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Sustainable Procurement of Medical Devices in an International Context - Part 2

Needs Assessment

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ABSTRACT

Background and Objectives: This article describes how sustainable procurement of medical devices (MDs) can be implemented in operational projects in developing countries. It also further details how sustainability principles and the needs assessment can be applied by the biomedical/clinical engineer lead (BCEL) responsible for the technical and quality aspects of the procurement process of MDs. It also emphasizes the importance of the BCEL considering the country's or region's specific healthcare context when working on MD procurement projects in developing countries.

Material and Methods: Based on the author's experience of more than 20 years in procurement projects and implementation of MDs in developing countries, the role of the BCEL will be analyzed from a theoretical point of view with the description of the first pillar of a sustainable purchase, the needs assessment, to how it can be operationally applied through the analysis of relevant literature, case studies and lessons learned from past projects.

Results: The BCEL has a key role in the sustainable procurement of MDs as an integrator able to understand clinical needs and translate them into requirements while being aware of the sustainability and safety risks linked to technology implemented in the fragile environment of a developing country with limited resources.

This context also creates additional challenges that can be managed if the BCEL is conscious of the country's health expenditure, geopolitical, healthcare, model of care, regulatory, infrastructure, and logistical conditions in which the MDs will be installed. Many equipment may remain unused if the technology implementation is not in line with the needs of the beneficiaries. Therefore, a thorough needs assessment performed by the BCEL to obtain the detailed list of MDs, their technological level and estimated budget is of utmost importance to increase the project's sustainability and mitigate the risk of unused MDs.

Conclusion: Besides traditional disciplines in biomedical and clinical engineering, the BCEL shall also learn at least basic principles in public health, healthcare planning, project management, health infrastructure, and development aid to facilitate the dialogue with stakeholders based on knowledge, flexibility, and capacity to anticipate and solve practical issues on the ground. To this extent, it is advisable for a BCEL new to the environment of developing countries to have progressive exposure to more complex projects and to extensively use the peer review mechanism to assure sustainability and quality during project implementation. A theoretical background based on sustainable procurement principles, analysis of the local and national health context and regulations, and knowledge of lessons learned from past projects should guide the BCEL's approach to performing the needs assessment while implementing a new project.

Keywords – *Medical device procurement, sustainable procurement, needs assessment, health services in developing countries, quality assurance, sustainability, Biomedical/Clinical Engineer role, international health procurement.*

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INTRODUCTION

In a previous article,¹ the concept of sustainable procurement of MDs has been discussed, and its importance regarding health services of developing countries emphasized. Public investments in MDs aim to improve health services and, thus the population's health. This creates a virtuous circle where a healthier population improves the economy, which translates into a better investment return. In this framework, the sustainability aspect in MD procurement projects has been defined as the critical factor that transforms financial resources into results: improved population health and wealth. This is particularly important in low-income countries (LIC) where healthcare financial resources are often scarce, and deciding where to invest them is paramount. An unsuccessful project, where for example, funds are spent to purchase equipment that is not needed or not efficiently used, can disrupt the virtuous circle by creating a major financial debt, which brings more poverty and, thus the population to a more fragile status.¹ The sustainability of MD purchasing projects is therefore intimately linked to their resulting impact on the population as well as the economy of the country. Therefore, the appropriate and efficient use of the purchased devices should be at the center of the efforts of the BCEL.

The concept of the three essential pillars to achieve sustainable procurement of MDs has been proposed as central to preventing the risk of purchasing equipment that will not be properly and efficiently used. This concept outlines the importance of concentrating the technical effort in assessing (1) the needs, (2) the local conditions, and (3) the conditions for the lifelong use of the MD. Consequently, technical decisions along the project should be strictly coherent with the results of these three assessments and the resulting planned project impact and objectives to guarantee the sustainable use of the purchased devices.

The objective of this article is to detail further how the first pillar for sustainability, the needs assessment, can be implemented in procurement projects within the environment of developing countries. The context of LIC creates additional challenges regarding MD procurement such as limited clinical, technical, and financial resources which

need to be considered, especially during the introduction of complex MDs. The BCEL has a key role in facing these challenges and ensuring the project's sustainability. The responsibility and recommended actions that the BCEL can take in these circumstances are discussed and analyzed using examples from implemented projects.

