENT IN AFRICA: A DECISION SUPPORT TOOL FOR CONSIDERING TOTAL COST OF OWNERSHIP





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Executive Summary

Low and middle-income countries (LMICs) rarely manufacture their own medical devices but heavily rely on importing up to 95% of these products.¹ LMICs rarely have the expertise to advise on procurement of medical devices suited for their resource-constrained settings coupled with the fact that medical device manufacturers are located in and accustomed to high-income countries.²

In addition to equipment that is often too expensive for LMICs, there are also challenges associated with procuring suitable devices to minimize recurring costs, operational expenses, or additional accessories and consumables. It is estimated that 40 to 70% of medical devices and equipment in LMICs are broken, unused, or unfit for purpose mainly due to indiscriminate procurement practices, including inadequate planning for lifecycle costs (total cost of ownership).²

For medical products, the total cost of ownership (TCO) considers the cost to purchase, install, operate, maintain, and dispose of medical equipment for its lifetime. It is estimated that most procurement decisions for medical devices are based on the initial purchase cost, which is only 20% of the total cost of owning medical equipment for its lifetime. The other 80% of the costs are mostly hidden. In healthcare, the TCO concept is rarely used during decision-making, and the process is not standardized.³ Therefore, our objective is to develop a simple TCO tool to guide the purchasing decisions of medical devices in West Africa and potentially other regions.

Through desk research and interviews with key stakeholders involved in medical device procurement in West Africa, we mapped the process of product purchasing in the region to identify the considerations and challenges, particularly concerning TCO. Ultimately, we aimed to develop a decision-making tool that addresses their challenges with incorporating TCO.

Our findings suggest that the challenges with medical device procurement related to a lower consideration for the TCO include budget constraints, lack of established guidelines and standards, and a low level of expertise in this regard.

We developed a preliminary decision support tool for TCO considerations for medical device purchasing in Africa through expert insights and desk research. Although this tool is still in development and requires further testing and validation to be fully operational, it is intended to address gaps in previous tools and help plan medical device procurement in West Africa, with potential application across the African continent. This tool is designed to be simple, widely applicable across different geographies and device categories rather than provide actual costs or quantitative information, which are so variable, to encourage prospective buyers to consider factors other than upfront cost when making a purchasing decision.

¹ Relinkglobalhealth.org, Medical Equipment Procurement in LMIC: Key Considerations for Suppliers and Recipients

² Diaconu, K., Chen, Y. F., Cummins, C., Moyao, G. J., Manaseki-Holland, S., & Lilford, R. (2017). Methods for medical device and equipment procurement and prioritization within low-and middle-income countries: findings of a systematic literature review. Globalization and health, 13(1), 1-16.

³ Hospodková, P., & Vochyánová, A. (2019). <u>The Application of the Total Cost of Ownership Approach to Medical</u> <u>Equipment—Case Study in the Czech Republic</u>. In World Congress on Medical Physics and Biomedical Engineering 2018 (pp. 361-366). Springer, Singapore.

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Importance of TCO for medical device procurement in sub-Saharan Africa

Medical devices and equipment are indispensable tools in healthcare as they aid in prevention, diagnosis, treatment and rehabilitation,⁴ addressing health emergencies and promoting healthier populations.⁵ Although medical devices are important, countries in sub-Saharan Africa mostly do not produce their own medical devices but rely heavily on importation.⁶ In fact, the World Health Organisation (WHO) estimates that 95% of medical devices in low and middle-income countries (LMICs) are imported with 80% funded by international donor organisations and foreign governments.⁷

Procurement planning for medical device purchasing is essential to ensure the best use of scarce resources and finances to ensure appropriate medical equipment for a particular health care need, especially in resource-limited environments.⁸ It is, however, estimated that 40 to 70% of medical devices and equipment in LMICs are broken, unused, or unfit for purpose mainly due to indiscriminate procurement practices including inadequate planning for lifecycle costs.

In this context, it seems relevant to consider the total costs of ownership (TCO) as the costs from purchasing to end of life of the medical devices.² The TCO accounts for all costs from initial purchase of a product to its end use and disposal. However, in healthcare, considering TCO is not widely adopted nor used in decision-making for medical devices.⁹ It is estimated that the purchase price makes up only 20% of the cost of owning a medical device whilst the other 80% are hidden costs.¹⁰

Thus, it is evident that African procurement bodies and buyers of medical devices should consider TCO in their decision-making, so as to ensure a long, sustainable use of the product. As such, this research aims to develop a support tool to enable buyers to evaluate and make informed decisions in the process of planning to own a medical device, not just the initial purchase price.

