Putting medical devices in context: a systematic review of evidence on design targeting low-resource settings

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Abstract

Most medical devices are inaccessible to healthcare facilities in low-resource settings (LRSs), severely limiting medical care for a vast proportion of the world's population. This article characterises the process used for designing medical devices for LRSs and investigate how the context-of-use is integrated into the process. A systematic review of 64 papers was conducted to identify peer-reviewed studies of devices intended for LRSs. Using the Biodesign process as an analytic framework, a qualitative meta-analysis was conducted. Findings show the studies predominantly describe the later stages of medical device design, whilst largely neglecting how knowledge of the context is considered. To support engineers and improve outcomes, it is imperative that an understanding of the context is integrated throughout the design and product development process. This article highlights this gap and hopes to stimulate research into how context can be better incorporated into the design process for medical devices targeting those populations most in need.

Keywords

medical devices; engineering design; context; low-resource settings; developing countries; global health; Biodesign process

Introduction

There are approximately 1.5 million types of medical devices available in the global market (Arasaratnam & Humphreys 2013) but, unfortunately, most of these are inaccessible to

healthcare facilities in low-resource settings (LRSs). This situation severely limits medical care for a vast proportion of the world's population. For instance, in the recent critical Ebola outbreak in West Africa the lack of equipment in healthcare facilities was one of the major challenges faced by health workers, despite the fact that the equipment required is not technologically advanced and is available in primary health care facilities in other parts of the world (WHO 2014). This lack of access to medical devices in LRSs is the result of a complex relationship between multiple factors that not only define the adoption of the technology, but also its affordability, accessibility, and its availability (Frost & Reich 2008).

The majority of medical device companies are based in high-income countries (HICs) and target most of their products to affluent markets (Howitt et al. 2012). Technologies are developed to function in fully operational healthcare facilities with fairly reliable and stable electrical supplies, large capital and consumables budgets, and highly qualified clinical and technical professionals (Richards-Kortum & Oden 2013). These companies, however, produce more than 95% of clinical equipment found in public sector hospitals in low- and middle-income countries (LMICs) (Malkin 2007b). Since conditions in LRSs are different to those the equipment was designed for, when technologies reach LRSs they are often unable to operate effectively, resulting in improper usage or total incompatibility with local needs and, in the long-term, technologies function poorly or not at all.

Designing for the low-resource settings

In the Lancet Commission for Technologies for Global Health, Howitt *et al.* (2012) proposed a set of recommendations to increase access to technologies for global public health challenges.

One of these recommendations refers to the development *frugal technologies* "specifically developed to meet the needs of the world's poorest people" (Howitt et al. 2012, p.509). Innovations for LRSs should create affordable and simple products and services that are "*good enough* to meet the demands of customers who could not afford state-of-the-art technology" (Howitt et al. 2012). Although the idea of simple and *good enough* technologies could be associated with an inferior technological capacity compared to modern technologies - a criticism of the appropriate technology movement (Willoughby 1990) - frugal technologies encourage designers to think about the needs that characterise the context in LRSs and differ from those in high-income country (HIC) markets.

Frugality is not about imitating or modifying technologies from HICs to make them cheaper for LRSs, but designing technologies with scarcity of resources in mind (Niemeier et al. 2014). "Glocalisation" was a strategy commonly used by multinational corporations (MNCs) for exporting to developing countries that proved to be a failure, as these adaptations did not suffice to meet the needs in LRSs (Govindarajan & Trimble 2013; Radjou et al. 2012; Arasaratnam & Humphreys 2013). Since technologies cannot always be translated from one context to another, designing for LRSs means introducing a new way of thinking to the engineering design process.

In order to achieve appropriately designed and marketable technologies that address health needs of communities with limited resources, there are several stages in the engineering design process that need careful consideration (Howitt et al. 2012). Devices should not only be cleverly designed, but they are required to be disruptive enough to make healthcare more cost-effective and add value in the context in which they will be used (Free 2004). Hence, designers need to

gain deep knowledge of the context of use and values existing in that context. The World Health Organization (WHO) proposed elements upon which the use of medical devices depend and defined them as *contextual factors* (i.e. characteristics of the healthcare facilities, supply of devices, organizational structure of the provision of health, and healthcare staff expectations for the device) and *characteristics of the setting* (i.e. income level and cultural beliefs surrounding healthcare) (WHO 2010). These are the elements that we will refer to as "context" throughout this article.