DEFINITION AND CONTEXT OF SUSTAINABLE PROCUREMENT OF MDS

The concept of the three pillars to achieve sustainable procurement of MDs¹ is an addition to the social, economic, and environmental considerations that are widely included in the policies of the four UN agencies mainly responsible for MD purchase: WHO,² UNICEF,³ UNDP,⁴ and UNOPS.⁵ The sustainability concept of a purchase shall be primarily linked to the use of the MD and only secondarily to its social, economic, and environmental impact. In fact, if the purchased MDs are unfit for purpose or wrongly installed and unused, they shall not be considered sustainable even if they are compliant to certain social, economic and/or environmental sustainability standards. A low environmental impact is unacceptable if the MD is not fit-for-purpose and brings no benefits (EG1 and Figure 1).



FIGURE 1. PubMed articles with relevant MAUDE terms in title/abstract.

EG1 *The purchase of a medical refrigerator meeting certain sustainability criteria such as durable material composition without ozone contaminants, high energy efficiency, reduced and recyclable packaging, ISO 13485 certification, and purchased at the best price available on the international market, faces risks to be unsustainable if the needs assessment was not correctly carried out. The refrigerator is not really needed or is too large for the needs of the beneficiary unit creating a problem of space and utilization that is solved with its early disposal.*

The context in developing countries creates additional challenges in the procurement of MDs. According to WHO: “in the Sub-Saharan Africa region, a large proportion (up to 70%) of equipment lies idle due to mismanagement of the technology, acquisition process, lack of user-training and lack of effective technical support.”⁶ Another study reported an average of 38.3% of out-of-service medical devices (MD) in developing countries due to a lack of training, health technology management, and infrastructure.⁷

EG2 *In an important procurement process managed by the Honduras Social Security Institute in 2011 and revised in 2014, it was found that about 20% of the purchased goods had not been used within 3 years from their installation while an additional 10% was seldom used.*

Developing countries conditions

The main conditions that a BCEL shall consider during the assessment of a new project in a developing country are:

1. Health expenditure conditions;
2. Geopolitical conditions;
3. Pre-existing healthcare conditions;
4. Model of care;
5. Infrastructure and logistical conditions;
6. Regulatory conditions.

Health expenditure conditions: the per-capita health expenditure (Figures 2 and 3) linked to the availability of human and material resources gives an overview of the economic conditions of each developing country. Low health expenditure is associated with few or limited trained medical and technical resources that might impact the technological level of the MDs to be purchased. It can

also limit the availability of consumables and spare parts on the local market and cause a lack of tools and knowledge to repair the MDs. A BCEL shall, therefore, consider that even when a budget is available for the purchase of MDs, funds for their consumables or maintenance might not be available in the long run and might compromise their efficient use.

