Access to Medical Devices In Low-Income Countries

Addressing Sustainability Challenges In Medical Device Donations

As leaders in health care in the United States, we know that supply chain plays a significant role in maintaining quality operations. This is equally, if not more, important when we are working/partnering in low-resource settings.

We are excited to share with you the release of the National Academy of Medicine Perspectives paper: Access to Medical Devices in Low-Income Countries: Addressing Sustainability Challenges in Medical Device Donations. *The paper was developed through the National Academy of Medicine's Forum on Public Private Partnership for Global Health and Safety's workgroup on medical device donations.*

As you will see, there continue to be issues with medical donations that hamper the quality of operations in low-income countries and settings. As we continue the healing ministry handed down to us over the centuries, this perspective paper points out some of the key issues that need to be addressed, suggests where additional data needs to be collected and provides an opportunity for Catholic health care to be leaders in quality at home and around the globe. — BRUCE COMPTON

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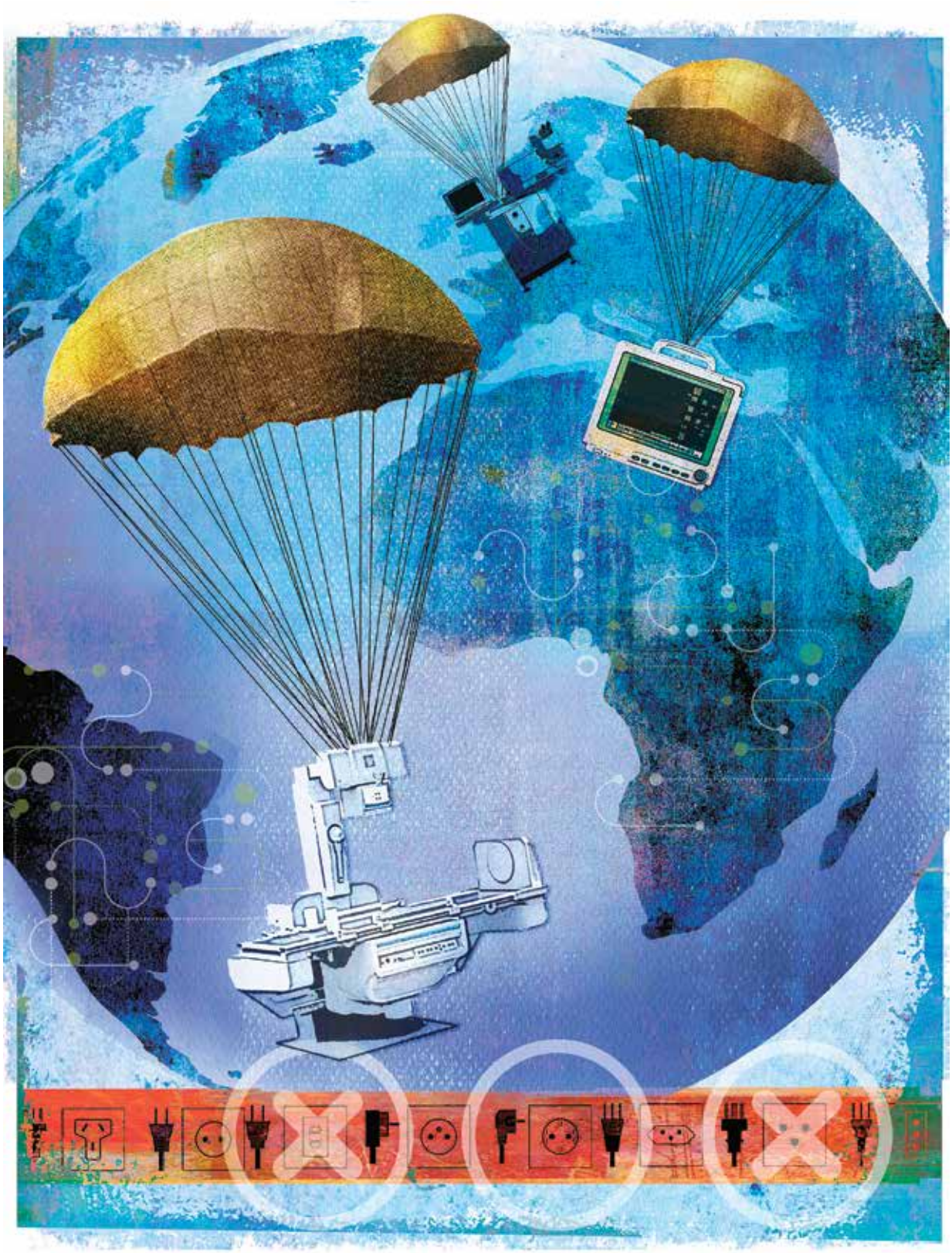
INTRODUCTION

