Chapter 11
Medical Devices and Information Communication Technologies for the Base of the Pyramid

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Abstract Providing adequate access to medical care in developing countries is a systemic and complex issue, driven by numerous challenges ranging from issues in delivery of care to broader development issues. One key issue is the lack of appropriate, low-cost devices to diagnose and treat what are often easily addressed medical conditions. The last decade has seen the development of numerous low-cost medical devices and the application of information and communication technologies. A limited number of projects, however, manage to pass the pilot testing stage and go on to achieve impact at scale. The reasons for this are multifaceted. In this paper, we discuss challenges presented by medical device markets and challenges in the development of these technologies. We argue that multidisciplinary dialogue and public–private partnerships are the essential factors that lead to the integrity and success of low-cost health systems in small and fragmented markets.

11.1 Introduction

Providing adequate access to medical care in developing countries is a systemic and complex issue, driven by numerous challenges ranging from issues in delivery of care such as a lack of trained practitioners to broader development issues such as malnutrition and poor living conditions. One key issue is the lack of appropriate, low-cost devices to diagnose and treat what are often easily addressed medical

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conditions. The last decade has seen the development of numerous low-cost medical devices and the application of information and communication technologies (ICT), often combined with health innovations on mobile phones (mHealth). A limited number of projects, however, manage to pass the pilot testing stage (Labrique et al. 2013) and go on to achieve impact at scale. The reasons for this are multifaceted. In the following paragraphs, we highlight some current challenges, addressing both challenges presented by medical device markets and challenges in the development of the technologies themselves.

11.2 Market Challenges

The medical device market for developing countries, particularly across sub-Saharan Africa and South Asia, is often described as a massive opportunity waiting to be unlocked. While there is a large future opportunity, and health care in developing countries is growing, the current market for medical devices is modest. Many countries in sub-Saharan Africa have only a few dozen hospitals with a meaningful equipment budget and, while there may be several thousand of primary care clinics in a midsized country like Kenya, these facilities have neither the funds nor the mandate to purchase equipment.

An example of this can be seen in vaccine refrigeration, a market where there is strong global attention, but a small actual market and a subsequent lack of appropriate products. The Bill & Melinda Gates Foundation (BMGF) which has funded billions of dollars of work in vaccination, reports that only 33 % of clinics in countries supported by the Global Alliance for Vaccines and Immunisation (Gavi 2013) are equipped with cold chain equipment (i.e., vaccine refrigerators), that 20 % of those facilities have nonfunctioning equipment, and as many as 20–25 % of vaccines are exposed to freezing temperatures that can reduce their efficacy (BMGF 2013). Clearly, vaccine refrigeration is an area with ample opportunity for improvement. However, while more than US$1 billion is spent annually on vaccines, spending on cold chain equipment is estimated to be only US$40 million (Gavi 2013). For large companies with the experience, expertise and resources to develop and distribute innovative, low-cost products at scale, the vaccine refrigeration market is simply too small. Top medical device manufacturers generate US$1 billion+ per year in revenue, while appliance manufacturers are larger. For multibillion dollar companies trying to drive top-line growth, a US$40 million market is not a large enough opportunity to provide business-relevant financial returns.

A second major issue is that the currently small ‘global market’ is, in fact, actually dozens of even smaller national markets. The vaccine cold chain equipment market, for example, exists across 50 countries, each having different purchasing processes, regulations, and requirements for doing business. This holds true for many recently introduced medical products including ultrasounds, infant warmers, phototherapy, and wheelchairs. Some countries purchase primarily through the national ministry of health while other countries, such as Kenya, have empowered

regional governments to manage their own budgets. Needs, existing infrastructure and strategies toward equipping clinics vary across countries as well.

In the absence of major medical device manufacturers, fragmentation exists amongst suppliers, exacerbating the difficulty of penetrating medical device markets by making purchasing and servicing more challenging for the customer. To equip a primary health clinic, a facility manager needs to purchase from multiple suppliers and often devices are designed to function independently. That is, each device comes with its own ICT interface (usually its own phone or tablet), power supply, and data tracking system (if there is one). Optimization occurs at the device level rather than the facility level. The customer is left having to work with multiple suppliers to purchase and service those devices.

This fragmentation and the resulting difficulty in fully equipping facilities create an additional "chicken-and-egg" problem for new devices attempting to enter the market. Many medical conditions co-occur (e.g., HIV patients frequently need treatment for tuberculosis in addition to HIV), and the ability to treat just one condition is of limited value. Another example is that preterm infants often suffer from jaundice and require treatment with a phototherapy device. However, these infants often require treatment for several other conditions as well, and the ability to treat jaundice, without the ability to provide the full scope of care such as feeding support, external warmth, or treatment for infections, can render a facility insufficient to treat infants with jaundice. A facility that wishes to provide care for preterm infants needs to provide a whole array of complementary services, and simply having one device is of limited use.

