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GUIDELINES

FOR

HEALTH CARE EQUIPMENT DONATIONS

WORLD HEALTH ORGANIZATION

Evidence and Information for Policy (EIP)
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March 2000

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— African Federation for Technology in Health Care (AFTH);
— American College of Clinical Engineering (ACCE), USA;
— Association for Appropriate Technology (FAKT), Germany;
— Centre for Health Technology, Cameroon;
— Churches Action for Health (CMC), World Council of Churches;
— International Medical Device Group (IMDG);
— Medical Research Council (MRC), South Africa; and
— Technical Cooperation Agency (GTZ), Germany.

These Guidelines are based on extensive field experience of these organizations, consultations with a large number of international experts, and review and merging together of several previous documents on this subject, particularly:

- Policy Position on Donating and Selling Used Medical Equipment by the International Medical Device Group (IMDG), 1992;
- Guidelines on Medical Equipment Donations by the Association for Appropriate Technologies (FAKT) and the Churches= Action for health (CMC) of the World Council of Churches, 1994; and
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- Policy on Acquiring Medical Equipment Through Quotation/Tender and Donation by the Ministry of Health of Kenya, 1987;
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- Guidelines for Purchasing of Medical Equipment by the Presbyterian Technical Services, Cameroon, 1990;
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- The Role of Appropriate Medical Technology Evaluation and User Maintenance Instructions for Developing Countries: Overview, Procurement, Donation and User Guidelines and Bibliography by the Equipment for Charity Hospitals Overseas (ECHO), UK, 1994;
- Guidelines on Donations of Drugs and Medical Equipment to the Health Sector by the Ministry of Health of Tanzania, 1995; and
- Emergency Relief Items: Compendium of Basic Specifications, Volume 2 on Medical Supplies and Equipment by UNDP and WHO, 1996.

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Those interested in obtaining ACCE, FAKT/CMC-WCC, or IMDG Guidelines can contact:

- Morse Medical, +1 206 2360628, www.morsemed.com, for the ACCE Guidelines for Medical Equipment Donation;

- ECRI, Fax: +1 215 8341275, for the IMDG Policy Position on Donating and Selling Used Medical Equipment; and

- FAKT, Fax: +49 711 2109555, for the FAKT/CMC-WCC Guidelines on Medical Equipment Donations.

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EXECUTIVE SUMMARY

Background and Need for Donor Aid Guidelines

Many developing countries are increasingly dependent on donor assistance to meet the equipment needs of their health care systems. However, because not all important parameters are taken into consideration, donations sometimes do not achieve their intended objectives, and could even constitute an added burden to the recipient health care system. There is therefore a need to improve the process of equipment donation, to the mutual benefit of both donors and recipients. These guidelines address this issue, but are not an international regulation. Instead they are to be used to develop national or institutional guidelines; by governments and organizations dealing with health care equipment donations. And although intended for application everywhere, there is a deliberate emphasis on developing country health systems.

Principles of Good Donation

Four underlying principles, which form the core of *Good Donation Practice,* are advocated.

1) Health care equipment donations should benefit the recipient to the maximum extent possible;
2) Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with government policies and administrative arrangements of the recipient country.
3) There should be no double standard in quality. If the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation.
4) There should be effective communication between the donor and the recipient, with all donations made according to a plan formulated by both parties.

Recipient Policy and Donor Coordination

Health care equipment donations should not be made in a policy vacuum. Potential recipients should use these guidelines to formulate their own national or organisational guidelines, and complement them with administrative procedures, where possible, linked to existing health care equipment procurement systems. In seeking donations, recipients should specify the need, stating the quantities required and prioritising them. Other donations in the pipeline, or anticipated should be indicated.

On the donor side, coordination is very important, and to this end, it is recommended that donors to a particular beneficiary identify a lead donor.

Donation Plan and Action Required from Donors and Recipients

The most important pre-requisite for a successful donation is that the potential recipient truly needs the requested equipment and has the expertise and the means to operate and maintain it. The donor should use this criterion to identify potential recipients.

A donation plan is required, and should cover all items in the accompanying checklist, notably availability of trained personnel for operation and maintenance, and support for other resources for operation (manuals, reagents, supplies, etc.) and maintenance (technical documentation, spare parts, etc.).

The donated equipment should meet general criteria covering quality of the equipment, safety, compliance with specifications and standards, non-obsolescence, and appropriateness of the technology for the user environment. In addition, donation plans must include detailed installation and commissioning procedures. Finally, any special requirements for the equipment such as, air or water cooling, electrical power, water quality,

mechanical lay-out or radiation or acoustic shielding requirements, specialized software required to install, operate, or maintain the equipment, should be communicated to the recipient.

The recipient should develop a plan for proper management of the donated equipment, covering site preparation for commissioning and installation, and training of both users and maintenance staff.

Implementation

The donor should ensure proper assembly, packaging and shipping, while the recipient should handle Customs clearance, local transportation, unpacking and reception. Installation should be carried out by technically competent staff, according to instructions received from the donor, and the equipment commissioned in accordance with good health care technical services practice. Periodic inspection, maintenance and calibration should be carried out.

Follow-up Evaluation

The donor and recipient should assess the level of operational success or failure of the donated equipment. The success of future donations will be enhanced as a result of such assessments.

Used Equipment

Donations often involve equipment removed from service in health care facilities in industrialized countries. However careful economic analysis should be done of both new and used equipment options, taking into account payment conditions and other financing mechanisms, leasing and rental options, reagent contracts, safety and performance criteria, as well as continued availability of spare parts.

Refurbishers of medical devices must be competent, and are expected to restore equipment to the manufacturer's original specifications, provide complete documentation, properly label equipment, assume responsibility for product defects, and be covered by adequate liability insurance.

Equipment Donations in Emergency Situations

The general rule of thumb is that capital equipment should not be donated in emergency situations, unless it is established that the emergency will continue over a long period. See United Nations guide, "Emergency Relief Items: Compendium of Generic Specifications", Volume 2, for exceptions.

Supplements to the guidelines

General guidelines such as these cannot cover in detail the complexity of all possible donation scenarios and the diversity of equipment considered for donation. Supplements to the guidelines, which deal with the specifics of particular types of equipment (e.g.. radiology, anaesthesia, ICU, etc.), will be considered in future, as a way of addressing this diversity.

