

### Sustainable Procurement of Medical Devices in an International Context - Part 3 Assessment of Local and Lifelong Use Conditions

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#### ABSTRACT

**Background and Objectives:** This article is the third in a series of three manuscripts published in this journal. It aims to describe how sustainable procurement of medical devices (MDs) can be implemented in operational projects in the context of developing countries. It also further details how the biomedical/clinical engineer lead (BCEL) in charge of technical support during the MD procurement process can apply sustainability principles and concepts of value-based procurement.

**Material and Methods:** Based on the authors' experience of more than 20 years in procurement projects and implementation of MDs, the role of the BCEL will be developed from a theoretical point of view with the description of the second and third pillars of a sustainable purchase following the needs assessment: the assessment of existing conditions along with local capacities and the evaluation of the use conditions during the lifetime of the medical equipment. The application of these principles in operational projects will be further discussed by analyzing literature and lessons learned from projects implemented in developing countries.

**Results/Proposal:** The BCEL has a key role in the sustainable procurement of MDs to design the technical specifications of the goods, related services, and post-sales conditions to maximize the benefit of the investment. As the specialist can analyze the local existing conditions and capacities while ensuring efficient use of the MDs during their lifespan, they can contribute to a sustainable implementation of MDs in developing countries.

The BCEL shall also be able to analyze the local and international markets to find all possible technological solutions that meet the needs, local conditions, and capacities and ensure quality use during the lifespan of the purchased MD. The BCEL shall have competencies in identifying all the risks related to the use of the MD from the safety risks linked to its installation, use, and maintenance to the sustainability risks linked to obtaining the conditions that guarantee the use of the device and maintaining them as long as possible. Examples of these conditions include the presence of qualified and trained users, availability of maintenance and consumable budgets, availability and maintenance of infrastructure conditions (access, electrical power, water, drainage, medical gasses, etc.), and last but not least, presence of patients requiring a diagnosis or treatment using the purchased MD who were identified during the evaluation of the first pillar: a sound needs assessment.

**Conclusion:** As an evolution of the BCEL's traditional biomedical and clinical engineering work, he/she shall assume the responsibility to guarantee the sustainability of the MD purchase. This quality assurance and control role is achieved by a sound theoretical background knowledge based on the three sustainable procurement pillars: the needs, existing and lifetime use conditions assessments, the analysis of the local and international markets, and a broad understanding of sustainability risks.

**Keywords** – Medical device procurement, sustainable procurement, technical specifications, local conditions, local capacities, lifetime use of MDs, total cost of ownership, health services in developing countries, quality assurance, sustainability, clinical engineer role, international health procurement, value-based procurement.

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### **INTRODUCTION**

In a previous article,<sup>1</sup> sustainability principles and their importance in MD procurement projects, especially in developing countries, has been described. A theoretical concept with three fundamental pillars was proposed to improve the sustainability in MD procurement projects and address the risk of purchasing MDs that will not be used by local clinical personnel. This concept suggests focusing the technical work of the BCEL on three assessments: (1) the needs, (2) the local conditions and capacities, and (3) the conditions for the lifetime use of the MD. All actions performed during the project are recommended to be coherent with the results of these three assessments linked to the project's objective to facilitate the sustainable outcome of the purchased MDs.

Without specific attention to the sustainable conditions of use, an investment in health technology, including MD purchases, has a high risk of becoming a burden for the local health system.

This article aims to further detail how these pillars for sustainability can be implemented in MD procurement projects within the environment of developing countries. This article will focus on assessing the MDs' local and lifetime use conditions since the needs assessment was already developed in a previous article.<sup>2</sup> The responsibility and recommended actions that the BCEL can take to perform these assessments are discussed and analyzed using examples from implemented projects. In this framework, a convenient approach is to focus on value-based procurement, a novel approach to purchasing that evaluates potential new MDs to maximize overall value for money (including their economy, effectiveness, efficiency, equity, and sustainability), rather than focusing only on the lowest purchase price will also be explored.<sup>3,4</sup>

### THE ASSESSMENT OF EXISTING CONDITIONS AND CAPACITIES

The second pillar of sustainability is the assessment of existing conditions and capacities where the MD will be used. This includes the analysis of the following conditions:

• The delivery logistics required to get to the installation site and the installation room from the nearest port/airport and the manufacturing site;

- The customs rules and regulations;
- The installation site infrastructure and installation conditions according to the technical requirements of the MDs to be implemented;
- The local and international rules and regulations on MDs, construction, electrical, fire prevention, health and safety, etc.
- The local capacities are clinical, technical, logistics, financial, etc.
- The availability of the MDs, services, and consumables on the local and international markets is needed to guarantee sustainability.

