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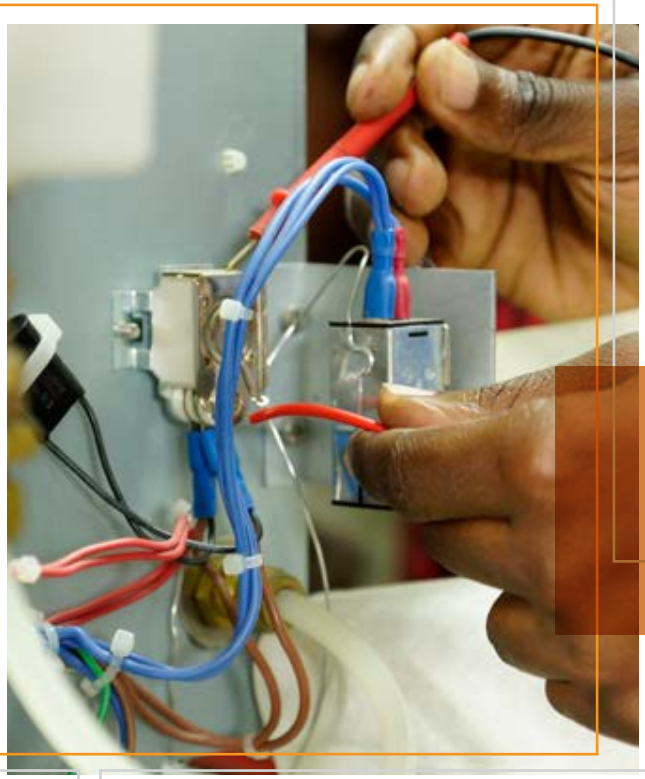
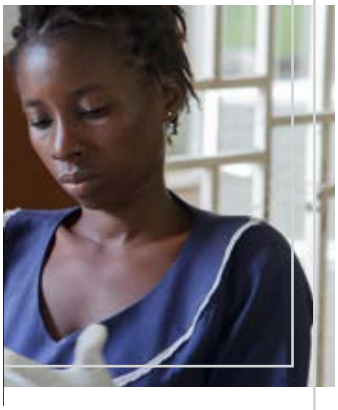
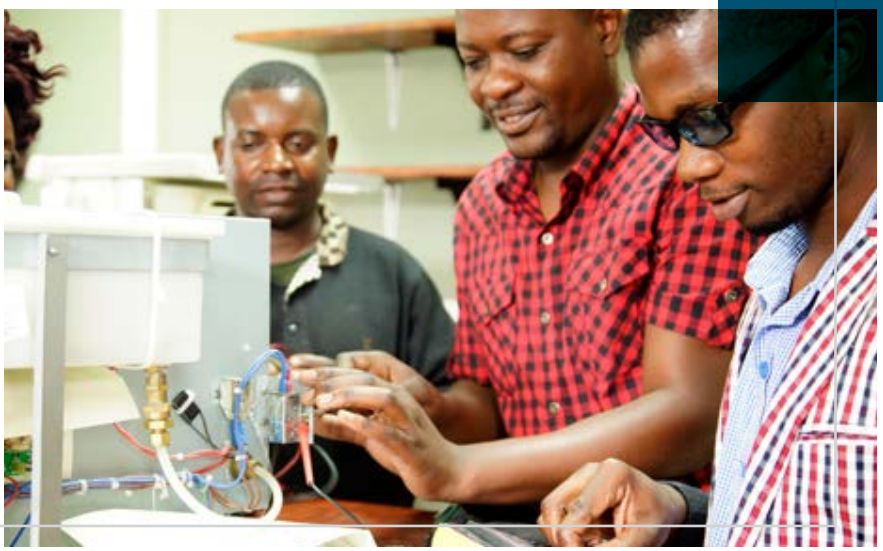
PARTNERSHIPS FOR GLOBAL HEALTH







MANAGING THE LIFECYCLE OF MEDICAL EQUIPMENT

CONTENTS

ABOUT THIS GUIDE

Health Partnerships working in low-resource settings frequently encounter challenges relating to medical equipment that can influence the success of their projects. These challenges include a lack of functioning equipment, and other aspects of what is called 'Healthcare Technology Management (HTM)'. HTM concerns the management of the medical equipment life cycle; from planning to purchase, installation, operation all the way through decommissioning and disposal.

This resource serves as a companion to the **Making it Work** toolkit, published by THET in 2013 and offers an overview of the steps of the equipment life cycle and ways for partnerships to integrate these considerations into their projects.

This resource identifies 'Assumptions'; expectations which might be valid for high-resource settings but which are not necessarily valid for low – and middle-income countries (LMICs). These are linked to 'Mitigations'; potential ways to prevent setbacks and to improve the progress of the project and the quality of healthcare in the LMIC. Some of the mitigations need the support of a technical expert, but many can be done without additional resources.

THE EQUIPMENT LIFE CYCLE

This resource follows the Equipment Life Cycle as it is often used in Healthcare Technology Management (HTM). The cycle is divided in 4 phases and 9 topics.

