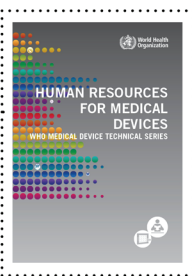




Medical device donations: considerations for solicitation and provision

WHO Medical device technical series





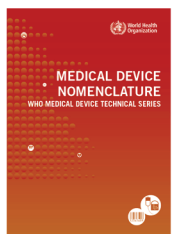
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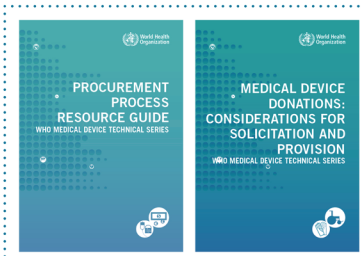
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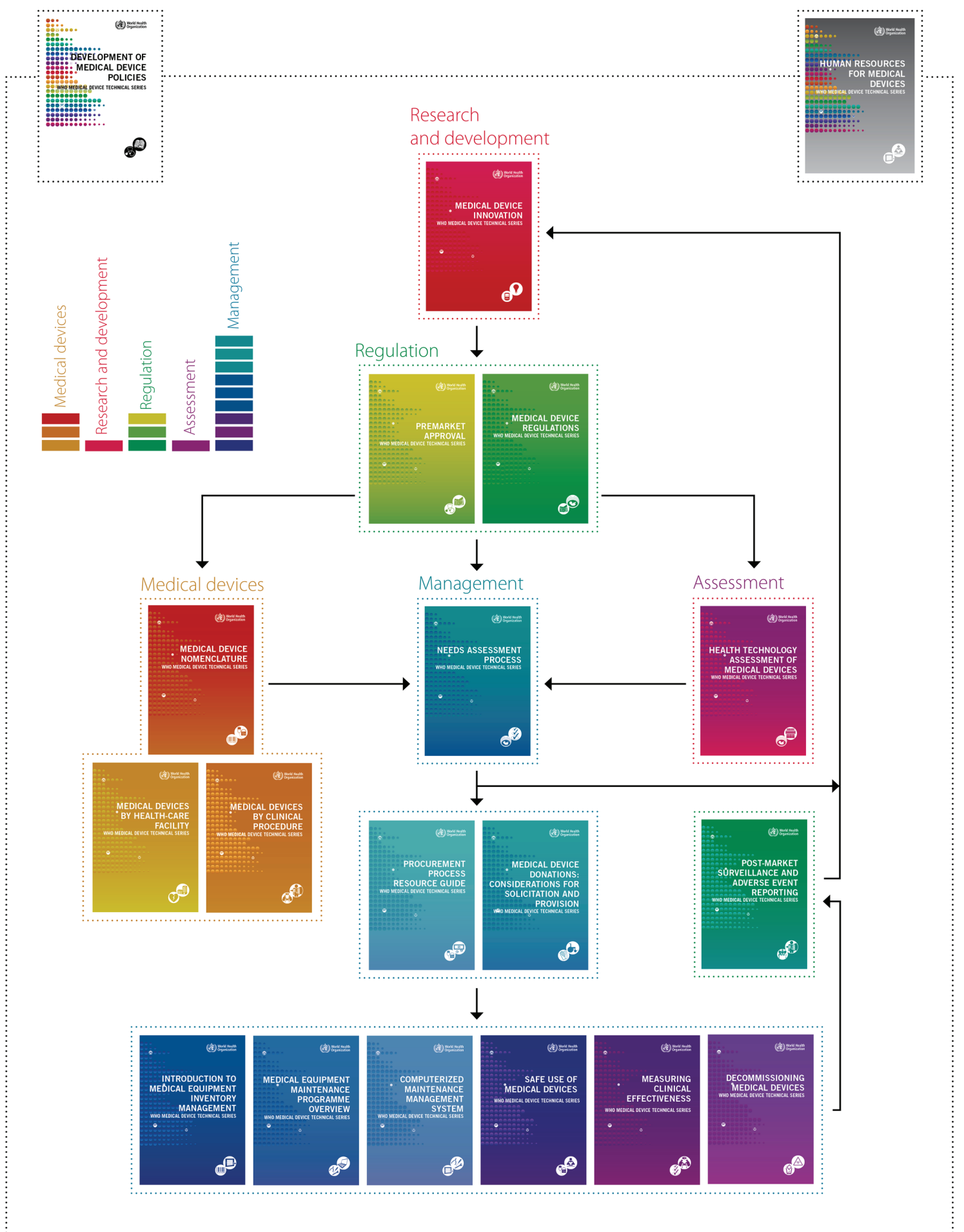
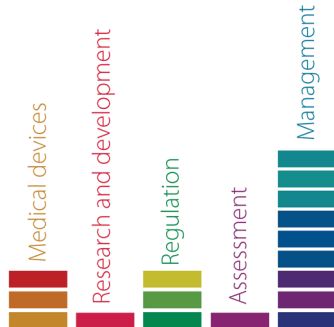
Medical devices



Management



Assessment



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WHO Library Cataloguing-in-Publication Data

Medical device donations: considerations for solicitation and provision.

