



PARTNERSHIPS FOR GLOBAL HEALTH

A toolkit for  
medical equipment donations  
to low-resource settings

# MAKING IT WORK

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## A toolkit for medical equipment donations to low-resource settings

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**Acknowledgments:** I am extremely grateful to all those who have helped to shape this resource. The contribution of time, expertise, experiences, photographs, case studies and opinion has been invaluable. Special thanks go to: everyone involved in the partnership between Guy's & St. Thomas' and Ndola Central Hospital and Arthur Davison Children's Hospital, Zambia - in particular Peter Cook, Rashid Brora & Lupiya Kampengele; Doug Choyce (DHL); Jim Methven (North Cumbria NHS Trust); Tim Beacon and MedAid staff; Mike Hilditch and Hilditch staff; Marian Surgenor (Manchester - Gulu); Steven Daglish and Amalthea Trust staff; Gilbert Musunda (MoH Zambia); Marium Qaiser (GSK); Everyone involved with the partnership between the South Devon Healthcare NHS Foundation Trust - Nanyuki District Hospital, Kenya; Sandra Kemp (Leicester-Gondar partnership); Sarah Hoyle & Tracy Hughes (Chester-Kisiizi partnership); Shona Lockyer (Kambia Appeal); Jo Vallis; Carolyn O'Leary (Wellcome Trust Tropical Centre Liverpool); Brenda Longstaff (Northumbria - Kilimanjaro Link); Jennifer Barragan (consultant) and finally to all the THET staff

Printed by: RAP Spiderweb Ltd (Manchester)

Designed by: Carbon Creative Ltd (Salford)

Cover Photograph: Winchester - Yei Partnership, South Sudan. Photo Tom Price

Caption: Yei Partnership: 'Repair to Care' between Yei Civil Hospital and County Health Department in Yei, South Sudan and Hampshire Hospitals NHS Foundation Trust. Engineers from the Hampshire Hospitals NHS Foundation Trust link are training and mentoring the maintenance staff in the repair of basic equipment. The project will additionally source repair manuals for the most common medical devices and will identify suppliers for spare parts. It is funded under the Health Partnership Scheme



The production of this publication was funded through the Health Partnership Scheme, which is funded by the UK Department for International Development (DFID) for the benefit of the UK and partner country health sectors and is managed by THET.

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ISBN: 978-0-9560942-2-3

# CONTENTS

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<b>Terminology</b> .....	2	<b>Section 6: Receiving the equipment</b>	
<b>Guide to acronyms</b> .....	3	• Clearing customs .....	61
<b>Foreword</b> .....	4	• Transporting to the DC partner.....	63
<b>About the Toolkit</b> .....	6	• Receiving the equipment at the facility.....	63
<b>Introduction</b>		<b>Section 7: Putting the equipment into service</b>	
• About THET and Health Partnerships.....	8	• Training the equipment users.....	67
• About medical equipment in low-resource settings.....	9	• Training the maintenance staff.....	69
• About medical equipment donations.....	12	• Using and maintaining the equipment.....	70
• Equipment donations globally .....	15	<b>What next?</b>	
• Who makes donations in the UK? .....	17	• Learning from and evaluating the donation .....	72
• Legislative context for equipment donations from the UK.....	19	• Share stories of successes and challenges.....	72
		• Support biomedical engineering capacity building .....	72
<b>Section 1: Deciding whether or not to donate</b>		<b>Glossary of key terms</b> .....	74
• What is needed and what can partners provide?.....	22	<b>References</b> .....	76
• Asking the right questions.....	25	<b>Useful Resources</b> .....	78
• How can suitability of the donation be determined? .....	26	<b>Appendices</b>	
• Considering donations of complex equipment .....	26	Appendix A: UK Medical Device Regulations and MHRA Guidance .....	84
• Deciding whether or not to proceed .....	28	Appendix B: Legislative Context for Pre-Owned Equipment Transfers Outside of the EU.....	85
<b>Section 2: Planning the donation</b>		Appendix C: To Donate or Not to Donate?.....	86
• Agreeing the terms of the donation.....	30	Appendix D: Overview of the Equipment Donation Process.....	87
• Developing a project plan for the donation.....	32	Appendix E: Meeting the WHO's Suitability Criteria.....	88
• Drafting a donation agreement.....	33	Appendix F: Sample Project Plan.....	89
<b>Section 3: Supplying the Equipment</b>		Appendix G: Donation Agreement Template.....	90
• Deciding where to source the medical equipment from.....	36	Appendix H: Sample Letter of Waiver or Indemnity.....	95
• Including usage and maintenance supplies.....	43	Appendix I: Example of Clearing a Container at Mombasa Port, Kenya .....	96
• Sourcing biomedical engineering tools and test equipment .....	45	Appendix J: Post-Donation Assessment Form.....	97
<b>Section 4: Verifying the Quality &amp; Safety of the Equipment</b>			
• For equipment supplied in the UK .....	47		
• For equipment supplied in the DC.....	48		
<b>Section 5: Storing, Packing &amp; Shipping the Equipment</b>			
• Storing and packing the equipment.....	51		
• Shipping Options.....	52		
• Carrying the equipment with the UK Partner on a support visit.....	53		
• Finding suitable Shipping Agents and Customs Clearing Agents.....	54		
• What is the export/shipping process?.....	55		

# TERMINOLOGY

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Medical equipment, for the purpose of this toolkit, can be broadly defined as any device that is used to diagnose, treat, monitor or rehabilitate a patient that is not implantable, disposable or single-use.

In this toolkit, the terms 'equipment' and 'device' are used interchangeably for readability.

Note however the following, more specific and more accurate, definitions of health technology, medical device and medical equipment provided by the World Health Organization (WHO):

**Health technology:** The application of organised knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. 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.

**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.

## **SYMBOLS:**

 Information which is specifically relevant to the UK partner

 Information which is specifically relevant to the DC partner

***"It is not enough to do good; one must do it in a good way."***  
Marquis de Condorcet, French philosopher (1743-94)

# GUIDE TO ACRONYMS

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<b>BIFA</b>	British International Freight Association
<b>BME</b>	Biomedical engineering
<b>BMET</b>	Biomedical engineering technologist
<b>BSI</b>	British Standards Institute
<b>CIC</b>	Community interest company
<b>CoP</b>	Community of practice
<b>CSR</b>	Corporate Social Responsibility
<b>DC</b>	Developing country
<b>DFID</b>	Department for International Development (UK)
<b>DGN</b>	Dangerous goods note
<b>EBME</b>	Electrical and biomedical engineering
<b>ECO</b>	UK's Export Control Organisation
<b>EEE</b>	Electrical and electronics equipment
<b>EU</b>	European Union
<b>FCL</b>	Full container load
<b>GHTF</b>	Global Harmonization Task Force on Medical Devices
<b>GMP</b>	Good Manufacturing Practice
<b>HTM</b>	Health technology management
<b>IATA</b>	The International Air Transport Association
<b>IEC</b>	The International Electro technical Commission
<b>IHPUK</b>	International Health Partners UK
<b>IMDRF</b>	International Medical Device Regulators Forum
<b>LCL</b>	Less than container load
<b>LIC</b>	Low-income country
<b>LMIC</b>	Low- and middle-income country
<b>MHRA</b>	Medicines and Healthcare Products Regulatory Agency (UK)
<b>MOU</b>	Memorandum of Understanding
<b>MoH</b>	Ministry of Health
<b>MSDS</b>	Material Safety Data Sheet
<b>NHS</b>	National Health Service (UK)
<b>PPE</b>	Personal protective equipment
<b>SMP</b>	Scotland-Malawi Partnership
<b>THET</b>	Tropical Health and Education Trust
<b>TIN</b>	Trader identification number
<b>WEEE</b>	Waste electrical and electronics equipment
<b>WHO</b>	World Health Organization

# FOREWORD

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Many visitors to poorly resourced hospitals in low and middle income countries are instantly struck by the lack of medical equipment and the sheer quantity that is broken, unused or inappropriate. Often, as a result of this experience people become aware of the potential for equipment donation.

However well-intentioned, donations of medical equipment are frequently ineffective and unsustainable, and can create more problems than they solve. To address the need for UK guidance for appropriate medical equipment donations overseas, THET has supported the production of this toolkit.

Health partnerships or 'links' between healthcare institutions in the UK and low or middle income country counterparts can provide a suitable framework within which to make a donation. Working in partnership means avoiding prescriptive projects, and focuses on collaboration, on-going dialogue and shared objectives between individuals and institutions at every level. In the context of medical equipment, this means low-resource hospitals and health centres not only get the right equipment, but crucially, the right training and support to maintain it for the long-term benefit of the hospital, health workers and, ultimately, patients.

This toolkit provides UK-specific guidance to health partnerships to assist them in evaluating whether or not to donate, and how to do so effectively. It aims to be a practical resource which also leads to an understanding of good practice for medical equipment donations, and an understanding of the role of medical equipment personnel and the root causes of why so much equipment ends up unused and unusable.

We hope that this will contribute to improved communication between UK and overseas institutions and result in appropriate donations or suitable alternatives in the future.



**Jane Cockerell**  
Chief Executive, THET





# ABOUT THIS TOOLKIT

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## WHO IS THIS TOOLKIT FOR?

This toolkit is designed as a guidance document for the UK and developing country (DC) partners involved in health partnerships.

A health partnership is a relationship between a health institution in the UK and a counterpart health institution in a low or middle income country which supports Human Resources for Health development through training, and education of healthcare workers overseas by UK volunteers.

The principles of good donation practice presented are intended to guide both the donors and recipients of medical equipment donations equally. However, there is a stronger focus on the practicalities for the UK partners (donors), given that logistics and regulations for equipment recipients vary by country.

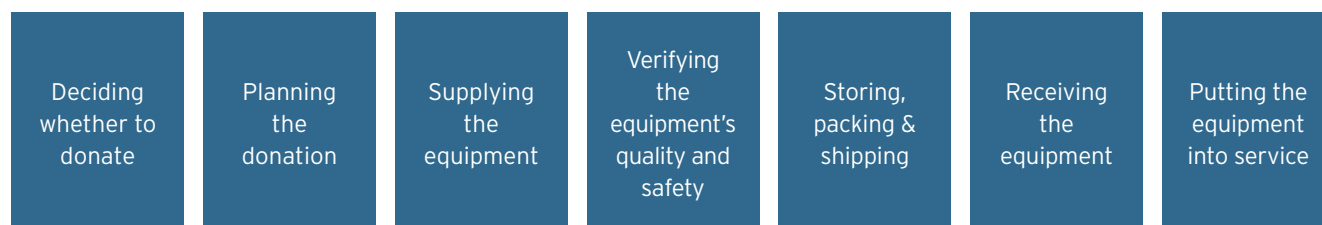
It may also be useful for anyone interested in finding out more about issues surrounding the donation and management of medical equipment in low-resource settings, such as medical charities and DC health institutions soliciting and receiving donations, policy makers, NHS managers, and health advisors from the UK or other countries.

While the case studies and research presented in this toolkit focus on the experiences of health partnerships in the UK and developing countries in sub-Saharan Africa, the principles of good practice are applicable to other contexts as well.

## WHAT DOES THIS TOOLKIT COVER?

Each section covers one stage of the donation process and offers guidance on the supply and shipping of an equipment donation and on how to ensure it is effectively put into service and maintained over its lifespan.

This includes the main activities and tasks; responsibilities of the UK and DC partners; key additional stakeholders; common challenges; practicalities to consider; and signposts to further resources and guidance.



This toolkit answers practical questions, such as how to perform a needs assessment for a medical equipment donation, and how to determine whether the partners have the capacity - together - to meet the needs. It provides guidance for developing a project plan to manage the donation, and for tools and resources to monitor and evaluate it.

## WHAT THIS TOOLKIT IS NOT

The intention of this document is to provide a simple step-by-step methodology and flag issues to consider when making donations of medical equipment to low-resource settings. Users are reminded that it is in no way designed to be prescriptive and the information in this toolkit does not constitute legal advice. International equipment transfers are complex and highly fact specific and this guidance should not be used as a substitute for obtaining personal advice and consultation prior to making decisions regarding individual circumstances.



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# INTRODUCTION OVERVIEW

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- **About THET and Health Partnerships**
- **About medical equipment in low-resource settings**
  - The importance of maintaining and managing equipment
  - The people behind the equipment
- **About medical equipment donations**
  - Power dynamics and cultural differences
  - Communication
  - Sustainability
  - What about medicine and medical supply donations?
- **Equipment donations globally**
- **Who makes donations in the UK?**
  - Health Partnerships
  - Equipment donation organisations & charities
  - Aid agencies
  - Other supply organisations
- **Legislative context for equipment donations from the UK**

## About THET and Health Partnerships

The Tropical Health and Education Trust (THET) is a specialist global health organisation that educates, trains and supports health workers through partnerships; enabling people in low- and middle-income countries to access essential healthcare.

THET has been working with structured health partnerships or 'links' between healthcare institutions in the UK and low or middle income country counterparts for twenty five years. These institutions may be hospitals, professional associations, universities or other training institutions whose primary focus is delivery of health services or the training of health workers.

Health partnerships are designed to improve the quality and capacity of the existing global health workforce through the training and education of health workers overseas. Training and peer-to-peer support is delivered by UK volunteers as part of strategic and long-term institutional agreements which respond to locally

identified needs. Health partnerships are characterised by collaborative relationships based on inclusivity, respect and mutual accountability and exist beyond the delivery of time-bound projects.

THET currently supports some 200 health partnerships that connect UK health professionals with colleagues in over 20 low and middle income countries to address a wide range of issues, including maternal mortality and child health, mental health, nurse education, clinical practice development and medical equipment maintenance and management.

THET also directly manages long-term partnerships with civil society and Ministry of Health institutions in Somaliland and Zambia, delivering large-scale programmes to support national health workforce development objectives in those countries.



*College electrical apprentices. Winchester - Yei Partnership, South Sudan. Photo Tom Price*

# About Medical Equipment in Low-Resource Settings

Many developing country hospitals lack the functional medical equipment they require to diagnose, monitor, treat and rehabilitate patients. It is one of the main challenges healthcare workers on the front lines of service delivery in developing countries report. Imagine the difficulties faced by a neonatal nurse caring for infants on a ward that doesn't have functional resuscitation equipment, incubators or oxygen.

## **There is no medical care without medical equipment.**

The World Health Organization (WHO) has estimated that 50-80% of medical equipment in developing countries is broken down, or 'out of service' [1]. The largest study done to date indicates that the figure is closer to 40% [2], as does recent country experience in Zambia [3,4]. In high-income countries by comparison, less than 1% of medical equipment is out of service [5].

These figures are high and yet they don't account for the differences between what equipment developing country hospitals do have compared with what they should have to deliver services, which is an even more significant gap.

## **Why is the scale of this problem so large? It's due in large part to:**

- Poor equipment maintenance and management systems and practices;
- A lack of human resources and training for both equipment users and maintenance personnel;
- Inadequate budgets for operating and maintaining the equipment;
- Problems with infrastructure and supply chains for supplies and parts;
- Weak policies and ad hoc planning at the health facility and health system level;
- Weak procurement and regulatory systems; and
- Challenges coordinating equipment from a wide variety of donors, both large and small.

## **Why is so much medical equipment out of service in the developing world?**

Low-resourced health systems and facilities face significant challenges with:

- Human resources, such as clinical staff who use the equipment to care for patients, and technical staff - often biomedical engineering professionals such as technicians, technologists and engineers - to maintain and manage the equipment
- Practical, competency-based training for both the clinical staff who use the equipment and the technical staff who maintain it
- Maintenance systems - workshops for the technical staff with proper tools, engineering test equipment, information resources (such as manuals) and spare parts
- Procurement and regulatory systems - that ensure safe, appropriate and good quality equipment is purchased
- Policy and planning - to ensure new equipment is meeting clinical needs, that training and maintenance are planned and budgeted for and that maintenance systems are established
- Budgeting for use and maintenance across the lifespan of the equipment
- A strong supply chain for consumables and spare parts to operate and maintain the equipment
- A reliable infrastructure to operate the equipment, which often includes good power supply, temperature and humidity control, and water and medical gas supply.

## The Importance of Maintaining and Managing Equipment

Maintenance systems run by well trained and resourced personnel - typically biomedical engineering technicians, technologists and engineers - are essential, as are national medical equipment management policies. Yet these two critical elements are often overlooked when medical equipment is being planned for and funded in developing countries. Without them, equipment lifespans are dramatically shortened, and costly equipment expenditures have a very low return on investment.

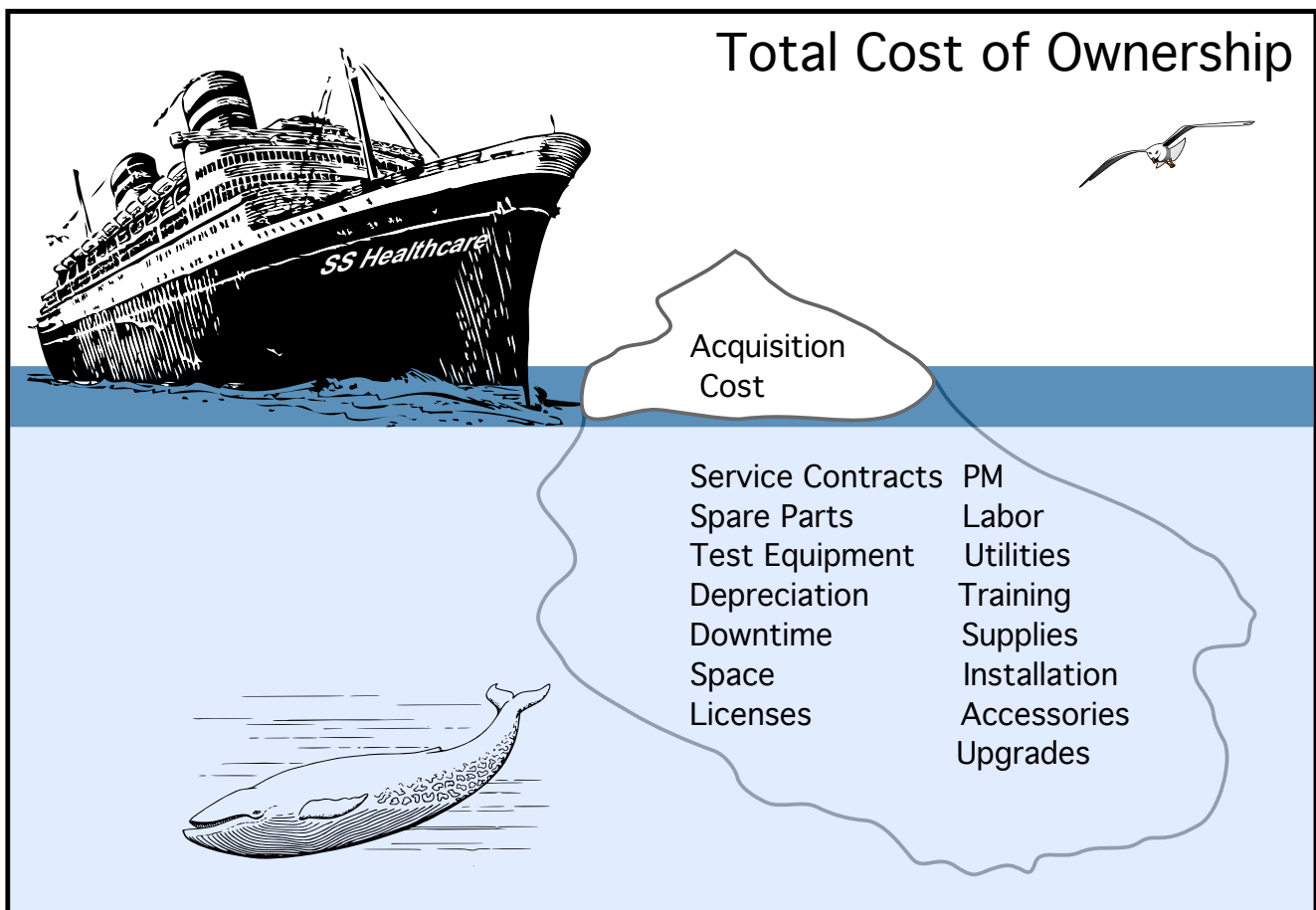
A study by the Swiss Centre for International Health found that equipment could lose 30% of its value before even being put into service due to improper procurement and over-sophistication. After equipment was put into service, improper use and a lack of preventive maintenance and repair (including access to spare parts) could devalue the equipment even further - until it is worth only 10% of the original financial investment [6].

A second study by Germany's technical cooperation agency GIZ (formerly known as GTZ) found that the lifespan of an anaesthesia machine varied between 2 and 15 years, depending on both the **quality** and **maintenance** of the device [7]. Another study found that improper use and maintenance of equipment has been shown to reduce its lifespan by 30-80% [8].

It is good practice to budget between 5 and 15% of the initial cost of the equipment for maintenance and usage each year, depending on the device. These costs are often neglected during procurement and even more frequently for medical equipment donations.

*"There's no point in getting equipment if you are not able to maintain it. Maintenance is key."*

- Dr. Joseph Musowoyo Consultant Surgeon. Acting Head of Clinical Care, Ndola Central Hospital, Zambia



Credit: Ismael Cordero, Clinical Engineer; [9]

## The People Behind the Equipment: Biomedical Engineering Professionals

In countries like the UK, hospitals have dedicated biomedical engineering (or 'clinical engineering', 'electrical and biomedical engineering (EBME)', 'medical engineering') departments that are responsible for maintaining and managing the hospital's equipment.

These engineering departments are staffed by qualified personnel, such as clinical/biomedical engineers, who specialise in particular types of equipment such as anaesthesia technology or renal technology.

The teams work not only on equipment maintenance, but also on managing the Trust's technology across the equipment's entire lifecycle, from acceptance testing, to putting equipment in service, advising and training the users, addressing patient safety issues and safely disposing of devices that have been decommissioned.

They work closely with the hospital's clinicians and have regular contact with manufacturers and suppliers of equipment. Biomedical engineering teams in the UK are active participants in capital equipment planning exercises and manage service contracts with manufacturers and external service providers.

In many developing countries, by contrast, there are few qualified biomedical engineering personnel working in hospitals and health systems.

A study of biomedical engineering services in low-resource settings found that 85% of African hospitals surveyed in a study of biomedical engineering services reported difficulty finding qualified engineers locally; 73% reported difficulty finding qualified technicians locally. These figures were high for Latin America and Asia as well: 78/79% and 60/65% respectively [10].

In Somaliland, for example, a recent needs assessment determined that there are no qualified medical engineers in the country to service medical equipment, the vast majority of which has been donated.

Similarly in Zambia, an assessment revealed that only one of 14 maintenance personnel interviewed in a needs assessment had any training in medical equipment prior to joining the workforce [4].

In Uganda, a research study on anaesthesia found that only 36% of anaesthetists worked in a setting where there were individuals trained to repair equipment [11].

One of the main reasons skilled personnel are in short supply is the dearth of training programmes in many low-resource settings, which can train biomedical engineering professionals as assistants, technicians, technologists and engineers.

### Biomedical engineering personnel - skill levels

The levels of skilled equipment maintenance personnel all require different levels of training:

**Craftsperson** - skilled person who works with their hands; a craftsperson is someone with craft skills such as a plumber, carpenter or electrician. The category encompasses both those with informal training (such as handymen) and also trade-test holders at various levels (known as 'artisans').

**Technician** - someone skilled in a craft such as medical equipment, mechanics, refrigeration, electricity with academic knowledge of how to put the science of their skills into practice. This category ranges from those with a craft certificate at various levels from a vocational training college, to those with a basic-level technical diploma from a technical college.

**Technologist** - someone highly-skilled in a craft such as medical equipment, refrigeration, electronics, electricity, with considerable academic knowledge of how to put the science of their skills into practice; someone with a technical diploma at various levels from a technical college.

**Engineer** - someone qualified in a branch of engineering such as biomedical, electrical, mechanical, or electronics, with advanced academic knowledge of controlling, designing, and building equipment, and using their skills to develop original ideas. This ranges from someone with a higher national diploma from a technical college to someone with a bachelor degree in engineering.

As a general rule of thumb, craftspersons spend 90% of their time on maintenance activities and 10% on management; technicians 80-20%; technologists 60-40%; and engineers spend the majority of their time on management.

[Reference: How to Manage series guide 1] - [http://www.healthpartners-int.co.uk/our\\_expertise/HCTGuide1.pdf](http://www.healthpartners-int.co.uk/our_expertise/HCTGuide1.pdf)



A study done for the WHO found only 19 African training institutions that offer biomedical engineering courses at any of these skill levels [12]. This limited number of training programmes translates into a severe shortage of qualified personnel to maintain and manage medical equipment.

Many of the individuals working in low-resource hospitals who are tasked with equipment repair have backgrounds in similar subjects, such as electrical or electronics technology or instrumentation.

They may be very skilled, but have rarely had the training required to properly maintain equipment or the resources they require – such as workshops with tools and the right engineering ‘test’ equipment – to do their jobs effectively.

To help improve this situation in Zambia, THET and the MoH developed the curriculum for a 3-year biomedical engineering technologist (BMET) programme that commenced in Sept 2013 [13]. Similarly, the Amalthea Trust, a UK charity, has set up a programme to train BMETs in Kampala, Uganda.

Certain countries in Africa, such as Kenya and South Africa, (<http://www.tut.ac.za/STUDENTS/FACULTIESDEPARTMENTS/SCIENCE/DEPARTMENTS/BIOSCIENCES/Pages/default.aspx>) do have very established training programmes and are helping others in the region to establish training programmes.

## About Medical Equipment Donations

Many health institutions in developing countries rely significantly on medical equipment donations. It is difficult to know exactly how much equipment is donated, but the WHO estimates that **up to 80% of medical equipment in developing countries is donated or funded by international donors and foreign governments** [14].

For example, between 1997 and 2001, the World Bank invested \$1.5 billion in medical devices in low-resource settings [15]. Many faith-based hospitals in developing countries receive their entire equipment base through donations from wealthier hospitals in their faith network.

When donations are well planned and coordinated, and when they are based on a genuine need, they can have a very positive impact on service delivery in the recipient health institution.

Unfortunately, many do not meet these criteria and it is estimated that **only 10-30% of donated medical equipment is actually put into service** in the recipient’s institution [16].

*“The donation of medical equipment is a good thing, but at times I feel we’re not given the opportunity to sit with the donor and ask some questions, little things they overlook like the issue of the manual. To us that’s very, very important because it is from the manual that we can be assisted and even come up with a preventive maintenance plan and other issues like educating the end users.”*

- Lupiya Kampengele, Senior medical equipment technologist, Ndola Central Hospital, Zambia

**The vast majority of donations are well intentioned. Yet so few are truly beneficial to the recipient.**

Many of them fail to take into account:

- Who the equipment users are, what capabilities they have and what training and support they will need to operate the equipment
- Who the maintenance staff are, what skills they have to maintain equipment and what training and resources (such as tools and test equipment) they will need to maintain the donation
- Whether consumables and spare parts will be available locally and how they will be purchased
- Whether there is local technical expertise, either in the hospital or externally, to provide maintenance services
- Whether the equipment is compatible with the electrical supply and other infrastructure requirements (such as ventilation, medical gases and water)
- Whether there is a budget for on-going use and maintenance of the equipment
- What the burden of disease is and whether the equipment is appropriate for the level of service currently offered in the hospital
- Whether the equipment is compatible with clinical current practices within the facility or requires significant behaviour change
- Cultural differences and expectations on both sides of the donation.