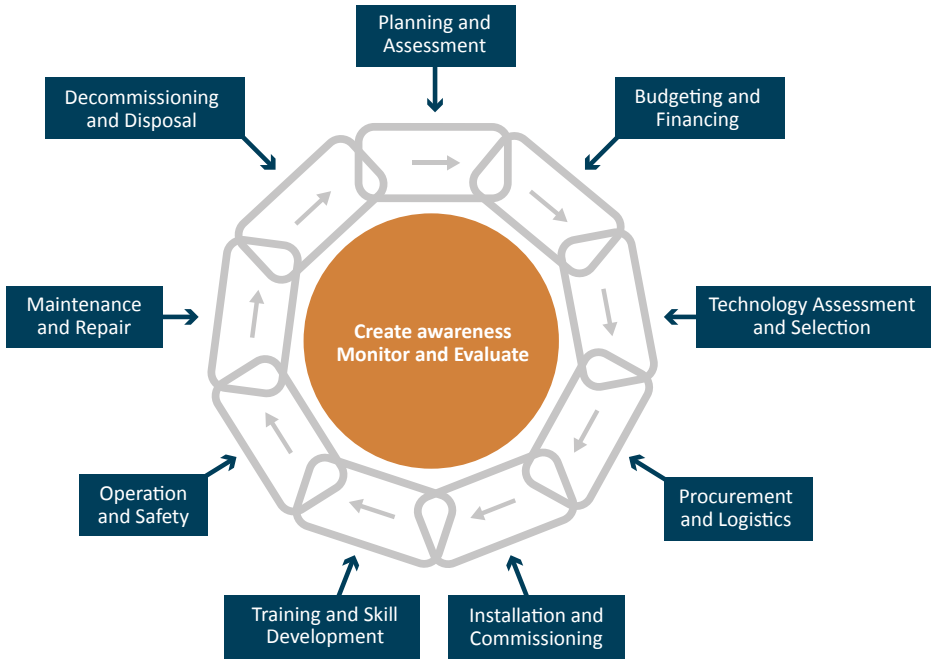
The first phase 'Planning' consists of **Planning and Assessment** of the needs in the healthcare facility appropriate to its environment, the equipment users and patients, and **Budget & Financing** in which the appropriate budgets are created and estimated for purchase and the 'cost of ownership'.

The second phase 'Purchase' contains **Assessment and Selection**, covering how to decide which equipment meets the needs identified earlier. Specifications are written and in **Procurement & Logistics** a tender is written, a less complicated purchase is done or a donation is agreed upon. The responsibilities and practicalities around logistics are prepared and executed. In **Installation & Commissioning** after the equipment has arrived in the healthcare facility and should be unpacked, installed, and commissioned.

After these two phases of preparation the third phase is the actual 'Lifetime'. Starting with the training of users and maintainers in **Skill Development & Training**, the daily **Operation & Safety** for and by users, and **Maintenance & Repair** mostly done by the Biomedical Equipment Professionals.

The last phase 'End of Life' is about **Decommissioning & Disposal** of medical equipment.

As indicated in the image, **Create Awareness, Monitor & Evaluate** are constant throughout the life cycle. Creating awareness with all participants, whether they are users, maintainers, administrators or politicians, is of great importance to improve systems and add to better biomedical and healthcare practices. Monitoring and evaluating contributes to keeping track of the equipment lifecycle, and creates opportunities to review and improve processes and share successes and learning.



Always Involve Local Technical Staff!

Throughout this resource this symbol will indicate the suggested involvement of a Biomedical Engineer (BME) from your UK trust. The added value of a BME in your team is well illustrated in case study 7 of the Donations Toolkit on p.71. However the involvement of local technical staff in the destination institution should always come first. When no local technical staff are present, it is worth looking for a local contractor.

PHASE 1: PLANNING & ASSESSMENT

The assumptions and mitigations described below apply to both planning donations and locally purchased equipment. For detailed information on Medical Equipment Donations, see the **Donations Toolkit** Chapter 1 and 2.

Assumptions

- Safe and stable electrical supply and clean running water is always available, as are medical gases
- Supporting departments function well and deliver quality controlled outputs e.g. sterilisation and laundry departments
- Data is available on which to base decisions on equipment purchases, like user and environmental data, appropriateness to setting, information from this and other hospitals
- There is consensus on and prioritisation of what is required. Users, maintainers, financers and managers give their input and requirements are written with everyone's agreement
- Long term plan (+budget) is in place for equipment purchases

Mitigations

Consider all the following when planning how you will address Planning & Assessment.

- Do a collaborative needs-assessment (UK and DC partner, including technical staff, users and management) including an inventory check, or creation of an inventory. Consider bringing a BME from your UK hospital to support this process
- Do an infrastructure check; what is available and what is working properly. Is there a non-electrical alternative for the identified needs? Work with robust equipment, plan a back-up (e.g. a generator)
- Do additional purchases (e.g. water filter, air-conditioning unit) and attach protective equipment like a stabiliser or UPS to protect equipment from surges

See Understanding Power Supply Considerations on p. 44 of the Donations Toolkit

- For bigger projects it might be worth bringing an electrician and plumber to site to make basic infrastructure improvements
- Check if supporting departments are functional and effective and take action if necessary
- Coordinate with other agencies, the government and other hospitals. Learn from others by finding out e.g. which organisations work in the same or similar hospital. Have they purchased equipment? How is equipment normally planned and purchased? Often the Ministry of Health (MoH) is in charge of centralised procurement and it is important to understand the dynamics between the parties.

For the role of the Ministry of Health in medical equipment management see p.24 of the donations toolkit

- Consider both the patient journey and all factors of service delivery when creating specifications
- Be prepared for reactive rather than planned purchases. Create awareness of expected lifetimes and long term planning.