(WHO Medical device technical series)

1.Appropriate technology. 2.Equipment and supplies - supply and distribution.
3.Technology assessment, Biomedical. I.World Health Organization.

ISBN 978 92 4 150140 8

(NLM classification: WX 147)

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Design & layout: L'IV Com Sàrl, Le Mont-sur-Lausanne, Switzerland.

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Preface

Health technologies are essential for a functioning health system. Medical devices in particular are crucial in the prevention, diagnosis, and treatment of illness and disease, as well as patient rehabilitation. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access, quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

- to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;
- to challenge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising 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 being developed for use at the country level. The series includes the following subject areas:

- policy framework for health technology
- medical device regulations
- health technology assessment
- health technology management
 - › needs assessment of medical devices
 - › medical device procurement
 - › medical equipment donations
 - › medical equipment inventory management
 - › medical equipment maintenance
 - › computerized maintenance management systems
- medical device data
 - › medical device nomenclature
 - › medical devices by health-care setting
 - › medical devices by clinical procedures
- medical device innovation, research and development.

These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels.

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and to help countries develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were discussed further during the First WHO Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level.¹

All meeting participants and persons involved in the development of these documents were asked to complete a declaration of interest form, and no conflicts were identified.

¹ *First WHO Global Forum on Medical Devices: context, outcomes, and future actions* is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf (accessed March 2011).

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.² It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.³

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

² World Health Assembly resolution WHA60.29, May 2007 (http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf, accessed March 2011).

³ *Information document concerning the definition of the term "medical device"*. Global Harmonization Task Force, 2005 (<http://www.ghif.org/documents/sg1/sg1n29r162005.pdf>, accessed March 2011).

Acknowledgements

Medical device donations: considerations for solicitation and provision was developed under the principal authorship of Ismael Cordero, ORBIS International, New York, United States of America, and under the overall direction of Adriana Velazquez-Berumen, World Health Organization (WHO), Geneva, Switzerland as part of the Global Initiative on Health Technologies funded by the Bill and Melinda Gates Foundation.

The document builds primarily on the foundation provided by the collaborative work encompassed in the WHO draft document *Guidelines for health care equipment donations (1)*. Unpublished revisions to this document made by Robert Malkin and Billy Teninty of Engineering World Health also contributed significantly to the content of this document.

The draft was reviewed by Matthew Baretich (Baretich Engineering), Jennifer Barragan (WHO), Ronald Bauer (Saniplan GmbH), Adham Ismail (WHO), Tania O'Connor (consultant) and James Wear (consultant), and edited by Cathy Needham.

We would like to thank Aditi A Sharma for assistance in proofreading and Karina Reyes-Moya and Gudrun Ingolfsdottir for administrative support throughout the development of this document.

Declarations of interests

Conflict of interest statements were collected from all contributors and reviewers to the document development. Ronald Bauer declared his employment at Saniplan GmbH, a firm that provides technical assistance and consulting services with the aim to improve the quality and accessibility of health systems and services, and Tania O'Connor declared her former employment with Johns Hopkins University-TSEHAI and Black Lion Hospital (ended in 2009) as remuneration from an organization with an interest related to the subject. None of these declared conflicts influenced the content of the document.

Executive summary

The health sectors of many developing countries rely significantly on donations of medical devices and medical equipment (also referred to in this document as “health-care equipment” or “equipment”). Although these donations are generally made with good intentions, the outcomes are not always positive if the donations are not properly planned and coordinated.

This document provides an overview of the issues and challenges surrounding medical device donations, and offers considerations and best practices that may be useful for making and soliciting donations. The document highlights the importance of an active participatory role for the intended recipients of medical equipment donations and emphasizes the importance of treating donations with the same rigour typically applied when purchasing medical equipment.

1 Introduction

The provision of modern health care is heavily dependent on technology, which includes health-care equipment. Because of economic constraints, the health sectors of many developing countries have to rely considerably on donations of equipment. In some countries, nearly 80% of health-care equipment is donated or funded by international donors or foreign governments (2). Although most donations are made with good intentions, the outcomes are not always positive if the donations are not properly planned and coordinated.

