A Case Study on the Optimal Method of Implementing Point-of-Care Ultrasound in Developing Countries

A Research Paper submitted to the Department of Engineering and Society

Presented to the Faculty of the School of Engineering and Applied Science

University of Virginia • Charlottesville, Virginia

In Partial Fulfillment of the Requirements for the Degree

Bachelor of Science, School of Engineering

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Spring 2022

On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

Medical device donations can mean life or death in third world countries. Due to the disparities in healthcare budget and accessibility of medical devices, low-income nations are often left far behind the standard of patient care. A primary area that this disparity can be seen is in diagnostic imaging equipment. The World Health Organization has reported that as of 2017, two-thirds of the world's population does not have access to diagnostic imaging (Mariani et. al, 2017). Aside from the high cost of most diagnostic imaging modalities such as CT and MRI, these machines require a radiology suite that allows for a certain level of cleanliness to maintain the devices. Of the diagnostic imaging modalities, ultrasound has become the most widespread and common modality used. While MRI and CT machines serve for more specific problems, ultrasound can be used in a number of situations including biopsies, heart rate monitoring, and guided needle placement (Ultrasound Imaging, 2020). Point-of-Care Ultrasound (POCUS) is a handheld ultrasound device with a monitor attached the device, alleviating the need for a cart attachment that restricts the device to a radiology room.

In recent years, portable ultrasound has gained increasing popularity as a cheaper alternative to classic diagnostic imaging modalities due to its versatility and portability. With a traditional cart-based ultrasound costing $30,000, POCUS is a much more affordable option for doctors, costing only $2,000 (Kuttler, 2018). The lower price of POCUS devices allows for an increased number of devices that can be acquired which results in increased patient throughout. POCUS allows for real time imaging without the need to have patients transported to a radiology suite. Another advantage of POCUS is its ability to scan the heart, lungs, abdomen, soft tissue, and musculoskeletal system with comparable or better quality than x-ray machines (Sorensen & Hunskaar, 2019). The use of POCUS in low-income countries offers a viable solution to closing the gap in the diagnostic imaging disparity. By implementing POCUS, more efficient and accurate diagnoses will be made and overall health in low-income countries will be improved. In this paper, a case study will be presented in which successful and unsuccessful attempts at medical device donation in Haiti, Uganda, Honduras, Cambodia, and Rwanda will be evaluated to determine the optimal method for providing low-income countries with the medical supplies they need.

Case Context

The topic of interest in this paper is developing the optimal strategy for donating POCUS devices to low-income countries. In low-income countries, the average healthcare budget is significantly lower than that of higher income countries, and because of this, the facilities and equipment are often severely lacking. In an effort to make medical equipment more accessible across the globe, some hospitals donate excess or outdated technology that they aren't using. While this seems like a good plan in theory, donations often end up as nothing more than useless junk that wastes away. The reason behind the technology not being utilized can be understood by looking into the facilities and personnel at the recipient hospitals. The hospitals that are receiving the medical equipment are often not as technically advanced as those in higher income countries and the doctors are only trained in the devices that they currently have access to. When hospitals are donating devices, they don't take this into account and donate anything they don't need. The result is that some donations arrive broken, some require outlet styles that are not available in the new hospital, and some are devices that doctors have never seen and are unsure of when and how to use them. A study by Marks et al. revealed that on average, only 10-30% of donated equipment is operational (Marks et al., 2019). This is an issue because rather than advancing the healthcare systems of low-income countries, they are turning into burial grounds for unwanted and unusable devices. With this issue in mind, when sending the portable ultrasounds to their recipients, it is crucial to establish a system by which the doctors can learn and achieve proficiency in ultrasound procedures. One key consideration is infrastructure. Understanding the area that the recipients are working in will allow for personalized training. In areas that will be using the device as a stethoscope, training can focus more on auscultation procedures, where the device will be used to quickly scan the heart, lungs, abdomen, and vasculature for any glaring issues. In areas that need the equipment primarily for women's health in pregnancy, the training needs to be tailored more towards fetal ultrasound. Building on the established norms of the doctors will make for a smoother transition than attempting to completely alter the way these countries operate their healthcare systems. Research has supported that there is a very clear need for POCUS in developing countries. Sippel et. al argues for the advancement of POCUS in low-income countries for its use in early identification of pregnant mothers at risk of Intrauterine Growth Retardation, detecting patients at risk of cardiovascular disease, and establishing fetal heart rate (Sippel et al., 2011). Because of the wide range of use cases that portable ultrasound offers, developing countries can begin to provide a higher quality of care in areas that would otherwise each require their own, more expensive imaging device. By analyzing prior attempts at medical device donations in low-income countries, and analyzing the disparity in healthcare spending between countries such as the United States, Uganda, Haiti, Honduras, Cambodia, and Rwanda, the pitfalls of current donation efforts can be avoided and new technology can be effectively integrated in the future.

