World Health Organization

Medical device donations: considerations for solicitation and provision

Second edition

WHO Medical device technical series

2011

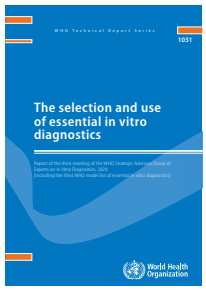
2022

2017

Regulation

2023

Medical devices



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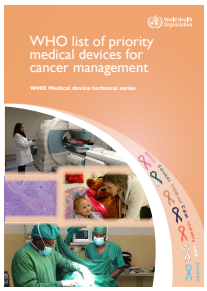

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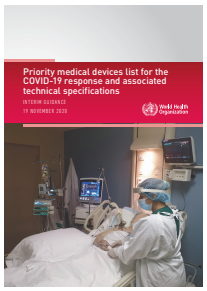

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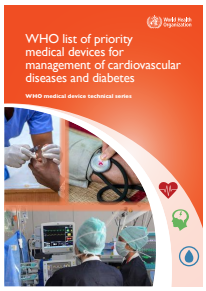

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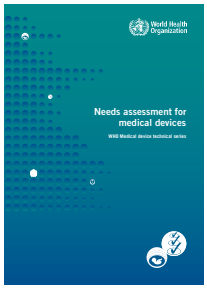

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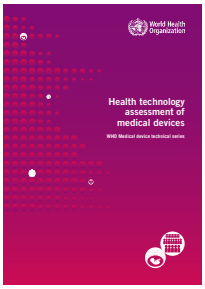

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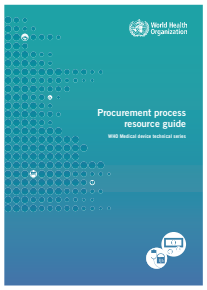

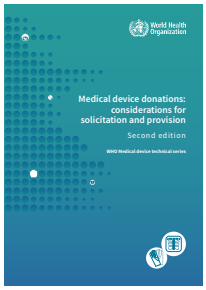

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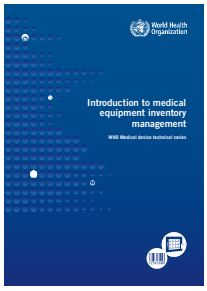

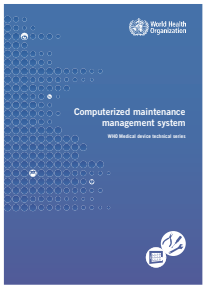

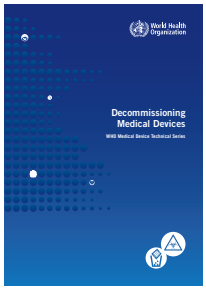

2011* 2011 2011* 2019

* To be updated in 2024

World Health Organization

Medical device donations: considerations for solicitation and provision

Second edition

WHO Medical device technical series

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Preface

Health technologies are essential for the functioning of health systems. Medical devices in particular are crucial for the prevention, diagnosis and treatment of illness and disease and for patient rehabilitation. In recognition of the important role of health technologies, the Sixtieth World Health Assembly in May 2007 adopted resolution WHA60.29, which addresses issues arising from inappropriate deployment and use of health technologies and establishment of priorities in their selection and management, specifically for medical devices. In adopting this resolution, Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise into the field of health technologies, in particular medical devices; and requested that WHO take specific actions to support Member States in this regard.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies", also during emergencies. To meet this objective, WHO and partners have devised an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents developed for use at country level. The series comprises the following subject areas:

- Development of medical devices policies (2011) *(1)*;
- Global model regulatory framework for medical devices, including IVDs (2017, 2023) *(2,3)*;
- Health technology assessment *(4)*;
- Health technology management:
  - needs assessment for medical devices *(5)*;
  - medical devices donation *(6 and this document)*;
  - medical device procurement *(7)*;
  - medical equipment inventory management *(8)*;
  - medical equipment maintenance *(9)*;
  - computerized maintenance management systems *(10)*;
- Decommissioning medical devices *(11)*;
- Lists of priority medical devices in the Medical Devices information system (MeDevIS) *(12)*:
  - for reproductive, maternal, newborn and child health;
  - for management of cancer diseases;
  - for management of cardiovascular diseases;
  - for COVID-19;
  - for eye care; and
  - for trauma and emergency surgery kit.

These documents are intended for use by any organization, expert or practitioner involved in the design, assessment, donation, procurement, management, maintenance or disposal of medical products and technologies, including health workers, biomedical engineers, health managers, policy-makers, donors, nongovernmental organizations and academic institutions involved in health

technology at district, national, regional or global level to meet the objectives of the WHO Global initiative on health technologies.

The best practices and considerations proposed in this document are intended to improve the quality of medical devices donations, including medical equipment, single-use medical devices and in-vitro diagnostics, to provide maximum benefit to all stakeholders. The considerations can be used to develop institutional or national policies and regulations for medical devices donations. Although the considerations can be applied anywhere, they may be especially useful for health systems in low- and middle-income countries (LMIC), which often depend on donations.

Acknowledgements

The World Health Organization (WHO) is grateful to the many biomedical and clinical engineers and medical devices regulatory experts and experts in health technology management and international cooperation, who provided input to the update of the original guidance on medical devices donations, particularly, during the COVID-19 pandemic, in 2021 and 2022: Cathy Blanc-Gonnet, Clarisse Delaspre, Émilie Durand, Benoît-Pierre Ligot, Gabrielle Morel de la Pomarède, members of Humatem, a nongovernmental organization in official relations with WHO; Dinsie Williams, Sierra Leone; Josee Hansen, WHO consultant on regulation of medical devices; Maurice Page, France, for his expertise in francophone African countries; Laura Lopez,[1] Mexico, clinical engineer; and Sasikala Thangavelu, biomedical engineer, former director of the National Regulatory Agency of Malaysia.

The following WHO staff reviewed the text and provided input: Ying Ling, Agnes Kijo, Alejandra Velez and Adriana Velazquez. WHO staff in the regional offices who provided input were Tifenn Lucile Marie Humbert from the WHO Regional office for Europe and Mohamad Wehbi from the WHO Regional Office for the Eastern Mediterranean. Complementary comments were received from Claudio Meirovich, WHO consultant, and Cathy Blanc-Gonnet at Humatem in a second round of revisions.

In August 2023, the document was presented to the members of the Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV[2]). The members of the Group are: Millicent Alooh, NEST360 and Association of Medical Engineering of Kenya, Kenya; Mulugeta Mideksa Amene, biomedical engineering consultant to UNICEF Middle East and North Africa, Ethiopia; Razan Asally, Saudi Food and Drug Authority, Saudi Arabia; Bukhari Tazeen Bukhari, biomedical engineer, Pakistan; Bukola Esan, EBME Engineering Ltd, Nigeria; Pedro Galvan, Health Science Research Institute, German-Paraguayan University, Paraguay; Susan Horton, University of Waterloo, Canada; Mouna Jameleddine, Health Technology Assessment Department, National Authority for Assessment and Accreditation in Healthcare, Tunisia; Tom Judd, Global Clinical Engineering Alliance, United States of America (USA); Brendon Kearney, University of Adelaide, Australia; F. Selcen Kilinc-Balci, National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, United States Centers for Disease Control and Prevention, USA; Dimitra Lingri, European Healthcare Fraud and Corruption Network, Greece; Duncan McPherson, Portsmouth Hospitals University, United Kingdom of Great Britain and Northern Ireland; Placide Muhayimana, Rwanda Food and Drugs Authority, Rwanda; Bousso Niang, Ministry of Health and Social Action, Senegal; Johnes Obungoloch, Faculty of Applied Sciences and Technology, Mbarara University of Science and Technology, Uganda; Maurice Page, Physicien Medical Sans Frontières, France; Ana Pérez Galan, Hygiene Institute, University of the Republic of Uruguay, Uruguay; Ledina Picari, Medical Devices and Cosmetic Products Unit, Ministry of Health and Social Protection, Albania; Khondkar Siddique-e Rabbani, Department of Biomedical Physics and Technology, University of Dhaka, Bangladesh; Madan M. Rehani, Global Outreach for Radiation Protection, Massachusetts General Hospital, USA and India; Sandy Rihana, Biomedical Engineering Department, Holy Spirit University of Kaslik, Lebanon; Elana Robertson, Global Health Innovation XCHANGE, Washington Global Health Alliance, USA and South Africa; Subramaniam Sathasivam, consultant physician, Malaysia; Jitendra Sharma, Andhra Pradesh MedTech Zone, India; Sanjita Sharma, Ministry of Health and Population, Nepal; Mery Vidal, Peruvian Association of Clinical Engineers, Peru; Woei Jiuang Wong, Medical Devices Cluster, Health Products Regulation Group, Health

[1] Deceased during the COVID-19 pandemic.

[2] Strategic Advisory Group on Medical Devices and Health Technologies (STAG MEDEV). Geneva: World Health Organization; 2024 (https://www.who.int/groups/strategic-and-technical-advisory-group-of-experts-on-medical-devices-(stag-medev).

Sciences Authority, Singapore; and Kun Zheng, Governance Risk and Compliance, Children's Hospital, Zhejiang University School of Medicine, China.

Observer to STAG MEDEV: Umberto Vitale, biomedical engineer, United Nations Office for Project Services, Denmark.

In October 2023, WHO commissioned the Intelligent Health Technology laboratory team at the University Campus Bio-Medico of Rome, Italy, to address all the comments of the Strategic and Technical Advisory Group on Medical Devices and to complement and update the references. The collaborators on this team were: Lemlem Degafu, Nahimiya Husen Ibrahim, Leandro Pecchia, Davide Piaggio, Nathan Samuel Ullman and Marianna Zarro.

Updating of the publication was coordinated by Adriana Velazquez Berumen, team lead for medical devices and in vitro diagnostics, WHO, who also drafted some sections.

All the collaborators involved in development of this document made declarations of interests, which were assessed by WHO staff, who found no conflicts that would disqualify them from participation.

Abbreviations

COVID-19	Coronavirus disease 2019
IVD	in-vitro diagnostic medical device
LMIC	low- and- middle- income countries
NRA	national regulatory authority
STAG MEDEV	Strategic and Technical Advisory Group on Medical Devices

Glossary

The terms listed below are defined here as used in this technical series.

Biomedical engineer	Biomedical engineering is considered to be the profession responsible for innovation, research and development, design, selection, management and safe use of all types of medical devices, including single-use and reusable medical equipment, prosthetics, implantable devices and bionics *(13)*. According to the International Federation of Medical and Biological Engineers, a nongovernmental organization in official relations with WHO that represents the professional and scientific interests of 59 national member societies, a biomedical engineer is defined as follows *(14)*: > Medical and biological engineering integrates physical, mathematical and life sciences with engineering principles for the study of biology, medicine and health systems and for the application of technology to improving health and quality of life. It creates knowledge from the molecular to organ systems levels, develops materials, devices, systems, information approaches, technology management, and methods for assessment and evaluation of technology, for the prevention, diagnosis, and treatment of disease, for health care delivery and for patient care and rehabilitation. Biomedical engineering includes medical engineers, clinical engineers and related fields as categorized in different countries across the world. Clinical engineers include those that manage medical devices in health care settings.
Biomedical engineering technician or technologist	A front-line practitioner responsible for daily maintenance and repair of medical equipment in hospitals, who has a specified minimum level of expertise. Those who work exclusively with complex laboratory and radiological equipment may become certified in their speciality without more general professional engineering requirements. The difference between a technician and a technologist is in the level and the number of years of training. Technicians are usually trained for 2 years and technologists for 3 years, although the length of training may differ by country *(13)*.
Consumable	Item that is used only once in combination with medical devices and is not reused, such as pipette tips or strips in in-vitro diagnostics medical devices (IVD) *(15)*, as well as items used in the operation of medical devices such as disposable electrodes for an electroencephalogram or filters for oxygen concentrators.
Donation	Provision of medical devices by a corporation, charity or other legal entity (e.g. not-for-profit charitable, educational, research, religious, health or public service organization), with no financial commitment from the recipient or any other material or immaterial value return from the recipient to the donor.