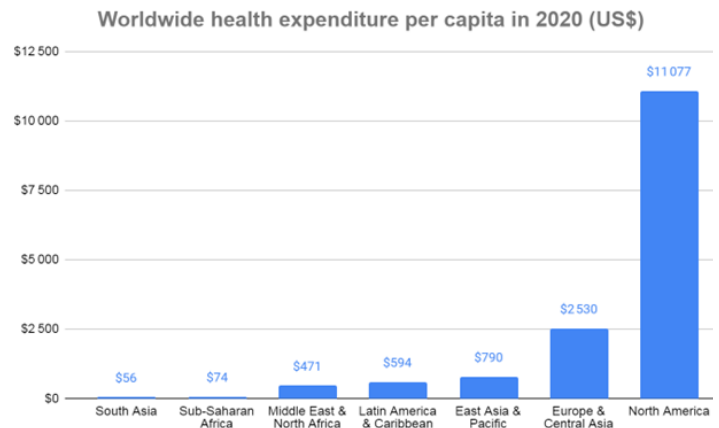


FIGURE 2. Worldwide health expenditure per-capita (US\$).⁸

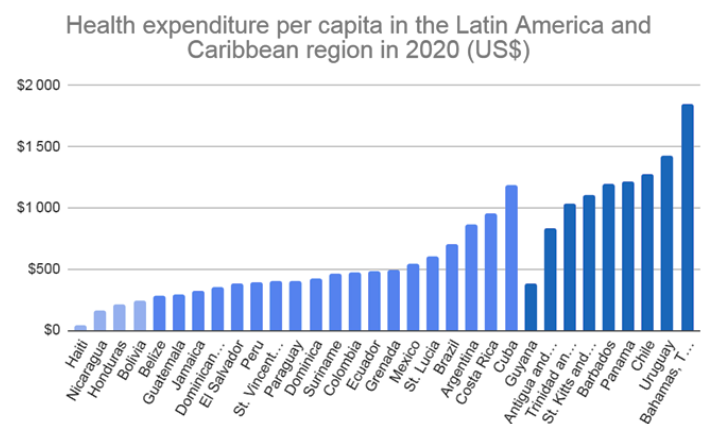


FIGURE 3. Health expenditure per-capita (US\$) in Latin America and the Caribbean region.⁸

The huge gaps in per-capita health expenditure between the different regions of the world also hide important gaps inside a particular region. For example, in the Latin America and Caribbean region, the health expenditure has a mean value of 594 USD. Still, when countries of this region are taken individually, there is a great variance between the Bahamas which has an expenditure

similar to Europe & Central Asia, and Haiti, which has an expenditure similar to the poorest countries of Africa and South Asia, (Figure 2).

While per-capita and public health expenditure can estimate a country's effort to manage healthcare and improve universal health coverage, life expectancy is to be considered as a parameter that can roughly summarize the results of this effort, not considering other factors like lifestyle, socioeconomic, and genetics. It can be observed that the higher the health expenditure per-capita the higher the life expectancy of the country (Figure 4) with some interesting exceptions like the US where the health expenditure is mainly out of pocket, leading to less efficient use of the expenditures and the countries where per-capita annual expenditures go below \$400. Over time, as countries invest more money in healthcare, the life expectancy of their population increases (Figure 5): *"on average, a 10% increase in health spending per-capita is associated with a gain of 3.5 months of life expectancy."*⁹

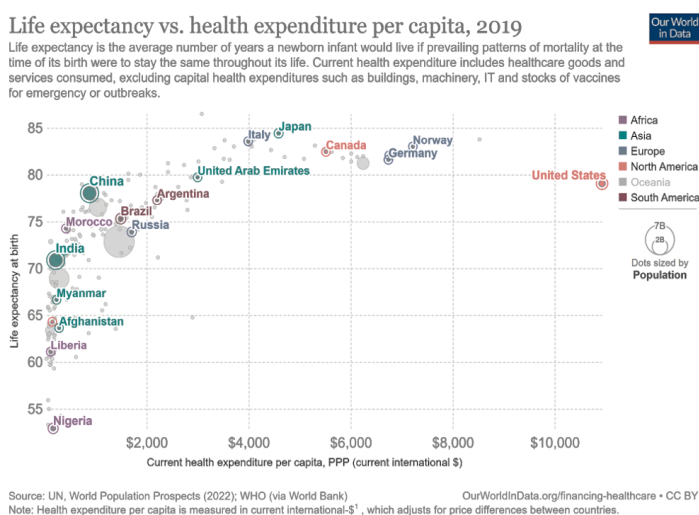


FIGURE 4. Life expectancy versus health expenditure per-capita in 2019.¹⁰

Geopolitical conditions: tense geopolitical conditions in countries affected by war zones, territories controlled by rebel or criminal groups, and high criminality zones might complicate the delivery of equipment or the travel

of technicians to perform the installation or the repair of MDs. In those cases, the delivery of the equipment or the maintenance technicians' access may require a police or military escort and pose additional challenges to the project.

Pre-existing healthcare conditions: available information on the local healthcare system, such as mortality/morbidity rates as well as health statistics on the population published by WHO¹¹ and data on the present workload and activity of the beneficiary center(s) supporting the assessment of the context in which the MDs will be implemented.