Framing the disparity in global diagnostic imaging capabilities

Doctors, patients, supply chains, and hospital administrations are all key human dimensions. Doctors perform the imaging and the patients receive the ultrasound. There needs to be a level of trust between the two parties that the doctor knows what they are doing and will provide the patient with the best care possible. Supply chains are responsible for the delivery of equipment. If items arrive broken or are sent to the wrong locations, they are useless to the hospitals that are receiving them. Hospital administrations have the ability to donate excess or aging equipment to developing countries. In terms of social dimensions, there needs to be a societal understanding of what the ultrasound does and why it is important. If the society is wary of ultrasound or is unaware of the value that imaging has in diagnosis, they may tend to opt out of receiving an ultrasound or not think to have one done when it is needed.

Connections between the technical and human dimensions work to paint a complete picture of what strides need to be taken to close the gap in access to diagnostic imaging equipment. The POCUS device is connected to the supply chains because the supply chains are responsible for handling and delivering the device to where it needs to go. There is also a connection between the doctors and nurses and POCUS training. Doctors and nurses need to be adequately trained in how to administer ultrasound so that they don't risk patient safety or obtain unclear images that would compromise the accuracy of the diagnosis. Hospital administrations connect to each of the previous connections. They work with supply chains to send equipment to other hospitals where doctors will use it to treat patients. It is important to make sure that the hospital administrations are working with the doctors to ensure that they are sending items that are actually useful and capable of being implemented (Marks et al., 2019). Each of these problems need to be addressed in the implementation of the device.

In order to fully grasp the process of implementation, it is necessary to understand the impacts of unintended consequences and what steps can be taken to prevent them. Harrison et al describes the relationship that exists between doctors and health information technology (HIT).

In many instances, doctors are resistant to change and blame technology when things go awry. In reality, the shortcomings of new technologies are often caused by a lack of understanding of how to use them. Harrison describes four factors that make up the Interactive Sociotechnical Analysis (ISTA) framework and need to be considered when implementing new technology. These factors include understanding what the actual uses of the technology are in comparison to the intended uses, the technologies impact on the physical and technical settings of work, the user's reinterpretation of the technology, and the interactions between the social and technical systems (Harrison et al., 2007). These factors are easily transferred into the deployment of POCUS. Due to the versatility in imaging capability, doctors in areas without other imaging modalities may use POCUS in place of x-ray and MRI. The portability of the device impacts the physical setting of work by allowing for doctors to perform exams outside of a radiology suite. Considering ISTA frameworks, unintended consequences of POCUS, can mitigate implementation failures.

Research question

I chose to ask the following research question: How should POCUS be introduced into developing countries to ensure successful implementation? Diagnostic imaging is currently significantly limited in developing countries (Compton, 2020). In 2016, a team of researchers from Stellenbosch University conducted a study to evaluate the disparity in the number of imaging devices in Tanzania vs. South Africa. The results of the study found that in the public sector, Tanzania has 5.7 general radiography devices per 1 million people. This is far short of the World Health Recommendation of 20 devices per 1 million people. South Africa, on the other hand, spends a significant amount more on healthcare and has 19.7 general radiology devices per 1 million people (Ngoya et al., 2016). By answering this research question, a plan has been made to make strides towards closing the gap in diagnostic imaging between developing and developed countries.

