

Standards for Medical Equipment Donations

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Introduction

Great intentions don't necessarily produce great donation results. This is because the challenges involved in supplying therapeutic and diagnostic devices to developing nations are complicated under the best of circumstances. Without experience it can be difficult to tell an inappropriate donation of medical equipment from an appropriate donation until after the fact. For instance:

- How is it that a Blood Gas Analyzer shipped to Accra, Ghana is a good medical equipment donation, but sending the same piece of equipment to Cape Coast, Ghana is a bad donation?
- Is it inappropriate to send a working, but out dated piece of medical equipment with an operation manual in the language of the user to a developing country?
- If a doctor working in a rural clinic with no surgeon or surgery room requests the donation of a new MRI which requires a trained operator and has the potential for expensive repairs, is it appropriate to send the clinic the equipment?

Sending appropriate medical equipment donations is critical because inappropriate donations consume valuable resources, patient's diseases may go undiagnosed, and in some cases, lives may be lost. On the other hand, appropriate medical equipment donations will benefit the end user.

"Achieving" an appropriate medical device donation is most likely to occur when the donor/supplier and recipient have knowledge and experience with health care devices in developing countries. Good communications and planning skills are also important in providing appropriate medical donations.

Common Mistakes in Medical Device Donations

Medical equipment donations go wrong because the donor/supplier and the recipient don't take the following factors into consideration BEFORE equipment is sent:

- Installation: The best equipment donations improperly or uninstalled are useless. It is vital to include installation planning as part of the donation or to establish an understanding of the technical and financial resources needed to make the donated devices usable.
- Repair/Maintenance Cost: The recipient must be aware of the ongoing cost of repairs. Many devices donated with a great desire to improve the health of underserved areas become storage relics after the first breakdown. Consider the costs and logistics for obtaining parts and technical expertise for maintenance when selecting equipment these services may create liabilities that cannot be supported by the recipient or end user.
- Underutilization: Donated equipment may be underutilized if the end user lacks the appropriate operator and service manuals, staff expertise or local support for the device. Other reasons for underutilization may include electrical power challenges, excessive operating costs and improper initial selection of patient load and device capability. Example: (It is inappropriate to supply an automatic chemistry analyzer with high volume capacity if the test demand is limited a more appropriate device may be a spectrophotometer or semi-automatic analyzer).

- The life expectancy of the equipment will be greatly diminished if proper routine maintenance is not completed. Many brand new and used devices are not functional within the first year of service.
- Accessories/Parts: There are numerous occurrences of devices never used due to lack of accessories, necessary ancillary equipment, and parts needed to operate and install. Example: (A new anesthesia machine is requested and delivered to a remote hospital in Ghana. The machine lacks the hoses, connectors and regulators to connect the unit to pressurized cylinders. This machine still sits in the corner of the room while an antiquated machine remains the only viable means for general anesthesia.
- Consumables: There are many examples where great care to consider every step of the donation process was considered. Despite the high level of concern taken the devices were provided but the consumables were either not included or only a limited supply was donated. It is important to include an agreed upon amount of consumables needed to operate the donated device. If the consumable costs create a financial or logistical burden on the end user it is necessary to consider alternative machines. An ideal target would be to provide a minimum of one year supply of consumables.
- Downtime: Equipment that frequently requires service is rarely appropriate in developing nations. The financial repair burden, inefficiency, lack of technical expertise and unreliability seldom outweigh the benefits the device brings.
- Safety – Quality –Benefits: It is important to consider safety, quality, durability, and how these factors compare to the benefits gained. Some devices are donated due to safety, quality and reliability concerns. If these are concerns in a developed nation, the problems will only be exacerbated in developing nations.

Standards for Donation of Medical Devices

If there is a Golden Rule of Medical Equipment Donations it is: **“Donor/suppliers and recipients must insure that the donation benefits the patient!”**

To ensure that end users receive a benefit, not a burden, as a result of medical device donations several organizations have developed comprehensive and reliable guidelines to improve the quality of medical equipment donations. Note -- Worthy standards for medical device donations have been promulgated by: The World Health Organization¹ (WHO), International Medical Device Group², Association for Appropriate Technologies and the World Council of Churches³, Technical Exchange for Christian Health Care⁴ (TECH), United Nations Kosovo Force for Organization and Reconstruction⁵, InterAction⁶, and The Partnership for Quality Medical Donations⁷ (PQMD).

