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Sustainable Procurement of Medical Devices in an International Context: Part 1 - Background and Definitions

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ABSTRACT

Background and Objectives: Sustainability is a working principle included in the United Nations (UN) procurement processes with the adoption of the Sustainable Development Goals (SDGs) in 2015. In the context of internationally funded projects in developing countries for procuring health-related goods during and following the COVID-19 pandemic, this article further investigates what sustainable procurement means when applied to purchasing medical devices (MDs), considering its impact on health services. It also proposes a reflection on the concepts of sustainability and quality assurance as guiding principles for technical teams during the process of MD procurement.

Material and Methods: This article aims to identify how sustainability can be implemented during the execution of a project based on the analysis of principles that guide procurement actions in the four UN agencies with the highest volume of MD procurement. The concept of sustainability is also explored from a macrosystemic point of view as the ratio between the impact of a procurement project on healthcare services and its investment. Its implications for population health and wealth is also discussed. Based on the experience of the authors in implementing purchasing processes of MDs, a framework for the specific technical activity is then proposed.

Results: In the UN system, sustainable procurement focuses on the social, economic, and environmental quality of the equipment and on the conditions of its production to guarantee that a sustainable good is procured. Not being enough, the focus should also be on the benefit of a procurement project, not as the possession of a new MD, but as the utility of the device: an instrument to provide healthcare services of the beneficiary country. Procuring sustainable goods should include planning their future use as an essential component for a sustainable positive impact on the health and wealth of the beneficiary population. Thus, the intended use of the procured devices should be defined, planned, and measured. In the proposed framework, sustainability is a ratio between an MD's social, economic, and environmental costs and the benefits of its use. When neglecting the essential factor of sustainable use of MDs, the risk of purchasing equipment that will not be properly and efficiently used is relevant. To guarantee the sustainable use of a MD, it is essential to assess the needs, the local conditions, and the conditions for its lifelong use. Further evolution of the concept of sustainability is developed towards the possibility of modulating the project's objective from procuring sustainable MDs to improving the sustainability of the health services by procuring MDs.

Conclusion: Sustainable procurement of MDs is a key factor in supporting the sustainable development of health services and health systems toward the SDGs. Post-pandemic investments to strengthen the resilience of health services in developing countries shall consider sustainable procurement, including the essential quality assurance process. This process, led by an expert clinical engineer, shall be centered on the future use of the equipment and not be limited to its quality as a material good.

Keywords – *Medical device procurement, sustainable procurement, needs assessment, health services in developing countries, quality assurance, sustainability.*

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INTRODUCTION

Sustainability principles have recently been included in the UN procurement processes.¹ Considering the opportunity to follow SDGs² and reduce health inequities by focusing on project implementation, this article investigates further what sustainable procurement means when purchasing MDs in a developing country and its impact on health services.

Quality in healthcare is a *comprehensive and multifaceted concept*, including technical competencies, effectiveness, efficiency, continuity, and safety. It is known that in developing countries, improving quality is not a luxury, and doing so often pays off.³

Therefore, It is essential and possible to place sustainability and quality assurance (QA) at the center of the biomedical engineer's efforts, aiming to improve quality healthcare services in developing countries.

Healthcare services save lives and increase the population's well-being, but at the same time, they have a relevant impact on the environment, social and economic aspects of the communities involved. If not correctly managed, this impact can weaken communities and threaten their ability to guarantee healthy lives for future generations.⁴

As the pandemic of COVID-19 progressed and the number of patients affected rose, the demand to procure materials and medical devices (MD) to deliver healthcare increased, especially in developing countries, which were more vulnerable to the pandemic due to a historical lack of investment in the health sector.⁵

In this context, the quality of the procurement process to ensure the sustainable purchase of MDs in developing countries becomes a key factor that goes beyond the technical characteristics of the device.