Case study: Ghana

The West African country of Ghana was chosen as a case study to investigate the role of TOC in medical device procurement. In Ghana, the Ministry of Health (MOH) is the central decision-making body in matters related to health. Ghana rarely manufactures medical equipment but relies on imports for about 85% of the total health consumption. The World Health Organisation and the United Nations Children's Fund (UNICEF) directly engages with and supports the healthcare system in Ghana.¹¹ As a LMIC with constraints in resources, consideration and adoption of efficient procurement practices like the TCO could help advance proper equipment uptake, ensuring appropriate functioning of medical equipment in its lifetime. An assessment tool is one way to guide and make informed decisions before the uptake of medical devices in Ghana and other West African countries with similar peculiarities.

⁴ World Health Organization, <u>Interagency list of medical devices for essential interventions for reproductive, maternal,</u> <u>newborn and child health</u>, 2016

⁵ World Health Organization, <u>Medical devices</u>, 2021

⁶ International Monetary Fund, <u>Trade in Medical Goods: Challenges and a Way Forward for Sub-Saharan Africa</u>, 2021

⁷ Campbell, B., <u>Medical Equipment Procurement in LMIC: Key Considerations for Suppliers and Recipients</u>, 2020

⁸ World Health Organization, <u>A Guide on How to Procure and Commission your Healthcare Technology</u>, 2005
⁹ Hospodková, P., & Vochyánová, A. <u>The Application of the Total Cost of Ownership Approach to Medical Equipment–Case</u> <u>Study in the Czech Republic</u>. In World Congress on Medical Physics and Biomedical Engineering 2018 (pp. 361-366). Springer, Singapore.

¹⁰ OMNIA Partners, <u>How to Drive MRO Savings with Total Cost of Ownership (TCO)</u>, 2021

¹¹ WHO Country Office for Ghana, <u>Working towards better health</u>, 2014

Research approach and methods

To achieve the objectives of the research, we conducted secondary and primary research targeting individuals and agencies involved in purchasing medical devices in sub-Saharan Africa. Ghana was considered as a specific case study because the country is a good representation of the research problem in the west African region and also because the research team had a strong network of experts there.

First, we conducted desk research to map the process of medical device purchasing in West Africa, to refine the scope of the study and to understand the approach and decision-making process for medical device procurement. The search included, but was not limited to, the following terms: 'Decision-making for medical devices,' 'Medical device purchasing decisions,' 'Decision-making tools for medical devices,' 'Requirements for medical device purchasing,' and 'Total cost of ownership of medical devices.' The papers and articles reviewed included academic journals, news articles, organisational guidelines, and policy briefs.

To support the development of a decision-making tool, we mapped the landscape of medical device purchasing in West Africa. We identified the stakeholders involved, including international donor organisations, government agencies, non-governmental organizations, individual hospitals, medical device experts, and biomedical engineers. Before recruiting stakeholders for interviews, the desk research captured initial requirements and attributes used during medical device procurement.

Interviews and data synthesis

We interviewed seven experts, including individuals directly and indirectly involved with medical device purchasing and procurement. We carefully selected experts who were very familiar with the African setting and have been involved in various projects related to medical device procurement decisions and considerations. The experts included individuals involved with health technology assessment in Africa, biomedical engineering experts involved with direct procurement of medical devices at the Ministry of Health level, and medical practitioners.

We conducted semi-structured interviews using an interview protocol with questions regarding the requirements of medical device purchasing in Africa, the procurement process and challenges of medical device procurement, and operation in Africa. The interviews were conducted over the video conferencing platform Zoom, phone calls, and in person meetings whenever possible. The interviews were recorded when participants gave their consent. Notes taken during interviews and transcripts were thoroughly reviewed to first identify themes and claims, then map out the main considerations for purchasing medical devices from the experts' perspectives, and finally the challenges encountered when purchasing and operating medical devices in the region.