The result of these analyses is the development of detailed technical specifications for the MDs to be procured, starting from the technological level defined in the needs assessment in line with the analysis of the intended use of the MD, together with an adequate delivery and installation plan translated into requirements to be included in the tender documents.

The technical specifications of the MDs shall be tailored to consider local clinical and technical capacities as well as their working method, standards, and cultural environment. Therefore, a dialogue with the MDs' clinical and technical beneficiaries is essential during assessing the existing conditions and capacities for defining the technical specifications.

**EG1** *MDs* required to equip a delivery room can be selected in very different ways depending on cultural aspects, including delivery positions and the presence of accompanying relatives. Depending on the local culture, the use of birthing balls, stools, supports from the ceilings together or instead of the classical delivery bed have to be discussed and considered when designing the equipment list and their technical specifications.<sup>5,6</sup>

Linked to the Incoterms used in the tender and purchasing contract, shipment conditions shall consider the logistics and safety of the sites. Sometimes, due to urgency or specific logistic complexity, the delivery costs may become higher than the costs of the goods. To minimize the carbon footprint and reduce costs, local suppliers shall be encouraged to participate in the tender processes since "goods sourced locally have a positive sustainability impact, e.g., eliminating transportation costs."<sup>7</sup> In most cases, the National Regulatory Authority certification is mandatory to import the goods, and relevant customs bureaucracy shall be managed.

The design of pre-installation requirements represents, for complex equipment, a critical issue since the installation shall comply with the manufacturer's recommendations and local rules and regulations. In most cases, international practices and safety standards for the installation shall be added to local rules and regulations depending on the maturity level of the beneficiary country.

The result of the assessment of the existing conditions are:

- 1. Detailed technical specification of the MDs;
- 2. Complete delivery conditions and specifications;
- 3. Exhaustive organization of the pre-installation responsibilities;
- 4. Pre-installation requirements;
- 5. Training requirements for the tender process;
- 6. Installation requirements for the tender process.

## The role of BCEL in the assessment of existing local conditions and capacities

Based on the assessment of the existing conditions: infrastructure, electromechanical installations, clinical and technical capacities, installed and available technologies, local market, intranet-internet connections, etc. the BCEL along with the local stakeholders and within the scope of the project agreement, will design, as summarized in Figure 1:

1. The technical specifications are the detailed requirements for the MD; In this process, the BCEL shall consider the technological level8 and the clinical objectives defined in the needs assessment as well as the installation conditions and, most notably, the local clinical and technical capacities, as well as the lessons learned in previous projects and the local and international market. This process implies a consistent workload depending on how the market analysis can be performed depending on the availability of lessons learned from previous projects. If an up-to-date database of previous successful projects with the same specific technology required for the project is available, the market analysis can be reduced. Suppose a new technology has to be purchased. In that case, the market analysis may require a larger technical effort and contact with potential suppliers and manufacturers, requiring several additional weeks for the specifications design of a single technology. Typically, this process is outsourced by the BCEL to other biomedical engineers who can work remotely while the BCEL focuses on the next steps.

According to the United Nations Office for Project Services (UNOPS)<sup>9</sup> and the United Nations International Children's Emergency Fund (UNICEF),<sup>10</sup> the BCEL could also perform additional sustainability considerations in the planning phase of the project:

• Plan a market analysis to understand and determine:

- Sustainable solutions that might already exist in the local market;
- Sustainable solutions that have been implemented internationally;
- The economic, social and environmental risks/ opportunities related to that specific MD;
- Standards and regulations requirements available for the MD.

• Assess the sustainability risks of the MD and adjust the procurement strategy consequently.

2. The delivery requirements, including temporary storage and transport conditions, safety rules for manipulation and transportation, possibly considering, during tender evaluation, the carbon footprint. For larger equipment, these requirements shall include the access pathway inside the beneficiary's infrastructure to the final installation site, considering the size and weight of the good's packages: the rigging plan. This includes onsite transportation that can become relevant for heavy or large equipment requiring a detailed plan, including health and safety considerations for the workers. Also, the disposal, recycling, or storage of equipment packaging can also be an important aspect to integrate into the technical specification preparation.