More than ever, the procurement of MDs needs to have a durable and positive effect on health services to improve patient care while reducing their environmental, social, and economic impacts according to the SDGs.⁶

This article presents the experience of the authors during the COVID-19 pandemic when the requests for MDs for developing countries exploded. Following this

increase, in 2021, UNOPS has become the second largest health procurement agency within the UN for MDs and supply, with USD 500 million in purchases, after UNICEF, the number one procuring Agency.

APPLICATION FRAMEWORK AND METHODS

The application framework can be depicted as an international procurement process where a *funding source* is donating or loaning money to a *beneficiary*, typically a public institution of a developing country, and the procurement is carried out by an *implementing agency*.

In developing countries, the knowledge asymmetry between private suppliers and public purchasers is more evident: "*Public procurers perceive it hard to know what the available market offerings are resulting in the problem of finding the best available solution. They also lack enough insight into the operations, making it hard to understand the need of which the procurement is meant to fulfill. In extension this problem makes it hard to mediate the need to the market.*"⁷

The rise of new technologies in the global market increases this knowledge gap, limiting the effort of public procurers toward a more sustainable procurement. It is essential to have public procurement institutions with enough technical capacities to challenge the market to reduce the dependence on information from manufacturers or suppliers that can be biased to their own advantage. To be able to take evidence-based decisions and choose only the innovative technologies that represent a real advantage, and finally to orient the market development toward sustainable innovations that are in the interest of developing countries. For these reasons, international implementing agencies are also responsible for bringing technical knowledge to strengthen local technical capacities.

This article focuses on the procurement of MDs, with particular attention on medical equipment that requires specific installation and safety measures. It also analyzes the main UN procuring agencies perspectives on sustainability and where the focus should be placed.

Consequently, this framework's target beneficiary of the procurement process will be part of secondary and tertiary care-level infrastructures. Expert in MDs, the

technical lead of the project should be a biomedical or clinical engineer leading the technical part of the procurement process; thus, they are institutionally in charge of ensuring the quality of the purchase.

Within the described framework, the procurement of MDs is a project limited in time, with a specific, well-defined schedule, budget, and expected quality. The Project Manager (PM) and their team will pursue these three dimensions simultaneously.⁸ If the PM is not an expert in MDs, they will pursue a schedule and a budget while relying on the technical lead to ensure the quality/scope.

Firstly, this framework will explore the meaning of 'sustainable' and its definition in the context of a procurement project of MDs. Secondly, what sustainable procurement means from the technical perspective of the project within the agency will be investigated. Finally, a discussion on quality and sustainability and their similarities and differences in the procurement of MDs will be made.

A MACRO APPROACH TO SUSTAINABLE MDS PROCUREMENT IN DEVELOPING COUNTRIES

The health of a population is positively correlated with economic development.⁹ A healthier population is more active and productive, thus increasing the development process of a country. In return, the development of a country increases its capacity to offer better health services to its population. If the third sustainable development goal 'Good-health and well-being'¹⁰ and universal health coverage, are to be achieved, countries must invest at least 5% of their GDP.¹¹ Focused investment is needed and funding agencies can play a key role in their strengthening.¹² Health capital expenditures and assets maintenance and management have been historically underfinanced. The pandemic pointed out this fragility and lack of resilience of health systems. As a result, in 2020, governments' increased health care expenditure to address the additional medical needs was observed.¹³

A procurement project of MDs represents the injection of funds into a developing country's health services, aiming to improve the population's health and contribute to the country's sustainable economic development. Implementing an investment project in the health sector is part of a virtuous circle: direct investments or loans coming from

present or future taxes are transformed into infrastructure and technologies that improve the population's health. The healthier a population is, the better the economy.

However, healthcare financial resources being limited, the high-quality (sustainable) or low-quality (unsustainable) of an MD procurement project is thus a critical factor that will impact the health services performance and thus, the population's health. This means that the work of the technical leads in MD procurement projects has a potential impact on the lives of millions of people.