Donor	A government, nongovernmental organization, corporation, charity, individual or other legal entity that makes a donation.
Health technology	Application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve the quality of life. The term is used interchangeably with "health-care technology" *(16)*.
Medical device	Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, in human beings for one or more of the following specific medical purposes: • diagnosis, prevention, monitoring, treatment or alleviation of disease; • diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury; • investigation, replacement, modification or support of the anatomy or • physiological process; • supporting or sustaining life; • control of conception; • cleaning, disinfection or sterilization of medical devices; • providing information by means of in vitro examination of specimens derived from the human body. (definition finalized by the Global Harmonization Task Force in May 2012 and now archived under the International Medical Device Regulators Forum) *(17).*
In vitro diagnostic medical device (IVD)	A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status. In some jurisdictions, certain IVD medical devices may be covered by other regulations *(18)*.
Life cycle	All phases in the life of a medical device, from conception to decommissioning and disposal *(19)*.
Recipient	A legally established organization that is responsible for consent to and acceptance of a donation

Executive summary

Medical devices are crucial for the prevention, diagnosis and treatment of illness and diseases and for patient rehabilitation. Many low-income countries depend on donations to improve access to and the quality and use of medical products and technologies, especially during emergencies.

WHO developed guidance on medical device donation in 2011, which has been now reviewed, with new evidence, new references on considerations for medical device solicitation and provision, risks associated with inappropriate donations, the responsibilities of donors and recipient, and the steps they should follow before, during and after a donation.

This document consist of three sections.

Section 1 describes major problems that may be faced during the donation process, involving people, institutions and technology, and presents some data on inappropriate donations.

Section 2 lists best practices for donors and recipients to ensure that donations meet the needs of end-users, including patients. It includes engagement of both parties from the onset and exportation from a source country or setting. An important part of the section addresses regulatory considerations for authorizing importation of donated medical devices before the donation, reception, considerations for procurement and supply systems, and ongoing support, including installation, service and consumables.

Section 3 presents situations requiring special attention that are more complex or require specific input. The section includes descriptions of donation of used and refurbished medical devices and also imaging equipment, laboratory equipment, single-use devices and in relation to decommissioning and emergency situations.

The document includes three annexes for further reading.

The first annex lists the criteria for the acceptability of a donation, including a document that recipients can adapt to their settings and needs.

The second annex includes a literature review on donations of medical devices between 2010 and 2023.

The third annex presents a flyer that could be used independently to remind donors and recipients of their responsibilities.

This document is intended to improve the appropriateness of medical device donations and to ensure maximum benefit for all stakeholders. The considerations can be used in developing institutional or national policies and regulations for medical device donations. Although they can be applied anywhere, they may be particularly useful for health systems in LMIC. It should be noted that the role of biomedical engineers is of the utmost importance in any donation, as they are experts on the subject. This document is the result of WHO collaboration with qualified experts from all continents.

1. Introduction

The provision of modern health care depends heavily on technology, which includes health-care equipment. The health sectors of many low and middle income countries (LIMIC) rely to a considerable extent on donations of medical devices. It is difficult to quantify the exact proportion of medical devices donated or funded by international donors, because it varies significantly from country to country, within the same country and between rural and urban areas. Moreover, the evidence on the proportion of donated medical device that is out of order is highly heterogeneous, due partly to lack of a standard method for conducting such assessments in the field. For instance, some hospitals store non-functioning medical devices on the premises, while other equipment is disposed of far from hospital premises with no tracking system, resulting in little possibility for experts to quantify their number. A systematic study of more than 100 000 pieces of equipment *(20)* concluded that the percentage of non-functioning medical devices in LMIC ranged from 0.83% to 47% *(20–23)*. The reasons for which donated medical device become non-functional have been investigated in several studies *(20,24,25)*. They include:

- people:
  - no training of local users (including medical doctors); and
  - mismatch of human resources, skills and capacity;

- organization:
  - poor management (e.g. lack of a maintenance plan to ensure long-term viability, lack of preventive maintenance); and
  - a poor supply chain, resulting in unavailability of material and resources required for correct functioning of device; and

- technology
  - poor medical infrastructure; and
  - inadequate characteristics of a donated device in respect of the local working environment, which may be significantly different from that in the donor's or manufacturer's country in several aspects (e.g. humidity, dust, temperature, stability of the power supply).

Many donations circumvent the selection, regulation and procurement systems of the recipient countries and institutions, where such systems exist. Consequently, little consideration is taken of local requirements, the burden of disease, the level of care, the number of staff who will use the equipment or their capacity, the availability of biomedical engineers or technicians and their technical expertise to provide maintenance or compliance with local regulations. Local representatives of manufacturers and distributors of the equipment, who may be expected to provide after-sales support, are by-passed, or no investigation is done to determine whether they are available.

Therefore, inadequacy of medical devices donations is often due to a combination of the donor's lack of awareness and poor communication between donors and recipients about challenges and needs. In particular:

- Donors are often unaware of the local contexts of the intended recipients, including legislation.

- Donors and recipients often do not communicate as equal partners towards a common goal.

- The recipient's circumstances may lead donors to consider that "anything is better than nothing".

Despite these challenges in donation of medical devices, mutual benefit can be achieved by both donors and recipients with proper planning,

communication and the involvement of manufacturers, distributors, national regulatory authorities and biomedical, clinical engineers and needs assessments and validation. This document describes some of the best practices for ensuring useful donations, synthetized in Annex 3. They are intended to improve the appropriateness of medical device donations and to ensure maximum benefit for all stakeholders. The considerations can be used in developing institutional or national policies and regulations for medical device donations. Although they can be applied anywhere, they may be particularly useful for health systems in LMIC.

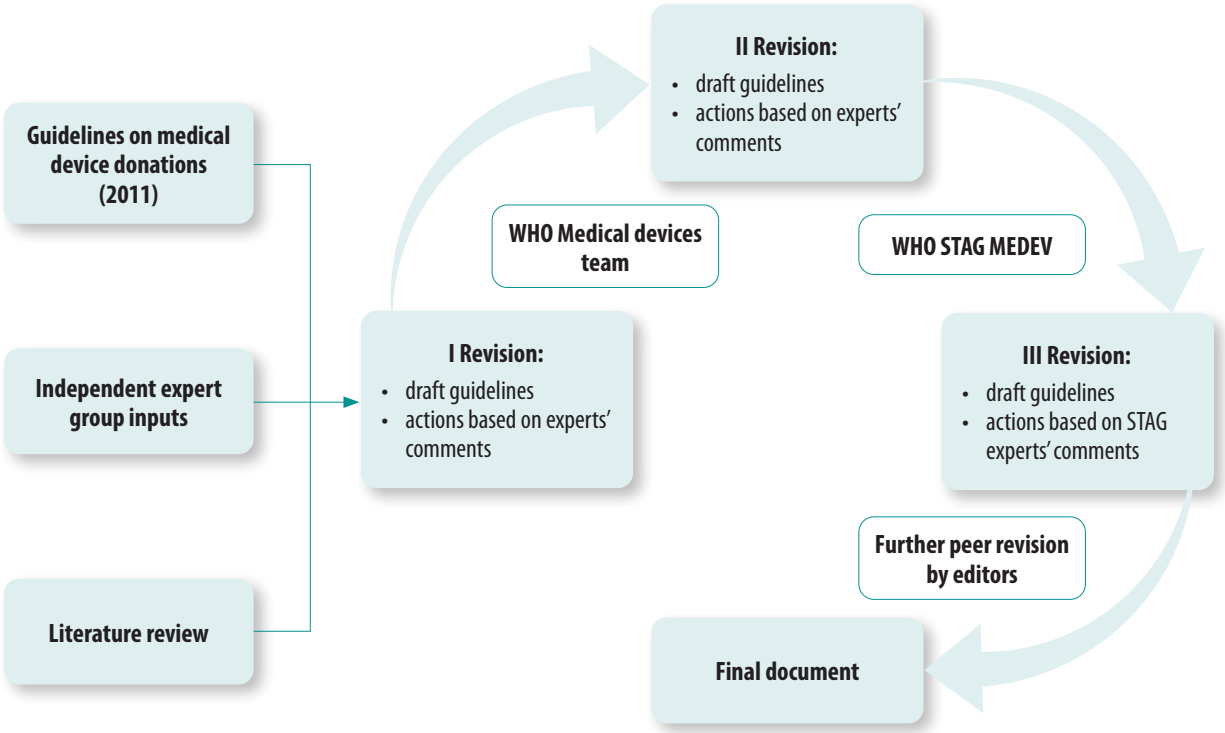
2. Method

Updating of the 2011 guidelines became imperative in 2021, during the coronavirus disease 2019 (COVID-19) pandemic, in view of the challenges of donating medical devices. Therefore, a first update was performed by WHO staff and WHO consultants. As a major gap was a section on regulation, the draft document was put on hold until the *WHO model regulatory framework for medical devices (3)* had been updated to include a section on donations of medical devices, which was approved in October 2022.

In December 2022, WHO established a new expert advisory group, the Strategic and Technical Advisory Group on Medical Devices (STAG MEDEV), and in 2023 the document was submitted for review to the STAG and to WHO regional advisers. It was noted that the references should be updated and that further editing was required.

WHO commissioned a consultant from the University Campus Bio-Medico, Rome, Italy, with expertise in donations to revise the publication in line with new requirements for WHO publications. The expert team reviewed the scientific literature on medical device donations published since 2010, and the grey literature, including guidelines issued by relevant institutions, and revised the guidelines in the light of their findings and comments, revisions and suggestions from the independent international experts (Annex 2). The draft document was further reviewed by experts in medical device donations and by the recipients of donated medical devices for their comments, including WHO collaborating centres and non-State actors in official relations with WHO. The draft was also reviewed by the multidisciplinary members of the STAG MEDEV, who approved the final draft to be submitted for publication. Fig. 1 illustrates the review process.

Fig. 1. Method used to update *Medical device donations: considerations for solicitation and provision* (6)



3. Best practices for donors and recipients

Medical devices are donated in several scenarios. Donors may include corporations that act directly or through other organizations, individuals, nongovernmental organizations, hospitals that support partner hospitals in other countries or governments that provide aid to other governments. The intended recipients range from individual health-care facilities to entire national health systems. Although the scenarios differ, the basic considerations discussed below apply to all. Moreover, in higher-income countries, there are minimum requirements for importation (even for zero-value donations), and regulation, needs assessment of hospital and other health facilities are clearly defined as a preliminary condition for permission for health facilities to accept a donation (license or accreditation). In addition, the requirements are checked periodically by biomedical, clinical and hospital engineers working for the hospital or for local authorities, to ensure that hospitals meet required standards of quality and health as a necessary condition to maintain a license or accreditation. In some LMIC, regulations for importation, customs clearance and supply management of donated products might not be clearly defined by law or by specific committees (e.g. for accreditation) and might not be regularly controlled by local authorities or health-care facility managers. Donors and recipients should explicitly determine how medical devices are governed by regulations with respect to location and technological infrastructure.

Donors and recipients must clearly ensure that the duration of any donation project must last longer than the lifespan of the donated medical device and that donors' responsibilities should span across all the donated medical device lifecycle. Neglecting this evidence can create risks for recipients, their patients, and the environment. In fact, medical device lifecycle varies significantly and can last from few minutes for disposable medical devices to many years for large machines such as diagnostic imaging ones.