3. The pre-installation responsibilities are linked to the installation site and MD's specific chosen brand and model. The BCEL shall design how to organize the contractual

responsibilities between the beneficiary hospital, the supplier, and the international purchasing organization, including, when relevant, the hospital's constructor. The exchange and approval of progressively more detailed technical drawings and the definition of responsibilities for the pre-installation work between all the stakeholders is essential to the success of the implementation. This process shall consider the standards and regulations applicable to the different installation aspects, such as structural capacities, radiation protection, hazardous material management, waste management, etc.

4. The pre-installation requirements which include all technical requirements for a safe installation and use of MDs that need to be specified by the BCEL to support hospital architects and engineers in designing new in-frastructures or renovating existing sites<sup>3</sup>; They can be organized as shown in Table 1.

**TABLE 1** Pre-installation Requirements, Which Include AllTechnical Requirements for the Safe Installation and Use Of MDs

Electrical supply	Temperature and humidity
Water hot/cold	Weight
Drainage	Radiation shielding
Medical gasses	Magnetic shielding
Other gasses	Biohazards containment
Network connections	

These requirements are specified when the equipment type is defined and adjusted with the manufacturer's documentation when the specific brand and model is awarded.

5. Human resources (clinical and technical) training requirements. The design of the training requirements is a critical issue, and the BCEL shall consider all available options from simple written instruction of use and maintenance to online training and tutorials or even in-person training by the manufacturer's certified instructor. The BCEL can also consider the possibility of longer training when introducing new technology. For example, the clinical and technical personnel could travel to a clinical or training center where the same equipment model is installed for several weeks of hands-on training. A good practice is to identify the trained personnel and restrict the use and maintenance of the MD only to trained staff.

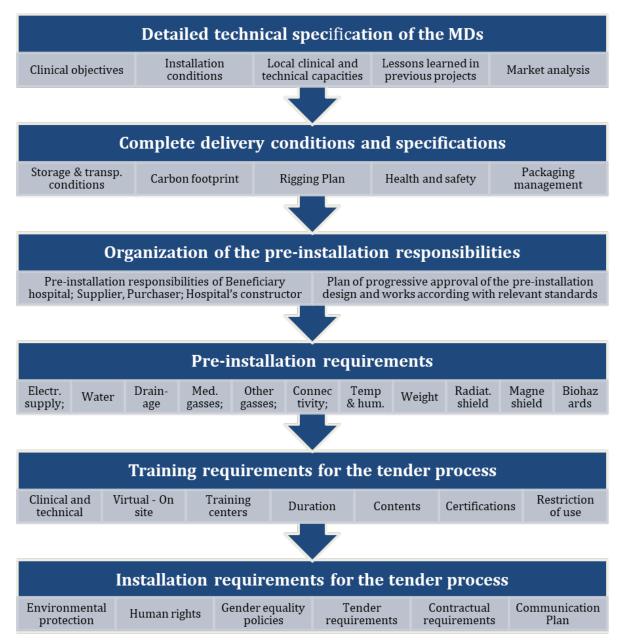
Another recommended strategy is training local technicians to maintain essential MDs, such as hospital furniture and simple equipment commonly found in primary care institutions that benefit a larger population.<sup>11</sup>

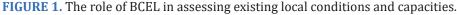
6. Detailed installation requirements in charge of the supplier to be included in the tender document. As the last step of the installation design, the BCEL will prepare the final installation requirements to be tendered with the equipment. These requirements shall match the onsite conditions, and the pre-installation works that the beneficiary or a third party eventually takes care of. It is a good practice to include the specific installation requirements in a framework considering environmental protection, health and safety of the installers, as well as human rights and gender equality policies. After installation completion, the supplier may be required to implement a communication plan to enhance the visibility of the project. If so, this activity shall be implemented under the strict supervision of the beneficiary.

The BCEL shall consider the impact of pre-installation works and installation activities on the hospital's clinical workflow and discuss it with the beneficiary before starting the purchasing process. In some instances, the impact can be so unacceptable for the beneficiary that the purchase of the new equipment is rejected, and a different technological solution shall be pursued.

To improve the quality of procurement processes, a standard template of technical specifications for the procurement of MDs with standards, regulations, and sustainability principles is recommended to be available for BCELs within an implementation agency. A peer-review mechanism of technical specifications, delivery, installation, and lifetime use plan by BCELs is also recommended to be incorporated into the procurement processes of MDs. The outcome of the project's implementation can be monitored, and lessons learned can be gathered to benefit future projects.