Although reactive purchases are often related to limited financial resources, it is important to create awareness on how working equipment is a source of income. An Equipment Development Plan can be found in Ziken's guide 2 Chapter 7.1. This information should be shared with hospital directors, financial managers, procurement officers, users and maintainers

Reactive Vs. Planned Purchase

Medical equipment is valuable and the purchase/tender process takes time. In the UK equipment is mostly replaced before the old equipment is permanently out of service. The Biomedical Technicians know when equipment reaches the end of their profitable life (when the cost of repair and down-time become too high), the users (doctors and nurses, but maybe also cleaning staff) know when equipment lacks functionality or speed. Before a tender process is initiated an internal process takes place in which the hospital prioritises the needs for the coming year(s). The users/departments make a request for a new piece of equipment, the technicians support the proposal with technical background and the financial department prioritises the request, which is then approved by the hospital director/direction. Normally not all requests are accepted due to limited budgets, but when the same request is proposed e.g. two subsequent years, the need is clear. This is called a planned purchase.

In developing countries purchases (or often donations) are done centrally by the MoH. This can be a random process in which users and technicians not always have a say. Purchases are often done after equipment has been out of service for a long time. For example: a district hospital's X-ray is out of service. It takes 6 months before a proper diagnosis is made (no service engineer in the country). It appears the tube is broken, and replacing a tube is a huge investment. The machine is already over 20 years old and it is decided it should be replaced. A request from the hospital to the MoH for a tender is done (in writing) and 3 months later the MoH decided to start a tender procedure. It is to be expected that it takes at least 1 year to execute the tender procedures, accept a bid, place the order, receive and install the equipment. The hospital in this example has to refer its patient for x-rays for almost 2 years before having solved the issue. Referring patients is inconvenient and leads to a loss in revenue.

See Phase 4: Procurement for an example of centralised procurement in the UK.

"An early intervention at Connaught Hospital was a full inventory of all hospital equipment. We were therefore able to work with hospital staff to redistribute existing equipment (much of which was needed but unused) and identify critical gaps."

DR OLIVER JOHNSON,
King's Health Partners, Programme director King's Sierra Leone Partnerships

PHASE 2: BUDGETING & FINANCING

Assumptions

- Hidden costs are covered and planned for, e.g. maintenance, HR, training, consumables, replacements
- Financial management and rules are understandable, available and applied
- Budget is existent, usable and realistic & implies responsibility/planning for the future
- Spare parts and consumables are available for reasonable prices

Mitigations

- Share the hippo model (see below). Create awareness and encourage budgets to be created for the equipment lifetime (Cost of ownership estimated by 10% of purchase cost /yr)
- Describe an equipment situation to show that maintenance makes economic sense
- Insist on transparent processes, for example by proposing the use of the long-term Equipment Development Plan and Core Equipment Expenditure Plan as described in chapter 7.1 and 7.3 of Ziken's Guide 2
- Clarify responsibilities & cost allocation, encourage flexibility on allocations
- Prioritise needs and link to available budgets to create a feasible plan
- Make use of local/historical knowledge & ownership e.g. local purchasing
- Research the availability of spare parts, consumables, and maintenance services. Try to avoid importing parts yourself; the local system should be encouraged and local economies stimulated.
- Learn from the BMEs in your UK hospital

More information on budgeting for medical equipment can be found in Ziken's Guide 2. Guide 6 covers the financing of Medical Equipment.

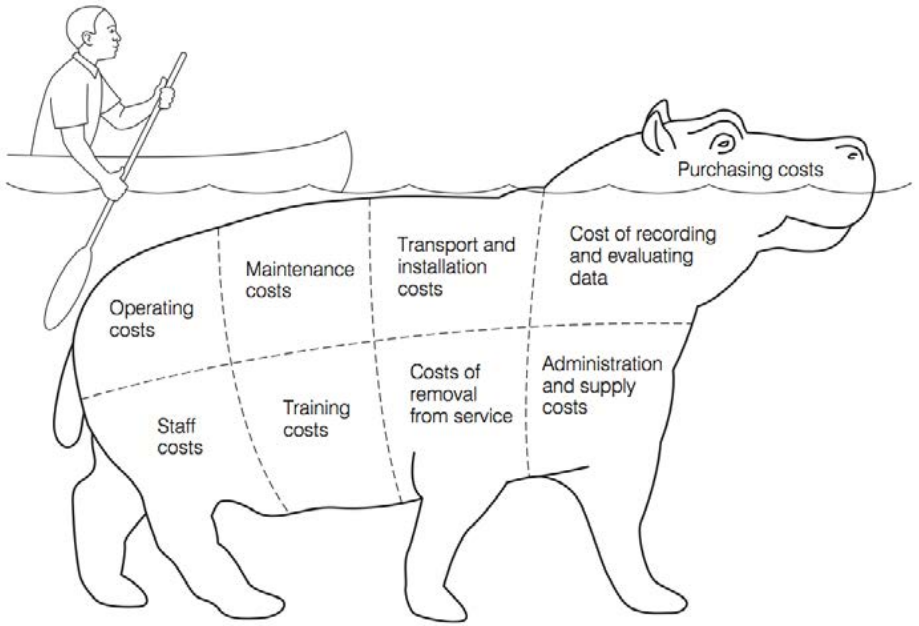
In Focus

The partnership between Guy's & St Thomas' NHS Foundation Trust, Arthur Davison Children's Hospital and Ndola Central Hospital in Zambia was set up in 2009, focusing on improvement of biomedical services in those two hospitals reaching out to other biomedical professionals in the Copperbelt region as well. The lack of spare parts has been a challenge and focus for this project. The Zambian government has procurement regulations that do not allow public hospitals to order parts from outside the country (for example online). The few Zambian medical equipment suppliers present in the country triple or quadruple prices and are in somewhat of monopoly position. The lack of competition and market control allows them to maintain this position. A potential solution that is currently being explored is to ask a local hardware store to order online and have a small commission. Often it is not necessary to be a formal agent to be able to order spare parts. In the meantime cases should be reported to the Ministry of Health to raise awareness and fight for improvement of the current situation and regulations.