Medical devices lifecycle encompasses several phases, including *(3)*: manufacturing, packaging and labelling, putting on the market, shipment, installation, training, use, maintenance, repair, disposal. Donors and recipients must ensure that all the requirements for the donated medical device phases observed during its lifespan are clearly analysed and addressed, avoiding hidden costs and budget for recipients (e.g., a donation of risky medical devices such as those using radioactive material, should address the issues related to radioactive material management in the recipient country, before moving forward; the donation of highly specialised medical devices, may require the training of highly specialised personnel before planning the donation, etc.).

3.1 Active engagement of recipients at all stages of donation

Often, the intended recipients of equipment donations are not consulted and do not have an active role in some or all stages of donation, even though they are the primary stakeholders. Recipients have to be actively involved in all stages of equipment donation (Annex 1), including:

- preparing a list of clinically relevant priorities for equipment with the desired specifications for their setting (e.g. electrical voltage and brands for which there is a local representative);
- assessing alignment among local requirements, preferred medical device and minimum requirements for expertise, infrastructure and technology;
- for the suggested brand and model, ensuring that consumables, accessories and spare parts are available on their local market or could be readily purchased when required and that trained technical support for

maintenance (preventive and corrective) is available, included or provided in the donation if necessary;

- in the case of medical software and medical devices with essential software or operating systems, with the donor, defining clear policies and procedures for software updates as standard procedure for software maintenance (e.g. adaptive maintenance if the operating system is changed and a new software version is required; perfective maintenance) for a sufficient length of time;
- defining clear policies and procedures for medical device maintenance (reactive, preventive and predictive);
- ascertaining the availability in the facility of competent clinical, biomedical engineering and technical staff and of the financial resources necessary to operate and maintain the requested medical devices;
- indicating, and if necessary providing, the required training for clinical and biomedical engineers, technical staff and health workers;
- considering local working conditions, including temperature, humidity, dust or an unstable power supply;
- considering the maintenance resources necessary to ensure proper long-term functioning;
- evaluating offers from donors with respect to their priorities for equipment and the desired specifications and brand or model preferences;
- preparing and following-up policies and procedures for equipment donations;
- preparing and using checklists to ensure that donations are appropriate and are transported, delivered and installed in a timely, safe, efficient manner;
- providing priority lists, policies and checklists for medical equipment donations to potential donors;
- providing feedback to the donor during donation and reporting the outcome of the donation; and
- rapidly refusing unsolicited, inappropriate, inadequate and/or incomplete medical device donations, preferably before the device leaves the donor´s facilities, through communication already established between the donor and the possible recipient.

Meeting the needs of end-users and patients

Before purchasing a medical device, it is good common practice to invite knowledgeable experts, usually biomedical or clinical engineers, to review the alignment between clinical requirements and the selected medical device (selection, rather than assessment). Manufacturers should be consulted for clarifications if necessary. This procedure is often overlooked. In the case of a direct donation from an organization to a health facility, it is important to foster a long-term partnership between the parties involved to facilitate efficient communication. In particular, it is suggested to arrange a visit to the health facility to evaluate its infrastructure characteristics. The criteria listed in Table 1 can be used as guide by both donors and recipients for a critical review of the technical specifications of a medical device for deciding on its suitability.

It is considered a best practice to establish a national or health facility committee, accordingly, to define the needs, supervise the donation and ensure successful process.

Table 1. Criteria for evaluating offers of medical device donation

Criterion	Desired characteristic
Appropriate to setting	• Suitable for the level of facility and services provided • Acceptable to staff and patients • Suitable for available operator skills with adequate training if necessary • Suitable for local maintenance support capacity • Compatible with existing equipment and consumables • Compatible with existing utilities and energy supplies once upgraded if necessary • Suited to the local climate, geography and working conditions • Can be run economically with local resources • Can be safely decommissioned at the end of its working life
Assured quality and safety	• Of sufficient quality to meet requirements and last a reasonable time • Made of durable materials with respect to local working conditions (e.g. dust and humidity), which may not be common in the premises of the donor or manufacturer • Made of material that can be easily cleaned, disinfected or sterilized without rusting, according to the substances available in the recipient country, which may be different from those commonly used on the premises of the donor or manufacturer • Manufactured to meet state-of-the-art standards for safety and performance (i.e. ISO and other relevant equivalents to international standards) • Approved for market by well-established regulators (such as: the US Food and Drug Administration, the Australian Therapeutic Goods and the European Commission) • Suitably (re)packaged so that it is not damaged in transit or during storage • Provided by a reputable, reliable, licensed manufacturer or registered supplier • Provided with user and maintenance manuals written in local languages
Affordable and cost-effective	• Affordable in terms of costs for e.g. freight, insurance, import tax • Affordable in terms of installation, commissioning and staff training • Affordable to operate (costs of utilities, consumables, accessories and spare parts during its lifetime) • Affordable to maintain and service • Affordable to dispose of safely • Affordable in terms of procurement (e.g. the cost of a procurement agent or foreign exchange, if necessary) • Affordable in terms of staffing (e.g. costs of any additional staff or specialized training) • Affordable in terms of end-of-life and waste management, including special waste (e.g. radioactive, acid, biohazardous material)
Ease of use and maintenance	• The recipient has the necessary skills for operating, cleaning and maintenance • Instructions and manuals are available in an appropriate language • User training is offered by the supplier or donor • Local after-sales support is available, with proven technical skills • Additional technical assistance through service contracts is possible • The equipment comes, preferably, with a warranty covering a reasonable length of time, of which the terms are well understood (e.g. covers parts, labour, travel, refunds or replacements) • A supply channel for equipment-related supplies (for example, consumables, accessories, spare parts) • Assured availability of supplies for a reasonable period (up to 10 years)
Conforms to donor solicitor's policies, plans and guidelines	• Purchasing and donations policy • Standardization policy • Technology level described in standard equipment lists and generic equipment specifications • Conclusions of a review of the literature and comparative products • Conclusions on feedback for previous purchases and donations

Regulatory and policy considerations

If medical devices are donated without regard for relevant national policies, regulations and guidelines for their selection, quality assurance, distribution, use and post-market surveillance, they may become a burden to the recipients, pose risks for patients and health workers and result in wasted resources for both donors and recipients and a burden on the environment.

If there are no local regulations, policies or guidelines on donations, the parties involved should develop institutional guidelines and standard operating procedures for both donors and recipients according to this document and the considerations summarized in Tables 2 and 3.

Table 2. Essential elements of a recipient's policy for accepting donations of equipment

Issue	Considerations
Policies and plans	Determine whether there is a donations policy. Recipients are in a much stronger position to negotiate if they have a policy. • List the equipment and supplies required and their quantities. Prioritize the list of requested items. • Provide potential donors with clear, comprehensive information on the items required and how they will be used. The requested items should comply with, for example, the specifications, standardization practices and model equipment list. • Check that national regulations allow such goods to be imported.
Review of donor and equipment on offer	Check that the donor has the capacity to fulfil the request. • Before accepting a donation, check that the equipment being offered conforms to national policy and is suitable for the recipient facility and staff. Confirm that the equipment requires only spare parts and consumables that are affordable from the available budget. • Before accepting a donation, check whether the relevant accessories, consumables, manuals and some spare parts are included, so that the equipment can function and be used. • Before accepting a donation, confirm whether the donor will be responsible for covering the costs of transport (including within the recipient country), freight, insurance, import duties, customs clearance, storage during custom clearance installation and commissioning costs, if applicable. If not, ensure that money is set aside for this. • Before accepting a donation, check whether a locally produced medical device is available at a price that is cost-effective. In this case, it could be appropriate to negotiate a cash donation instead of a medical device donation. • If the goods include reagents or sterile supplies, check whether they will have an adequate expiry date (at least 1 year, or half the shelf life if the expiry date is < 1 year). Additionally, be mindful of required special storage conditions, such as cold chain. • Check that the equipment on offer conforms to your "good selection criteria". • Determine who will be responsible for the inputs required during the remaining useful life of the equipment.
Acceptance of purchases	If pre-installation work is required, prepare the site and personnel for receiving the equipment, and notify the donor when all preparations are complete. • When the donation is received, check the packaging for damage, and make sure that the equipment is fully functioning and is accompanied by the relevant, agreed manuals, spare parts, consumables and accessories. Check expiry dates and labelling of recurrent supplies. • Confirm receipt of the donated equipment with the donor, including information about the condition and appropriateness of the equipment. • Keep a record of all donations received. • Check whether the required end-of-life management (e.g. recycling, waste management of devices and its parts, including fluid ones) of the medical devices is compatible with local law and that the required infrastructure and competence are available in the country, with reference to special waste (e.g. radioactive, biohazard, acids).
Refusal of a donations if necessary	Refuse inappropriate donations, and explain the reasons for refusal. • Keep a record of all donations that were not requested, and inform donors of unsolicited donations. • Refused donations should be disposed of at the donor's expense.
Disposal	The donor and solicitor should agree on a standard procedure for final disposal of medical equipment at the end of its technical life.

Source: Marks et al. *(24)*.

Table 3. Essential elements of a donor's policy for medical devices donations

Issue	Considerations
Ensure that a donation is necessary or requested	• Make donations only in response to requests and expressed needs. • Extend the knowledge of the recipient. • Confirm the need for the donation, and check the capacity and financial resources of the recipient for accepting donations. • Consider whether a donation of goods is the most appropriate form of support. A cash donation may be more effective in some cases. For example, it may be cheaper to procure a hospital bed locally than to transport a donated bed from overseas. Check whether there are locally registered providers of medical devices with the relevant authority. • Consider alternatives to donating conventional medical devices: purchase or donation of medical devices specifically developed for environments with certain constraints; supply or donation of accessories and spare parts to restore existing equipment to working order. • Coordinate donations with other donors to ensure that there is no duplication.
Involve the recipient	• Ensure that the device conforms to the device development plan of the country or facility, and consult recipients about their equipment requirements and preparation of specifications and purchase documents. • Check that the donation conforms to national requirements for selection of equipment. • Ensure that the recipient clearly specifies the items required. • Involve the recipient in evaluation and in final recommendations on the equipment to be purchased for donation. • Before sending donations, obtain consent from the recipient and authorization for exportation (if applicable) and for importation into the recipient's country (if applicable) by providing the recipient with all the documents required by the national regulatory authority. • Confirm the items to be sent and when they will arrive, so that the recipient can plan their reception, installation and training. • Ensure that the medical device is fully certified (e.g. if it emits radiation for medical purposes, a certificate from a radiation control institution must be included that provides details of its origin, type and, when appropriate, the intensity and distribution of the radiation).
Offer only good-quality products	Ensure that only appropriate medical devices and supplies are donated. • Ensure that the donated equipment is in full working order and is accompanied by all the necessary technical documents, accessories and parts. • Check the quality and safety specifications of the donated equipment. Avoid supplying equipment that does not meet up-to-date technical and safety specifications (although this does not imply that the equipment must be a sophisticated model). • Check with the recipients that the donation is acceptable. If you are offering alternatives, check that the alternatives are acceptable.
Additional costs involved in the donation	• Clarify and agree which party will cover the costs of international and local transport, freight and insurance, warehousing, customs clearance, storage and handling, installation and support. Provide the recipient with detailed information on the installation, operation and maintenance of the equipment.