Therefore it is possible to define sustainability as a critical 'gain factor' (Figure 1), which depends on how the project is implemented. A high-quality project will have a highly positive factor so that the investment will produce results that will exceed the loan reimbursement, thus increasing health services resilience.

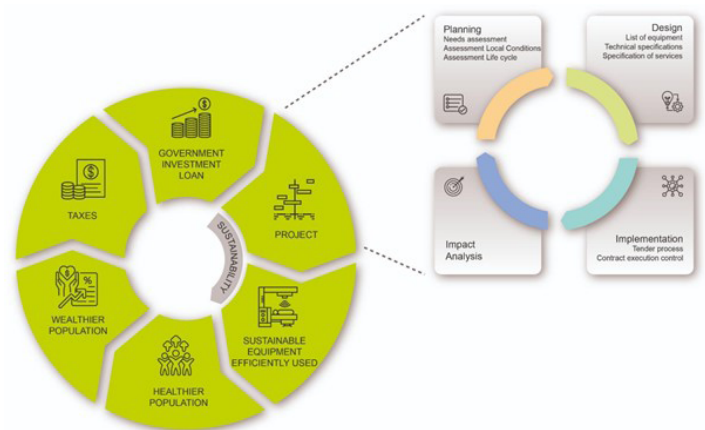


FIGURE 1. The virtuous circle of investments in health technology. The procurement project's sustainability is a critical factor in achieving the intended impact of a healthier population.

This factor is what makes a project sustainable for the convenience of the beneficiary country's population. In light of this top-down definition of 'sustainability' it is possible to define the sustainability of a project with the ratio between the impact of the project on the SDGs and the amount of the investment. From this macro perspective, QA and sustainability assurance are synonymous, depending on the project's impact.

When the impact of the project is reduced, null, or worse, negative (when for example, there are high costs to maintain brand-new medical technologies that are seldom

used), what will remain for the population is a debt that will be paid by their own taxes (Figure 2).

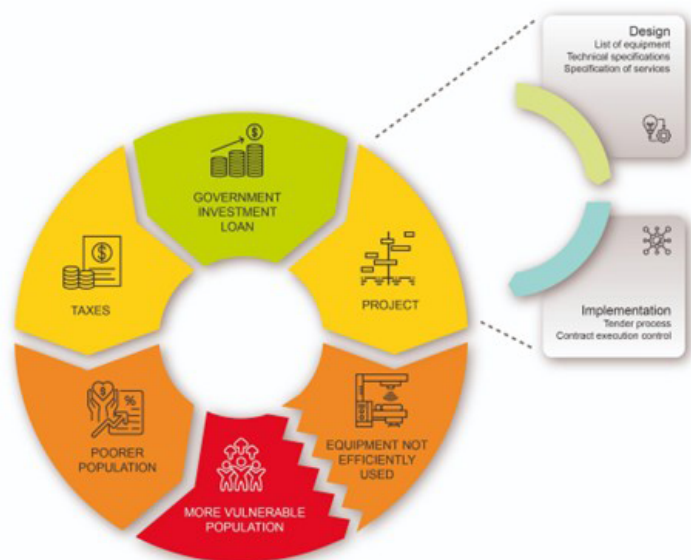


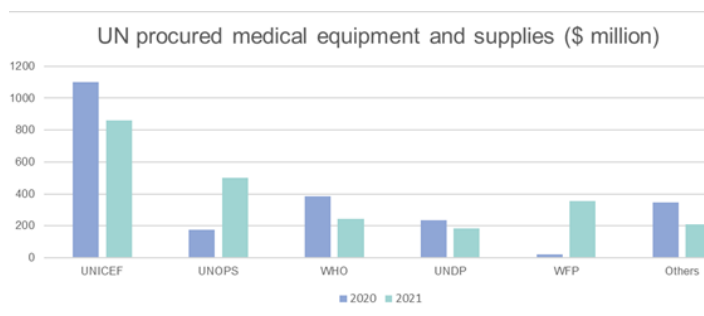
FIGURE 2. Disruption of the virtuous circle of investments in health technology: when quality Assurance/sustainability of the procurement project is lacking, sustainable growth of the population’s health and wealth associated with the project are not guaranteed and often negatively affect the population.