In eastern Uganda, a regional hospital receives a much-needed donation: an X-ray machine that appears to be in good working condition upon arrival. The hospital staff quickly puts the machine to use, only to have it fail during a procedure. With no trained biomedical technicians at the hospital, the machine sits unused for months. Eventually, an available technician is located in Kampala. He travels to the hospital and examines the machine, identifying the replacement part that is likely needed, but he cannot verify the part without the machine's accompanying manual. The hospital finds the new part to be more costly than anticipated and must be special ordered because it is not available in the country. When balancing the costs against the other demands on its limited budget, the hospital administration regretfully decides it cannot afford to spend time and money on securing the new part. Despite the need for its services, the X-ray machine remains out of use.



Medical devices (the terms "medical device" and "medical equipment" are used interchangeably here) like the X-ray machine have been deemed essential to health care systems in the prevention, diagnosis, and treatment of illness and disease for all populations. The advances and innovation of medical devices over time have improved accuracy, efficiency, and efficacy within health care systems, allowing people to live longer, healthier lives. However, health systems in low-income countries (LICs) often have limited access to even seemingly commonplace medical devices (the authors chose to direct their discussion toward low-income countries due to the greatest need for medical device donation in these settings). As a result, these countries rely heavily on donations, with some LICs receiving donations that make up 80 percent of their supply of medical devices.[2] While most donations are given with the intent to strengthen health systems and improve the well-being of the populations being served, an estimated 40 percent of donated medical equipment in developing countries is out of service.[3] As the example from Uganda illustrates, this mismatch between intentions and usability results from breakdowns that can occur at many points in the complex system of donations.

As countries evaluate the capacity of their health systems in response to the United Nations Sustainable Development Goals,[4] the lack of available appropriate medical devices and the impact on health outcomes in LICs are put into clearer focus. Health systems depend in part on a supply chain that ensures access to high-quality, safe, and reliable medical products (http://www.wpro.who.int/health_services/health_systems_framework/en). If the supply chain, which is inclusive of all activities and resources involved from acquisition to delivery, results in medical devices that are unusable or inappropriate to treat patients, then the health system is disadvantaged — impeding the delivery of the highest quality of care. In LICs, health systems are often less equipped to handle any breakdown in the supply chain. In these countries, the donation of medical devices that are inappropriate or unusable can be costly, burdensome, and potentially detrimental to the health system that it is purporting to aid.

To increase the percentage of donated medical devices that succeed in strengthening the capacity of health systems in LICs, we, the authors of this paper, have identified three key areas for further exploration and research: quality and appropriateness of the donations, sustainability after the donation is made, and visibility of the flow of donations globally.

In this paper, we aim to:

1. describe the major identified barriers impacting these three areas,
2. acknowledge existing guidance that has been developed to address them,
3. introduce approaches employed by donors based on existing guidance or experience, and
4. recommend targeted action to improve the system of donations overall.

KEY BARRIERS TO SUCCESSFUL DONATIONS

Several barriers preventing high-quality and appropriate donations, the sustainability of donations, and the optimization of donations have been identified.

There is often a mismatch between the types of equipment that are needed or usable and those that are received.