Methods and Data Analysis

To begin the analysis of medical device donation, I collected data on healthcare expenditure per capita in the United States, Haiti, Uganda, Honduras, Cambodia, and Rwanda. Looking at these countries' healthcare expenditures provided insight into the financial burden that developing countries face and why medical device acquisition is difficult. In addition to this, world health outcome data, specifically average life expectancy, was analyzed to determine the current quality of healthcare. This data, show in figure 1, shows the disparity in the medical care that can be provided between developing and developed nations (Ortiz-Ospina, 2020). Data on previous medical device donation in Haiti, Uganda, and a joint evaluation of Honduras, Cambodia, and Rwanda were also collected. The data from these cases came in the form of evaluations of the state of medical equipment that had been donated to hospitals and what the underlying cause of unused devices were. This data illuminated the major successes and pitfalls of implementing devices in these countries. Analysis of the data from the perspective of the ISTA framework determined where improvements in the donation process could be made to ensure success moving forward. By analyzing the prior cases and healthcare spending, the proper implementation process has been determined to ensure successful implementation of POCUS in developing countries.

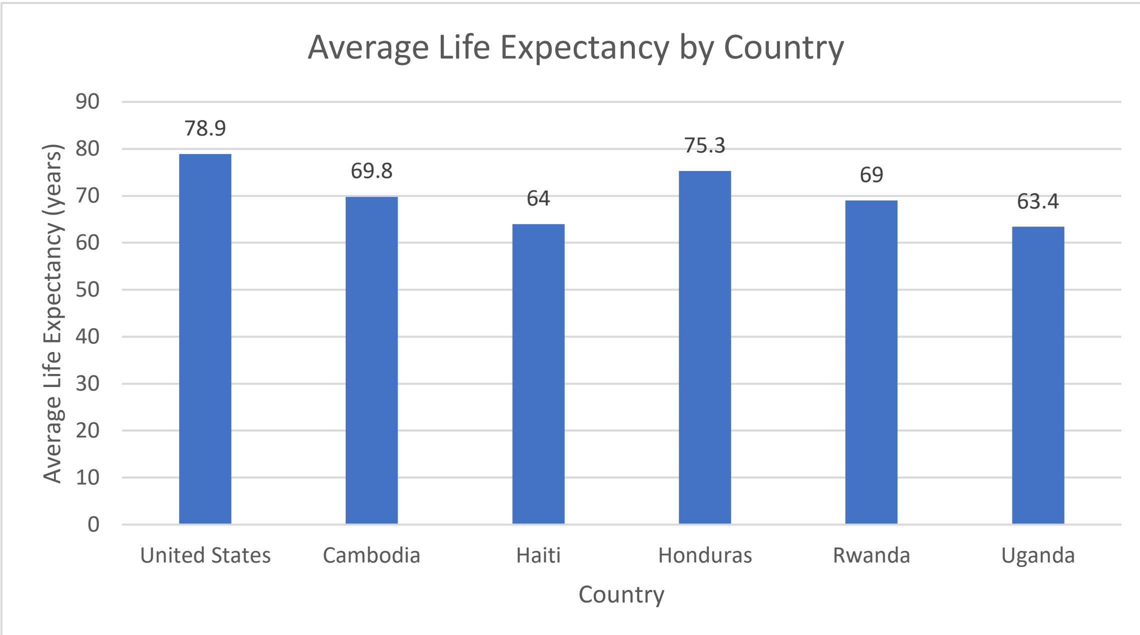

Figure 1. This figure depicts the average life expectancy of the evaluated countries. The data in this figure shows that on average, citizens of developed nations outlive citizens of developing nations.

