NHS National Services Scotland

NHSScotland Assure - High Level Guide to Ethical Donations of Medical Equipment

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Contents

1. Introduction

1.1. Globally, there are significant disparities in healthcare service provision between high-income countries and low or middle-income countries (LMIC). A major contributing factor to these disparities is the lack of medical equipment in LMIC. The donation of medical equipment has long been seen as a compassionate response to these global health disparities. Non-governmental organisations (NGOs), governments, and private entities often send surplus or decommissioned medical equipment to countries with limited healthcare infrastructure, aiming to improve access to healthcare services. While these donations can have a profound positive impact when managed correctly, they also present many challenges, including ethical issues that can undermine their effectiveness.

1.2. Several studies and reports have documented various aspects of donating equipment to countries with low to medium economic income, aiming to avoid past mistakes. This document does not intend to replace these studies but rather to guide NHS boards through a process, from start to finish, to ensure maximum benefit and minimise unintended negative outcomes that have previously been encountered with inadequately planned donations.

1.3. Scottish Governments International Development Policy-How We Work outlines eight key principles that any organisation should aim for when donating medical equipment. It is recommended that anyone wishing to donate equipment read this report, however the eight key principles are as follows:

1. partner country-led development (for example Scotland-Rwanda)
2. equality
3. amplify global south voices
4. inclusion and diversity
5. collaboration and partnerships
6. innovative, adaptive, and sustainable
7. embrace technology
8. accountable, transparent, and safe

1.4. This guidance highlights the challenges of donations and proposes strategies to navigate them ethically, ensuring Scotland is at the forefront of good practices when donating overseas. The Scottish Government recently published a 10 Step Guide, offering a clear roadmap outlining key considerations for ensuring safe and effective donations, which will form the foundation of this guidance. If at any stage the requirements for good practice donation cannot be met, consideration should be given to stopping the donation process and evaluating alternative arrangements. Stopping a donation and evaluating other options is not a failure but a sign of a strong partnership if done within a trusting relationship.

2. Background

2.1. The opening paragraph of the 'Short Life Working Group on Donating Medical Equipment' report prepared by the Chief Medical Officer (CMO) states:

> **"The World Health Organization (WHO) estimates that up to 70% of donated equipment is non-operational. This suggests that globally we are still not getting equipment donations right and this is leaving a deficit and a burden on the receiving country as well as wasting resources in terms of time, effort and potentially costs in donor countries".**

2.2. This is reflected in an article published in 2022 on 'Medical Equipment Donation: An End in Itself or a Means to an End', which highlights many issues experienced by recipients of donated medical equipment, such as:

- **lack of technical support**: often, there is no support for initial installation, demonstration, or essential training in safe use, troubleshooting, and preventative maintenance
- **absence of warranties or maintenance contracts**: donated equipment usually does not come with a warranty or comprehensive maintenance contract and after-sales support
- **incompatible parts**: replacement parts may be prohibitively expensive due to incompatibility

2.3. The report also details other considerations, such as the lack of supporting infrastructure within recipient organisations, including suitable electrical supply and medical gas outlets with appropriate connectors. This can result in donated equipment not being used or having a shorter working life than intended by the donating organisation. If equipment cannot be used or is inappropriate for use, it can lead to unintentional negative outcomes.

2.4. While different reports indicate varying percentages of unused, redundant, or unsuitable equipment, it is recognised that donations are made with good intentions. However, if these donations are not planned correctly, the costs associated with planning, preparing, shipping, and commissioning the equipment may be better applied in other ways.

3. Guidance for donating equipment

3.1. This guide is intended for anyone in Scotland involved in donating medical equipment to low or middle-income countries (LMICs). While the primary focus is on medical equipment, the core principles also apply to other types of donations, such as consumables, rehabilitation, therapeutic equipment and any non-medical equipment that could be donated. Numerous documents and guides cover how to donate medical equipment and the associated pitfalls, aiming to meet the eight principles detailed earlier. This guide draws from the '10 Step Guide' and other related documentation to ensure that donated equipment is suitable and meets its intended purpose.