DONATION PROCESS
FLOW CHARTS AND CHECK LISTS

Figure 1. Process

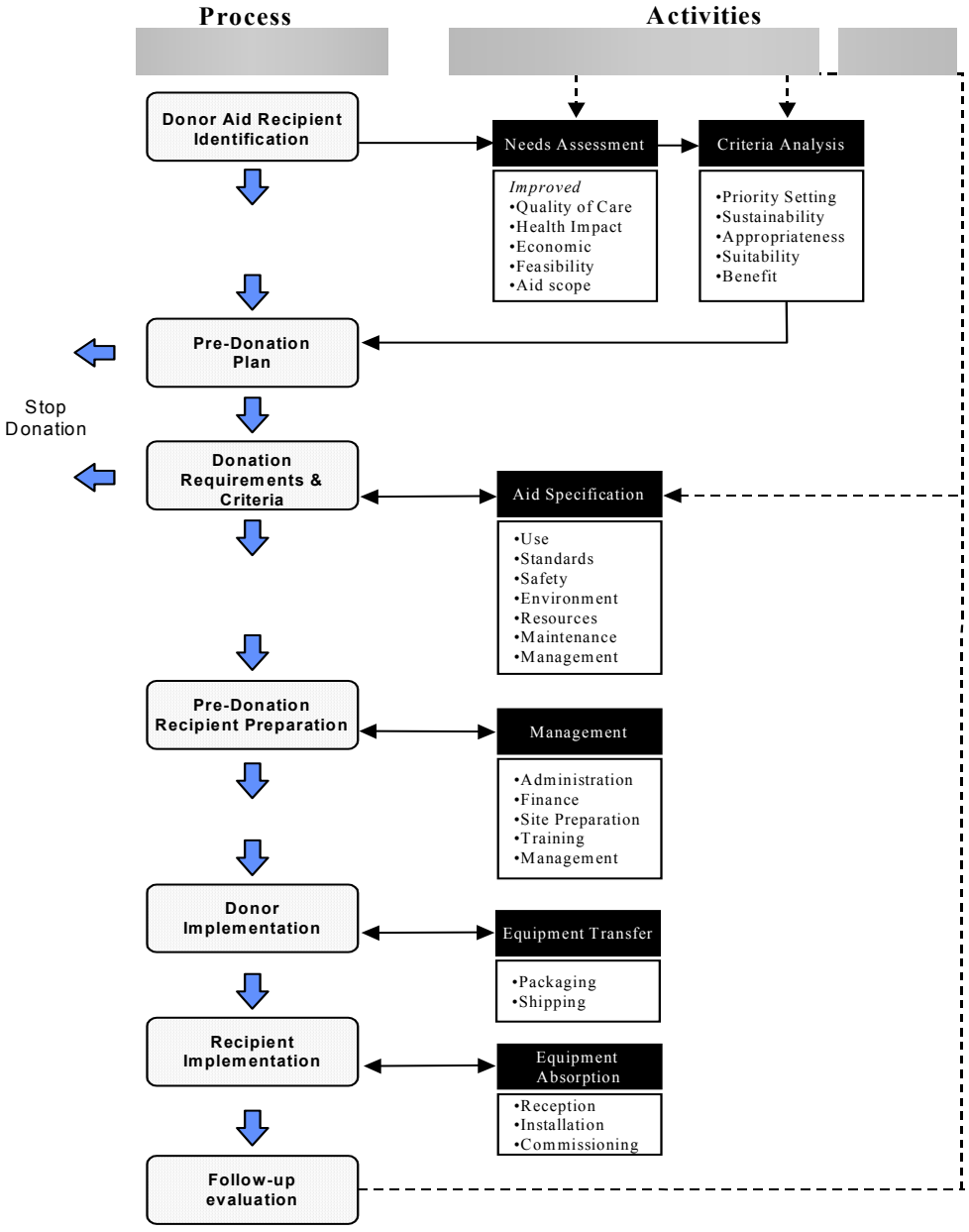


Figure 2. Beneficiary/End-User

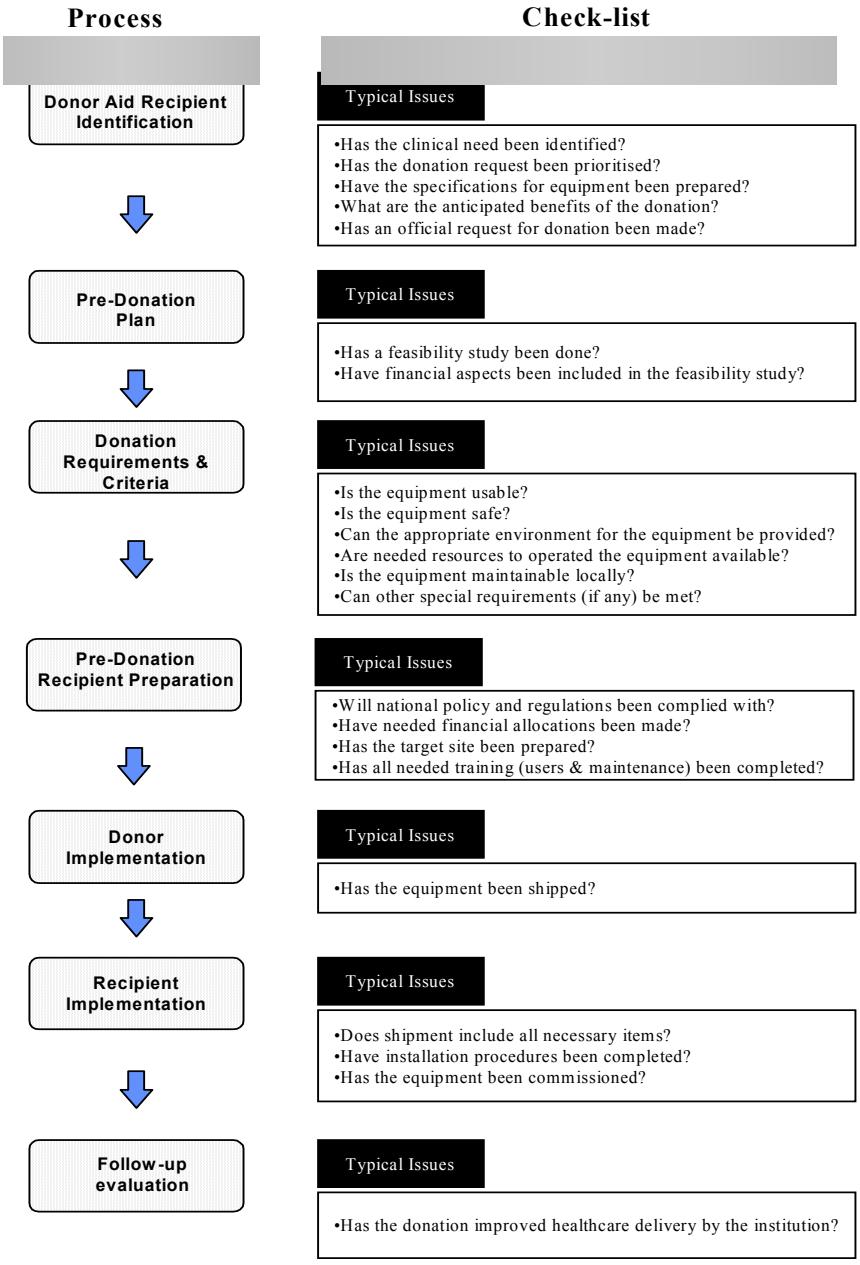


Figure 3. Recipient Government

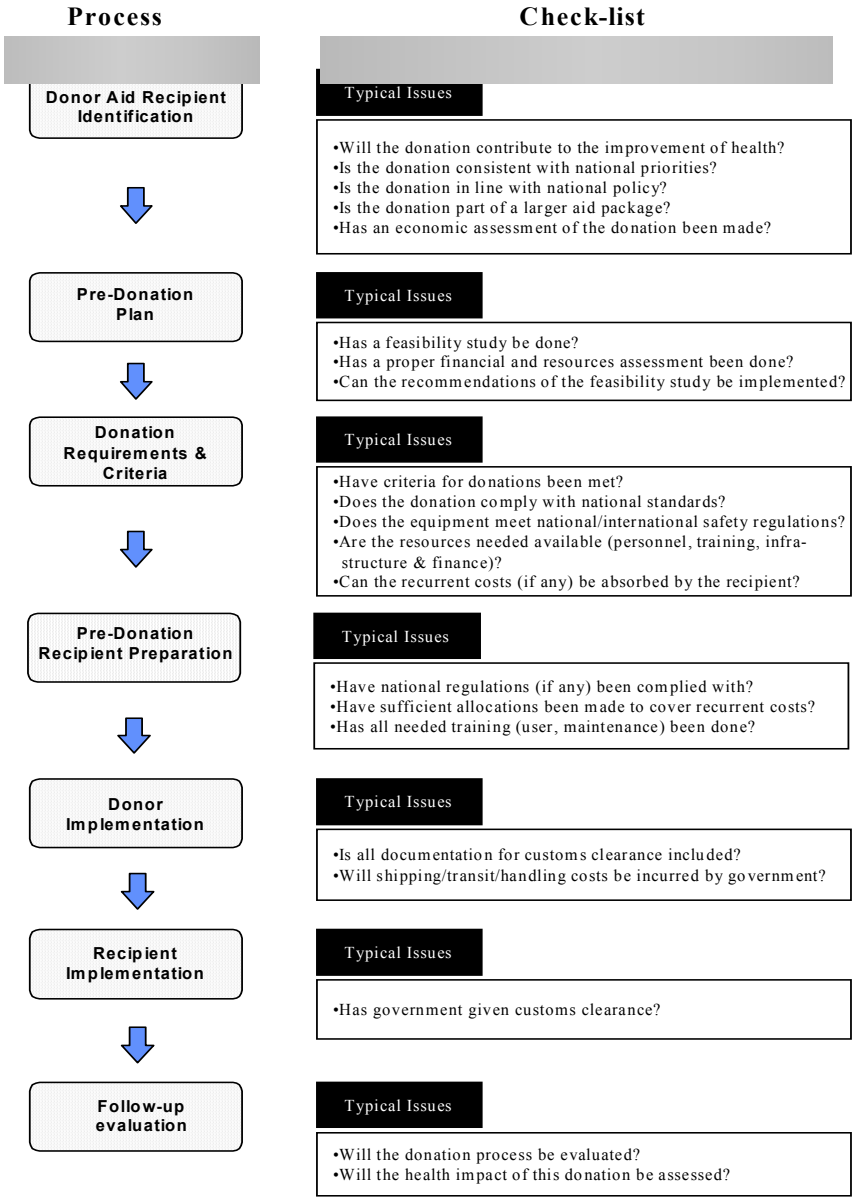


Figure 4. Donor

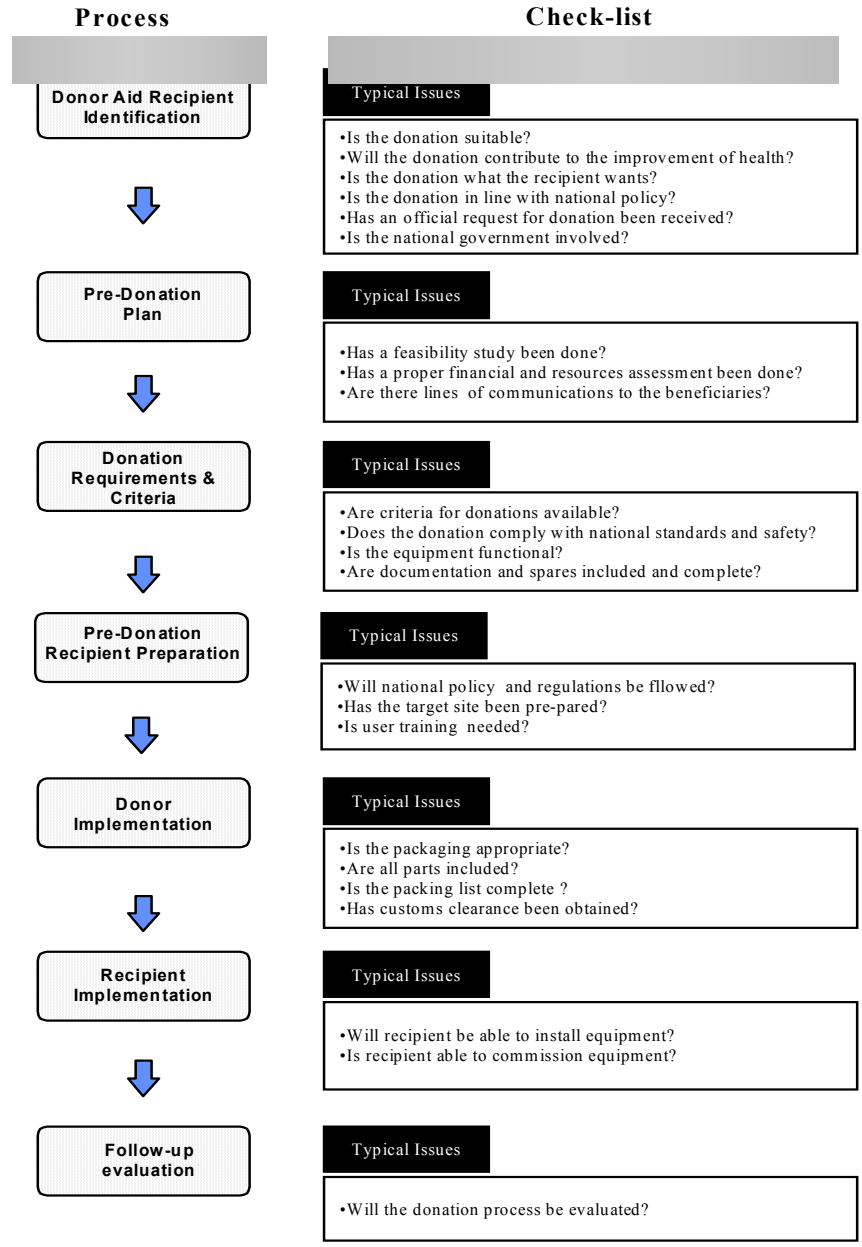


Figure 5. Advisors, Technical Experts, Agencies

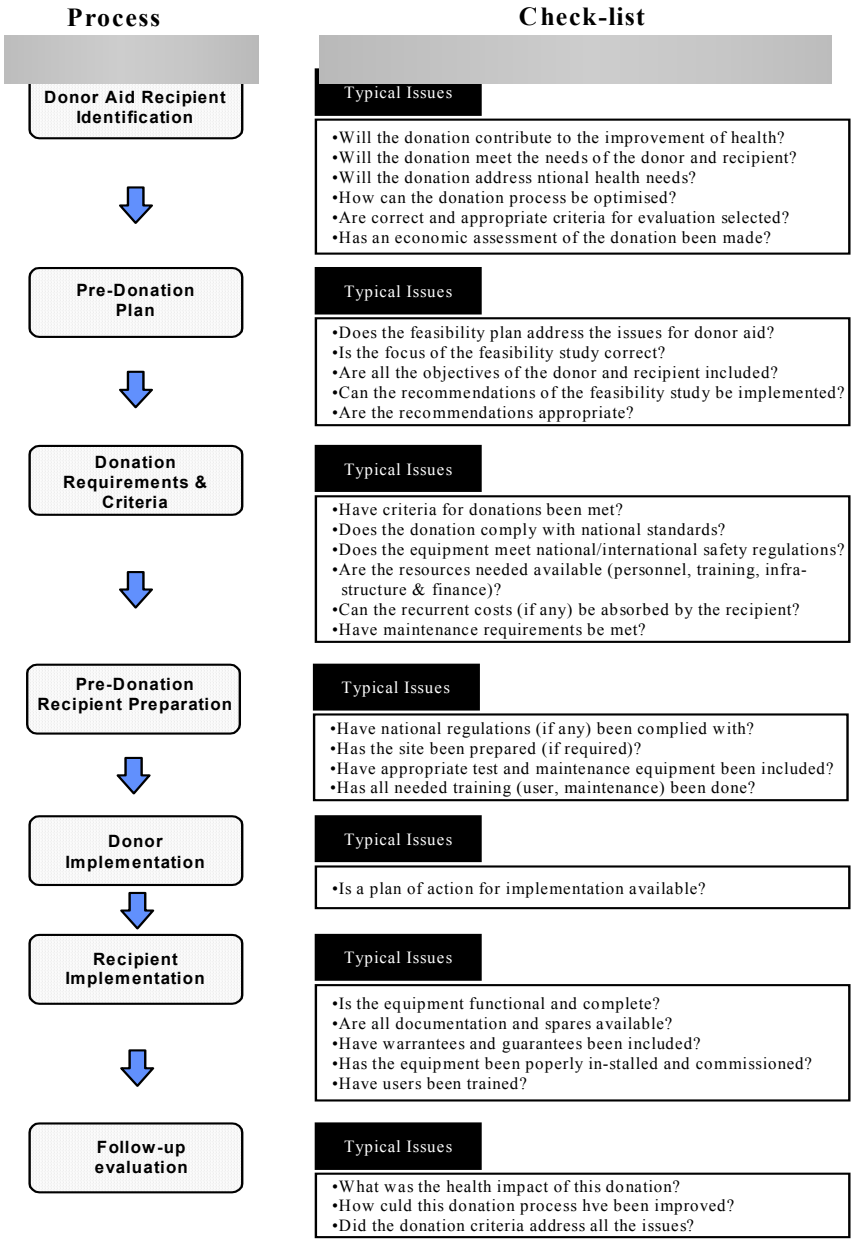
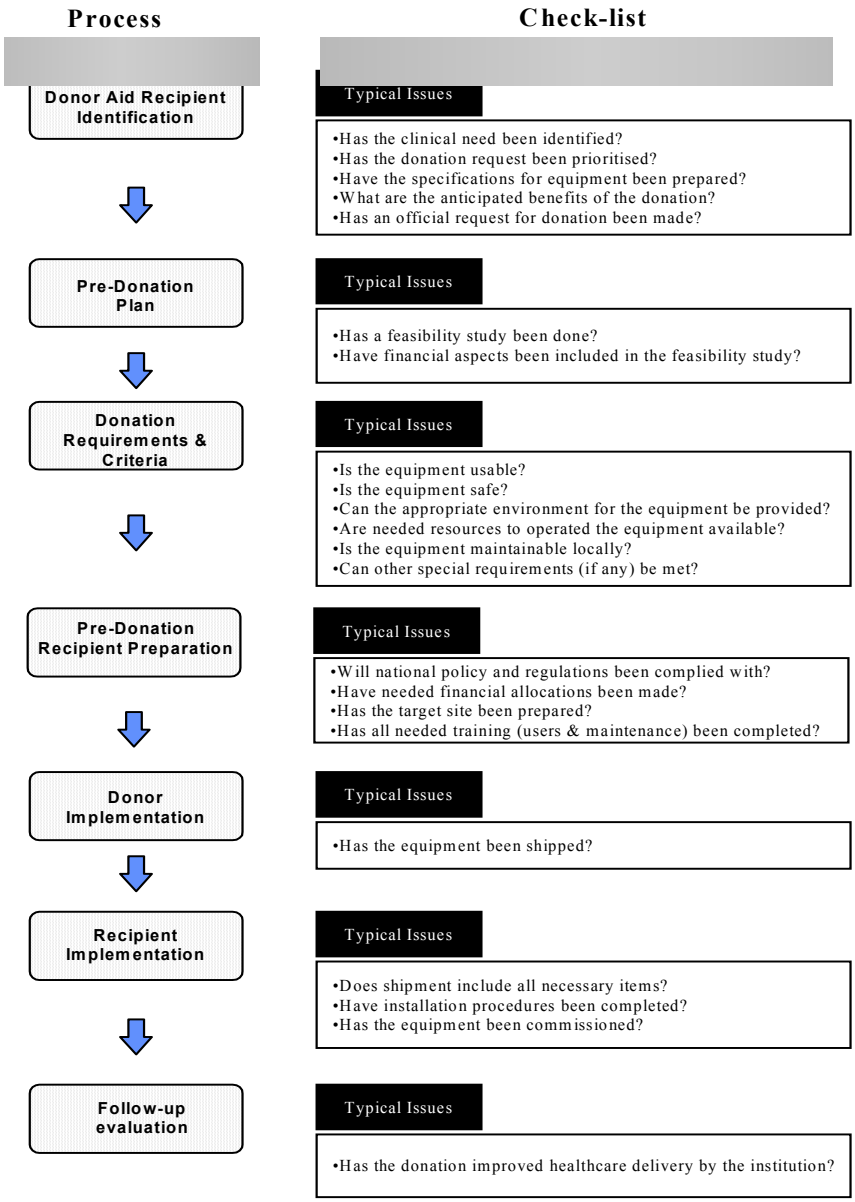


Figure 5. Beneficiary



PART 1 - GENERAL CONSIDERATIONS

INTRODUCTION

These guidelines are derived from a number of similar efforts developed by organizations such as, the Association for Appropriate Technology (FAKT) jointly with the Churches= Action for Health (CMC) of the World Council of Churches, the American College of Clinical Engineering (ACCE), the International Atomic Energy Agency (IAEA), the International Medical Device Group (IMDG), the International Foundation for Science (IFS) jointly with the Swedish Agency for Research Cooperation with Developing Countries (SAREC), several national guidelines.(by Ministries of Health in Kenya and Tanzania), and the Christian Medical Association of India. The structure and the format of the document, to a large extent, are inspired by the WHO Guidelines for Drug Donations produced by the WHO Action Programme on Essential Drugs, and reflect the desire for some uniformity in the presentation of such guidelines.

The purpose of the guidelines is to improve the quality of equipment donations, as these play an important part in the health sector in many developing countries. The guidelines are precisely that "guidelines", from which national or institutional guidelines for medical equipment donations can be developed through a process of review, adaptation and implementation by governments and organisations dealing with health care equipment donations. They are not meant to be an international regulation and although they have undergone several reviews in draft form, will be reviewed regularly after publication, on the basis of comments received from users.

Health care equipment donations occur in many different scenarios. Donors could be corporations acting directly or through private voluntary organisations, or governments providing aid to other governments. The intended beneficiaries range from individual health care facilities to entire health systems. There are thus legitimate differences between these scenarios. Even so, there are many basic rules for an appropriate donation that apply to all. These guidelines aim to describe this common core of Good Donation Practice. When necessary for specific situations, possible exceptions to the general guidelines are indicated. Finally, the guidelines are aimed not only at actual health care equipment donations, but at the process of making such donations.