**EG2** A purchasing project for a few computed tomography (CT) scanners installed in specific hospitals where the clinical engineer has also designed their sustainable use can be further investigated and improved if analyzed nationally. The national distribution of imaging equipment in a network scheme that minimizes the distance to the





nearest CT scanner for the population, their connections, and their interactions through local and national PACS/RIS systems allows a broader assessment that can suggest some adjustments to the technical specifications for purchasing the CT scanner in the benefit of its future optimized use.

## The sustainability risks of a weak assessment of existing conditions

A incomplete or absent assessment of the local conditions is, together with a weak needs assessment, the main cause for an unsuccessful project: the equipment is delivered but not used. The opportunity to improve the health system's quality and the investment are lost, and the equipment becomes a burden to be removed and disposed of. The World Health Organization states, "According to one estimate, only 10–30% of donated equipment becomes operational in developing countries. Reasons for unused equipment include mismanagement in the technology acquisition process, lack of user training, and lack of effective technical support."<sup>12</sup> Other risks associated with a poor assessment of existing conditions can include the following examples<sup>-</sup>

- An impossibility to deliver, install, test the equipment or train personnel due to poor road conditions, war zones, etc.;
- A lack of services for the safe and effective use of the device: absence of a reliable electrical power source, unavailability of medical gasses, inadequate water quality, insufficient mechanical structure, no protection against radiation or bio risks exposure, lack of information technology, etc.;
- A lack or absence of training and qualified clinical and technical resources to use and maintain the MD;
- A lack or absence of proper accessories and consumables to make effective use of the device;
- Non-compliance of the device to local standards and regulations.  $^{\rm 3}$

The BCEL shall avoid additional examples of frequent pitfalls and derived lessons learned during the design phase:

1. Absent, insufficient, or wrong pre-installation conditions when the installation works are supposed to start. To prevent this situation, it is possible and useful in some cases to delegate the pre-installation works to the beneficiary hospital even when the beneficiary has a weak technical capacity. In these cases, the supervision of the works and the final approval shall be assumed by the BCEL and the equipment supplier. Only a close follow up of the execution of the pre-installation works can guarantee that the proper pre-installation conditions will meet the requirements.

2. A lack of personnel to be trained: The BCEL shall ensure that the beneficiary users are available and prepared to receive the appropriate training at the planned time. The final users and the final responsibility for maintenance shall be formally designated by the beneficiary authority to receive the training and be available during the training days. Furthermore, recording the training sessions to guide new users and creating a formal document to register who has been trained and is habilitated to use and maintain the equipment correctly is advisable.

3. A lack of specific tools and consumables on the local market. The BCEL shall verify in advance and search for alternatives when a particular tool or consumable is unavailable on the local market.

4. The local supplier representative lacks capacities for installation and post-sales services delivery. The BCEL shall confirm that the local representative of the supplier/manufacturer has been properly trained to install the equipment. The BCEL shall require appropriate certification of local technical people delegated for equipment installation from the manufacturer. In past projects, situations where local representatives could not install the equipment properly and damaged the new equipment during the installation attempt happened. The presence of the BCEL and close supervision of the installation process is recommended, especially for sensitive and high-technology equipment. In case of doubt, a video record of the installation can be useful.

5. During the installation planning, especially in large projects with tens or hundreds of installations, the climate factor has to be considered. The BCEL shall know the difference between the dry and wet seasons in the beneficiary country since some critical delivery operations of managing important loads from trucks to rural sites may be affected by heavy rains.

Working in a developing country environment requires additional flexibility and problem-solving capacities to face some unforeseen issues that arise during the installation. These issues can also be much more complex in a fragile environment.

**EG3** During the installation of a MD in a remote hospital in Haiti, a broken specialized tool represented an issue: the nearest market in the capital was far away, and most probably the specific tool was not available there. An overseas purchase was needed, adding a delay of at least 3-5 days on the overall installation. However, it's not all about risks, many opportunities can be analyzed and pursued during the project's design and implementation. A relevant approach recommended to the BCEL is to constantly seek opportunities to improve the sustainability of the health system through the introduction of technologies.

**EG4** In Jamaica, nurses use most of their work time to manually measure patient vital signs and copy them on paper registers. They report that up to 90% of their time is used to perform similar paperwork. A simple device to monitor and record vital signs in a database can abruptly reduce nurse routine work and help nurses spend more time attending to patient's needs.