3.2 Export of unsafe and unfit medical devices to third countries

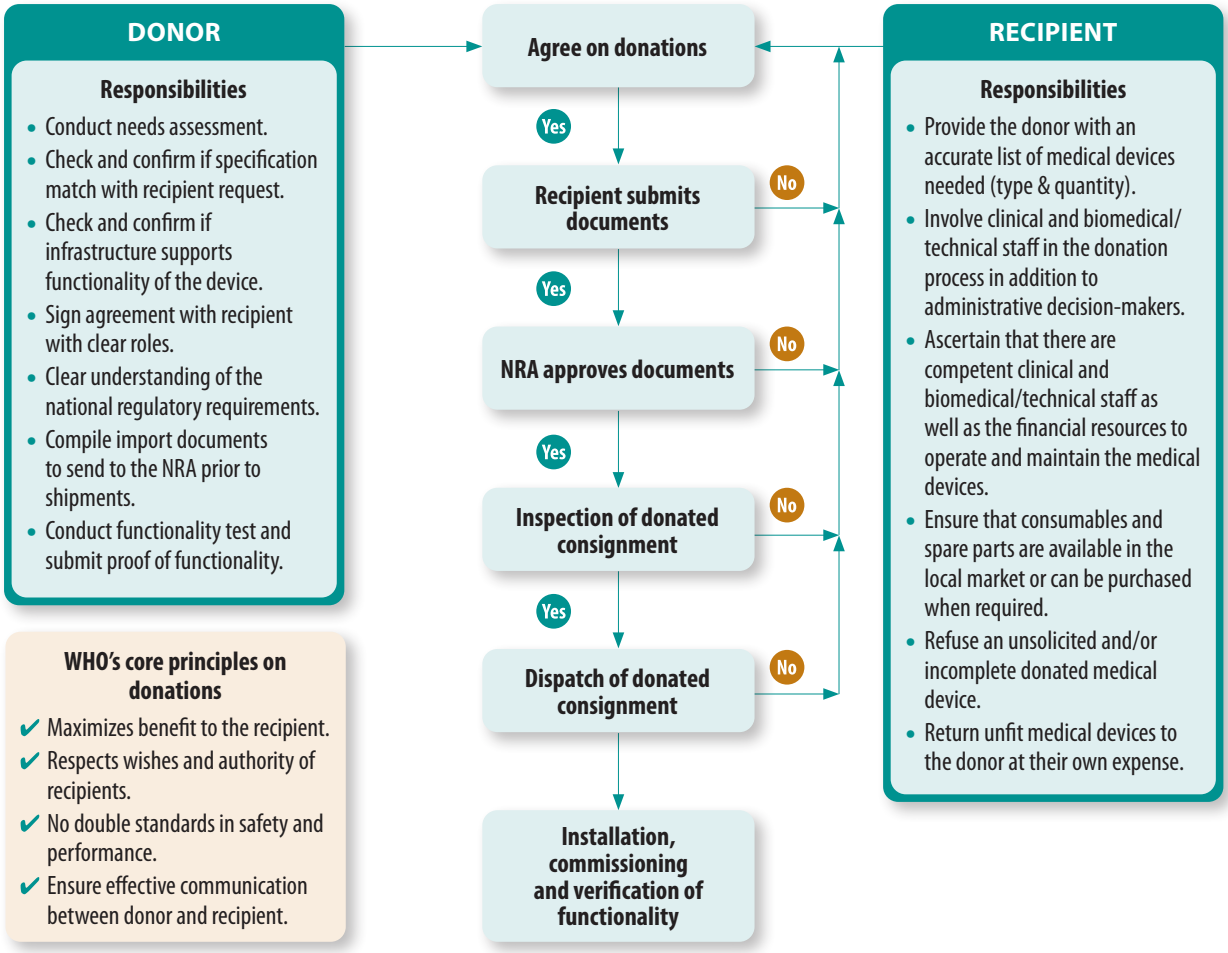
From the perspective of global health as a common responsibility of all WHO Member States, the States should, when appropriate, through their national regulatory authorities (NRAs), develop policies and regulations to protect not only their population but also exportation of unsafe or unfit medical devices to other countries. An example of a protective mechanism can be found in the legal orders of the member states of the European Union. As European Union members, they are obliged to transpose into their national laws the Waste Electrical and Electronic Equipment Directive (European Union 2018/849), which lays down minimum requirements for shipment *(26)*. The Directive imposes obligations to prevent shipment of waste, including faulty equipment. The requirements include written proof of equipment evaluation and proper functioning as well as appropriate protection against damage during transport due to insufficient packaging or

inappropriate stacking of a load. The preamble of the Directive emphasizes the will of the European legislator "to avoid unwanted shipments of non-functional electrical and electronic equipment to developing countries" (recital 15). The transfer of non-functional electrical and electronic waste, including medical equipment, out of Europe is illegal and subject to sanctions.

3.3 Regulatory considerations for authorizing importation of donated medical devices in the 3 phases (pre-donation, donation and post-donation)

The WHO Global Model Regulatory Framework for medical devices, including in-vitro devices *(3)* calls on NRAs to establish mechanisms for verifying and authorizing importation of donated medical devices. NRAs are responsible for performing regulatory controls to ensure that the medical devices placed on the market comply with legal requirements. Additionally, NRAs should authorize donated medical devices to ensure safety, quality and performance, and should not differ in this regard from devices imported through a regular supply chain. All parties involved in a donation must follow the NRA's legal requirements for importing medical devices into the recipient's country to avoid rejection or unnecessary delay in delivering the devices to the end users. If the NRA or another state entity does not have a mandate to enforce legal requirements for medical devices, including IVDs, the entire responsibility lies with the recipient of the donation (Fig. 2).

Fig. 2. Steps and responsibilities in the donation of medical devices



Source: Adapted from WHO Expert Committee on Biological Standardization: seventy-sixth report *(3)*.

If the device emits radiation for medical purposes, a certificate from a radiation control institution must be included that provides details of its origin, type and, when appropriate, the intensity and distribution of the radiation.

It is recommended that medical devices intended for donation be obtained or procured from a legal entity, e.g. a licensed business, to ensure the traceability of the product in case of an adverse event or incident that affects patient safety and if field safety corrective actions are required.

Medical devices that have not been authorized for use in the donor's country or country of origin because of concern about quality, safety or performance should not be considered for donation.

Before the donation, the donor and recipient must check that the recipient's national regulations allow such goods to be imported and, if so, apply for an import authorization by submitting the required documents to the NRA. An application for authorization to import donated medical devices must be submitted by the recipient to the NRA of the recipient's country before shipment of the donation. Typical supporting documentation to be provided by the donor includes:

- a list of products to be donated;
- the label on each product (package);
- the name and address of the manufacturer(s) of the products;
- evidence that the product is approved or authorized in the donor's country or the manufacturer's quality management system certificate (for high-risk medical devices);
- a letter confirming the safety and performance of the devices to be donated, with all documents of proof of proper functioning;
- a document approving exportation (if applicable);
- the expiration dates, as applicable, to address sensitive products with short expiry dates; and
- the recipient's legal entity or registration certificate or the contact details of the recipient's public health facility issued by the government of the receiving country.

Any consignment containing donated medical devices should be shipped only after approval has been granted by the responsible institution in the recipient's country.

After fulfilment by the donor of all the requirements listed above and submission by the recipient to the NRA, the NRA will issue a letter, permit or certificate to allow importation of a donated medical device.

3.4 Importing donated medical devices into the recipient country

The NRA should work with other local government institutions, including customs and the procurement agency, to ensure that donated medical devices are safe for use in the country. At the point of entry, every consignment should be inspected for verification. Any donated consignment that does not meet the conditions for approval by the NRA must be held at the border and returned to the exporting country at the donor's expense.

Verification before release of a consignment may include:

- **Document verification:** Verification of the availability and integrity of all documents listed in the pre-donation phase.
- **Physical inspection:** Verification that the donated medical devices were transported, stored and handled in accordance with the requirements outlined in the manufacturer's documentation and are undamaged and otherwise in a good functional state. The expiration dates of disposable devices and

consumables must represent more than 50% of the entire shelf-life after the date of inspection and last at least 12 months to ensure use of the entire donated lot.

- **Verification studies (for IVDs):** The national control laboratory will test the donation according to an assessment of the risk of the IVD (source, risk class, robustness of the transport conditions) including a risk-based lot verification of high-risk IVDs.

Post-market surveillance is the responsibility of the manufacturer. The responsibility for donated medical devices is that of the donor. The recipient develops a system for receiving reports of incidents and adverse events to be sent to the donor. The donor should take appropriate action if an incident or adverse event requires safeguarding of patient safety. The NRA should include in their market surveillance plan mechanisms for receiving feedback on the safety and performance of donated medical devices. Market surveillance activities should be based on WHO *Guidance for post-market surveillance and market surveillance of medical devices and in-vitro diagnostics (27)*.

The safety and performance of donated medical devices must be monitored throughout their life cycle.

3.5 Consideration of established procurement systems

The proposed procurement pathway for donations must reflect, as closely as possible, standard pathways approved for devices purchased directly by the government. Some donor organizations or agencies may have procurement practices that contradict those of national procurement agencies or do not result in the optimal solution for a recipient. National procurement protocols must supersede those of donors or their partners. It is critical to defer to the standards practised in the recipient country to maximize synergy among various donation proposals and to minimize duplication of efforts.

3.6 Consideration of public health needs

Although some donations are of large, sophisticated imaging medical equipment, most of the medical devices required by any health system are more basic, such as blood pressure measurement devices, clinical laboratory equipment and otoscopes. In this regard, the WHO model lists on Priority Medical Devices[3] and Essential in vitro diagnostics[4] may be used as relevant references. One way of estimating the proper balance between sophisticated and basic equipment when contemplating a donation is to consider the burden of disease beyond the hospital or recipient organization, to include multiple levels of care in the locality, region or entire country. Lack of appropriate, functioning basic technologies, especially in primary care and at first referral in remote areas, can limit access to preventive and curative interventions. These basic devices have a far greater impact on public health than more sophisticated devices. The provision of sophisticated equipment to intensive care units in hospitals may have less of an impact on health than far less expensive devices, such as weighing scales for use in areas in which there is malnutrition, point-of-care in vitro diagnostics to detect infectious diseases or pulse oximeters for monitoring hypoxaemia and to indicate oxygen therapy in case of pneumonia.

Conventional devices designed for hospital environments in high-income countries that are donated to health-care facilities in low-resource settings may be found to be intrinsically difficult to use and maintain. An alternative worth considering is donation of innovative health technologies that can be operated safely and efficiently in all types of health-care facility and are specifically designed for low-resource settings with severe constraints (e.g. unstable or minimal electrical distribution, high temperature and humidity, limited financial resources). Such devices are designed to be easy to use, easy to

[3] MeDevIS. Priority medical devices information system including in vitro diagnostic, some assistive products and other related health products. Geneva: World Health Organization; 2024 (https://medevis.who-healthtechnologies.org/).

[4] WHO Model List of Essential In Vitro Diagnostics. Geneva: World Health Organization; 2024 (https://edl.who-healthtechnologies.org/).

maintain, cost-effective, sturdy and sustainable. The WHO *Compendium of innovative health technologies for low-resource settings may be a relevant reference (28)*.

3.7 Inclusion of health facility input for donations coordinated nationally

Many donations are made to a country via the ministry of health or other national body. In these situations, it is important that the recipient institutions be consulted before requesting or accepting donations. Without understanding of the specific needs of recipient institutions, it is likely that the donation will not be suitable. Thus, it is important that national policies and guidelines for equipment donations, as well as purchases, include as a norm the solicitation of input and feedback from the intended end-users.