### **Donations should be treated with as much care as the procurement of new equipment would be.**

This includes deciding *what* equipment is needed, *who* should be consulted and *how* the process is handled. Clear, regular communication is essential to overcoming these challenges.

Many hospitals perform an annual planning exercise that brings together key stakeholders to determine priorities and plans for the upcoming year, including medical equipment needs. These plans are often fed up through a health system, to district or provincial medical offices and then centrally, in order to coordinate certain priority activities, such as training and medical equipment procurement.

Since most donations bypass this planning process, it is **even more important** to ensure the right people are consulted and involved in the process. It's also important for the donor to remember that different individuals within DC partner institutions may have very different priorities and views on what is needed, whether they can maintain a proposed donation and what support they will need to use and maintain it.

Without careful consideration, well-intentioned donations can - and often do - become a burden instead of help. The DC partner may be required to pay costly customs fees to receive the equipment without having the capacity to put it into use, and then be required to find a way to dispose of it safely.

Medical equipment donations can present technical challenges, such as electrical compatibility and sourcing of spare parts, which are covered in this toolkit. But it's important to remember that the 'softer' challenges at play - such as cultural differences and power dynamics, communication, sustainability- are even more important to understand when making a donation. Without them, even the best technically planned donations are unlikely to succeed.

### **Power Dynamics and Cultural Differences**

There is an inherent power differential between the donor and the recipient in the transaction. Therefore while both parties need to communicate actively and openly, the onus is on the donor to ensure an open and honest dialogue exists between both parties, particularly because the donor can access information and resources more easily.

*"We are a poor country, we need donations. And we cannot give conditions, that ... you have to do this, you have to do a manual."*  
- Informant from a Gambian hospital [17]

It's also important to remember that just as there are different individuals involved in a donation on the UK partner side, so too are there many on the DC partner side - and they may each have a very different idea of what is needed and what the current capacities are. It will take time to build up trust and ensure that both sides have a clear picture of what the other can offer.

Cultural differences and expectations between donors and recipients are also important to understand. Because donations are so common in many low-resource settings, sometimes they are expected of visitors from a higher-resource setting who wish to work together in partnerships; they are seen as a gesture of goodwill that demonstrates commitment.

### **Communication**

The most important characteristic of good practice for medical equipment donations is communication. Donations don't tend to fail because of the equipment involved; they fail because the people involved fail to communicate effectively with each other, and with other key stakeholders involved in the process. Active, open, two-way communication between UK and developing country partners is vital to success.

*"Most donated equipment is usually perfectly serviceable. If it's in the wrong place or isn't being used or maintained properly, or if it's just the wrong equipment, it's not the fault of the equipment; it's the fault of the people involved in the agreement. They got it wrong."*

- Rob Parsons, Healthcare Technology Management consultant, Health Partners International

### **Sustainability**

What makes a medical equipment donation sustainable? This is a tricky question, because donations are inherently unsustainable; they are not addressing the root causes of why so much medical equipment is out of service in low-resource settings. Instead, they are providing short-term relief to fill an immediate need.

This short-term support is often very necessary, but it's important to remember that medical equipment donations alone - even those that are effectively managed and work well - will never solve the systemic problems previously outlined. Bearing that in mind, some guidance to help assess whether a donation may be sustainable in the short term will be provided in this toolkit.



### An 'emphasis imbalance' between drugs and equipment

Some biomedical engineers refer to an 'emphasis imbalance' in public perception and response to drug shortages vs. equipment shortages in low-resource settings:

In one African nation there was a public outcry when one year's worth of drugs valued at \$3 million US dollars had to be destroyed because their expiry date had passed. At the same time in the country, thirty times that value of medical equipment was out of use (\$90 million US dollars), yet this received little attention by the public, the media or policy makers [8].

In another Latin American country with a stock of equipment valued at \$5 billion USD, 40% of the equipment is out of use, representing a loss of \$2 billion US dollars. Yet the pharmaceutical programme in the country receives far more attention from policy makers, the public and the media - and it has an annual operating cost of several hundred million US dollars [8].

## What About Medicine and Medical Supply Donations?

There are similarities between many of the issues faced when donating medicines (or 'pharmaceuticals', 'drugs'), medical supplies and medical equipment. For example the ethics and guiding principles are similar.

Yet there are also significant differences such as the stakeholders involved, the import and export regulations and processes, and the type of ongoing support required post-donation.

Good practice for medicine donations is very specific and not covered in this toolkit. The WHO provides [guidelines for donation of pharmaceuticals](#) that many other international organisations (such as pharmaceutical industry associations and international aid agencies) follow.

Donations of medical supplies (such as gloves, syringes, suture kits and cannulae) are also common. They may be sent on their own, or added to containers of donated equipment to 'top them up' and get maximum value for the shipping cost.

Donating small quantities of these devices can provide short-term relief, but again it is important to remember that they do not represent a sustainable solution to challenges the DC partner may face securing adequate medical supplies. While supply donations are often perceived as being 'lower risk' than medical equipment donations, they too can have serious, unintended negative consequences and should be treated with caution.

Supplies also tend to be more widely available on the local market than equipment, through central medical stores, pharmacies and other local suppliers so local sources of supply should always be investigated when supplies are requested.

# Equipment Donations Globally

It is not possible to know exactly how much medical equipment is donated to developing countries globally each year or precisely what practices are followed. Some organisations, however, are making significant contributions to the evidence base and are producing useful guidance for their networks on good donation practices.

Some of the key global contributors are:

## World Health Organization (WHO)

The WHO first published guidance on donations of medical equipment in 2000, entitled '[Guidelines For Health Care Equipment Donations](#)'. This guideline was prepared in close collaboration with a number of national and international organisations from both high- and low-resource settings, some of whom had developed their own guidance prior to contributing to this effort.

This guidance was updated to produce the 2011 reference document '[Medical Device Donations: Considerations for Solicitation and Provision](#)' which is part of the WHO's Medical Device Technical Series. The series provides very useful reference documents on a variety of medical device issues to improve access, quality and use globally.

The donations reference document is the most comprehensive overview of best practice for both donors and solicitors of equipment donations and recommended reading for anyone considering involvement with a medical equipment donation.

The WHO reference document highlights the importance of an active, participatory role for the intended recipients of donations and discusses the following key considerations:

- Ensuring that the recipients are actively engaged in all stages of the donation process
- Ensuring that the needs of the end-users and patients are met
- Regulatory and policy considerations
- Considerations for existing local markets of medical equipment
- Considerations for established procurement systems
- Considerations for public health needs
- Inclusion of health facility input when donations are coordinated at a national level
- Considerations for support for installation, service and supplies
- Considerations for special environmental and human resources to support equipment
- Communication

The reference document provides particular guidance for donations of used and refurbished equipment (as opposed to new), laboratory equipment and imaging and radiology equipment. A link to this and more resources prepared by the WHO are presented in various relevant sections throughout this toolkit and in the Useful Resources Section.

 **See page 78 for the Useful Resources section**

## HUMATEM

Based in France, HUMATEM is an association that has developed a platform for dialogue and services for those donating medical devices with the aim of improving the quality of medical equipment support projects in developing countries and in particular the quality of transfers of medical device to health facilities.

Together with its network of collaborators, HUMATEM has developed a series of resource guides to improve the quality of 'medical equipment support projects' between partners in low- and high-resource settings. These resources include guidance on assessment and planning, evaluating and measuring quality, a step-wise guide for equipping a facility and a factsheet on medical equipment support projects and the role of biomedical engineering professionals.

 **See page 78 for the Useful Resources section**

## Catholic Health Association of the United States (CHA)

In 2010, CHA performed a study of donation practices amongst its membership in the United States. The study included CHA member hospitals and health systems, medical surplus recovery organisations (MSROs) in the developing world.

Based on the study, CHA produced a tool for its membership and other potential donors to assess the practices and effectiveness of MSROs and partnered with the Partnership for Quality Medical Donations (PQMD) to develop a code of conduct for MSROs.

CHA has also produced a resource that shares the findings of a second study in 2012 to determine high-impact leading practices every hospital and/or health system should adopt when starting or enhancing a medical surplus recovery programme.

 **See page 78 for the Useful Resources section**





Medical Equipment Donations. Photo Shauna Mullally

### Partnership for Quality Medical Donations (PQMD)

PQMD is an alliance of non-governmental organisations (NGOs) and pharmaceutical, biotechnical, and medical supply manufacturers dedicated to raising the standards of medical donations globally. In 2008, PQMD published standards for medical equipment donations of its membership.



See page 78 for the Useful Resources section

### Duke University's Developing World Healthcare Technology Laboratory

The 'Developing World Healthcare Technology Laboratory' (called the DHT-Lab) at Duke University in the USA is one of the leading contributors to the global evidence-base on medical equipment in developing countries.

One study published in 2011 analysed over 100,000 pieces of medical equipment across sixteen developing countries to determine that close to 40% was out of service. The three leading causes were a lack of training, health technology management (HTM) and infrastructure [2].

Another study done by the DHT-Lab showed that the majority of equipment in low-resource health facilities could be put back into service using basic knowledge and without importing spare parts. The knowledge required was broken down into five main technical knowledge areas, which now form the basis of a biomedical engineering assistant curriculum [18].

DHT-Lab is closely affiliated with [Engineering World Health \(EWH\)](#), which is an organisation that runs training programmes for biomedical engineering professionals in Honduras, Ghana, Rwanda and Cambodia.

### 'How to Manage' Series of Health Care Technology Guides

The 'How to Manage' series provides those working in low-resource settings with guidance on setting up a system to manage health technologies. They provide comprehensive, appropriate guidance for those working in developing country health systems on:

- Guide 1 - how to organize a system of healthcare technology management

- Guide 2 - how to plan and budget for healthcare technology
- Guide 3 - how to procure and commission your healthcare technology
- Guide 4 - how to operate your healthcare technology effectively and safely
- Guide 5 - how to organize the maintenance of your healthcare technology
- Guide 6 - how to manage the finances of your healthcare technology management team

The series was developed by experts from low- and high-resource settings through funding provided by DFID, and is available online through Health Partners International.



# Who Makes Donations?

## Health Partnerships

Many hospitals, professional associations and training institutions within the UK health partnership community have donated medical equipment to meet the objectives of their partnerships. For example, an [evaluation](#) conducted of the International Health Links Funding Scheme found that 56% of 113 partnerships funded were involved in the procurement of new equipment.

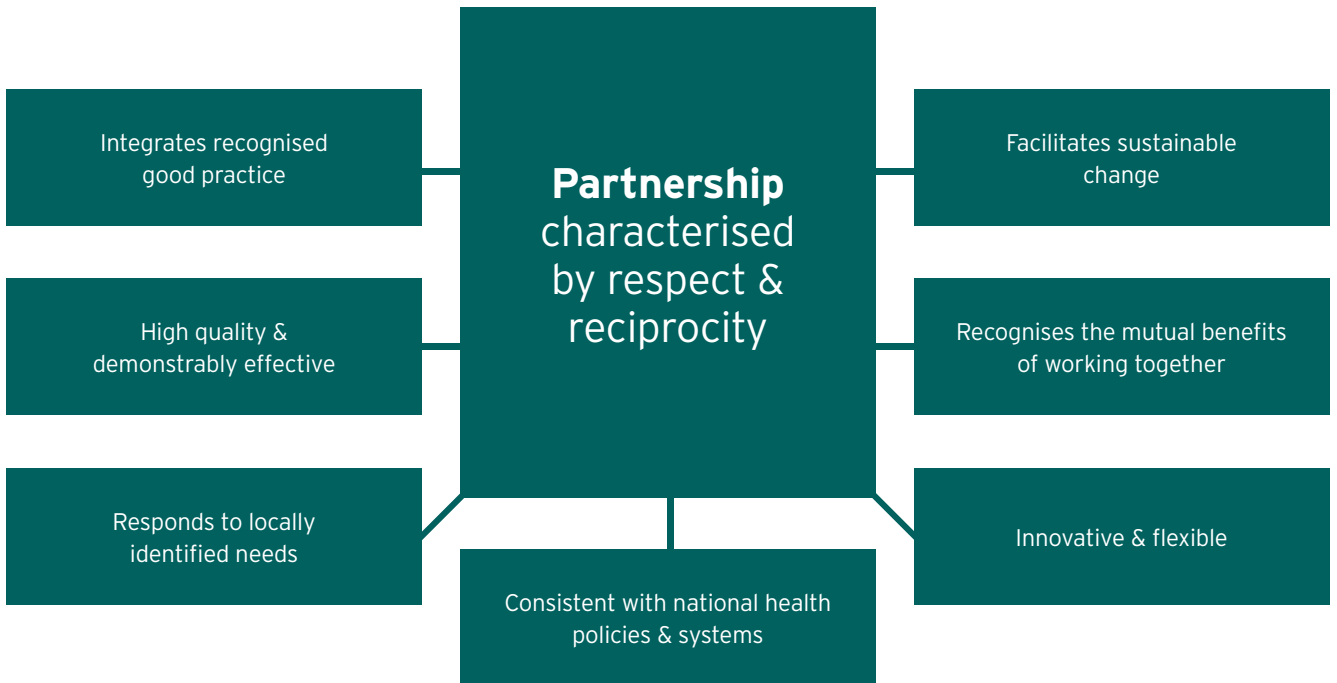
The experiences of many of the partnerships from within THET's health partnerships community are presented as case studies throughout this toolkit.

THET's medical equipment partnerships, which focus on building equipment maintenance and management capacity through training and support of biomedical engineering and technical professionals, have also coordinated donations of engineering tools and test equipment for the developing country workshops.

THET's guiding principles of good partnership

Donations made within the context of an existing health partnership can have a very positive impact on both partnership activities and patient care in the low-income country partner's facility.

The guiding principles of good partnerships can also provide a reference framework for evaluating proposed donations.





*Dental technician's laboratory, Dental Department QECH, Blantyre, Malawi*

## **Equipment Donation Organisations & Charities**

Some organisations - charities and for profit organisations - are solely dedicated to collecting used medical equipment from high-resource settings and arranging for the transfer of it to recipient institutions in low-resource settings. Examples include Med Aid International, a Community Interest Company (CIC), Mercy Trucks and Dentaaid. Aid to Hospitals Worldwide (A2HW), a charity with a similar mandate, has recently ceased operations.

Many other medically focused UK charities donate medical equipment as part of their work. These include organisations such as International Health Partners UK (IHPUK), Medical Support Romania, International Development Partnerships, HealthProm, Motivation, CBM UK, Handicap International UK, Kids for Kids Partner Aid, Maternal and Childhealth Advocacy International, Progressio, 500 miles and many others.

Contacts for these organisations can be found in the Useful Resources section.

## **Aid Agencies**

It is common for global health organisations and aid agencies - such as Save the Children UK, Médecins Sans Frontières (MSF) UK, DFID and the World Bank - to donate equipment (often new) or support developing countries to procure medical equipment, as part of larger health projects and programmes. This is often done through their in-country programmes via direct budgetary support and/or technical assistance.

These organisations and their practices are outside of the scope of this toolkit. However, it is very useful to know who is involved with medical equipment at an 'in country' level, and the DC partner may approach these organisations' offices for support, either directly or through the MoH if deemed appropriate. They may be able to provide logistical support for the procurement of new devices, as an

alternative to donation, or help with the shipment of a device from the UK.

## **Other Supply Organisations**

Many other UK organisations are involved in the supply of equipment to developing countries. These include international procurement organisations, manufacturers, suppliers of new equipment and equipment re-sellers (both those who sell equipment 'sold as seen' and those who refurbish equipment to new working order prior to sale).

While these organisations are involved with equipment supply, again their practices are outside of the scope of this toolkit. Relevant sections of this toolkit do, however, include overviews of some of the main organisations involved in supply of both pre-owned NHS equipment and new devices to developing countries. These organisations can be good sources of suitable equipment and often take an active role in shipping the equipment on behalf of the donor.

# Legislative Context for Equipment Donations From the UK

As part of the European Union (EU), the UK must comply with EU legislation regarding medical devices and the transfer of pre-used equipment to recipients in countries outside of the EU. There are two types of legislation: EU regulations that must be complied with directly and EU directives that are 'transposed' into law through UK regulations.

**There is no specific legislation in the UK on medical device donations to low-resource settings.**

Medical devices are regulated by the [Medicines and Healthcare Products Regulatory Agency \(MHRA\)](#), which provides guidance on lifecycle equipment management, including how to prepare used equipment adequately for safe and effective reuse and transfer to another party. For more information about how the MHRA regulates medical devices in the UK see Appendix A.

The EU legislation on waste electrical and electronic equipment (WEEE) has recently been updated. This is of **particular importance to readers of this toolkit** because the updated legislation ([Directive 2012/19/EU](#), which 'recast' [2002/96/EC](#)) includes new **minimum standards for shipments of pre-owned equipment outside of the EU** in order to cut down on illegal 'dumping' of WEEE in developing countries and the UK is the first country to develop new regulations to meet the Directive.

These standards are not meant to impede legitimate transfers of used equipment, but certain criteria must now be met to **demonstrate that a device being transferred is fit for reuse**, including the passing of tests to confirm it is functional and free of hazardous substances, and the provision of full documentation of the service history of the device. the directive does not allow for the transfer of devices in need of repair.

Briefly, the minimum standards for shipments require:

- Evidence that the equipment is fit for re-use (testing depends on the specific equipment; a functionality test is sufficient for most devices)
- Evidence that the equipment is free from hazardous substances
- A copy of the transfer of ownership documentation (including full contact details for both parties)
- Identification of the equipment (manufacturer, make/model, serial number, type using standard medical device nomenclature where applicable and reference to the Annex II category of the Directive)
- Records of all tests performed to meet the above requirements (including the responsible organisation)
- Appropriate protection against damage during transportation, loading and unloading
- Declaration by the sender that no items in the shipment are WEEE as defined by Article 3(1) of [Directive 2008/98/EC](#)
- Relevant transport documentation such as a bill of lading (sea freight) or air waybill (air freight)

At the time of publication of this toolkit, Directive 2012/19/EU is currently being transposed in the UK. In October 2013, the UK government issued the [outcome of a consultation](#) on implementing the recast WEEE directive. The final version of the new Waste Electrical Electronic and Equipment Regulations 2013 is due to be laid before parliament to come into force on 1 January 2014.

Further details about the minimum shipment requirements are covered in subsequent sections of this toolkit and Appendix B provides more detail about the relevant sections of the new legislation and links to further reading. **It is the responsibility of the reader** to consult the UK government agencies referenced in the links at the time of reading for specific guidance on how to meet the new requirements.

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## CHAPTER OVERVIEW: DECIDING WHETHER OR NOT TO DONATE

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- **What is needed and what can partners provide?**
  - Who should be involved in the UK?
  - Who should be involved in the DC?
- **Asking the right questions**
  - What should be asked in the UK?
  - What should be asked in the DC?
- **How can suitability of the donation be determined?**
- **Considering donations of complex equipment**
- **Deciding whether or not to proceed**

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## CHAPTER CHECKLIST:

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- ✓ Clarify what equipment is needed, and what support is required for it to be useful
- ✓ Determine whether the needs can be met by both partners
- ✓ Based on this assessment, decide whether or not to proceed with the donation

# 1 | DECIDING WHETHER OR NOT TO DONATE

**During this stage, the UK and DC partners are first proposing a donation of medical equipment.**

**This may be because:**

- The UK partner has equipment becoming available through removal from service within their Trust
- The partners agree more equipment is required to meet the partnership's objectives
- The DC partner has a specific need for equipment, either within a clinical area addressed by the partnership or external to it
- The UK partner has been approached by another organisation who wishes to support the partnership through the donation of medical equipment

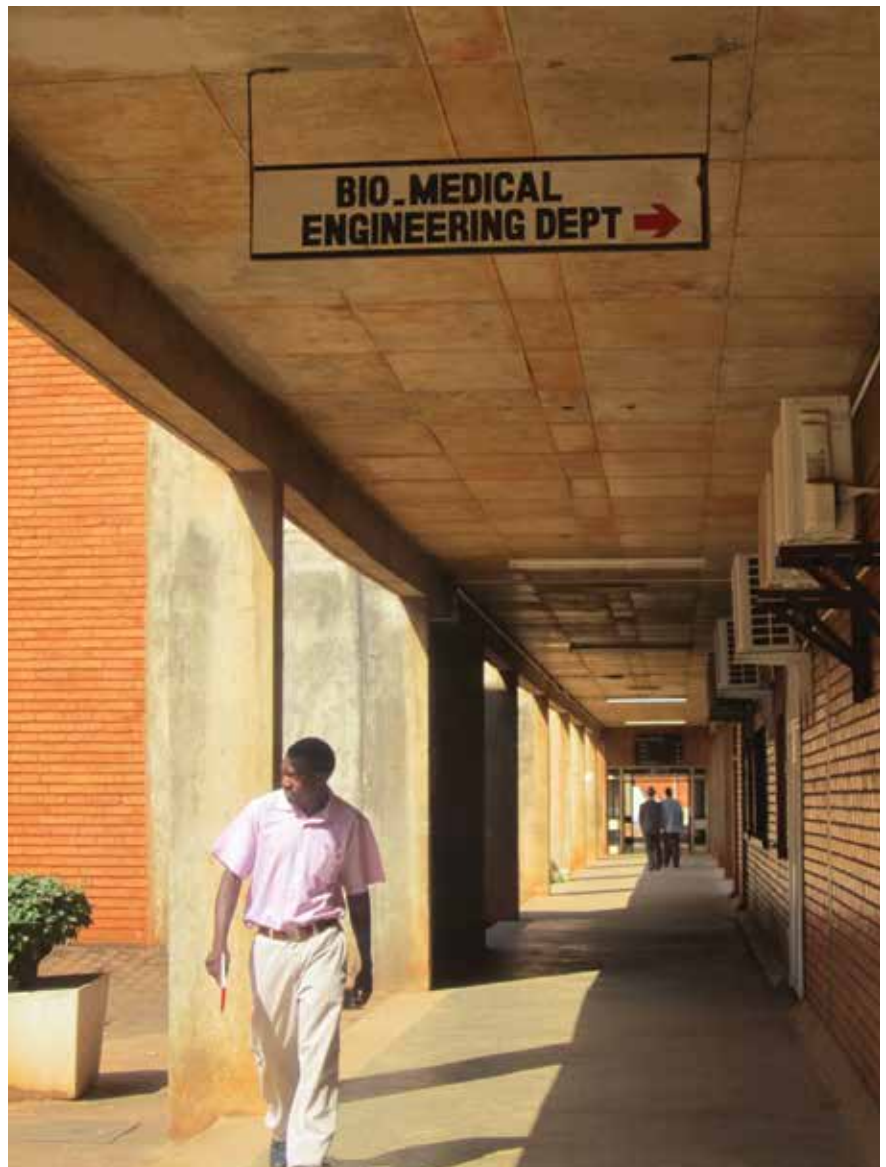
**Equipment donations should *always* be in response to an identified need.**

Imagine if someone gave you a gift they wanted to discard and assumed you would need - without asking you.

It is possible the DC partner may have a need for equipment the UK partner is taking out of service, but it's important to ensure that the clinical and training needs of the DC partner drive what equipment is selected for donation... not the other way around.

Regardless of how the process is initiated, the most important first activity during this stage is a thorough assessment of both need and capacity. In other words:

1. Is there a genuine clinical or training *need* for the equipment?
2. Is the equipment appropriate for the DC partner to meet the *need*?
3. Does the DC partner have the *capacity* to use and maintain the equipment?
4. Does the UK partner, alone or with the DC partner, have the *capacity* to



*University Teaching Hospital, Zambia. Photo Shauna Mullally*

finance the costs associated with the donation?

Input from various stakeholders must be sought in order to answer these questions. This section provides detailed questions that form a 'needs and capacity' assessment and links to additional resources that can be used.

By the end of this consultation, the partners should have a clear idea of whether the proposed donation should proceed or not. If the partners agree that together they have the capacity to meet the needs discussed, they should move on to the next section of this toolkit, which covers planning the donation.



## What is Needed and What can the Partners Provide?

At this stage, both the UK and DC partner will need to consult a wide variety of stakeholders, both within, and possibly external to their institutions.



### Who Should be Involved in the UK?

Someone with significant experience working with the DC partner should lead this process; this could be the partnership coordinator, the lead for the clinical area involved, or someone else significantly involved with the partnership.

Who to involve	Why
Partnership lead/coordinator(s)	context
Clinical leads	users of the equipment such as doctors and nurses
Head of the clinical area	for equipment being taken out of service in a Trust
Biomedical engineering department	for technical advice and records of the equipment
Senior leadership (Trust Board and chief executive) and/or Any other Trust staff who may be involved in removing the device from service, moving, storing and/or preparing equipment for shipment such as Estates and Facilities, Procurement and Supplies, Health and Safety.	for permissions (depending on the partnership's leadership and governance arrangements within the UK partner)  for support for moving, storing and/or preparing the equipment
Supplier/manufacture or Any other organisations that may be involved in sourcing the equipment outside of the Trust	to advise on potential donation, their agents in or near the DC partner, terms of support and supply of parts and consumables
Shipping agents	to advise on costs, methods and requirements for shipping



### Who Should be Involved in the DC?

Similarly, either the partnership lead or someone else who is very engaged in the partnership (preferably in the clinical area for which the donation is being proposed) in the DC partner will need to consult a wide variety of stakeholders within his/her institution.

Who to involve	Why
Partnership leads/coordinator	context
Clinical leads & head of the clinical area (users of the equipment such as doctors and nurses)	to advise on usage requirements and clinical aspects
Senior administration, such as the medical director and chief executive	for permission and guidance on asset management
Team responsible for medical equipment maintenance (this may be a biomedical engineering department, a general 'hospital engineering' team, an electrician or maintenance team)	to advise on maintenance requirements and capacity
Facilities manager	for advice on transporting large items of equipment safely
Support staff such as: Procurement and Stores, Finance Environmental Health Officers Facilities Any other staff who may be involved in receiving, accepting and commissioning the equipment	for procuring and stocking spare parts and consumables, and asset management  for advice on environmental issues and disposal  for support moving the equipment if necessary and/or any installation work required (electrical wiring, etc.)
Relevant MoH staff (administration, clinical and biomedical engineering)	to advise on wider MoH context, policy and planning, maintenance needs and capacity
Other partners working with the DC partner on medical equipment supply and/or capacity building	to coordinate activities
Local suppliers	to advise on new equipment, supply of parts and consumables, and technical services they may offer
Local shipping and customs clearing agents	to advise on process, timeframe, method, cost and requirements for shipping and clearing customs



**Make sure you know who the other medical equipment actors are, both within the health system and external to it.** There may be opportunities for collaboration.

In order to determine these actors, an understanding of the DC's strategy and system for medical equipment maintenance and management is necessary.

For example, in the last decade, Zambia has created 'Provincial Medical Equipment Officer' posts in each of the provinces. These officers oversee equipment at the provincial level, and also provide the interface between hospital-level technical staff and the central Ministry of Health.

