Donation of medical devices in low-income countries: preliminary results from field studies

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Abstract. Most of the world population is being treated in low-income countries, where there are not only harsh environmental conditions but also a failure to meet international standards and minimum requirements of the medical devices and locations. This can jeopardize the safe and efficient functioning of the medical devices. This paper draws on 5 field studies that took place in Sub-Saharan Africa, presenting few examples of donated medical devices and discussing the possible steps in order to strive for a more universal free healthcare coverage.

Keywords: Medical devices, medical locations, donations, low-resource settings, international standards, minimum requirements.

1 Introduction

Most of the world population does not benefit from the use of medical devices (MDs): in fact, less than 15% of the global population accounts for the use of over 75% of the MDs, suggesting inequitable access to healthcare in favor of higher resource settings [1].

Indeed, the people who need healthcare the most (i.e., the ones living in lower-resource settings) are also the ones who have less access to it. In order to tackle this, the United Nations (UN) promoted several sustainable development goals (SDGs) in the 2030 Agenda for Sustainable Development, which strives for the achievement of inclusive and sustainable development for all, drawing on the principle of "leaving no one behind". For biomedical engineering, the most relevant ones are *good health and well-being* (SDG3), *quality education* (SDG4), *clean water and sanitation* (SDG6), *industry, innovation and infrastructure* (SDG9) and *reduced inequality* (SDG10). The SDGs are

one of the 6 leadership priorities of the World Health Organization (WHO), who defined them to give focus and direction to their work, aiming at promoting global health and wellbeing [2].

When it comes to SSA, 80% of the available medical devices are donated [3], and over 70% of them are broken or non-functional because of different reasons [1]. Williams and Kohler [4] confirm that these donations have, in many cases, become a financial burden for end-users, who have to reallocate their scarce resources in attempts to fix or get rid of the equipment. The paper [4] also explains that this situation is not only unfavorable for the end-users, but also for the donors: in fact, 62.5 to 87.54 cents are wasted out of every dollar spent on medical equipment.
During the past two years, we have been running 5 field studies in 3 Sub-Saharan countries (i.e., Benin, Ethiopia and South Africa). Such field studies helped us start understanding some of the reasons behind the non-use or the breakage of the MDs: the lack of spare parts, expertise, an efficient maintenance program, a management system, harsh environmental conditions, of unreliable and unstable electrical power sources, and failure to define and meet minimum requirements for MDs and medical locations [5-8].
This paper presents the results from the 5 field studies along with a discussion on the possible future steps towards a more sensible and informed approach to the donation of MDs, both on the donors' side and the end-users' one.

2 Methods

2.1 Case studies, focus groups and conferences

For the past 24 months, members of the Applied Biomedical Signal Processing and Intelligent eHealth (ABSPIE) Lab (University of Warwick, Coventry, UK) have been running 5 field studies, anticipated and followed by some focus groups to plan the following study and to sum up the results from the previous one. The field studies took place in Benin (2017 and 2018), Ethiopia (2018) and South Africa (2016 and 2017), the focus groups in the School of Engineering of the University of Warwick. Relevant literature was also taken into consideration.

Focus groups were held during relevant international events, including:

- The International Union for Physical and Engineering Sciences in Medicine (IUPESM) world congress, held in Prague, Czech Republic, on 3-8 June 2018;
- The first UBORA conference, held in Pisa, Italy, on 1-2 September 2018;
- The 4th World Health Organization (WHO) global forum on medical devices (4GFMD), held in Visakhapatnam, India, on 13-15 December 2018.
  These events were great opportunities for exchanging ideas, opinions, receiving feedback and promoting part of the work of the ABSPIE Lab.

3 Results

3.1 General conditions

The field studies, which were set in vocational hospitals, confirmed the severe conditions presented in the scarce literature. Although vocational hospitals may be representing only a part of the scenario, they still are a significant part of the healthcare system in these settings. High temperatures, humidity, dust, vermin are some of the characteristics, along with inefficient electrical circuits and grounds (see Figure 1). The pictures portray the conditions of the hospitals, including, for instance, dust over the wiring and equipment, which could become conductive and cause short circuits and damage to equipment in case of wet weather. Electric panels, power transformers, UPS, cables and electric cabins were not installed, maintained or services as expected [9]. Vermin is clearly apparent, with a wasps nest being on one of the pieces of equipment.

Fig. 1. The conditions of the electrical panels, wiring and equipment.

3.2 Minimum requirements and international standards

In higher-resource settings, medical locations and medical devices are regulated by international standards and minimum requirements. International scientific societies and technical commissions issue such standards and requirements in order to harmonize the state-of-the-art for medical location design (including but limited to electrical installations, rooms layouts, ventilation et cetera) and building and medical device design and production (see Figure 2) [9]. While in most of the higher-resource settings the legislation promotes these standards and minimum requirements in different ways (e.g., in Italy they become law, while in the U.K. they only are strong recommendations), in most of the lower-resource settings there is a lack of standardization and a failure to meet such requirements [10].