3.8 Considerations for support for installation, service and supplies

If the recipient cannot sustain the costs of installation, service and supplies required to operate and maintain the medical equipment offered or requested for donation, the donor may wish to consider an alternative donation package that includes operation and maintenance costs, especially as the costs of purchasing medical devices represent only part of the total costs incurred during the life of equipment. For instance, instead of donating 20 dialysis machines, a donor could instead, for the same cost, donate 10 dialysis machines with installation of the required water treatment equipment, dialysers, tubing and chemicals to operate the machines for several years. In this way, the complete costs of operating medical equipment are taken into account while ensuring complete operability of the equipment for a known time.

3.9 Special environmental and human resources for use of equipment

Detailed instructions for the installation, operation and maintenance of equipment allow the recipient to start pre-installation tasks, including training personnel in operation and maintenance.

The recipient should provide the expected date of completion of pre-installation and give the donor details such as floor plans, architectural drawings and blueprints so that the donor can identify any potential problems and recommend solutions. Training of personnel to operate and maintain the equipment is an important facet of preparation and requires preparation and planning. In addition, the training of health care workers should also be provided, if needed.

If the recipient or the donor does not have the technical knowledge to perform pre-installation or training, proper assistance and consultation should be sought from qualified experts, such as biomedical or clinical engineers. It is strongly recommended that biomedical and clinical engineers be involved in the donation process, for both the donor and the recipient *(21)*.

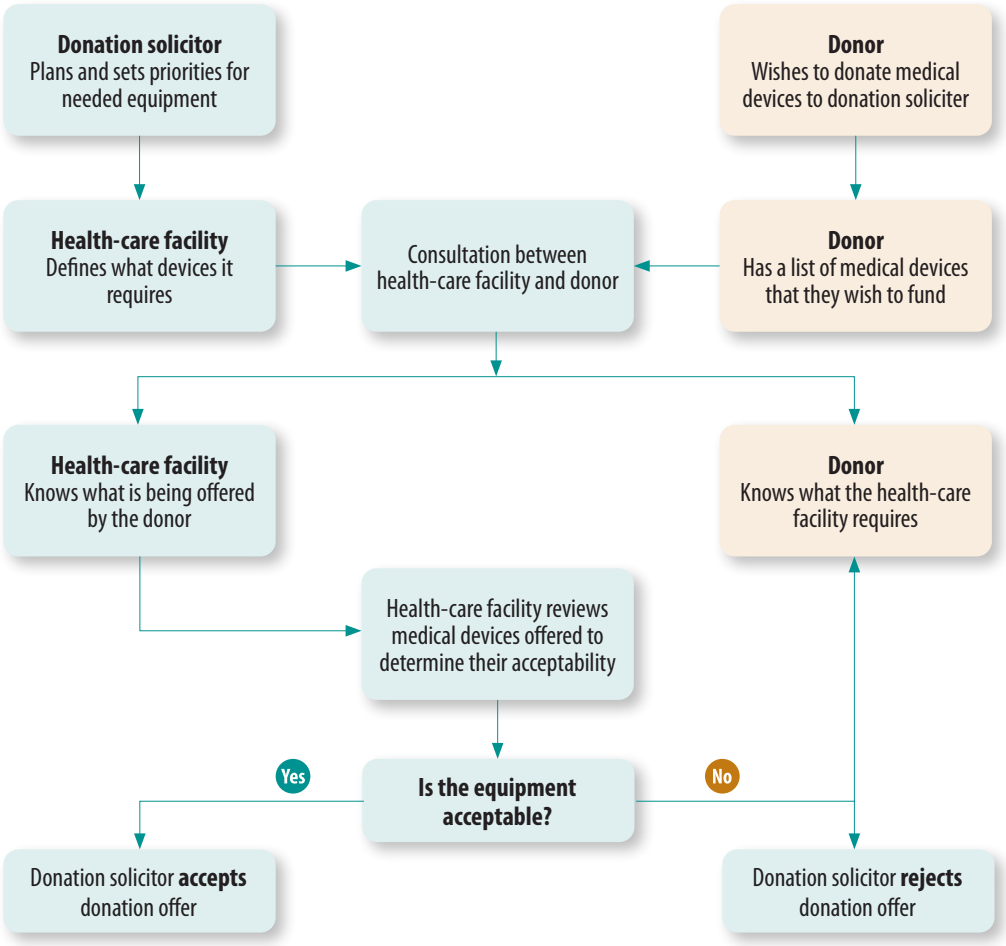
After the preparatory requirements have been fulfilled, the recipient can request the donor to assemble and package the equipment for shipping.

3.10 Communication

Continuous communication between donors and recipients throughout the donation process (Fig. 3) can determine the success of the donation. Some desirable characteristics of communication are:

- active involvement of and input from the recipient as the main stakeholder;
- inclusion of facility input if the donation is coordinated nationally;

Fig. 3. Soliciting and offering donations of medical devices



- assessment visits to the recipient facility by donors before the donation;
- evaluation visits by donors to the recipient facility after the donation;
- feedback from the recipient to the donor during and after the donation;
- donor understanding of the recipient's needs and challenges;
- appropriate consultation with medical device experts if the donor or recipient does not understand the implications of the donation;
- consultation with national suppliers and distributors of medical equipment;
- consultation of donors and recipients with appropriate national and international regulatory and standards agencies and bodies;
- sharing of information with clinical end users, biomedical engineers and technical personnel and administrative staff; and
- a final decision to accept or reject a donation by the national authorizing body.

3.11 Considerations for shipment

Medical Equipment donations may require shipment from one country or region that may have different tariff norms, such as local taxes, customs duties, International Goods & Service

Tax. Besides, storage of shipment in airport/port warehouses, may require payment for demurrage charges. Hence, the following is suggested:

- The receiver of donated medical equipment may take written undertaking from the donor, as to who will be responsible for payment of taxes and customs duties on shipped goods.
- Such duties and taxes are to be applied on taxable value as declared on invoice. Hence the valuation of donated devices or equipment would be important.
- The donor and receiver may endeavour to file for exemption of customs duties within the country of receipt, if so permitted under the national laws.
- The inspection of goods by customs may require suitable declaration as to determine that the goods are being donated free of cost.
- The customs duties and taxes as may be applicable, may be estimated beforehand, and if not exempted, undertaking may be taken from the donor for covering the value of duties.
- The storage of such goods is permitted only up to a limited time in the customs warehouses. Early clearance of such goods may be endeavored so as to avoid demurrage charges on goods, if any.

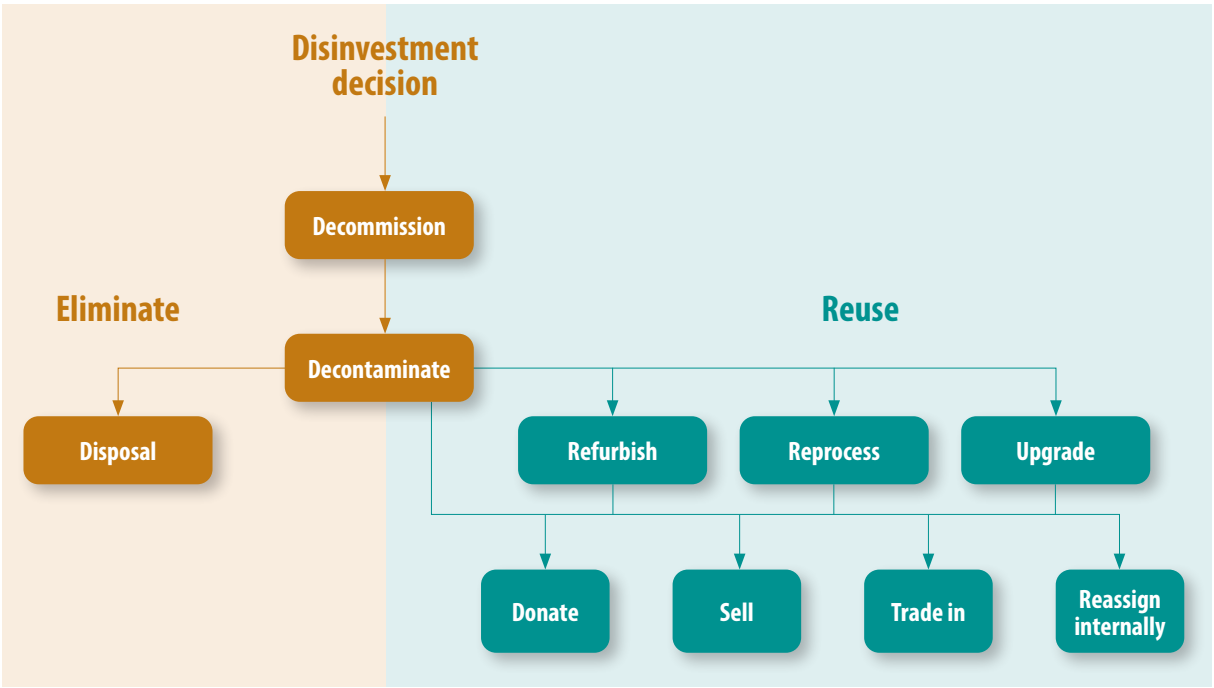
4. Situations requiring further attention

4.1 Used medical devices

Some donations consist of used medical devices that are still functional from hospitals in higher-income countries. Functioning equipment is often made available for donation when it is decommissioned and replaced because of changes in the hospital structure or to upgrade the technology. Donations of used devices should be accepted only if documentation is available to demonstrate that the device has passed standard performance and functionality testing. The device must meet international manufacturing standards for state-of-the-art quality (such as of the International Standards Organisation). Used equipment must be disinfected and decontaminated before donation and must include clear instructions on disinfection and decontamination *(24)*. In any case, all medical devices should be cleaned before donation *(11)*.

Used equipment, such as new equipment, requires maintenance, spare parts, user training and manuals for service and operation. Manufacturers are, however, less willing to provide support for used donated equipment, leaving the recipient with little or no recourse when the equipment breaks down. Donations of used equipment are more useful when the manufacturer provides assurance of proper support in the form of accessories, repair parts, service and consumables for an appropriate length of time. Both donors and recipients should establish the minimum acceptable period during which manufacturer support will be available, such as 5 years. As the serial numbers of medical devices are usually registered in the name of the original buyer, manufacturers and vendors may be more willing to provide support if they are informed of the identity of the new owners of the equipment. Moreover, the donor should provide the necessary training for basic maintenance procedures, if required by the recipient. Reuse of used implantable devices should be considered only when a new device is not accessible, with adequate information provided to potential

Fig. 4. Decommissioning medical devices *(11)*



recipients about the risks of reprocessed items and to obtain informed consent. Although reuse is not recommended and goes against the intended use of the device, some studies have demonstrated that the reuse of properly refurbished implantable devices is feasible and safe *(11,29)*, provided that used implantable devices are reprocessed and sterilized appropriately *(30)*.

The donor should consider donation of used medical devices as a mean of decommissioning. Decommissioning consists of removing a medical device from service in a health-care facility after a decision to disinvest in the device itself or in the service in which it is used. The two main pathways for decommissioning a medical device and determining its final disposition after decontamination are permanent elimination (e.g. recycling, cannibalizing or incineration) and re-use (i.e. donated, sold, refurbished, reprocessed, traded-in or reassigned internally to another location) (Fig. 4). See *Decommissioning of medical devices in the WHO Medical Device Technical Series (11)*.

4.2 Refurbished equipment

Refurbished medical devices *(31)* are those with restored functionality and appearance, including replacement of worn-out parts, cleaning, decontaminating, repairing and repainting. Refurbishers are expected to restore equipment to the manufacturer's original specifications and follow the good manufacturing practices established by their national authorities for manufacturers of health-care equipment. Reputable refurbishers provide user manuals and all the accessories necessary to use the equipment. Equipment from a reputable refurbisher is, therefore, preferable to a donation of used equipment directly from a hospital, if they fulfil a refurbisher certificate.