The population subsequently receives fewer benefits, and the economy doesn’t grow as expected based on social determinants of health studies. The lower the income, the worse the health.¹⁴ Therefore, an MD procurement project always impacts the wealth and the health of the population it aims to help. This impact depends on its sustainability.

Being aware of its impact during the project’s planning, design and implementation will improve its sustainability, in fact: *“...Economic growth and increased health spending alone are not enough to scale-up healthcare coverage and achieve better health outcomes. These must be combined with accountability of results, transparent management of public funds, and multisectoral efforts with community involvement at implementation level.”*¹⁵

PRINCIPLES AND DEFINITIONS OF SUSTAINABILITY APPLIED BY THE UNITED NATIONS AGENCIES

In 2015, the United Nations (UN) adopted the SDGs to end poverty and hunger, ensure prosperity for all and protect the environment by 2030.¹⁶ These goals and their targets, especially the third one ‘Good-health and well-being’,¹⁷ serve as a foundation to the MDs sustainable procurement strategies of the UN agencies working in the healthcare sector. UN procurement of medical equipment and supplies amount has grown from \$640 million (average 2013-2019) to \$2.26 and \$2.35 billion in 2020 and 2021.¹⁸ A group of these agencies, the UN Sustainable Procurement in the Health Sector (SPHS), whose objective is to contribute to more sustainable health services and greener economies through sustainable procurement in the health sector, has an estimated annual purchasing volume of \$5 billion in health products which represents the largest market share in the health sector.¹⁹ Therefore, UN agencies are committed to lead by example and may also influence manufacturers and suppliers in the healthcare market toward more sustainable products concerning the SDGs.²⁰ Graph 1 presents the five UN agencies that purchased the most medical equipment in the 2020-21 biennium.



GRAPH 1. Amount of medical equipment purchased by UN agencies in 2020 and 2021 in \$ million. WFP procures mainly food and clinical nutrition supplies that are out of the scope of this article.²¹

UN Agencies sustainable procurement approach

The sustainable procurement of MDs approach is slightly different depending on the specific mandate of each agency. However, the policies of WHO,²² UNICEF,²³ UNDP²⁴ and UNOPS²⁵ all have in common three dimensions

of sustainability: economic, environmental and social which are applicable throughout the life cycle of the MD. Table 1 summarizes the sustainable procurement principles of the four mentioned UN agencies working in the healthcare sector, and details the elements considered for a sustainable purchase. According to the UN agencies' policies, these three dimensions of sustainable procurement must be considered in all phases of the implementation project (program design, budgeting, implementation, and monitoring). The key to a successful project is to plan procurement collaboratively with the relevant stakeholders in the early phases of the project.²⁶

The definitions of sustainable procurement of the UN agencies include three dimensions: an environmental

aspect which focuses on the quality of the MD purchased - its carbon footprint - a social aspect which focuses on the quality of the manufacturing conditions of the MD - the condition of the labor force for its production - and an economic aspect which focuses on the quality of the financial resources allocation - its life cycle cost.

All the UN definitions of sustainability are centered on the quality of the device and the quality of its production and transportation. However, delivering a quality device to a beneficiary is insufficient to ensure sustainability. A sustainable device directly becomes unsustainable if not used because its environmental, social, and economic costs are compared with no benefits as discussed in the following paragraphs.