The introduction, utilization and maintenance of health-care equipment require considerable financial, organizational and human resources. Unfortunately, this is not always fully recognized. According to one estimate, only 10–30% of donated equipment becomes operational in developing countries (3). Reasons for unused equipment include mismanagement in the technology acquisition process, lack of user training and lack of effective technical support.

In many cases, donations circumvent the selection and procurement systems of the recipient country and institution, where such systems exist. Consequently, little consideration is taken of actual local requirements, the burden of disease and level of care, the number of user-staff and their capability, and the available level of technical expertise to provide maintenance. Even local manufacturer

representatives and equipment distributors, who may be expected to provide after-sales support, are bypassed. Further difficulties related to the purchase of consumables and availability of spare parts, among many others, could transform the donated equipment into a liability, rather than an asset, to the recipient.

Inadequate medical equipment donations are often due to a combination of the donor's lack of awareness of the particular challenges and needs of the end-users, and poor communication between donors and recipients about these challenges and needs. In particular:

- donors lack awareness of the local realities of the intended recipients;
- donors and recipients often do not communicate as equal partners in the pursuit of a common goal;
- recipients have difficulty articulating to the donor how best they can be helped;
- the recipient's circumstances may lead them to believe that anything is better than nothing.

Despite the many challenges associated with donations of medical equipment, the mutual benefit of both donors and recipients can be achieved with proper planning and communication. This document describes some of the best practices that can help lead to successful donations.

2 Purpose

The best practices and considerations covered in this document are intended to improve the quality of equipment donations and provide maximum benefit to all stakeholders. These considerations can be used to develop institutional or national policies and regulations for medical equipment donations.

Although these considerations can be applied anywhere, they may be especially useful for health systems in developing countries, which often depend on donations. Although this document only covers health-care equipment, many of the considerations can be also applied to other types of donations such as medical supplies and consumables.



3 Best practices for donors and donation solicitors

Health-care equipment donations occur in many different situations. Donors include corporations acting directly or through other organizations, individuals, nongovernmental organizations, and governments providing aid to other governments. The intended recipients range from individual health-care facilities to entire health systems of countries. Although there are differences between these scenarios, the basic considerations discussed below can apply to all situations.

- preparing and using checklists to ensure that donations are appropriate and delivered in a timely and efficient manner;
- sharing with potential donors the priority lists, policies and checklists concerning medical equipment donations;
- providing feedback to the donor during the donation process as well as final outcomes of the donation;
- refusing unsolicited or inappropriate donations.

3.1 Ensuring that the recipients are actively engaged in all stages of the donation process

Often the intended recipients of equipment donations are neither consulted nor do they take an active role during some or all of the stages of the donation process, even though they are primary stakeholders in the process. For the purpose of emphasizing the indispensable active role of potential donation recipients, from this point forward in this document, potential recipients will be referred to as “donation solicitors”. Donation solicitors are encouraged to be actively involved during all stages of any equipment donation action. This includes:

- preparing lists of prioritized equipment needs indicating desired specifications, model preferences, needed consumables, desired spare parts and training requirements;
- evaluating offers from donors against priority equipment needs and desired specifications and model preferences;
- preparing and following policies and procedures concerning equipment donations;

3.2 Ensuring that the needs of the end-users and patients are met

When medical equipment is purchased, effective health-care providers thoroughly review equipment choices prior to purchase to ensure that the needs of the end-users and the patients are met. However, equipment donation offers are generally not given the same level of attention and deliberation. The criteria listed Table 1 are typically used when evaluating equipment purchases and also apply for evaluating equipment donation offers. They can be used by both donors and donation solicitors to critically review the technical specifications of the equipment and to decide on the suitability of the equipment being considered for donation.

3.3 Regulatory and policy considerations

Donations of medical equipment are to be done in accordance with a country’s regulations and policies pertaining to the donation, importation, marketing and use of medical devices.