11.3 Technology and Design Challenges

Medical devices and sensors that are established in industrialized nations' hospitals are often not adequately designed for point-of-care use in a low resource setting. Physical dimensions and power consumption prevent the direct adoption of the technology. Further, the rural setting adds tighter constraints to robustness and maximum allowable cost. Costs for maintenance, spare parts, and disposable components need to be considered. For mHealth applications, more targeted sensors for the mobile framework are needed (Kumar et al. 2013). Further, medical devices and user interfaces are traditionally designed for the medically trained experts. Medical devices and mHealth tools can easily become a burden to health workers if the solution is too technology focused (Strachan et al. 2012). It has been suggested that mobile devices should be transformed into functional job aids, which can become an additional motivating factor for technology uptake. For example, this effect was observed in a recent pilot study on implementing mHealth for maternal health monitoring in Ethiopia (Little et al. 2013). Health workers were able to develop a sense of ownership and consequently stay motivated in using and maintaining the device functionality. Therefore, we consider it important to evaluate new mHealth solutions rigorously for usability and acceptance to assure the

solution is functional and aligns with cultural, societal, and institutional constraints. Attaining usability of mHealth solutions can be facilitated by user-centered and participatory design that includes users in the design process throughout all steps of product development.

Certain medical sensors, such as pulse oximeters (Karlen et al. 2011; Payne et al. 2014) or ultrasound probes have been successfully interfaced with mobile phones to monitor vital signs in remote settings. Similarly, microscopy and spectroscopy are available through mobile phone cameras (Coskun 2013). While size and power consumption have been addressed, a major challenge remains in the maintenance of quality and robustness of these systems in a challenging environment. To ensure quality, developers and engineers rely on standards. Many standards for medical devices are written and updated with companies and customers in industrialized nations in mind. This leads to overregulation in a resource-poor setting. Often, the standards are not appropriately designed for these settings and cannot be implemented cost-effectively. A shift toward a minimum requirements standard would be desirable. The risk of creating dual standards needs to be discussed more widely. The issues of data security, privacy, and confidentiality should be added to the discussion. Countries with well-established regulatory systems have made advances in providing guidelines for ICT security in health systems. We argue that further research and discussions on privacy options with mobile systems are needed, especially for resource-poor settings with different cultural backgrounds.

It is evident that data collected in a remote location by health workers with little experience and training can interfere with quality and lead to poor decisions. Despite this, very little research on quality control for ICT and mHealth data has been undertaken. We observed an increased awareness on the importance to monitor quality and adoption during the EPFL-UNESCO Conference on Technologies for Development (2014 Tech4Dev). Open data models have been suggested to improve quality and transparency of medical devices for low resource settings (Ettinger 2015, Chap. 8), as well as the analysis of recorded biomedical signals with mobile devices (Stroux and Clifford 2014). As discussed in Chap. 12 (Beratarrechea et al. 2015), it is very difficult to demonstrate evidence of interventions with randomized control trials (Philbrick 2013). The monitoring of adoption and effectiveness with data tools is one of the many opportunities that open data can provide and therefore increase confidence in technology.

Scaling up of technological solutions in developing countries is still one of the largest challenges. Appropriate methods to achieve scale-up for mHealth are often not implemented (Tomlinson 2013) as businesses or other entities experiences in at-scale delivery are often not interested in these markets (see also Sect. 11.2 on market issues). Further, since competing health system priorities can prevent the uptake of mHealth solutions into state funded health systems (WHO 2011), often the political environment, or preexisting organizational structures (Densmore 2012) can impede the widespread distribution of successfully piloted systems.

The development of biomedical devices is a multidisciplinary undertaking between engineers, developers, social entrepreneurs, health providers, patients, policy makers, and researchers from social, business, medical and basic sciences,

and it is beneficial to enable the dialogue between these stakeholders early in the development process. This essential multidisciplinary dialogue as well as public–private partnerships could be the most important factor that leads to the integrity and success of health systems. As we see an increase in low-cost medical devices and a growing interest of large biomedical companies in health care technology for resource-poor settings (Leeds et al. 2015, Chap. 15), we are confident that challenges with small and fragmented markets can be resolved and the focus will shift toward implementing appropriate standards and scaling-up of robust products and markets.

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