"We use an ultrasound to identify liver disease/cancer in patients, which is non-invasive, quick and acceptable to patients. This machine often broke down, due to lack of care/maintenance on the local site. Also, the high temperatures often contributed to the machine malfunction. Without the machine, accuracy of patient diagnosis was limited and it slowed the project down. The latter was due to the need to undertake a biopsy to diagnose disease. This is invasive, disliked by patients and requires a skilled surgeon, requiring additional resources to obtain confirmation of those patients with liver disease. Lack of this data would limit the data and effectiveness of the project."

"We procured additional (back-up) ultrasound machines to cover for breakdown and had medics experienced in using/caring for the machine spend short intensive periods in Africa diagnosing the patients. We also paid for regular machine maintenance/service to keep the machines active. Both solutions allowed diagnosis of patients and sufficient data for the project outcomes."

DR D GARSIDE
Imperial College London – Gambia partnership, Project Manager



The hippo model

When purchasing (medical) equipment, care providers should budget and plan for all cost hidden under water level; Purchasing costs cover only a minor part of the total cost of ownership.

The Hippo model is an alternative way of depicting the iceberg, which can be found on p.10 of the Donations Toolkit p.10

PHASE 3: TECHNOLOGY ASSESSMENT & SELECTION

Assumptions

- All equipment is available to be purchased and within reach & you can trial it before purchase
- Users know how to use equipment and are systematically educated
- What is advertised (equipment +service) is available
- You can trust the market to deliver equipment of good quality and safety
- Manufacturers or agreed agents are locally present
- Qualified and trained technicians are locally present
- Local spare parts stock is present
- Honesty & ethics of manufacturer are strong
- Consumables and spare parts continue to be available throughout the lifetime of the equipment
- Equipment fits the purpose and is appropriate to setting
- "Household name" or "well-known brand" companies operate in the same manner in an emerging economy as they do in the UK

Mitigations:

- Pilot the equipment, visit the agents or vendors, share information and experiences with other parties/hospitals (try available equipment in other hospitals, and look for existence of national standards (if not, use European standards), verify the reliability of vendors)
- Establish training needs, including basic awareness of safety and equipment care
- Check what local vendors can deliver on, which timescale and what kind of service they offer. Meet the vendors, check their facilities, and their reputation.
- Stick to FDA and/or CE medical marked equipment. Do not fall for cheap options. Check if the Ministry of Health has adopted standards and regulations on medical equipment
- Check which vendors are present in the country and if they are recognised by the manufacturers. Think of service support as well, check the presence of licensed service engineers.
- Internationally recognised manufacturers do not gamble with ethics and honesty. They avoid risks to their reputation. However, it is advisable to ask around for references. Check if the Ministry of Health keeps a black list.
- Check the availability (and price!!) of spare parts and consumables beforehand. Consider re-usable accessories for remote areas but bear in mind that this only works if sterilisation is done properly. Consider simpler equipment to avoid the use of expensive spare parts. Use whole-life cycle costing, and write a tender for spare parts or ask for price guarantees for 3 years.
- Check specifications on appropriateness to setting and, during assessment, include local productions or non-profit equipment that is developed for low-resource settings. Also consider standardising the equipment; if all public hospitals use the same brand equipment, it might be advisable to purchase the same. This helps to secure access to service and parts.
- Learn from the BMEs in your UK hospital

See p.25 of the Donations Toolkit for 'Asking the right questions' to understand whether the equipment is appropriate to setting

"We standardised our BP, pulse, temp and sats monitors on the wards, and bought the most simple to use and maintain."

DR BIPLAB NANDI
Queen Elizabeth Central hospital Blantyre, Malawi & Great Ormond Street Hospital London, developing country lead

In Focus

Rwanda has introduced law saying that no second hand equipment can be brought into the country. For donations and refurbished equipment this can mean that equipment is not cleared and sent back to its origin at a cost to the sender. Although second-hand high-end equipment might be more appropriate to the setting (safe and reliable) than new Chinese equipment, often these rules are strict and without exceptions.