Medical device procurement in West Africa

Key stakeholders in the region

There are a variety of stakeholders involved in medical device procurement in LMICs.¹² Medical device procurement in LMICs is predominantly completed at the domestic level; local government agencies and ministries of health engage in equipment acquisition planning, tendering and equipment distribution. However, international donor organisations often partner with governments of LMICs to secure medical devices and

¹² Diaconu, K., Chen, Y. F., Cummins, C., Moyao, G. J., Manaseki-Holland, S., & Lilford, R. (2017). Methods for medical device and equipment procurement and prioritization within low-and middle-income countries: findings of a systematic literature review. Globalization and health, 13(1), 1-16.

equipment to facilitate their programs and causes. Two multilateral organisations, UNICEF and WHO, are relevant examples:

UNICEF: To support its programs, UNICEF procures medical devices and equipment worldwide by sending out bids and publishing specifications documents on their website.¹³ Interested suppliers and manufacturers submit specifications of the intended medical equipment to meet UNICEF's technical requirements for medical devices. UNICEF evaluates each application and awards contracts to suppliers meeting their requirements and specifications. They define minimum requirements for procuring medical devices to ensure quality and equity in their procurement process. Manufacturers and suppliers of medical devices are expected to comply with a variety of technical specifications and requirements, including quality management system standards such as ISO13485 and ISO 9001, production standards as described by the International Medical Device Regulators Forum (IMDRF), regulatory requirements for market clearance as described by the International Medical Device Regulators Forum (IMDRF), product documentation (including material datasheet), standards for shelf life and lifecycle, standards for consumables and renewals sterility, and production and distribution sustainability plans.

WHO: Regional and national health organisations often follow WHO guidelines to inform their requirements during procurement processes. For example, the Food and Drugs Authority (FDA) in Ghana uses the WHO specification guideline for procurement as reference standards for testing medical devices.¹⁴ Technology assessment is the first consideration for the medical device procurement process. The regional and national health service bodies are required to review existing assessment reports including reports by the International Network of Agencies of Health Technology Assessment (INAHTA). This process helps in adequate decision-making and planning to provide better procurement outcomes. Other considerations in the guide include device evaluation, planning and needs assessment, procurement, installation of products and goods, commissioning, and monitoring to collect data to inform future procurement decisions.

The WHO and UNICEF's guides each give clear guidelines for medical device procurement, however, these are general guides that do not have a step-by-step guide or checklist that can be explicitly used by buyers and procurement bodies to make decisions. Importantly, they also lack detailed TCO considerations.

Medical device procurement considerations

LMICs mostly rely on recommendations from recognised international policies and guidelines developed by public health agencies and research institutions like the WHO.¹⁵ A popular and widely adopted guideline is the WHO guide: How to Procure and Commission your Healthcare Technology.¹⁶ The aim of the guide is to inform procurement teams in the selection of and appropriately choosing equipment that are most suitable to their settings. In order to make the best use of scarce resources, procurement teams incorporate various considerations to make suitable choices that will be sustainable in the long run (Figure 2).

¹³ UNICEF, <u>Technical Requirements For Medical Devices (Md)</u>, 2021

¹⁴ Bennie, J. Y., <u>Medical Devices Regulation In Ghana</u>, 2021

¹⁵ Diaconu, K., Chen, Y. F., Cummins, C., Moyao, G. J., Manaseki-Holland, S., & Lilford, R. (2017). Methods for medical device and equipment procurement and prioritization within low-and middle-income countries: findings of a systematic literature review. Globalization and health, 13(1), 1-16.

¹⁶ WHO, <u>How to Procure and Commission your Healthcare Technology</u>, 2005

CONSIDERATIONS FOR MEDICAL DEVICE PURCHASE: GUIDELINES BY WHO

Appropriateness	Assurance of	Affordability and	Ease of use and	Conformity to
to settings	quality and safety	cost effectiveness	maintenance	existing policies
The equipment fits into your health facility, is compatible with climatic conditions and you have the skills to operate it	Ensure to buy from reputable companies, compliance to recognised safety standards	Plan for Lifecycle costs and not just initial purchase cost	Make sure staff have skills to operate and plan for additional training where necessary	guidelines Comply to existing policies of your facility to ensure sustainable products

Medical device procurement teams are to ensure that all equipment they select are appropriate to the settings where the device will be operated. Ensuring that the facility has staff that can properly operate and manage equipment with little or no additional training should also be a consideration. In assuring quality and safety, planning for and buying a high performance equipment from reputable manufacturers should be a consideration. Patient and staff safety should not be compromised with unsafe equipment and therefore, it is important to ensure that the device is manufactured to meet recognized safety standards.

