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Barriers for medical devices for the developing world

'... the WHO estimates that 70% of medical equipment coming from the most developed nations does not work in developing world hospitals.'

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The fastest growing market for medical devices is not the USA or Japan, but is found in the lesser and least developed nations of the world. While they are currently relatively small markets, they hold tremendous potential. At first, it might seem appropriate to attempt to sell the same equipment used in developed nations to the developing world hospital. However, the WHO estimates that 70% of medical devices designed for use in the developed world, don't work when they reach the developing world. This article will outline the major causes for these failures and discuss unique barriers that must be considered when designing for the developing world hospital.

According to the UN, 1.2 billion people live in the most developed nations on earth. However, 4.9 billion people live in the lesser and least developed nations (which will be referred to as the developing world for the rest of this article) [1]. Despite the inherent poverty and complications, when the enormous size of the developing world is considered, it becomes clear why it is an attractive market. For example, while the gross domestic product (GDP) per capita is approximately 4.5-times smaller in the developing world, when looking at aggregate GDP the developing world is roughly comparable with the most developed nations (both at approximately 22 billion adjusted US dollars) [1], yet market penetration is close to zero for most medical devices. When looking at healthcare expenditures, at approximately US$2500 per capita in the most developed nations and US$250 per capita in the developing world, close to 30% of the world's healthcare expenditures are in the developing world and this percentage is growing [1].

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Unfortunately, designing for the developing world market presents unique challenges not seen elsewhere. The clearest evidence of these challenges is the current failures; the WHO estimates that 70% of medical equipment coming from the most developed nations does not work in developing world hospitals [2]. Another example is the 'Health Care for All by 2000' project [3]. Several known, inexpensive technologies were selected to carry out major health improvements (oral rehydration solutions, food supplements, antibiotics, vector control agents, water pumps and latrines). Despite some early success, the 'Health Care for All by 2000' campaign was largely a failure [4].

How is it possible that 70% of imported equipment does not work when it reaches a developing world hospital? How can known and effective technologies fail? The focus of this article is to review which unique obstacles exist to the successful design and diffusion of medical devices for the developing world.

The developing world medical device landscape

Of the 5 billion people living in the developing world, 1 billion are illiterate, 1 billion lack access to safe drinking water, and 2.5 billion

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lack access to basic sanitation [5]. The life expectancy in the poorest country in the world is 38 years; that is half of that in the USA and Europe. Many developing world nations have military or one-party (person) rule, lack a commitment to international standards in human rights and have recently (or currently) experienced civil war [5].

Many developing world nations have a thriving private sector healthcare system. In fact, in the last decade, the developing world has seen a dramatic shift towards the private sector [6]; only 8% of those using hospitals sought them in the private sector in 1991 and this rose to 27% in the year 2000. The private sector can have a negative impact on healthcare as the high cost of the private sector combined with its increased perception as being superior, has driven fewer to seek medical help in the developing world [6]. However, the private sector can also serve as a model for the public hospitals, and in that sense can have a positive impact beyond the small fraction of the population they serve.

Hospitals are also competing with traditional medicine. For example, in rural Thailand, only 30–40% of those who are ill seek professional medical attention [6]. However, neither the private clinics nor the traditional healers serve the majority of the population. The majority of the developing world population uses the professional, public healthcare system. Public hospitals receive government support [7] and foreign support. In many cases, foreign support represents the majority of the health care expenditures [8], (although often badly targeted [9]).

Over 95% of medical equipment in public hospitals is imported. There is essentially no local production of medical equipment [10] and, when there is, it is controlled by multinational corporations [7], often for export. Most of the imported equipment is of very poor quality, 96% is not working just 5 years after donation and 39% never worked due to lack of training, manuals or accessories [7].

To some extent, medical device purchases are more heavily dominated by public health considerations. Among public health professionals, many feel that investment in social services should be favored over medical devices [11–13].

Developing world hospitals differ from those in the most developed nations in that the developing world is fragmented with a lack of clear power and organization [14]. This is particularly problematic when a technology is imposed from a central authority, such as The WHO or the Ministry of Health. There is little recognition in the developing world that the individual, local healthcare provider can be the agent of change [14], a system where doctors select the technology they will use to treat patients.