These biomedical engineering professionals may also have useful contacts with other organisations, such as NGOs or projects run by aid agencies that are working on medical equipment training or supply. It's always useful to ask who else is working in the area. It may even be surprising who you can collaborate with.

#### **Understanding the role of the Ministry of Health (MoH) in medical equipment management**

Often the MoH has either an individual or a team that is responsible for coordinating medical equipment and maintenance activities across the country. There may also be a main referral maintenance workshop whose staff should be consulted.

- Advising MoH directorates on medical equipment issues in line with the national health plan
- Donor coordination of medical equipment introduction and training activities
- Country-wide procurement for major equipment (ex: diagnostic imaging)
- Central management of maintenance contracts for some equipment (ex: laboratory diagnostics)
- Country-wide human resource management for medical equipment personnel
- Writing guidelines and policies for medical equipment

There may also be biomedical engineers or other medical equipment specialists in positions at the provincial level in provincial health offices.

*Guy's & St. Thomas' - Ndola Central Hospital and Arthur Davison Children's Hospital, Zambia. Photo Howard Bland*

# Asking the Right Questions

The more information that is gathered, the more informed a decision partners can make about whether or not to proceed. These questions are also available in Appendix C. To answer some of these questions, it will be very helpful to review the sections of this toolkit.

UK

## What Should be Asked in the UK?

- Do you have a very clear idea of what equipment is required?
- Do you have an understanding of the DC partner's capacity to use and maintain the equipment?
- Is the proposed equipment appropriate and suitable to their current situation?
- Are you able to either provide or arrange for any training that may be required for the recipients to both use and maintain the equipment?
- Have you factored in the costs of this training?
- Are you able to provide ongoing advice to the DC partner if they require it?
- Do you know what the electrical requirements are at your partner hospital?
- What voltage and frequency does their power system operate on?
- How reliable is the electrical supply in the hospital? Do they have scheduled or unscheduled interruptions?
- If the equipment requires 3-phase power, is it available or does it need to be set up?
- Are you able to source all of the necessary support items initially required for the equipment, such as user and service manuals, accessories and consumables, spare parts and any necessary electrical equipment (such as voltage regulators, converters, or uninterruptible power supplies) for a certain period of time?

- Do you have clinical and technical (engineering) staff available to provide this advice? If not, can you arrange for it with another agent, such as the supplier or manufacturer?
- Do you know how the equipment can be sourced?
- Have you looked into in-country procurement of new equipment? Would you be able to finance this as an alternative to UK sources of equipment?
- Do you know much it will cost to ship the equipment and what is required of you?
- Do you have the capacity to finance the operation and maintenance costs for the equipment (for a specific time period) if your partner does not?
- If you are planning to donate equipment that is currently owned by your Trust, are you aware of all relevant policies and procedures relating to removal from service and transfer of ownership?
- Are you adhering to all relevant Trust policies on equipment disposal and donation?
- Do you have the support of your Trusts' leadership for the donation?
- Do you understand the requirements of the EU directive 2012/19/EU and are you able to meet them? Who will you need to engage to provide the technical services to meet these requirements?

DC

## What Should be Asked in the DC?

- Does your hospital - or your MoH - have a policy on equipment donations? If so, what requirements are outlined in it and will the proposed donation meet them?
- Does your hospital - or your MoH - have a procurement policy? If so, will the donation meet its main requirements?
- Is there a genuine clinical need for the equipment?
- Would the equipment require changes in processes and if so, have these been discussed and are you able to manage the changes?
- Do you have clinical staff already trained on the type(s) of equipment?
- If the equipment is sophisticated, does your clinical staff require additional training on an unfamiliar brand of the device (i.e. a new manufacturer, make/model)?
- Are your technical/maintenance/engineering staff aware of the proposed donation, and do they have input about the maintenance requirements?
- Have the technical/maintenance/engineering staff been trained to maintain this type of equipment?
- Do they have the right tools and any special engineering equipment to do the maintenance?
- Are they able to order any spare parts they may need?

- If you don't have a technical/maintenance/engineering team who can do the maintenance, is there someone locally who can be contracted to service the equipment?
- Is there enough space for the equipment in the area in which it is needed?
- What is your electrical supply situation?
- Is there proper infrastructure for the equipment? For example, it may require room ventilation, three-phase power or uninterruptible power supply (UPS), water and/or medical gas supply.
- Is your senior leadership aware of the proposed donation, and do they support it? Are they aware of the financial implications of using the equipment?
- Is there a budget in place for ongoing costs associated with the equipment, such as consumables and reagents, maintenance materials (such as spare parts) and a service contract if necessary?

**Different people and teams within each partner institution may have different ideas and priorities.**

It's important to remember that there won't necessarily be homogenous priorities within either institution.

## How can Suitability of the Donation be Determined?

The WHO's medical equipment donation guidance document includes five indicators of suitability that can be used to evaluate specific offers for donation. These five criteria are met when:

1. The equipment is appropriate to the setting
2. The equipment is good quality and safe
3. The equipment is affordable and cost-effective
4. The equipment is easy to use and maintain
5. The equipment conforms to the recipients policies, plans and guidelines

Appendix E includes specific indicators for these five suitability criteria and is a useful tool to review at this stage of the process.

## Considering Donations of Complex Equipment

**The more complex the equipment, the more caution should be used when considering the donation.**

Additional caution should be taken when considering making donations of complex equipment that requires specialised training to operate and maintain, good supply chain for consumables and significant changes to infrastructure:

- New medical imaging equipment such as fixed x-ray (as opposed to mobile) may require significant changes to the infrastructure and health and safety protocols.
- Automated laboratory analysers have high operating budgets for consumables and need regular supply chain and refrigeration.
- Many anaesthesia machines require compressed gases that may be difficult to keep in regular supply, as well as highly trained operators.

*"The anaesthesia machine we received is very good quality. But we don't have an anaesthetist here at the hospital so we can't use it properly."*

- Operating theatre nurse at Chama District Hospital in Zambia



## Education, Expertise & Equipment: Medical Equipment Partnership for radiotherapy

The paRTner project is an initiative started in 2011 by the Department of Medical Physics and Bioengineering at UCL, in collaboration with the Radiotherapy Departments of University College Hospital, the Royal Berkshire NHS Foundation Trust and Korle Bu Teaching Hospital, Ghana. The aim of this partnership is to develop a continuing infrastructure of high quality training and support for radiotherapy professionals in Ghana and neighbouring African countries. The initiative has three main areas of work - the provision of education, expertise and equipment.

A large quantity (>£100k worth) of essential radiotherapy equipment has been collected from ten UK hospital departments for donation to Ghana. An equipment inventory was performed by the Ghanaian teams so the project team could identify the most needed items and agreement has been reached with the Ghana High Commission in London to ship the equipment. The project team appropriately prepared, packaged and costed the current value of the equipment in advance.

“In terms of equipment we’re looking at small, medium and very large. Equipment becomes redundant quite quickly in the NHS. The turnover is very high. Most equipment has a lifespan of thirty years and is guaranteed for that, but the UK gets rid of it in five. For example, we were offered forty eight computers that were just three years old because the Trust was changing its IT service provider. We were also offered equipment for planning cancer treatments that would have originally cost £500,000 for £18,000 i.e. the cost of decommissioning and packing it up. We were welcome to it as otherwise the NHS would have to spend that money dumping it.

I think there are many opportunities to find a lot of equipment in the NHS but it’s not just about working out how to find it or how to get it over there (which is a big logistical fuss); it’s also about preparing the place to receive it. It needs to be brought into patient work plans. They need somewhere to put it, they need to know what to do with it and they need to know how to maintain it. For example, the issue of spare parts is crucial. Donating without them, or the means to get them, is a bad idea because equipment is going to break. Our linear accelerator breaks down about once a month but we have the spare parts to keep it churning. If you don’t have the parts then that’s a waste of a whole hospital room.

I think for equipment donation practice, it is essential to train UK and overseas partners on how to perform basic quality control and not to accept or donate any equipment as charity. It’s got to be more of a business arrangement whereby the donor has to essentially sign a contract with who they are donating to, to say ‘we’ll not only donate this but we’ll keep in touch with you to make sure it’s working’. That’s a lot to ask from the UK partner but it’s something that should be place for certain pieces of equipment.”

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**Dr Kate Ricketts**, Radiotherapy Physics department, University College London Hospital, UK

**Prof Gary Royle**, Medical Physics department, University College London, UK

**Dr Paul Burke**, Medical Physics department, University College London, UK

These types of complex equipment often require specialised technical expertise from outside of the DC partner's facility, such as a private local contractor or a service contract directly with the manufacturer or its distributor working in the region.

WHO guidance on more special considerations for medical imaging and laboratory equipment is available in the Useful Resources section.

 See page 78 for the Useful Resources section

### **Determining the needs and capacities should be proportional to the proposed donation.**

For a small donation with few items, this should not be too onerous. If, however, a very large donation is being proposed - such as one or more container loads of equipment, or support equipping a whole area of the DC partner hospital - a more comprehensive needs assessment for medical devices should be done.

In this case, these resources will provide more guidance on a larger needs assessment:

HUMATEM's 'Preliminary Assessment Method' guide provides a framework for performing a detailed assessment of whether or not a 'medical equipment support project' should be pursued. It takes into account contextual factors such as the health system and all of the devices currently in use within the DC partner institution. The guide also includes fact sheets for various stages of the process. The English version is not yet available online at the time of publication of this toolkit, but due to be on HUMATEM's website early 2014.

The WHO also provides guidance for performing thorough equipment needs assessment for a facility in its '[Needs assessment for medical devices](#)' guidance document, which is also part of the Medical Device Technical Series found here:

## **Deciding Whether or not to Proceed**

There is no special framework or formula for this. It's pretty simple: if the partners are confident they have the resources required to meet the needs - the appropriate equipment and supplies, the finances to ship it, provide training if necessary, and operate and maintain it - and the support they require from the other stakeholders to make it happen, they can commit to it and start planning.

UK and DC partners should also review each upcoming section of this toolkit before making this decision, to ensure they are clear about what is required of them.

If a decision is made not to proceed, there are many other ways the UK partner can support the DC with their medical equipment needs and challenges. For example, they could:

- Send supplies and parts for existing equipment
- Offer training on existing equipment
- Bring an engineer along on an upcoming support visit
- Support a full equipment needs assessment
- Advocate for the DC partner's equipment maintenance staff
- Discuss medical equipment issues with DC partner leads and senior decision makers
- Be a champion on the DC partner's behalf with manufacturers and suppliers

*"We received these two brand new ventilators from a donor. We want to use them in the ICU but we haven't had any training on them and we don't have any tracheostomy tubes. Our director is trying to source the tubes but we can't find any from the suppliers we have here in Somaliland."*

- ICU in-charge at Hargeisa Group Hospital in Somaliland

**About equipment needs assessments** Comprehensive medical equipment needs assessments are a significant undertaking. Needs assessments are used to prioritise new equipment needs based on existing equipment, facilities and services, factoring in constraints due to human, financial and logistical resources. They are typically done by trained biomedical engineering personnel and involve many different stakeholders within a facility and wider health system. The prioritised list of new equipment can then be used to plan procurement and evaluate proposed donations against.



*Ventilators at Hargeisa Group Hospital ICU. Photo Shauna Mullally*

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## CHAPTER OVERVIEW: PLANNING THE DONATION

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- **Agreeing the terms of the donation**
- **Developing a project plan for the donation**
  - Who should draw up the plan?
  - What should the plan include?
- **Drafting a donation agreement**

---

### CHAPTER CHECKLIST:

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- ✓ Agree on the terms of the donation
- ✓ Develop a project plan outlining the activities, tasks, stakeholders and timelines for the donation
- ✓ Draft a donation agreement



## 2 | PLANNING THE DONATION

When the partners are confident they have the resources required to meet the needs, they can begin to plan the donation together.

It is important to remember that while preparing a plan and drafting an agreement are crucial stages in the process, the work involved should always be *proportional to the donation exercise*. The remaining sections of this toolkit will provide input for the specific details of the plan and agreement.

### Agreeing on the Terms of the Donation

At this stage, the partners should have had a clear and honest discussion about what they are able to contribute. Now comes the time to officially commit.

Agreeing on the terms may come naturally for the partners; it may be their established way of working, developed through their existing partnership memorandum of understanding (MoU) and a trusting relationship that has built up over time.

Nevertheless, it's useful to discuss each of the activities involved in the process and how the cost implications will be handled. This includes not only the actual (i.e. financial) costs, but also the 'human capital' costs (i.e. volunteer time). For example:

- Does the DC partner have the budget to clear the shipment through customs, and to operate and maintain the equipment for an agreed upon period of time?
- If the DC partner cannot contribute these finances, is the

UK partner willing and able to do so, and arrange a transfer for the appropriate amount?

- If so, how will the funds be transferred, and audited?

**Remember to follow the adage "if it's not written down, it's not done".**

Be sure to record communications with all stakeholders during the process.

The most effective way to clarify and agree on the terms of the donation is to develop a project plan for the donation. By using a step-wise methodology to identify all of the necessary activities and associated tasks, then clarifying who will do what and under what time constraints, the partners can be confident they have planned well for the exercise.

## Who to involve in an equipment donation

**“Everything has to be approved by both the sending and the receiving organisation at the highest level and the operational level”**

**Since 2001, Northumbria Healthcare NHS Foundation Trust has provided training, equipment and management support to contribute to the sustained development of health services at Kilimanjaro Christian Medical Centre in Tanzania. Brenda Longstaff, a project manager from Northumbria Healthcare NHS Foundation Trust, has developed the international health partnership for more than ten years. As a senior operational manager within the NHS, Brenda has experience of commissioning new hospitals and decommissioning hospitals. This has provided an opportunity to re-evaluate equipment that is still in working order but at the end of its NHS life.**

The Northumbria Healthcare Trust covers 10 hospitals and over 2,000 square miles. Within that we have a lot of staff who are quite passionate about the work that we do in Tanzania. I frequently get a call or an email about equipment that is about to be decommissioned, and that sets off a chain of events.

Firstly, I ensure that the equipment is actually available, and that it isn't already earmarked to be resold, or put forward in part exchange for other items of equipment. I will always check with the general manager or the executive director for that area to make sure that there are no other issues. Once I have formal email confirmation from the senior managers that I can have the equipment I will add it to my list.

The engineers at Northumbria thoroughly check all equipment donations to make sure that they are in full working order, and that they've got a reasonable life span to come. We also make sure that all related items, such as leads, operational manuals, care manuals etc. are sent out with the donation.

Before anything goes anywhere, we make sure that the Chief Executive in our partner hospital is agreeable to receiving the donation. The alternative is that you end up with an equipment graveyard. We send through a list of available equipment, and we receive an email confirmation with a check list of which items to send. Surprisingly, things that I thought might be really useful, are things that have been declined. Sometimes the technology is too advanced or there is no clinical need or supplies of consumables such as paper are not readily available.

At our link hospital the supplies manager and the engineering or maintenance department should be involved. They know where the spare parts are going to come from. They know where the nearest engineers or support engineers can be found, so we have to listen to their local knowledge and if it's something that will be problematical for them, then the equipment would just not be sent.

The senior clinician within the area it is going to be donated should also be involved to make sure it is in line with plans for service delivery and that staff would be happy to use the equipment.

I think a lot of people genuinely want to help their link hospital with donations of medical equipment. They think that equipment, any equipment, if it's in good working order, is a significant gift for the recipient but sadly that isn't often the case. The risks involved in sending pieces of equipment can be high at times. If the donor cannot use the equipment it becomes a disposal issue, and what's more, if it's something that they're not trained to use, and they use it inappropriately, it can actually cause harm.

**Brenda Longstaff**, Project manager from Northumbria Healthcare NHS Foundation Trust



*Gift transport. Northumbria - Kilimanjaro Partnership, Tanzania.*





## Developing a Project Plan for the Donation

The plan should outline the activities, tasks, stakeholders and timelines for the donation. It should be flexible and used throughout the process, not prepared as a one-off activity at the start.

Again, the planning exercise should be proportional to the donation. Managing it should not be so onerous as to interfere with actually carrying out the activities in the plan. Instead, the plan should serve as a useful guide to clarify who is doing **what**, **when**, **where**, **how** and **why**.

Many tools exist for project planning that could be employed for this plan. It's wise to select one that you are already familiar with that you will find easy to use.

### Who should draw up the plan?

The plan should be drawn up together by UK and DC partner project leads, with input from those who contributed during the needs and capacity assessment when necessary.

### What should the plan include?

The plan should include the main activities involved in the donations exercise, broken down into discrete tasks that can be tracked over time. Each task should include a description of the:

- person(s) responsible
- resources required
- conditions (what tasks must be completed before this one can be done, 'due date', etc.)
- outputs of the task

Appendix F provides a basic sample template for those who have not used a project plan before. It is a basic guide only and can be adapted as needed by the partners.



### USEFUL RESOURCE BOX:

HUMATEM's 'A Planning Method' resource provides comprehensive guidance for planning medical equipment support projects that is meant to be adaptable to specific partners and projects. It includes sample fact sheets for a specific example project's problem tree, flowchart, list of expenses, and logical framework (project plan). This resource is an excellent guide for partners to use during the planning phase.



### USEFUL RESOURCE BOX:

THET's '[International Health Links Manual](#)' provides guidance on planning within a partnership context in Section 2. The HPS Resource Library also includes [guidance on project planning](#) using the 'theory of change' methodology.

# Drafting a Donation Agreement

Your partnership may already have a Memorandum of Understanding (MoU) in place that sets out the general parameters of the relationship and makes it clear who is responsible for what.

At this stage, it is also useful to develop a clear agreement that outlines the terms of the donation, including the costs and risks incurred by both partners. This donation agreement can also provide documented evidence for some of the new minimum shipping requirements legislation.

If the partnership has an active MoU in place, the recommended content for this agreement could also be prepared as an addendum to the MoU, particularly if it already covers some aspects of medical equipment donations within the partnership.

A donations agreement should cover the commitments made by the UK and the DC partners, at a minimum. Reading through the sections of this toolkit will be useful when preparing this agreement. While drafting this agreement, it's important to remember:

- That both the UK and DC partner draft the agreement together
- That those who draft and sign the agreement have the authority to enact it
- That all costs should be expressed in a shared currency, and that maximum budgetary allowances for specific expenses should be clearly noted
- To reference to any relevant statutory documents for both partners (such as UK legislation on shipping pre-owned medical equipment outside of the EU)
- That the agreement includes contractual elements such as modification and termination clauses, etc.

- That at least one third party review the agreement for clarity

Appendix G provides a template for a donations agreement. It is intended to serve as a guide and partners are free to adapt it as they wish to.



## USEFUL RESOURCE BOX:

THET's '[International Health Links Manual](#)' provides guidance on developing and using a MoU in Section 2.



*Sister Mampewo Sarah Senkungu scans a pregnant mother at Kasangati Health Centre in Uganda.  
Photo RCOG/Mile 91/Ben Langdon*

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## CHAPTER OVERVIEW: SUPPLYING THE EQUIPMENT

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- **Deciding where to source the medical equipment from**
  - From the UK partner's Trust
  - From an equipment donation organisation
    - \* Assessing the quality of services provided by equipment donation organisations
  - From an equipment manufacturer or supplier
    - \* UK suppliers that specialise in developing country markets
  - From a second-hand equipment re-seller/refurbisher
  - From another charity
  - Supplying appropriate technologies designed for low-resource settings
  - Supplying the equipment locally in the DC
    - \* Pricing
    - \* Quality & Safety
    - \* Working within existing policies and procedures
  - Understanding the role of international supply organisations
- **Including usage and maintenance supplies**
  - Getting the right service manuals
  - Understanding power supply considerations
- **Sourcing biomedical engineering tools and test equipment**

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## CHAPTER CHECKLIST:

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- ✓ Examine all options for sourcing equipment and select the best one
- ✓ Source all the materials needed to use and maintain the equipment, including tools and test equipment
- ✓ Helpful to supply equipment or use manufacturers that are already used by the DC partner

# 3 SUPPLYING THE EQUIPMENT

Medical equipment and associated supplies can be sourced in the UK or locally in the DC. They can also be provided by organisations outside of both countries but - with the exception of international organisations that specialise in equipment supply and organisations with significant in-country experience - this can be administratively burdensome.

Very occasionally, large international organisations that supply medical equipment to developing countries may be engaged to provide the equipment. These organisations tend to supply only large volume orders, and so the partners would need to engage them through another larger partner working in country, such as an aid agency.

## UK

### Sources of equipment within the UK

The UK partner's Trust
An equipment donation organisation (charity or for-profit)
An equipment manufacturer or supplier, of standard equipment or devices designed specifically for use in 'challenging environments' such as DCs
A supplier of pre-owned (second-hand) equipment, sometimes called a 'refurbisher' if they return all equipment to new working order prior to sale

## DC

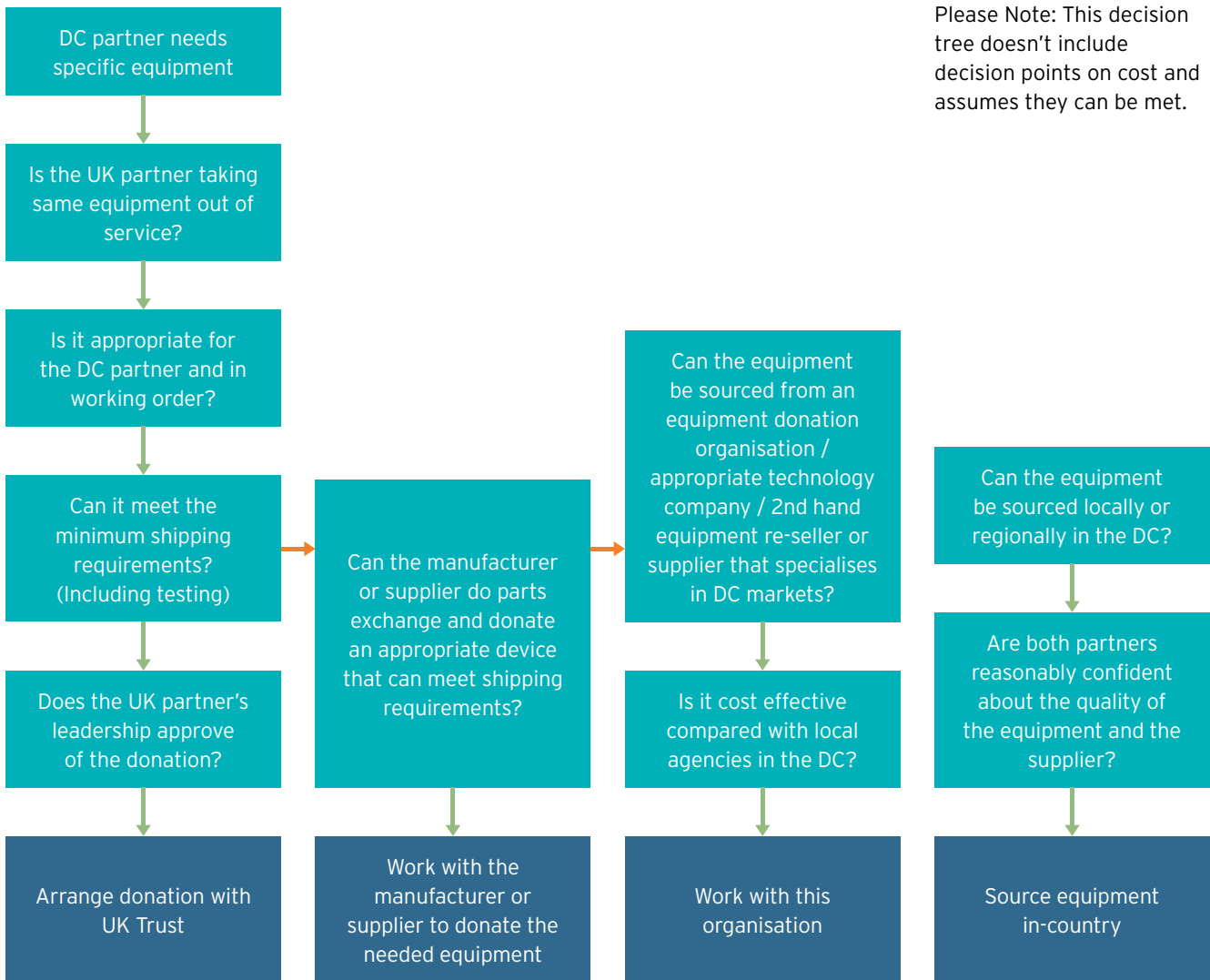
### Sources of equipment within the DC partner country

A local supplier, that may carry a wide range of equipment or be the authorised representative of a specific manufacturer
Central Medical Stores (if they stock basic devices)
Another organisation that has partnered with the hospital, directly or through its networks



A baby lying in an incubator in Kisiizi Hospital, Uganda. Photo RCOG/Mile 91/Ben Langdon

# Deciding Where to Source the Medical Equipment From



Please Note: This decision tree doesn't include decision points on cost and assumes they can be met.

**Flow Chart: Decision Making Tree.**



It's always helpful to supply equipment from manufacturers the DC partner knows, and ideally specific kinds already in use. This is called equipment standardisation and makes training, usage and maintenance easier.

## From the UK Partner's Trust

When a Trust is removing equipment from service, it is generally subject to:

- A specific medical devices policy
- A general Trust-wide asset disposal policy that covers all assets being 'condemned' or 'disposed of'
- A separate capital equipment policy (if one exists) for equipment over a certain threshold value

National Health Service (NHS) institutions have their own policies for medical devices across their lifecycle, including end of use procedures such as removal from service, decommissioning and transfer of ownership. While policies are unique to their institution, they generally follow guidance from the MHRA on good equipment management practices.


The MHRA's guidance document for medical devices is '[Managing Medical Devices Guidance for healthcare and social services organisations](#)' [DB2006\(05\)](#). At the time of publication, this guidance is currently being updated and readers are encouraged to consult the MHRA for the latest information at the time of reading.


### **UK partners should seek guidance from the head of the medical engineering team about Trust-specific medical device decommissioning and donation policies.**

Regarding transfer of ownership, MHRA guidance stresses the importance of both parties (donor and recipient) being clear about their legal liabilities. It also recommends that the recipient sign a disclaimer to the effect that the donor has no future legal responsibility for the equipment. Appendix H provides

a sample 'Letter of Waiver or Indemnity'. This is an example only and each Trust is encouraged to develop their own.

### **Reducing risk of transfer**

 <b>Responsibilities of UK partner</b>
Ensure the equipment is tested and found to be safe and functioning to standard
Prepare a file with: <ul style="list-style-type: none"> <li>• All original invoicing information and packaging</li> <li>• The complete service history of the equipment</li> <li>• Any other information that should be passed to the recipient</li> </ul>
Assess any increased hazard likely to arise due to the age of the equipment and inform the recipient of this (in writing)
Ensure all user and maintenance manuals are passed to the recipient

 <b>Responsibilities of DC partner</b>
Accept responsibility for having the equipment maintained appropriately to ensure its continued safe and effective use (in writing)
Accept responsibility for following any instructions, advice or warnings issued by the manufacturer or other competent body (in writing)
Sign a disclaimer to the effect that the UK partner has no future responsibility for the safe and effective use or maintenance of the equipment

By meeting these requirements, the UK partner can present a strong case to their leadership that equipment being removed from service can be donated appropriately to the organisation's DC partner.