TABLE 1. Summary of the sustainable procurement principles of WHO,²² UNICEF,²³ UNDP,²⁷ and UNOPS.²⁵

	Economic	Social	Environmental
WHO	Entire life cycle cost. Local communities and small and medium enterprises (SMEs). Promoting sustainability throughout the supply chain.	Human rights and labour issues. Inclusions of persons with disabilities. Gender equality and women's empowerment. Social health and well being.	Prevention of pollution to air, land and water. Sustainable resource use. Climate change mitigation and adaptation Protection of the environment, biodiversity and restoration of natural habitats
UNICEF	Best value for money (price, quality, availability, functionality and innovation). Life cycle costing. Total cost of ownership. Economic development. Employment. Good Governance.	Human development. Education, Social inclusion. Human-labour rights. Poverty and inequality reduction. Security. Promotion of small and medium enterprises (SMEs).	Preservation of natural resources, ecosystems and biodiversity. Reduction of ecological footprint. Reduction of greenhouse gas emissions. Waste management.
UNDP	Costs of products over their entire life cycle (Acquisition, maintenance, operations and end-of-life management costs including waste disposal)	Recognizing equality and diversity. Observing core labour standards. Ensuring fair working conditions. Increasing employment and skills. Developing local communities and their physical infrastructure.	Natural resource use and water scarcity. Emissions. Climate change. Biodiversity.
UNOPS	Local Micro, Medium, Small Enterprises (MSMEs). Total Cost of Ownership (TCO). Long term cost efficiencies.	Local development and resilience. Protection of human rights. Improved labour conditions. Gender equality disability inclusion.	Reduced carbon emissions. Materials to be used in production. Packaging.

UNICEF explicitly includes a “*Definition of Need - Planning supplies with programme specifications*” at the beginning of the procurement process and an “*End-user Utilization - Fit for purpose Impact*” at the end to measure the impact of the purchase.²⁶ Nonetheless, this does not directly link the use of the goods with their sustainability and the design of their requirements.

SUSTAINABILITY LEVELS IN THE IMPLEMENTATION OF A MD PROCUREMENT PROJECT

As discussed previously, the sustainability principles depend on the project results and impact on the health services and can be summarized into different levels. The technical lead can pursue these levels according to their experience, awareness of sustainability principles, and role in the dialogue with the PM and the project stakeholders. It will also be linked to the policy and regulations of the purchasing agency. Local regulations have to be considered as well.

Basic sustainability level: procurement of a sustainable device

This level is the first level of sustainability to achieve and as depicted previously, most of the procurement policies within the UN system are focused on this level to purchase goods produced sustainably. However, owning a sustainable MD does not guarantee *per-se* a benefit for the health services and the population.

Moreover, an environmentally friendly MD purchased at a low price and with high ethical standards that are not used at all, or not appropriately, or scarcely used during all its expected lifetime harms the environment since its environmental cost cannot be balanced with an adequate health and economic benefit. And therefore, it represents a low-quality unsustainable purchase that will damage the financial wealth and thus, the health of the population it intends to benefit.

Intermediate sustainability level: procurement centered on the sustainable use of an MD

Reflecting on the procurement processes during the COVID-19 pandemic, the authors present *three pillars*

that guarantee sustainable use of the procured device and thus contribute to sustainable procurement.

The lessons learned during the assessment of several hospitals in various developing countries show a significant percentage of medical equipment (estimated by the authors to up to 20%) that is not working or not efficiently used. It has been reported that about 40% of donated MDs in developing countries are out of service.²⁸ The main reasons for this situation are: the lack of patients and healthcare resources resulting from a weak needs assessment; inadequate installation of the equipment; absence of funds for consumables, maintenance, and spare parts; lack of experience and training of technicians and healthcare staff; delays in approvals/permissions as per local regulations.

Pictures like the ones shown in Figures 3 and 4 are quite common in developing countries where a significant amount of MDs is not used with high environmental, social, and economic costs.



FIGURE 3. Photos of unused MDs in three different hospitals, the first in the Caribbean, the second in Central Asia and the third in Central America.



FIGURE 4. Pictures of stored new laboratory equipment. The boxes on the pictures were never opened several months after their delivery. The third picture shows equipment waiting for years to be completely installed.