3.2. It is recommended that anyone wishing to donate equipment familiarise themselves with the documents detailed in the '10 Step Guide' as a starting point. There is a risk that once these documents are read, possibly for the first donation, they may not be referred to again. This can lead to omissions, meaning subsequent donations may not meet the same high standards. A summary of each document will be provided below but reading this should not be a substitute for reading and applying the guidance within the documents themselves. However, the references below may be useful as part of a checklist to confirm that each step has been thoroughly completed each time a donation is planned or made.

3.3. Each of the 10 steps will be listed to provide an easy-to-follow approach to the decisions that should be taken. It is recommended that individual donations be considered a project, with a documentation pack created each time a donation is considered or made. This will make it easier to check at key stages and assess the effectiveness of meeting the donation's aims.

3.4. Often the cost associated with a donation is underestimated but must be planned for. To improve visibility of this, it is encouraged that thought is given to identifying potential costs, in advance. Organisations should maintain records of time, resources, and expenditure as part of the documentation pack. Sharing this information across NHS boards will enable accurate accounting and cost allocation, support transparency, and enhance planning for future donations.

3.5. By following these guidelines, you can ensure that donations are made thoughtfully and effectively, aligning with the principles of ethical and sustainable giving.

Step One: your partner has identified a need and made a donation request

3.6. **Understand the Request**: Communicate with the hospital or person making the request to fully understand their needs, building the relationship by establishing effective

communication, fostering trust, and identifying available technical skills that can be shared for Step 2.

3.7. **Training and Guidance**: Undertake relevant training and read available guidance, such as:

- Tropical Health and Education Trust (THET) 'Making it Work' (THET is now known as Global Health Partnerships (GHP))
- World Health Organization (WHO) Guidelines
- Partnership for Quality Medical Donations (PQMD) Guidelines
- Scotland Malawi Donation Guidance

Establishing a partnership

3.8. It is encouraged that any organisation wishing to donate equipment establish a close partnership with the recipient in the LMIC. By following the steps outlined in the following documents, the chances of donations being appropriate for use, supportable, and having a sufficient service life can be maximised. It is strongly recommended that any organisation wishing to donate medical equipment familiarise themselves with the following publications:

- **THET Making it Work**: (THET is now known as Global Health Partnerships (GHP))

  This UK-wide toolkit ensures that donations are appropriate, providing the right training for support staff and clinical teams, ultimately offering long-term benefits for the hospital and patients. Use it as a step-by-step guide to ensure each step is followed:

  - deciding whether to donate (page 21)
  - planning the donation (page 29)
  - supplying the equipment (page 35)
  - verifying the equipment's quality and safety (page 47)
  - storing, packing, and shipping (page 51)
  - receiving the equipment (page 61)
  - putting the equipment into service (page 67)
- **WHO Guidelines**: these guidelines ensure that the recipient organisation and donors work in partnership, highlighting regulatory and policy considerations:
  - table 1: Criteria for evaluating equipment donation offers (page 11)
  - figure 1: Essential elements of a donation solicitor's policy for equipment donations (page 12)
  - figure 2: Essential elements of a donor's policy for equipment donations (page 13)
  - figure 3: Process for soliciting and offering donations of medical equipment donations (page 12)

- **PMQD Guidelines for Quality Medical Product Donations**: an alliance of non-profit and corporate organisations) Provides guidance for companies and non-governmental organisations (NGOs) on suitable policies and processes, consistent with WHO guidelines. The document includes:
  - section I: Organisational considerations (Governance, Finance, Policies, Organisational Evaluation, General Assessment)
  - section II: Procedural steps of donation (Needs Assessment, Appropriateness, Quality, Logistics, Disposal, Emergency, Monitoring and Evaluation, Valuation)
  - section IV: NGO and Corporate Checklist
- **Scotland Malawi Donation Guidance**: Although written with Malawi in mind, this guidance can be applied to any donation of medical equipment, forming an easy-to-understand approach:
  1. is it needed?
  2. is it appropriate?
  3. is it cost-effective?
  4. is it sustainable?
  5. will it get there?
  6. who 'owns' the donation?
  7. what is already in Malawi?
  8. can the goods be sourced locally?
  9. how will the goods be distributed?
  10. how do you know if you've got it right?