UK partners will further increase their likelihood of securing exemptions for direct donations if they are familiar with the EU Directive 2012/19/EU's minimum shipping requirements and can prove that the transfer (donation) will meet these requirements.

### 'Part Exchange'

The Trust may also do a 'part(s) exchange' - also called a 'trade up' or 'trade back' with the manufacturer or another supplier. During this exchange, the equipment being taken out of service is traded back either for new equipment at a reduced price, or credit with the supplier.

This provides an opportunity to approach the manufacturer/supplier as a potential donor, and can be done prior to the part exchange. Manufacturers are often willing to donate; it contributes to their corporate social responsibility (CSR) and provides a 'good news' story.

There is the added benefit for the UK partner of transferring liability to the company, whose systems for international transfers systems for refurbished equipment may be more established.

The UK partner can also investigate using a re-seller or equipment donation organisation and negotiate the terms of transfer, testing and shipment.

If the UK partner is transferring the equipment to another organisation that will then take the lead on a donation, documentation demonstrating transfer of the equipment and associated liabilities must be prepared.

## Engaging Manufacturers: Church of Uganda Kisiizi Hospital and Countess of Chester Hospital NHS Foundation Trust

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"The donations have made a real difference to the quality of x-ray and ultrasound images now produced in Kisiizi. X-ray dose to patients has also reduced and the staff are working in a much safer environment." Tracy Hughes, Senior radiographer at Countess of Chester Hospital and the team leader for the Radiology Kisiizi Partnership

**The partnership between Church of Uganda Kisiizi Hospital and Countess of Chester Hospital NHS Foundation Trust began in 2008 with a focus on radiology, nursing and pharmacy. Radiology services require functional medical imaging equipment, such as ultrasound and x-ray machines and x-ray processing equipment. Chester has donated a significant amount of radiology equipment to Kisiizi over the last three years.**

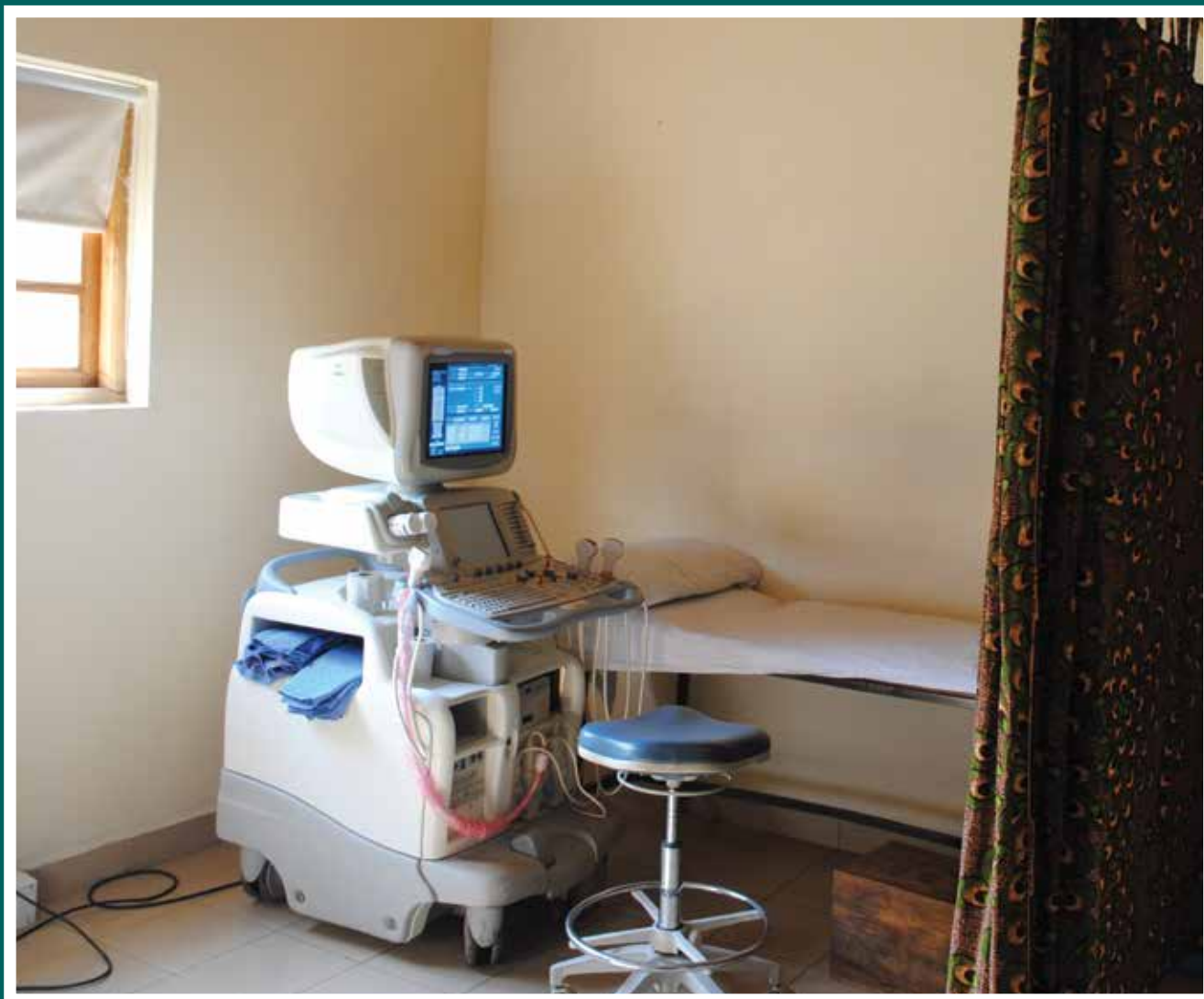
### Donating an ultrasound machine

The ultrasound machine that Kisiizi's sonographers had been using was in very poor condition. When Countess of Chester Hospital took two of ultrasound machines out of service and replaced them with two new units, Sarah Hoyle, who manages the partnership, asked the electro-biomedical engineering (EBME) department what had happened to the two older units that were still in very good condition.

It turned out they had been sent back to the manufacturer, as a 'trade-up' deal for the two new machines. The radiology manager contacted the manufacturer to enquire about the older units and see if they would be willing to donate them. One of them was still in the manufacturer's warehouse, and they agreed to donate it free of charge to Kisiizi Hospital. The Chester team engaged a reputable shipping company to ship the scanner to Kisiizi, and they advised on and managed all of the paperwork required for international shipment.

### Donating an x-ray film processor

The need for an automatic x-ray film processor at Kisiizi was identified at the outset of the partnership. Most hospitals in the UK are changing from traditional film x-ray to digital images, and as a result lots of traditional x-ray equipment, such as film processors, is being decommissioned. However Chester was one of the first hospitals to move to digital x-ray and so did not have any film processors that had been recently decommissioned.



*The logic 9 ultrasound machine & scanning chair. Countess of Chester Hospital - Kisiizi Partnership, Uganda*

Chester's radiographers approached a medical imaging company for their assistance sourcing a suitable unit for Kisiizi. The company sourced a desktop processor before the first radiography visit to Kisiizi by Chester staff, and a company engineer helped them dismantle the unit and pack it into four boxes that they brought with them in their luggage. On arrival in Kisiizi, the radiographers then reassembled it and successfully got it up and running. The following year, the company funded their engineer to go to Kisiizi to service it and provide additional training.

### **Providing training and putting the equipment into service**

Chester's sonographers and radiographers provided all of the initial training to Kisiizi staff, including basic maintenance training. The company's engineer provided refresher training on his service visit. Both machines are still in use; they've increased the quality of radiology services Kisiizi can provide its patients.

### **Lessons learned:**

- Working with the EBME department is important because they know the whole history of a device that is being taken out of service
- The EBME team can advise on the service requirements for decommissioned equipment and also has contacts with the manufacturer/vendor
- Manufacturers are often very willing to donate equipment free of charge or provide it at a very reduced cost; it's good for the partnership and good for the manufacturer's corporate social responsibility profile as well
- Donating equipment in the context of a partnership focus (such as radiology in this case) can build goodwill and contribute to the partnership meeting its objectives

## From an Equipment Donation Organisation

The main objective of some organisations – both charitable and for profit – is to supply developing country health institutions with equipment, supplies and/or drugs that are no longer required by health systems in high-resource settings. Examples of these types of organisations within the UK include: Medical Aid International, Dentaid, Mercy Trucks and until recently, Aid to Hospitals Worldwide. Overviews and contact information for these organisations is found in the Useful Resources section.

 See page 78 for the Useful Resources section

Many similar organisations exist in other high-income countries. The United States in particular has a large number of non- and for-profit ‘medical surplus recovery organisations’ (MSROs) that supply surplus equipment and supplies to developing countries. Some of the largest American MSROs ship approximately 250 containers per year to developing world institutions [19]. Some examples of American MSROs include: REMEDY, MedShare, and Project Cure. The American College of Surgeon’s Operation Giving Back programme also provides a list of organisations that operate in each American state.

**UK partners should ask their DC partners which other organisations might be supplying them with medical equipment in order to coordinate more effectively.**

## Assessing the Quality of Services Provided by Equipment Donation Organisations

The quality of services provided by equipment donation organisations can vary widely. As an unregulated industry, it may be hard to determine how effectively they meet their objectives.

The CHA has developed a [guide](#) and [an assessment tool](#) for selecting high-quality MSROs. The tool identifies three main ‘key drivers’ of effective (surplus) donation related to the organisation, its relationships and its operations. These drivers are:

- Organisation: leadership, container price/value and staffing
- Relationships: with hospitals, beneficiaries and business/financial partners
- Operations: sorting/quality management, shipping/distribution, inventory management

They serve as a useful guide, both to evaluate potential equipment donation organisations and for UK partners to self-assess even if they do not contract another organisation to supply the equipment or manage the donation.

### USEFUL RESOURCE BOX:

UK partners would benefit from using the CHA’S MSRO guide and tool to self-assess, even if they do not contract another organisation to supply the equipment or manage the donation.

- [Guide and an overview of the assessment tool](#)
- [Online version of the assessment tool](#)

## From an Equipment Manufacturer or Supplier

While manufacturers are generally less willing to provide support for used, donated equipment than for new equipment, many are willing to provide either new or refurbished equipment as donations. They also have contacts for their networks of distributors and approved technical service providers in the DC’s region.

If a manufacturer or supplier is willing to be involved, the UK and DC partners should determine the minimum amount of time they require for technical support from the manufacturer – or whether it must be provided from elsewhere, such as the UK partner’s EBME team. The WHO recommends considering a period of five years of technical support from a qualified organisation.

## UK Suppliers that Specialise in Developing Country Markets

Some suppliers specialise in developing country markets. A leading example of this type of organisation in the UK is [Durbin PLC](#), whose NGO and Charities division specialises in supplying medical equipment, drugs and consumables for use in difficult environments.

## From a Second-Hand Equipment Re-Seller/ Refurbisher

Equipment re-sellers buy second-hand equipment from healthcare providers and re-sell them to new customers. They can sell the equipment ‘as is’ or refurbish it to a certain standard of functionality.



## USEFUL RESOURCE BOX:

Equipment re-sellers include: [the Hilditch Group](#) - all types of equipment, [GB Medical](#) - pre-owned (and new) medical, dental and orthopaedic equipment, [Freelance Surgical](#) - pre-owned (and new) surgical equipment, [Colco](#) - pre-owned medical and laboratory equipment. Details can be found in Useful Resources



See page 78 for the Useful Resources section

There is a very large market of suppliers in the UK. UK partners should contact those they have worked with, and can ask their EBME teams for recommendations and contacts as well.

Some have even found specific devices (that they are familiar with and know to be good quality) for low prices new online, such as on eBay. This can be a cost effective way to source quality equipment, but extra caution should be employed buying anything online. The MHRA recommends suspicion of the following with online retailers:

- “Labels. If the instructions are in many languages or if measurements are not in metric units, the product may be intended for sale in another country. This may mean the product does not meet UK requirements and may be of inferior quality.
- Sites that do not include an address and telephone number in the UK. A legitimate site will provide a way for you to talk to someone if you have a problem.”

MHRA: General safety information & advice.



## USEFUL RESOURCE BOX:

Due diligence checks on suppliers are always recommended. If in doubt - don't buy.

## From Another Charity

Many health charities donate medical equipment to low-resource settings as part of their overall operations. Diaspora networks often coordinate donations, as do professional associations for their various specialties.

UK and DC partners may wish to partner with a charity, either for supply or other stages of the donation process. Useful Resources includes links to a variety of UK charities that have donated medical equipment to health facilities in the areas they work in.



See page 78 for the Useful Resources section

## Supplying Appropriate Technologies Designed for Low-Resource Settings



## USEFUL RESOURCE BOX:

Organisations that supply appropriate technologies include: [Diamedica](#), [Gadian Health Systems](#), [Lifebox](#), [Laerdal](#) and [Embrace](#). Many more appropriate health technologies are profiled in the WHO's [compendia of innovative health technologies](#). Details can be found in Useful Resources.



See page 78 for the Useful Resources section

Many companies and charities also provide technologies that have been designed specifically for use in low-resource settings. These tend to be simpler to operate and maintain, robust and require fewer consumables, accessories and parts. They are often also significantly less expensive and can make excellent donations.

## Supplying the Equipment Locally in the DC

Local procurement can be a good alternative to sourcing the equipment in the UK and shipping to the DC partner. It may be more cost effective and easier to manage overall.

**The WHO estimates that 95% of medical equipment in developing countries is imported. [6]**

Very basic medical equipment may be manufactured locally in low-resource settings. For example, basic patient beds may be made locally with readily available materials, while specialised delivery beds would likely be imported.

Many middle-income countries, such as India, Pakistan, Brazil and China manufacture large amounts of medical equipment and supplies. China, for example, exports more medical devices than it imports [23].

Some DCs have central medical stores that stock and supply drugs, supplies and also sometimes basic equipment. For example, [Joint Medical Stores \(JMS\)](#) in Uganda is a non-profit medical store that supplies equipment as well as drugs and supplies.

JMS offers equipment through their catalogue and also does special orders for particular devices to customers' specifications. They have a technical department that provides maintenance services as well, and supply customers both within Uganda and in other countries in the region.

## Pricing

While small devices may be quite inexpensive on the local market, internationally recognised brands



can be significantly more expensive in DCs due to smaller markets, distance from the manufacturers and main service engineer base and import costs.

A preliminary study by the WHO on device pricing found that the exact same device could cost up to four times as much in developing countries as it does in higher-resource settings. This study is yet to be published; at the time of writing, a larger study of this issue is currently underway by the WHO.

### Quality and safety

Many developing countries lack robust regulator systems for medical devices. In fact, many countries don't have an agency to regulate medical devices or the companies that sell them in the country at all. This means that unregulated vendors can easily sell equipment that doesn't conform to international quality or safety standards and may be counterfeit.

*"We bought all of the blood pressure machines only 6 months ago. But the rubber has worn away on most of them already and now have to buy new ones again."*

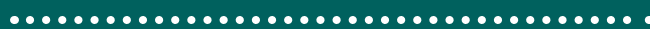
- Senior nurse at Boroma Group Hospital in Somaliland

Therefore, it is important to ensure that either the DC partner or another local technical group has the capacity to properly assess the quality and safety of equipment being sold locally, and for the UK partner to provide support in this respect if necessary.

### Working within existing policies and procedures

Any existing policies the DC partner or the MoH has for medical equipment procurement should be followed. For example, hospitals will often have budget limits for equipment expenditure, and anything about this threshold limit must be procured centrally through the Ministry of Health.

## "Don't presume there's not a system in place"



**The Gulu-Man Link was founded in 2006 as a collaborative partnership by The University Hospital of South Manchester, Gulu University Faculty of Medicine and Gulu Regional Referral Hospital in order to improve healthcare in Uganda through local clinical education programmes. The partnership sought to identify deficits in training needs and determine appropriate teaching programmes to assist both undergraduate learning and continued professional development of hospital staff. Mrs Marian Surgenor, a nurse and midwife with over 40 years of NHS service, has been Lead Clinical Skills Tutor for the Undergraduate Medical Education Department, UHSM, and is currently Head of Global Health/Inter-professional Lead at the UHSM Academy.**

"Too often we gather lots of equipment and think 'this is a great idea' when really we should be talking to our partners to establish what it is that they really need and would benefit from. We have to remember that often the hospitals in question will have annual budget lines. For instance, Gulu has a budget for equipment and within that they have a list of the equipment which they want to procure in the forthcoming financial year. We get a copy of that so we know what is on their list and we can talk to them about whether or not they are managing to source it. Sometimes other organisations will procure equipment for them and other times they will buy it from the budget. I think it's very important not to presume that they don't have a system in place. I think that's an error that lots of Links make.

One of the exercises we undertook during the initial scouting at Gulu was to look at whether or not it is cheaper to source equipment in the country rather than going through the process of procuring it in the UK and sending it out. Although there are companies available that can help you, donating from the UK is often quite a difficult process - it's time consuming, it can be costly and you can actually lose your consignment. I think if you can procure something in country it's better. It can help stimulate the local economy and it also means that you have a guarantee and access to on-going maintenance and repair via the supplying company."

The DC may have a national list of recommended medical equipment or minimum specifications. In exceptional cases, the MoH may have a list of pre-approved suppliers and devices. Whenever possible, additional focus on maintenance support should be added when local policies don't include it in pricing or contracting with suppliers.

**The time to ask for all that is needed is before the purchase has been made.**

Of course, this doesn't guarantee suppliers will honour their contractual commitments and so it is also important to get feedback on suppliers if possible.

*"Sometimes the suppliers will drop orders off in the middle of the night, leaving the boxes in front of the hospital. That way, we don't have the chance to look through them and test them, to make sure they are OK."*

- maintenance lead at hospital in central Zambia

Technical leads from the DC partner may know who within the MoH is responsible for medical equipment centrally. The WHO's baseline country survey for medical devices also provides information about medical equipment in each country, including a focal point contact. The country profiles can be found [here](#).

Essential equipment lists for health facilities may also be included in MoH's basic package of essential services (BPES) and/or their national strategic health plan (NSHP), such as [Sierra Leone's Basic Package of Essential Services](#).

## Understanding the Role of International Supply Organisations

For- and non-profit international supply organisations can also procure equipment on behalf of a partnership. These organisations typically work directly with MoHs in developing countries to support their strategic health plans and with donors working in the health sector. They have expertise with shipping and supply chain logistics and may be able to advise on the DC specifics.

While they tend to supply large volume, high capital orders, these organisations may be approached through the MoH, country offices for aid programmes or INGOs they work with.

**The DC partner may have very useful contacts for international supply organisations that work in their country.**



### USEFUL RESOURCE BOX:

Guide 3 of the 'How to Manage Your Healthcare Technology' series 'How to Procure and Commission Your Healthcare Technology' provides a very detailed overview of different international supply organisations and what factors should be considered when procuring equipment through them.

## Including Usage and Maintenance Supplies

It's vital that supplies are included with the equipment, to enable the DC partner to use and maintain it. The quantities should cover an agreed period of time; a minimum of two years is recommended.

If the equipment is sourced in the UK, it may still be more appropriate to source some of the supplies separately in the DC. **Some supplies such as lithium batteries, laboratory reagents and x-ray film developer require specialised shipping and should be sourced locally in the DC if possible.**

### Checklist: Don't forget the following supplies:

- User manuals
- Service (maintenance) manuals
- Accessories, such as the correct ultrasound probes for the intended use
- Consumables, such as printer paper for the ultrasound
- Reagents, such as x-ray film developer - remember these may have specific freight restrictions
- Maintenance materials - commonly used spare parts, any special tools and test equipment required to maintain the equipment that the DC partner does not have
- Any electrical equipment required to adapt the equipment to the DC partner's infrastructure

## Getting the Right Service Manuals

Complex equipment will often have a troubleshooting manual, supplied readily to end users, and a full service manual for service engineers (often called a 'field service engineer' (FSE) manual). FSE manuals typically include parts listings, detailed troubleshooting and preventive maintenance procedures.

If appropriate for the level of technical expertise within the DC partner, be sure to request FSE manuals. Some manufacturers are not willing to provide FSE manuals to technical staff in end-user facilities unless they are qualified engineers and are trained and certified directly by the manufacturer or an authorised agent (such as a regional distributor/ service agent).

Often, however, companies are willing to provide the manuals and train technical staff in low-resource settings with lower formal qualifications, particularly if they are engaged to provide the training, or work with the UK partner's engineers who can then train the DC partner's staff.

**It's always worth asking which types of service manuals are supplied, and asking for a parts list even if you can only get a basic troubleshooting service manual.**

Again, remember that the manual should be appropriate for the user and maintenance lead who need to interpret them. If the FSE level of service manual is being supplied, it's important that the maintenance staff in the DC partner facility are trained on the procedures it contains.

The following are good sources of service manuals:

- The manufacturer or supplier
- The UK Trust's biomedical engineering department
- Frank's Hospital Workshop (see Useful Resources)
- The INFRATECH mailing list (see Useful Resources)

User manuals are often freely available on the manufacturer's website for download, as are some basic troubleshooting manuals.

 **See page 78 for the Useful Resources section**

## Understanding power supply considerations

Mains power can be both erratic and unavailable in many DC health facilities. DC health facilities are often affected by:

- Scheduled blackouts - when mains power is only scheduled to be available for certain periods of the day, such as between 9am-2pm and 7pm-2am
- Unplanned blackouts - unforeseen power cuts
- Brownouts - when the voltage drops below a suitable range
- Surges - when the voltage surges above a suitable range, often when power resumes (after a blackout or when a generator is first switched on)

Backup generators can be configured to switch over automatically when power cuts out or can be turned on manually by an electrician or other member of staff. Remember that some facilities won't have a functional generator, or the fuel required to run it.

Each of these scenarios can damage the medical (and other electrical) equipment in a facility. There are a

Many major equipment manufacturers have provided FSE level training to the biomedical engineering staff of the UK's Medical Research Council (MRC) Unit in the Gambia, all of whom are technologists. It has been a win-win: the MRC now has technical staff on site to respond to service problems, and the manufacturers now have certified technical personnel in the region who can troubleshoot and assess problems at other sites and feed back to them to reduce the number of trips their service engineers need to make [20, 21].



*FSE training with the biomedical engineering staff of the UK's Medical Research Council (MRC) Unit in the Gambia. Photo Shauna Mullally*

### Example of power supply issues

A study of power interruptions was performed on paediatric wards in Gambian health facilities. It found that the mean length of unplanned power interruptions ranged from half an hour to almost 4 hours. The facility with the worst power supply had 56 brown outs per day. [22]

number of electrical devices that help protect equipment and keep it running during outages:

- Voltage regulators (also called surge protectors) ensure a regulated power supply
- Uninterruptible power supplies (UPSes) regulate the voltage and have an inbuilt battery that charges when power is being supplied and turns on automatically to run the equipment when it cuts out

If a UPS is needed, make sure the power rating (KVa) is adequate to run the equipment.

### Supplying equipment that is the wrong voltage can be very problematic for the DC partner.

Different countries have different voltage levels for their power supply. While the UK's single-phase mains power is supplied at 220 Volts/50 Hertz, in North America it is provided at 110 Volts/60Hertz.

This will likely require:

- Transformers to convert the voltage to the appropriate level
- Adapters to convert the plug and pins to the correct configuration

Adapters should be glued on to make sure they stay attached.

Power requirements are specific to the equipment and should be carefully noted. For example, heavy-duty devices such as autoclaves may require three-phase power.

Many DC health facilities also have deficiencies in their electrical systems, such as improper earthing (or grounding), that can also damage equipment and be unsafe for staff and patients. Electricians and biomedical engineering professionals can assess these parameters using an electrical safety tester.

If voltage regulators, UPSes or transformers are required, it's best to look at the local DC market first. These items can be difficult to ship due to special requirements for batteries, and they are also relatively inexpensive on local markets because they tend to be widely available.

## Sourcing Biomedical Engineering Tools and Test Equipment

The DC partner's equipment maintenance staff may require engineering tools or test equipment to maintain the equipment being donated. If so, these items should be supplied with the medical equipment to enable the DC partner to maintain it.

*"We had a really good training course on maintenance. But I came back to my hospital and I don't have any tools in my workshop to do the maintenance I was trained to do."*  
- anonymous technician from equipment audit in Zambia

A very basic toolkit that includes basic tools and a digital multimeter to measure electrical parameters will cost ~ £200 and is an excellent investment for the DC partner's equipment maintenance staff if they don't have one.

Engineering 'test' equipment enables the maintenance staff to test whether or not medical devices are functioning as expected or require calibration. For example, a patient simulator will simulate various physiological parameters to test vital sign monitors and an oxygen analyser will test the output of an oxygen concentrator to ensure it's within range.

The following resources provide recommendations for toolkit contents and test equipment:

HTM How to Manage Guide 3, Annex 6 provides a very detailed list of tools and test equipment

HTM How to Manage Guide 5, Box 12 provides examples of safety and calibration testing instruments by work type and skill level



### USEFUL RESOURCE BOX:

The following organisations may assist in the supply of engineering tools and test equipment; Amalthea Trust, the Hilditch Group, Rigel Medical, and Ultramedic. Durbin PLC also supplies engineering workshop equipment, tools and general and specialised (device-specific) test equipment. See Chapter 8 of Durbin's catalogue.

The following are additional suppliers of electrical components, such as fuses, capacitors and electrical wiring: RS Components, Rapid, Bitsbox, Farnell.

EBME teams, medical equipment partnerships and members of the mailing lists included in the Useful Resources Section can also advise on what tools and test equipment would be useful. It's good to engrave and register any higher value items as belonging to the DC partner's medical equipment team, as these items are often in demand with other technical departments as well.



See page 78 for the Useful Resources section

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## CHAPTER OVERVIEW: VERIFYING THE QUALITY AND SAFETY OF THE EQUIPMENT

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- **For equipment supplied in the UK**
- **For equipment supplied in the DC**

### CHAPTER CHECKLIST:

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- ✓ The quality and safety of the equipment must be verified prior to sending it to the DC partner
- ✓ The equipment must be proven to be functional or it will not meet legislative requirements for transfer
- ✓ A medical engineering team is essential to verify and document the quality, safety and functionality of the equipment



# 4

# VERIFYING THE QUALITY AND SAFETY OF THE EQUIPMENT

*“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.” [24]*

## For Equipment Supplied in the UK

The quality and safety of the equipment must be verified prior to sending it to the DC partner. This is good practice, and has also become necessary to meet the requirements of EU Directive 2012/19/EU on shipping WEEE outside of the EU.

For equipment supplied by a Trust, all activities in the Trust’s medical device policy related to decommissioning, except *making the device unusable*, must be followed. These procedures must be done by technical staff certified to perform them and will include:

- Decontaminating the equipment as per procedure
- Erasing any confidential information contained on the equipment
- Verifying the safety of the device, as per manufacturer’s instructions\*
- Testing full functionality of the device in order to verify that it is fit for re-use

Records of all of tests required to meet the above must accompany the device.

In addition to these tests, all information that **enables the recipient to operate the device properly and safely and maintain it to standard (manufacturer’s recommendations)** must be sent to the DC partner.