Model of care: different countries have different organizations and operationalization of health services, including different referral systems, processes of care, providers' organization and services management. These differences directly impact the distribution of technologies in the health infrastructures according to their complexities. It is recommended that the BCEL adopts the vision of a supply chain: a patient with a specific disease can be progressively attended to in infrastructures of different levels according to the diagnosis of the severity of the illness, and thus, the complexity of the technology shall be planned accordingly.

Infrastructure and logistical conditions: Delivery of MDs in remote areas can be difficult due to poor road conditions or accessibility by boat only. Remote areas might also have limited or no access to reliable electrical or water resources, which might affect the utilization of MDs.¹²

Regulatory conditions: The BCEL working in developed countries is usually part of a multidisciplinary team including medical planners, clinical experts, architects, and engineers with an exhaustive background of norms, regulations, and guidelines. In opposition, the BCEL working in developing countries has to cope with a multidisciplinary team that is significantly reduced or sometimes absent in a context of international rules and regulations that may not apply to fragile contexts.

The presence of a local National Regulatory Authority (NRA) in the country and its level of maturity as defined by WHO facilitates the understanding and implementation

of national regulations and the acceptance (or not) of international standards in MDs procurement projects. The efforts of WHO and the Pan American Health Organization (PAHO)¹³ to improve the capacities of NRAs in developing countries shall also be considered and monitored as part of the BCEL action in MDs procurement projects. The BCEL shall also be aware of the WHO Listed Authority,¹⁴ which will assess and classify the maturity level of NRAs based on a transparent and objective set of indicators established in the WHO Global Benchmarking Tool.¹⁵

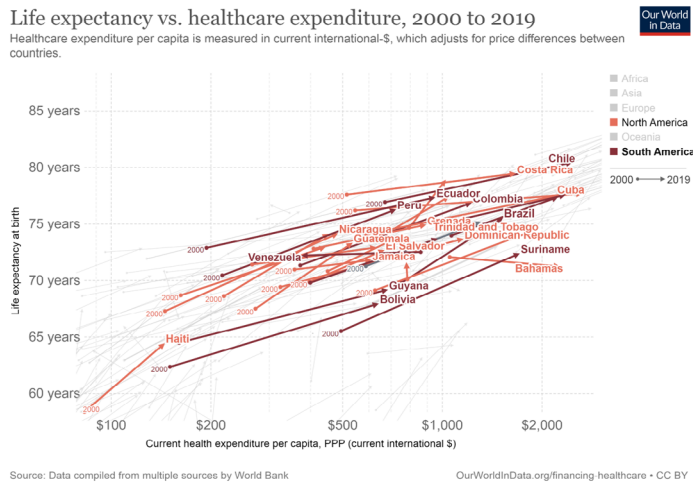


FIGURE 5. Life expectancy versus healthcare expenditure per-capita from 2000 to 2019 in Latin America and the Caribbean region.¹⁰

The role of the BCEL

When a procurement project of MDs for an LIC is assigned to the BCEL, he should always consider the beneficiary country's conditions during all project steps. In fact, the knowledge and consideration of the local health realities is essential to ensure a sustainable result of the procurement process and, finally the purchase of sustainable MDs that will meet the needs of the local beneficiaries in the long term. The role and expertise of the BCEL are crucial in addressing the challenges related to the implementation of MDs and the promotion of sustainable procurement practices in developing countries. BCELs with adequate experience should participate right from the start of the planning phase of an MD procurement project to ensure that sustainability criteria will be considered.