Table 1. Criteria for evaluating equipment donation offers

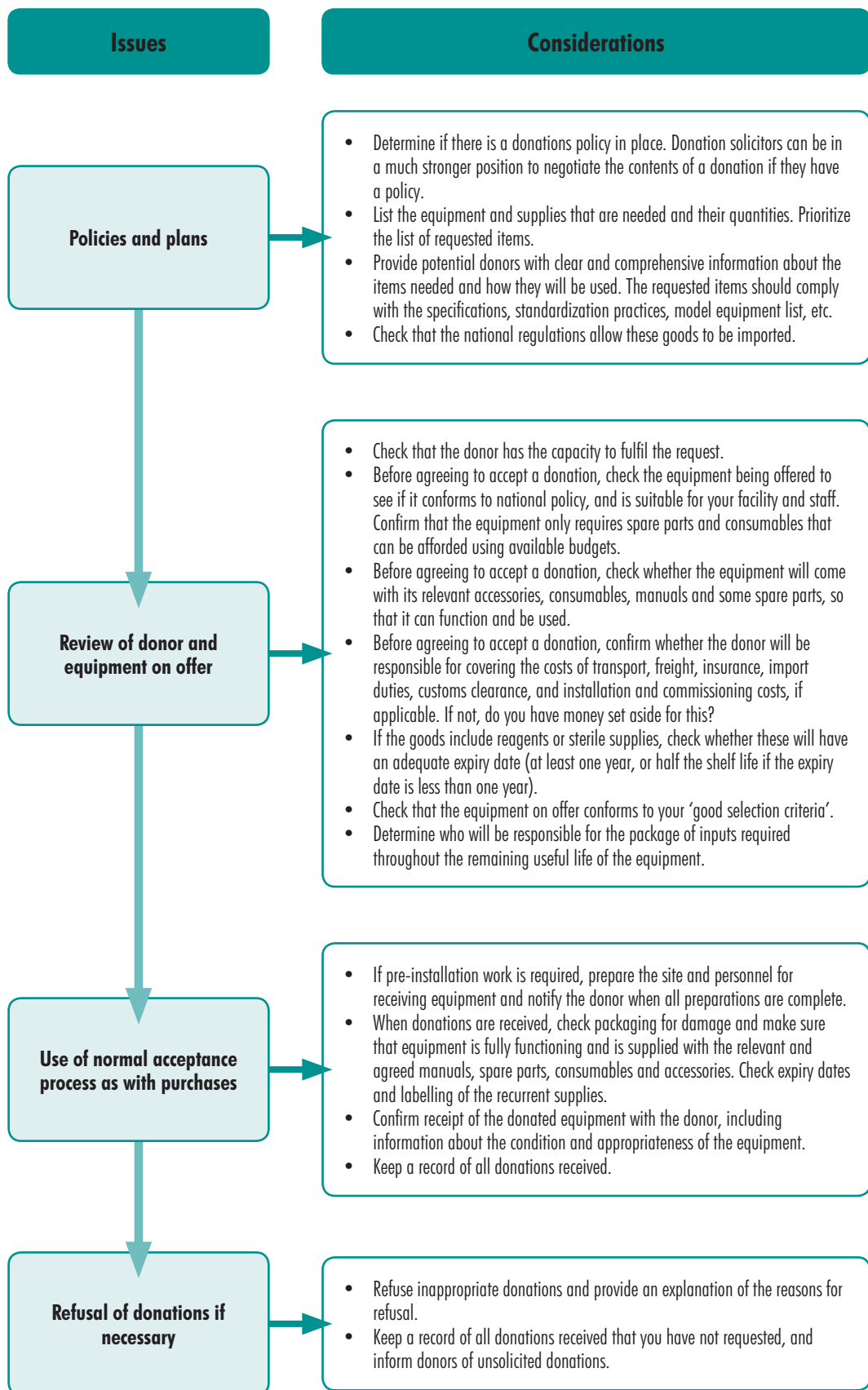
Indicators of suitability	Criteria
Appropriate to setting	<p>Desired characteristics:</p> <ul style="list-style-type: none"> • suitable for the level of facility and service provided • acceptable to staff and patients • suitable for operator skills available • suitable for the local maintenance support capabilities • compatible with existing equipment and consumable supplies • compatible with existing utilities and energy supplies • suited to the local climate, geography and conditions • able to be run economically with local resources.
Assured quality and safety	<p>Desired characteristics:</p> <ul style="list-style-type: none"> • of sufficient quality to meet requirements and last a reasonable length of time • made of durable materials • made from material that can be easily cleaned, disinfected, or sterilized without rusting • manufactured to meet internationally recognized safety and performance standards • suitably packaged and labelled so that it is not damaged in transit or during storage • provided by reputable, reliable, licensed manufacturers, or registered suppliers.
Affordable and cost-effective	<p>Desired characteristics:</p> <ul style="list-style-type: none"> • available at a price that is cost-effective. Quality and cost often go together (for example, the cheaper option may be of poor quality and ultimately may prove to be costlier in the long term) • affordable in terms of costs for freight, insurance, import tax, etc. • affordable in terms of installation, commissioning, and training of staff to use and maintain them • affordable to operate (costs of consumables, accessories and spare parts over its life-time) • affordable to maintain and service • affordable to dispose of safely • affordable in terms of the procurement process (for example, the cost of a procurement agent or foreign exchange) • affordable in terms of staffing costs (for example, costs of any additional staff or specialized training required).
Ease of use and maintenance	<p>Equipment selected/accepted if:</p> <ul style="list-style-type: none"> • the donation solicitor has the necessary skills in terms of operating, cleaning and maintenance • instructions and manuals are available in the proper language • user training is offered by the supplier or donor • local after-sales support is available with proven technical skills • the possibility of additional technical assistance through service contracts exists • the equipment comes, preferably, with a warranty covering a reasonable length of time, for which the terms are well understood (for example, does it cover parts, labour, travel, refunds or replacements?) • a supply channel exists for equipment-related supplies (for example, consumables, accessories, spare parts) • there is assured availability of needed supplies for a reasonable period (up to 10 years).
Conforms to donor solicitor's policies, plans and guidelines	<p>Equipment accepted/selected if it conforms with:</p> <ul style="list-style-type: none"> • purchasing and donations policy • standardization policy • the technology level described in standard equipment lists and generic equipment specifications • conclusions resulting from review of literature and comparative products • conclusions resulting from feedback regarding previous purchases and donations.