Effective procurement is based on getting the correct goods to meet the functional needs of the beneficiary. That is to say that the planned use of the equipment has to provide planned benefits to the population. In fact, the entire procurement process is based on a needs assessment as its essential starting point. When a procurement process has been carried out transparently, efficiently, and coherently with the objectives, the reliability of the needs assessment is still to be confirmed to get quality results.²⁹

To guarantee that the purchased MDs will be correctly used, the project's technical lead should investigate its intended use by discussing the pretended use of the MD with the beneficiary. Thus, the first pillar of sustainability should be: the needs assessment where the following aspects shall be investigated:

1. The demand - design of the list of MDs to be procured: is there an evidence-based health need that justifies the proposed MD?
2. The intended use - design of the technological level: when the intended use is clarified, it is possible to choose the appropriate technological level of the MD and its accessories.
3. The expected quality/durability - design of technical specifications: by balancing the available budget with the expected quality, the technical characteristics of the goods to be purchased can be designed.

Therefore, an **adequate MD** will result from a procurement process that begins with a needs assessment strongly correlated to the population's health needs through a constructive technical dialogue involving the beneficiary and the clinical end-user.

The needs assessment and the preparation of the equipment list is usually a process carried out before the project starts to estimate the project budget and formalize the agreements between the beneficiary, the donor, and the implementing agency. Nevertheless, it is recommended that this preliminary needs assessment is validated and strengthened by a deeper analysis at the project's start, because the conditions may have changed, and the preliminary needs analysis is usually too quick and does not consider the intended use and the expected durability/quality.

The second pillar of sustainability is the **assessment of existing conditions**.

It is essential to focus on the context where the goods will be used. To this extent, the focus shall be on: (1) the sustainable and safe delivery of the equipment from the fabrication site to the installation site; (2) the infrastructure that will receive the MDs and the design of the interface of the equipment within the existing environment; (3) the interaction of the equipment with other equipment or technologies; and (4) the capacities of the human resources that will use and maintain the MDs.

The result of the assessment of existing conditions is an **adequate delivery and installation plan**.

The third pillar of sustainability is the **assessment of the lifelong use conditions** of the MD. As mentioned before, it is not enough to purchase an adequate MD and install it; a sustainable purchase should also include assessing its useful life conditions. To this extent, the focus shall be on: (1) The adjustment of the equipment's life span based on the project's conditions; (2) The warranty and post-warranty services; (3) The existence of organizational conditions such as trained resources for sustainable use and maintenance of the equipment; (4) The existence of funds for maintenance and consumables; and (5) The existence of a plan for disposal of the equipment.

The result of the assessment of the conditions during the life expectancy of the MDs is an **adequate lifelong use plan**.

Advanced sustainability level: purchasing an MD with a sustainable impact on the health service

When implementing an MD project, it is possible to broaden the framework approach to the national health service level by considering a targeted population and the entire national system of secondary and tertiary care infrastructure. In this broader vision, it is possible to achieve a wider needs analysis during the planning and implementation of a project to adjust the list of the equipment and their characteristics.

Some international procurement processes can be designed to target the population of an entire country so that the needs assessment of the project is focused

on the national healthcare services. In contrast, others are limited to infrastructures of specific regions or sites such as the equipment of a new health infrastructure. In an ideal international procurement project, the technical lead can include considerations on the impact of the purchase of MDs on the entire national health service. In this case, it is recommended for the technical lead to open a dialogue with the National Ministry of Health counterpart and request access to consolidated and updated health statistical data. This represents a challenge since during the implementation of a procurement project, the pressure to comply with the schedule and the budget may limit these kinds of actions and considerations.

Higher sustainability level: Purchasing MDs to increase the sustainability of the health service

The final level of sustainability definition includes the case when an MDs procurement project's objective is to increase the health service's sustainability. Since we are focusing on secondary and tertiary care, this means a more efficient and environmentally friendly way to provide care to patients through innovative technology. Targeting the improvement of health services quality through advancing technical competencies, effectiveness, efficiency, continuity, and safety can be the primary objective of an MDs procurement project.³⁰

New technologies and innovation in the health processes following their introduction in the health service is a major theoretical subject that includes health technology assessment (which is not the focus of this paper). Nevertheless, at least one specific aspect of introducing new technologies is worth underlying: the integration of medical equipment with information technology (IT) systems.³¹ This interface is an aspect that deserves to be further discussed since it has several well-known clinical benefits and improves workflow and efficiency.

