

Framework for Student MedAID London Operations

By Student MedAid London

Introduction

The 'Framework to Review Student MedAID Operations' is a format to guide Student MedAID and its branches to measure and monitor the quality of their operations, in order to maintain a high standard of service while implementing changes for improvement.

This framework was created using recommendations from the Tropical Health and Education Trust (THET) in their publication 'A toolkit for medical equipment donations to low-resource settings: MAKING IT WORK' (1). Care has been taken to ensure the framework meets the 'WHO Guidelines For Health Care Equipment Donations (2).

Section 1: Describing Good Donation

The following section will include common standards for medical equipment donation as outlined by the Guidelines For Health Care Equipment Donations (2). The Framework is set up in order to meet these standards.

1. Principles of Good Donation

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

- a. Health care equipment donations should benefit the recipient to the maximum extent possible
- b. Donations should be given with due respect for the wishes and authority of the recipient, and in conformity with government policies and administrative arrangements of the recipient country.
- c. 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.
- d. There should be clear and effective communication between the donor and the recipient, with all donations made according to a plan formulated by both parties

2. **Desirable Equipment**

Desirable equipment has the following characteristics:

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

3. **Sustainability**

Despite medical equipment donations forming the crux of Student MedAID's operations, it is important to acknowledge that donations are inherently unsustainable, as they do not address the root cause of why so much medical equipment is out of service in low-resource settings. Instead, they provide short-term relief, and should always be thought of as a stopgap solution to reduce avoidable losses of life or limb.

a. **Meeting the WHO's sustainability criteria**

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:

i. **The equipment is appropriate to the setting**

1. Suitable for the level of facility and service provided
2. Acceptable to staff and patients
3. Suitable for operator skills available
4. Suitable for the local maintenance support capabilities
5. Compatible with existing equipment and consumable supplies
6. Compatible with existing utilities and energy supplies
7. Suited to the local climate, geography and conditions
8. Able to be run economically with local resources

ii. **The equipment is good quality and safe**

1. Of sufficient quality to meet requirements and last a reasonable length of time
2. Made of durable materials that can be easily cleaned, disinfected, or sterilised without rusting
3. Manufactured to meet internationally-recognized safety and performance standards
4. Suitably packaged and labelled so that it is not damaged in transit or during storage
5. Provided by reputable, reliable, licensed manufacturers, or registered suppliers

- iii. **The equipment is affordable and cost-effective**
 - 1. Available at a price that is cost-effective.
 - 2. Affordable in terms of costs for freight, insurance, import tax, etc.
 - 3. Affordable in terms of installation, commissioning, and training of staff to use and maintain them
 - 4. Affordable to operate (costs of consumables, accessories and spare parts over its life-time)
 - 5. Affordable to maintain and service
 - 6. Affordable to dispose of safely
 - 7. Affordable in terms of the procurement process (for example, the cost of a procurement agent or foreign exchange)
 - 8. Affordable in terms of staffing costs (for example, costs of any additional staff or specialised training required)
- iv. **The equipment is easy to use and maintain**
 - 1. The donation solicitor has the necessary skills in terms of operating, cleaning and maintenance
 - 2. Instructions and manuals are available in the proper language
 - 3. User training is offered by the supplier or donor
 - 4. Local after-sales support is available with proven technical skills
 - 5. The possibility of additional technical assistance through service contracts exists
 - 6. 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?)
 - 7. A supply channel exists for equipment-related supplies (for example, consumables, accessories, spare parts)
 - 8. There is assured availability of needed supplies for a reasonable period (up to 10 years)
- v. **The equipment conforms to the recipients policies, plans and guidelines**
 - 1. Conforms with any active purchasing and donations policy that may exist
 - 2. Conforms with any equipment standardisation policies that may exist
 - 3. Conforms with the level of technology described in any standard equipment lists and generic equipment specifications that may exist
 - 4. Conforms with any conclusions resulting from a review of literature and comparative products
 - 5. Conforms with any conclusions resulting from feedback regarding previous purchases and donations

4. **National Policy**

- a. There is no specific legislation in the UK on medical device donations to low-resource settings
 - i. Medical devices are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA)

Section 2: Framework to review Student MedAID operations

Student MedAID London will work with its partners to meet the above requirements to ensure ethical practices within the WHO recommendations, by following clauses of the following framework