From a global viewpoint, donation of used and refurbished devices can improve the environmental impact of medical devices by bypassing unnecessary disposal. Because of very short life cycles, many devices are disposed of, generating large amounts of waste *(32)*. Thus, used and refurbished devices that have undergone proper restoration and testing, can continue to be valuable while minimizing the environmental footprint of medical devices. Such donations not only bridge resource gaps but also promote a sustainable, circular approach to health care, ensuring that equipment continues to serve a purpose beyond its initial use *(33)*.

4.3 Laboratory equipment

In addition to reviewing laboratory equipment according to the criteria listed in Table 1, donors and recipients should answer to the following questions about reagents, calibration controls, consumables and accessories to facilitate decisions:

- What is the average turn-around time for tests, and is it suitable?
- What reagents are required, and how much do they cost?
- Can all the reagents be purchased in the country and in what volume?
- Do the reagents require refrigeration, and how should they be stored?
- Do calibrators or standards have to be purchased for each test, and are they available?
- What ongoing supplies are necessary for operation of the equipment?
- Are all essential accessories included, such as a printer and printer paper if necessary?
- What daily, weekly and monthly maintenance is required?

4.4 Imaging and radiology

When considering donation of radiological equipment, attention must be paid to complex matters such as specialized training, professional installation and the requirement for specialized

maintenance support in the field. Items to be considered include:

- age and condition of the equipment and the approximate number of exposures on the tube head(s);
- type of machine – stationary or mobile, special procedure or straight radiographic, mammography or fluoroscopic;
- type of tube stand – floor-to-wall, floor-to-ceiling, attached to the table or ceiling mount;
- minimum ceiling height for installation of ceiling mount units;
- load-bearing requirements for the ceiling;
- inclusion of uncut and unbent high-voltage cables, with the correct number of conductors, correct length and wire size and with terminal connectors for each cable;
- professional assistance in crating for shipment and disassembling;
- possible inclusion of a new X-ray tube with each unit to ensure a working replacement;
- installation instructions, service manuals and professional assistance for installation; and
- a service contract.

The cost of the service contract is by far the greatest cost in a donation and may even exceed the purchase price of used equipment. This can make it uneconomical to donate a used digital X-ray, fixed fluoroscope or computed tomography device to a resource-limited setting *(23)*.

4.5 Re-use of medical devices labelled "for single use"

The re-use of single-use medical devices should be discouraged and should not be part of donations. Yet, in a scenario of severe scarcity of medical devices or personal protective equipment, such as during the COVID-19 pandemic, this practice has been reconsidered *(36)*. Nonetheless, donors and recipients should consider that:

- It may not be possible to take apart some devices for proper cleaning and disinfection.
- Single-use devices may not be cleaned and re-sterilized properly.
- The mechanical integrity and/or functionality of some single-use devices may not resist reprocessing.
- The effect of cleaning chemicals or sterilizing agents on reprocessed devices or on patients may not have been determined.
- Because of the design or the materials of a device, some models may be suitable for safe reprocessing while others may not.
- There may be no evidence of how many times a device can be safely reprocessed.
- Some devices, such as single-use injection syringes, should not be reused because of a very high risk of infection.

When reprocessing and re-use of a device labelled "for single use" is considered, knowledge of possible hazards must be thorough, with a comparison of the impact on patients. Are there adequate facilities and trained personnel for reprocessing? Some possible hazards may not have been foreseen. Ethical questions and the potential consequences of patient infection are important considerations and pose a question of legal responsibility for reprocessing and reuse of single-use devices. Policies for reusing single-use medical devices differ by country. For instance, the European Union allows exemptions *(35)*, and, in the USA, the Food and Drug Administration applies the same standards to new and reprocessed devices. In Egypt, some health-care facilities that have shortages have resorted to reusing masks and nebulizer tubing,

guided by national guidelines from 2008 *(36)*. In Australia, the National Safety and Quality Health Service Standards include requirements for reprocessing devices for both health care and non-health settings *(37)*. Many countries have laws or recommendations, some of which ban reuse of such devices.

4.6 Donation of implantable devices

Implantable devices considered for donation fall into three categories:

- devices that have never been used;
- devices implanted during surgery but removed when they were found not to fit the patient; and
- devices implanted in patients that were later removed because, for example, of component fatigue or site infection.

Devices in the last two categories must be re-sterilized and undergo special preparations for reuse, which may compromise the functioning of the device. Use of such devices is therefore generally questionable, and donation of such devices should be avoided or discussed with the manufacturer *(30, 40)*.

4.7 Donation and reprocessing of single-use medical devices

The COVID-19 pandemic stimulated discussion and scientific dialogue about donation, reprocessing and reuse of medical devices (and personal protective equipment) intended by the manufacturers to be used only once. Regulators such as the US Food and Drug Administration *(38)*, the European Commission *(35)*, the Ministry of Health of South Africa *(37)* and the Egyptian Ministry of Health *(37)* have published dedicated guidance, which should be considered by donors and recipients. Risks highlighted by the Joint Commission International should be also reviewed *(39)*.

4.8 Emergencies

Donations of medical devices require numerous exchanges between donors and potential recipients, commitments on both sides, technical operations, management and administrative follow-up. As the impact of a donation extends beyond the physical transfer of products, it must be done with forethought and consideration of the effects on the recipient's health-care system. The question, therefore, arises as to the relevance and potential success of donations made in emergency situations, such as public health crises (outbreaks, epidemics), disasters or conflicts. In critical contexts, it is recommended that preference be given to donation agreements:

- between donors and recipients with existing partnerships, especially if previous donations have been successful;
- by organizations and agencies with experience in emergencies; and
- provide the most basic, universal medical devices (preferably brands that are available in or close to the emergency).

Given the nature of emergencies, with a rapidly changing public health situation, it may not be possible to adhere to these recommendations, and ad-hoc opportunities for donating items are more likely. Nonetheless, stakeholders should respect WHO's core principles of meeting the basic requirements for any acquired device. Devices must, at a minimum:

- meet an expressed request from the end users, corresponding to a real clinical need;
- be approved by regulatory authorities;
- meet international safety standards;
- contain all its parts and accessories and be functional and safe for use on arrival;
- be accompanied by documentation in a language understood by the recipient;

- be adapted to the local context (e.g. electrical power, medical fluids);
- be operational and maintained by the available human skills and capacities and/or be accompanied by training; and
- be imported with a plan for its disposal in the receiving country after investigation and (if possible) identification of a disposal solution to be implemented once the medical device can no longer be used.

To facilitate emergency donations, it is suggested that lists of requirements for donations be developed by biomedical engineers and medical doctors, or a committee in the Ministry of Health, so that the donor can consult them, particularly in emergencies and disasters, and meet local needs. The list would make it possible to determine the quantity of devices required in the event of an emergency, to validate the quantity and to provide the devices to donors. Donors would refer to the single list for evolving needs and fill gaps, to avoid duplication. Even when donors work directly with health-care facilities rather than through national governments, allowance can be made for modifying the database to reflect their activities. The WHO priority lists of medical devices could be used in creating a list, referenced and extended as necessary (e.g. the WHO list of priority medical devices for COVID-19[5] case management).

In emergencies, the most efficient form of communication in the recipient's country must be used to facilitate the donation process.

4.9 Criteria for assessing the acceptability of donations of medical devices

During consultation on a donation of a medical device, potential recipients and potential donors should collaborate in establishing the acceptability of the devices for introduction into the potential recipient's health-care system. This involves ensuring that only devices of suitable quality enter the system and that their quality will be maintained to ensure that they have a sustainable, positive impact on patient outcomes. This requires intricate interactions among potential donors, suppliers and recipients. Recipients must involve representatives of the community that will use and maintain the device and regulators – and not only the administrators of health-care facilities or representatives of ministries of health.

Irrespective of the source of a medical device (donation or direct purchase, new or refurbished) that is acceptable to a health-care system, it must be the most appropriate solution for (i) sustainably meeting one or more clinical demands; (ii) improving specific patient outcomes; (iii) adaptation to the infrastructure, the skills of clinical, biomedical engineers and other technical staff and the budget of the target facility; and (iv) minimal environmental harm. An acceptable medical device is not necessarily the cheapest option available to the donor, nor is it the medical device that can be obtained most rapidly.

Verification of acceptability is most critical in an emergency. The less suitable a device, the more likely it is to cause harm and create a burden for a potentially crippled health-care system. Therefore, all countries should establish criteria for acceptability pre-emptively rather than in an emergency.

To help potential recipients and potential donors to prepare for the donation process, criteria have been set for assessing the acceptability of donations of medical devices, with considerations for solicitation and provision. Meeting the criteria requires input from clinical staff, biomedical engineers and other technical staff, regulatory authorities, public service officials and donor representatives. WHO expects Member States to use this guide to create their checklist for accepting or rejecting donation proposals. The checklist will also be useful in negotiating the terms and conditions of donation proposals at national, regional and institutional levels.

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Annex 1. Criteria for assessing the acceptability of a proposed donation of a medical device

1. Is the device clinically relevant, and will it strengthen the health-care system?

- A letter and a questionnaire from the prospective recipient are attached.
- The report of a facility assessment of infrastructure, resource availability and clinical demand is attached.
- The device is approved for treating the targeted clinical condition in the recipient's country.
- The number of devices does not exceed the number requested by the recipient.
- The number of devices available in the country, including this donation, will not exceed the needs for the patient population (including donations from other sources).
- The device represents the most appropriate solution for the specific clinical demands outlined in the prospective recipient's request or facility assessment.
- The device meets the specifications outlined in the recipient's request or facility assessment.
- The donation proposal should be revised.

2. Is there a sustainability plan?

- A partnership agreement signed before starting the donation process is attached.
- Responsibility has been accepted for:
  - shipment by: .....
  - customs clearance by: .....
  - storage by: .....
  - distribution by: .....
  - facility preparedness by: .....
  - commissioning and installation (including quality control and calibration) by: .....
  - training of end users by: .....
  - operations (staff) by: .....
  - consumables, accessories and supplies by: .....
  - spare parts by: .....
  - service and maintenance (biomedical engineer and other technical staff, tools, contract) by: .....
  - disposal by: .....
- Monitoring and evaluation of specific patient outcomes has been planned.
- The device has a reasonable lifespan beyond the expected commissioning date.
- The manufacturer or distributor will continue to support the device for at least 3 years from the date of purchase.
- A supply chain for spare parts is available.
- A supply chain for consumables and accessories is available.
- A contingency plan if the device cannot be used is attached.
- End-of-life disposal has been planned.

3. Does the device meet safety and technical regulations?

- Labels, service manuals and all other information are written in a language that is commonly used in the recipient's country. Specify language: .....
- Use of the device complies with national policies and regulations, and the national regulatory authority has approved the device for the intended purpose. A copy of a license or letter of approval is attached.
- If a regulatory authority in the recipient's country has not confirmed use of the device, indicate the internationally recognized safety standards to which the device was manufactured (e.g. European Commission, US Food and Drug Administration): .....

4. Will the device be functional if installed as instructed?

- A functionality test certificate or other proof of a pre-shipping functionality test (quality control) is attached.
- All used devices have undergone refurbishment protocols and passed functionality tests.
- All parts and accessories are included with the device.
- Names of biomedical engineers and technical staff who will complete a functionality test at the target facility:
  .....
- All required ancillary or supporting devices that are necessary for use of this device are available or being procured.
- The donation proposal should be revised.

5. Is the device compatible with the recipient's infrastructure?

- There is sufficient space to accommodate the device at the target facility.
- The targeted facility has the necessary amount and quality of power, water and medical gases.
- If the device is electrical, the input power matches the facility's power supply, and surge protectors are available.
- The infrastructure will be ready before arrival of the device to ensure that the device can be installed and used immediately.