As a reminder, this information includes:

- a clear statement that the equipment is being donated (transferred)
- certificate of decontamination
- user manuals and training requirements
- full details of maintenance and servicing requirements
- service history and manual
- usage history
- quality assurance test details
- safety updates, including MHRA and manufacturer documents that have been released since the medical device was first supplied.

Note: \* If the manufacturer is no longer in business and/or supporting the device, the MHRA should be contacted for appropriate safety verification procedures. If this is the case, bear in mind that the lack of manufacturer support may reduce the chances of making a sustainable donation. For example, if parts are not available through the manufacturer for a certain number of years past donation - such as the expected lifespan of the device - this is unsustainable.



### USEFUL RESOURCE BOX:

The MHRA’s [safety warnings related to the devices](#) (known as ‘medical device alerts’).

A medical engineering team will be essential during this stage of the process. If the UK partner's Trust is unable to provide the necessary support, you may wish to enquire with the following service providers: [Medical Equipment Management Organisation \(MEMO\)](#), [Hilditch Group's Medical Engineering team](#), [Medical Aid International](#). Full contact details are available for these organisations in the Useful Resources section.

 **See page 78 for the Useful Resources section**

The manufacturer/supplier may also be able to provide these technical services. For new equipment supplied directly by the manufacturer or supplier, the safety and quality of the equipment will have been verified prior to the device being placed on the market in order to meet the UK's regulatory requirements ([the Medical Device Regulations 2002](#)).

 **USEFUL RESOURCE BOX:**

Partially refurbished equipment has been 'reconditioned'; it has undergone a routine cleaning and maintenance procedure. Full refurbishment is a more comprehensive procedure whereby the device is essentially remanufactured and placed back on the market like new (by taking it apart, testing each component and replacing as necessary, re-assembling and testing the whole against original or revised criteria). Fully refurbished devices require a new CE mark. See [MHRA guidance on managing medical devices](#) for more information.

For equipment that has been pre-owned and is being sourced by an organisation external to the UK partner, it is important to confirm that these requirements have been met. If equipment is described as 'refurbished', clarify whether it has been partially or fully refurbished.

Review documentation of the tests undergone and the certification of the technical staff performing the tests, as well as the organisation itself as appropriate.

 **USEFUL RESOURCE BOX:**

**About Electrical Safety Standards for Medical Equipment**

The International Electrotechnical Commission (IEC) publishes standards for the general requirements for electrical safety and performance of medical equipment. These standards comprise the IEC 60601 series; in the UK they are adopted by the British Standards Institute (BSI) in the [BS EN 60601](#) series [25]. Various other standards relate to medical devices in the UK. Read more [MHRA Guidance](#).

**For Equipment Supplied in the DC**

Equipment should conform to safety and performance standards, regardless of where it is purchased. It must be acknowledged that this is more difficult to do in the absence of a strong national regulator and processes that ensure equipment standards are met.

If the DC partner has standardised the use of a particular make/model of equipment, it is good to procure new equipment or donate equipment in line with this, as staff are already familiar with it. When standardised

equipment is provided it is generally accepted to be appropriate.

In the absence of a strong regulatory system, partners can perform some due diligence on potential equipment suppliers and the product itself:

- Find out which local suppliers are licensed distributors of preferred brands; ask to review their licenses and double check through the manufacturer directly that they are licensed sellers
- Ask about the technical services they provide (such as repair under warranty) and if possible, to see their workshop facilities
- Ask what training and certification their technical staff have undergone to perform the technical services (if the supplier is licensed as a technical service provider as well their staff will have undergone technical training with the manufacturer or one of its certified agents)
- Ask for feedback about the suppliers from the DC partner, other MoH technical personnel, other NGOs and international organisations that may have used their services
- Ask about the device's conformity to performance and safety standards that enables it to be marketed in different economic areas (for example, the CE marking for the EU)



Equipment graveyard at West African hospital. Photo Shauna Mullally



## USEFUL RESOURCE BOX:

### Harmonising medical device regulations

The International Medical Device Regulators Forum (IMDRF) brings medical device regulators from the EU and other countries together to work towards global harmonisation of medical devices. The [IMDRF](#) builds on the work of the Global Harmonisation Task Force on Medical Devices (GHTF). As regulations for high-resource settings continue to become more harmonised, it will be easier for institutions in low-resource settings to build regulatory capacity.

Remember that markings such as the CE mark can be counterfeited, and should not be interpreted - particularly on their own - as complete quality assurance.

Properly evaluating local suppliers is outside of the scope of this toolkit. The [How To Manage Guide 3](#) provides very comprehensive guidance on the subject and should be used by any partnerships dealing with suppliers on local DC markets. Annex 5 of the Guide in particular provides tools to assess suppliers including:

- A pre-purchase evaluation questionnaire for suppliers
- Suggested criteria for evaluating new suppliers
- Suggested criteria for evaluating current and past suppliers
- The characteristics that make a good supplier

Once the equipment has been specified, the DC partner can begin any site preparations that may be required, such as changes to infrastructure to prepare for the equipment prior to arrival. This work should be done according to the manufacturer's advice and may require input from other local technical staff.

*"Why do people think that if something doesn't work in wealthy countries, it will work merely by shipping it across the sea, without taking the relevant actions taken to restore it to good working condition?"*

Dr. Nicholas Adjabu, Deputy Director, Clinical Engineering Department, Ghana Health Service

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## CHAPTER OVERVIEW: PACKING & SHIPPING THE EQUIPMENT

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- **Storing and packing the equipment**
- **Shipping options**
  - Couriering the equipment
  - Sending the equipment by Air Freight
  - Sending the equipment by Sea Freight
- **Carrying the equipment with the UK partner on a support visit**
- **Finding suitable shipping agents and customs clearing agents**
- **What is the export/shipping process?**
  - Determining the value of the equipment
  - Determining tax and duty
  - Verifying the contents
  - Understanding and preparing the documentation
  - Managing pre-shipment inspections
  - Dispatching the goods

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## CHAPTER CHECKLIST:

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- ✓ Follow manufacturer's instructions for storage, packing and shipping
- ✓ Know the import requirements and work with a reliable courier or freight company that sends goods regularly to the DC
- ✓ Investigate all options for receiving tax and duty waivers

# 5

# STORING, PACKING AND SHIPPING THE EQUIPMENT

## Storing and Packing the Equipment

**Manufacturer's instructions must be consulted for moving, storing and packing the equipment.**

If equipment is being collected from the UK partner for donation, it is important to identify an adequate storage area for the equipment. The collection point should ideally be convenient for both deliveries from Trust staff and pick up by the organisation responsible for testing and/or shipping the equipment.

This may be a spare warehouse or a rented container outside of the UK partner's facilities. For small amounts of equipment, it may be within a Trust department, such as the EBME department or the storage area of whichever clinical area it is being donated from.

This collection area should provide adequate space to both store and pack the equipment and it should meet manufacturer's instructions for storage. For example, there is an acceptable temperature and humidity range within which equipment must be stored.

Some sensitive equipment requires calibration after each change of location; moves from one location to another should be limited for devices such as these. Heavy equipment may need to be packed on a pallet and moved with a forklift; in this case, the storage area should be easily accessible.

If the donation programme within the UK partner is large and involves multiple clinical areas, it may be worth setting up small collection points at various locations within

the departments. This would require a centralised tracking system and training for staff, but could be done relatively simply.

If there is no suitable location to collect equipment from the UK partner on site, storage may be negotiated with any of the organisations responsible for testing and/or shipping it. If space is rented with a local storage or freight company, the UK partner will need to pay for this unless they can negotiate in-kind support for the donation project. Local storage companies may be willing to provide space at a reduced cost.

It's very worthwhile to hire professional packers, particularly considering the cost of replacing equipment that is damaged in transit. All items should be packed in sturdy boxes with multiple layers of bubble wrap. The manufacturer can advise on specific packing requirements and any materials that may be required (for example, a device-specific supportive frame and/or crating).

**Packing companies may also provide reduced cost or free services to support the initiative.** A 'good news' story in the local press can go a long way.

When equipment is being collected from various departments within the UK partner, be sure to secure the following for each item:

- Name of donating department and lead contact
- Name of DC partner's receiving department and lead contact
- Signed proof the equipment is a donation for the DC partner (which could be as simple as a confirmation signature against the donation certificate and packing list)

If the equipment is packed at the UK partner's site, the shipping agent will come to collect it from there. The agent will require specific information in advance of collection, such as what items are included, the weight and dimensions of the boxes/crates, any specific handling instructions and details of any items classified as dangerous goods (that will need to be sent by courier).

When the agent comes on site to load the transport container, there will be a limited time window (typically 3-8 hours) before they start charging for the driver's time. Be aware of this and confirm it in advance with the company.

For heavy items that require a forklift, it's important to know the weight of each crate and to make sure it does not exceed the load capacity of the forklift (which vary but are typically less than 1000kgs). The shipping agent will advise on this.

Be sure everything in the shipment is packed, clearly labelled and organised well prior to pick up. Ideally, items should be organised and packed as they arrive but this may not be possible depending on when and how the items are brought to the collection point. Each box should include a contents list and reference for the items it contains on the master packing list. The master (detailed) packing list must be prepared during this stage as well.



## Shipping the Equipment

Shipping the equipment overseas can be the most difficult part of the donations process, as many partnerships and charities have found. Working with a courier or freight company that sends goods regularly to the DC partner's country can help make the process much smoother and is well worth the investment.

The most important elements to remember to increase the chances of transport going smoothly are to:

- Make sure you understand the import regulations in the DC
- Make sure all documentation is complete and that all parties have full copies of them
- Make sure there is ongoing communication between all parties involved in the shipment - both partners, the shipping agent(s) and local customs clearing agent



### USEFUL RESOURCE BOX:

#### Background reading

The following three resources provide very useful background reading:

- 1) Freight forwarding: [Overview of freight forwarders and their responsibilities.](#)
- 2) Logistics: 'A brief introduction to logistics' produced by the [British International Freight Association \(BIFA\)](#)
- 3) Exporting (and importing) goods from the UK: [Guide to Importing & Exporting: Breaking down the Barriers](#)

## What are the Shipping Options?

There are three standard options for transporting the equipment from the UK to DC partner country: courier, airfreight and sea freight. A fourth option, which partnerships frequently employ, is for the UK partner to personally bring the equipment when on a support visit. Insurance is necessary regardless of the method.

**As a general rule of thumb - the faster the shipping method, the more it costs per unit (kg).**

### Courier

Best when the shipment is relatively small, high-value, contains dangerous goods and/or is required urgently.

### Sea freight

Best when there is a large volume of equipment (enough for a partial or full 20 or 40 ft. container load) without sensitive environmental requirements and is not required urgently.

### Airfreight

The cost and speed of airfreight falls between couriating and sea freighting the shipment. Specialist freight companies can advise on the break-even point between couriating and airfreighting.

For a rough estimate, airfreight is on average 10 times as expensive as sea freight per unit of volume.

## Couriering the Equipment

This method is preferred for small, high value shipments and also for shipping any items classified as [dangerous goods](#) or which require storage conditions that cannot be guaranteed in a shipping container.

### DHL

DHL is a courier company that provides specialised logistics and discounted rates to aid and development organisations through its Aid, Relief and Humanitarian Services team. THET partnerships are eligible for these discounted rates and can use the team's services.

In order to qualify, the partnership must submit the following to DHL:

- A letter or email from the DC partner confirming that the shipment, as itemised, is required for partnerships activities
- A statement as to the use and purpose of the equipment
- A brief overview of the partnership activities it will contribute to (for example, training nurses on emergency neonatal resuscitation techniques)

[Read more](#) or contact DHL on +44 208 754 5114 to find out more.

## **Sending the Equipment by Airfreight**

Most commercial airlines offer airfreight or 'cargo' services. Courier and shipping companies may also offer airfreight services; some have their own planes and others sub-contract airline cargo companies.

Major airlines that fly frequently to the DC can be contacted directly for enquiries about their cargo services. They will provide a quotation based on the per kg cost to the destination. Verify that insurance is included in the quotation (usually it is).

If these services are employed directly, the shipment will need to be packed and delivered to the cargo depot. The UK partner or a packing/shipping company can do this. The full packing list and documentation package will need to be provided at the time of drop off.

## **Sending the Equipment by Sea Freight**

Freight is shipped by sea in one of two sizes: 20 ft. containers (approx. 33m<sup>3</sup> total volume, or 5.9m long x 2.3m wide x 2.3m tall) and 40 ft. containers (approx. 67.5 m<sup>3</sup> total volume, or 12m long x 2.3m wide x 2.3m tall).

Standard 20 ft. and 40 ft. containers usually accommodate 25-30m<sup>3</sup> and 55-60m<sup>3</sup> of cargo respectively. Some companies also offer a taller 40 ft. container called a 'high cube container' with a height of 2.7m and there are various other non-standard sizes for special shipments.'

For both 20 and 40 ft. containers you can either ship a full container load (FCL) or a less-than container load (LCL). The second option (LCL) may be employed when there aren't enough items to fill the entire container. In this case the forwarder sells the remaining space in the container to another customer. A rule of thumb is to select FCL when you have approx. 70% of the cargo capacity or more.

FCL is often the preferred method even with less than 70% of an FCL because it reduces the number of times the container will be opened and the goods will be moved, which can result in damage or items being lost. FCL may not be significantly more expensive than LCL depending on the quantity of goods; ask the shipping agent for more details.

A container can be dispatched from the shipping agent to the UK partner facility and loaded there if it is a full or close to full load (remember that time on site about a certain window is chargeable).

If the UK partner has a container on site that is being used as the collection point and storage area, the shipping company can collect it. Note that containers need to be maintained to standard. If the UK partner has sourced the container independently, it is good to enquire about this.

The container must be insured for the entire trip, from the UK partner site (or other point of storage and dispatch) to arrival at the destination seaport and onwards to the DC facility.

The total cost of shipping a container varies, based on a number of factors such as fuel costs and extra charges during peak season. A rough estimate to ship a 40 ft. container from the UK to Southern Africa with a reputable company is ~ £10-12 000.



### **USEFUL RESOURCE BOX:**

A real life example from a member of the Scotland-Malawi Partnership (SMP) is included in their [good practice guide](#) for Scottish organisations shipping donated goods to Malawi. This is an excellent resource full of practical information and recommended reading for any partners planning to ship donated equipment, not only those working in Scotland or Malawi.

## **Carrying the Equipment with the UK Partner on a Support Visit**

Some UK partners also chose to transport goods with them on support visits.

Excess baggage for UK registered charities

British Airways offer 1 complimentary bag of 23kgs per person or no more than 10 complimentary bags on group bookings for UK registered charities or those traveling on charity rates. To request a baggage waiver send an email to the Community Investment Team on charity headed paper, giving at least two weeks' notice. The waiver is added for the outbound flight only. [community.branch@ba.com](mailto:community.branch@ba.com)

Depending on the type of equipment being carried, many partnerships have had success with this method. Remember that customs clearance procedures can be complicated, particularly without the use of a local customs clearing agent who knows the system well. With this option, it's very important to understand the import regulations, carry all necessary paperwork and have a local contact (the DC partner or their contacts) to assist clearing the goods through customs if necessary.

Due to airline restrictions and the roughness of baggage handling, this method is not appropriate for many types of medical equipment that require gentle transportation to prevent damage. For more robust items, however, such as training mannequins or additional spare parts for a device that was donated previously, this method is relatively straightforward and does reduce the cost of shipment.

## Understanding Freight Forwarding Terminology

International freight forwarders and suppliers use standard terminology for terms of service called incoterms ('international commercial terms'). For example the incoterm DAT means 'delivered at terminal', while DAP means 'deliver at place'; CRF means 'cost and freight', while 'CIF' means 'cost, insurance and freight'. Clarify the terms with the shipping agent and supplier (if applicable) using these codes, in order to be clear about who is responsible for what and the cost implications. Read more about incoterms in Annex 8 of [How To Manage Guide 3](#) which provides a very useful overview of commonly used incoterms.

## Finding Suitable Shipping Agents and Customs Clearing Agents

### Using Known Companies

For both UK and DC partners, it's useful to ask around for reputable freight companies operating in the area. The DC partner can ask the MoH and in-country offices of donors and NGOs for recommendations for local freight and customs clearing agents.

UK freight forwarders that have a lot of experience shipping to a particular country will have contacts with local counterparts who can clear the goods through customs and arrange for shipment to the DC partner. The freight forwarders may also be willing to work with the partners' recommendations for local agents.

In many countries, importers must be registered with the government's customs and revenue agency; it is good to enquire about this when evaluating potential companies and organisations.

### Diplomatic channels

The British High Commission in the DC partner country (if one exists) may be able to recommend a suitable local agent. Depending on the shipment being planned, it is possible they may even be able to assist in other capacities, such as including small items in their own regular shipments. [Contact information for British High Commissions](#) around the world.

*"We got in touch with the British High Commission in Sierra Leone and asked them for a recommendation for a local clearing agent. They told us who they used and this proved to be a great referral - not only because they were tried and tested, but also because we were able to say 'you were referred by' so it gave them an incentive to do a good job for us."*

- Shona Lockyer, Chair of Trustees, The Kambia Appeal

Similarly, the embassy or high commission of the DC partner country in the UK may be able to assist with the shipping logistics and would also have contacts for agents they employ who are used to shipping to the country. [Contact information for all high commissions and embassies in the UK.](#)



### USEFUL RESOURCE BOX:

THET's community of practice (CoP): this may be a useful resource for finding out which shipping companies have been employed by partnerships and what their experiences have been. Registration [here](#)

Some companies that THET partnerships have used include:

- [AZ Intercargo](#)
- [Brendon International Limited](#)
- [Intercare](#)
- [Merlin Shipping\\*](#)
- [Safmarine](#)
- [SDV UK](#)

\* Unrelated to Merlin, international health charity.



### USEFUL RESOURCE BOX:

#### Additional options for finding an agent

The following sites may also be useful to identify local freight forwarders and those who have agents or full offices in the DC:

- British International Freight Association (BIFA)'s member directory <http://www.bifa.org/content/Member.aspx>
- Identify airlines that fly to the DC and may offer cargo services [www.skyscanner.net](http://www.skyscanner.net)
- [Freightbook](#)
- [FreeIndex UK](#)
- [UK Directory](#)

# What is the Export/Shipping Process?

The process for exporting and shipping the goods from the UK is:

- determining the value of the goods for customs purposes
- determining whether tax and duty needs to be paid
- preparing all documentation properly
- determining whether an export license or other official (legal) documents are required
- managing a pre-shipment inspection (PSI) if required
- loading the goods onto the transport vessel
- sending all documentation to the clearing agent and DC partner

## Determining the Value of the Equipment

- The equipment being sent must be assigned a value for customs valuation purposes.
- If the equipment is new, the initial purchase cost should be used. Include the VAT-exempt invoice for customs officials as evidence of the cost.
- If the equipment is pre-owned the depreciated value should be used - medical engineering staff, asset managers and suppliers can provide these values.

**Do not use a zero value for items, as it is likely this will be unacceptable to the DC customs officials.**

- If the value is too low, customs officials will use their own value.

## Determining Tax and Duty

Every country is different in terms of what duty and tax rates they impose on imports, and to whom exemptions are granted. Charities and NGOs are often exempt. Government ministries for health and education are also often exempt from paying duty and tax.

Similarly, most INGOs have exemption status and may be very useful partners for shipping the goods and importing them. A letter of support from the Ministry of Health or one of these INGOs may be very useful.

Remember to factor tax and duty costs in to cost projections when weighing UK vs. DC sourcing. For example, a device that costs £1000 to purchase may have 16% tax and 25% import duty levied against it during import. Without a tax or duty waiver (exemption), it will cost £1410.

## Verifying the Contents

Make sure all items included in the shipment will be accepted for import in the DC. Countries have lists of goods (and their materials) that are permissible; these lists change regularly and so should be verified at the time of shipment.

For example:

- Lithium batteries may be banned or classed as dangerous goods and require special shipment. [Read more](#)
- IT equipment, such as computers, is rarely duty waived
- Low-specification IT equipment is banned from import in many countries
- Some countries ban imports of any pre-owned electrical equipment, including medical equipment
- Non-electronic items such as blankets and bedding may be banned, or require pre-shipment inspection

When in doubt about the materials contained within a device or its associated usage and maintenance materials, consult the manufacturer and the shipping agent. For example, laboratory reagents' material safety data sheets (MSDSs) provide detailed information about the hazardous ingredients found within the reagent and how it must be shipped.

The freight agent and DC customs officials/clearing agents should advise on what is permissible in a particular country. The revenue and customs agency in the country will also provide a list of tariff numbers for each permissible commodity. The tax and duty rates charged depend on the tariff number, which must be included in the shipment documentation.

## Understanding and Preparing the Documentation

A full set of documentation must be prepared, with input from the UK partner, freight agent, supplier, DC partner, clearing agent and others as required. Once the documentation is completed and the shipment is dispatched, full copies of the documents must also be sent to the DC partner and their customs clearing agent. Originals may be necessary to meet the import requirements of the DC, in which case these documents will need to be couriered. Be sure to budget for the cost of the paperwork, which often costs ~ £200.

### What Documentation is Required?

BIFA categorises the documents involved in exporting and shipping goods as:

1. Transport documents
2. Official documents
3. Commercial documents

## 1 Transport documents

The transport document will either be a bill of lading (for sea freight) or an air waybill (for air freight). For truck and rail, the waybill is called a 'CMR'. This document is like the passport for the shipment: it provides all necessary information to allow the goods to move from the UK to the DC and also serves as contract and proof that the goods are on board the transport vessel. The shipping agent will provide the template for the bill of lading or air waybill, which will be prepared in triplicate.

The bill of lading or air waybill will include the following information:

- Full, itemised list of contents
- Number of packages, volume, and weight
- Full contact details for the 'consigner' (who the shipment is from; the UK partner) and the 'consignee' (who the shipment is for; the DC partner)
- Value of goods for customs purposes
- Notification of charity status

The shipping agent will require this transport document to begin customs formalities. The DC partner and clearing agent will also require the completed transport document to clear the shipment through customs. For sea freight, the original copy of the bill of lading must accompany the shipment.

## 2 Official documents

These are the regulatory documents that are required by law for the declaration of export of goods, such as dangerous goods notes, certificates of origin or licenses. They will depend on what is being sent, and to where.

### Dangerous goods notes

A 'dangerous goods note' (DGN) is required for shipments of substances categorised as dangerous goods. These must be shipped by courier or airfreight. When in doubt, always ask the supplier and the freight agent if a DGN is required.



## USEFUL RESOURCE BOX:

### Dangerous goods regulations

The International Air Transport Association (IATA) defines the standards for transportation of dangerous goods by air. Read more here:

[www.gov.uk/freight-forwarding-moving-goods#freight-forwarders-regulations-for-moving-dangerous-goods](https://www.gov.uk/freight-forwarding-moving-goods#freight-forwarders-regulations-for-moving-dangerous-goods)

[www.iata.org/publications/dgr/Pages/index.aspx](https://www.iata.org/publications/dgr/Pages/index.aspx)

### Export licenses

While the MHRA issues export licenses for medicines, there is currently no similar export-licensing scheme for medical devices. More information about medicine export licensing can be found here. An export license may be required for the equipment if the goods are considered controlled and being sent somewhere that has trade sanctions and embargoes in place.

### About exporting controlled goods

The UK's Export Control Organisation (ECO) is responsible for issuing export licenses for controlled goods such as military equipment, radioactive sources, products used for torture and 'dual-use goods' that can be used for both military and civil purposes.

While the majority of medical equipment does not fall into the category of controlled goods, certain devices (such as blood irradiators and mass spectrometers) meet the criteria and may require an export license from the ECO, depending on which country the goods are being exported to.

Three main factors determine whether an export license is required:

1. Is the equipment controlled? This needs to be verified by the ECO.
2. Which country is it going to? There may be sanctions and embargoes in place.
3. Is this a one-time export or the start of an ongoing export relationship?

Legislation is subject to change and it is advisable to continue to refer to the ECO links for current legislation:

- [www.gov.uk/government/organisations/export-control-organisation](https://www.gov.uk/government/organisations/export-control-organisation)
- [www.gov.uk/do-your-goods-need-an-export-licence](https://www.gov.uk/do-your-goods-need-an-export-licence)
- [www.gov.uk/sanctions-embargoes-and-restrictions](https://www.gov.uk/sanctions-embargoes-and-restrictions)



### 3 Commercial documents

The commercial documents in a transaction are many and varied. They will depend on the nature of the consignment, parties involved and method of payment. Commercial documents include invoices, insurance certificates, letters of credit, shipping instructions and others.

For partnerships managing equipment donations, this will include:

- Donations certificate or 'free of charge (FOC) invoice'
- Insurance certificate
- Possibly shipping instructions and other documents

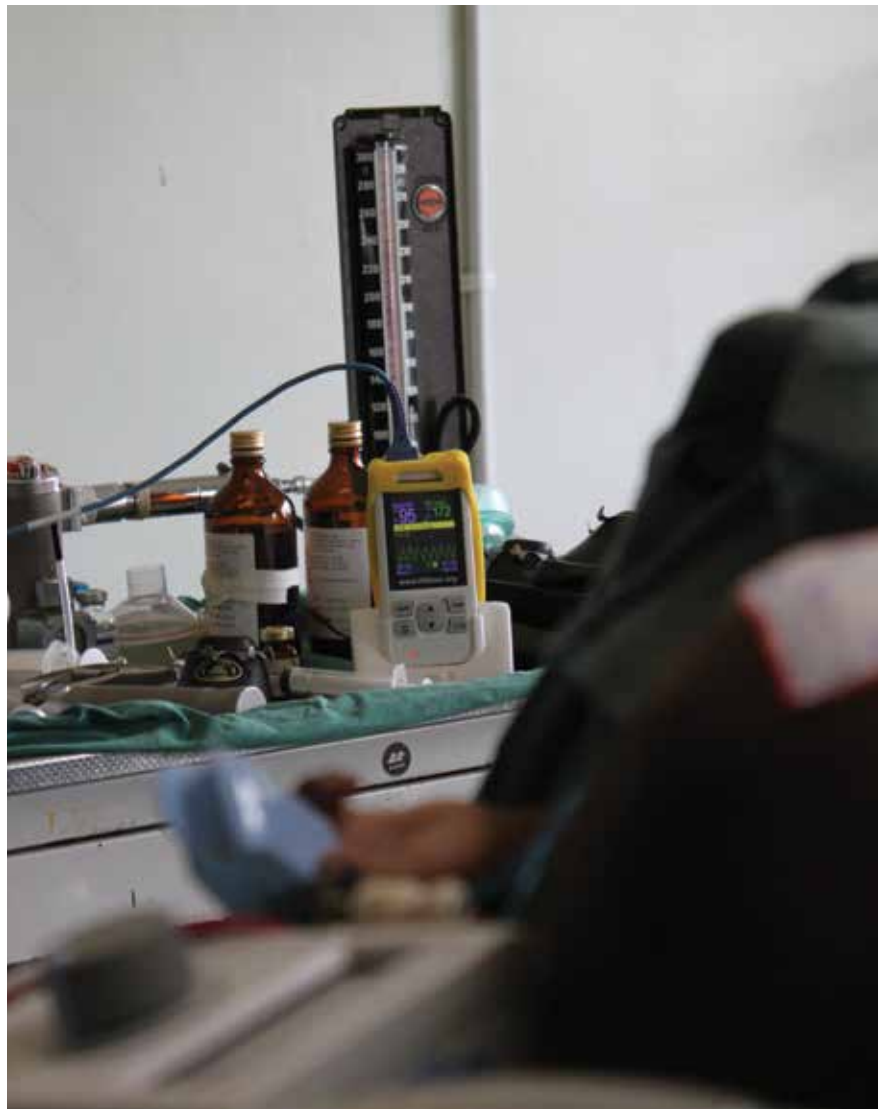
A donations certificate or FOC invoice is important to minimise payment of import duties. All boxes/items must be labeled with this certificate, which should include the full contact details for both partners, the estimated valuation of the items and a clear statement about the nature of the donation. Commodities listed on the certificate should include their tariff numbers for the country of import.