STANDARDS FOR MEDICAL EQUIPMENT DONATIONS

Edited with permission from Technical Exchange for Christian Health Care (TECH)

- Be Clinically and Economically Appropriate: The donor/supplier will provide equipment that: (1) Performs the needed clinical function, (2) Operates in the appropriate environment and is realistically maintained, and (3) Is economically reasonable (is it sustainable?).
- Assure Equipment Quality: The donor/supplier will ensure that equipment is fully operational with all essential accessories and supplies before shipping to the

recipient. The supplier should follow a basic checklist to see that all components have been included and will provide the recipient with a like list.

- Consider Ancillary Equipment: The supplier will ensure that the recipient is aware of all ancillary equipment, ongoing supplies needed and utilities necessary to the support of the device or equipment being donated. An acknowledgement that these ancillary devices exist or a commitment to procure these devices is necessary before the primary equipment need can be addressed. The donor may need to consider these as part of the primary equipment supplied.
- Include Technical Manuals: The donor/supplier will provide appropriate Operator, Service and Maintenance manuals for all equipment.
- Include Installation Instructions: The supplier will provide detailed installation instructions for all equipment that requires installation. All components should be clearly identified and referred to in the installation instructions.
- Provide for Technical Assistance in Installation: When necessary and possible, the donor/supplier will provide technical assistance for the installation of the equipment.
- Provide Equipment Training: Where possible, the donor/supplier will ensure that the recipient has the necessary expertise to use the provided equipment. The donor/supplier will promote, recommend and provide technical training for the operation of equipment.
- Be Adequately Packed for Shipping: The supplier will crate and pack equipment so as to minimize damage during shipment.
- Consider Desired Equipment Features: When considering what equipment, if any, to provide, suppliers will consider to the following characteristics – simplicity, portability, minimal amount of required accessories, availability of supplies necessary for operation, and standardization of equipment in the user's area.
- Start with a Supplier-Recipient Agreement: Communication between the supplier and end user shall determine the appropriateness of the equipment before it is shipped.

Donation Process

If the awareness of guidelines for health care equipment donations and knowledge of the pitfalls inherent in medical equipment donations are the foundation for good medical device donations, information sharing (communication) and planning are the building blocks. A donation process based on communication and planning will probably include the following steps:

- Evaluate the recipient and their request (Likewise, the recipient should investigate the capabilities and experience of the donor/supplier)
- Conduct a Needs Assessment
- Establish effective communications between the donor/supplier and recipient
- Determine what is an appropriate donation

- Prepare a Site Plan for the equipment
- Standards for Packing/Shipping/Customs
- Plan for equipment installation
- Personnel training
- Conduct a post donation follow-up

Evaluate the Recipient and their Request

It is important to realize that not all requests are appropriate or needed. It is also vital to establish the credibility of the recipient. Some individuals make requests based on self-interest, or misconceived ideas rather than fact and data gathered from a team representing the most significant needs of the institution or health community.

Care and respect should be exercised when evaluating perspective recipients. It is important to be concerned, but understand that questions and advice may be misunderstood as an insult or disregard for their judgment and abilities.

A Check List for Reviewing the Recipient and Their Request can be found at Addendum A

Conduct a Needs Assessment

The most important prerequisite is that there is a true need and that the donation and efforts will benefit the health of the community served to the greatest extent.

However, before it is possible to assess the need it is necessary to establish effective communications and a partnership with the prospective recipient. This partnership is vital to the success of the entire process and endeavor to improve the health impact of the area.

Prepare an Impact Statement

An Impact Statement will measure the effect on a community. Questions answered in an Impact Statement include:

- How would the equipment impact the morbidity and mortality of the region?
- Is the catchment area sufficient?
- What is the best location? (Village, region, etc.)
- What negative effects must be considered? (Cost, competition, unforeseen secondary effects such as commercialization for the wealthy.)
- Who will be served? Who will not be served?
- Will this donation burden the resources of the facility served such as time and financial stability of other important social, commercial and health related services?
- In short, after researching the recipients area of influence, will the benefits and improvements outweigh the additional cost, time, and resource burdens of the donated equipment?

If it is determined that the need is insufficient to warrant the donation, the donor or supplier should respectfully inform the requestor in writing with the pertinent data and statistics indicating the reasons why the donation is inappropriate. Alternative solutions or

equipment may be suggested to the requestor. It is inappropriate and wrong to donate the equipment for reasons other than for the benefit of the end user.

Establish effective communications

Effective communication is essential in the development of an equipment donation plan. It's a given that good communication is a necessary for a good health device donation to take place – it also leads to good relationships and healthy partnerships.

Tools for effective communications include mutually developing a checklist of each partner's responsibilities or preparing a written agreement to promote understanding of each partner's expectations.