Case Study Analysis

Analysis of 2019 healthcare expenditures per capita in the United States, Haiti, Uganda, Honduras, Cambodia, and Rwanda revealed that the United States spent significantly more than the developing countries, as can be seen in figure 2 (Current health expenditure per capita (current US$), 2022). Healthcare expenditures are defined by "all expenditures for the provision of health services, family planning activities, nutrition activities and emergency aid designated for health" (Healthcare Expenditure, 2022). Understanding this definition shows that medical devices are just a small piece of the puzzle and sheds light on just how little funding developing nations have for improving the overall health of their citizens. Case studies on the functionality of donated medical devices in the previously mentioned countries revealed a number of obstacles to successful implementation. The most prevalent issue was a lack of trained technicians. Biomedical engineers and technicians in these countries maintain a high volume of devices from a variety of manufacturers. In addition to lack of training, donated devices rarely come with service manuals, further preventing the ability to perform maintenance on out-of-service devices. Another commonly reported obstacle was a lack of infrastructure to support device installation. In each case study, a portion of devices were found to be in working condition but unused due to lack of clean rooms and space in the hospital to put the devices. Along with this, some devices required different power voltages than the hospitals supported. Finally, lack of preparation was a major shortcoming of donated devices. In all cases, devices were sent without spare and accessory parts. By leaving parts out of the donation, maintenance became impossible. With these pitfalls in mind, it was determined that for POCUS to be successfully implemented in developing countries, meetings between recipient hospitals and POCUS representatives need to be had to ensure the infrastructure is suitable, maintenance needs to be performed prior to delivery to ensure each device is functioning, and biomedical technicians from recipient hospitals need to be given training on how to service the devices when issues arise.

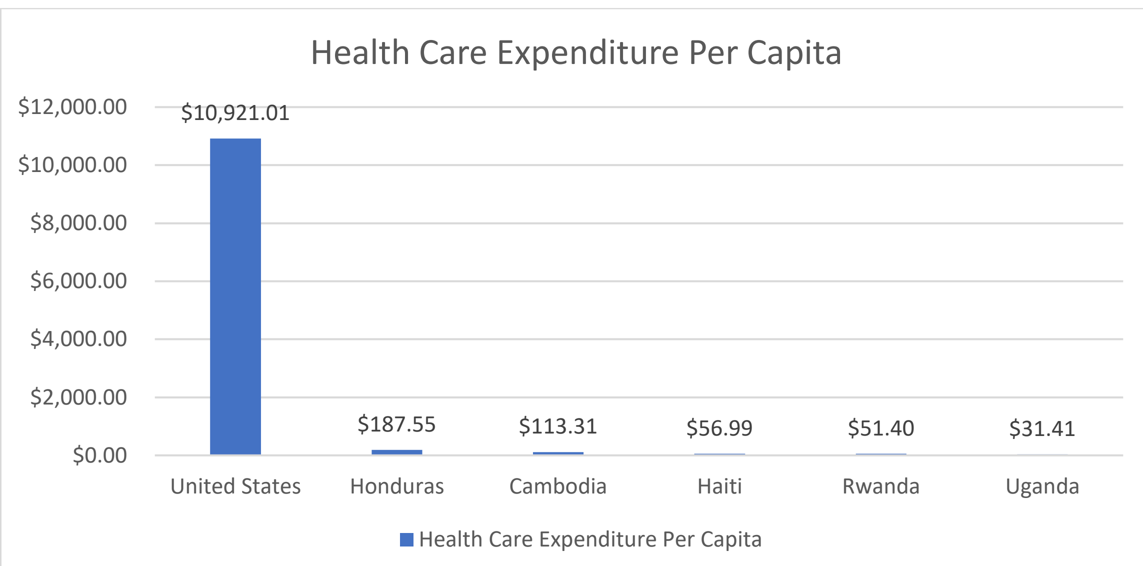

Figure 2. This figure shows the breakdown of healthcare expenditures per capita in 2019 of the United States, Honduras, Cambodia, Haiti, Rwanda, and Uganda.