For a medical device to be affordable and cost effective, the cheapest purchase price should not be the only consideration because a low cost might imply a low quality product which will require frequent repair and replacement of parts in the long run and might end up being more expensive than a high quality, high cost product. Considering and planning for the life cycle costs of a product like cost to maintain, repair, replace parts and operate the device could ensure a more cost effective purchase.

Ease of use and maintenance meaning procurement should be done with staff to operate and manage equipment in mind by considering that they have the expertise and necessary training. It is also important to ensure and plan for maintenance and support services after procurement. The last consideration is to ensure that procurement is done in conformity with existing facility guidelines and requirements. Consideration of other national and international standards and regulations should not be left out.

Procurement of medical devices case study: Ghana

The Ghana Ministry of Health (MOH) and the central medical stores are responsible for procuring medical devices for the entire country by ensuring local and international standards. They conduct, first, a national procurement assessment and then make tender announcements for internal and national competitive bidding and public bid opening. The Ghana MOH has a repository of specifications that guide them in their procurement decisions.¹⁷ Ghana operates a three tier distribution system of medical equipment supply as shown in figure 1. The three key stakeholders include: (1) the Central Medical Store, which is the largest and national storage facility serving all the regional medical stores, (2) Regional Medical Stores, which includes roughly 10 locations nationally, and (3) the Service Delivery Points (i.e., the local levels), which includes over 900 locations.¹⁸ Medical

¹⁷ Interview with anonymous expert, July 2021

¹⁸ MOH Ghana, <u>Assessment of medicines procurement and supply management systems in the public health sector</u>, 2009

device procurement is also done at the individual health facilities levels, when they receive funding to supplement their technological needs.¹⁹



Figure 1. Ghana's three tier distribution system of medical device supply.

Medical equipment are largely not manufactured locally in Ghana but are imported.²⁰ Ghanaian buyers of medical devices consider products that are registered with the approved regulatory bodies both locally and internationally. Most importantly, after sales servicing, maintenance, availability of consumables and accessories and user training services are of top priority to the Ghanaian purchasers of medical devices largely because of low expertise in these areas. Buyers need assurance from manufacturers that all after sales related aspects are sorted out before they commit to buying. We found out through our discussions with experts that the buyers prefer to buy from manufacturers that have local distributors and provide after sales services, maintenance and user training as stated by a representative from the Korle-Bu Teaching hospital.²¹ Furthermore, they consider manufacturers and distributors with a wide range of devices and with credibility as buyers, they look out for testimonials to verify if they are buying from the right source as reported by one of our interviewees.²² Although experts for this study stated the above mentioned considerations as key in procurement decisions, literature suggests that LMICs underestimate the true costs of owning medical devices as they neglect to account for the important factors like the TCO.²³ Although some of their considerations align with that of the WHO, there are some gaps.

The considerations discussed in the previous section are desirable key factors in medical device purchasing but there are some challenges encountered which do not make these desirable considerations possible. Experts involved in procurement decisions and advising like Biomedical engineers are rarely locally present. The few available are usually not consulted when it comes to decisions related to procurement of medical devices as explained by one interviewee from the Ghana society of Biomedical engineers.²⁴ In Ghana, there are guidelines by

¹⁹ Diaconu, K., Chen, Y. F., Cummins, C., Moyao, G. J., Manaseki-Holland, S., & Lilford, R. (2017). Methods for medical device and equipment procurement and prioritization within low-and middle-income countries: findings of a systematic literature review. Globalization and health, 13(1), 1-16.

²⁰ Export.gov, <u>Healthcare Resource Guide: Ghana</u>, 2018

²¹ Interview with anonymous expert, August 2021

²² Interview with Kenneth Rubango, MOH, Uganda, August 2021

²³ Diaconu, K., Chen, Y. F., Cummins, C., Moyao, G. J., Manaseki-Holland, S., & Lilford, R. (2017). Methods for medical device and equipment procurement and prioritization within low-and middle-income countries: findings of a systematic literature review. Globalization and health, 13(1), 1-16.

²⁴ Interview with anonymous expert, July 2021

the FDA²⁵ for accepting medical equipment donations but it was reported by one of our interviewees that those get bypassed sometimes and lead, therefore, to abandonment due to lack of expertise to operate them or missing parts/consumables. It appears that many equipment bought by the government are not in use because of the same reason as reported by a Biomedical engineer at the Korle-Bu teaching hospital in Ghana.²⁶ Another challenge with medical device procurement is the budget constraints as reported by a representative from the Ghana MOH.