Communication doesn't stop once a piece of equipment is shipped. Follow-up, problem resolution and support after the unit is placed in service are required!

Keep in mind the communication tools taken for granted in developed countries -- phones, fax machines, and e-mail -- are not so common or reliable in rural areas of many developing countries. Differences in technology are likely to cause time consuming delays -- be prepared to deal with it!

Determine what is an appropriate donation

An appropriate donation is challenging to determine and may require technical expertise from a specialist for the type of devices under consideration. **It is also important to incorporate a site plan with the determination of appropriateness.**

It is important to remember that what is appropriate at one location may be entirely useless at another. Minimal guidelines for selecting the most appropriate equipment for the requestor or intended recipient are provided in Addendum B.

Compare the advantages or disadvantages related to the choices between the selections of new, refurbished or used equipment. At first glance one might think that newer devices are always the best choice, but experience has shown that refurbished devices may serve the requirements more effectively than new devices. Microprocessor controlled, digital devices are generally more susceptible to power fluctuations, temperature, line distortion and computer related faults. New equipment may also require use of proprietary software, consumables, service literature and fewer service options. A greater level of skills is generally needed to service these devices. Acquisition of new equipment may be financially unattainable for donors.

Factors to consider when selecting New, Refurbished, or Used Devices

Refurbished equipment with analog or digital control devices generally offer lower acquisition costs, simplicity (fewer things to go wrong), a better ability to handle power problems, and less temperature sensitivity. Usually refurbished equipment is less expensive to operate. Disadvantages of refurbished devices includes possible difficulties obtaining repair parts and service, shorter life expectancies, higher levels of skills needed for manual techniques for operation or interpret results, lack operator and service information, lack of support from the manufacturer.

Used equipment donations should be treated with careful thought and handling. Used devices are attractive to many providers and recipients because they can be obtained at seemingly low or no acquisition cost. It is estimated that nearly 80% of all used medical devices are not fully operational upon arrival to the recipient. If used equipment is to be considered for donation, the criteria or quality should not suffer. All devices should be checked, accessorized, include service and operation manuals, be viable for at least 2 years, and meet the need and expectations of the recipient. Used equipment devices should not be donated unless they include these critical components.

In general it is best to evaluate all the needs, costs, quality and life expectancy for every individual item proposed to the recipient. It is better to provide nothing at all than to burden the recipient with useless equipment or equipment which cannot be operated with the means and resources available to the recipient.

Prepare a Site Plan

To avoid expensive mistakes or discouraging results a Site Plan should take into consideration what facility changes will be required, any special requirements to operate the device, and government regulations.

Initial consideration should be given to determining if the physical openings to the facility will allow for the movement of the device(s) through the building to the final planned location! Other facility changes to accommodate a new installation of equipment include:

- Structural enhancements and alterations for floors, ceilings or walls
- Plumbing and sanitation changes to meet equipment requirements
- Electrical changes to meet equipment requirements
- Security and safety enhancements to protect staff and patients

Special equipment requirements may be the likes of:

- Lead/copper shielding for radiology or imaging equipment
- Acoustic shielding for audiometers or equipment with unwanted noise interference.
- Air conditioning – heating systems
- Humidity control
- Water treatment or specified pressure requirements
- Medical air & gases (pressures & volumes needed)
- Exhaust hoods (Filters example: HEPA)
- Hazardous waste handling equipment
- Ancillary equipment

National, State, district and local ordinances may prohibit or regulate the installation, operation, or administration of medical devices or their use. Proper documentation may be necessary before installation or use is permitted.

A facility use and flow study is helpful to determine best location for new installs.

Conduct a post donation follow-up

A post donation evaluation is necessary to resolve problems, evaluate installation and training, provide feedback and appreciation to donors and to learn how to improve the process, standards, and procedures. A post donation evaluation also provides the recipient with support past the initial placement of the equipment into service.

Problem resolution can be expensive and logistically difficult. An understanding of who is responsible for these resolutions and expenses should be reviewed before the follow-up stage of a donation.

Lessons learned from a post donation evaluation should be shared with colleagues and technical organizations in order to improve the quality of future medical donations.

Conclusion

Considerable effort is required on the part of donor/suppliers and recipients to assure that medical equipment donations are a benefit (and not a burden) to end-users and patients. Every one involved in donations of health care devices need to know and practice the highest standards for medical equipment donations.

It is better to provide nothing at all then to burden the recipient with useless equipment or equipment which cannot be operated with the means and resources available to the recipient.