When purchasing equipment there are roughly 4 options:

1. New equipment from big manufacturer
- Plus + good quality
- Plus + access to service, spare parts and consumables
- Minus- expensive in purchase
- Minus- difficult and expensive to maintain/repair
- Minus- more functionality than necessary

2. Second-hand or manufacturer refurbished equipment from big manufacturer
- Plus +less complicated in use
- Plus +attractive price/quality
- Plus +Refurbished equipment might come with a guarantee for availability of spare parts and consumables
- Minus -not as desirable as new equipment (wanting the 'gold standard)

3. Equipment produced for low-resource settings (often start-ups or NGOs)
- Plus +appropriate to setting (functionally and technically)
- Plus +not expensivec
- Minus-unsure if the company will last (availability of spare parts)
- Minus- not as desirable as new equipment (wanting the 'gold standard)

The Donations Toolkit mentions several of these initiatives on p. 41 "Supplying Appropriate Technologies Designed for Low-Resource Settings" and p. 81 for contact details

4. New equipment of inferior quality mostly produced in Asia
- Plus +not expensive
- Plus +fast delivery
- Minus -no quality guarantees (CE/FDA)
- Minus -access to service/spare parts
- Minus -short life time
- Minus -higher level of break downs

PHASE 4: PROCUREMENT & LOGISTICS

Assumptions

- Tender procedures are well known and respected
- Logistics are costed, including customs and transport (effective/reliable/timely and safe) from port to hospital
- Supplier is honest & efficient
- Specifications are relevant & appropriate
- Company honours warranty
- User knows warranty is there, and can use the information
- In case of accidents there is insurance in place

Mitigations

- Follow local rules e.g. customs and use local experience. Often the ministry of health centrally procures medical equipment and knowledge of tender procedures and logistics are available there

The process of Clearing Customs is well described in Chapter 6 of the Donation Toolkit and can be found on p. 61

- Include transport in specifications. Delivery in port/airport or in the hospital? Best to include transport until the exact place of installation.
- Check if the space in the hospital is available and appropriate. Go and look.
- If supplier does not do clearance and local transport, prepare a transport plan and ensure reliable carriers, who take ownership for each leg of the journey. Include worst-case scenarios.

More information can be found in Donations Toolkit Chapter 5, p. 51-59

- Access standard specifications (WHO, Nepal)
- Get references on reliable partners – use consumer power
- Make use of a pre-purchase demo or loan
- Make sure user knows exact warranty conditions and has access to service provider
- User involvement in every stage of the procurement process
- Verify if all stages of the transport are insured and under which conditions.
- Learn from the BMEs in your UK hospital

See p.52/53 of the toolkit

For more information on logistics see the Donations Toolkit Chapter 5 and 6, and Ziken's Guide 3 accurately describes all elements of Procurement and Commissioning

Centralised Procurement in the UK

In the UK Hospitals procure their own equipment, but often use joint supply agencies ('consortium') to process. That route uses some bulk discount, and there is an 'NHS catalogue' of approved products and prices. So it is a sort of prequalified system, but hospitals are free to act on their own.

In Focus

In the Comoro Islands, technicians were receiving a container with an X-ray in the port of Anjouan. When they opened the container, the forklift was struggling to get the crate out of the container and the technicians assumed the wood had warped, and consequently it was jammed in the container. After transporting the equipment to the hospital the technicians started installing the equipment and found out it was broken. Although the crate was not visibly damaged, apparently an impact from outside had bent the container wall, crushing the equipment inside. No proof was present that the damage was caused during transportation and insurance didn't want to take responsibility. Therefore, ALWAYS check all packaging before opening, and take photos in case of abnormalities. And only remove crates when they have arrived at the final destination. Crates also protect during local transport. Report to supplier, insurance and transporter within 24hours in writing, adding photos.

PHASE 5: INSTALLATION & COMMISSIONING

Assumptions

- Facilities exist and are appropriate, e.g. space to store the equipment, doors big enough for equipment entry, floors strong enough, water and power supplies are available
- Room preparation needs assessment has been done; everyone knows what needs to be done
- Room preparations are done
- Someone will receive it at site, supervise and sign off the installation
- The equipment is delivered and installed by the supplier
- Test equipment and skilled technicians are present to perform functional and safety tests
- Financial penalties for delays are well communicated and understood by all parties

Mitigations:

- Perform a Needs Assessment, create plan for room preparation

More information Pre-installation work can be found in Ziken's Guide 3 p.200 and estimation of pre-installation cost in Ziken's guide 2 p111

- Cross-department communications and agreement on who is responsible for which part of the installation and commissioning
- Follow up on room preparation plan, check well in advance
- Plan for user approval on delivery (no damage, is it well installed, is it functioning properly? – standard forms available)
- Let the vendor's service engineer open the boxes, let it be supervised by the hospital's technician
- Makes sure this is included in the tender document or purchase agreement
- Ideally the supplier performs installation and tests under supervision of the hospital technician (directly training the technician). Often test equipment is not available and if available the technician does not always know how to use it. Providing the technician with test equipment and following the Acceptance log sheet helps the partnership to be guided through all the possible checks, but bringing a UK Biomedical Engineer with test equipment for a release test visit (and training) might be the most feasible solution

Chapter 4 of the Donations Toolkit for more information on verifying the quality and safety of equipment, p48 onwards.

- Financial penalties and insurance clarified on delays, damage and malfunctioning equipment
- Warranty commences and payment made only after successful installation
- End users are aware of warranty conditions. Confirm in writing that the supplier will honour the warranty if purchased in-country
- For smaller items that do not need installation the reception process should be well planned as well. The content of the boxes should be checked against the packing list and the content should be checked on completeness and functionality. In case of discrepancies the supplier should be contacted directly.

For more information on receiving equipment: Donations Toolkit Chapter 6 and Ziken's Guide 3

Acceptance log-sheets guide technicians through the procedure of receiving, testing and installing equipment. Such a sheet is an extensive document of about 10 pages and includes all steps to be undertaken, such as technical tests, execution of training of personnel, presence of manuals, consumables and spare-parts. An example of an acceptance log-sheet can be found in Ziken's Guide 3 p332.