3.9. By following these steps and familiarising yourself with the relevant documents, you can ensure that donations are made thoughtfully and effectively, aligning with the principles of ethical and sustainable giving.

Step Two: liaise with your partner and read 'Managing the Lifecycle of Medical Equipment'

3.10. In this step, it is important to recognise that managing medical equipment in the donating organisation may have similarities, but also significant differences compared to the organisation receiving the equipment. Well-intentioned donations, made in response to witnessing shortages or being informed of deficits, can result in inappropriate donations if not properly managed.

3.11. By following the guidance in the 'Managing the Lifecycle of Medical Equipment' document and using the 'Making it Work: A Toolkit for Medical Equipment Donations to Low-Resource Settings', many past mistakes can be avoided. The primary goal is to ensure effective

management of the full equipment lifecycle by challenging assumptions, identifying a technical contact, building trust and relationships, and implementing mitigation measures. This toolkit is designed for health partnerships to assess whether equipment should be donated and to maximise its effectiveness.

3.12. The document contains phases to follow, and once familiar with the document, the list below can be used as a quick reference to direct users to the correct section as they work through the steps, with a final action to monitor, evaluate, and learn:

Making it Work: a toolkit for medical equipment donations to low-resource settings

3.13. This toolkit provides a structured process tailored to UK-specific guidance. Following it will help understand the role of medical physics and inform whether a donation should be made. Once familiar with the whole document, the following can be used as a quick reference to direct the user to the correct section:

3.14. By addressing each step and questioning all assumptions, effective mitigations can be put in place, ensuring that each stage of the lifecycle of the medical equipment is considered.

Step Three: stop and reflect

3.15. This stage is intended to allow for reflection and ensure that the process includes a checkpoint. It is easy to work through each step methodically without referring to earlier stages to ensure there are no conflicts. Each of the steps previously taken should be revisited to ensure that an effective, ethical, sustainable, and safe donation, as set out in the good practice guidance, can be achieved. If any element of the good practice guidance is in question, it should be examined, and if it cannot be addressed, an assessment of whether the donation should proceed should be made. If all elements have been achieved, it is safe to assume that it is appropriate to progress to the next stage. This will allow an exit before committing extensive resources on the part of both the donating organisation and the recipients.

Step Four: is your donation new or second-hand equipment?

3.16. Even if the equipment is new and you have all the relevant service, repair, and user manuals, considerations regarding accessibility on the recipient's side should be addressed. For example, if the manuals are in digital form, do they have the correct Information Technology (IT) systems to open them? Are they in the correct language for the area? Is a hard copy desirable to cover for power outages? Additionally, a check should be made to ensure all relevant targeted letters, Field Safety Notices, and Alerts are provided, and if required, up-to-date documentation is supplied, and a link to the manufacturer to keep up to date with any future notices. Liability will be handed over with the equipment.

3.17. Consideration should be given to the recipient's access to consumables and spare parts. This requires partnership working between the donating organisation, the recipient, and the suppliers in the recipient's area. Information may also need to be sourced from the donating organisation's supply chain to ensure the correct codes and descriptions are supplied.

3.18. It is important to work with the recipient to understand if the infrastructure for supporting and using the equipment is either in place or can be put in place. This may require device-specific training or engineering support by the supplier, which may not be available in the recipient's area. Both engineering and clinical training should be assessed to ensure the equipment can be supported and used safely and effectively. If any of these areas cannot be addressed suitably, then the donation should not take place.

3.19. To allow effective support by the recipient organisation, any specialist tooling required for the support of the equipment should be identified and a check should be made to ensure that this is in place or can be easily obtained/ supplied. If any of the checks in the stage

cannot be met, alternative plans should be evaluated and if suitable arrangements cannot be made, consideration should be given to halting the donation.

Step Five: are the necessary plans in place?