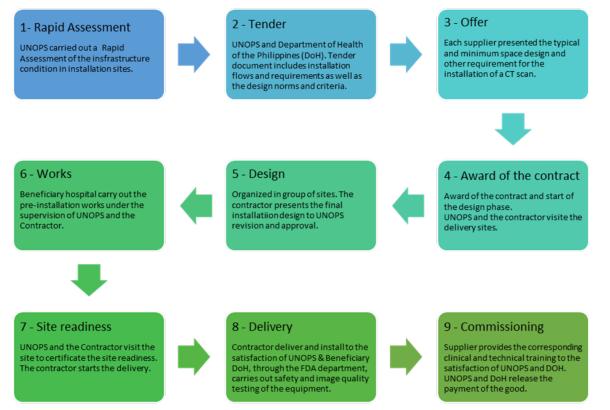
### **Examples of local conditions assessments**

Figure 2 shows the workflow for the pre-installation requirements responsibilities as designed by the BCEL in charge of the procurement project of <sup>32</sup> CT scanners in 2022 in the Philippines. Four main actors were involved: UNOPS

organization, the Philippines Department of Health at a national level, the supplier, and the beneficiary hospitals.

Constraints at the beginning of this project were that installation site plans were not all available for every hospital, and it was urgent to implement the project according to certain emergency response programs. Based on the decision that each hospital had to be responsible for complying with the pre-installation requirements, the following operational workflow was designed by the BCEL in charge during the project launch.

In 2008, during a project in Uruguay, a communication plan was proposed by the BCEL and implemented by the project team to inform the recipient health units and the general population of the equipment to be delivered and of their schedule so that the units were prepared for the immediate inclusion of the new technologies in the clinical activities.<sup>13</sup> The Ministry of Health (MSP) implemented a component of the plan through radio messages and local newspaper advertisements. Each supplier implemented



**FIGURE 2.** Workflow of 32 CTs Installation Process: From the Analysis of Local Conditions to the Definition of the Requirements, Implementation and Use (Klappenbach F. With The Permission Of The Author)

a second component under the strict supervision of the MSP. Tender requirements detailed the services required to the suppliers: national television advertisements, national written press advertisements, and labels while establishing that the Ministry of Health will keep the rights to all information managed by the supplier, being the supplier forbidden to use it without written authorization.

In many cases, citizens, after a communication campaign on local radios and newspapers, went to the health units to see the new technologies. This process of local conditions assessment to implement the Italian loan for MDs purchase was successfully presented by the Ministry of Health to the Health Commission of the Uruguayan parliament on February 26th, 2008.

### **ASSESSMENT OF THE LIFETIME USE CONDITIONS**

The third pillar of sustainability is the assessment of the lifetime use conditions of the MD. The result of this analysis is an adequate lifetime use plan. A key factor is to plan the duration of the useful life of the MD. The manufacturers are not used to expose the planned life duration of their goods, but this might change since "manufacturers are required to provide definite expected lifetime for the certification of their product under the new EU medical device regulations (EU MDR 2017/745)."<sup>14</sup> However, the US Food and Drug Administration does not require manufacturers to establish an expected life for a device.<sup>15</sup> The expected minimal life duration of the equipment is an essential element of any purchase since it is relevant to evaluate the total cost of ownership and is the basis of any asset management plan for existing and future technologies.

### The role of BCEL in the assessment of lifetime use conditions

While considering the project's constraints such as the available budget, the local conditions, and resources, the BCEL shall explore their awareness and interest with the stakeholders on the purchase's mid- and long-term benefits. The BCEL shall also promote all the actions needed to maintain the equipment during its lifespan and keep the benefits and positive impact of the investment as long as possible. The BCEL in accordance with the beneficiary, will design and propose, as summarized in Figure 3:

1. The planned lifetime use duration of the equipment. One of the impacts of the life expectancy definition is in the specifications for the materials of the goods. Certain kinds of steel or plastic can increase or reduce the life expectancy of medical furniture or a medical device while simultaneously increasing or reducing its value and purchasing cost. Once the expected duration of the equipment is determined, the BCEL shall revise the technical specifications of the MD to adjust and adapt them consequently to the available technologies on the market.

2. The post-sale services requirements, including warranties, maintenance, consumables contracts, and documentation, are to be provided with the MD.