In addition to getting donations that are faulty or nonfunctioning, hospitals may receive donations that they already carry in surplus or cannot accommodate because their facilities do not meet the initial mandatory device requirements, such as a running supply of distilled water or a supply of oxygen. Equipment may be sent with operating manuals in languages that are unfamiliar to recip-

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ients or without instructions altogether. Equipment also may be given without crucial parts or consumables that are specific to the device and are unavailable, or difficult or costly to obtain in the receiving country.[5] Sometimes hospitals receive a much-needed device as a donation, but during setup and testing, hospital staff realize that the electrical plug needed to run the device is incompatible with their country's electrical outlets. Even more problematic are devices that do not align with the frequency or voltage capacity of recipient facilities. These types of issues may seem minor but will be an ongoing cost to the hospital in time and resources, and sometimes prevent the use of donations altogether.

Keeping a donation in use largely depends on whether the recipient's setting can sustain the long-term operations and costs of the device.

Long-term needs include maintenance and management systems to use donated equipment, sufficient financing to operate and maintain it, adequate infrastructure, supply of consumables, and trained equipment users.[5] In LICs, these needs often go unmet and consequently become significant barriers to the sustainability of donations. Another barrier to sustainability is the lack of local biomedical technician training, leading to a shortage of individuals in the health system adept at using, maintaining, or repairing equipment. Health systems that offer biomedical technician training to build a workforce skilled in medical device maintenance and repair means a greater likelihood that equipment will be in service more often and last longer. Tools and resources, such as a skilled biomedical workforce, are needed in country to sustain donations. Without this ensured sustainability, the value of donations is diminished.

Equipment that is unsustainable will remain unused and must be disposed of, but often, health systems have no established process or dedicated funding for disposal.

In 2010, medical equipment was in high demand in Haiti after a disastrous earthquake hit the region. Donations of medical devices, both new and used, arrived quickly to aid hospitals in treating the flood of patients that came with the destruction. The need for medical equipment existed, and donors responded, intending to provide some relief to the country's overextended hospitals. However, months after the earthquake, a visit to one hospital receiving donations uncovered a bleak scene. A hospital administrator opened a door to a large storage room to reveal stockpiles of abandoned medical equipment. The hospital deemed the equipment useless, sent by donors either damaged or unsupportable given the hospital's resources. The administrator disappointedly admitted the hospital's inability to spend spare funds to dispose of the equipment, so it remained as waste. For this hospital, the donations were an overwhelming burden, with few good donations being delivered at the cost of disposal for countless other donations. Adding to the general difficulties of disposal are environmental concerns, including those surrounding equipment containing toxic components. Those disposing of equipment must also consider patient concerns. Equipment may store a patient's medical information and therefore must be disposed of appropriately to maintain their privacy. Issues around disposal can go beyond being burdensome to causing harm to the environment, patient, and health system.

Donors and other stakeholders have limited access to information about the global donation landscape and, as a result, are unable to maximize the health impact of their donations.

The barriers mentioned above focus more on the difficulties experienced by recipient stakeholders, but there are a number of stakeholder groups involved in the medical device donations ecosystem. Each of these stakeholders affects or is affected by donation issues. Stakeholders approach the donations system in various ways, setting different objectives for donations based on incentives and expertise. As a result, each encounters different challenges, including challenges in the relationships between stakeholders due to a lack of information and communication. Among the considerable challenges shared by stakeholders are the lack of understanding on the part of each stakeholder of the larger donation landscape, of each stakeholder's roles and responsibilities, and of the role of donations at a global level. These challenges result from a general lack of information on the global supply and demand of donations, such as the identification of the most prevalent types of donations and the

countries that send or receive donations. Information on the flow of donations globally grants a visibility that can assist stakeholders in focusing their efforts, allowing them to optimize the health impact of their donations.

Existing Guidance and Approaches for the Donation of Medical Devices

Stakeholders may consult existing guidance on donations to develop or improve their understanding and approaches in ways that address some of the recurring barriers in the donations system. A number of guidelines, checklists, and frameworks have been developed to steer donors and recipients from procurement to donation. Guidance has primarily focused on two areas: 1) informing donors of best practices, helping them overcome established challenges when donating medical equipment to LICs and 2) empowering and equipping recipient organizations and local public-sector actors in the decision-making process of accepting or declining donations. Prominent guidance has come from the World Health Organization (WHO), the Catholic Health Association of the United States (CHA), MedSurplus Alliance (MSA), Partnership for Quality Medical Donations (PQMD), and Tropical Health Education Trust (THET).