Considering TCO in procurement decisions

The TCO encompasses all costs associated with use of a medical device for its lifetime.²⁷ Since TCO can be up to four times the initial cost of a product,²⁸ it is a necessary consideration, especially in low-resource settings. However, it is reported that most medical device procurement decisions are primarily based on the initial purchase price,²⁹ likely due to financial constraints.³⁰ Figure 3 provides an illustration of the concept of the TCO where purchasing costs are the tip of the "hippopotamus" whereas different costs are hidden and not considered.



Figure 3. Hippopotamus syndrome of the total cost of ownership: graphic source from the WHO.³¹

Planning for lifetime costs of medical equipment can be a complex task since those costs are not apparent and cannot be fully known at the exact moment of purchasing the devices. Many procurement decisions are made by

Equipment—Case Study in the Czech Republic. In World Congress on Medical Physics and Biomedical Engineering 2018 (pp. 361-366). Springer, Singapore.

³⁰ Interview with Dr. Nicholas Adjabu, President, Head of of Biomedical Engineering Unit MOH Ghana, August 2021

²⁵ FDA Ghana, <u>Guideline For Donation Of Medical Devices</u>, 2021

²⁶ Interview with Ing De-Graft, Biomedical Engineer, Korle- Bu teaching Hospital, Ghana, August, 2021

²⁷ Hospodková, P., & Vochyánová, A. (2019). The Application of the Total Cost of Ownership Approach to Medical

²⁸ World Health Organization, <u>A Guide on How to Procure and Commission your Healthcare Technology</u>, 2005

²⁹ Hospodková, P., & Vochyánová, A. (2019). The Application of the Total Cost of Ownership Approach to Medical Equipment—Case Study in the Czech Republic. In World Congress on Medical Physics and Biomedical Engineering 2018 (pp. 361-366). Springer, Singapore.

³¹ WHO, A Guide on How to Procure and Commission your Healthcare Technology, 2005

relying on previous procurement decisions, e.g., taking inventories of how those devices have been operated over their lifecycle to make informed decisions about a similar type of product in the future.³²

Tools for incorporating TCO in decisions

Various organisations have developed guidelines and tools to consider TCO in procurement decisions. Among the TCO calculators and guides investigated in the frame of this study, we had a closer look at the TCO quick calculator and guide by the procurement division of the New Zealand government.³³ This calculator has various cost categories and subsections that accounts for all costs in a device's lifecycle. Although this tool is great in evaluating the TCO accurately as shown in Figure 4, it requires a user to input actual cost values which are mostly not available to the buyer at the time of purchasing. Distributors and sellers of medical devices will most likely provide only the purchase price of devices on their website and not every cost item needed to calculate the TCO like in <u>VIA Global Health's website</u>. As a result, buyers of medical devices might not be able to use this tool if they don't have all the inputs to the tool. Based on the field experience of the partner organisation for this research, a tool not requiring users to input actual cost values is preferred and might make the tool easier to use. That is because buyers may not have all of the details about costs or amounts, but instead a general sense. It also would be challenging to create an accurate tool for the diverse range of medical devices and categories.

EXPENSES		enter	data here
Cost category 1	Cost items	subtot	al costs \$
All initial costs on purchase (one-off)	Purchase price	\$	3,453.00
	Accessories	\$	2,345.00
	Legal costs (eg conveyancing)	\$	2,345.00
	Duties / taxes on purchased item (excludes GST)	\$	543.00
	Packaging	\$	543.00
	Delivery costs	\$	654,565.00
	Installation / integration / engineering / calibration costs	\$	34,545.00

Figure 4. A section of TCO calculator by procurement division of new zealand government

Gaps Identified in the existing Tools

The existing TCO tools are great in evaluating the total cost of ownership but have some limitations that we hope to address. The identified limitations include:

- The tools require users to input actual cost values which are mostly unavailable: The lifecycle costs of medical devices are hidden as illustrated in figure 3 and therefore not available for TCO Consideration in procurement planning.
- The tools are tedious and complex to use
- The tools are mostly not adopted: These tools exist but it was found in the desk research that procurement bodies do not perform TCO nor use those tools.

³² Interview with Kenneth Rubango, MOH, Uganda, August 2021

³³ New Zealand Government, <u>A Guide to Total Cost of Ownership</u>, 2013

Developing a decision-making tool for TCO

Based on the case study from Ghana, we developed a decision making tool to guide buyers to make informed purchasing decisions of medical devices. The tool is general enough to be adopted by other contexts other than Ghana and is still to be tested and validated.