The four core principles underlying the guidelines are:

1) a health care equipment donation should benefit the recipient to the maximum extent possible;
2) a donation should be given with due respect for the wishes and authority of the recipient, and in conformity with existing government policies and administrative arrangements;
3) there should be no double standard in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation;
4) there should be effective communication between the donor and the recipient, with all donations resulting from a need expressed by the recipient. Donations (solicited) should never be sent unannounced.

This document contains background information, which highlights some common problems and the need for guidelines. The guidelines include practical recommendations on how all stakeholders, donors and recipients could make use of the guidelines in their own situation to maximise the quality and potential impact of health care equipment donations. Flow diagrams, of

the process and associated activities, are presented to facilitate understanding.

Although these guidelines are intended for application everywhere, there is a deliberate emphasis on developing country health systems, as these are often the intended beneficiaries of health care equipment donations. Also, the term health care equipment is used in a broad sense and should be understood to include not only medical equipment but also all other equipment used in the delivery of health care, such as hospital plant, vehicles, water and sanitation equipment, etc.

BACKGROUND

Growing Dependence on Donor Aid Interventions

Economic changes and financial problems, and a growing burden of disease have contributed to an increasing dependence on donor assistance in the area of health care for many developing economies. This assistance usually includes physical equipment and spare parts, and in some countries, nearly 80 percent of health care equipment is funded by international donors or foreign governments. The introduction, utilisation and maintenance of health care equipment require substantial financial, organisational and human resources. Often, this is either not recognized, or not enough attention is paid to it. In the Sub-Saharan Africa region, for example, a large proportion (up to 70 per cent) of equipment lies idle due to mismanagement of the technology acquisition process, lack of user-training and lack of effective technical support.

The Challenge

There is a clear need to improve the process of aid intervention and its contribution to health care delivery, to the mutual benefit of both donors and recipients. A key problem to be addressed to ensure that health care equipment interventions are optimised, is to link the technology intervention to the health care delivery processes. At present, health care technologies are seen as peripheral to health care delivery and subsequently receive little attention from health care planners. Similarly, donor aid in the form of equipment is seen merely as an addition to the peripheral aspects of health care delivery and seldom as part of an integrated health care plan. Equipment management should be part of this plan.

This marginalization of health care equipment issues is likely to change during the next decade not only because of the health care reform processes under way in various regions, but also because of changing environmental issues. These environmental issues will include increased litigation by the public due to the incorrect application or non-availability of equipment. Furthermore, there is likely to be a trend towards diagnostic and therapeutic interventions using increasingly sophisticated equipment and this will force many countries to incorporate a higher equipment content in the health care delivery process. These issues, coupled with the fact that health education and modern communications will raise the level of awareness of the populations served about possible health care options, will force many countries to adapt and improve the health care equipment intervention process.

This applies to the donor aid process as well. To ensure that the donor aid process is optimized, the need for aid should be clearly identified and mechanisms to ensure effective application of donor aid, with a sustained impact, should be implemented. This includes the creation and measurement of criteria for appropriateness and sustainability of the technology.

In particular, the limitations and special needs of mobility and appropriateness (in terms of usefulness for the intended level of care) desirable for developing economies should be recognised. It is vital, however, that these desirable elements are not confused with sub-standard care procedures. A common finding in developing economies is that not only is there poor treatment coverage of populations, but that the quality of care given suffers from a predominance of poor techniques and sub-standard equipment. Despite the very limited resources available (or perhaps because of this), it is imperative that health care is provided with full adherence to the principles of adequate quality and sound technology.

THE NEED FOR DONOR AID GUIDELINES

Donor policies have influenced the pattern of equipment procurement. In most cases, donations circumvent the selection and procurement systems of the recipient country, where such systems exist. As a result, little consideration is taken of actual local requirements, the number of user-staff and their capability, and the level of technical expertise of available maintenance personnel. Even local manufacturer representatives and equipment distributors, who may be expected to provide after-sales support, are bypassed. Further problems related to equipment calibration and operation, purchase of consumables and availability of spare parts may transform the donated equipment into a liability, rather than an asset, to the recipient institution, district or region.

Well documented examples of inappropriate donations in terms of medical devices and equipment constitute ample reasons to develop international guidelines for health care equipment donations. In brief, guidelines for health care equipment donations are needed because:

- Although donors' intentions are unquestionable, often, their lack of awareness of the local realities of the intended beneficiaries leads to unforeseen consequences of the donation at the recipient's end;

- donor and recipient do not communicate as equal partners in the pursuit of a common goal. The recipient's circumstances are often such that there is a mistaken belief that anything is better than nothing Recipients sometimes have difficulty articulating how best they wish to be helped, and may need assistance in clarifying this to the donor;

- The recipient's circumstances are often such that there is a mistaken belief that anything is better than nothing Hence, the situation at the end-user of the equipment is not sufficiently investigated. Needs vary between countries and from situation to situation. Health care equipment donations must be based on a thorough analysis of the needs, and their selection and distribution must comply with existing technology policies and be compatible with the local administrative systems. Unsolicited and unnecessary health care equipment donations are wasteful and should not be made;

- The situation with equipment is more complex than with other donated items, such as food and clothing Equipment is used to provide a service, and so a holistic approach must be adopted. Besides the quality of the equipment, availability of consumables and other items required for this service must be factored into the donation process.

Core Principles for Equipment Donations

The most important principle is that health care equipment donations should benefit the recipient

to the maximum extent possible. Therefore all donations must be based on an expressed and validated need. Unsolicited donations usually violate this principle, and are to be discouraged.

The second principle is that a donation should be given with due respect for the wishes of the recipient and their authority within the health system, and must be in conformity with existing government policies and administrative systems at the recipient end.

The third principle has to do with quality. If an item does not meet quality standards in the donor country, it is unacceptable as a donation. Furthermore, the prevailing situation with health care equipment support services at the recipient's end may even require that quality standards of donated equipment be higher than in the donor country.

The fourth principle is that there should be effective communication between the donor, the recipient authority and, whenever possible, the end-user, before, during and after the donation.

Health Care Equipment Donations as Part of Development Aid

Health care equipment donations made as regular development (commodity) aid allow time to consider the specific demands of the recipient. On the other hand, there is also time to include more restrictive linkages to the donation, e.g. specification of products from manufacturers in the donor country.

It should be recognized that health care equipment is not delivered into an administrative vacuum. Donations should not create an abnormal situation which may obstruct or delay national or institutional capacity building in selection, procurement, storage, distribution, rational use and appropriate maintenance of equipment. Special care should therefore be taken that the donated health care equipment respond to an expressed need, comply with the national or organisational policy (if there is one), and are in accordance with national guidelines in the recipient country, if they exist. The donated health care equipment should be treated with the same attention to administrative procedure as if it were procured. This means that they should be registered or authorised for use in the country through the same procedure that is used for government tenders. They should be entered into the inventory, distributed through the existing distribution channels and be subject to the same quality assurance procedures.

Recipient Policy on Health Care Equipment Donations

There is a need to develop local policy, guidelines and regulation governing health care equipment donations, if these do not already exist.