Over a decade ago, WHO first published guidance on medical equipment donations. WHO prepared this guidance in close collaboration with a number of national and international organizations from both high- and low-resource settings. To ensure improved access, quality and use of medical devices globally WHO updated the guidance in 2011 as part of a technical series on medical device issues. The guidance now offers considerations and best practices that may be useful for both donors and solicitors of equipment donations.[6] More recently, WHO has produced guidance for countries regarding the development of regulatory standards for medical devices. The 2017 Global Model Regulatory Framework for Medical Devices recommends guiding principles and harmonized definitions and specifies the attributes of effective and efficient legally enforceable regulation.[7]

CHA surveyed stakeholders at recipient hospitals, health systems, and medical supply recovery organizations (MSROs) to gather input on best practices, determine the greatest advantages of

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a surplus donation program, and identify additional areas of improvement in the relationships between hospitals and MSROs. The research resulted in a framework of leading practices for use at the hospital and health system levels to increase the quality and appropriateness of medical surplus donations.[8]

Using external assessments and the knowledge and experience of its membership, PQMD has provided practical advice for donors and distributing partners on managing the supply of medical product donations in a manner consistent with WHO Guidelines for Drug Donations. The PQMD guidelines focus on products donated from an original manufacturer directly to a nongovernmental organization (NGO) partner.[9,1]

The MSA has developed and adopted guidelines in the form of a code of conduct and toolkit geared toward MSROs but promoted to other stakeholders as well. The code of conduct comprises voluntary standards of practice to guide the operations and decision making of MSROs. The toolkit provides supporting guidance through examples of best practices and other resources to help MSROs understand and follow the code of conduct. Additionally, an MSA accreditation program gives MSRO members the opportunity to assess their adherence to the code to improve donation practices.[10]

Using prior research and case studies, THET has created a toolkit for the United Kingdom and developing countries engaged in health partnerships. The toolkit offers practical guidance on supplying and shipping medical equipment donations, ensuring donations are put into effective

use, and maintaining donations for long-term use. THET aims for the toolkit to guide both donors and recipients on the donation process, but the resource has a stronger focus toward donors, given that logistics and regulations of donations vary by recipient country.[5]

Guidelines, like those mentioned, offer information and best practices for various stakeholders to approach and evaluate how to send and receive usable donations. However, for the guidelines to have an impact on the donations system, each individual stakeholder will need to contextualize them for their specific organization. As stakeholders approach the donations process and apply existing guidance in different ways, perhaps lessons can be learned from how the following individual companies consider equipment donation.

Global medical technology companies such as Becton, Dickinson and Company (BD) and Medtronic are active medical equipment donors and member organizations of PQMD. (In addition to developing donation guidelines, PQMD is a membership organization. It is composed of different stakeholders in the donations ecosystem in order to facilitate collaboration among members through knowledge and experience sharing: (https://www.pqmd.org/). In its mission to provide quality health care for vulnerable populations and to improve patient outcomes, BD approaches its medical equipment donations with attention to sustainability. When considering equipment or instrument donations in a particular country, BD first works with an NGO partner to conduct a needs assessment to determine suitability. During this stage, BD ensures that the necessary technical support is in place in the event the equipment will require maintenance or replacement of parts. In managing the donation process, BD treats the recipient as a customer, setting up a two-year customer service agreement for applicable donations. Building the service agreement into the donation streamlines the process for the end user in the event that a technician is needed to make equipment repairs. BD's service agreement typically includes a requirement for it to donate the materials (e.g., reagents) necessary to operate the product for two years, mitigating any possible interruptions in the use of the product that may be due to a lack of consumables. BD's Social Investing Department covers the cost of the equipment and the service agreement.

At Medtronic, organizations requesting product donations for delivery outside the United States must complete a form of eligibility and sign a certificate of compliance to be considered as a potential recipient. Both requirements reference product sustainability. The eligibility form asks organizations if local physicians are adequately trained to provide patient follow-up care. The certificate states that the requestor must guarantee the ongoing maintenance of any equipment received, appropriate product storage controls, and the presence of quality and safety measures on-site (http://www.medtronic.com/us-en/about/corporate-governance/medtronic-charitable-donations/donation-request-forms.html). Medtronic also works closely with donation partners — Americares, Direct Relief, and MedShare — to distribute product donations to nonprofits and clinics globally (http://www.medtronic.com/covidien/en-us/support/us-customer-service/product- donations.html).