We developed the tool to bridge the gaps identified and to provide a simple TCO supporting tool to help buyers in making purchasing decisions. We went through a series of reviews into documents and resources like the <u>Engineering for Change (E4C) Solutions Library</u> taxonomy for the sector, <u>UNICEF oxygen system planning tool</u> and the WHO specifications and <u>guidelines</u> for medical device procurement to find parameters that should be included in our tool. Under the E4C taxonomy for the health sector, we reviewed the performance parameters to identify which performance parameters were important in considering a medical device for purchase. The UNICEF oxygen planning guide was a resource and an example of how a decision making tool could look whilst the WHO guidelines informed us about what considerations and parameters we should include in our tool to guide buyers of medical devices in making purchasing decisions.

Based on the WHO guidelines as presented in Figure 3, five main categories for consideration in medical device procurement decision making were presented. We then developed an initial prototype of the tool based on that. We focused on cost effectiveness and maintenance and not the other three considerations as shown in figure 5 because they were directly linked with the TCO. The idea was to have a tool that required the user to input data as shown in figure 5. The tool will sum the user inputs and present a recommendation to the user to enable them to select a device. We had 2 concepts for the user input which included a score board (Figure 6) and a checklist (Figure 7).



Figure 5. First concept of the tool development.



Figure 6. Scorecard Concept for user input with an example of question.



Figure 7. Checklist Concept of user input with an example of a question

We finally selected the Concept in figure 6 because we wanted a way to present feedback on the user inputs and response, a simple checklist would not enable this feature.

We set out some generic requirements for the tool, including:

- Be general for all kinds of devices in order for it to be widely acceptable
- Not be algorithmic: To make it simple as possible
- Only include cost considerations(Total cost of ownership)
- Not require users to input actual cost values because it is mostly not apparent and available

Based on these requirements, we focused on the factors relevant to the TCO, including:

- Cost of acquisition: This includes cost of purchasing, shipping, warehousing and delivery
- Cost of commissioning: Cost of equipment setup, personnel training.
- Cost of operation: This includes cost of consumables, cost of energy use, labor costs associated with the use of the equipment.
- Cost of maintenance: This includes cost of replacing parts of the equipment, cost of system update and preventive maintenance costs
- Cost of disposal: Medical waste are harmful and must be disposed of appropriately with some costs associated³⁴

³⁴ REMI, <u>The 5 Key Components of Total Cost of Ownership (TCO)</u>, 2019

For each of the cost areas stated above, we developed questions for the users of the tool to help them think through the TCO. The questions are structured in a way to help the user assess their decision based on their own constraints and settings. The questions were structured based on the five cost considerations explained previously. Through several iterations and expert insights we came up with the questions for the tool.

The top section on the tool allows the user to state the name of the device they are using the tool to evaluate. On the left side of the tool, we have the cost categories, in the middle we have the questions and on the right we have the user ratings. portion. A user is required to answer the questions based on their own requirements for that device. For example if the user budgets 500 USD as their requirement for a device but the device they are evaluating costs 1000 USD, they might rate the first question shown in figure 8 as high based on whether they are or are unable to purchase it. The users go through all the other sections to answer the questions. At the end, the tool provides a recommendation as to whether the device has a low or high cost of ownership.

There is no standard formula for calculating the TCO³⁵ but there are examples of how it can be done. An article ³⁶suggested that it could be the sum of all the 5 cost areas discussed above while another resource illustrates it as the sum of costs to procure, costs to maintain, and manage, costs for decommissioning and disposal minus the resale value. This informed our decision to sum all the cost areas in our tool.

Key: The user question in the t 5=Very high 3=Moderate 1=Low 0=N/A (use if a s	should enter one of the values (0, 1, 3 or 5) based on the following scale for each tool (do not enter monetary values): specific cost is not applicable to your context)	[Name of Device A]	[Name of Device B]
Cost of acquisition	How does the price of this product seem to you? (For example if the purchase price is far above your budget you might choose to input '5' [which corresponds to Very High])		
	How does the cost of any auxiliary equipment required for the device to function seem to you? (For example if you expect to need to buy another expensive device to support your equipment or make it function properly, input '5', but if the other devices are not so expensive, input '1' or '3', and if no auxiliary equipment is required, input '0')		
	How high do the freight/transport costs for this device seem to you? (Cost of shipping or transport can be very high and unsuitable depending on location - input '5' if you expect these costs to be very high, otherwise '1' or '3')		
	How does the cost for product registration in your country/ Import registration seem to you? (Input '5' if the cost seems very high, otherwise '1' or '3')		
	What will the cost of human resource or expertise be? (If you expect to need to pay staff, particularly experts, specifically to operate this device, input what you expect the cost to be: '0', '1', '3' or '5')		