IT systems produce a large amount of data that can be used for future needs assessment. Therefore, as a valuable side effect, the digitization of health services in developing countries will bring the decision-makers the data needed for evidence-based strategic investment decisions.

Projects that want to strengthen the sustainability of health services through medical technology procurement

cannot be considered pure MDs procurement since other soft components such as "change management" are essential for their successful implementation, which usually is spread over several years and requires a joint effort of the beneficiaries with the implementing agencies.

CONCLUSION

There are different definitions of sustainability in MD procurement within the UN system. The definitions used by the four main agencies in health procurement (UNICEF, UNOPS, WHO, and UNDP) are centered on environmental, social and economic sustainability, in the sense of the environmentally friendly quality of the MD, the socially acceptable conditions of its production and its economic impact on local communities.

Nevertheless, the attention to the long-term use of a MD is essential to its sustainability and will be achieved by considering aspects related to environmental, social, and economic development in addition to its impact on health services.

Selecting equipment that meets the beneficiary needs, the human resources capacities, and the local infrastructure conditions while considering its lifelong use brings to the health services much more benefits and is more sustainable than focusing only on the quality of the equipment itself. The technical lead in a procurement project is responsible for introducing and strengthening the analysis of the needs, the local conditions, and the conditions that can guarantee optimal use of the equipment during its lifespan. These analyses are the foundation that will guarantee a sustainable and efficient design of the equipment list, the technical specifications, the installation and training requirements, and the post-sales services, all in line with local conditions and capacities. No solution fits all. Each MD procurement project should be tailored to the local situation and the project's framework.

In an internationally funded project, the technical lead working for the implementation agency must establish a technical dialogue with the beneficiary to understand local needs and peculiarities and propose tailored solutions based on international sustainable standards adapted to the context. This technical dialogue is also a key factor for

knowledge transfer and will strengthen the local technical capacities to plan new projects.

Once the needs assessment is completed, the project's objective will be defined; therefore, all the effort during the implementation phase should be spent on keeping coherence with the specified objective. Once the project is completed, measuring the impact of the MD purchase on health services by determining how much of the project's aim has been achieved will provide lessons learned to guide future purchasing projects. Examples of "outcomes performance indicators include cost effectiveness, compliance level, and client satisfaction and service leadership."³²

Considering a project's critical factor (correlation between the invested amount of money and the impact on the healthcare system) means investigating the needs, planning the objectives, and quantifying the outcome. Therefore, evaluating the project's sustainability as the gain produced by its implementation is possible. A critical factor with a positive impact can be achieved by ensuring that the project's objectives are built on the available country's evidence data to reach a planned outcome that can be measured at the end of the project. This implies a deep technical dialogue with the local beneficiary and will enrich the beneficiary's technical capabilities and the knowledge of the implementing agency about the local situation.

The SDGs can therefore be achieved by maintaining a strict coherence between any project's objective (or intended outcome) and the activities during its implementation. Careful planning addressing sustainability issues before the execution of the project is a fundamental recommendation. Still, in practice it often conflicts with the schedule and pressure to implement the project within a specific timeframe linked to the loan and political conditions.

On the other hand, investments in capacity building, health technology management and infrastructure could significantly improve existing medical equipment efficacy in a sustainable way, saving the costs of production and shipping of new equipment.³³ according to UNDP, "*in order to preserve a healthy environment and human well-being, there is a recognized need to move away from overconsumption, waste and ecological harm*"³⁴ which is

especially true and applicable in the context of MD sustainable procurement.

CONFLICT OF INTEREST

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

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