The first case study evaluated 9 tertiary hospitals and 5 research facilities in Uganda. Of 2,338 medical devices, an average of 37% were nonfunctional. Of these nonfunctional devices, 489 pieces were identified as either in use but in need of repair or out of use but repairable. These devices had not been repaired due to a lack of spare parts and manuals. 157 were in working condition but not in use due to a lack of training on the equipment. The breakdown of device status can be seen in figure 3. Of the 9 hospitals in the study, there were a total of 12 biomedical engineers and technicians. Each engineer was tasked with maintaining an average of 167 pieces of equipment from 51 different manufacturers. This creates an issue because each manufacturer has their own design, making maintenance of all the equipment difficult. Another key barrier to implementation was lack of infrastructure to support installation. Some donated equipment was identified as nonfunctional because it required a 110V power supply but the hospitals ran on 240V. Using these devices was impossible without a step-down transformer, creating an additional cost for the Ugandan healthcare system. Finally, only 37% of facilities had the budget to receive routine maintenance and repair. This shows that in 63% of facilities, non-functioning equipment was used while damaged or thrown out because of an inability to fix the issue (Ssekitoleko et al, 2021). It is clear when analyzing this case that there was a breakdown in the connection between the donor and the recipient hospitals. Had the two worked together, the donor would have been aware of what types of devices the recipient hospital was capable of repairing and not sent devices that were going to go to waste due to lack of understanding. In addition, when this case is put in the scope of the ISTA framework, it is clear that the donation process did not account for the impact of technology on the physical and technical setting of work (Harrison et al., 2007). By not looking at the physical restraints of Uganda's infrastructure, donors failed to realize that devices requiring 240V would be incapable of making the intended impact. The implications of this case show that while the Ugandan healthcare system did receive a donation of which the majority of devices were able to be put in use, the fact that 37% of the devices were useless posses a huge issue. These out of service devices create unnecessary waste that the hospital either has to dispose of or leave laying around, taking up space. The larger implication of this case study is the fact that while healthcare capacity did increase from the donation, the large number of out of service and broken devices shows that had the donation effort been more strategically planned, the healthcare capacity could have been even more greatly improved without causing unnecessary waste.

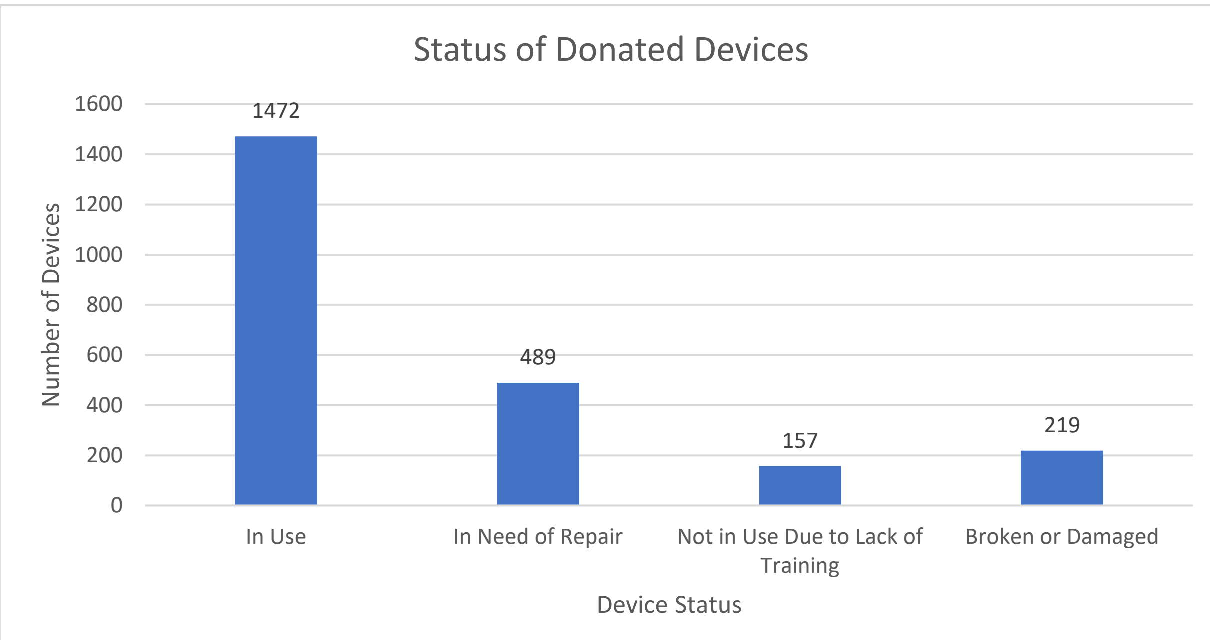

Figure 3. This figure displays the status upon arrival of the donated medical devices between Honduras, Cambodia, and Rwanda.