The freight agent, local customs clearing agent and DC partner can advise on the specifics for the DC. Remember that every country is different!

#### The following documents are required to clear customs in Ghana:

1. Original Bill of Lading/Airway Bill
2. Invoice
3. Packing List
4. Final Classification and Valuation Report (FCVR)
5. Import Declaration Form (IDF) from the Ministry of Trade and Industry.
6. Tax Clearance certificate from the Domestic Tax Revenue Division issued in the name of the importer or 1% of CIF payment fee.
7. Tax Identification Number (TIN) from the Ghana Revenue Authority.
8. Permit or License from the appropriate Ministry/Agency Department/ as applicable for restricted goods.
9. Appropriate letter of Exemption from payment of duty and/or taxes as applicable.

Reference: [Ghana's customs guide \(page 7\)](#)



*St Francis' Hospital, Katete, Zambia. Photo Lifebox Foundation*



Winchester - Yei Partnership, South Sudan. Photo Tom Price

## Managing Pre-shipment Inspections

Pre-shipment inspection (PSI) is a procedure in which goods are inspected for conformity prior to being shipped from the country of export. PSI is also referred to as 'pre-conformity assessments' and 'pre-export verification of conformity.'

Many countries require PSI, some for all goods being imported and others for goods in certain categories (including medical equipment) and/or those over a set threshold financial value.

### Some examples for Kenya, Nigeria and Tanzania:

- [Kenya's PVoC programme](#)
- [Nigeria's 'Standards Organisation of Nigeria \(SON\) Conformity Assessment Programme' \(SONCAP\)](#)
- [Tanzania's PVoC programme](#)

The freight agent can advise on procedure and cost when a PSI is required.

## Dispatching the Goods

Once all paperwork has been prepared and a PSI has taken place (if necessary), the shipment will be loaded on to the carrier vessel for transport. All completed paperwork can then be sent to the local customs clearing agent and the DC partner, who take over the process of clearing it through customs and receiving it in the DC.

## In Summary

**Every country is different. Always seek advice on import requirements from the freight agent and DC clearing agent. For example, a country may:**

- Ban the import of any used goods, without exception.
- Ban the import of second hand bedding and furniture, including hospital beds.
- Not offer tax exemptions, but cover the cost of the tax for certain goods.
- Ban the import of low-specification IT equipment.

**Be careful what you add in to a shipment.**

Donors like to add soft, light items such as blankets and clothing in to a container to fill up space, but

these items can cause problems. In one instance, a container of donated wheelchairs was filled with blankets. Pre-export verification of conformity wasn't required for the wheelchairs - but it was for the blankets and this resulted in costly delays clearing the shipment.

**Make sure everything in the box/container is listed on the contents list.** Any difference in the contents compared with the list can result in delays and additional costs.

Make sure the paperwork is complete and all copies (originals if necessary) are received by the customs clearing agent and DC partner in time for them to prepare for the arrival of the shipment.

While these shipping requirements can seem complex, a knowledgeable freight forwarder will make all of the difference and is the most worthwhile investment the partnership can make.

In worst-case donation scenarios, recipients have been known to pay thousands of dollars in demurrage charges ('parking fees') while a shipment was held at customs for equipment that wasn't even useful. Don't be part of this.

Many INGOs and government institutions have import duty and tax exemption status.

Make sure the DC partner engages the relevant government institutions for letters of support if required, and consider approaching INGOs for support with the import process if appropriate.



*Lumley- Basildon & Thurrock Partnership, Sierra Leone. Photo Tom Bradley*

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## CHAPTER OVERVIEW: RECEIVING THE EQUIPMENT

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- **Clearing customs**
  - Process
  - Documentation
- **Transporting to the DC partner**
- **Receiving the equipment at the facility**
  - Checking the shipment and registering the asset(s)
  - Performing technical acceptance tests on the equipment
  - Preparing the environment for use of the equipment
  - Entering the equipment into the inventory used by the biomedical engineering team

### CHAPTER CHECKLIST:

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- ✓ Be aware of the customs clearance process in advance and make sure everything in the container is listed on the packing list and allowable for import
- ✓ The DC partner's processes for receiving goods, registering new assets and testing their integrity should be followed
- ✓ Important that the DC partner feeds back to the UK partner any issues with the shipment



St Francis' Hospital, Katete, Zambia. Photo Lifebox Foundation

## 6 RECEIVING THE EQUIPMENT

### Clearing customs

When the shipment arrives in the DC, the clearing agent/importer are responsible for clearing the goods through customs. This clearance process can be complex.

In many countries, goods can only be sent to organisations (commercial or otherwise) that are approved importers or consignees by the customs and revenue authority. Approved importers are typically assigned a unique tax or trader identification number (TIN) that is used in the port's clearance system. An organisation other than the DC partner may be the official importer.

### Process

The UK and DC partners should have a basic understanding of the clearance process, regardless of whether the DC partner is the official consignee or not. The clearing agent may require more information from the partners during the process as well, which involves:

- Undergoing customs valuation assessment (in which goods may be assigned a different value than the one submitted) and paying any taxes and duties required
- Undergoing verification of the shipment against the documents and obtaining a release for the goods from the port authority
- Being issued a loading slot so the shipment can be moved onto a transport vehicle

**The description of goods on the tax/duty exemption certificates must accurately reflect the contents of the shipment.** If it is selected for physical search during the verification process and the contents do not match the description exactly, the process will need to begin all over again, resulting in costly delays.

This process easily takes several days. When ports are backlogged it can take much longer, and demurrage fees may still be charged even though the consigner and consignee are not responsible for the delay. Ask the clearing agent what timeframe is expected for clearance once the goods arrive. If the UK partner is funding clearing costs, it's important to ensure finances are transferred either to the DC partner or the agent directly for these fees.



## Carefully prepare customs paperwork and plan for delays

**Since 2009, the Leicester-Gondar Medical and University Link has been involved in the WHO African Partnerships for Patient Safety (APPS) programme, focusing on infection control and prevention through sharps disposal and hand hygiene. Staff at University of Gondar Hospital found the alcohol-based hand rub bottles they were using weren't very user friendly and were discouraging use: they didn't fit in peoples' pockets or have a flip lid. Sandra Kemp, the African Partnerships for Patient Safety (APPS) lead for University Hospitals of Leicester shares her experiences involving the donation of hand-held alcohol-based hand rub bottles**

Sandra approached a UK-based manufacturer about donating some bottles to Gondar, and they were happy to donate enough for the whole hospital. The courier who shipped them to Ethiopia was extremely helpful and detailed every step of the process and what paperwork was required from UK and Ethiopian partners for each step. Unfortunately, despite all of the paperwork being in place, the bottles were held at customs in Addis Ababa for several months before being released. When the bottles did reach the hospital, they were happily accepted and staff report being much more pleased with them than those they replaced.

### Lessons Learned:

- Carefully prepare customs paperwork and plan for delays
- It is important to have good shipping agents in place on the receiving end and for the developing country partner to have a system in place as well for 'receiving' donated items
- It is important to have all paperwork prepared correctly but accept delays may still happen
- Little things can make a big difference - the more user-friendly design of the bottle has encouraged staff to sanitise their hands
- Manufacturers are often very happy to provide in-kind donations - it is a good news story for them as well so it's always worth asking

## Documentation

The clearing agent will need to arrange the following documentation:

- Bill of entry (the written account of the goods entering the DC, submitted to customs to verify and approve the release of the goods)
- Duty exemption certificate (with supporting documentation of the charitable nature of the donation and a letter of support from in-country duty exempt organisation if appropriate)
- Import license (if applicable for the item(s) in the shipment, based on the DC's import regulations)
- Import declaration form (with all necessary supporting documentation)

Copies of the shipping documents will need to be submitted as supporting evidence for this documentation. For example, the bill of lading/air waybill, packing list and invoice are required to support the bill of entry.

An example scenario of the customs clearance process is presented in Appendix I, courtesy of DHL's Aid, Relief and Humanitarian Services team. This scenario outlines all of the steps necessary to clear a container through Mombasa port in Kenya and gives a good idea of the systems, offices and processes involved.

The container should be checked for damage prior to opening it. Any issues should be documented and if they are significant, it should remain unopened until the issuer of insurance can be notified. Photos should be taken to document any damage. The same applies to opening the boxes in the shipment and removing the items from the container.

## Transporting to the DC partner

The mode of transportation will depend on the size of the shipment as well as any specific transportation requirements. FCLs are often transported in the container to the final destination, while LCLs may be moved out of the container into another transport vehicle.

The clearing agent, a local transport company or the DC partner may provide transportation. Note that port authorities often grant entry to the port only to registered vehicles, which may be problematic if the DC partner sends their own vehicle to collect the shipment.

Regardless of who transports the shipment, it is important to ensure that the goods are properly packed, secured (by straps or nets) and protected from rain (transported in closed vehicles and not left outside between loading and unloading at the port or the DC partner facility). They must also be insured for this last part of the journey.

Depending on the size and weight of the shipment, heavy lifting equipment may be required at the DC partner facility, and storage space may need to be identified in advance. Casual labourers may be hired to assist in moving the boxes; if so it's important to ensure they have adequate personal protective equipment (PPE) for the task, such as steel-toed boots for moving heavy boxes.

## Receiving the Equipment at the Facility

Once the shipment arrives at the DC partner there are several teams within the facility that should be involved in formally 'receiving' it.

**Remember that equipment arriving via a donation should not be treated any differently than equipment that has been procured.**

## Checking the Shipment and Registering the Asset(s)

The DC partner's processes for receiving goods, registering new assets and testing their integrity should be followed.

The shipment should first be brought to the Stores department (where one exists) or another suitable location so that the integrity of the shipment can be verified. This includes counting the boxes against the packing list and then opening them and verifying their contents against the list too. This may involve staff from Stores, the clinical area 'receiving' the equipment and the maintenance team.

Any discrepancies must be noted in writing, using whatever documentation the DC partner uses, such as a Stores Receipt Ledger or record book. Once this shipment integrity check is complete, the DC partner should feedback to the UK partner to let them know it has arrived and whether any issues need to be addressed.

The equipment must be registered in the facility's asset register. If any spare accessories or consumables were sent along with the equipment, these should be stocked in the central Stores or the storeroom of the suitable department. Similarly for spare parts, these should either be sent to the maintenance workshop or kept in Stores as appropriate.

If the equipment requires support from the Stores or procurement team to order replacement consumables, accessories or spare parts, information for placing these orders locally should be registered in whatever system is employed.

If the donation included any biomedical engineering tools or test equipment, these should be verified in the same manner and then sent to the maintenance workshop with all necessary manuals.

Again, it's important for the DC partner to feed back to the UK partner - and to be comfortable raising any issues with the shipment as well as the good news that it has arrived. The UK partner won't be able to provide support to resolve any issues without constructive feedback.

If the shipment is large, this process may take some time. Be sure to retain all packing materials until all acceptance tests are complete and the equipment has been officially accepted or commissioned by the biomedical engineering team. If there are any problems, it may be required to re-pack the equipment to send offsite for further investigation.

## Performing Technical Acceptance Tests on the Equipment

### Don't bypass the biomedical engineering team.

Regardless of the level of sophistication of the individual or team responsible for equipment maintenance within the facility, it's essential that the staff responsible for maintaining medical equipment be engaged in the registration process.

Before the equipment is put into service, it should be tested to ensure it is functioning correctly and is safe to use. The same tests that were performed to verify the safety and functionality of the equipment prior to shipping it should be performed again in this new environment.

This series of 'acceptance tests' is part of any robust biomedical engineering service and is particularly necessary in the case of devices that have been shipped and then transported overland, possibly on rough roads.

The technical tests required to 'accept' the equipment can be performed by in-house staff with the appropriate skills and training, by engineers from the UK partner or by external technical service providers identified during the initial donation evaluation and planning phases (See Sections 1 and 2).

Once these steps are complete, the equipment can be 'commissioned' for use in its new environment. For more information about commissioning and links to additional resources, see the How To Manage Guide 3.

These tests generally include:

- Running through function tests
- Verifying the electrical and mechanical integrity of the equipment
- Verifying the electrical safety of the equipment
- Running calibration tests for equipment that require it
- For specialised equipment, running through any additional tests necessary to ensure the equipment is safe and fit for purpose (for example, radiation integrity tests for x-ray equipment, gas cylinder checks for equipment with oxygen cylinders such as anaesthesia machines and resuscitaires)

New equipment may also require assembly prior to performing these tests - if so manufacturer's instructions should be followed. Some equipment may require different electrical plugs that should be fitted and glued on at this time.

Any issues should be noted and discussed with the relevant competent technical advisors. These must be resolved before the equipment is put into service. All tests must be recorded and the records should be attached to an acceptance form - if the DC partner uses such as record - and signed by the technical staff who performed them.

## Preparing the Environment for use of the Equipment

If any infrastructure works were done to prepare for the arrival of the equipment, such as extending electrical connections or pipes, these works must be verified before the equipment is placed into service. The environmental conditions must also be appropriate as outlined by

the manufacturer. For example, any temperature or humidity requirements should be verified.

## Entering the Equipment into the Inventory used by the Biomedical Engineering Team

The DC partner may have an equipment inventory that is managed by the equipment maintenance personnel or an administrator that is separate to the facility's main asset register. If this is the case, the equipment should be tagged with a unique identifier for traceability and entered in to the inventory.

If there is no specific engineering inventory or logbook for the equipment, it is still useful to record the type of information an inventory would capture. This is a fragmented approach to building up an inventory, but for the purpose of the donation exercise, still very worthwhile. The recording mechanism need not be sophisticated.

**At a minimum, the inventory should capture:**

- The unique identification number assigned to the equipment
- The type of equipment
- A brief description of the equipment
- Manufacturer
- Model
- Serial number (the manufacturers' unique ID for the equipment)
- Location within the DC partner facility
- Status ("in service" or "out of service")
- Power requirements
- Any special requirements for using and maintaining the equipment
- Who the main technical service provider is and contact information for them
- Where supplies can be sourced locally, including contact information
- The donor of the equipment and contact information for the main lead
- When the information in the inventory was last updated

Reference [WHO Medical Device Technical Series: Introduction to medical equipment inventory management](#)

Annex 9 of the HTM Guide 3 provides an excellent sample acceptance test log sheet that covers all necessary activities required to officially accept or commission the equipment.



The information captured in an inventory record should enable future users and maintenance staff to have a history of the device and contact details for support.

There are many useful resources that provide detailed guidance on clearing customs, receipt of goods at the facility and acceptance testing:

- HTM Guide 3 Section 8 (How To Receive, Commission, And Store Goods On Site)
- WHO's [first guidelines for equipment donations](#) (2000) have detailed transportation guidance (important to note that these have been updated to produce the [current version](#) (2011) which should be the main reference for current good practice)
- UK partner's EBME team can advise on acceptance testing procedures

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## **CHAPTER OVERVIEW:** PUTTING THE EQUIPMENT INTO SERVICE

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- **Training the equipment users**
- **Training the maintenance staff**
- **Using and maintaining the equipment**

### **CHAPTER CHECKLIST:**

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- ✓ Train the clinical staff who will use the equipment
- ✓ Train the engineering staff who will maintain the equipment
- ✓ Look at partnership activities to assess and build biomedical engineering capacity



# 7 PUTTING THE EQUIPMENT INTO SERVICE

## Training

If training is required for either the clinical staff who will be *using* the equipment and/or the biomedical engineering staff who will be *maintaining* it, this should be done before the equipment is put into service. Doing so before the equipment is put into 'service', or use, is particularly important for the users.

*"We are using this resuscitator from the little knowledge we have."*

- registered midwife at Serenje District Hospital in Zambia

*"I know what this is and what it is for, but I don't know how to use it."*

- registered midwife at Malole Rural Health Centre

### Training the equipment users

Training the clinical staff how to use the equipment can be done by a variety of people:

- Senior clinical staff within the DC partner may be very knowledgeable and able to train the more junior clinical staff.
- UK partners often provide training on their support visits, employing a 'train the trainer' model.
- A manufacturer or supplier representative can also provide this training; in some cases they have been very involved with equipment donations and traveled to the DC partner to assist in commissioning the equipment and providing training on it.
- If the biomedical engineering team is highly trained themselves, they too can provide this training.

*"One of the most important things we do as biomedical engineering technologists is train the users how to operate the equipment safely and properly."*

- Peter Matoke, Biomedical Engineering Technologist, Kenyatta Hospital in Nairobi, Kenya

If staff responsible for equipment maintenance require more training themselves - which is often the case in DC facilities - it is very useful for them to attend the training for users alongside the clinical staff, as well as their own training on how to maintain the equipment.

**Training users and maintenance staff together builds rapport and gets them talking about the equipment.**

### The training for users should cover:

- How to use the equipment safely and properly
- How to understand the user manual
- What to do if a problem is suspected
- How to care for the equipment (user care and maintenance)

### The importance of user care and maintenance

In an ideal medical equipment scenario, users are also active participants in the routine care and maintenance for the equipment. 'User care and maintenance' includes routine activities performed on medical equipment by the operator (user) to ensure it is in good working order. Depending on the equipment, it may also include cleaning and disinfection, calibration and changing of very minor parts.

It's recognised that many clinical staff - particularly junior ones - are exceptionally busy with their routine job tasks and that a training session to use a new piece of equipment is an additional activity in an already busy schedule.

That being said, not receiving proper training can compromise the safety of patients and it is therefore important to make the training session efficient, but thorough enough to cover what is required and practical or 'hands on' so that they become comfortable with the device.

The training should be practical and appropriate to the language needs and education level of the users. It can be helpful to simplify the key steps for operating the equipment safely and properly and to put these on a piece of paper that can be put up on the wall near the equipment. Similarly, it is good practice to do the same for user care instructions, and to have a logbook nearby to record the user care and maintenance in.

## The importance of dialogue to understand expectations and cultural differences

“We’ve learned a lot over the years about equipment donations. The most important thing is to ensure that they are in response to a specific request and that both sides are clear about each other’s expectations up front. There also has to be a maintenance team at the hospital to look after what’s given, or the donation won’t go very far.”

- Sandra Kemp

**The Leicester-Gondar Medical and University Link began in 1996 to support undergraduate and postgraduate programmes at Gondar University in northern Ethiopia. Sandra Kemp, the African Partnerships for Patient Safety (APPS) lead for University Hospitals of Leicester (UHL), has been visiting Gondar since the partnership began to train nurses at University General Hospital (UGH). Throughout the years the partnership has coordinated various donations to help refurbish UGH’s maternity ward, improve infection control and facilitate training programmes.**

In 2002, six neonatal simulators were donated as training aides for a neonatal resuscitation course in Gondar run by Leicester staff, which included training of local trainers. When the first course finished, four of the simulators were left at the hospital on the maternity and neonatal wards and two were left at the nursing school in order to be used

for future training.

However on subsequent visits to Gondar, Sandra and her colleagues began to realise that the simulators weren’t being used for training between their visits and had in fact been locked away in a cupboard. Through careful dialogue with their partners in Gondar they began to realise why.

Lessons learned:

- Senior staff kept the simulators locked away for safekeeping to ensure they were working when Leicester staff were there for training visits
- Importance of dialogue - particularly to understand everyone’s expectations prior to donating - from senior medical staff to junior ward staff and maintenance personnel
  - Leicester staff assumed simulators would be used frequently to make most of them for training
  - Gondar staff assumed they should be kept in good condition for training visits
- Issue of ownership - senior staff who have ‘received’ a donation on behalf of their hospital or training institute may feel ownership over it and restrict access to it to limit the chance of damage

# Training the Maintenance Staff

This is a crucial activity yet one that is all too often overlooked. In a study of the effectiveness of biomedical engineering services in developing world hospitals, 82.5% had not received maintenance training for any donated equipment they had ever received [10].

Similarly, engineers from the UK partner can provide this training, as can those from the manufacturer or supplier, or local technical staff who are skilled with the particular device(s).

A useful training exercise is for the maintenance staff to prepare 'quick reference guides' for the users, for each device on one sheet of paper. These guides can cover basic instructions for use and troubleshooting, as well as contact information for the maintenance team in case of a problem. These quick reference guides can be reviewed by the trainer and then posted on the wall near the device. Reviewing them with the users will also build rapport with the maintenance staff.

## The training for maintenance staff should cover (as required):

- Overview of the equipment - what is it and what is it used for?
- Principles of operation - how does it function and what are its basic principles of operation?
- Inside the equipment - what are the major components inside, how do they interact with one another and what are the main inputs and outputs of the equipment?
- Troubleshooting - what are the common faults and how are they rectified? What tools and test equipment are required to do this?
- Preventive maintenance - what routine maintenance should be performed on the equipment? What components should be tested, and replaced if necessary?
- Safety - what adverse effect could the equipment have on patients or staff (users or maintenance personnel) and what should be done to minimise these risks?
- Maintenance tools and test equipment - what is used and how?

If a full service manual was included with the donation, this should form the basis of the training. The maintenance staff should be trained on both 'corrective' and 'preventive' maintenance. Any engineering equipment (such as test equipment) that is new will also require some training.

## Defining maintenance

**Corrective maintenance** is another term for repair, which is performed on medical equipment by trained biomedical engineering personnel to correct equipment malfunction.

**Preventive maintenance** is routine maintenance performed on medical equipment by trained biomedical engineering personnel to prevent equipment malfunction.

*"Before the course, I didn't realise that maintenance was more than just something you did after something had broken down."*

- Participant of DFID funded ECHO International training programme in the Gambia

While preventive maintenance is routine in places like the UK, in DC health facilities it is much less common due to lower maintenance capacity. Resources may not be allocated to this activity, but the donation is a good opportunity to advocate for this.

To help prepare service-training materials, the following may be useful:

- The UK partner's EBME team
- The manufacturer and supplier
- [Frank's Hospital Workshop](#) (manuals and device overviews)
- [INFRATECH](#)
- [WHO: Hospital Medical Equipment](#)
- [How to Manage Guides 4 and 5](#) (including sample preventive maintenance protocols)



*A view through the window of the main theatre door, as Doctor Ivan Nyenje performs a caesarean section at Kasangati Health Centre in Uganda. Photo RCOG/Mile 91/Ben Langdon*

## Using and Maintaining the Equipment

Using and maintaining the equipment beyond when it is first placed in service requires careful attention, particularly when the DC partner doesn't have a high equipment maintenance and management capacity.

HTM Guide 4 'How to Operate Your Healthcare Technology Effectively and Safely' provides guidance on how to ensure continuous operation of equipment, including:

- security
- user care and maintenance (called 'user planned preventive maintenance' in the guide)
- testing the electrical and mechanical integrity of the equipment
- reporting faults
- decommissioning, disposal and replacement of equipment

The WHO's Medical Equipment Maintenance Programme Overview also provides very useful guidance on maintenance systems, including templates and recommended engineering equipment.

In addition to these activities, there must be a reliable supply chain for consumables and parts in place.

It's recognised that some of these suggestions include systemic barriers to well-functioning equipment (such as strong supply chain and good equipment maintenance and management systems).

This highlights the importance of activities - within the partnership but also with other organisations the DC partner interacts with regularly, such as MoH structures and other NGO partners - that focus on building this capacity. The UK partner can also contribute to supporting the DC's engineering or maintenance team if it is identified as a partnership priority. Finally, remember that the DC partner will eventually have to decommission the equipment, and guidance should be provided on how to do so if required.

# Assessing biomedical engineering capacity in Mbeya, South Tanzania

“In a sea of difficulty there were islands of best practice.”  
- Jim Methven

Mbeya Referral Hospital in south-west Tanzania faces many challenges, including a high attrition rate of health workers, considerable prevalence of HIV/AIDS, malaria and pneumonia and over 60,000 blind people in the catchment area, which contains around 6 million people. The link was established following an evaluation visit to Mbeya Referral Hospital led by Mr. Soonu Verghese, one of North Cumbria University Hospital's consultant ophthalmic surgeons in the summer of 2007. Four pressing areas of need were identified during the evaluation visit: ophthalmology, accident and emergency, infection control and biomedical engineering.

Jim Methven, Head of Medical Physics at North Cumbria University Hospital, was brought on board through the link committee to address the biomedical engineering needs. With prior experience of working in the Middle East, the Far East and the South Pacific for organisations such as the World Health Organization and the UK Crown Agents for Overseas Governments, Jim was well positioned to support a further assessment of biomedical engineering capacity.

The initial evaluation visit had identified a severe shortage of medical equipment at Mbeya hospital. In addition, there was a lack of trained staff to operate and maintain the existing equipment and inadequate logistical resources to manage the equipment. In the summer of 2008, Jim travelled to Mbeya for a two-week visit with a senior ophthalmology sister.

His primary role was to examine, analyse and comment on biomedical engineering within the hospital. To make the most of the visit, he also looked at estates management and IT capacity. A tour of the wards on the first day confirmed that there was an obvious lack of equipment and consumables, and much of the equipment was unused due to faults and an inability to obtain spare parts. The facilities themselves were also in need of maintenance.

Jim's counterparts at Mbeya were Rwiza and Namlanda, a mechanical engineer and an electrical engineer. There were no dedicated medical engineers or technologists working in the hospital.

Working together, they identified the major medical equipment challenges:

- No records of maintenance work so it was difficult to determine what repair work had been done and what parts were ordered/needed

- Challenging administrative systems for sourcing and purchasing spare parts
- Poor equipment donations, with no user or service manuals or consumables
- An equipment inventory existed, but the engineering department didn't have a copy!
- No overall equipment management system in place
- Lack of suitable workshop facilities, tools and test equipment

Jim also undertook some repair work while he was in Mbeya, although he was conscious of the fact that some local staff had high hopes he could repair all of the faults and the primary purpose of his visit was to assess the biomedical engineering situation at the hospital.

Based on the work done during the visit, Jim made the following recommendations:

1. Increase size of engineering department and strengthen priority within hospital planning
2. Appoint a dedicated biomedical engineer and biomedical engineering technologists and artisans
3. Review the administrative systems for ordering parts and other biomedical engineering materials

## Favourable factors

Many senior equipment users (such as the head of clinical laboratories, senior operating theatre sister, and senior central sterilisation department sister) took great care with the limited functional equipment they had and had established good equipment care practices for the staff in their areas.

With access to a good internet connection, Jim was able to source information and parts specifications from various manufacturers to assist in repairs.