3. For certain types of equipment, it is recommended to use the financial planning of the total cost of ownership. This costing methodology considers the total cost of a product over its lifetime. In addition to the initial procurement costs, transportation, maintenance, operations, utilities, training, consumables, and waste management costs are also evaluated based on the expected lifetime of the purchased equipment.<sup>16</sup> If the cost of post-sales services or consumables is substantial compared to the cost of the equipment, it is recommended to consider the total cost of ownership during the financial analysis of the purchasing process.

4. When the consumable and maintenance costs are comparable with the equipment cost, other options besides the purchase can be considered by the BCEL such as leasing or renting the equipment by purchasing a certain amount of consumables. These types of contracts may represent a valid strategy alternative to the purchase depending on the market and on the contracting rules of the beneficiary and donors.<sup>17</sup>

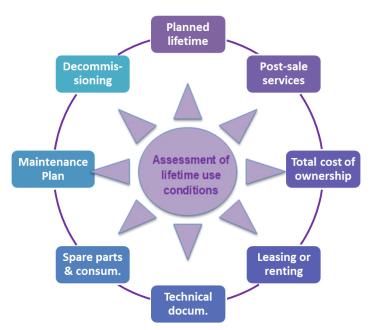
5. How to manage the technical documentation accompanying the equipment from the commissioning to the disposal, including all user and maintenance manuals, training and maintenance actions, measures and tests, calibrations etc., shall be planned by the BCEL.

6. Designing the maintenance requirements, including the in-warranty and post-warranty preventive and corrective maintenance requirements according to the complexity of the equipment and the local needs, is an essential duty of the BCEL. Indeed, procuring MDs without a maintenance plan can be wasteful and reduce the device's lifetime.<sup>18</sup> It is also advisable to include the software updates in the maintenance requirements.

7. It is part of the BCEL role to analyze the availability of spare parts and consumables on the local market and to include appropriate requirements in the purchasing tender conditions to encourage the availability of such goods. The BCEL also needs to confirm with the beneficiaries the availability of a budget for these consumables and their capacity to manage efficiently the purchase of spare parts and consumables.

8. Ideally, when a BCEL plans the lifetime use of the MDs, he/she shall include a plan for its decommissioning and consider the expenses associated when calculating the total cost of ownership.<sup>19</sup>

All the requirements mentioned above, excluding decommissioning, will be included by the BCEL in the tender documents and act as relevant contractual conditions once the device has been received, installed, and commissioned properly.



**FIGURE 3.** The role of BCEL in the assessment of lifetime use conditions.

# The sustainability risks of a weak assessment of lifetime use conditions

The risks associated with a poor or absent assessment of the lifetime use conditions may render the MD unusable after some time and thus threaten the sustainability of the project:

- Insufficient planning or lack of financial resources needed to purchase consumables and spare parts to maintain the MD throughout its life expectancy;
- A lack of properly trained clinical and technical staff during the lifetime of the MD;
- An absence of the equipment documentation: contractual warranty, user and service manuals, etc. probably caused by the lack of hand-over of the project's contractual documents regarding warranty and post-sales services to the beneficiary;
- Absent, inadequate, or inappropriate warranty requirements in the tender documents. The manufacturer's default warranty conditions may require to send the equipment to the production site in case of malfunctioning or to demonstrate that the malfunctioning is not due to improper use;
- A lack of managerial capacities to follow up with the supplier regarding maintenance, repairs, and upgrades included in the warranty;
- Unavailability of consumables or spare parts on the local market, which does not allow or makes the use or the repair of the equipment too expensive;
- A premature failure of the purchased MD due to materials inappropriate to the hospital environment where aggressive cleaning agents are frequently used;
- A lack or insufficient program of continuous training on how to use the MD for new users;

#### SUSTAINABLE RISK ASSESSMENT

The recommended approach to sustainability is to start the project with a proper risk analysis involving the different project's stakeholders. Sustainable risk assessment is performed at the start of the purchasing projects, in the evaluation of the three pillars -needs, existing and lifetime use conditions, and capacities - allows the BCEL to identify the challenges and evaluate the potential risks related to sustainability that could have an impact on the outcome of the project.