3.20. Once there is reassurance that the equipment is in full working order and that the correct spare parts, consumables, and training are available, plans should be drawn up to ensure that the equipment can be:

- **installed**: some equipment requires specialist installation and can involve estate workers, medical physics, local advisers such as laser protection advisors, and manufacturer participation. If all required groups cannot coordinate to carry out specific tasks, such as the setup and calibration of a laser system, this would prove a barrier to donation as the equipment could not be put into use
- **tested for availability**: although the availability of spare parts and consumables may have been checked, this should be tested, and the cost implications evaluated
- **disposed of safely**: during the lifetime of the device and at the end of its life, there will be waste material from both maintenance and clinical usage. Consideration should be given to the disposal of this waste to ensure it is managed safely from both an environmental aspect and for the safety of clinical, patient, and other service users. Additionally, the end-of-life disposal of the device itself should be planned, and it should be remembered that donating equipment should not be seen as a way of disposing of old equipment

Step Six: plan for logistics of transportation

3.21. It is crucial to meticulously plan the logistics of transportation. This includes ensuring that you have all the necessary documents for customs clearance. Without these documents, you cannot be certain that the donation will arrive safely at its destination. Here are the key steps to consider:

1. **documentation**: ensure you have all required documents, such as export licenses, shipping manifests, and customs declarations. These documents are essential for smooth customs clearance and to avoid any legal or logistical issues
2. **customs regulations**: familiarise yourself with the customs regulations of both the donor and recipient countries. This includes understanding any restrictions, tariffs, taxation or special requirements for importing medical equipment. Please note that you may have to demonstrate that all equipment is in full working order, this may be in the form of test documentation, otherwise Customs Regulations may prevent you from exporting the equipment as it could be classed as exporting waste, which is prohibited. Just because it is medical equipment, being offered, as charitable donations, does not necessarily make it exempt to any of these regulations

3. **shipping arrangements**: choose a reliable shipping company experienced in handling medical equipment. Ensure they are aware of the specific requirements for transporting sensitive medical devices, including packaging, handling, and temperature control if necessary
4. **insurance**: obtain insurance for the shipment to cover any potential loss or damage during transit. This provides financial protection and peace of mind
5. **tracking and communication**: use a tracking system to monitor the shipment's progress. Maintain regular communication with the shipping company and the recipient to ensure timely updates and address any issues that may arise
6. **contingency plans**: prepare contingency plans for potential delays or complications. This includes having backup documentation and alternative shipping arrangements if needed
7. **local on the ground**: if possible, having people on the ground at each stage of the shipment can be advantageous. Preferably someone with local knowledge or contact that can facility resolution of problems as they arise

3.22. If any of these steps cannot be put in place or fully resolved, it is advisable to halt the donation process until all logistical and documentation issues are addressed. Ensuring that the donation arrives safely and without complications is paramount to the success of the donation effort.

Step Seven: discuss and agree end of life plan

3.23. As mentioned earlier, it is essential to discuss and agree an end-of-life plan to ensure the equipment is safely disposed of once it is no longer usable. Here are the key steps to consider:

1. **initial discussion**: engage in a thorough discussion with the recipient organisation about the end-of-life plan for the donated equipment. This should include understanding their capabilities and resources for handling equipment disposal
2. **regulatory compliance**: ensure that the disposal plan complies with both local and international regulations regarding medical waste and electronic waste disposal. This includes adhering to environmental and safety standards
3. **disposal methods**: identify and agree on appropriate disposal methods. Options may include recycling, safe dismantling, or disposal through certified waste management services. Ensure that hazardous materials are handled correctly to prevent environmental contamination
4. **training and resources**: provide the recipient organisation with the necessary training and resources to manage the end-of-life process. This may include guidelines on how to safely dismantle equipment, segregate hazardous components, and contact certified disposal services

5. **documentation**: maintain detailed records of the end-of-life plan, including agreements, procedures, and any certifications from waste management services. This documentation is crucial for accountability and transparency
6. **monitoring and evaluation**: establish a system for monitoring and evaluating the end-of-life process. This ensures that the agreed-upon plan is followed and allows for adjustments if any issues arise
7. **partnership with disposal services**: if the recipient organisation lacks the capacity to handle disposal, consider partnering with local or international disposal services that specialise in medical equipment. This can provide a reliable solution for safe disposal

3.24. By discussing and agreeing an end-of-life plan, you can ensure that the donated medical equipment is disposed of safely and responsibly, reducing any potential negative impact on the environment and public health.