In Focus

It happens that hospitals are not aware of the arrival of medical equipment. Often these are donations, agreed upon by a certain doctor or administrator or the central government deciding equipment should go to this place. Many hospitals in developing countries have a lack of space. When a piece of equipment arrives without notice, it can happen that this equipment sits outside until space is created. This can take a while, with a lack of ownership and awareness, a rainy season and a dry season and the equipment is rusted and rotten without having been used at all.

Testing Equipment

Mulago National Referral Hospital in Uganda has not had access to test equipment for many years. Once the devices are fixed, the technicians have to rely on the users to tell whether they are functioning normally. Recently, new test equipment have been donated and the hospital technicians are slowly getting adapted to their use. Oxygen concentration test device is missing yet the hospital produces its own oxygen. Volunteers are routinely asked to bring some of these tester around to test for the concentration.

PHASE 6: TRAINING & SKILLS DEVELOPMENT

Assumptions

- People are used to working with technology
- People have had full medical training and participate in/have access to continuous professional education
- Training is seen as good for skills and prospects both at management level and working on the floor
- Training is included in a tender and executed by the supplier
- Training takes place between installation and taking the equipment into service
- Training is repeated if needed

Mitigations

Refer to Donations Toolkit Chapter 7 – putting the equipment into service, p.67 training of users and maintainers

Consider all the following when planning how you will address training and skills needs.

- Include training in tender specifications (describe needs), and specify who should be trained for how many days with what outcomes
- Cover essential safety and care before putting equipment into service for both maintainers and users
- Begin by doing an assessment of current knowledge, both for users as technicians. Consider bringing a UK BME to identify the needs
- Create training that fits the local needs. The materials and examples used in the training should resemble reality
- Ensure training includes assessment of individual competencies
- Build motivation for the future, explain how training can increase status and respect
- Identify champions, train the trainer, to guarantee continuation of training for new staff and repetition for current staff
- Repeat user training every 6 months, for changing staff. It is possible to include follow-up training in a tender, e.g. 50 hours of training in the following 2 years.
- Explain to management the value of training
- Give the BMET the responsibility for user training; let him/her join the vendor's training. Collaborate with Head of Departments for planning and content.
- Award trained people with a certificate

Ziken's Guide 3 covers initial equipment training and Guide 4 covers user training

Local Champions

In every department, team or professional group you can find champions. Potential champions are those who pay serious attention to the subject, who ask the most questions and who want to talk to the teacher at the end of the class. When you are looking for sustainability of your training, you should look for people who can perform your training in the future. Identify a potential champion and help him/her to get a champion status by providing extra time with him/her, asking him/her to share or take over your class, or even taking him/her to lunch: rewarding their effort and creating a status that will support them to perform training in the future.

User Training

Biomedical Equipment professionals are often not well respected in the hospital, due to the invisibility of their work. By making the BMET responsible for executing regular user training (s) he/she has the opportunity to make him/herself visible and to spend some time on explaining his role in the healthcare system. This only works with support from the head of departments, the head of nursing and administrators.

"We try to teach the importance of maintaining equipment when we are there, and produce guidance on maintenance on simple documents. We always take one team member now who has better understanding of the equipment that we have introduced, such as the oxygen concentrators, and spends time with potential maintenance champions at the hospital."

FRANKIE DORMON
Medical Lead in Poole Africa

"We saw student nurses and midwives trained in a lovely new college, with excellent equipment then going out to clinical areas and experiencing little equipment and what there is being of poor quality or not working. This is demotivating for staff and unhelpful for patients. There are sparse supplies of oxygen for example and so nurses in the special care baby unit have to decide which babies get it and which don't."

SANDRA PAICE
Juba link Isle of Wight, Nursing and midwifery advisor

Coincidentally, the first cohort of the Rwandan BMET training in Kigali had the opportunity to spend a day with a representative of Zeiss, training the technicians on the working principles and basic maintenance of microscopes. The students insisted on receiving a Certificate, which was created, printed, and signed on the spot. The value of training is not only in increasing your knowledge, but also in having proof of the trainings you've participated in.

PHASE 7: OPERATION & SAFETY

Assumptions

- Training is followed, assimilated, practiced, and knowledge shared
- Governance & training of trainers is in place
- There is a safety culture and personal protection is available
- The hospital is clean and hygiene is highly respected
- Patient Safety comes first, protocols exist, are used and respected
- People will say when they need training
- Errors are reported and followed up
- Equipment present is working
- Single use consumables are disposed after use.
- The sterilisation service delivers clean and sterile devices.