THE NEEDS ASSESSMENT

The first pillar of sustainability is the needs assessment, which involves investigating the demand and the intended use of the MD requested by the beneficiary. Considering the user's needs is a central concept in the procurement process definitions of the 4 main UN agencies procuring MDs. WHO states that the benefits of good procurement include: *"the most economically advantageous terms for the equipment acquired – not necessarily the lowest price obtained through tender, but the best deal for the organization's needs"* and defines the needs assessment as the *"quantification of gaps between desired health service provision and the current situation"*.¹⁶ UNICEF and UNDP also include the importance of meeting the needs of the end-user and the *"fit-for-purpose"* concept¹⁷ in their procurement processes: *"The selected offers from a competitive tender should display the optimum combination of quality, whole life cost, effectiveness, and other factors such as social, environmental and other strategic objectives, to meet end-user needs."*¹⁸ UNOPS also mentions to *"Re-consider the needs, i.e. consider specifically whether those goods or services need to be purchased."*¹⁹ According to the clinical engineering handbook,²⁰ the first step in the planning phase of MDs acquisition projects is *"Demonstrated needs and benefits"*. Effective and sustainable procurement is thus based on getting the right goods to respond to the needs. In fact, the whole procurement process is based on a needs assessment as its essential starting point. Public investment in MDs through the implementation of an international purchasing process is a long journey, and as *"most journeys we take are considered successful if we arrive at the right place, at the right time, and in good condition. The "right place" is vital. Identifying where you should head and justifying why you should get there will provide you with the critical data upon which to do planning, design, development, implementation, and monitoring and evaluation."*²¹

The objective of the needs assessment

The final objective of an MD procurement project is the intended impact on population health. Thus, the needs assessment's objective has to align with this intended impact on patient care.

It is important to clarify that the objectives and impact of an MD procurement project shall be designed and measured by clinical variables such as the number of patients treated or the reduction of waiting lists, rather than by the amount of equipment or money spent during the project. Therefore, performing a thorough needs assessment to define the project's objectives and identify the clinical variables upon which the project's success will be measured is essential. The project's objectives and clinical variables shall also be defined based on the country's health policy and statistics²² as well as on the analysis of the context as developed in chapter 2.1. When possible, it is recommended to involve, right from this initial step of the project, the beneficiary country's health personnel that has, at different levels, a deep knowledge of the local technical capacities, conditions, and needs.

The role of the BCEL in the needs assessment

A medical planner usually carries out the analysis of the clinical needs along with the establishment of the project's clinical objective. The BCEL has to understand the clinical objectives and the process that has been carried out to define them by dialoguing with the medical planner. Therefore, the BCEL should deeply understand healthcare systems in developing countries and their dynamics. Profound knowledge of the healthcare needs and the locally and internationally available commercial solutions are essential for the BCEL to evaluate and propose technological solutions for the assessed clinical needs and objectives. Starting from this essential dialogue with the medical planner, the BCEL can complete the needs assessment by defining the objectives of the procurement process in terms of technologies. Based on the planned clinical activities and workloads, the BCEL can determine the equipment list. In fact, an equipment type that may be included in the list corresponds to an equipment class that requires a technological-level definition to associate the expected clinical throughput with its estimated value and technical requirements in terms of space, installation, electricity, etc.

EG3 *A 20L tabletop autoclave used to sterilize laboratory equipment performing a few analyses per day is technologically much different and less complex than a 500L pass-through autoclave of a surgery center, requiring more*

complicated installation steps. Still, often they are simply referred to as autoclaves in the purchasing lists provided to the BCEL.

To define the project objectives, the needs assessment should be analyzed, validated, and updated in the planning phase of the procurement process. All stakeholders must be involved in the needs analysis, which must be as detailed and complete as possible. The scope of this assessment should also include present and future needs in a 5 to 10-year projection. By focusing on the specific use of the device, the procurement process can be tailored to meet the needs of the beneficiaries and select the most adequate equipment. The quality of the MD procurement process can be maximized when all the actions of the BCEL are coherent with the project's objectives.

In the planning phase of a procurement project, the BCEL should also consider the following conditions as recommended by the clinical engineering handbook:

- “1. Demonstrated needs and benefits of the MDs
2. Available qualified users
3. Approved and reassured source of recurrent operating budget
4. Confirmed maintenance services and support
5. Adequate environment support
6. Regulatory compliance”²⁰

Analyzing these conditions before purchasing the equipment allows the BCEL to prevent potential issues related to the use of the MD. These conditions are also included as part of the three pillars of sustainability. This process results in adequate equipment that meets the beneficiary's needs and thus is more likely to be used by the clinical personnel (Figure 6). To perform a proper needs assessment, the BCEL should always involve the clinical end-user as stakeholders and purchase MDs and services from local manufacturers whenever possible.