There are bright spots on the medical device landscape in the developing world. Many immunization programs have been successful, such as small pox, polio and measles campaigns. Technologies such as cold chain maintenance and one-time use syringes [15,16] have vastly improved these and other aspects of primary healthcare delivery. However, advances in the primary healthcare arena are not necessarily mirrored in the referral clinic or hospital, where this article is focused.

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Expert commentary

Faced with a landscape as complicated and pot-holed as the developing world, there are numerous unique barriers to the introduction and diffusion of medical equipment. These are revealed in both existing and new medical devices. However, there are very little firsthand data on the unique barriers to healthcare technology development and introduction for the developing world.

Spare parts

The most important design barrier is the lack of spare parts in the target countries. Any device designed for the developing world will be likely to stop working as soon as the first replacement part is required. For example, if a filter needs to be replaced every 6 months, then the device will likely only last for 6 months when placed in a developing world hospital. This can be because spare parts may not be available in the developing world, because the parts may not be made anymore, or the part may require a credit card to purchase (few people in the developing world own a credit card).

However, data from recent studies [17,18] suggests that the lack of spare parts may be overly often cited as the problem. When examining equipment, participants in the Engineering World Health (EWH) study only identified 12.3% (120 out of 975) of the broken pieces of equipment as requiring a spare part that could not be found or manufactured in the developing world. Therefore, lack of spare parts may be a relatively less significant problem than often claimed.

Other possibilities for the failure to replace parts exists. The cost may be prohibitive or the hospital may lack the expertise or tools required to execute the repair. Most hospitals do not have a technician with more than a high school education.

In some cases, the hospital may perceive the expenditure to be a poor use of resources. One reported EWH interview revealed that a hospital found it easier to request a new oxygen concentrator from their European sponsor, than to spend the $5 required to repair the concentrator they owned [17,18].

Another issue with spare parts in the developing world is the lack of motivated technical staff. Many participants in the EWH study [17,18] reported that staff frustration led to their inaction. The lack of tools and manuals, corruption in the government, perhaps extending to the public hospitals or centralized biomedical engineering facilities can create frustration. This frustration can lead technicians to not even attempt a repair or maintenance procedure.

Consumables

One of the most common problems encountered in developing world hospitals is the lack of consumables. Consumables are liquids or supplies required for the use of the equipment, but allowing only limited, or no, reuse (e.g., test strips, ECG electrodes, blood pressure transducers or electrosurgery tips). In most cases, the consumable is simply not available in the country.

In some cases, specialized consumables cannot be avoided or common consumables must be packaged in specialized containers. However, more often, the packages or requirements are added as part of an economic model (the color printer is inexpensive, but the toner cartridges are expensive).

The inability to find replacement consumables is one of the most common barriers to the purchase of medical equipment by developing world hospitals, or by donating organizations.

Other barriers

Designing equipment that does not require consumables or frequent maintenance are the principal barriers to successful design for the developing world. However, there are other barriers.

One clear barrier is the lack of trained technical staff. When qualified staff are found, they are often lost to 'brain drain'. Brain drain refers to educated workers emigrating from their developing world nations [19]. A 'brain leak' also occurs, where workers are educated to a specific task in the hospital, making them now eligible to be drained. The brain leak makes some hospitals and medical device providers reluctant to invest in employees' education. Unfortunately, modern medical equipment often requires highly skilled technicians to operate and maintain them.

The lack of reliable power and water [20] is a barrier to healthcare technology. Some equipment is designed for an existing infrastructure of at least water and electricity [21]. Sometimes distilled, deionized water must be available. Power is rarely available on a continuous, reliable basis in developing world hospitals. Roads are often in poor quality. Therefore, a trip to a larger city to fetch specialized water can be the principal expense in the use of a piece of equipment. Largely owing to a lack of public infrastructure, as much as 75% of developing world has no oxygen supply for their patients [22].

Kochar points out that 'every technology has a cultural load' [23]. The most striking hospital example is the mismatch in the economical model. Few hospitals in the developing world are strongly driven to reduce hospital stays or procedure costs the way that American and European hospitals are. In agricultural efforts [24] and some medical efforts, this mismatch between economic conditions has led to an altered design process [25] where the technology's design is not considered complete until it is adopted (as opposed to being considered complete when it meets standards). As an example, WHO developed a standard for oxygen concentrators that many manufacturers have met [26], but this has not solved the developing world's problems with oxygen supply [27–30].