Step Eight: seek final confirmation that the donation is still required

3.25. Before proceeding with the donation, it is crucial to seek final confirmation that the donation is still required and to ensure that all necessary steps have been completed. Here are the key actions to take:

1. **reconfirm the need**: contact the recipient organisation to reconfirm that the donation is still needed. Circumstances may have changed since the initial request, and it is important to verify that the equipment will still be beneficial
2. **review completed steps**: conduct a thorough review of all the steps taken so far. Ensure that all documentation, training, logistics, and end-of-life plans are in place and have been agreed upon by both parties
3. **final checklist**: create a final checklist to confirm that every aspect of the donation process has been addressed. This checklist should include:
    i. verification of equipment functionality and condition
    ii. availability of user manuals and training materials
    iii. confirmation of spare parts and consumables
    iv. completion of all necessary documentation for customs clearance
    v. agreement on the end-of-life disposal plan
4. **recipient confirmation**: obtain a written confirmation from the recipient that they are ready to receive the donation and that all preparations on their end are complete. This includes confirming that they have the necessary infrastructure and resources to support the equipment
5. **final coordination**: coordinate with the shipping company and the recipient organisation to finalise the transportation details. Ensure that all parties are aware of the shipment schedule and any specific requirements

6. **contingency planning**: discuss and agree on contingency plans in case of any unforeseen issues during transportation or installation. This ensures that both parties are prepared to handle any challenges that may arise

3.26. By seeking final confirmation and ensuring that everything has been done, you can proceed with confidence, knowing that the donation will be successful and beneficial to the recipient organisation.

Step Nine: make the donation

3.27. Once all preparations are complete, it is time to proceed with making the donation. Here are key steps to ensure a smooth and successful donation process:

1. **final verification**: double-check that all documentation, equipment, and logistics are in order. Ensure that all necessary customs clearance documents are ready and that the recipient organisation is prepared to receive the equipment
2. **coordinate shipment**: arrange for the transportation of the equipment with a reliable shipping company. Confirm the shipping schedule and ensure that all parties involved are aware of the timeline and any specific requirements for handling the equipment
3. **communication**: maintain open lines of communication with the recipient organisation throughout the shipping process. Provide them with tracking information and regular updates on the shipment's status
4. **installation and setup**: once the equipment arrives, coordinate with the recipient organisation to ensure proper installation and setup. This may involve working with local technicians, medical physics teams, or manufacturer representatives to ensure the equipment is installed correctly and safely
5. **training and support**: provide any necessary training for the recipient's staff on the use and maintenance of the equipment. This may include hands-on training sessions, user manuals, and access to technical support
6. **documentation and handover**: complete all necessary documentation for the handover of the equipment. This includes signing any transfer agreements and providing the recipient with all relevant manuals, warranties, and support contacts

3.28. By carefully managing each of these steps, you can ensure that the donation process is successful, and that the equipment provides maximum benefit to the recipient.

Step Ten: follow up, feedback and evaluate

3.29. After the donation has been made, it is essential to engage in a thorough follow-up, gather feedback, and evaluate the process through an agreed-upon framework with your partner organisation. Here are key steps to ensure continuous improvement and successful partnerships:

1. **regular follow-up**: maintain consistent communication with the recipient to monitor the equipment's performance and address any issues that may arise. This helps ensure that the equipment is being used effectively, and any problems are promptly resolved
2. **feedback collection**: actively seek feedback from the recipient regarding the donation process, the condition and usability of the equipment, and the overall impact on their healthcare services. This feedback is invaluable for understanding the strengths and weaknesses of the donation process
3. **evaluation framework**: establish a structured evaluation framework to assess the success of the donation. This should include key performance indicators (KPIs) such as equipment functionality, user satisfaction, and the impact on patient care
4. **joint review meetings**: schedule regular joint review meetings with the recipient to discuss the feedback and evaluation results. These meetings provide an opportunity to collaboratively identify areas for improvement
5. **documentation and reporting**: document the feedback and evaluation findings in a comprehensive report. This report should highlight the outcomes of the donation, any challenges encountered, and recommendations for future donations
6. **continuous improvement**: use the insights gained from the feedback and evaluation process to refine and improve future donation efforts. This may involve updating guidelines, enhancing training programs, or adjusting logistical arrangements
7. **sustaining partnerships**: strengthen the partnership with the recipient organisation by demonstrating a commitment to continuous improvement and mutual support. This instils trust and ensures long-term collaboration

4. Conclusion

4.1. In conclusion, the ethical donation of medical equipment is a critical and compassionate response to addressing global healthcare inequalities. However, it requires meticulous planning and adherence to established principles to ensure its effectiveness and sustainability. By following the 10 Step Guide, donors can maximise the positive impact of their contributions while minimising potential negative outcomes. This approach not only supports the immediate healthcare needs of recipient countries but also promotes long-term partnerships and development. Ultimately, thoughtful and well-managed donations can significantly enhance healthcare access and quality in low and middle-income countries, embodying the true spirit of global solidarity and cooperation.

Appendix A Scottish Government ten step guide

Figure A.1 - 10 Step Checklist

Scottish Government
Riaghaltas na h-Alba

10 Steps to Safe Medical Equipment Donations checklist

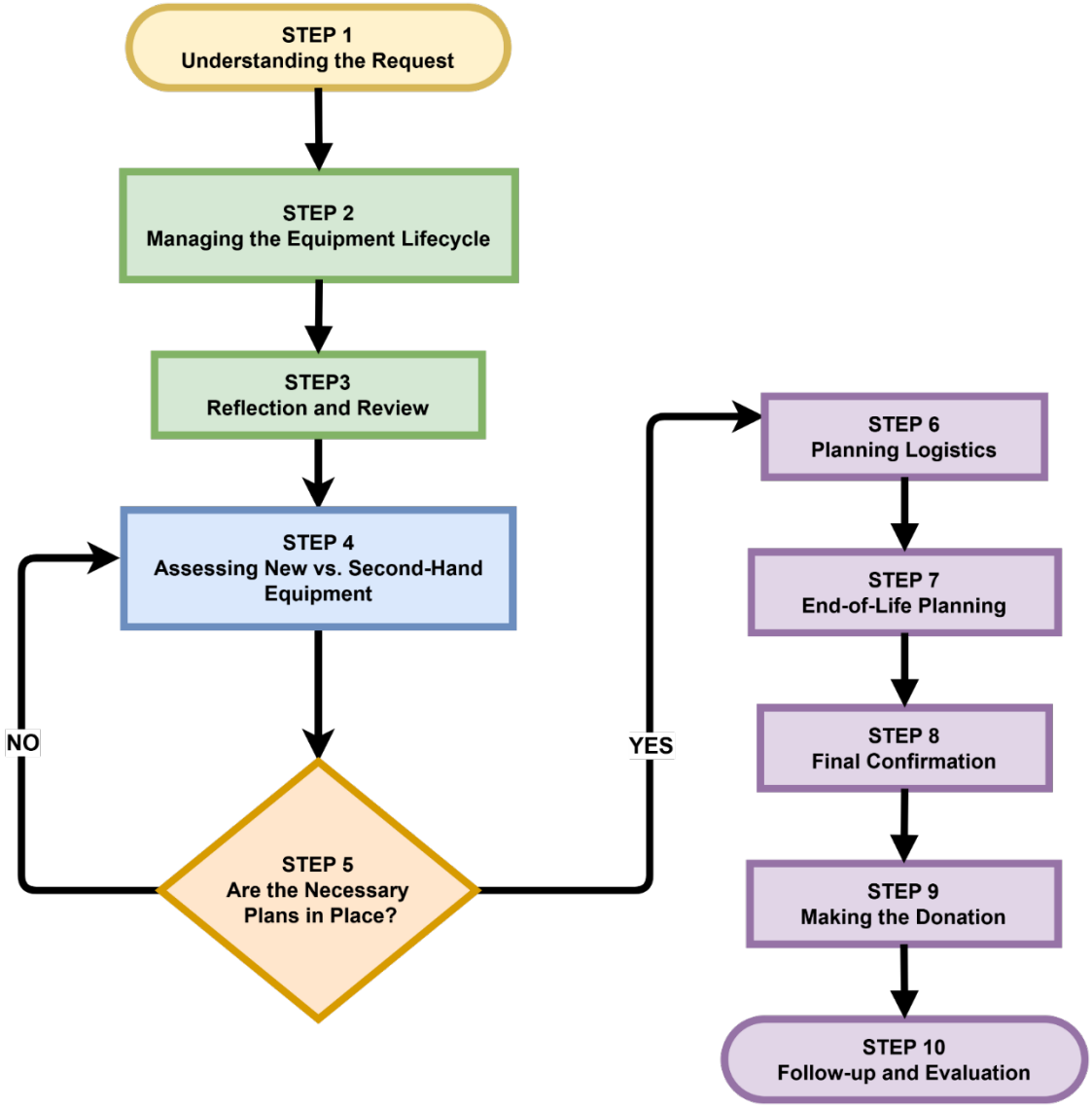
As you work through the 10 steps to a safe and effective donation you can use this checklist to capture important information and ensure nothing is forgotten. You may find it useful to share this checklist with others involved in the donation. Include your overseas partner who is central to any decision on whether to progress a donation. If you find that you are unable to fulfil any of the steps it may be worth exploring an alternative form of support with your partner.