Mitigations

For more information on using and maintaining equipment see the Donations Toolkit Chapter 7, p70

- Plan for refresher training, Train the trainer, BMET to remind heads of departments to organise trainings. Encourage briefings and debriefings for exchange of knowledge
- Do safety checks eg: every 3 months, train on awareness and safety practices. Check personal protection is available (e.g. gloves, face masks but also radiation protection items like aprons)
- Organise training on sterility and hygiene. Check what products are used to clean. Do not only focus on the cleaning staff. Hygiene is a basic skill for everyone working in a healthcare setting.
- Introduce good practice protocols and train the staff how to use them
- Encourage staff to identify their needs with head of departments and other leaders
- Create awareness around errors and how we can learn from them. Avoid guilt and blame culture. Introduce anonymous reporting to be able to track errors and create an investigation structure
- Check if equipment is operational. Bring or report malfunctioning equipment to the BMET department. Remove faulty equipment from the workspace.
- Consider reusable consumables and not single use. Verify the quality of the sterilisation equipment
- Teach technicians or sterilisation staff how to clean, disinfect and sterilise devices, and to verify whether autoclaves are working (measure pressure and Temperature cycles)

Ziken's Guide 4 describes all elements of daily operation and safety of medical equipment

For more information on logistics see the Donations Toolkit Chapter 5 and 6, and Ziken's Guide 3 accurately describes all elements of Procurement and Commissioning

Protocols

Medical guidelines or protocols are not always common in developing countries. Introducing best practices guidelines in trainings and distributing them/ sticking them to wall helps staff to work consistently. The WHO has developed some useful tools as well, like the surgical safety checklist.

In Focus

Mariette Jungblut, an expert of sterile medical devices from the Netherlands, was teaching about sterility and hygiene in a South-African nursing college when she came across cleaners that disinfect the entire hospital with chlorine. Chlorine is very aggressive and not suitable to clean medical equipment or e.g. mattresses with. Hospital mattresses are supposed to be watertight, to prevent body fluids to enter the foam, but by using chlorine, the cover becomes porous and the mattress far from hygienic. Her advice: stick to cleaning with soap and warm water. Use chlorine only on floors, walls or sanitary if it is soiled with body fluid. Never use chlorine to disinfect medical instruments, because corrosion will destroy your instruments. Good hygiene is cleaning with soap and warm water.

PHASE 8: MAINTENANCE & REPAIR

Assumptions

- The environment in which the equipment is used is stable and known (24h/24h).
- Maintenance culture exists and is respected by the technicians, users and other staff
- Technical staff present, trained and know how to maintain and repair the equipment
- Technical staff respected
- Preventive maintenance (PM) schedules exist and PM is performed regularly
- Technicians have access to an equipped workshop
- Technicians have access to spare parts, on stock in the hospital or ordered in and spare parts are delivered within 24 hours if necessary
- Technicians have access to digital or paper service and user manuals
- Technicians have access to and know how to use test equipment to calibrate and test medical equipment
- Users know how to use and take care of the equipment

Mitigations

For more information see the Donations Toolkit chapter 7; using and maintaining the equipment p. 70

- Prepare for environmental challenges, e.g. humidity, dust and heat
- In case of a lack of technical staff, see if there is a way to create contractual obligations to support maintenance
- Identify the technical staff, get an idea of their skills and knowledge and encourage/organise training
- Help technicians to structure their ways of working and spread these principles in the hospital (e.g. users understand what to do with broken equipment). Help to create visibility and encourage technicians to keep track of their work and successes, to be able to report to the hospital director. Consider inviting a UK BME to your team to cover this work
- See if the technicians make use of Planned Preventive Maintenance Schedules and if not, create them for your most crucial equipment. Instructions can be found in the Service manuals
- Check what space and tools the technicians have to perform maintenance and repair. In case of insufficient infrastructure, it is worth the effort to create an inventory, identify the needs and write to the director/MoH.

See the Donations Toolkit p.45 for more information on sourcing biomedical engineering tools and test equipment

- Check that supply chains for service support exist. Access to spare parts is one of the biggest challenges for biomedical technicians in low-resource settings. Estimate in advance spare parts and consumables needs, and discuss budget needs and supply chain
- Often Medical Equipment in developing countries is donated and manuals are not present. Manufacturers are protective of their manuals and these are normally not easy to find online. See box below for available resources
- Consider bringing a UK BME with test equipment to check crucial equipment for safety and quality
- Often equipment failure is caused by user errors. Train the users to properly operate the equipment but also to take care of the equipment. Most of the weekly preventive maintenance can be performed by the users (e.g. nurses can clean filters)
- Label all tools and test equipment and inform management about them. Nominate a person to be in charge of them and have others to sign them out and upon return so that equipment are not easily lost

See Ziken's Guide 5 for more information on Maintenance Management of Medical Equipment.

Service manuals are often missing in developing countries' hospitals, and it's difficult to find manuals online. However there are several resources where we can find manuals:

The manufacturer, the UK trust biomedical workshop, **Frank's Hospital Workshop** the INFRATECH mailing list and manuals collected by the French NGO **Humatem**.

Also see the Donations Toolkit p. 44 "Getting the right service manuals"

PHASE 9: DECOMMISSIONING & DISPOSAL

Assumptions

- Disposal channels are available for when equipment reaches the end of its life
- When disposing equipment the environment is considered
- There are clear regulations on waste disposal
- Companies that buy old equipment exist
- Decommissioning regulations exist, e.g. erasing of patient data and decontamination and the technicians know how to do this
- When purchasing new equipment the supplier may take responsibility for the equipment that is being disposed

Mitigations

- Create awareness and share best practices on disposal from the UK
- Awareness-raising, explain the environmental impact
- Encourage hospitals to create disposal routes and raise awareness on Ministry level
- Teach technicians how to decommission, e.g. decontaminate and erase patient data
- Include disassembly and disposal of equipment in the tender specifications, consider if that is acceptable for the owner (the hospital/MoH might see a value – auction to scrap buyers. Try to convince that cleaning up is a more suitable solution than keeping a junkyard)

MONITORING, EVALUATION & LEARNING

Make sure that monitoring and evaluation is on-going process by establishing the systems that you will use to gather, manage and analyse data at the start of any project you undertake; do not leave data collection to the end of the project.