The minimum requirements can be divided into structural, organizational and technological [11]. Examples of such standards could be the following (i.e., minimum requirements for activities of diagnostic imaging) taken from the Italian Legislative Decree n.484 [12]:

- Structural: a diagnostic imaging ward should have, among other things, a room for radiodiagnostics, with annexed spaces/changing room for users, a room/storage for clean materials and a room/storage for dirty materials and separate toilets for staff and users.
- Organizational: a diagnostic imaging ward should have, among other things, a number of healthcare operators and/or technicians appropriate for the complexity of the services offered and a quality control system.
- Technological: a diagnostic imaging ward should have, among other things, a high voltage generator (>30 KW) and a console table and a double focus rotating anode X-ray tube.

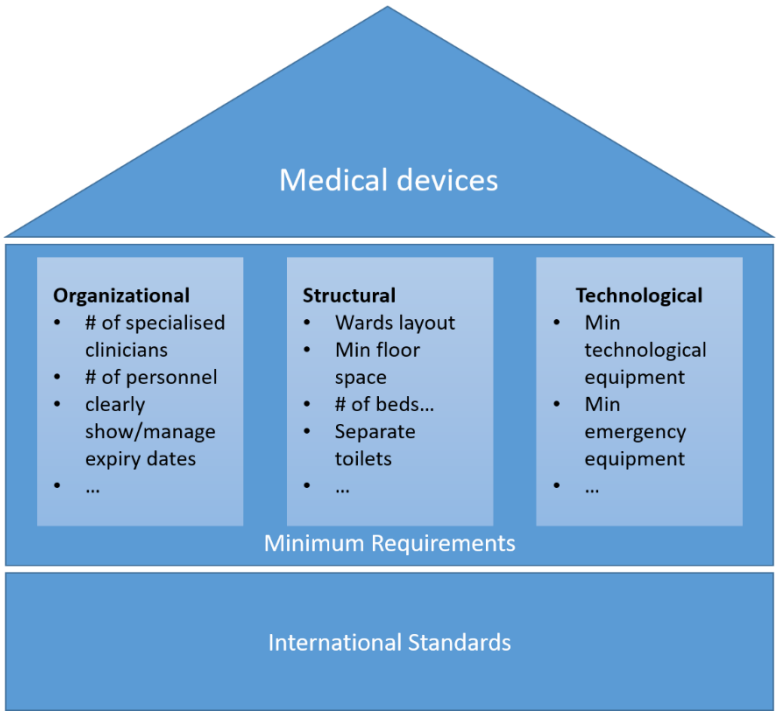

Fig. 2. The fundamental role of international standards and minimum requirements for the safe and efficient functioning of medical devices.

3.3 On donations: x-ray machine and oxygen concentrator

This section provides two examples of donated medical devices along with related issues.

X-ray machine. Figure 3a,b,e show an x-ray machine that was donated to a hospital in Sub-Saharan Africa. The equipment was completely analogic and had been disassembled perfectly working in a European Hospital and sent with 5 sheets of instructions (see Figure 3d), written in a language non-locally spoken. The local technician had tried to assemble the parts, but he concluded that one of the non-fused terminal blocks was damaged (see Figure 3c). Thus, he decided to send the supposedly broken part to Nigeria in order to replace it. Some members of the ABSPIE team were luckily on time to stop this process, retrieving the part. During the next field study, they came back with an experienced retired x-ray technician, who helped install the machine correctly collaborating with the local technician, promoting capacity building (see Figure 4).

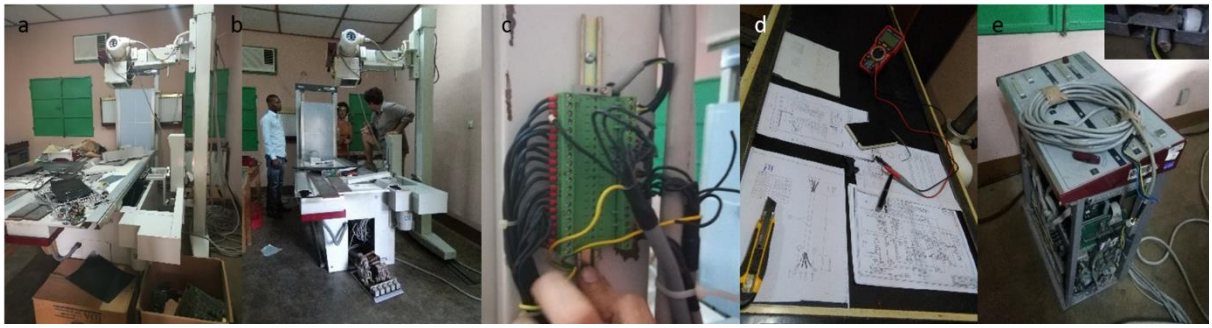

Fig. 3. a), b) and e) show the donated x-ray machine; c) shows one of the non-fused terminal blocks; d) shows the set of instructions.