Source: Adapted from Kaur M et al. (2005)

If national donation regulations, policies and guidelines are not available, donation solicitors can develop their own donation policies and guidelines following the best practices described in this document and the considerations summarized in Figure 1. Similarly, donors are encouraged

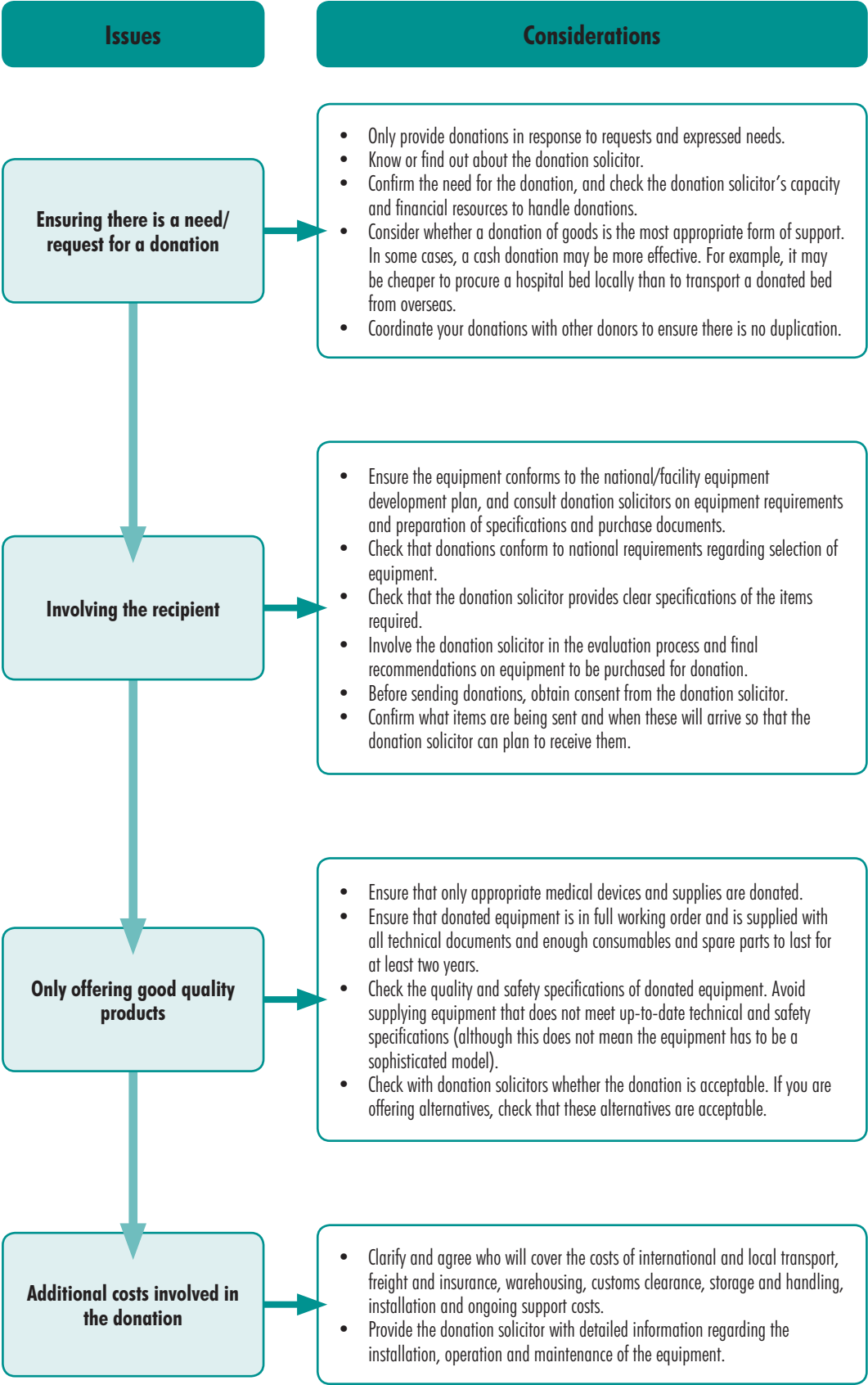
to develop their own donation policies for situations where there are no national or institutional donation policies and regulations. Some of the main elements that may be included in a donor's policy are summarized in Figure 2.