1. ***Define national or organizational guidelines for health care equipment donations***

It is important for health care equipment donations not be made in a policy vacuum. Potential recipients should use these international guidelines to formulate their own national or organisational guidelines for health care equipment donations. Such guidelines should be an integral part of national or organisational health care equipment policy, where they exist. The process of dissemination of the national or organizational guidelines to all stakeholders, should include formal presentation and explanation to the donor community. The guidelines should be enforcement only after they are officially published.

National and institutional guidelines will help avoid difficult situations where a recipient

is obliged to accept a donation simply because it has already arrived and out of respect for, or politeness, to the donor. An ounce of prevention is better than a pound of cure. Recipients need to point out to prospective donors what kind of assistance they need and how they wish to receive it. Most donors will appreciate this and comply, if they are given the opportunity of making their contributions within clearly defined institutional and organizational frameworks.

2. *Define administrative procedures for receiving health care equipment donations*

The adoption and publication of the general guidelines on the selection, quality and management of health care equipment donations is very important. However, this is not enough. In order to maximize the potential benefit of the donation, administrative procedures for donations need to be developed by the recipient. As much as possible such procedures should be linked to existing health care equipment procurement systems, but it should be realized that there are issues which apply specifically to donations. The following is a sample of questions, which have to be answered in each recipient country or organization are:

- Who is responsible for defining the needs, and who for prioritize them?
- Who co-ordinates all health care equipment donations?
- Which documents are needed when a donation is planned, and who should receive them?
- Which procedure is used when donated health care equipment does not follow the Guidelines for Health care Equipment Donations?
- What are the criteria for accepting or rejecting a donation, and who makes the final decision?
- Who co-ordinates reception, storage and distribution of the donated health care equipment?
- How are donations valued and entered into the budget/expenditure records?
- Who will take care of recurrent costs implications, and how will this be done?
- How will inappropriate donations be disposed of?

3. Specify the need for donated health care equipment

The third important preoccupation in guidelines for donated health care equipment, is the requirement that, as much as possible, the recipient must specify the need for such donations. The recipient is responsible for carefully preparing the request, which should clearly identify the needs and prioritises them, with proper indications of the quantities required. As much information as possible should be given, including information on donations in the pipeline, or anticipated. This provides a more complete and clearer picture not only of the recipients needs, but also of who else is providing assistance, and contributes to avoiding overlaps and gaps in coverage of the recipients needs. Ultimately, everyone involved in the process comes out a winner, when complete and accurate information is communicated by the recipients to the donors.

4. Identify a lead donor

Coordination among donors is very important, and to this end, it is recommended that donors identify a lead donor. Although this may be difficult to achieve in practice, the advantages are significant, as the lead donor can then co-ordinate donor activities as well serve as act as focal contact point in discussions with the recipient organization or government. The need to provide information applies equally to donors, who should provide detailed information with plenty of

advance notice to the recipients about approved donations, clearly indicating when each donation is to arrive. This can be best be done for all donors through a lead donor, and will greatly facilitate the co-ordinating body in the recipient country to plan for the proper reception of the donations. Coordinated donations also make it easier to identify the need for additional assistance.

PART 2 - DETAILED GUIDELINES

This part of the guidelines provides detailed practical recommendations on how both donors and recipients could make use of the guidelines in their own situation to maximize the quality and potential impact of health care equipment donations. A set of flow diagrams illustrate the recommended process and activities associated with each part of the process (fig. 1), provide checklists for donors, recipient governments, advisors and beneficiaries (figs. 2 - 5), and indicate the recommended assignment of responsibilities among the stakeholders (fig. 6). Advisors are defined here as resource persons (including consultants) called upon to provide technical expertise in the evaluation of various aspects of the equipment donation.

ACTION REQUIRED FROM DONORS

Donors should always respect the four core principles:

1) a donation should benefit the recipient to the maximum extent possible;
2) a donation should respect the wishes of the recipient and their authority within the health system;
3) there should be no double standards in quality;
4) there should be maximum communication between donor and recipient. Donors should also respect the national guidelines for health care equipment donations and respond to the priority needs indicated by the recipient. Although they are a reality of life, unsolicited donations should be discouraged as much as possible.

The public at large in the donor country is not always aware of common problems with health care equipment donations. It is therefore important that governments and organisations in donor countries spend some effort to create more public awareness on "good donor practice". The best time for this is probably when a public appeal is made through the media.

IDENTIFICATION OF POTENTIAL RECIPIENTS

The most important pre-requisite for a successful donation is that the potential recipient truly needs the equipment being requested and has the expertise and the means to operate and provide maintenance for it. Although equipment supplied may be completely functional, it will be ineffective if it is not appropriate for the services provided at the recipient site and if it is not able to be financially supported through its remaining life cycle. Previous recipient experience with donations is a plus, but not essential for the success of the operation.

Health Care Need

To properly justify the need for the goods being requested, the donor should demand from the potential recipient(s) the following information:

a) what specific interventions the equipment will be used for, and in the case of clinical equipment, which and how many procedures will be performed using the

requested equipment;

b) why the resources presently available (attach a list with descriptions) are not satisfactory;

c) an analysis on how the requested equipment will help meet the expected demand.

PRE-DONATION PLAN

Feasibility and Formulation of Requirements

The recipient should demonstrate that it has the resources (human and financial) to install, operate, and maintain the requested equipment.

Readiness to Absorb the Technology

The potential recipient entity should provide information showing that it is ready to install, use and maintain the equipment being requested. Such readiness includes trained operators, appropriate environment, ancillary equipment, maintenance capability, and financial viability. If there are any shortcomings in these areas the recipient entity should demonstrate that it has plans and means to address them.

Human Resources

The recipient must have properly trained physicians, nurses, and/or technicians who will operate the requested equipment. If none are available currently an explanation should be given of how training of such personnel will be achieved.

Environment

The recipient should describe available facilities, such as physical space, electrical and pneumatic power, water supply, heating, ventilation, and air conditioning, to install and operate the requested equipment. Where sophisticated health care equipment is involved, particular care should be devoted to the availability of a stable electrical supply, air conditioning, and humidity control which are vital to its performance.

Material Resources

If the donated equipment is not accompanied by all necessary ancillary equipment, their availability locally should be confirmed. Alternatively, the recipient entity could demonstrate that it has the means to acquire them. Local availability of supplies needed to operate the equipment should be researched and confirmed.

Special scrutiny should be given to requests for equipment which requires special and/or expensive supplies such as x-ray film, medical gases and laboratory re-agents.

Maintenance Resources

The recipient should describe human, material and financial resources available in house to service and maintain the requested equipment. Information about services available from local

manufacturer representatives and independent service organisations should also be given.

Recommendation and Plan

Assuming that the donor is reasonably convinced that the potential recipient really needs the equipment and can support it for the remainder of its useful life, a recommendation should be made to go ahead with the donation, and both donor and recipient should start planning for the donation.

DONATION REQUIREMENTS AND CRITERIA

Prior to making a piece of equipment available for donation, it is crucial that the potential donor makes a critical evaluation of it. It is not only a waste of precious resources to move useless and unsafe equipment from one place to another, it also undermines the good will and trust that those involved are trying to build.