A second case was evaluated in Haiti six months after a 7.0 magnitude earthquake. 3 American and 4 Haitian clinical engineers conducted a study on the functionality of equipment that had been donated before and after the earthquake. No difference was found in the functionality of devices obtained before and after the earthquake. On average, out of the 951 pieces of equipment, it was found that 28% of the equipment was working and in use, 58% was either working and not in use or not working but repairable, and 14% was not working and unrepairable, as shown in figure 4. A number of reasons were described as playing a role in the lack of functioning equipment. The main reasons were lack of training, equipment that was broken upon arrival, lack of spare parts, and lack of service manuals. Of the 951 pieces of equipment, only 2 were found to be maintained by a third-party provider, meaning the biomedical technicians were in charge of servicing almost all devices. A number of pieces of equipment were described as non-functioning upon arrival, which raised suspicion as to if maintenance checks were performed prior to shipment. Many devices were missing spare parts, making it impossible to perform needed maintenance, and it was discovered that only 10 of the devices had a user manual and only 4 had a service manual. In addition to these issues, 38% of the devices had the age of the device available, and of these, 88% were over 5 years old. Equipment that old is not only out of date compared to newer models, but is also prime for breakdowns from high volume of uses (Dzwonczyk & Riha, 2012). This case shows clear limitations of the donation process, especially in times of need. In terms of the human and technical connections, there was a clear breakdown of the connection between the supply chains and the recipients. 14% of the donated devices were broken and unrepairable. The supply chain is responsible for transporting the donations to their recipients and if a large number of devices are breaking before ever reaching their intended users, there is a clear breakdown in the process. In cases where donation is spurred as a response to a crisis scenario, it is important to take into account the ISTA framework. The first rule of the framework is to think about the actual uses of the technology in comparison to the intended uses. This rule is very applicable because natural disasters affect so many people that healthcare workers have to get creative to provide the proper care. The implications of this case study show the lack of adequate response to disaster that currently exists. In situations such as this, where there is a major natural disaster that causes harm to both infrastructure and people, it is crucial that working medical equipment be given to the hospitals in a timely manner to ensure citizens can receive the care they desperately need. In this case, only 28% of the donations were able to be put in use which indicates that the Haitian hospitals did not receive nearly enough working equipment to adequately provide their citizens with medical attention. Moving forward, in all donation efforts, but especially in response to natural disasters, the donation process needs to be drastically improved.