Figure 1. Essential elements of a donation solicitor’s policy for equipment donations



Source: Adapted from Kaur M et al. (2005)

Figure 2. Essential elements of a donor’s policy for equipment donations



Source: Adapted from Kaur M et al. (2005)

3.4 Considerations for existing local markets of medical equipment

When local markets for medical equipment are ignored or bypassed, it is likely that the required after-sales support for service, parts and consumables may not be adequately available. Consulting and involving local vendors, where they exist, will help to establish beneficial relationships between the users and the vendors of equipment and can prove to be less expensive than donations. Additionally, procuring locally helps foster local markets and this will in time reduce the reliance on importing equipment for every purchase, shipping the equipment abroad for service, and paying for service technicians to travel from abroad to repair the equipment. Available local sources of medical equipment are many times a preferable alternative to vendors outside of the recipient country, who may not be concerned with or in a position to properly support the needs of the users.

3.5 Considerations for established procurement systems

While many health systems purchase medical equipment by following established guidelines, policies and procedures at the institutional, regional or national levels, donations are often not subject to the same level of rigour, which contributes to inadequate equipment being donated. Proper planning, evaluation, selection and approval according to governing policies and procedures, is applicable to both purchases and donations.

3.6 Considerations for public health needs

Frequently, attention is given to donating large and sophisticated medical equip-

ment, such as magnetic resonance imaging (MRI) machines. However, the majority of medical devices required in any health system are much more basic, such as stethoscopes, blood pressure machines and otoscopes. The lack of appropriate and functioning basic technologies, especially at the primary and first referral levels in remote areas, can limit access to preventive and curative interventions. These basic devices can have a far greater impact on public health than more sophisticated devices.

One way to estimate the proper balance of sophisticated and basic equipment is to consider the burden of disease when contemplating a donation. This analysis goes beyond the hospital or recipient organization to cover multiple levels of care in the locality, region or entire country. Providing sophisticated equipment to intensive care units in hospital facilities may have less of an impact on health than donating far less expensive devices such as weighing scales to use in areas where malnutrition is predominant, or respiratory timers for the diagnosis of pneumonia, for example.

3.7 Inclusion of health facility input when donations are coordinated at a national level

Many donations are made to the country via the ministry of health or other national bodies. In these situations it is important that the input of the recipient institutions is considered before requesting or accepting donations. Without an understanding of the specific needs of the recipient institution, it is very likely that the donation may not be suitable. Thus, it is important that national level policies and guidelines for equipment donations, as well as purchases, incorporate 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 donation solicitor is not able to sustain the costs of installation, service and supplies required to operate and maintain the medical equipment offered or requested for donation, then the donor may want to consider an alternative donation package that includes the operation and maintenance costs, especially considering that the purchase costs of medical equipment only represent about 20% of the total costs incurred during the life of the equipment (3). For instance, instead of donating 20 dialysis machines, the donor could instead, for the same cost, donate 10 dialysis machines along with an installation of the required water treatment equipment, dialysers, tubing, and the required chemicals to operate the machines for several years. This way, the complete costs of operating medical equipment are taken into consideration while ensuring complete operability of the equipment for a known amount of time.

3.9 Consideration of special environmental and human resources to support equipment

Detailed information about the installation, operation and maintenance of the equipment will enable the donation solicitor to begin pre- installation tasks, including the training of personnel for operation and maintenance.

In addition to providing the expected completion date of pre-installation work, it is also desirable that the donation solicitor provides the donor with details such as floor plans, architectural drawings and blue-prints, which could enable the donor to identify problems and recommend solutions based on previous experience.

Training of personnel to operate and maintain the equipment is also an important facet of preparation.