General Quality

The donor should ensure that donated health care equipment is fully operational at the system and sub-system levels, and that all essential accessories and supplies are available. The donor should complete a checklist to ensure that all sub-systems, components, accessories, and supplies (for initial operations) are included, and should supply the recipient with such a checklist. (Checklists are often found in operating manuals produced by the manufacturer or prepared by the former operators, in the case of previously used equipment). Documentation, especially operating and service manuals with part lists, is critical to the usability of the donated equipment.

Safety, Specifications and Standards

All health care equipment should meet or exceed existing safety and performance specifications provided by the manufacturer. If necessary, they should meet standards promulgated by international bodies such as International Organization for Standardization (ISO) and International Electrotechnical Commission (IEC). Equipment that has not been approved by the appropriate regulatory agency of the donor country should not be donated. Equipment that is the subject of manufacturer recalls or hazard alerts should be updated to the new requirements or not be donated. Equipment that has non-functional sub-systems may be donated provided that those sub-systems are clearly identified and labelled.

Obsolescence

A minimum of two years, preferably four years, of manufacturer=s sales support is required. This support should include spare parts, accessories (either reusable or disposable), and trouble-shooting, repair and maintenance assistance. Obsolete equipment or equipment for which replacement parts are unavailable should be donated only if they are destined "for parts only", and so designated.

Appropriate Technology

In considering the provision of health care equipment to developing economies, potential donors should favour the following desirable characteristics in such equipment:

- Simplicity of operation.
- Minimal number of accessories required.
- Availability of necessary operating supplies (particularly disposable) in the recipient country, at affordable cost.
- Standardization with other equipment in the locale.
- Low energy consumption.
- Does not use environmentally hazardous substances.
- Ease of maintenance.
- Tolerance to hostile electrical and physical environment.

Installation, Operation and Maintenance Requirements

Installation Requirements

The donor should specify the following requirements for proper use of the equipment: installation location, safety requirements (such as shielding), accessibility, floor loading capacity, space and electrical power (voltage, frequency, phase, and dissipation), water volume and pressure (and drainage) needed, and environmental conditions. Care should be taken to identify any unusual extremes of temperature, humidity, dust and electrical power fluctuations that could adversely affect the equipment's operation. The donor should ensure that detailed installation instructions are provided. Most, if not all, of this information is available in the equipment's operating, technical reference or service manual.

Operation Requirement

The donor should inform the recipient of all the necessary sub-systems, such as cables, re-agents, filters, electrodes, and recording paper, that will be required to operate the equipment to be donated. Often test equipment and calibration standards are required to ensure performance and accuracy of the equipment. Availability of these items throughout the remaining useful life of the equipment should be ascertained. Again, operator training should be clearly stated if such training will be needed.

Maintenance Requirement

The donor should seek guidance from its own service personnel so it can provide detailed maintenance requirements, such as technician training, special tools, preventive maintenance materials, and test and calibration equipment needed, as well as necessary documentation, including such information as recommended preventive schedule, etc..

Special requirements

Any special requirements for proper use of the equipment should be identified and communicated to the recipient. These include, but are not limited to, air or water cooling, electrical power, water quality, mechanical lay-out or radiation or acoustic shielding requirements. Sometimes specialized software may be required to install, operate, or maintain equipment.

In extreme cases, the recipient may cancel the donation after realizing that it cannot support the equipment.

PRE-DONATION RECIPIENT PREPARATIONS

Plan for Proper Management of Donated Equipment

The value of donated health care equipment can be considerable, and the gift should be treated with due care. Donations should be seen as an investment paired with an expense since the recipient will have to bear the ongoing operating, maintenance and repair costs. Some donor countries and agencies have recognized these problems and have been pro-active in addressing shortcomings in their programmes and implementation strategies. Others have attempted to analyse patterns and volumes of demand for maintenance services in developing economies, drawing on the experience of industrialized countries. Results show that caution needs to be exercised in drawing too readily from practices and norms which have evolved to meet the technical needs and legal requirements of the health care systems in industrialized countries, when considering, for example, affordable and realistic maintenance arrangements for equipment in developing economies. Other considerations are warranty terms, energy consumption of the equipment, and disposal of waste and disposables.

Site Preparation

The donor needs to provide the recipient with detailed information regarding the installation, operation, and maintenance of the equipment. This information will enable the recipient to begin pre-installation tasks, including the training of personnel for operation and maintenance.

After receiving the information listed above, the recipient should start preparing the site for the equipment. When all the preparations are ready, the recipient should notify the donor.

If pre-installation work is required, the recipient should state when the work will be completed. It is advisable that the recipient 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

Training of personnel to operate and maintain the equipment is an important aspect of the preparation. If the recipient has difficulty organizing training for operators and maintenance personnel the donor should suggest alternatives. One alternative could be for the donor to provide such training, with or without the contribution from the recipient.

When all requirements have been satisfied, the recipient should notify the donor to assemble and package the equipment for shipping.

DONOR IMPLEMENTATION

Assembly, Packaging and Shipping

Prior to packaging the equipment to be donated, the donor should ensure that it is safe and performs within manufacturer's specifications. This can be accomplished by performing an operational verification procedure found in most operating manuals. In addition, all accessories and supplies should be checked. All software necessary for equipment operation should be included. Training aids such as slides, books, and videotapes should be supplied if available. The checklist mentioned above should be used to verify that all sub-systems, components, and accessories and supplies are included. This checklist is also helpful in the preparation of the shipping documents.

Equipment that may contain patient material should be properly de-contaminated prior to packaging and shipment. Radioactive sources should be removed and properly packaged in special shipment containers (with radioactive marking on outside). Fluids should be drained and fragile parts, packaged with great care. International shipments are often handled roughly by people without proper training and equipment and, therefore, subject to high probability of damage.

It is important that the end-user of the equipment receives operation and service manuals. Experience has shown that manuals are sometimes lost when they are shipped with the equipment. If the end-user is known to the donor, it is best if the consignment is accompanied only by shipping documents giving full details of contents, and the user documentation is transmitted separately to the user: in some cases it may be appropriate to use the diplomatic pouch. If the end-user can be identified at the time of shipment, one copy of all documentation should be shipped but also a plaque should be attached to the equipment giving an address from which the necessary documents can be obtained, with some reference code to easily identify the equipment. The supplier should retain a second copy of the manuals in order to meet any subsequent requests from the end-user.

Software version numbers and significant hardware updates if applicable should be noted. The operation manual should contain detailed operating instructions and list all necessary sub-systems, accessories, user replaceable parts, re-agents, and other supplies such as chart paper, gases, coolants. and chemicals. The service manual should contain specifications, schematics, operating instructions, troubleshooting, repair and maintenance procedures, cleaning and/or sterilization recommendations, and replacement parts list. If available, procedures or recommendations for periodic inspection, maintenance and calibration to assure that the equipment is maintained in a safe and effective operating condition should be provided by the supplier. If the documentation is not available, the donor should consider purchasing it to unsure the eventual usability of the donated equipment.

Donated equipment should be packaged in accordance to the method of shipment to minimize damage in transit. For surface shipment, waterproof wrapping and wooden cases are a necessity. Air shipment requires less sturdy packaging, but limitations in size and weight are more severe. Materials with a limited shelf life should be shipped separately, if necessary, and the recipient should be informed of this situation.