The sustainability risks related to a weak needs assessment

A reliable needs assessment conducted under the responsibility of the BCEL is, therefore, the central point of an effective health procurement process. It also helps

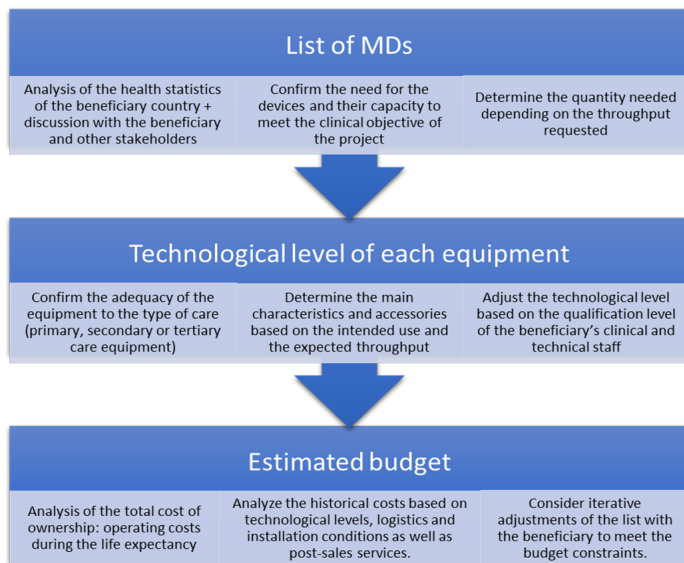


FIGURE 6. Description of the three main activities for each needs assessment deliverables that the BCEL shall focus on.

minimize sustainability risks, such as insufficient adequacy between the clinical personnel's needs and the purchased MD's characteristics, compromising its usage. However, this analysis can sometimes be difficult to achieve due to the following pitfalls:

- Inadequate involvement of the relevant stakeholders in the project is caused either by the difficulty of implicating all the necessary stakeholders in the needs analysis, deficient identification of the clinical beneficiaries, or lack of consideration of the position of the beneficiaries in the health system network.
- An outdated needs analysis caused by a significant delay between the completion of the analysis and the official launch of the project or by a change of the actors or some of their characteristics (evolution of the private sector, new government, new strategies in the distribution of health services, change in the clinical team, etc.).
- A short-term needs assessment does not consider future needs caused by an analysis that considers only the current necessities and lacks to foresee future perspectives for at least the next 5-10 years related to the new etiologies of diseases and the emergence of new diagnostic and therapeutic needs.

Depending on the project's starting point when the BCEL begins to be involved, the needs assessment may be included or not in the project scope. The projects that start from a list of MDs and technical specifications already defined are considered "purely transactional." They can be considered high-risk projects since the procurement project is separated from the needs analysis and the evaluation of the impact of the purchase on the local healthcare system. Implementing these transactional projects represents a high risk to the sustainable impact of the procurement project because no one in the project team is responsible for ensuring that the MDs to be purchased are genuinely needed and that the local conditions allow for their efficient use. The clinical needs are unknown to the project team, and the coherence of the implementation is jeopardized. Other types of projects, such as those where the dialogue between the BCEL and the medical planner who defined the clinical objectives is impossible, and has moderate risks. These risks shall be mitigated by the BCEL, which can revise and validate the medical planner's analysis when possible or at least the clinical objectives, focusing on the purchase of MDs.

Case studies

In the following discussion, 2 case studies of projects implemented in the Latin America and Caribbean region, one in Uruguay and the other in Haiti, representing extremes in terms of per-capita health expenditure differences in the region, will be presented. Uruguay has a high health expenditure and a mature public health system with established capacities to understand and properly use the funding for capital investment in MDs. On the other hand, Haiti has minimal health planning capacities and lacks technical experts.

In 2008, in Uruguay, as part of a project funded by a soft loan from Italian corporations, 34 types of MDs were purchased and destined for more than 300 health centers nationwide.²³ The needs assessment process carried out before the beginning of the project has been an example of good practice of sustainability (Figure 7). The project's agreement stated the general objective: "Sustain the capacity of the Uruguayan Public Health System to meet the population's needs while prioritizing the most vulnerable groups."