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Misconceptions

The EWH interviews [17,18] revealed some misconceptions concerning healthcare technology in the developing world. One misconception is that instruments must be simple. Of the 331 pieces of equipment that could not be returned to the patient bedside or clinical laboratory, none of these failed repairs were due to a failure to be able to train the users.

A related misconception is that removing features from a design to reduce cost will make the device appealing to the developing world. In fact, stripped-down versions of medical equipment are sometimes rejected, despite the lowered cost, because accepting them is sometimes perceived as admitting a lesser status. Developing world citizens may be less financially wealthy, but they often do not see themselves as being of lesser status. In fact, many are very proud that they are not from a more developed nation such as the USA. Designs and sales approaches must consider this high degree of pride when approaching the developing world market.

A second misconception is that the cost of the medical equipment is always a barrier. In the case of the simple laboratory kits, the cost of the equipment is negligible compared with the consumables. Even when the equipment is very expensive, hospitals can sometimes pool resources to purchase them. When these items fail, it is because the hospital cannot maintain the equipment, not because it cannot afford it.

Five-year view

Whereas doctors have, in many cases, learned to adapt their practice to developing world conditions [31], engineers have not developed medical equipment design practices specifically for developing world conditions. However, there are examples of successful strategies that we can expect to proliferate in the next 5 years.

Duke University is piloting a program to train engineers specifically for developing world design [32]. Duke-EWH Competition for Underserved, Resource-poor Economies (CUREs) is a nonprofit business plan competition that works with student teams and nonprofit corporations to design medical devices for developing world use. CUREs is conducted like a business plan competition, where student teams conduct need finding through on-the-ground market research in developing world hospitals; nonprofit business development with a national panel of experts, and prototype development through a formal design class at Duke University.

The Program for Appropriate Technology in Health (PATH) has taken a different approach based on large-scale collaboration. The PATH approach is to select problems where the public and private sectors in the most developed nations can work in harmony. Such harmony requires that; the need be clearly defined, there be a consensus among the public health community and there is a public–private collaboration to fund, design, field test and promote the product. Despite these formidable obstacles, PATH can be effective, as illustrated by the single-use syringe project [15].

Project Impact may represent yet another approach to implementing healthcare technology in the developing world [33]. Project impact is a nonprofit in the earned-income model, where earned-income nonprofits sell products to produce revenues. The products can be sold at a profit (perhaps to wealthier

individuals) or at a loss (perhaps to poorer individuals), but the corporation is prevented from distributing any net profits to individuals [34]. As a nonprofit without owners, Project Impact can focus on maximizing service to the developing world, instead of maximizing profits. Project Impact's intraocular lens is a notable success.

There may be a bright future for the developing world medical device industry. The market is large and largely untapped. Some biomedical engineers are being trained in the developing world, designing medical equipment for the developing world and manufacturing it in the developing world for the developing world. However, the numbers are currently very small. Only a limited number of universities are offering biomedical engineering classes focused on designing for the developing world.

Engineering design problems for the developing world can be envisioned for x-ray, ultrasound, electrosurgery and clinical laboratory equipment, for example. Alternative designs could avoid disposables, take advantage of the low cost of labor, require little power, minimal service (or easily delivered service) and modest specialized training for servicing.

There are billions of people who have a strong need for healthcare technology solutions and are willing to pay, albeit relatively little, for that technology. Companies that can successfully tailor their designs, avoiding the many barriers, will profit from their efforts.

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Key issues

- The developing world represents a market size approximately five-times larger than the developed world.
- Successfully capturing the developing world market will require more than selling the same devices at lower prices. Most medical devices transplanted from the developed world to the developing world hospital fail.
- The most important unique design barriers for medical devices in the developing world hospital are the lack of spare parts and the lack of required consumables.
- Other unique barriers include a lack of reliable power and water, public infrastructure and technical expertise.
- It is a misconception that designs must be simple and that capital cost is always the primary barrier.
- Stripped-down designs may be perceived as lesser quality and rejected, despite lower cost.

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