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

1. Pre-donation plan

- 1.1. **Feasibility and formulation of requirements:** Student MedAID London will communicate recipients through email to ensure that recipients have the **resources (human and financial) and the readiness (trained operators, appropriate environment)** to install, operate, and maintain the requested equipment. If any shortcomings are identified in these areas, the recipient must demonstrate that it has plans and a means to address them prior to a donation plan being agreed upon.
- 1.2. **Human Resources:** Student MedAID London will communicate with the future receiving organisation, through email or other forms of written correspondence, to ensure that recipients have properly trained physicians, nurses and/or technicians who would operate their requested equipment. If none are available, an explanation should be given of how training of such personnel will be achieved.
- 1.3. **Environment:** Student MedAID London will communicate with recipients, through email or other written forms of correspondence, to ensure that recipients have available facilities, such as **physical space, electrical and pneumatic power, water supply, heating, ventilation, and air conditioning**, to install and operate the requested equipment (as appropriate).
- 1.4. **Maintenance Resources:** Student MedAID London will communicate with recipients through email to ensure that recipients have human, material and financial resources available in house to service and maintain the requested equipment (as appropriate).
- 1.5. **Memorandum of Understanding between Student MedAID London and Donating Organisation**
 - Both Student MedAID London and the Donating Organisation will act under mutual presumption of good faith.
 - Both Student MedAID London and the donating organisation draft the agreement together.
 - Both parties that draft and sign the agreement have the authority to enact it.
 - All costs are to be expressed in a shared currency, and that maximum budgetary allowances for specific expenses should be clearly noted.
 - All Memoranda must make reference to the 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.

1.6. **Memorandum of Understanding between Student MedAID London and Receiving Partner**

- Both Student MedAID London and the Receiving Organisation will act under mutual presumption of good faith.
- Both Student MedAID London and the Receiving Organisation draft the agreement together.
- Both parties that draft and sign the agreement have the authority to enact it.
- All costs are to be expressed in a shared currency, and that maximum budgetary allowances for specific expenses should be clearly noted.
- All Memoranda must make reference to the relevant statutory documents for both partners.
- That the agreement includes contractual elements such as modification and termination clauses, etc.

2. Verifying Quality & Safety

- 2.1. Student MedAID London will request, by email or other means, that donating organisations include a user manual for any donated equipment, if applicable.
- 2.2. Student MedAID London will inform the Receiving Partner, by email or other written means, of the increased hazard of donated items due to the age of equipment, prior to the memorandum of understanding between Student MedAID London and the Receiving Partner being signed.
- 2.3. Student MedAID London will request, by email or other written means, that donating organisations provide identification of the equipment (e.g. manufacturer, make/model, serial number, type using standard medical device nomenclature) as completely as possible, if applicable to the type of equipment being redistributed
- 2.4. When transferring more complex pieces of equipment, Student MedAID London will liaise with donating organisations, by email or other written means, to attempt to identify and record all tests performed to meet the above requirements, including the organisations responsible for performing these tests.
- 2.5. When transferring more complex pieces of equipment, Student MedAID London will liaise with donating organisations through email to attempt to provide complete service history of the equipment
- 2.6. When transferring more complex pieces of equipment, Student MedAID London will liaise with the donating organisation through email to attempt to decontaminate equipment where appropriate. Student MedAID London will not be responsible for decontamination efforts of complex pieces of equipment.
- 2.7. When transferring more complex pieces of equipment, Student MedAID London will liaise with donating organisations through email to attempt to provide appropriate protection against damage during transportation, loading and unloading

- 2.8. Student MedAID London will work together with the Donating Organisation to ensure that no items in the shipment are waste electrical and electronic equipment (WEEE), and will obtain a signed declaration from the Donating Organisation stating the fact.
- 2.9. Student MedAID London will acquire information from the donating organisation through email on any special requirements for proper use of the equipment, and will communicate this to the receiving organisation (through documentation). Examples of such needs may include air or water cooling, electrical power, water quality, mechanical lay-out, radiation shielding, or acoustic shielding requirements.
- 2.10. Student MedAID London will ensure that donated equipment is fully operational, and that all accessories and supplies necessary to the normal function of the equipment are available. As far as possible, at least **TWELVE** (12) months' worth of accessories will accompany the donated medical equipment, as per the recommendations made by the 2015 WHO Medical Device Donation Guideline for Ebola Outbreak. (3)
- 2.11. Student MedAID London will work with the donating organisation to complete a checklist ensuring that all sub-systems, components, accessories, and supplies are included in the shipment. Student MedAID London will then supply a copy of the checklist to the receiving organisation. Checklists are often found in operation manuals produced by manufacturers of medical equipment, or prepared by the former operators, in the case of previously used equipment. If the equipment was previously used, copies of any available maintenance logs should also be handed over to the receiving organisation.

3. Pre-donation Recipient Preparations

- 3.1. Student MedAID London will provide recipients with detailed information regarding the installation, operation, and maintenance of the equipment, as provided by the Donating Organisation. This information will enable the recipient to begin pre-installation tasks, including the training of personnel for operation and maintenance
- 3.2. The receiving organisation will notify Student MedAID London upon the completion of site preparation.