Be clear from the outset what information you need and why so that you can plan your data collection systems accordingly with a clear rationale for your monitoring activities and to keep your efforts focused.

Robust, well-thought out M&E processes will mean that the partnership can better understand what is working, what isn't and ways to address challenges that arise. The information that your M&E system yields will be: a tool for programme and partnership development, data to back up advocacy activities, and to raise the awareness of your work with key stakeholders.

Assumptions

- Data is accessible and of adequate quality to demonstrate progress, understand successes and challenges
- Staff understand the importance of data collection, management, and analysis
- Staff are willing to undertake monitoring and evaluation tasks
- Staff reflect on findings from the data to review practices and implement change where it's needed
- There is resource to transform data into information that can be used to engage with stakeholders
- There is an appetite to engage with stakeholders with findings from institution data
- The institution fosters a culture of learning

Mitigations:

- Include exploration and discussion of data accessibility in the planning phase of the project. Where data is missing, establish a means to gather the data or agree proxy measures.
- Gain consensus for data collection tools, especially if introducing a new tool and wherever possible, use existing data collection systems/tools
- Decide on what data is actually needed, and limit collection to that
- Include training on data collection, management and analysis in the project plan. Seek out individuals willing to champion the importance of data
- Plan for regular project meetings that include data review and action components
- Discuss who your stakeholders are, what they want to know about the project, and how best to provide them with this information e.g. in a project meeting, a report, a poster, etc

For more information on evaluation and learning, see Section 7 of the Donation Toolkit.

THET has tools and guidelines for health partnerships to assist them with monitoring and evaluation. See **http://www.thet.org/health-partnership-scheme/resources** for details.

REPORTING FOR BMEs

In general, low- and middle-income countries struggle to procure, manage and maintain medical equipment. This is due to many factors, not least the lack of training and education opportunities for technicians and a lack of spare parts (and consumables). Part of the solution to these two challenges is to collect data. When technicians can prove there is a work overload and a structural lack of spare parts there is a chance that directors and Ministries of Health will become more aware, and will create budgets/priority for solutions; solutions like training people and facilitating access to spare parts.

The way to collect data is well described in the 6 HTM guides we follow in this resource. Some elements are creating, updating and archiving an equipment inventory and equipment history files, which contain manuals, acceptance log sheets, planned preventive maintenance plans and work orders (to know the number of breakdowns and fixes or equally if it is not possible to fix due to lack of spare parts, and to be able to track the equipment through its lifetime. An example of a work order can be found in Ziken's Guide 4 p208.

In general technicians do not like paperwork and prefer to work with tools and equipment. However, the relevance of these types of documents to technicians is that it gives them the opportunity to create a monthly report, which they can present to the hospital director to give visibility to their work, successes and struggles. In Rwanda, working on the administration side of the BMET job has proven very successful and many cases of improvement of status and success have been reported.

Additional resources:

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

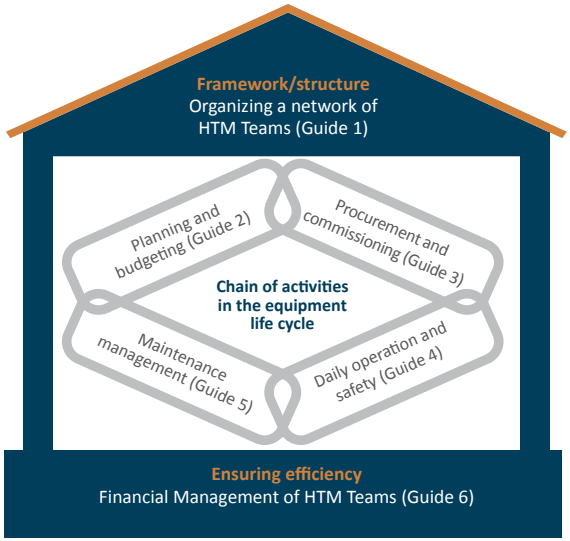
Guide 4: How to Operate your Healthcare Technology Effectively and Safely

Guide 5: How to Organize the Maintenance of your Healthcare Technology

Guide 6: How to Manage the Finances of your Healthcare Technology Management Team

http://resources.healthpartners-int.co.uk/resource/how-to-manage-series-for-healthcare-technology/

WHO resources **http://www.who.int/medical_devices/management_use/en/**



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With an MSc in BioMedical Engineering from Delft University of Technology (the Netherlands) Anna set up a BSc in BME in Ghana at Valley View University (2007-2008), then joined Philips Healthcare Interventional X-ray headquarters in the Netherlands (2008-2011) before returning to Africa to become Country Manager for Engineering World Health in Rwanda (2011-2013), where she successfully ran a BMET diploma programme. Since the end of 2013 Anna has worked as an independent Biomedical Engineering Consultant for THET. Anna Lives in Benin, West-Africa.

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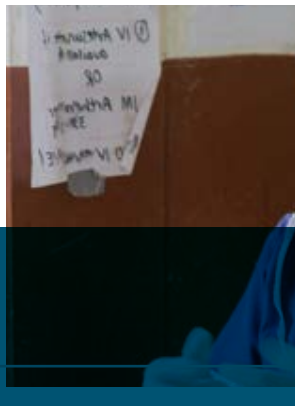

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