6. Does the budget cover the device's operating costs?

- Responsibility has been accepted for providing the following in sufficient quantity when required:
  - medical staff by: .....
  - technical and maintenance staff and tools by: .....
  - consumables and accessories (specific to the device, e.g. reagents, cables, sensors) by: .....
  - consumables (power) by: .....
  - consumables (water) by: .....
  - consumables (medical gases) by: .....
  - consumables (other) by: .....
  - spare parts by: .....
- Confirmation of responsibility is attached in writing.

7. Is a senior technical leader available to provide consistent oversight?

- A description of the qualification of the senior technical leader at the target facility is attached (e.g. chief technical officer, director of clinical engineering).
- A description of how technical oversight will be provided is attached.

8. Does the donation meet national regulations for procurement, exportation and importation?

- A description of the national legal procurement framework is attached. Or, an acceptable alternate procurement framework is attached.
- Preference has been given to brands and device models that have been used previously in the recipient's country and/or were designed to meet constraints specific to the target facility's operating environment.
- A description of the donor's national exportation framework is attached, if applicable.
- A description of the recipient's national importation framework is attached, if applicable.

Annex 2. Literature review on donations of medical devices, January 2010–November 2023

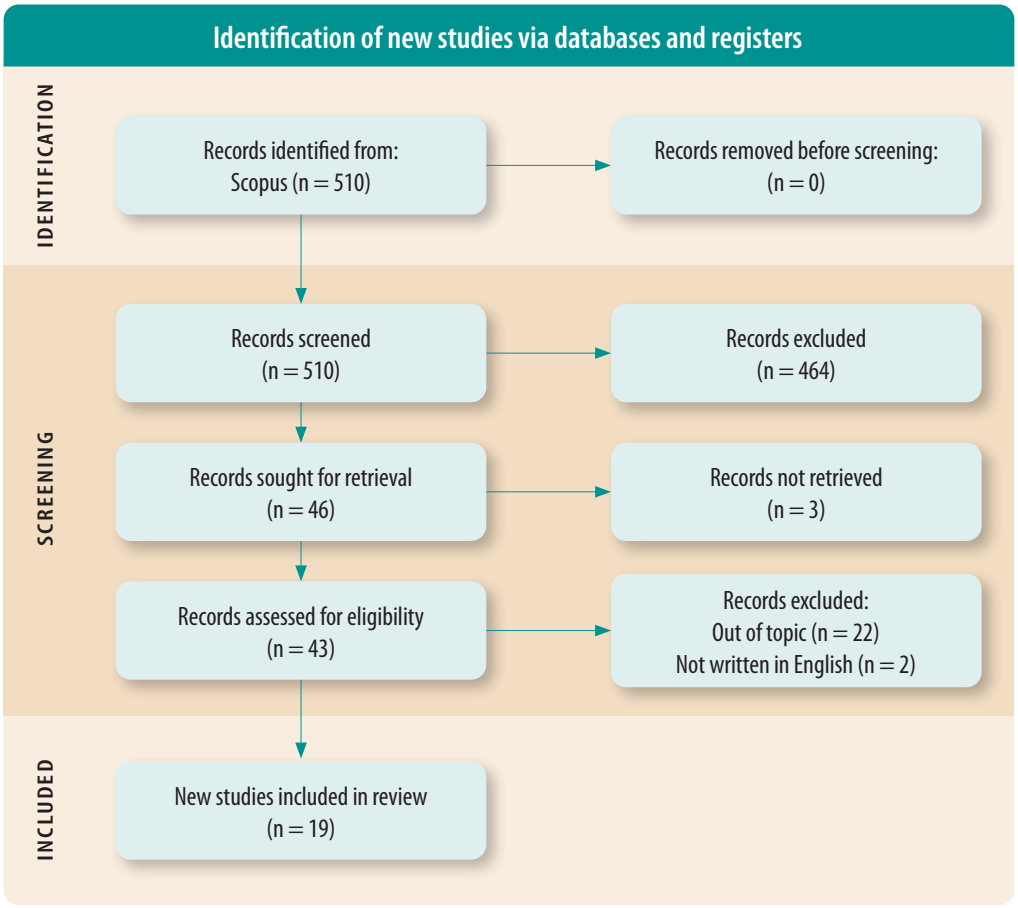
Aim

The primary objective of this review was an investigation and evaluation of literature on medical device donation to inform and update relevant WHO guidelines. This literature review has not been registered.

Search strategy and selection process

A search was performed between January 2010 and November 2023 according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) guidelines. Publications were searched in the Scopus database with the following search string: (“donat*” OR “donor”) AND (“medical devic*” OR “medical equip*” OR “healthcare technolog*” OR “personal protective equip*”) AND (“organ” OR “organs”) AND PUBYEAR > 2009 AND PUBYEAR < 2024. The search string was limited to titles, abstracts and keywords. A total of 510 articles were identified. The titles and abstracts of the studies were screened against inclusion and exclusion criteria for eligibility by two separate pairs of two independent reviewers. The articles selected then underwent a full text review. In case of any disagreement, a third reviewer was consulted.

Fig. A2.1. PRISMA workflow for the scoping review



Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Report on	Medical device donation, including medical equipment, single-use medical devices and in-vitro diagnostics	
Geographical setting	low, lower-middle, upper-middle, and high-income countries	
Clinical setting		No exclusion criteria
Type of publication	Journal articles, reviews, conference paper, book chapters	Letters to editors, editorials
Language	English	Languages other than English
Time frame	2011–2023	<2011

Information extraction and synthesis

The information from the extracted papers was gathered using an ad-hoc Excel spreadsheet and synthesized through a narrative synthesis method by one reviewer. Quality appraisal has not been performed.

Results and conclusions

A significant body of evidence on medical device donation to LMICs has emerged in the past 10 years, which indicates that donation of medical devices is a common practice of well-meaning donors, with the objective of improving capacity for safe, effective health care. Inadequately planned and executed donations, however, often fail to achieve the intended outcomes and can even impose an unnecessary burden on health-care providers and organizations that are already facing significant challenges. Most of the extracted papers dealt with medical devices donation *(13)*, two studies dealt with refurbished medical devices, two dealt with medical device management and maintenance in low and middle income countries, one paper described a frugal design innovation in the contest of a donated medical device, and one dealt with regulation of donated medical devices.

The literature, while limited, emphasizes the importance of an equitable relationship between donors and recipients. An often overlooked factor that leads to suboptimal long-term donations is funding for maintenance teams and spare parts or consumables. Planning of a donation must include a clear system for the long-term sustainability of the device. Ultimately, the success of a donation depends on clear, honest communication by recipients of their needs and any foreseeable limitations that could undermine the integrity of the donation. Unfortunately, there is minimal evidence of widespread adherence to published guidelines, and additional evaluations should be conducted of medical device donations to identify solutions for the remaining gaps. Table A2.1 summarizes the 19 full papers included in the final review, which were used in rewriting this guideline.

Table A2.1. Articles on donations of medical devices identified in the literature review, January 2010–November 2023

Title	Author(s)	Year	Geographical and clinical setting	Aim of the study	Relevance for WHO donations guidelines	Relevant numbers (e.g. percentage of medical devices available, percentage of donated medical devices)
Effectiveness of medical equipment donations to improve health systems: How much medical equipment is broken in the developing world?	Perry, Malkin	2011	LMICs	To assess the amount of equipment in the developing world that is out of service		40% of medical equipment is not functional in low-resource settings
Medical equipment donations in Haiti: Flaws in the donation process	Dzwonczyk et al.	2012	Haiti (medical centres)	To examine the status of medical equipment in Haiti and demonstrate persistence of flaws that were addressed by WHO over a decade previously	Challenges faced in LMICs regarding medical devices: preventive maintenance was not part of the mode of operation (i.e. maintenance was reactive, not proactive)	In seven hospitals: • 28% of equipment was functional and in use • 28% of equipment was functional but not in use for technical reasons • 30% of equipment was not functional but was reparable • 14% of equipment was not functional and was irreparable • 86% of the equipment had been donated At least 38% of the equipment had been used before donation
Medical equipment maintenance personnel and training in Zambia	Mullally et al.	2013	LMICs	To conduct a needs assessment of medical equipment maintenance and management personnel in Zambia	Challenge faced in LMICs regarding medical devices: hospitals were hesitant to reject any unsuitable donations for fear of not receiving any potentially useful future donations	Only 35% of medical equipment in three Zambian provinces is out of use, approximately one third of which had been donated.
Medical imaging in the global public health: Donation, procurement, installation, and maintenance	Malkin et al.	2014	LMICs	To highlight major considerations for donation of medical imaging equipment to a resource-poor hospital		• Nearly 40% of all medical equipment in the developing world is out of service, with a significantly higher rate (nearly 50%) for X-ray equipment • 25% of all out-of-service medical equipment can be traced to user-related issues such as training.

Table A2.1. *continued*

Title	Author(s)	Year	Geographical and clinical setting	Aim of the study	Relevance for WHO donations guidelines	Relevant numbers (e.g. percentage of medical devices available, percentage of donated medical devices)
How the thet partnership model is different; looking back at two years of medical equipment partnerships in five african countries	Worm et al.	2014	Sub-Saharan Africa (medical centres)	To describe five medical equipment partnership projects, enabled by the Tropical Health and Education Trust, between health institutions in the United Kingdom and Ethiopia, Ghana, South Sudan, Uganda and Zambia	Proposed solution: A medical equipment partnership should be based on a needs assessment led and owned by the overseas partner; these projects offer peer-to-peer continuous support and training of local staff.	• By the end of the project, an estimated 50% of equipment was operational, up from 30% in November 2012. In Africa, at least 40% of medical equipment is out of service, many studies citing 50–80%. • Up to 80% of medical equipment in many sub-Saharan African countries is donated or funded by foreign sources. • 70–90% of donated equipment is never operationalized.
The potential role of IFMBE in improving the state of medical equipment in developing countries	Worm et al.	2015	LMICs	To highlight the cause of the poor state of medical equipment in developing countries and link them to potential solutions		An estimated 40% of health-care equipment in developing countries is out of service, as compared with < 1% in HIC.
Determining the utility and durability of medical equipment donated to a rural clinic in a low-income country	Bauserman et al.	2015	Democratic Republic of the Congo (medical centre)	To determine the utility and durability of various diagnostic instruments and equipment to better guide donations	Challenges faced in LMICs regarding medical devices: local health-care providers use equipment with which they are familiar. Proposed solutions: • Donations of medical devices and equipment should be made in collaboration with local providers to determine the level of training required by the end-user. • Education on use and maintenance of complex pieces of equipment can increase their usefulness and should be provided when these donations are made.	