Step	Actions	Your comments	Complete
1.	**Your partner has identified a need and made a donation request to you.** Communicate with the hospital/person making the request to fully understand what they want. Undertake the relevant training and read the available guidance* (THET Making it Work, WHO Guidelines, PQMD and Scotland Malawi donation guidance)		☐
2.	**Liaise with your partner, read Managing the Lifecycle of Medical Equipment** and talk to the local technical expert in the hospital/ setting to ensure they understand what has been agreed to be sent and that they are able to maintain it.		☐
3.	**Stop and reflect** Are you able to fulfil the requirements for an effective, ethical, sustainable, and safe donation as set out in the best practice guidance? Are there any elements you are unable to fulfil? If there are then you should stop the donation process. Donating medical equipment in an unsafe way can do more harm than good.		☐
4.	**Is your donation new or second- hand equipment?** Do you have all the necessary manuals and an agreed plan for consumables and maintenance with the hospital?		☐

Step	Actions	Your comments	Complete
5.	**Are the necessary plans in place** for installation, maintenance, accessories & spare parts and decommissioning? If this has not been possible then you cannot be certain the equipment will be safe for use once it arrives. Until this is resolved you should stop the process of making a donation.		☐
6.	**Plan for logistics of transportation**, ensuring you have all the documents needed for customs clearance. If this has not been possible then you cannot be certain that the donation will arrive safely. You should stop until this is fully resolved.		☐
7.	**Discuss and agree an end-of-life plan** for the donation so it will be safely disposed of.		☐
8.	**Seek final confirmation that the donation is still required** and confirm that everything has been done.		☐
9.	**Make the donation.**		☐
10.	**Follow up, feed back and evaluate**, through an agreed process as partners.		☐
Any further reflections			
Contact details of key individuals			

Appendix B Ethical donations flow chart

Figure B.1 - 10 Steps Flowchart



Abbreviations

CMO: Chief Medical Officer

GHP: Global Health Partnership

IT: Information Technology

KPI: Key Performance Indicator

LMIC: low- or middle-income countries

NGO: Non-governmental organisation

PQMD: Partnership for Quality Medical Donation

THET: Tropical Health and Education Trust

WHO: World Health Organization