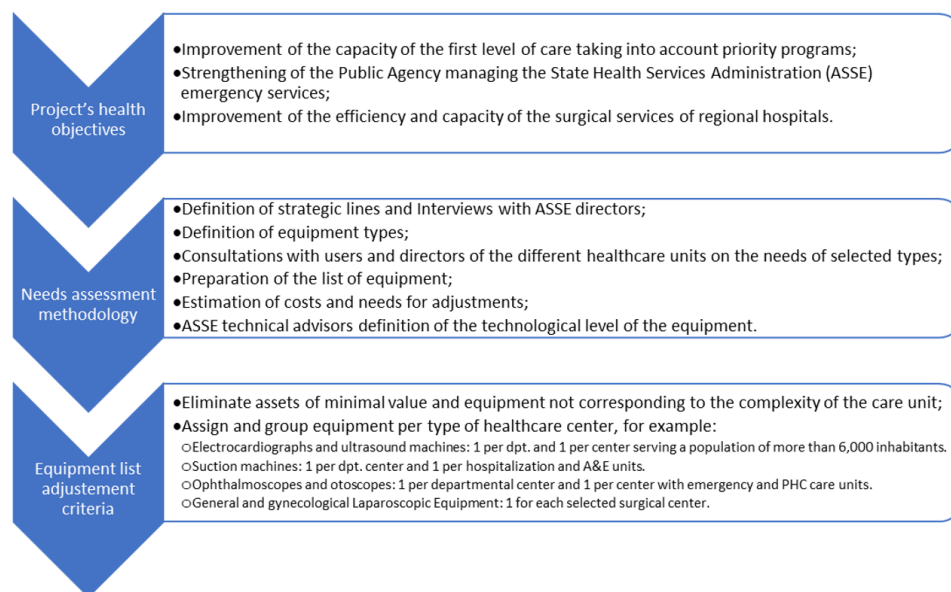


FIGURE 7. Methodology of the needs assessment of the project “Italian Loan to support Uruguayan Health Services” implemented in 2008, starting from the project’s objectives definition and ending with the types of equipment included, the list of equipment requested by the beneficiary centers and its adjustment to meet the available budget.

This process, carried out transparently with an outstanding maturity by the central office of the Ministry of Health in contact with the regional directors, has produced the expected results: each center was aware and prepared to receive the equipment from the loan investment. The BCEL validated the needs assessment carried out by the beneficiary and assured coherence of the purchase with the needs assessed.

In 2012, in Haiti, during the design phase of the construction and medical equipment procurement project of the Gonaïves hospital, no local medical counterpart was involved (Baio A. Gonaïves Hospital Project - Raising from destruction - The challenge of building in Haiti - International Federation of Hospital Engineering. Buenos Aires, October 15th, 2014). The only person from the Haitian Ministry of Health participating in the technical dialogue was the recently appointed, but not yet contracted, director of the new hospital. In this case, the BCEL had to plan a methodology to define the list of equipment since no dialogue with the clinical beneficiary could plan medical equipment adequate to the intended level of care and size of the hospital (a regional hospital with a 200-bed capacity). To mitigate this risk, a workshop was organized involving all the stakeholders working on MDs in the

country. This workshop resulted in a scheme to follow for the definition of the equipment list, primarily oriented towards implementing simple technologies to facilitate local maintenance (Figure 8). For example, manual operation tables rather than electrical ones were chosen to allow for ease of use and maintenance.

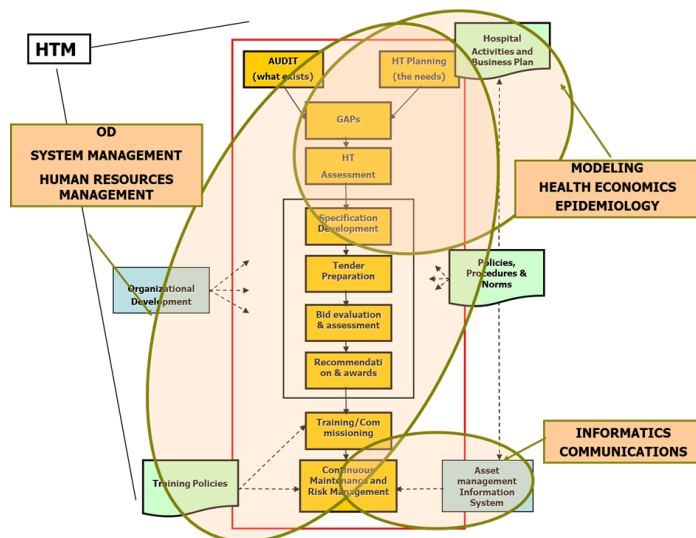


FIGURE 8. Health Technology Management Scheme (Nunziata E. Technical workshop on MDs - towards health technology management in Haiti. Haiti, June 15th 2012).