If the donation solicitor or the donor does not have the technical knowledge to perform the necessary pre-installation or training preparations then proper assistance and consultation by qualified experts can be sought.

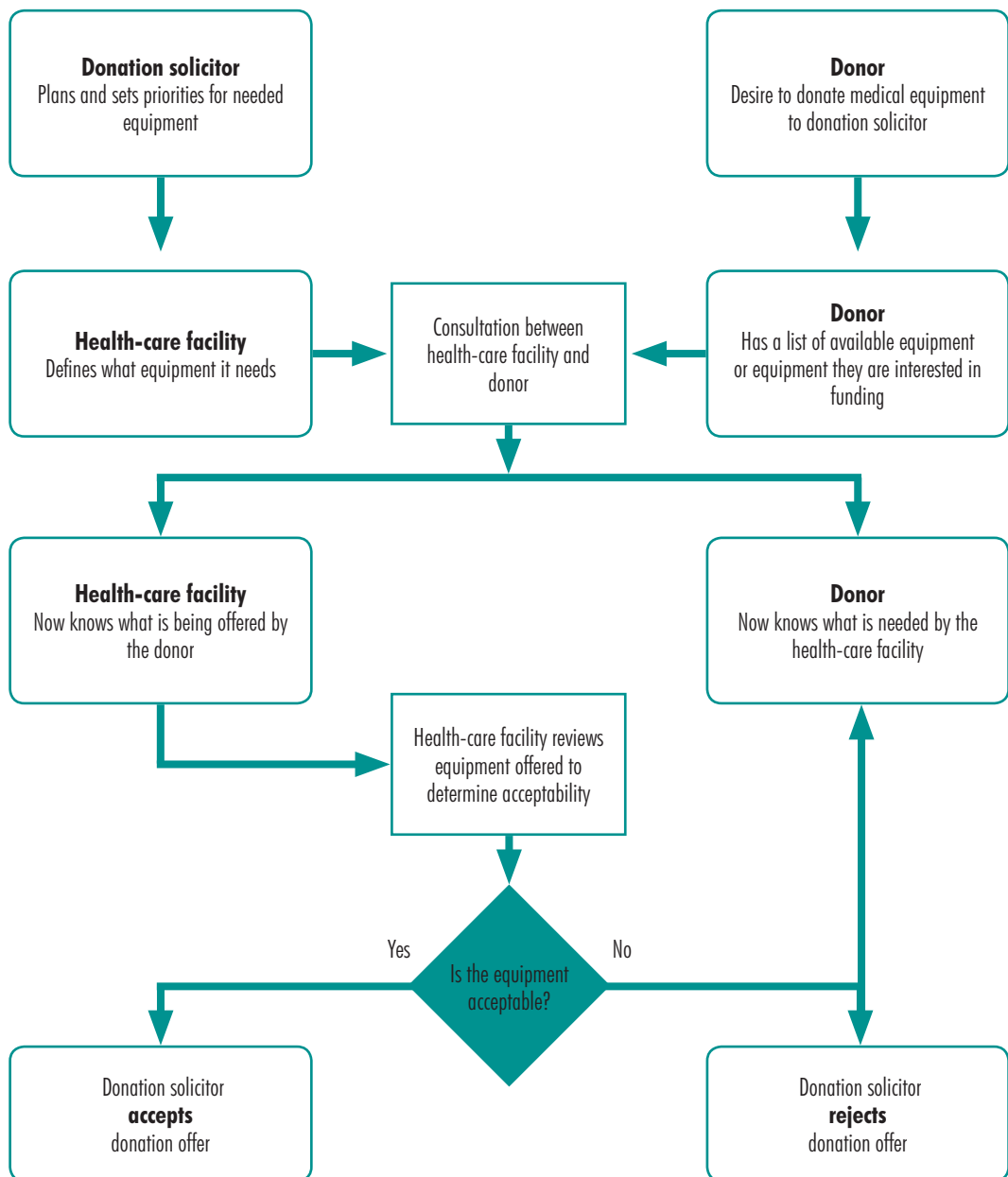
After all preparatory requirements have been satisfied, the donation solicitor can notify the donor to assemble and package the equipment for shipping.

3.10 Communication

Continuous communication by donors and donation solicitors throughout the entire donation process, which is summarized in Figure 3, is a very important factor that can determine the success of the donation. Some desired characteristics for these communications are:

- the active involvement and input of the donation solicitor, as the main stakeholder;
- the inclusion of facility-level input if the donation is being coordinated at a national level;
- assessment visits to the recipient facility by donors prior to the donation;
- evaluation visits by donors to the recipient facility after the donation;
- feedback by the donation solicitor to the donor during and after the donation;
- the donor's understanding of the donation solicitor's needs and specific challenges;
- appropriate consultation with medical device experts if the donor or donation solicitor does not have the background to understand the implications of the donation;
- consultation with in-country suppliers and distributors of medical equipment;

Figure 3. Process for soliciting and offering donations of medical equipment



- consultation of donors and donation solicitors with applicable national and international regulatory and standards agencies and bodies;
- the final decision to accept or reject donations is made by the donation solicitor.