Once the sustainable risk assessment is performed and the specific risks of the procurement project have been identified, a mitigation plan can be prepared. Different risk mitigation strategies to ensure sustainable procurement practices of MD implementation can be applied to different projects, including:

- 1. Openly discuss the sustainability risk of scarce or improper use of the purchased MDs with the different project stakeholders.
- 2. Openly discuss sustainability challenges with manufacturers or distributors of MDs during the market analysis.
- 3. Center the procurement process on the added value of the intended use of the MDs rather than on their possession.
- 4. Give relevance to the requirements on the supporting services of the goods that can guarantee proper and long-term use of the device.
- 5. When applicable, choose a procurement process that allows an evaluation of the quality and performance of the MD during the selection phase, discarding the minimum price approach and considering alternatives to the purchase.
- 6. Ask for a list of reference centers during the selection phase to validate the quality and performance of the bided MD in the mid and long term.
- 7. Discuss and share experiences with other health technology assessment experts from UN agencies or international institutions on evidence-based procurement of MD.
- 8. Build within the implementation organization a record of the performances of the MDs and suppliers to build a knowledge database.

### **CONCLUSION**

Sustainable procurement of MDs, especially in developing countries, is of utmost importance<sup>-1</sup> The BCEL has a key role and responsibility in assuring the implemented MDs' quality and sustainability. This article further detailed the proposed theoretical background of two fundamental pillars besides assessing the needs<sup>2</sup>: local and lifetime use conditions and capacities analyzes that the BCEL can follow as a guideline to achieve sustainable projects.

It also emphasizes the role of the BCEL as the technical expert conscious of the project's sustainability and responsible for the quality assurance process, raising awareness on the possible issues and discussing solutions with the rest of the team, the beneficiary, and the project's stakeholders to minimize the risks.

Since the BCEL has to work in a multidisciplinary team<sup>20</sup> and be able to dialogue with different stakeholders from various backgrounds, they require expertise to cover all the aspects of the project, from public health to project management, while also considering clinical aspects, hospital design, infrastructure, installation, MDs design and technology.<sup>21</sup>

The assessment of the local capacities and conditions is a key element in the work of the BCEL to:

- Ensure that the technology level is adequate to the site conditions which in developing countries may be challenging because of the lack of adequate infrastructure, stable electrical power supply, controlled working temperature and humidity, accessibility, and
- Ensure that the MD is adequate to the local capacities of use and of maintenance since, in most developing countries those capacities are scarce. Expert professionals, when available, have a high turnover because they are constantly searching for better conditions.

Once the BCEL confirms that the technology design is fit for purpose and adequate to local conditions and capacities, including the design of the support services for delivery, installation, and training, they have to ensure that these sustainable conditions will last during the device's lifetime.

This can be done by planning the intended lifespan of the MD and verifying that the main conditions will remain stable: availability of trained personnel, planned maintenance by trained technical personnel, availability of consumables, adequate electrical supply, etc.

The focus on the lifespan of the MD will bring the total cost of ownership criteria in the evaluation and add the analysis of alternative ways of procuring the goods, such as renting or lending the equipment with a consumable contract. The benefit procured by using the purchased MD should be the central matter of the procurement process rather than the ownership of the MD. Additionally, to communicate efficiently and integrate the different collaborators' viewpoints, perceived risks, and suggested mitigation measures, the BCEL must know all these aspects to understand and use the appropriate language. When the BCEL is entrusted with an international procurement project, professional preparation, progressive exposure to complex projects, and a peer-review mechanism are recommended.

The BCEL can contribute to accomplishing the desired outcome by first confirming that the project objectives are built on evidence-based data and that the purchase of the MD will indeed improve the health services of the beneficiary country. Then, they must keep a high coherence of all their actions with the desired objectives and outcomes. This coherence needs to be maintained throughout the project, be it during the preparation of the purchasing list and the technologies' specifications or the installation and design of the post-sales services. All these actions must be consistent with the desired outcome, and the local situation, resources, and capacities available on the field must always be considered.

Finally, monitoring the results of a procurement project by visiting the installation sites and recording the use of the MDs within 6 months or one or several years after their commissioning will allow us to understand the impact of the project and learn lessons on the choices made by the BCEL along the way. The public procurement process has the weakness that most, if not all, of the choices have to be made at the very beginning when the requirements of the tender documents are prepared. How these choices will positively impact the use of the MD in the specific local context is a vision that the BCEL can achieve with experience and guidance from peer-review processes and senior experts. Preparing tender requirements is thus equivalent to designing an infrastructure where everything is to be forecasted in advance, giving the BCEL freedom to express their imagination, creativity, and experience during the process.

#### **CONFLICT OF INTEREST**

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

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