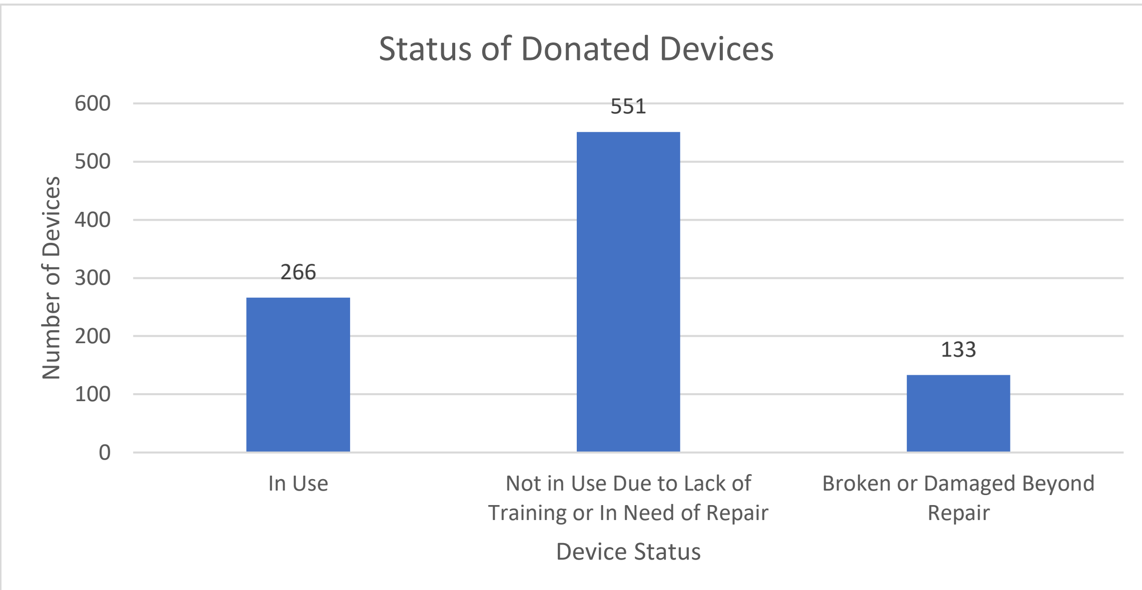

Figure 4. This figure displays the status upon arrival of the donated medical devices in Haiti following an earthquake.

The final case study evaluated 2537 pieces of medical equipment over the course of two years in 64 hospitals in Cambodia, Honduras, and Rwanda. The study found that an average of 18% of the equipment in these hospitals was out-of-service, as shown in figure 5. A further breakdown showed that the percentage of out-of-service equipment was 17% in Honduras, 19% in Cambodia, and 24% in Rwanda. When looking at the difference between equipment that had been donated and purchased, it was found that donated equipment was out of service at a significantly higher rate than purchased devices. The research team interviewed technicians to learn why the out-of-service devices were not able to be repaired. For 49% of the devices, the technicians were missing a spare part that was essential for the repair. In 24% of the cases, there was a lack of communication which left technicians with little understanding of what was wrong with the equipment. The remaining 38% of cases were not able to be repaired either due to a lack of knowledge on maintenance procedure or lack of authority to perform maintenance on the device (Emmerling et al., 2017). This study also found that modern equipment poses a challenge to developing countries due to sensitivity to lack of temperature control and dust. This sensitivity can shorten the lifespan of the device and cause technical difficulties (Center for Devices and Radiological Health, 2018). Similar to the first case study presented, this case shows a clear breakdown between the human dimensions of the donor and recipient. Having 18% of devices be out of service and 24% of those devices be out of service because the recipient technicians were unaware of the issue shows the breakdown in communication between the two groups. This case failed to account for the interactions between the social and technical systems from the ISTA framework. Had they anticipated this interaction, they would have provided the service manuals needed to allow for maintenance of out of service equipment. The key takeaway from the results of this case study is that the failures in medical device donation are not limited to one geographic location. These issues are present in developing nations all around the world and point to the need to improve the way that donations are done and ensure that all devices are capable of being put into use to maximize the healthcare capacity of these nations.

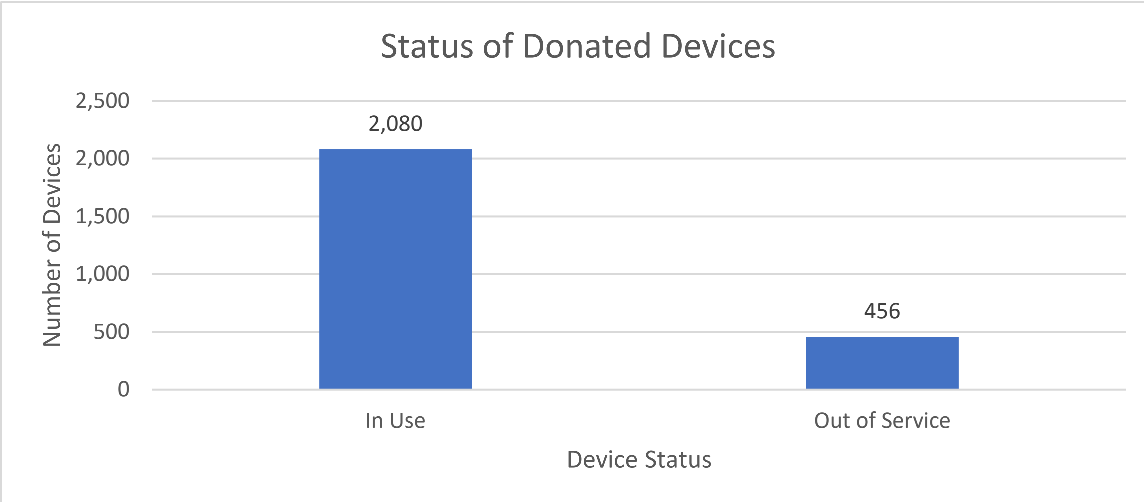

Figure 5. This figure displays the breakdown of in use and out of service devices donated to hospitals in Honduras, Cambodia, and Rwanda.