3.11 Considerations for special situations

Used equipment

Donations often involve removing used equipment from hospitals in industrialized nations and providing it to hospitals in

developing nations. Used equipment, like new equipment, requires user training, maintenance, spare parts and manuals for service and operation. However, unlike for new equipment, the manufacturer is less willing to provide support for used, donated equipment, leaving the recipient with little or no recourse when the equipment breaks. Donations of used equipment are more likely to be beneficial when there is assurance that proper support from the manufacturer in the form of repair parts, service and consumables can be provided for an appropriate period of time. Both donors and donation solicitors can establish in their policies the minimum acceptable period where manufacturer support will be available, for instance five years. Since the serial numbers of medical equipment 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 new owners of the equipment. In general new equipment is preferable over used equipment.

Refurbished equipment

Refurbishers of medical devices, who are responsible for restoring equipment to its original working condition for the purpose of resale, are subject to general principles of liability. They are expected to restore equipment to the manufacturer's original specifications and follow the good manufacturing practices (GMP) established by their national authorities for manufacturers of health-care equipment. Reputable refurbishers provide user manuals and all accessories required to use the equipment. For these reasons, equipment from a reputable refurbisher is preferable to a donation of used equipment originating directly from a hospital.

Laboratory equipment

In addition to reviewing laboratory equipment using the standard donation equipment criteria in Table 1, the following questions about reagents, calibration controls, consumables and accessories can help in making decisions.

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

Imaging and radiology

When considering donation of radiological equipment, careful attention is required due to complex matters such as specialized training, professional installation and the need for specialized maintenance support in the field. Some items to consider 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 the 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 when crating for shipment;
- possible inclusion of a new x-ray tube with each unit to ensure availability of a working replacement;
- installation instructions, service manuals and professional assistance with installation;
- inclusion of a service contract.

The reuse of medical devices that are labelled “for single use”

When a manufacturer designs devices and consumables that are labelled “for single use”, this is done with the intention that they will not be reused. Therefore:

- it may not be possible to take apart some devices for proper cleaning and disinfection;
- single-use devices may not clean and re-sterilize properly;
- the mechanical integrity and/or functionality of some single-use devices may not stand up to reprocessing;
- it may not have been determined how cleaning chemicals or sterilizing agents affect the reprocessed devices or the patient;
- because of the design or the materials of the device, some models within a particular type of device may be suitable for safe reprocessing while others may not;
- there may not be evidence of how many times a device may be safely reprocessed;

- some devices, such as single-use injection syringes, should never be reused because the risk of infection is very high.

In considering the reprocessing and the reuse of a device labelled “for single use”, a thorough knowledge of possible hazards is needed together with an assessment of the impact on patients against the potential cost savings. Are there adequate facilities and trained persons to do the reprocessing? Some possible hazards may not even be foreseen. The ethical questions and the potential consequences of patient infection are important considerations, along with the question of legal responsibility for reprocessing and reuse of single-use devices. In the United States of America, for instance, the Food and Drug Administration (FDA) subjects the reprocessor of a single-use device to the same regulatory requirements as those for the original manufacturer of the device.

Donation of implantable devices

Implantable devices considered for donation can fall into three categories:

- devices that have never been used;
- devices implanted during surgery that were then removed during the same surgery upon discovering they were not a proper fit for the patient;
- devices used in patients that were later removed because of component fatigue, site infection, etc.

Devices in the last two categories require re-sterilization and special preparations for reuse, which may compromise the device. Because of this, these devices are generally questionable and it is advisable to avoid the donation of such devices.

4 Concluding remarks

Donations of medical equipment can provide mutual benefit to donors and donation solicitors by following the best practices delineated in this document. The keys to successful donations are effective communication between donors and donation solicitors, and the active

involvement of donation solicitors in reviewing and approving donation offers. The capacity of donation solicitors to reject donation offers that do not meet their needs is essential to avoid inappropriate donations and to build capacity in planning and managing medical devices.



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Useful resources

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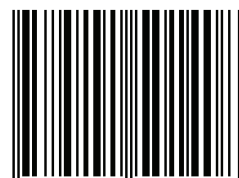
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ISBN 978 92 4 150140 8



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