Figure 8. Prototype of Total cost of ownership tool for decision making in medical device purchase

³⁵ PATH, <u>Value based procurement of medical equipment</u>, 2020

³⁶ Hospodková, P., & Vochyánová, A. (2019). <u>The Application of the Total Cost of Ownership Approach to Medical Equipment—Case Study in the Czech Republic</u>. In World Congress on Medical Physics and Biomedical Engineering 2018 (pp. 361-366). Springer, Singapore.

We included color codes to the users' responses. The color codes are red, yellow , green and white corresponding to high, moderate, low and not applicable explained in the key before each question. These color codes enable the user to see which cost areas might be of concern, they are meant as attention-getters. For instance the color code red implies high cost of owning the device and should draw the attention of the user to the need to reconsider this specific aspect before making a decision. It also enables the user to see which device cost will be favorable when comparing two or more devices. Once the user inputs ratings for all the cost sections, the tool sums up the ratings. If the user compares two devices as the example in figure 9, then the user gets to see which device has a lower cost of ownership. In the event that the two scores are the same we recommend that the user consider other factors unrelated to costs like appropriateness of the device to their settings, the quality and safety of the device amongst others as in figure 2.

Testing the tool

We developed a strategy for the testing of the tool. We prepared four case studies, each case included two similar devices which were selected from VIA Global Health's website for the testing. The case studies included the following device categories; Patient monitors, phototherapy, BCPAPs and oxygen concentrators. We identified eleven Individuals as potential participants for the first testing of the tool. These individuals included the experts we interviewed during the research and other biomedical engineers in order to accurately assess and evaluate the effectiveness of the tool. The sum of the ratings from both devices were compared in order to select the one with the lowest TCO. The testers were required to compare two similar devices as we provided the specifications and information on the devices. They were supposed to rate the devices based on the information we provided. An example of the test result completed by one of our testers is shown in figure 9. In this particular case, there is a clear indication that the first device had the lowest score and suggests a lower TCO for these settings. The few individuals who partook in the testing made some suggestions to clarify the questions in the tool for which we took note of and made adjustments. We sent out forms to the testers to gather their feedback for improvement of the tool.

We faced difficulties getting individuals for the tests due to the tight schedule of the research. We would need to perform further testing and validation of the tool, and gather feedback from the users to be able to iterate and improve. We could think about distributing the tool to test to individuals making real purchases in order to accurately assess the effectiveness of the tool.

Limitations of the Tool

Decision-making tools, such as the one developed here, have limitations. First of all, although the tool was developed to be applied to many types of medical devices in the procurement process, only one type can be evaluated at a time (i.e., a user can only compare devices of the same functionality and category). Furthermore, the tool neither tells the user the actual TCO cost nor accurately predicts how they would be. The outcomes are solely based on the judgement and experience of the user. Moreover, the tool is not intended to substitute a proper decision making process, it provides only recommendations, leaving it up to the buyer to decide to follow them or not. Importantly, this tool is still under development and has not been tested extensively, particularly in contexts outside of Ghana and West Africa.

We've included a disclaimer on the use of this tool, which states: "Since this tool works based on purchaser estimates of various costs that might be experienced over a typical product lifetime, associated costs may change while a product is in use, initial estimates may be incorrect and there may be other non-financial factors

that make an alternative product more suitable for any specific need. In this case other factors like appropriateness of the equipment to the settings, credibility of the manufacturer amongst others should be considered."