Shipping documents should list everything inside the respective packages and clearly indicate that the shipment is a donation. Sample shipper's export declaration form and instructions can be obtained from the appropriate authorities in the donor country.

Donors not familiar with packaging, shipping, and documentation may consider seeking assistance of freight forwarders - companies which specialize in assisting exporters in the transfer of goods to other countries.

All documentation should be supplied in a language commonly understood by the staff who will use and maintain the equipment: if necessary translations should be supplied. It is also important that legends on instrument controls, meters, etc. be in the same language, or that conversion labels be provided; at the very least a list of translated terms should be affixed. If this language provision cannot be made, prospective recipients should seriously question the wisdom of accepting the donation.

RECIPIENT IMPLEMENTATION

Customs Clearance, Local Transportation, Unpacking and Reception

Customs clearance is the sole responsibility of the recipient. If special documentation is needed, the recipient should request it prior to the shipment. The recipient should also make provision for the cost of transportation within the country, from the port of entry to the site where the equipment will be installed.

On arrival of the shipment, the recipient should inspect all containers and contents for damage and should verify that the contents are intact and nothing is missing. If the equipment is technically complex, the recipient should ensure that the unpacking and verification are done by a technically competent and knowledgeable person, (if necessary by the manufacturer=s agent) to reduce the risk of damage. Receipt should be confirmed to the donor. Any irregularities should be reported immediately to the donor and to the shipping company for insurance claims. The manuals received with the equipment should be distributed to the appropriate personnel: operating manual to the operator and service manual to the maintenance section. If a centralized library exists, the manuals may be forwarded to that location, provided that the end-user also has copies or ready access to the manuals.

There must be due vigilance to ensure that donated products are not diverted for export, commercial sale, or into illicit channels. Experience has shown that in some countries explicit labelling of consignments, e.g. AMedical Supplies@ is contra-indicated, as it invites theft in transit.

Installation, Commissioning and Maintenance

Installation should be performed according to the instructions received from the donor, by a technically competent person. The equipment should then be commissioned in accordance with normal principles of good health care technical services practice, by adequately trained professionals. Commissioning includes verification of proper and safe operation, which must be performed prior to clinical use.

Once the equipment is put into service, the recipient should implement a program of periodic inspection, maintenance and calibration to ensure that the equipment is maintained in a safe and effective operating condition for its remaining useful life. If in-house maintenance services are not

available, the recipient should create such a department, or recommend its creation to the institution's administration.

FOLLOW-UP EVALUATION

The mere supply of equipment does not guarantee a positive impact on health care delivery and health outcomes. When the equipment is operational, the donor and the recipient should assess the level of operational success or failure of the health care equipment donated. This assessment fosters communication between donor and recipient, encourages the continued support of the donor, and allows both parties to learn to improve from previous experience.

Both donor and recipient should not hesitate to identify mistakes made by each side or by the other. An honest and timely evaluation should be made of the activities, particularly as concerns the outcomes, effects and impact of the donated equipment. The success of future donations will be enhanced as a result of such assessments.

USED EQUIPMENT

Used equipment deserves special mention, as donations often involve equipment removed from service in hospitals in industrialized nations, and provided to hospitals in developing economies. Donation and sale of used equipment sometimes presents overwhelming problems, especially to the recipient. Most such equipment never works for any significant length of time. Even when it does work, it can rarely be supported for very long without adequate local arrangements for the necessary training, maintenance, spare parts, and user's and service manuals.

Few documented case histories are available to tell us what actually happens to used health care equipment that arrives in developing nations. However, the sense among some biomedical engineers and health care professionals who have extensive work experience in these countries is that less than 30%, perhaps as low as 10%, of used equipment ultimately becomes operational.

Refurbished Equipment

Refurbishers of medical devices, who are responsible for restoring equipment to its original working condition for the purpose of re-sale, 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, and the refurbished equipment should equal, or sometimes surpass, the original equipment manufacturer's specifications.

Careful Analysis of New and Used Equipment Options

Careful economic analysis should be done of both new and used equipment options. Some used equipment that is sold to second owners is functional or refurbished and, therefore, deserves careful financial scrutiny. Hospitals are typically paid 10% to 15% of the original price for their used equipment by brokers and dealers. After the used equipment is refurbished, it is typically

sold for 45% to 60% of its original cost. But new equipment can usually be purchased at discounts ranging from 95% to 80% of the list price. This means that buying equipment that is 5 to 15 years old and increasingly difficult to support usually costs one-third to two-thirds the cost of new equipment. In addition payment for used equipment usually becomes due in a lump sum on delivery, while leasing, rental, re-agent contracts, and other financing mechanisms for new equipment may often prove wiser than the purchase of used equipment. And new equipment often has safety and performance advantages, as well as better availability of spare parts and training.

Refurbishment Appropriate for Some Types of Equipment

Some types of equipment are more appropriate choices for refurbishment and resale. CT scanners (generally not recommended for developing country recipients) and other costly radiographic systems often offer opportunities for real savings. The same may prove true for expensive clinical laboratory equipment. But much electro-health care equipment, such as infusion pumps, ventilators, electro-cardiographs, and patient monitoring systems, usually prove costly to refurbish and sell. Simple, unsophisticated equipment, such as mechanical hospital beds and operating tables or examining tables, that is obsolete rather than badly worn may also be appropriate for donation to developing economies. However, the cost of shipment must be weighed against the cost of locally produced equivalents.

Some foundations receive and refurbish used equipment for the purpose of donating it, using qualified personnel to do the repair or rebuilding. Unquestionably, competent and ethical commercial used-equipment refurbishers and sellers do exist. However, until such time as a serious study is undertaken that determines the utility of used equipment after it is recommissioned, a high degree of scepticism about its value is warranted. The resale price, plus packing and shipping costs and - in some cases, shipping costs alone - frequently exceeds the real value of used equipment. There are however, cases where refurbished equipment have made successful donations. Careful study should be made of each case.

Additional Guidelines for Used Equipment

- Document the source of all purchased equipment.
- Document the components that were replaced in, and the repair services that were performed on, the equipment.
- Document the source of the repair parts and provide an acceptance report for these parts.
- Label the equipment with the remanufacturer's name.
- Verify and document the operation of the equipment and the performance standards used to calibrate it.
- Maintain a customer complaint file and document the actions that were taken to resolve customer complaints.

The purchaser, for later donation, should attempt to obtain a "hold harmless" agreement from the refurbisher that relieves the purchaser of the responsibility for product defects. The purchaser should make a special effort to ascertain the refurbisher's competence (e.g., through references) a determine whether the refurbisher is covered by adequate liability insurance.

EQUIPMENT DONATIONS IN EMERGENCY SITUATIONS

The general rule of thumb is that capital equipment should not be donated in emergency situations, unless it is established that the emergency will be continued over a long period. The exception to this is any equipment listed in the guide published by the United Nations entitled AEmergency Relief Items: Compendium of Generic Specifications@, Volume 2.

SUPPLEMENTS TO THE GUIDELINES

General guidelines such as these cannot cover in detail the complexity of all possible donation scenarios and the diversity of equipment considered for donation. Supplements to the guidelines, which deal with the specifics of particular types of equipment (e.g.. radiology, anaesthesia, ICU, etc.), will be considered in future, as a way of addressing this diversity.

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