The GE Foundation, the philanthropic arm of General Electric, is also thinking critically about the sustainability of medical equipment in low-resource settings. In 2004, GE Foundation established the Developing Health Globally™ program, which works to improve access to quality health care for vulnerable populations. The program supports capacity building by upgrading equipment and infrastructure and providing ongoing training and support in country. All equipment upgrades are carefully managed through comprehensive service contracts and training at the facility level to account for sustainability. GE Foundation partnered with Assist International, Engineering World Health, and the Developing World Healthcare Technologies Lab at Duke Uni-

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versity to develop an evidence-based curriculum for biomedical equipment technicians that can be used in local training programs. In collaboration with ministries of health, the program has established in-country training programs in Cambodia, Ghana, Honduras, Nigeria, Ethiopia, and Rwanda, and provides ongoing resources to foster a professional community of biomedical technicians. Furthermore, the GE Foundation partnered with the AAMI (Association for the Advancement of Medical Instrumentation) Foundation to develop recommendations for a scalable, replicable, and sustainable model to train biomedical equipment technicians in low-resource settings.[11] Recently, as part of the Safe Surgery 2020 commitment,[12] GE and partners coordinated with the Ethiopian Federal Ministry of Health and regional health bureaus in the Ethiopian cities of Amhara and Tigray to install ultrasound machines, anesthesia machines, and patient monitors. In considering the proper management of medical devices, program partner Assist International conducted user training with clinical care providers and biomedical equipment technicians, among others. All of the products will be monitored over a three-year period, in partnership with GE Healthcare.

A Direction Forward: Addressing Knowledge Gaps and Identifying Solutions.

The capacity of health systems in LICs relies partly on the donation of medical devices to determine the level and quality of care provided to their populations. However, significant barriers to the usability and sustainability of donations persist, disadvantaging health systems. Creating an effective medical device donations system, where needs are met and failures in donated equipment are minimal, requires a whole systems approach. Applying this approach will take time and significant resources, but meanwhile, stakeholders can still work to identify interventions and solutions that can be easily developed and implemented to target parts of the health system that are ripe for improvement. For example, one often-cited barrier to the sustainability of medical device donations is the lack of technical expertise to use, maintain, and repair donated devices. Innovative solutions can be developed to target training on managing donated devices for engineers, technicians, and users. These solutions could strengthen the health system more broadly by building capacity to not only maintain donated equipment, but also increase capabilities to service new technologies. Stakeholders may also identify opportunities where solutions can be integrated into other health system priorities and initiatives — for example, addressing health system infrastructure capacity such as the development of safe surgery facilities to support the use of donated equipment. Another low-hanging opportunity lies in educating those stakeholders that are not directly involved in making or procuring donations, so they are aware of the extent and nature of donation issues. Increasing their understanding of the issues can help to build interventions and solutions could expedite improvements in the medical device donations system.

To offer effective feedback, recipients must first feel empowered to make decisions based on their interests, which may include declining donations.

While these small-scale solutions are being piloted, the larger field of medical device donations must advance a global research initiative to improve the understanding of the donations system landscape among all stakeholders, illuminate the specific needs across countries and regions, and identify potential system-level interventions. There are several key gaps in knowledge that a global research initiative may explore to better understand and address the most prevalent barriers to the medical device donations system, including:

Evaluation of the efficacy and impact of guidance for donors and recipients at a global, country, or organizational level.

Assessing the efficacy and impact of existing guidance may generate best practices that allow future donors and recipients to steer their relationship in a manner more conducive to evaluation. Such evaluation may subsequently lead to improvement in the quality and appropriateness of donations. A critical piece of this evaluation would be obtaining feedback from recipients on

what devices are needed prior to donation, what donations are usable or nonfunctioning after they are received, and when donations are not wanted altogether. Recipients may not have the opportunity to provide feedback, or they may be hesitant to be forthright out of concern of losing donations altogether or fear of damaging the relationship with a donor. To offer effective feedback, recipients must first feel empowered to make decisions based on their interests, which may include declining donations. Empowering recipients to have a voice and take action to benefit the populations they serve is an important part of the process of evaluation. Empowerment and feedback are complicated issues to address, but stakeholders must begin to work through these issues to fully discern the value and suitability of guidance for different stakeholder groups. For donors, as an important first step in evaluating whether existing guidance is useful for their operations, they must critically review their donation practices against existing guidance to determine where they are meeting the standards or falling short.