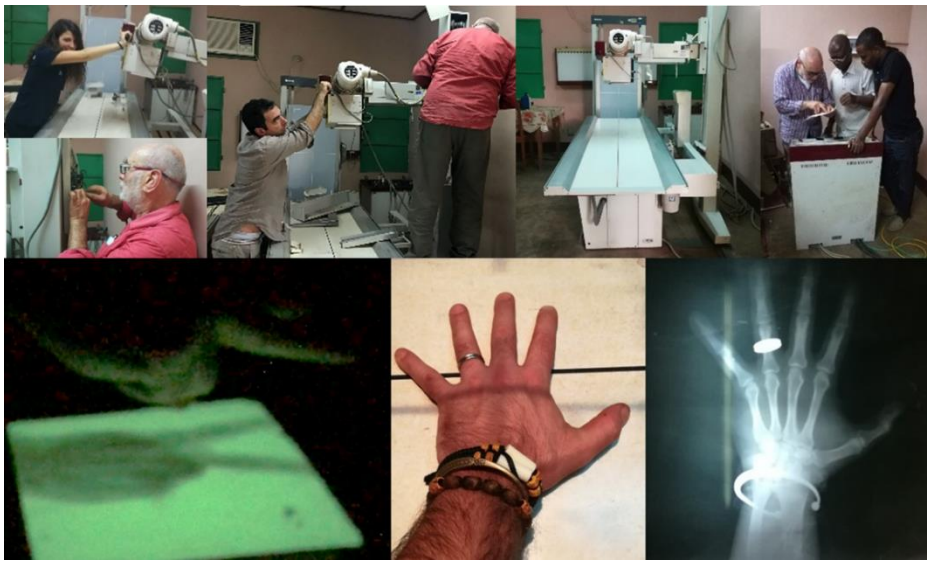

Fig. 4. Members of the ABSPIE team along with the local and the experienced technician assembling and testing the x-ray machine.

Oxygen concentrator. Figure 5 shows an oxygen concentrator that is a medical device used to deliver oxygen to patients who need it. The attention of some of the members of the ABSPIE group was caught by a nurse, who suspected that the oxygen concentrator they had was not working properly (i.e., when switching the switch from 1 to 2, the flow of oxygen was not doubling). After checking the device, the issue was identified with the filters.

This kind of MD is designed taking into consideration the above mentioned international standards and minimum requirements. In the case of the oxygen concentrator, this kind of device has two types of filters, external and internal. The external filters should have been washed weekly and had never been, while the internal filters should be changed after 4380 hours of work and had already been working for 6501 hours without having been changed [13]. These requirements are based on higher-income countries settings, where strict standards regarding medical locations are respected (e.g., the air in a surgical room has to be filtered at a 99.97% level [12]). This situation is utopic for many low-resource settings, where there is a lot of dust, and there is not filtering and not to 99.97%. Consequently, the minimum requirements regarding the filters of the oxygen concentrator should be even stricter or these devices should be redesigned to be more resilient.

Figure 5 shows that the filters were full of dust (and most likely of bacteria), thus hindering the correct, safe and efficient functioning of the device and being a potential threat to patients' health.

Fig. 5. Oxygen concentrator and its components; c),d) details of dust and filters; e) display with numbers of hours that the device had been working.

4 Discussion and conclusion

This paper aimed to report on our preliminary field experience on low-resource medical locations and on the donated MDs, which are often not working or working improperly. This is due to many reasons, first of which is the fact that 80% of the MDs market is ruled by higher-resource settings (namely the USA, Japan and Europe) [14], which define and set standards de facto that are not met in most of the lower-resource settings. Not only there should be a complete change in the way of designing medical devices towards a user-driven and contextualized design, but also there should be a harmonization of the regulations of medical devices and locations between Europe and Africa. The ABSPIE group is also working on this front, cooperating internationally to promote this harmonization. The International Federation of Medical and Biological Engineering (IFMBE) African working group was funded at the IUPESM 2018 in Prague for this purpose.

Donations, as they are conceived now, should be made more carefully and could be regulated by the viability model proposed by Williams and Kohler [4], in order to avoid that donors waste resources and that the donations become a burden for the end-users. They should also be supported by a working local management system (paper-based or computerized) in order to keep track of the devices, their status, their maintenance schedule et cetera. Moreover, donations should always come along with installation and maintenance support in order to avoid problems, like the ones that were mentioned above.

In conclusion, there is a clear need to regulate donations in a more sensible way and work towards new standards for medical devices to make them more resilient to harsh environments, such as the ones that can be found in lower-resource settings.

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