Understanding the connection between the disparity in average life expectancy of developing and developed countries and the access to working medical equipment shows the importance of perfecting the way that devices such as POCUS are implemented. It is crucial to heed the lessons from the three case studies and consider the ISTA framework to avoid mistakes that will diminish device utilization. In order to ensure that the recipient environment is suitable for the device, meetings need to be conducted to clarify the diagnostic imaging needs of the recipient and confirm the intended uses. The next step of the preparation process is to provide training to biomedical technicians at the recipient hospitals. Giving the technicians hands-on training on common issues that may arise will prepare them for any required maintenance. Physicians should also be given training and perform practice examinations to ensure comfort and competency with the technology. Finally, maintenance checks need to be performed on each device being delivered to ensure that none of the ultrasounds need to be serviced before a scan has even been performed.

Discussion

The research presented in this paper can be applied to the implementation of new technologies in hospitals. Harrison et al reveal the resistant nature of physicians when it comes to change. Because of this, it is relevant to do preparation and make sure new technology is implemented in departments where it will be utilized to the maximum potential. It is also crucial to train physicians and nurses prior to implementation. If new technology is installed but physicians are not trained on the technology, they will be hesitant to use it and will default to the technology they are comfortable with. The breakdown in the cases presented previously were caused by lack of infrastructure and lack of knowledge to repair devices. These issues are translatable to the implementation of new technologies and need to be addressed to ensure a smooth transition.

The major limitation of this research is lack of diversification in location of the developing nations. Most of the cases evaluated countries in sub-Saharan Africa. The third case study included Honduras and Cambodia, but it looked at those countries in unison with Rwanda rather than as their own entities. This lack of geographical diversification means the results may not be generalizable to other countries with different environments. With these limitations in mind, if this research were to be replicated, it would be important to gather data from developing nations across the globe and evaluate the findings of each in their own section rather than grouping them together and taking the averages.

Moving forward, if this research were to be redone, the most important change would be diversifying the population. The data presented showed there is clear breakdown of the donation process in sub–Saharan Africa and alluded to the fact that the issue extends to other parts of the world but does not present isolated data from those countries. Adding isolated data on other parts of the world would show how broad the overall issue is. A second change would be to include interviews with medical device donors. The case studies focused primarily on survey counts of devices and accounts of the recipient technicians. Including the donor's perspective would provide a holistic view of the donation process and the obstacles donors face. Making these changes would aid in creating a more well-rounded and generalizable report that may be valuable to a larger audience.

The information gained through the process of answering this research question will vastly advance my engineering practice. Through evaluating the case studies, I discovered that many of the solutions to the shortcomings of medical device donations are applicable to any engineering design process. The data showed that communication with technicians is one of the most important aspects of successful donation. Communication is also one of the most important aspects of engineering design. Having effective communication with the relevant stakeholders during the design process is crucial for having an effective product that fulfills all of the design criteria.

Conclusion

Medical device donation is a good concept that is plagued with flaws in its current form. By analyzing the pitfalls of the current donation process, not only can the issues be remedied, but the solutions can be applied in various other areas such as implementing new technologies. To improve further upon this research, analysis into how to get developing nations onto a level playing field needs to be conducted. Health outcomes are not a competition and should not inherently benefit those who are born into a developed nation. Actions like implementing

POCUS in developing nations have vast impacts on the medical capacity of their healthcare systems and are just a step in the right direction of equalizing health outcomes all around the world. Communication is the root of all issues with medical device donation, as well as with new technology implementation. It is crucial that donors and companies communicate with their intended recipients to ensure that the incoming devices are able to be used and repaired as needed so that they avoid unloading useless equipment on those in desperate need of help. Understanding the need for communication will have the single greatest impact on the success of POCUS implementation.

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