Data collection may also be used to isolate trends and identify gaps in health care. This evidence can serve to build interest at the local, regional, or country level in integrating medical equipment needs into the planning of the health system.

Routine collection of data on the effects of donations on recipients at all levels of health care delivery.

Routinely reviewing the effects of donations may have broad consequences in determining their value and health impact. Data can indicate whether a donation is put to use and its level of benefit or harm. For example, a donation may be beneficial in treating a population but may be too costly for hospital administration to maintain, decreasing the likelihood that the donation will be sustained. Data can be collected to evaluate the costs incurred in making donations, receiving donations, and disposing of donations. This data can build research around the economic impact of failed donations, which stakeholders can then use to justify improvements to their donation processes. Data may be conveyed to donors to highlight the need for increased assessment of their donations, to better ensure that the donation is high quality, appropriate, and valuable to the recipient's setting. Donors may also use data in their donation strategies to maximize benefit and minimize cost to the recipient, ultimately increasing the prospects for sustainability. Data collection may also be used to isolate trends and identify gaps in health care. This evidence can serve to build interest at the local, regional, or country level in integrating medical equipment needs into the planning of the health system. Identifying which equipment is most valuable to the specific health needs of a setting and building the health system with that knowledge may increase the number of lives saved or improved. Obtaining recipient feedback is a critical factor in accurate data collection, alongside strengthening the capacity of hospitals or health centers in developing countries to have the systems, infrastructure, funding, or trained staff in place to monitor, collect, and transfer data.

Country-specific information on medical device donations.

Understanding a country's existing policies on donations can illuminate some of the incentives for making donations that are specific to the country, as well as the barriers that prevent effective and sustainable donations. Making country-specific information clear and available to stakeholders can result in better coordination between donors and recipients to accommodate barriers. It can also result in better coordination to develop country-specific solutions to those barriers, so the quality of donations is not compromised. Having information up front on a country's policies and process for donations, including the types of donations that are allowed, reduces waste in country and reduces inefficiencies for the donor. This information can also push countries to address major barriers, such as difficulties with infrastructure and supply chains, inadequate health system policies on the ground, and weak procurement and regulatory systems.

Information on the global supply and demand of medical device donations.

While country-specific information is needed, global visibility on where donations are needed, going to, and coming from is also imperative. This information informs donors, MSROs, and other stakeholders on the donation- making side about where to focus their efforts. Mapping the supply and demand of donations can shed light on the types of donations that are most prevalent and those that are scarce. This kind of visibility can be useful in managing and optimizing the flow of donations so that dissemination of donations is more equitable and donors can respond to equipment needs more quickly and appropriately. Greater access to this kind of information could increase coordination among multiple donors and recipients, and invite participation from new donors to fill gaps in supply. Increased transparency could also allow donors to pool resources for securing equipment that is most in demand, and for supporting the creation of a supply depot that can provide replacement parts and group trainings to fix commonly encountered issues with the most used medical devices. In the end, global visibility is needed for a whole systems approach to donations. A whole systems approach recognizes that different stakeholders manage different components of the donations system, but each component affects and influences the others. A whole systems approach requires integration and coordination among the strategies of all stakeholders, and this cannot be achieved without increased global visibility.

Ultimately, we, the authors of this paper, encourage stakeholders in the medical device donations ecosystem to take steps now to develop and implement smaller scale innovative solutions that may tackle some of the recurring challenges in making and receiving donations. While these steps are underway, we call for a broad effort to further research the quality and appropriateness, in-country sustainability, and global visibility of all medical device donations. We call for in-depth research in these areas to improve the process and outcomes of the medical device donations system, to strengthen health systems, and, more broadly, to support the health and development of receiving LICs.

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