Кеу	The user should enter one of the values (0, 1, 3 or 5) based on the following scale for each question in the tool (do not enter monetary values): 5-Very High 3=moderate 1-low	Oxygen Concentrator 10L OX-10A	Oxygen Concentrator KSOC-10
	0=N/A (use if a specific cost is not applicable to your context)	Purchase price is \$599.20 for 1 pcs.	Purchase price is \$616.00 for 1 pcs.
	How does price of this product seem to you? (For example if the purchase price is far above your budget you might choose to input '5' (which corresponds to Very High)). How does the cost of any auxillary equipment required for the device to function seem to you? (For example if you expect to need to buy another expensive device to support your equipment or make it function properly, input '5', but if the other devices	3	5
Cost of acquisition	are not so expensive, input '1' or '3', and if no auxiliary equipment is required, input '0') How high do the freight/transport costs for this device seem to you? (Cost of shipping or transport can be very high and unsuitable depending on location - input '5' if you expect these costs to be very high, otherwise '1' or '3')	3	3
-	How does the cost for product registration in your country/ import registration seem to you? (input '5' if the cost seems very high, otherwise '1' or '3') What will the cost of human resource or expertise be? (If you expect to need to pay staff, particularly experts, specifically to operate this device, input what you expect the cost to be: '0', '1', '3' or '5')	3	1
	What do you expect the Setup/Installation cost of the device to be? (Some products may require construction work or new utility connections for setup. If you expect these costs to be very high, input '5'. Otherwise input: '0' for no setup costs. '1' or '3')	5	3
Cost of commissioning	What do you expect the training costs for this product to be? (If you anticipate needing to pay for training on how to use the product, input what you expect the cost to be. Input: '0' if no training, '1', '3' or '5')	1	
- - -	How high do you expect the IT cost for deploying this product will be? (If the product require that you purchase software separately, estimate the cost of this. Input '0' if no IT component to device, '1', '3' or '5')	1	1
	What will the energy costs for this product be? (Some devices require electricity, battery or gas to operate. Consider the cost of powering this device over its whole lifetime. Input '0' (no energy cost), '1', '3' or '5')	1	3
Cost of operation	Over it's entire lifetime, how high do you expect the cost of consumables to keep the product functioning properly will be? (Consider clinical volume, how often the product & consumables will be used and the cost involved in acquiring these consumables depending on sourcing options. Input: '0' (if no consumables required', '1', '3' or '5')	3	3
- 	For the lifespan of the device, how high do you expect the cost of accessories to keep the device functioning properly will be? (Consider clinical volume, how often the device will be used and how often the accessory needs to be replaced. Input '0' for no accessories, '1', '3' or '5')	5	5
	What do you expect the cost associated with software upgrades to be? (Consider device lifetime and how often software upgrades may be needed. Input '0' for softwareless product, '1', '3' or '5')	3	5
	What do you expect the cost associated with hardware upgrades to be? (Input: '0', '1', '3' or '5')	1	3
Cost of maintenance	What do you expect the service contract/warranty offer cost to be? If you will not purchase a service contract/warranty, consider the cost of necessary servicing on-demand over product lifetime (Input: '1', '3' or '5')	1	3
	What do you expect the cost associated with on-going IT charges to be? (Some products might require internet to operate. Input: '0', '1', '3', '5')	5	1
	What do you expect the costs associated with replacement parts to be? (Input: '1', '3' or '5')		
Cost of decommissioning	How high will the cost of disposal of consumables for or waste from this product be? (Input: '0', '1', '3' or '5')	5	3
	TOTAL SCORE	46	49
	A lower score typically means lower overall ownership cost, so is		· .
	more desirable and might be a better option than other high-scoring alternative products, however there may be other considerations		
	that are important in making a decision to purchase, such as:		
	Disability of Disas this test water based on any based of the based of the		
	Disclaimer: Since this tool works based on purchaser estimates of various costs experienced over a typical product lifetime, however associated costs may change while a product is in use, initial estimates may be incorrect and there may be other non-financial factors that make an alternative product more suitable for any specific need.		

Figure 9. Prototype of tool for performing TCO.

Conclusion

Adequate planning in medical device procurement, such as incorporating TCO, can improve the sustainability of medical devices, particularly in West Africa. TCO considers the life cycle and operational costs of the medical devices, such as maintenance services, user training, and local access to consumables and accessories for the proper function. Medical device buyers should adopt practicing the assessment of TCO in their selection and ownership considerations of medical devices.

Ultimately, the goal of the tool presented in this report is to encourage decision-makers to incorporate TCO into their purchasing decisions. The testing and validation of the tool is still ongoing; future work includes field tests and surveys to potential buyers of medical devices in Africa. It is expected that the tool will continually evolve as we incorporate the feedback we get from various stakeholders and potential users.

The total cost of ownership consideration in medical device procurement is important in planning for effective uptake of medical devices especially in low and middle income countries. The developed TCO tool through this research could be helpful in assessing this aspect, we hope to further test, validate and improve the tool for future use and upscaling.



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