Table A2.1. *continued*

Title	Author(s)	Year	Geographical and clinical setting	Aim of the study	Relevance for WHO donations guidelines	Relevant numbers (e.g. percentage of medical devices available, percentage of donated medical devices)
Problems with systems of medical equipment provision: an evaluation in Honduras, Rwanda and Cambodia identifies opportunities to strengthen healthcare systems	Emmerling et al.	2018	LMICs	To evaluate problems in systems of medical equipment provision	Challenges faced in LMICs regarding medical devices: • lack of access to working medical equipment; • lack of biomedical engineers to maintain medical devices; • lack of spare parts, utilities, accessories, consumables such as reagents, test equipment; • lack of technician training, service contracts or other means of supporting installation, preventive maintenance, corrective maintenance and decommissioning; • much equipment is non-functional when donated.	Estimated 40% of medical equipment in resource-poor settings is out of service.
Donation of medical devices in low-income countries: preliminary results from field studies	Piaggio et al.	2019	Sub-Saharan Africa (Benin, Ethiopia and South Africa) (medical centres)	To describe two donated medical devices and difficulties in maintaining minimum requirements	Challenges faced in LMICs regarding medical devices: • X-ray machine donations: instructions for assembly written in a language not spoken locally, no expert technician • Oxygen concentrator donations: Reported limitations: minimum requirements used in high-income countries do not apply in low-resource settings, maintenance of medical devices should reflect that. Proposed solutions: • implement local management system, installation and maintenance support • new standards for MDs in harsh environments	80% of the medical devices market is ruled by higher-resource settings (Europe, Japan and the USA)

Table A2.1. *continued*

Title	Author(s)	Year	Geographical and clinical setting	Aim of the study	Relevance for WHO donations guidelines	Relevant numbers (e.g. percentage of medical devices available, percentage of donated medical devices)
Medical donations are not always free: An assessment of compliance of medicine and medical device donations with World Health Organization guidelines	McDonald et al.	2019		To assess adherence of identified medicine and medical device donations to the WHO Guidelines for Medicine Donations and/or the WHO Medical device donations: considerations for solicitation and provision and WHO Guidelines for Health Care Equipment Donations		Estimated 40–70% of donated medical devices are not used as they are not functional or appropriate or staff lack training
Medical equipment donation in low-resource settings: A review of the literature and guidelines for surgery and anaesthesia in low-income and middle-income countries	Marks et al.	2019	LMICs	To evaluate how medical equipment is sourced and donated and the responsibilities of donors, users, manufacturers and managers	Recommended considerations for medical equipment donation in LMICs: • Presence of trained physicians, nurses and biomedical technicians to operate and maintain the equipment • Sufficient space, electricity, water, oxygen supply and ventilation. Standardization with local equipment, low energy consumption, ease of maintenance and avoidance of environmentally hazardous substances • Ancillary equipment supplied either locally or from overseas, replacement parts and associated supply chains • Workforce training, considering both material and financial capacity • Capacity to train the workforce in clinical use of the equipment and in correct interpretation of results	

Table A2.1. *continued*

Title	Author(s)	Year	Geographical and clinical setting	Aim of the study	Relevance for WHO donations guidelines	Relevant numbers (e.g. percentage of medical devices available, percentage of donated medical devices)
Responding to maternal, neonatal and child health equipment needs in Kenya: A model for an innovation ecosystem leveraging on collaborations and partnerships	Ayah et al.	2020	Kenya (medical centres)	To describe the first phase of a project ("maker hub") that will, at the last stage, "test the effectiveness of an innovative partnership ecosystem network, the 'Maker Hub', in reducing gaps in the supply of essential medical devices for maternal, newborn and child health"	Proposed solution: Most laboratory and medical equipment can be put back into service without importing spare parts, as long as the right skills are available.	• Pulse oximeter and vacuum extractors, which are relatively low-technology devices, were functional in 3 and 15 of the 22 surveyed hospitals, respectively. • In the 31 health facilities surveyed, essential equipment such as phototherapy machine, suction machine and warming equipment—radiant heaters, resuscitators, complete caesarean section sets and diathermy machines were lacking.
Improving the use of surgical suction pumps in Sierra Leone	Mucha et al.	2021	Sierra Leone (medical centre)	To improve use of surgical suction pumps, an essential item in surgical care, and local design and manufacture of tubing connectors	Challenges faced in LMICs regarding medical devices, and solutions: • poor infrastructure • health care relies on NGOs • donations delayed by customs • reuse of consumables is the norm • no local production of medical devices or consumables • lack of access to consumables (no local production, unreliable and expensive importation) Proposed solution: innovative, frugal design with locally available resources and technology (3D printing), reducing medical device waste and disruption of hospital procedures	About 95% of equipment is second-hand refurbished devices from western countries

Table A2.1. *continued*

Title	Author(s)	Year	Geographical and clinical setting	Aim of the study	Relevance for WHO donations guidelines	Relevant numbers (e.g. percentage of medical devices available, percentage of donated medical devices)
Medical technologies procurement, management and maintenance in developing countries: The case of health challenges in Africa	Trunfio et al.	2021	Benin (medical centres)	To quantify donated medical equipment that is out of service in two hospitals in Benin	Challenges faced in LMICs regarding medical devices: • no culture of maintenance • preventive maintenance often not performed and corrective maintenance performed only if the equipment is completely unusable Proposed solutions: • in-depth needs assessments of beneficiary structures before making a shipment • donations must be accompanied by initial user training • the key to a successful donation is effective communication between donors and recipients, as well as correct involvement of the recipient in evaluation and approval of the donation proposal • the recipient must be able to refuse a donation that does not meet the country's needs to avoid inappropriate donations.	• 50% of donated equipment was not functional • 22% of donated equipment was not in use • 28% of equipment received was used • in 72% of cases, donors did not support beneficiaries in installing technology • in 74% of cases, donors did not support beneficiaries in operational checks • staff training courses provided in only 25% of cases • in 57% of cases, replacement parts were not available on site • in 71% of cases, replacement parts were not included in the donation • in 93% of cases, no instruction or maintenance manuals were included • in 64% of cases, no consumables were included • in 67% of cases, no accessories were included
Lessons from the frontline: Documenting the pandemic emergency care experience from the Pacific region – Infrastructure and equipment	Cox et al.	2022	Pacific region	To outline operational themes, enablers and barriers to the WHO Building Blocks infrastructure and equipment from the project and lessons for supporting health-care workers during the COVID-19 pandemic	Challenges faced in LMICs regarding medical devices: • Lack of trained staff can result in unopened and unused donated equipment. • Equipment donated without consideration of biomedical, maintenance, distribution and economic systems is suboptimal. Donations must be coordinated with health priorities and leaders on the ground, with awareness of the system's strengths and limitations to increase use and sustainability of the donation.	

Table A2.1. *continued*

Title	Author(s)	Year	Geographical and clinical setting	Aim of the study	Relevance for WHO donations guidelines	Relevant numbers (e.g. percentage of medical devices available, percentage of donated medical devices)
Spanish Rhythm Association member´s perspectives on cardiac implantable electronic device reuse in LMIC	Ruiz et al.	2023	LMICs and Spain (medical centres)	To describe the preferences of electrophysiologists and device implanting cardiologists in Spain on the management of explanted cardiac implantable electronic devices and their opinions and concerns on reuse in LMIC	Challenges faced in LMICs regarding medical devices: • Reuse of used (implantable) devices is a safe practice, provided that they are reprocessed and sterilized appropriately. • The most commonly cited concerns about device reuse were malfunction (cited by 24 participants: 57.1%) and infection (23 participants: 54.8%). Reuse of (implantable) devices should be considered only if a new device is not accessible, with adequate information for potential recipients about the risks of reprocessed devices and obtaining informed consent.	Approximately 21% of explanted devices could be reused.
How to improve regulatory practices for refurbished medical devices	Shukla et al.	2023	LMICs and HICs	To investigate regulations, opportunities and challenges for refurbished medical devices in major markets and propose regulatory guidelines for importing, selling, labelling and using these products to ensure high-quality and safety standards	Challenges of refurbished medical devices in LMICs: • dominance of major multinational companies over domestic companies; • substandard refurbishing to charge less for reconditioned equipment than their organized counterparts; • perception that used or pre-owned products are of inferior quality; • most consumers import refurbished medical equipment without after-sales service	
Medical device regulation and oversight in African countries: A scoping review of literature and development of a conceptual framework	Nasir et al.	2023	LMICs	To explore the literature on how medical devices are regulated and overseen in governance arrangements for health systems in African countries	Challenges faced in LMIC regarding medical devices: • Regulatory guidance for medical device donation is poorly implemented, ineffective and lacking, potentially due to funding constraints, insufficient personal and lack of technical expertise • Poor compliance with WHO guidelines	

HIC, high-income countries; LMIC, low- and middle-income countries

Table A2.1. *continued*

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Annex 3. Flyer providing reminders for donors and recipients of medical equipment

Goal

"Ensure improved access, of safe and good quality medical devices" **following the 5A principles:**

Affordable, Accessible, Acceptable, Appropriate and Available

Donor responsibilities

- Ensure that a donation is necessary and requested.
- Involve the recipient, and obtain consent from the relevant authorities and authorization for exportation and for importation into the recipient's country (when applicable).
- Offer only good-quality, safe, functional medical devices, including accessories, spare parts and consumables, if necessary, for at least 12 months.
- Analyse and disclose additional costs involved in the donation (e.g. transport, insurance, installation, maintenance, updates).
- Provide labels, user manuals and all other useful information in a language understood by the recipient.

Recipient responsibilities

- Prepare a detailed list of the medical devices required after assessing local health needs.
- When evaluating a donation, consider the resources necessary for proper functioning of the medical device in the short and long term (e.g. training, installation, technical staff, infrastructure, consumables, spare parts).
- Before accepting a donation, check whether there is a locally produced medical device is available at a cost-effective price. If so, explore whether a cash donation could be negotiated instead of a medical device donation.
- Prepare and use checklists to ensure that donations are appropriate and are transported, delivered and installed in a timely, safe and efficient manner.
- When the donation is received, check the packaging for damage and make sure that the equipment is fully functioning and is accompanied by the relevant, agreed manuals, spare parts, consumables and accessories. Check expiry dates and labelling of recurrent supplies.
- Refuse in a timely manner unsolicited, inappropriate, inadequate and/or incomplete medical device donations.

Joint responsibilities

- Review alignment between local needs and the selected medical device. Consider the following criteria: appropriate to setting, assured quality and safety, affordable and cost-effective, easy to use and maintain, conforms to donor policies, plans and guidelines, can be suitably disposed of in the recipients' country at the end of its life cycle.
- Follow relevant national policies, regulations and guidelines. If not available, the parties should develop institutional donation guidelines and standard operating procedures.
- Ensure continuous, effective communication between donor and recipient.
- Clearly define the terms of a formal collaboration, including who is responsible at each step (e.g. testing, shipping, customs clearance, commissioning, installation, training, maintenance, servicing, returning unfit products).

Maximize benefit to the recipient in the short and long term

Respect the recipient's needs and authority, including during emergencies

No double standards for safety, quality and performance

Ensure effective donor–recipient communication before, during and after donation.

In line with the WHO Global Model Regulatory Framework for medical devices, including in vitro diagnostic medical devices (2024): states should, when appropriate, through their national regulatory authorities, develop policies and regulations to protect the population in their jurisdiction and also prevent export of unsafe and unfit medical devices to other countries. Additionally, the national regulatory authority of the recipient country should register donated medical devices, to ensure that safety and quality standards are met.

Considerations for special situations

Donation of used medical devices:

- Used medical devices should be donated only if they have passed standard functionality testing and were properly refurbished, if necessary.
- The donor and the recipient should agree on a maintenance plan for a donated device, especially after the manufacturer's guarantee has expired or does not cover the donor premises.

Donation of refurbished medical devices:

- Equipment from a reputable refurbisher is preferable to a direct donation of used equipment from a hospital.
- It is preferable on the condition that the refurbisher provides a certificate of compliance with current safety and efficacy requirements.
- Used and refurbished devices, when properly tested or restored, can continue to be valuable.
- This approach helps minimize the environmental footprint associated with medical devices.

Donations during emergencies:

- During emergencies, preference should be given to donation agreements that:
  - are made between donors and recipients with an existing partnership.
  - are made by organizations and agencies with experience in emergencies;
  - involve provision of the most basic, universal medical devices; and
  - preferably apply to brands that are available in or close to the emergency.
- Stakeholders must respect WHO's core principles to meet the basic requirements for any acquired device.

If you identify any gaps, consider revising your donation plan.

More information needed?

Please see https://www.who.int/health-topics/medical-devices#tab=tab_1

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