## Limiting factors

Without an adequate system in place, or the budget or training to establish one, the maintenance team was generally only capable of being reactive to equipment breakdowns as opposed to being proactive with planned period maintenance and inspections.

The lack of a dedicated medical equipment engineer or technologist with the requisite knowledge was a significant gap.



# WHAT NEXT?

## Chapter checklist

- ▶ Learn from and evaluate the donation
- ▶ Share stories of successes and challenges
- ▶ Support biomedical engineering capacity building

### Learn from and Evaluate the Donation

Health Partnerships are in a strong position to effectively monitor and evaluate their equipment donations.

The partners can jointly assess the donation exercise on the UK partner's annual support visit, for example, or the DC partner can feed back at a particular interval to the UK partner.

Appendix J provides some questions to guide this learning and evaluation. This can be reviewed and updated periodically.

HUMATEM's 'Method of Evaluation' resource is also an excellent guide for a very thorough evaluation of wider 'medical equipment support projects'.

### Share Stories of Successes and Challenges

Sharing lessons learned through the donation experience with others - both good and bad - is very useful. Challenges encountered can be learning opportunities for others, while positive experiences can serve as models of good practice.

As mentioned in the introduction, the evidence base for equipment donations is sparse; most data is found in 'grey literature', such as development project reports, or in clinical engineering journals that don't have a wide global health readership.

Consider sharing your experience by publishing it - either in a mainstream medical, global health or policy journal or as a reflection in the publication of your professional society.

Also, share any success stories and challenges with suppliers and manufacturers of equipment, to advocate for better links with and services for DC health facilities and systems that are often so far away from technical support.

The Useful Resources Section provides a very good starting point for contacting organisations, discussion forums, journals and professional associations who may be interested in your experiences.

### Support Biomedical Engineering Capacity Building

While some clinical areas are more equipment heavy than others, there are very few that don't rely on the presence of functional medical equipment.

UK partners can start small by:

Bringing an engineer along on a support visit to do an initial needs assessment and work with the equipment maintenance leads within the DC partner

Starting to ask questions about equipment maintenance and management needs and priorities in meetings with senior management

Getting to know the maintenance staff at the DC partner hospital and become an advocate for them as important health professionals, and for their training and capacity building needs

Encouraging UK EBME teams to network with other UK engineers who have done similar work and become involved in some of the online communities that focus on medical equipment in low-resource settings

Engaging with manufacturers and suppliers on behalf of their DC partners about some of their acute challenges with specific pieces of equipment - being a crucial link and advocate

Well-established partnerships could also consider developing a medical equipment partnership, provided it was identified as a priority by the DC



#### USEFUL RESOURCE BOX:

THET's Resources Library provides good practice guidance on evaluating and learning from health partnership projects.

- [Monitoring and Evaluation Toolkit "What difference are we making?"](#)
- [THET Theory of Change](#)
- [After Action Review \(AAR\)](#)
- [Guidance on Project Monitoring](#) (with strong emphasis on the context you are working in and with a strong awareness of stakeholders/audiences).



Sister Mampewo Sarah Senkungu scans a pregnant mother at Kasangati Health Centre in Uganda. Photo RCOG/Mile 91/Ben Langdon

partner and an area the UK partner could contribute expertise in. Initial activities would likely involve a needs assessment, an inventory and initial training on equipment maintenance but would depend on the specific situation of the DC partner.

Many of the challenges faced by the BME teams within UK and DC partner institutions are similar, albeit differing in scale and the resources they have to overcome them.

*"We come from a medical physics department that has over 100 staff, here, there are three of them and they are expected to do everything.... I think there is some usefulness to them knowing that we appreciate their difficulties, because they do have a harder job than we've got."*  
 - Rashid Brora, Head of Medical Equipment Management Services Guy's and St Thomas' NHS Foundation Trust.

#### Medical Equipment Partnerships Programme

THET currently funds five medical equipment partnerships working in Ghana, South Sudan, Ethiopia, Uganda and Zambia. Their primary focus is to build equipment maintenance and management capacity, and the projects are led by biomedical engineers and medical physicists.

For example, staff from the University College London (UCL), University College London Hospital (UCLH) and Royal Berkshire Hospital are working in partnership with Korle Bu to prepare for the arrival of Ghana's first linear accelerator in a public hospital. Read about the project in [SCOPE, the magazine for the Institute for Physics and Engineering in Medicine \(IPEM\)](#).

In a perfect world, there would be no need for medical equipment donations. Unfortunately most DC health institutions lack enough suitable equipment to deliver services to their patients, and struggle to manage and maintain what medical equipment they do have.

Donations can be a great burden on DC health facilities, or a great help. The difference lies in what motivates them and how they are executed. Following the good practice outlined in this toolkit will increase your chances for a successful donation, but remember that ultimately, donations are more about people and how they communicate than they are about the actual equipment.

# GLOSSARY OF KEY TERMS

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## Scene setting (partnerships)

Health partnership is a relationship between a health institution in the UK and a counterpart health institution in a low-income country. It is typically developed by institutions with complementary objectives and made up of volunteers from the UK partner.

United Kingdom partner (UKP) is the partner organisation based in the UK; typically UKPs are equipment donors.

Developing country partner (DCP) is the partner organisation based in the developing country; typically DCPs are recipients of equipment donations.

Donor is the individual or organisation who is donating medical equipment to a recipient in a low-resource setting. In this toolkit, this is the UK partner and the terms are used interchangeably.

Recipient is the health institution in a low-resource setting who is receiving a donation of medical equipment. In this toolkit, this is the DC partner and the terms 'recipient' and 'DC partner' are used interchangeably.

## Scene setting (biomedical engineering)

Medical equipment is broadly defined as any device that is used to diagnose, treat, monitor or rehabilitate a patient that is not implantable, disposable or single-use. For a more detailed definition that explains how medical equipment differs from 'health technology' and 'medical device' see 'Terminology'.

Biomedical engineering personnel are technical professionals, typically technicians, technologists or engineers, who are responsible for the management and maintenance of medical equipment.

Medical equipment lifespan refers to all stages across the lifespan of a device, from pre-selection to post-use (end of life).

Medical equipment maintenance encompasses all of the technical activities across the lifespan of a device that ensure it is safe to use and in good working order. These activities include acceptance and electrical safety testing, calibration, commissioning, preventive maintenance, corrective maintenance (repair), decommissioning and disposal.

Medical equipment management encompasses all of the planning and management activities across the lifespan of a device that ensure it is appropriate for its intended use and provides the best return on investment. These activities include: needs assessment, selection and procurement, budgeting for use and maintenance, training for users and maintenance staff (biomedical engineering personnel), running a maintenance programme, quality and risk management, and inventory and asset management. Medical equipment management is led by

biomedical engineering personnel and involves a variety of stakeholders within the health institution.

Equipment standardisation (also known as rationalisation, normalisation, and harmonisation) is the process of reducing the range of makes and models of equipment in a health facility or system, in order to maintain and manage it more effectively.

## Equipment maintenance

Acceptance testing and commissioning is a series of tests and adjustments made by trained biomedical engineering professionals to ensure the equipment is functioning correctly and safely before use.

Installation is required when substantial assembly work on-site is necessary. For example, equipment that needs to be permanently fixed in place (such as a fixed x-ray system) or requires permanent plumbing, electrical and/or gas pipeline connections (such as an autoclave).

Electrical safety testing is a series of technical tests to ensure the device is electrically safe to use and won't harm the operator or patient. Electrical safety standards are produced by government agencies and international standards organisations, such as the International Electrotechnical Commission (IEC).

Preventive maintenance is routine maintenance performed on medical equipment by trained biomedical engineering personnel to prevent equipment malfunction.

Corrective maintenance is another term for repair, which is performed on medical equipment by trained biomedical engineering personnel to correct equipment malfunction.



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# USEFUL RESOURCES

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## Global Organisations

Many organisations are involved in different capacities in supplying medical equipment to low-resource settings, managing donations, delivering training programmes and working in partnership to improve medical equipment and biomedical engineering services in low-resource settings.

### WHO

The WHO is a global hub for information and resources about medical devices, including policies and resolutions, quality and safety regulations, core and innovative technologies, and the assessment, use and management of [medical devices](#). Some of the resources available include:

- a [baseline country survey](#) that provides a global reference for medical devices by country, including what equipment and services are available
- the [medical device technical series](#), which provides countries with guidance on needs assessments, procurement, [donations](#), inventory management, maintenance and computerised maintenance management systems
- the [compendia of innovative devices](#) to raise awareness of technologies that have been designed specifically for use in low-resource settings
- the [fact sheets on core medical devices](#) that are important for operations in health facilities
- the [‘Managing the Mismatch’ report](#) from the priority medical device project that assessed the availability and current use of medical devices

- profiles of biomedical engineering [success stories](#) in Brazil, Peru, Jordan and the Gambia presented at the WHO’s first global forum on medical devices in Sept 2010

The WHO’s medical device team works with the regional and country offices to implement the resolution [WHA60.29](#) on health technologies, and collaborates with many global [organisations](#) to develop and disseminate its extensive library of medical devices resources.

### HUMATEM (France)

Based in France, HUMATEM is an association that has developed a platform for dialogue and services for those donating medical devices with the aim of improving the quality of medical equipment support projects in developing countries and in particular the quality of transfers of medical devices to health facilities. In order to do this, they manage medical devices for the international solidarity bank, a service which makes it possible to structure medical device donations between healthcare donors and requestor stakeholders.

HUMATEM also runs Biomedon, a French language humanitarian biomedical network that offers international humanitarian workers biomedical technical services (dismantling of equipment, performance controls, recalibration and parameter setting, etc.).

Together with its network of collaborators, HUMATEM has developed a series of excellent resource guides to improve the quality of ‘medical equipment support projects’ between partners in low- and high-resource settings.

These resources include guidance on assessment and planning, evaluating and measuring quality, a step-wise guide for equipping a facility and a factsheet on medical equipment support projects and the role of biomedical engineering professionals:

- Preliminary Assessment Method
- Planning Method
- PRECIS: Quality Reference Framework
- Evaluation Method
- Kitting out a health facility: 5 steps to success
- From the maintenance man to the biomedical operator: for optimal use of all the medical equipment

Note: At the time of writing, these guides had very recently been translated from French into English and will appear in their final English versions on HUMATEM’s website in early 2014.

**Website:** [www.humatem.org](http://www.humatem.org)

**Email:** [contact@humatem.org](mailto:contact@humatem.org)

**Telephone:** +33 (0) 4 50 54 68 83

### CHA International Outreach (USA)

The Catholic Health Association of the United States (CHA) is a membership association of more than 600 hospitals and 1,400 long-term care and other facilities in all 50 American states. It is the nation’s largest group of not-for-profit health care organisations, committed to improving the health status of communities and creating quality health care that works for everyone, especially the vulnerable.

CHA’s international outreach supports members, partnering organisations and the church in a global mission of healing through research, education, consultation and collaboration. Their goal is to foster the development of best practices and expansion of international initiatives that create

effective, sustainable programmes that reduce human suffering and improve health outcomes.

The international outreach team has produced guidance for its members on responsible medical supply and equipment donations, based on a research study that identified leading practices amongst its membership. It has also developed an assessment tool for 'medical surplus recovery organisations' that members can use to evaluate them to ensure their donations are made appropriately.

- [Medical Surplus Donation Study: How Effective Surplus Donation Can Relieve Human Suffering](#)
- [First Do No Harm: Assessing and Selecting High Quality MSROs](#)
- [Responsible Redistribution of Medical Supplies & Equipment: Leading Practices for Hospitals & Health Systems](#)

**Website:** [www.chausa.org/internationaloutreach/medical-surplus-recovery](http://www.chausa.org/internationaloutreach/medical-surplus-recovery)

**Email:** [BCompton@chausa.org](mailto:BCompton@chausa.org)

**Telephone:** +1 314 253 3476

Examples of donation policies

- [South Sudan](#)
- [Pacific Island countries](#)

Others

Most international NGOs are involved in equipment supply and/or training and many bilateral aid agencies are as well. It's best to enquire within the DC about specific organisations who may be working in the area.

## UK-Based Organisations

Amalthea Trust

Amalthea Trust is a UK based NGO committed to improving healthcare in developing countries by providing training and support to biomedical engineers and technicians. As well as training technicians, they work with local educational and healthcare institutions to help with the development and implementation of sustainable biomedical engineering training programmes, allowing countries to produce their own engineers and technicians.

**Website:** [www.amaltheatrust.org.uk](http://www.amaltheatrust.org.uk)

**Email:** [stevend@amaltheatrust.org.uk](mailto:stevend@amaltheatrust.org.uk)

**Phone:** +44 (0) 07803504218

Dentaid

Dentaid is an oral health charity that delivers equipment, training and education to oral health professionals in low-resource settings. It provides UK dental health professionals with volunteering opportunities and has developed a portable dental surgery in a wheelie bin: the "DentaidBox".

**Website:** [www.dentaid.org/](http://www.dentaid.org/)

**Phone:** +44 (0) 07803504218

Durbin PLC

Durbin PLC supplies medical equipment, pharmaceuticals and consumables to healthcare professionals in over 180 countries worldwide. Its NGO and Charities division specialises in sourcing and supplying equipment and pharmaceuticals for use in difficult environments. Teaching materials, test equipment and tools are also available. Durbin also offers worldwide shipment by air or sea freight.

**Website:** [www.durbin.co.uk](http://www.durbin.co.uk)

**Email and phone contacts for different divisions:** [www.durbin.co.uk/contact-us/contact.html](http://www.durbin.co.uk/contact-us/contact.html)

Health Partners International (HPI)

Health Partners International strengthens health systems in developing countries, including health technology management. HPI developed the Planning and Management of Assets in Health Services (PLAMAHS) tool that is used to plan and implement the physical assets component of health reform processes, such as building, utilities and equipment.

**Website:** [www.healthpartners-int.co.uk/](http://www.healthpartners-int.co.uk/)

Hilditch Group

The Hilditch Group sells redundant assets on behalf of most of the UK's hospitals. They hold auctions of all types of medical equipment. All items are 'sold as seen' but Hilditch also has a large medical engineering department that provides condition reports. Every month, thousands of lots of equipment are sold to buyers from every corner of the globe. To receive details of the Hilditch Group's sales and to bid, register on their website..

**Website:** [www.hilditchauctions.co.uk](http://www.hilditchauctions.co.uk)

**Email:** [mikeh@hilditchgroup.co.uk](mailto:mikeh@hilditchgroup.co.uk)

**Phone:** +44 (0) 1666 822577

Imaging in Developing Countries Special Interest Group (IDCSIG)

The Imaging in Developing Countries Special Interest Group (IDCSIG) is a virtual community of radiographers and related professionals with a special interest in imaging in developing countries. The group manages a mailing list, runs a brokering service for 'wanted and available' imaging equipment and promotes good equipment donation practices.

**Website:** [www.idcsig.org](http://www.idcsig.org)

**Email:** [idcsig@yahoo.co.uk](mailto:idcsig@yahoo.co.uk)

## International Development Partnerships

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International Development Partnerships supports communities in rural Ethiopia. As part of its health programme, the organisation has collected used medical equipment from UK hospitals such as beds and sent them to Ethiopian communities.

**Website:** [www.idp-uk.org](http://www.idp-uk.org)

## International Health Partners UK

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International Health Partners is a not-for-profit relief and development organisation that works through partnerships to increase access to medicine and improve health in the developing world. They serve all people regardless of religion, race, ethnicity or gender and according to Christian values (per IHP's Memorandum & Articles of Association).

**Website:** [www.ihpuk.org](http://www.ihpuk.org)

**Email:** [info@ihpuk.org](mailto:info@ihpuk.org)

**Phone:** +44 (0) 1892 784 118

## Medical Aid International

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Medical Aid International is a Community Interest Company that offers practical and on-going equipment support to health care projects in the developing world. They have a track record of success and have the ability to source and deliver the correct medical equipment and supplies from legitimate, high quality and verifiable donors.

Often this is pre owned equipment but they do recognise that sometimes ex-lease or new equipment is more suitable. They have proven experience in managing the logistical process to ensure that the equipment and supplies are delivered making sure in the process that all the money is spent wisely. This project management model means we can equip facilities for a reduced cost compared to buying new or even if they themselves explored the pre-owned market.

It is a fundamental principle of Medical Aid International that we support on

an on-going basis any given project or organisation that they supply and that they work very closely with the local population and existing infrastructures to ensure effective, sustainable provision of health care. This can involve education and data collection. This ensures that our support will be long-term, effective and that there is accountability. Everything that they send out is in working order and they check that it is right for the health care providers who will receive it.

**Website:** [www.idcsig.org](http://www.idcsig.org)

**Email:** [tim@medaid.co.uk](mailto:tim@medaid.co.uk)

**Phone:** +44 (0) 1234 930394

## Medical Support in Romania

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Medical Support in Romania (MSR) exists for the relief of sickness in Eastern & Central Europe, especially Romania, through the promotion of high standards of health care and good clinical practice. MSR focuses on a single institution, Zalău County Emergency Hospital; to upgrade and support its development through the provision of appropriate equipment, consumables, expertise & training.

From 1990 through 2012, 238 mostly British medical & specialist personnel have made 425 visits (inc. 167 visits by 83 Addenbrooke's staff ) to Romania, usually to Zalău Emergency Hospital (twinned with Hinchingsbrooke Hospital). In the same period there have been 113 UK visits by Romanian medical & other staff.

**Website:** [www.msr.org.uk](http://www.msr.org.uk)

**Email:** [pcolquhoun@msr.org.uk](mailto:pcolquhoun@msr.org.uk)

## Mercy Trucks

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Mercy Trucks is a volunteer organisation of professionals and dedicated individuals who help link the resources of one part of the world to the needs of another by using shipping containers and trucks. The organisation provides equipment and supplies and converts trucks into mobile medical and dental units.

**Website:** [www.mercytrucks.org](http://www.mercytrucks.org)

**Email:** [RoyDixon@MercyTrucks.org](mailto:RoyDixon@MercyTrucks.org)

**Phone:** + 44 (0) 870 126 9120

## Scotland Malawi Partnership (SMP)

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SMP is an umbrella organisation that advocates, facilitates sharing and provides good practice guidance for Scottish - Malawian partnerships such as their [good practice guide on shipping donations](#).

## Aid to Hospitals Worldwide (A2HW)

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This organisation is no longer operational. Aid to Hospitals Worldwide was a UK-based equipment donation charity that worked with NHS Trusts to supply health facilities in low-resource settings with equipment and supplies. The organisation ceased operations in 2013 but can still be contacted with queries at the time of writing; contact details are on the website.

**Website:** [www.a2hw.org.uk/](http://www.a2hw.org.uk/)

## Others

### Motivation

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[www.motivation.org.uk](http://www.motivation.org.uk)

### CBM UK

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[www.cbmun.org.uk](http://www.cbmun.org.uk)

### Handicap International UK

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[www.handicap-international.org.uk](http://www.handicap-international.org.uk)

### HealthProm

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<http://healthprom.org>

### Kids for Kids

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[www.kidsforkids.org.uk](http://www.kidsforkids.org.uk)

### Partner Aid

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[www.partneraid.org](http://www.partneraid.org)

### Maternal and Childhealth Advocacy International

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[www.mcai.org.uk/](http://www.mcai.org.uk/)

### Progressio

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[www.progressio.org.uk](http://www.progressio.org.uk)

500 miles

[www.500miles.co.uk/](http://www.500miles.co.uk/)

## Appropriate Technologies

### Diamedica (UK)

Diamedica (UK) Ltd specialise in anaesthetic equipment for harsh environments and low-resource settings. Designed for simplicity, economy and reliability, our equipment functions effectively in locations lacking first world infrastructure. Used in over 50 countries, our range extends from full hospital anaesthetic machines, to portable equipment for field hospitals and humanitarian situations.

**Website:** [www.diamedica.co.uk/english/](http://www.diamedica.co.uk/english/)

**Email:** [info@diamedica.co.uk](mailto:info@diamedica.co.uk)

**Phone:** +44 (0) 1598 710066

### Gradian Health Systems

Gradian Health System's Universal Anaesthesia Machine (UAM) is designed to deliver anaesthesia in any hospital, including those where unreliable electricity and shortages of compressed oxygen preclude the use of conventional machines. In addition to installing the machine, Gradian trains clinicians and biomedical technicians on how to use and service the UAM at every hospital where it is installed. The machine is currently in use in 15 countries around the world and is a critical component to enabling safer surgery to take place at the district level.

**Website:** [www.gradianhealth.org/universal-anaesthesia-machine](http://www.gradianhealth.org/universal-anaesthesia-machine)

**Phone:** +1 212 537 0340

### Lifebox

Lifebox is a global health charity working to make surgery safer in low-resource countries. Lifebox provides training in the World Health Organization (WHO) Surgical Safety Checklist and an intelligently designed, environment-appropriate pulse oximeter to hospitals working

without this vital monitoring. Inquiries can be made about oximeter package donations to DC partners.

**Website:** [www.lifebox.org](http://www.lifebox.org)

**Email:** [info@lifebox.org](mailto:info@lifebox.org)

**Phone:** +44 (0) 0203 286 0402

### Others:

- [D-Rev](#)
- [Medical Technology Transfer and Services](#)
- [Laerdal](#)
- Many more in the WHO compendia of innovative technologies [2010](#), [2011](#) and [2012](#)

## Shipping

DHL - The Logistics company for the world

DHL is the global market leader in the logistics industry and "The Logistics company for the world". DHL commits its expertise in international express, air and ocean freight, road and rail transportation, contract logistics and international mail services to its customers. A global network composed of more than 220 countries and territories and about 275,000 employees worldwide offers customers superior service quality and local knowledge to satisfy their supply chain requirements. DHL accepts its social responsibility by supporting climate protection, disaster management and education.

DHL is part of Deutsche Post DHL. The Group generated revenue of more than 51 billion euros in 2010.

**Website:** [www.dhl.co.uk](http://www.dhl.co.uk)

## Additional Resources for Partnerships

### THET Resource Library

THET has created an online [Resource Library](#) that houses publications, presentations, case studies and toolkits that give advice and guidance on implementing and managing a health partnership successfully. The resources have been created by THET

and external contributors working directly in health partnerships. As such, the material draws on extensive knowledge in order to provide clear and accessible guidance to make sure partnership work achieves its goals.

- [THET's International Health Links Manual](#)
- ['What difference are we making?': A Toolkit on Monitoring and Evaluation for Health Links](#)

### [Resource Package for African Partnerships for Patient Safety \(APPS\)](#)

The resource package was co-developed by frontline health professionals through a pioneering WHO programme, African Partnerships for Patient Safety (APPS), which pairs 14 African hospitals each with a hospital in England, France or Switzerland.

APPS is concerned with advocating for patient safety as a precondition of health care in the African Region and catalysing a range of actions that will strengthen health systems, assist in building local capacity and help reduce medical error and patient harm.

## Journals, Textbooks And Other Learning Resources

### HINARI library

Many journals are available free of charge for health care professionals working in developing countries through the WHO's HINARI programme.

### Journal of Clinical Engineering

This journal is a quarterly publication for biomedical engineering professionals. It covers health technology management research and experiences on topics such as regulation, quality control, assessment and management of devices. It is available through HINARI.

### IPEM Medical Engineering and Physics

This journal used to be known as the



Journal of Biomedical Engineering. It is published by IPEM for engineers and clinicians and focuses on the application of physics and engineering to develop medical devices and technology. It is available through HINARI.

#### AAMI Biomedical Instrumentation & Technology

Biomedical Instrumentation & Technology (BI&T) is a bimonthly journal for developers, managers and users of medical technology published by the US-based Association for the Advancement of Medical Instrumentation (AAMI).

#### **Care and Safe Use of Hospital Equipment**

VSO Books (1995) - Skeet M and Fear M

This resource provides practical advice for hospital staff about proper management of equipment, including guidelines on preventive maintenance and service, simple user instructions, checklists for correct and safe use of equipment and basic technical information for training of first-line maintenance staff.

#### Clinical Engineering Handbook (1st edition)

Elsevier (2004) - J. Dyro (editor)

This textbook provides best practice for clinical engineers from an international perspective, and includes case studies of clinical engineering in developing countries.

#### Medical supplies and equipment for primary health care: A practical resource for procurement and management

ECHO (2001)

This book is for health workers responsible for selecting and managing medical equipment for

primary health care services in low-resource settings.

#### Diagnostic Imaging in the Community: a Manual for Clinics and Small Hospitals

PAHO and Rotary International (2011)

This manual is for clinics and small hospitals that are deciding whether or not to offer diagnostic imaging services, or already have the equipment and need to set it up and run it safely.

#### MAINTENANCE Manual for Laboratory Equipment (2nd edition)

WHO and PAHO (2008)

This maintenance manual for laboratory equipment covers the purpose, operation, installation, use, troubleshooting, preventive maintenance and good practice for laboratory devices including: microplate readers, microplate washers, pH meters, balances, water baths, biological safety cabinets, centrifuges, water distillers, dilutors, spectrophotometers, autoclaves, drying ovens, incubators, microscopes, pipettes, heating plates, refrigerators and freezers, chemistry analysers and colorimeters.

#### Guide to Ophthalmic Equipment

ORBIS (2004)

This guide introduces some of the more commonly used devices and is mainly written for persons who are not eye care professionals wishing to know what each device looks like and to understand how it is used.

#### Study on donations in Ghana

PQMD (2008)

This mapping of donation practices in Ghana provides good context for how donations happen and by whom.

#### **'How to Manage' series of health care technology guides**

This series of guides detailing how to manage health care technologies in low-resource settings is the most comprehensive set of resources

available on the topic.

Published in 2005, the series of guides was developed by Ziken International in partnership with experts from international organisations such as ECHO International Health Services in the UK (no longer in existence), FAKT in Germany, the World Health Organisation (WHO), the Pan American Health Organization (PAHO), GIZ (formerly GTZ), the Swiss Tropical Institute, and the Medical Research Council of South Africa.

The production of the guides was funded by DfID.

The series of six guides cover the following topics:

- Guide 1 - how to organize a system of healthcare technology management
- Guide 2 - how to plan and budget for healthcare technology
- Guide 3 - how to procure and commission your healthcare technology
- Guide 4 - how to operate your healthcare technology effectively and safely
- Guide 5 - how to organize the maintenance of your healthcare technology
- Guide 6 - how to manage the finances of your healthcare technology management team

Each guide includes guidance, templates and resources for further reading.

#### Frank's Hospital Workshop

This website is a collection of documents, experiences, best-practice procedures and teaching and learning materials about biomedical technology. It includes electronic and biomedical training modules, a library of service and user manuals, and datasheets for medical devices.

#### Open University Course on Healthcare Technology Management

The Open University offers a free online course on health technology

management via OpenLearn LabSpace that is approximately 15 hours long.

#### TALC (Teaching Aids at Low Cost)

TALC is a charity that supplies affordable books and teaching aides for health promotion and community issues in developing countries.

## Discussion Groups

#### EBME (UK)

The EBME website has over 7000 members from the medical engineering profession. It includes discussion forums, UK supplier information, product information, news and events.

#### Medical physics listserv (UK)

Email-based listserv is for UK medical physics professionals to network, discuss new developments and field questions to colleagues.