If the donors and distributors are inexperienced or unaware of issues and challenges involved with supplying therapeutic and diagnostic devices to developing nations, they should seek assistance from experts in the delivery, operation and support of devices provided to developing health communities. Several Non Government Organizations (NGOs) specialize in this area. Partnering with professional technical and international health and relief organizations will in able the inexperienced to provide appropriate medical equipment donations.

ADDENDUM A**Check List for Reviewing the Recipient and Their Requests**

Recipient Reputation:

Yes	No	Question
___	___	Has a Needs Assessment been completed?
___	___	If a Needs Assessment has been completed, does it warrant further evaluation of the recipient and action plan?
___	___	Is the recipient known by the donor or a reputable source? <i>(References preferred)</i>
___	___	Is diversion by the recipient a concern?
___	___	Is the underlying reason for the requested donation acceptable to the donor, government and community? <i>(For example: training unit for education, used for financial institutional support, personal gain, community health concerns, method to attract health professionals, etc.)</i>
___	___	Does the recipient agree in writing to provide necessary follow-up information for donor evaluation?

Request Evaluation:

Yes	No	Question
___	___	Does the requested device fit into an overall health improvement plan? <i>(An example of an inappropriate fit may be a CAT scanner in a facility that has yet to acquire or upgrade other more basic imaging equipment.)</i> Is the device truly needed?
___	___	Will the device require specialists that the facility cannot acquire?
___	___	Is the device requested one of the highest priorities, making the greatest impact on the community or facilities health?
___	___	Will the recipient be able to sustain the equipment over its entire life expectancy? <i>Some devices create new financial burdens on the health institution.</i>
___	___	Does the recipient have personnel that have the necessary skills and training to operate, maintain and interpret results for the new equipment?

<u>Yes</u>	<u>No</u>	<u>Question</u>
—	—	Can the recipient meet the requirements of the site plan for the device? (<i>For example: cost to upgrade electrical system to accommodate the power and stability specifications for the new device.</i>)
—	—	Is the recipient aware of all costs associated with the operation, consumables and service of the requested item?
—	—	Can additional consumables and service be acquired from local sources?
—	—	Does the device meet existing government guidelines or requirements?
—	—	If the device requires installation expertise – Is the recipient technically capable of safe and proper installation?

ADDENDUM B

Check List for Determining What is an Appropriate Donation

Yes	No	Question
___	___	Is there a true need?
___	___	Will the device meet the need?
___	___	Is this the most efficient means to achieve the expected result?
___	___	Is it the most cost effective means to achieve the goal?
___	___	If the device requires the recipient to modify their facility will this cost be beyond the resources or capability of the facility?
___	___	Will the cost to operate the device threaten the recipient's financial stability?
___	___	Does the device meet the electrical requirements for the recipients location? Does the plug, voltage and current requirements match the recipients? <i>Many devices sent from 115 volt countries do not operate and can even be seriously damaged when plugged into 220 volts. Frequency and phase may also adversely affect the device. Electrical noise and voltage stability may also be of concern with sophisticated electronic devices.</i>
___	___	Does the device require special, gases, water, chemicals, filters or routing maintenance parts which are unavailable or too expensive to operate the device over the long term?
___	___	Does the recipient have the training to operate, analyze results and maintain the device?
___	___	Does the equipment require consumables or reagents that are difficult to obtain in the local area and does the recipient have the means to acquire them?
___	___	Does the equipment require additional ancillary devices such as refrigerators, laminar flow hoods, processors, readers, view boxes, etc.?
___	___	Are there safety concerns that must be addressed prior to operating the device? <i>(For example: radiation, biological, flammables, etc.)</i>
___	___	Does the device require special hazardous waste handling and disposal methods that are not available or require additional education?

YesNoQuestion

If the device is used:

Do all of its functions operate? Has the equipment been tested, accessorized, and included all service and operator's manuals? Have the routine maintenance parts been included? Does the unit have an agreed upon supply of consumables? Can the unit be supported for at least 2 years? Is the unit acceptable; does it meet the recipient's expectations?

Does the recipient meet the criteria set forth in the recipient evaluation?

Will the device operate in the environment where it is to be located? *(For example: temperature, humidity, dust, etc.)*

Will a contracted installer be necessary? If yes, who will bare the burden of this cost?

Check with the Department of Health to determine:
Does the equipment meet government regulations? Does it fit into the overall health plan?

If a standardization plan exists determine if it is sensible to follow based on: the quality, serviceability, cost effectiveness and simplicity of operation. If the standardized manufacturer does not meet these criteria an alternative manufacturer that meets the criteria may be more appropriate.

Does the donation conflict with existing laws or policies?