The demand for local maintenance support was solved during the tender process by asking the suppliers to establish a maintenance center in the country (at that time, no maintenance capacity - private or public - were present in the country). To help suppliers comply with this challenging requirement, the contracting authority included a financial incentive: an important advanced payment during the procurement process. Eight local technicians were also hired and trained under the guidance of international technical experts to open packages, assemble, and install all the hospital furniture purchased. At the end of the project, the hospital could recruit trained technicians as maintenance employees. This also reduced the costs for suppliers since they did not have to travel to Haiti to assemble the purchased furniture.

In both case studies, a component of the procurement project was focused on strengthening local technical capacities in terms of equipment maintenance to improve the project's sustainability. In Uruguay, maintenance tools were purchased and provided to regional hospitals where biomedical engineers trained during the project execution could use them to maintain and repair MDs.²³ In Haiti, training and tools for medical furniture repair was provided to local technicians, and an incentive for international suppliers to establish local maintenance centers was added to the procurement project. As a lesson learned, improving and strengthening local technical capacities is strongly recommended as an objective of MD procurement projects in developing countries to enhance sustainability.

CONCLUSION

Sustainability is essential in implementing an internationally funded project in a developing country to procure MDs. This factor determines if the project will improve the population's health conditions or the country's impoverishment.¹ Sustainable procurement of medical devices shall be driven by the BCEL using the framework of the three pillars: assessing (1) the needs, (2) the local conditions, and (3) the conditions for the lifelong use of the MD. The BCEL is responsible for ensuring the quality of the project's results and, thus, its sustainability. This article presented the theoretical background of the first pillar, the needs assessment, that the BCEL can follow as

a guideline in the project's planning phase. In this way, he can assume the responsibility for the quality assurance processes and the project's sustainability while raising awareness of the possible issues and discussing solutions with the rest of the team, the beneficiary, and the stakeholders to minimize the project's risks.

An international procurement project of MDs requires high technical specialties in a multidisciplinary team, including project management. The needs assessment step requires competencies and knowledge in public health, clinical aspects, hospital design, infrastructure, MDs, project planning, and market and technology analysis. The BCEL has to dialogue with several stakeholders and, therefore, understand and use their languages to integrate their points of view, perceived risks, and suggested mitigation measures. A good approach for the BCEL is to begin the project from a risk analysis perspective. While different stakeholders can raise any risk, the BCEL shall focus on quality risks, which in the light of the previous discussion means sustainability risks: the main risk being the investment of money in the purchase of MDs that are not or scarcely used because they do not respond to the needs of the beneficiary. During the analysis, the BCEL can integrate different viewpoints and brainstorm possible prevention and mitigation measures.

Considering sustainability as the center of their activity and responsibility, the BCEL's role in a project is much more important than simply writing technical specifications or performing technical evaluations. Therefore, the BCEL needs thorough professional preparation and progressive exposure to the complexity and the issues specific to the context of developing countries. In this sense, the peer review mechanism is a tool commonly used in organizational processes to assure higher quality in project implementation and the continuing education and professional growth of BCELs interested in leading international procurement projects.

When implementing a specific project, balancing the impact of time and budget constraints with quality assurance actions is the main goal that any BCEL has to focus on. The needs assessment should be included in the planning phase of the procurement project and coordinated by the BCEL, which can integrate the different stakeholders' points of view. The assessment of sustainability risks performed

during the project's planning phase allows the BCEL to identify the challenges and evaluate the potential risks that could impact the project's outcome.

CONFLICT OF INTEREST

The authors declare no conflict of interest regarding the publication of this paper.

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