#### IET Appropriate Healthcare Technologies (AHT) for Low Resource Settings conference (UK)

The AHT conference brings together biomedical engineers, researchers, academics, manufacturers, NGOs and policy makers to discuss medical technology challenges and opportunities for low-resource settings and is an excellent networking and discussion opportunity. The Institution of Engineering and Technology (IET) hosts it every two years and in alternate years it hosted by the Institution of Mechanical Engineers (IMechE). In September 2012, Lord Nigel Crisp launched THET's medical equipment partnerships programme at the AHT.

#### THET's Community of Practice (UK and DC)

Online discussion group to communicate with other partnerships or individuals, ask questions, seek advice, offer opinions and announce events.

#### INFRATECH

An email-based discussion forum (a listserv) for biomedical engineers and related professionals globally, with a focus on issues in low-resource settings. It's an excellent network and source of information. There is also a web archive of past discussions online.

#### ECRI Institute Biomedtalk

Biomedtalk is an online discussion forum for clinical technicians, technologists and engineers, run by the ECRI Institute. While some topics are specific to the US, many of the discussions would be useful to UK-based practitioners as well.

#### Diigo INFRATECH group

This group is a collection of health technology management and global health articles and resources. Registration settings can be configured for how new content is received.

## Professional Societies and Organisations

#### **UK professional societies**

#### Institute of physics and engineering in medicine (IPEM)

IPEM is a professional organisation representing Physicists, engineers and technologists. They are a charity with over 4,000 members from healthcare, academia and industry. IPEM have an online discussion area for members.

- [IPEM policy statement: Managing Medical Physics and Clinical Engineering Services](#)
- [IPEM Scope magazine \(Quarterly magazine for IPEM members\)](#)

#### Institution of Engineering and Technology (IET)

The IET is a professional organisation sharing and advancing knowledge to promote science, engineering and technology across the world. It has more than 150,000 members worldwide in 127 countries

#### Institute of Healthcare engineering and estate management

IHEEM is an International Professional Engineering Institute, a specialist Institute for the Healthcare Estates Sector. IHEEM's primary purpose, as a professional development organisation, is to keep members up to date with developing technology and changing regulations, and various types of membership are available.

#### **Global professional societies**

- [International Federation for Medical and Biological Engineering \(IFMBE\)](#)
- [International Federation of Hospital Engineering \(IFHE\)](#)
- [International organization for medical physics \(IOMP\)](#)
- [American College of Clinical Engineering](#) runs health technology management workshops in DCs

#### **Other national professional associations and training institutions**

- [www.who.int/medical\\_devices/support/en/index.html](http://www.who.int/medical_devices/support/en/index.html)

# APPENDIX A:

## UK MEDICAL DEVICE REGULATIONS AND MHRA GUIDANCE

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### Medical device regulations

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Medical device regulations require manufacturers to ensure their devices are safe and fit for purpose before being placed on the market.

As part of the European Union (EU), the UK must comply with [EU legislation regarding medical devices](#) and the transfer of pre-owned equipment. There are two types of EU legislation:

- Regulations that apply directly to member states
- Directives that must be 'transposed' in member states (legally implemented through national regulations)

The level of regulatory oversight for particular devices is proportional to the risks associated with them, determined by a [standard classification](#).

Medical devices in the UK are regulated by the [MHRA](#) through the [Medical Device Regulations \(2002\) as amended](#), which are issued under the Consumer Protection Act (1987). There are various other pieces of UK legislation that also apply to devices, such as the Health and Safety at Work Act (1974).

The [CE mark](#) is a symbol placed on a medical device that declares its compliance with [EU medical device Directives](#) regarding the health and safety of patients, users and third parties. It represents a certificate of performance and compliance generated by the manufacturer, and enables the device to be traded on the European Economic Area market.

### Guidance on managing medical devices

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The MHRA also provides guidance on good practice for organisations that manage medical equipment: [Managing Medical Devices](#). This guidance covers lifecycle management of medical equipment including:

- monitoring/audit
- reporting adverse incidents
- acquiring the most appropriate device
- acceptance procedures for newly delivered devices
- maintenance and repair
- training
- adequacy of manufacturer instructions
- prescribing the best device
- decontamination
- decommissioning
- disposal
- transfer of ownership and legal liabilities

### Specific guidance on transfer of ownership

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Medical equipment donations to developing countries are not explicitly covered in the current version of the guidance. However it does provide specific guidance on the transfer of ownership of equipment that should be applied appropriately to any transfer, regardless of the destination.

The MHRA recommends that all requirements a manufacturer must meet for a new device (to conform to the UK's medical device regulations) apply equally to the transfer (sale or donation) of pre-owned equipment. The main requirement states that manufacturer provide the buyer with: "all the information needed to verify

whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times."

The guidance also suggests the following be provided along with the equipment being transferred:

1. a clear statement that the equipment is being resold/donated
2. certificate of decontamination
3. user manuals and training requirements
4. full details of maintenance and servicing requirements
5. service history and manual
6. usage history
7. quality assurance test details
8. safety updates, including MHRA and manufacturer documents that have been released since the medical device was first supplied.

Finally, MHRA guidance stresses that for any transfer of pre-owned equipment, both parties must be clear about their legal liabilities and the donor should ask the recipient to sign a disclaimer that the donor has no future responsibility for the equipment.

Note that at the time of writing, the guidance is currently under review. The new edition is scheduled to be available by the spring of 2014. Readers are encouraged to check with the MHRA for information about the updated version at the time of reading.

# APPENDIX B:

## LEGISLATIVE CONTEXT FOR PRE-OWNED EQUIPMENT TRANSFERS OUTSIDE OF THE EU

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### EU and UK legislation

The UK is the first EU member country to transpose the [EU Directive 2012/19/EU on waste electrical and electronic equipment \(WEEE\)](#) into national regulations. This Directive covers the management of electrical and electronic equipment waste through reuse, recycling and other forms of recovery to reduce the environmental impact of disposal.

Directive 2012/19/EU 'recast' 2002/96/EC to cut down on illegal dumping of waste both in landfills within the EU and through transfers outside of the EU (often to developing countries). It was estimated that despite the 2002/96/EC directive, only 1/3 of the EU's WEEE was being treated appropriately.

Medical devices are contained within the scope of the directive according to Annex II: 8. Two additional categories of equipment relevant for readers of this toolkit who wish to donate engineering tools and test equipment for maintenance staff are: 'electrical and electronic tools' (Annex II: 6) and 'monitoring and control instruments' (Annex II: 9).

The [UK's implementation of the directive](#) includes draft [Waste Electrical and Electronic Equipment Regulations 2013](#) that are due to come into force in January 2014.]

### Minimum requirements for shipment

The minimum requirements for shipment of pre-owned electrical and electronic equipment outside of the EU to prove they are not WEEE are covered in Annex VI of the EU directive and Schedule 14 of the UK's draft regulations.

Certain criteria must be met to demonstrate and document that the equipment is fit for re-use:

- The device must be tested and shown to be free of hazardous substances. The testing depends on the device but for medical equipment a functionality test that demonstrates the device is fit for purpose is sufficient.
- The test results should be described, dated and provided with full contact information for the entity responsible for the tests (be it the manufacturer, a re-seller, an engineering department with certified staff and an accredited quality system, or another responsible organisation).

The transfer must also be accompanied by the following information/records:

- Copy of the invoice and contract relating to the sale and/or transfer of ownership of the equipment which states that it is destined for direct re-use and that it is fully functional
- Name of the item, with reference to the category in Annex II of the EU Directive if explicitly listed and reference to a unique nomenclature system identifier if applicable (such as the [GMDN](#) code or the [UMDNS](#) code)
- Identification of the item, including details such as make and model, manufacturer, serial number, year of production, etc.
- Records of all technical tests (functionality, safety and decontamination) as described above for each item within a consignment, including an explicit statement that the equipment is free from hazardous substances

- A declaration by the liable person on its responsibility
- A declaration made by the holder who arranges the transport that none of the material or equipment within the consignment is waste as defined by Article 3(1) of [Directive 2008/98/EC](#)

During a transfer, the results of these tests must accompany the device; if the device is unpacked they should be attached securely but not permanently to the device itself. If the device is packed, they should be affixed to the packaging so they can be read without unpacking the equipment.

The transfer must also ensure appropriate protection against damage during transportation, loading and unloading in particular through sufficient packaging and appropriate stacking of the load. It must also be accompanied by a relevant transport document such as a bill of lading or an air waybill.

This is necessary to be able to properly demonstrate that the donation shipment contains functional equipment intended for re-use that should reach the DC partner institution in good working order. Otherwise, the shipment may be assumed to be a shipment of waste EEE outside of the EU, which is illegal and subject to Articles 24 and 25 of [EU regulations on shipment of waste](#).

Readers are encouraged to consult the UK government at the time of reading for the final version of the new UK WEEE regulations and guidance on compliance. The EU also provides [further reading](#) about the WEEE and the new Directive.

# APPENDIX C:

## TO DONATE OR NOT TO DONATE?

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The partners should read through the remaining sections of the toolkit for more detailed information while answering these questions.

### What Should be Asked in the UK?

- Do you have a very clear idea of what equipment is required?
- Do you have an understanding of the DC partner's capacity to use and maintain the equipment?
- Is the proposed equipment appropriate and suitable to their current situation?
- Are you able to either provide or arrange for any training that may be required for the recipients to both use and maintain the equipment?
- Have you factored in the costs of this training?
- Are you able to provide ongoing advice to the DC partner if they require it?
- Do you know what the electrical requirements are at your partner hospital?
  - What voltage and frequency does their power system operate on?
  - How reliable is the electrical supply in the hospital? Do they have scheduled or unscheduled interruptions?
  - If the equipment requires 3-phase power, is it available or does it need to be set up?
- Are you able to source all of the necessary support items initially required for the equipment, such as user and service manuals, accessories and consumables, spare parts and any necessary electrical equipment (such as voltage regulators, converters, or uninterruptible power supplies) for a certain period of time?
- Do you have clinical and technical (engineering) staff available to provide this advice? If not, can you arrange for it with another agent, such as the supplier or manufacturer?
- Do you know how the equipment can be sourced?
- Have you looked into in-country procurement of new equipment? Would you be able to finance this as an alternative to UK sources of equipment?
- Do you know much it will cost to ship the equipment and what is required of you?
- Do you have the capacity to finance the operation and maintenance costs for the equipment (for a specific time period) if your partner does not?
- If you are planning to donate equipment that is currently owned by your Trust, are you aware of all relevant policies and procedures relating to removal from service and transfer of ownership?
- Are you adhering to all relevant Trust policies on equipment disposal and donation?
- Do you have the support of your Trusts' leadership for the donation?
- Do you understand the requirements of the EU directive 2012/19/EU and are you able to meet them? Who will you need to engage to provide the technical services to meet these requirements?
- Does your hospital - or your MoH - have a policy on equipment donations? If so, what requirements are outlined in it and will the proposed donation meet them?
- Does your hospital - or your MoH - have a procurement policy? If so, will the donation meet its main requirements?
- Is there a genuine clinical need for the equipment?
- Would the equipment require changes in processes and if so, have these been discussed and are you able to manage the changes?
- Do you have clinical staff already trained on the type(s) of equipment?
- If the equipment is sophisticated, does your clinical staff require additional training on an unfamiliar brand of the device (i.e. a new manufacturer, make/model)?
- Are your technical/maintenance/engineering staff aware of the proposed donation, and do they have input about the maintenance requirements?
- Have the technical/maintenance/engineering staff been trained to maintain this type of equipment?
- Do they have the right tools and any special engineering equipment to do the maintenance?
- Are they able to order any spare parts they may need?
- If you don't have a technical/maintenance/engineering team who can do the maintenance, is there someone locally who can be contracted to service the equipment?
- Is there enough space for the equipment in the area in which it is needed?
- What is your electrical supply situation?
- Is there proper infrastructure for the equipment? For example, it may require room ventilation; three-phase power or uninterruptible power supply (UPS), water and/or medical gas supply.
- Is your senior leadership aware of the proposed donation, and do they support it? Are they aware of the financial implications of using the equipment?
- Is there a budget in place for ongoing costs associated with the equipment, such as consumables and reagents, maintenance materials (such as spare parts) and a service contract if necessary?

### What Should be Asked in the DC?



# APPENDIX D:

## OVERVIEW OF THE EQUIPMENT DONATION PROCESS

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### **Stage 1: Deciding whether or not to donate**

- Clarify what equipment is needed, and what support is required for it to be useful
- Determine whether the needs can be met by both partners
- Based on this assessment, decide whether or not to proceed with the donation

### **Stage 2: Planning the donation**

- Agree on the terms of the donation
- Develop a project plan outlining the activities, tasks, stakeholders and timelines for the donation
- Draft a donation agreement

### **Stage 3: Supplying the equipment**

- Examine all options for sourcing equipment and select the best one
- Source all the materials needed to use and maintain the equipment, including tools and test equipment
- Helpful to supply equipment or use manufacturers that are already used by the DC partner

### **Stage 4: Verifying quality & safety**

- The quality and safety of the equipment must be verified prior to sending it to the DC partner
- The equipment must be proven to be functional or it will not meet legislative requirements for transfer
- A medical engineering team is essential to verify and document the quality, safety and functionality of the equipment

### **Stage 5 Storing, packing & shipping**

- Follow manufacturer's instructions for storage, packing and shipping
- Know the import requirements and work with a reliable courier or freight company that sends goods regularly to the DC
- Investigate all options for receiving tax and duty waivers

### **Stage 6: Receiving the equipment**

- Be aware of the customs clearance process in advance and make sure everything in the container is listed on the packing list and allowable for import
- The DC partner's processes for receiving goods, registering new assets and testing their integrity should be followed
- Important that the DC partner feeds back to the UK partner any issues with the shipment

### **Stage 7: Putting the equipment into service**

- Train the clinical staff who will use the equipment and the engineering staff on both 'corrective' and 'preventive' maintenance
- Commission the equipment
- Look at partnership activities which could assess and build biomedical engineering capacity

# APPENDIX E:

## MEETING THE WHO'S SUITABILITY CRITERIA

The WHO has five criteria for determining whether a proposed donation is suitable. These questions help determine whether the proposed donation is suitable or not.

### 1. Is the equipment appropriate to the setting? Yes, if it is:

- 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

### 2. Is the equipment good quality and safe? Yes, if it is:

- 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 sterilised without rusting
- manufactured to meet internationally recognized safety and performance standards
- suitably packaged and labeled so that it is not damaged in transit or during storage
- provided by reputable, reliable, licensed manufacturers, or registered suppliers

### 3. Is the equipment affordable and cost-effective? Yes, if it is:

- 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 specialised training required)

### 4. Is the equipment easy to use and maintain? Yes, if:

- 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)

### 5. Does the equipment conform to the recipient's policies, plans and guidelines? Yes, if it:

- Conforms with any active purchasing and donations policy that may exist
- Conforms with any equipment standardisation policies that may exist
- Conforms with the level of technology described in any standard equipment lists and generic equipment specifications that may exist
- Conforms with any conclusions resulting from a review of literature and comparative products
- Conforms with any conclusions resulting from feedback regarding previous purchases and donations

[WHO donation guide, page 16]



# APPENDIX G:

## DONATION AGREEMENT TEMPLATE

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Some of these sections will be more applicable to pre-owned equipment being supplied from the UK than to new equipment procured in the UK or the DC. Be sure to reference relevant standards and legislation being met.

Content can be filled in as the planning progresses, and the agreement should be consistent with other partnership documentation and processes. This agreement is a template only that can and should be adapted by the partners.

### 1. Background

#### Guidance for section 1: Background

---

Recommended content:

- Who are the partners and what is the history of the partnership?
- What is the motivation for the donation?
- How will it contribute to the partnership objectives?
- What were the outcomes of the needs and capacity assessment?

An example of the motivation for a donation is: “to provide Katete General Hospital with an appropriate, functional ultrasound scanner to improve prenatal screening services.”

Any documentation from the needs and capacity assessment that is relevant can be appended to the donations agreement.

## 2. The equipment and related items



### Guidance for section 2: The equipment and related items

#### Recommended content:

- What medical equipment is being donated?
- What tools and test equipment are being supplied with the equipment?
- What accessories, consumables, reagents and spare parts are being supplied as well?
- What information and training materials are being supplied with the equipment?

This is a good place to state that the equipment is fully functional and intended for re-use in the DC.

If the donation includes several items, a list can be drawn up with quantities and details and appended to the back of the agreement.

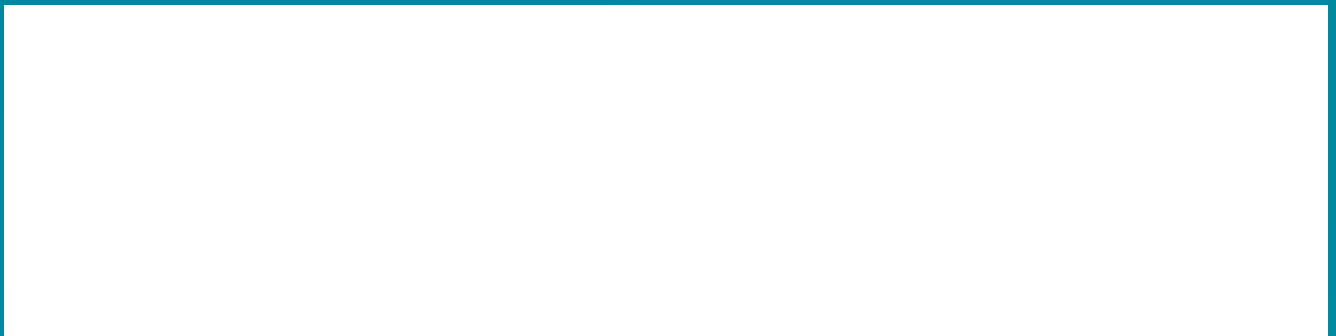
Include as much specific information as is known at this stage of the process about the medical equipment being supplied, such as type, manufacturer, make and model, serial number, quantity, etc. Include the same type of information for the maintenance resources (tools and test equipment).

Include details of which accessories (such as leads), consumables (such as filters and tubing), reagents and spare parts are being supplied and/or required for the equipment for a specified agreed upon period of operation.

Include details about the information and training materials being supplied with the equipment, such the user manual, the maintenance manual, spare parts listings, accessory, consumable and reagents parts listings (and supplier contact details), and other training materials included.



## 3. Supplying the equipment and related items



### Guidance for section 3: Supplying the equipment

#### Recommended content:

- Who is involved in equipment supply from the UK and what certification do they have?
- What else are they providing (i.e. shipping, technical support to the DC partner, etc.)?
- Are they offering a guarantee or warranty if they are a manufacturer or supplier?
- What is the total cost and how is it being covered?

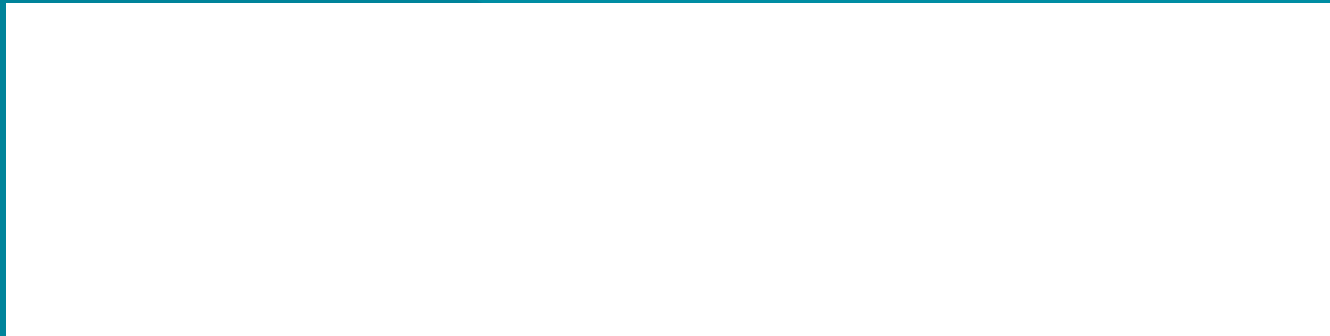
Provide all information about the UK supplier(s) of the equipment, including their terms and conditions and the standards they meet.

If it's the UK partner itself, be clear about the transfer of liability for the equipment (which differs from a supplier that may offer a guarantee or warranty).

If equipment is being supplied locally in the DC, provide details of the local policies and procedures that will be followed and the availability of technical services locally.



#### 4. Technical services for pre-owned equipment from the UK



##### Guidance for section 4: Technical services for pre-owned equipment from the UK

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Recommended content:

- Which technical services have been performed on the equipment before it is shipped?
- Who has performed the tests and what certification do they have to perform the tests?
- What records of the tests are provided?
- What are the costs associated with the services and who is covering them?

This should include a summary of the technical tests performed to ensure the device is fit for re-use (if pre-owned), free of hazardous substances and any maintenance done on it.

The summary doesn't need to contain details of the tests; this is captured in the reports, which can be appended to the agreement when ready. Remember some of them are requirements for shipping pre-owned equipment.

For equipment being supplied locally in the DC, provide similar details about the technical services being provided initially.



#### 5. Storing, packing and shipping the equipment



##### Guidance for section 5: Storing, packing and shipping the equipment

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Recommended content:

- How is the equipment being stored and packed?
- Which shipping agent has been identified and how are the goods being shipped?
- What are the DC's customs requirements and how are they being met?
- What are the costs associated with the shipment and who is paying them?

Reference any specific DC import requirements that must be met and any special shipping requirements.

Include organisations that may be involved in supporting a tax and duty waiver application.

## 6. Receiving the equipment

### Guidance for section 6: Receiving the equipment

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Recommended content:

- Who is clearing the goods through customs?
- How are they being transported to the DC partner facility?
- Who is receiving the equipment at the facility and verifying its contents?
- Which technical service providers (from within the DC partner or external to it) will perform acceptance testing and commission the equipment?

Include details about the local freight agent and customs clearance, the transportation plan and any special requirements. Reference any local standards for transport, acceptance at the facility and testing.

The DC partner should commit to feeding back to the UK partner with any problems. Provide a brief commitment to regular communication between all stakeholders in this process.



## 7. Using and maintaining the equipment

### Guidance for section 7: Using and maintaining the equipment

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Recommended content:

- What user training is required and who will provide it?
- What service training is required and who will provide it?
- Will it include training of trainers?

Reference any materials identified for the training course(s), as well as the plan for follow up support (if any).

## 8. Monitoring and evaluating the donation

### Guidance for section 8: Monitoring and evaluating the donation

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Recommended content:

- How will the donation be monitored as it's progressing?
- How will the partners evaluate it?
- How will this inform future partnership's activities?

Describe the monitoring and evaluation plan for the donation. It should be useful and not very onerous.



## 9. Communication

### Guidance for section 9: Communication

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Recommended content:

- How will the partners communicate about the donation?
- How will issues be addressed and resolved?
- Are both partners clear about the other's expectations?

Provide very brief details about the partnerships usual communication channels and who may be involved in more frequent communications regarding the donation.

# APPENDIX H:

## SAMPLE LETTER OF WAIVER OR INDEMNITY

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{Donor's address}

Date:  
{Project's address}

Dear .....

Letter of Waiver or Indemnity

Please we would ask you to sign this letter of waiver or indemnity.

I, {project rep or coordinator} on behalf of {name of project}, hereby agree that:

The .....{Donor}.....will not be liable for any issues with the equipment, with regards to inaccuracy of data and the infrastructure.

Any problems that may be seen as misuse from the equipment or incident thereof will be ..... {project}..... sole responsibility.

The testing and accuracy of the equipment and subsequent incorporation to your department quality systems is also your sole responsibility.

There will be no legal commitment on the part of .....{donor}..... or any of it's employees if an injury or incorrect treatment is delivered to the patient due to the use of the equipment.

There will be no expectation of resources from .....{donor}....., and if any is required, the cost will be negotiated between the relevant parties.

Signed: .....

Kind regards  
Sincerely,

.....

(Donor)

# APPENDIX I:

## EXAMPLE OF CLEARING A CONTAINER AT MOMBASA PORT, KENYA

This is an example of the process undergone to clear a container of equipment at Mombasa's seaport in Kenya, provided by Manager for UK and Ireland Aid and Relief Services with DHL

### Documents required:

- Bill of lading
- Commercial invoice
- Gift certificate
- Packing list
- Freight invoice or charge information

Obtain confirmation of vessel arrival and shipping line's manifest info

Enter details onto customs' SIMBA system - if the system is up and the internet is working

Obtain Mombasa Port Release Document from Port Authority after unloading from vessel to add to our docs for customs endorsement

Shipping line will also enter info to customs - if there is an error allow an extra day

Wait for customs response on duty/tax calculation. On many entries customs will re-assess values/classifications - if this happens...

- Request customs to cancel the original entry so we can re-enter
  - customs often take 24 hours to action request
- Pay duty by cheque and obtain official receipt - often 2 hours queue

Once entry is passed, clerk goes to the Central Docs Office (CDO) within Mombasa port with hard copies of all docs. CDO officers will check all docs are genuine and compare with info on SIMBA - if the system is up and the internet is working! If not, go back the following day

Take the approved docs from the CDO to the officer who decides which containers will be allowed normal verification and which are selected for scanning or physical search - hope ours isn't one of them

Take documentation to the Kenya Bureau of Standards Quarantine/Heath office for their approval

Go to the Port Authority Office for confirmation and payment of the port charges

The Port Authority checks our docs against hard-copy docs from the shipping line - any discrepancy will be a one day delay while an amendment is filed

Container is transferred to the verification area - normally around 6 hours unless selected for scanning/physical search, in which case 24-48 hours is normal

If the cargo is not as described on the documents customs may require any or all of the above steps to be repeated!

When customs are happy the release order is handed to the port authority who issue a loading slot for the truck collecting the container from the port - bookings are rarely for the same day





# APPENDIX J:

## POST-DONATION ASSESSMENT FORM

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Which items of equipment were donated?

Did any of them arrive damaged?

What is the current status of the different pieces of equipment?

Which items are not working (if any), and why?

Which clinical areas were they sent to?

**Was installation required for any of the equipment? If so, who did the work and were there any problems encountered?**

**Did the maintenance staff test the equipment when it first arrived? If so, what tests did they perform?**

**Do you have the consumables you need to operate the equipment (if required)? If not, which ones are difficult to source and why (cost, hard to find supplier, etc.)?**

**Do you have any parts to repair the equipment if needed? If not, what are you missing and why (expensive, hard to find supplier, etc.)?**

**Did any training for users take place? If so, who performed the training and when did it take place? How long was it and what (generally) was covered?**

**Did any training for the maintenance staff take place? If so, who performed the training and when did it take place? How long was it and what (generally) was covered?**

**Do the maintenance staff have any tools or test equipment to perform maintenance on the equipment? If yes, which ones?**

**Is the equipment on a service contract? If so, do the engineers come on schedule and are you satisfied with their work?**

**Do you have user and service manuals for the equipment? Where are they?**

**Who do you call if the equipment stops working?**

**Has the equipment enabled you to offer new services?**

**Has it enabled you to expand services?**

**Have there been any unintended bad consequences of the equipment?**

**How often do you contact your partner hospital about the equipment?**

**Feedback on the overall experience - 3 things that went well and 3 things to change**