4. Storing, Packaging & Shipping

- 4.1. In case of an expected gap between dates where medical equipment is available, and dates where medical equipment can be safely handed over to the receiving organisation, Student MedAID London will identify an adequate storage area for the equipment.
- 4.2. Student MedAID London will record the name/type of equipment, date of collection, date of redistribution, quantity of equipment, expiration date, and donation source in the Student MedAID London Inventory database.
- 4.3. Student MedAID London will attempt to ensure that collection points for medical equipment should ideally be convenient for both deliveries from donating

- organisations, and for pick up by the organisation responsible for testing and/or shipping the equipment
- 4.4. Student MedAID London will ensure that the following information is secured from the donating partner:
 - Name of Student MedAID London lead contact
 - Name of the receiving organisation's department and lead contact
 - Signed document affirming that the equipment is a donation intended for the receiving organisation
 - 4.5. Once a shipment of donated equipment is released by the Donating Organisation (either directly to the Receiving Organisation, or to Student MedAID London representatives), de facto, liability is said to have been transferred over to the party receiving the shipment.
 - 4.6. For instances where medical equipment is hand-delivered by volunteers to the receiving organisation, Student MedAID London will secure the following from the volunteer:
 - Signed document waiving Student MedAID London, the donating organisation, and the receiving organisation from personal liability and legal liability
 - Signed declaration that the volunteer will act in good faith.
 - 4.7. Student MedAID London will also prepare a handover memorandum, to be signed by both the volunteer and the receiving organisation, after inspection of the shipment. It is the responsibility of the receiving organisation to provide Student MedAID London with a copy of the signed handover memorandum, following inspection.
 - 4.8. As an added precaution, Student MedAID London will seal any hand-delivered equipment in a sealed package, so as to prevent tampering of the equipment.
 - 4.9. Should equipment delivered during the shipment appear to be tampered with in any way, at any point during the shipment process, either the volunteer or the receiving organisation may lodge a complaint to Student MedAID London, through email or other forms of written correspondence.
 - 4.10. A shipment can be terminated at any point during the shipment process, should emerging concerns fail to be resolved. This may be performed at the discretion of the donating organisation, the receiving organisation, or Student MedAID London, under the mutual implied duty of good faith.
 - 4.11. Upon completion of the handover process (after completion of the handover memorandum), the liability associated with the equipment will be transferred over to the receiving organisation.

5. Shipping the Equipment

- 5.1. Student MedAID London will comply with all import regulations of the country that the receiving organisation resides in, as informed by the RO.
- 5.2. Student MedAID London will work with the receiving organisation to understand the import regulations of the country that the receiving organisation resides in.
- 5.3. Student MedAID London will check that all necessary documentation is complete, and that all parties have full copies of these documents.

- 5.4. Student MedAID London will ensure that there is ongoing communication between all parties involved in the shipment – including Student MedAID London itself, the donating organisation, the receiving organisation, the shipping agent(s), and local customs clearing agents.
- 6. Receiving the Equipment, Custom clearance, Local Transportation, Unpacking and Reception**
- 6.1. Student MedAID London will receive written feedback from the individual/organisation performing the handover, regarding issues emerging during the shipment process
 - 6.2. Student MedAID London will receive feedback from recipients regarding any issues with the shipment process.
- 7. Follow-up Evaluation**
- 7.1. Student MedAID London and the receiving organisation will jointly assess the level of operational success or failure of the donated equipment.
 - 7.2. Student MedAID London and the receiving organisation will jointly evaluate the activities, immediate and long-term concerns, long-term outcomes, short-term effects and long-term impact of the donated equipment. This requires open, honest communication between both parties, engenders trust in Student MedAID London, and allows both parties to improve from previous experiences.
 - 7.3. The feedback form can be found on the Drive.
 - 7.4. Student MedAID London will undertake a review of the Feedback form at least every two years, to ensure that the information obtained through the form is informative for quality improvement purposes.

REFERENCES

1. Mullally, S., 2013. *A Toolkit For Medical Equipment Donations To Low-Resource Settings*. [online] Thet.org. Available at: <https://www.thet.org/wp-content/uploads/2017/08/THET_MakingItWork_Toolkit_Final_Online.pdf> [Accessed 29 December 2020].
2. WHO. Guidelines For Health Care Equipment Donations. Geneva 2000. Available: https://www.who.int/medical_devices/publications/en/Donation_Guidelines.pdf
3. Who.int. 2015. Medical Device Donation Guidelines For Ebola Outbreak. [online] Available at: <<https://www.who.int/publications/m/item/md-donation-ebola>> [Accessed 30 December 2020].