In recent years, there have been increasing efforts to redesign and adapt technologies for the context in LRSs (Richards-Kortum & Oden 2013). Niemeier *et al*. (2014) consider that designing for LRSs is equivalent to designing for scarcity (frugal design) and for scalability (with strong value propositions and support from the private sector), and provide a "template for success" composed of five recommendations: (i) simple and inexpensive designs may override complex technological solutions, (ii) traditional solutions may be more appropriate than modern technological options, (iii) long-term planning of solutions aiming at short-term results may prove to be more effective, (iv) engineering students in LRSs need to be engaged also as practitioners of design for frugality, (v) and design should be inclusive of the social and political challenges from the context. Different approaches for how this has been done are broadly described in the literature. Examples of these approaches include: (i) send university students (generally from HICs) to research the needs, and design technologies for an organization working in the field; (ii) develop public-private collaborations and partnerships for product development; and (iii) create earned-income non-profit organisations that design and develop

technologies, and generate revenues by selling them (Richards-Kortum & Oden 2013; Oden et al. 2010; Benchetrit 2012; Malkin 2007b).

Although all these approaches and recommendations provide a broad overview of the mechanisms in which the devices could be designed more appropriately and scaled-up, questions remain unanswered about how engineers can integrate these recommendations and understanding of the context across the engineering design process. For instance, who should engineers ask about the needs? How can they investigate the context of use? Which design methods and techniques are most effective for these projects? To answer these questions is key for these designs to succeed, considering the geographic and cultural separation between the user and engineers and the numerous stakeholders and partners involved in the process of designing. Whilst an increasing number of devices are being designed for LRSs, there is still little success in scaling them up globally because of a lack of understanding of the broader context in which the devices will be manufactured, deployed, and distributed (Malkin & Oldenburg Beer 2013; Chao et al. 2014). Research is lacking on the integration of information about the context into the decision-making strategies during the engineering design process for these devices.

In this article, the analysis included studies of prototypes of devices designed for LRSs and how researchers have integrated the knowledge of the context in the design process. The processes that were followed to arrive at the devices that are the subjects of the study were explored in detail, stage by stage.

Definitions

To set the scope in which this paper will navigate, we follow the definition by Moultrie *et al.* (2015), based on the definition by the Food and Drug Administration (FDA) and the EU, as "articles manufactured specifically for diagnostics, monitoring, treatment, or modification of the human body, that are not solely pharmaceutical goods". We focused on medical devices that required primarily design of hardware and physical interactions with the context and the user. For that reason, the scope of the definition of medical devices used in this paper includes equipment for diagnosis, treatment, surgical interventions, neonatal and maternal care, and prosthetics. Due to our research interest, medicines, vaccines, in-vitro diagnostic devices (i.e. laboratory equipment), mobile phones or other telecommunications applied to healthcare (mHealth or eHealth) are out of our research scope. Devices for homecare were also excluded.

We define a *low-resource setting* (LRS) as a resource-constrained (human, economic and environmental) area, rural or urban, in a low- or middle-income country (LMIC), as defined by the World Bank, that has limited or inexistent infrastructure or basic services. By using the term "engineers" we intend to describe someone involved in a design team for developing medical devices, including biomedical engineering practitioners and students, researchers in the field of medical device design, innovators and designers.

Review

Methods

Literature searches and results

We searched for peer-reviewed literature in Scopus, Web of Knowledge and Pubmed, using the keywords “medical devices” or “medical equipment”, and “low-resource settings”, “developing countries”, or “low-income country”. These keywords were combined using the Boolean operators AND and OR. We only included articles in English, and did not set a timeframe. Searches were done in May 2014, and updated in April 2015.

From a total 490 titles resulting from the searches, we selected 152. Duplicates were removed. We reviewed abstracts for devices within the research scope, and studies about their design or product development process. At this stage, papers were selected if they described at least one stage of the design process, even if given to a minimal degree of detail. After reviewing the abstracts, we selected 116 papers for full-text review.

After the full-text review, we selected forty-seven papers for analysis. These studies came largely from medical-related journals (i.e. Prosthetics and orthotics international, Anaesthesia, etc.). Thus, we did a supplementary search in the IEEE proceedings from the Global Humanitarian Technology Conference and the Appropriate Health Technologies for Developing Countries Conference. The keyword “appropriate” was added to the searches, as it was identified to be common in these publications. This search gave a total of 481 titles, of which total of 68 papers were chosen based on title and abstract. The selection process was the same as described

above. Ten duplicates were eliminated. After a full-text review of 58 studies, 17 papers were included for analysis. The flowchart of decision making for inclusion of studies is shown in **Figure 1**. This decision process gave a total of 64 papers for analysis.

[Insert **Figure 1**]

Analytic framework: Stanford Biodesign process

To highlight the key stages for developing medical devices for LRSs, the Biodesign process was used as the analytic framework. Though the Biodesign process is not intended to be used as analytical framework, for the purpose of our research it helps by providing a validated framework of stages of product development (from design to commercialization) for medical devices (Zenios et al. 2010). It aims to increase success in identifying relevant needs, inventing appropriate devices for that need, and delivering the device to patients. Hence, using the Biodesign process as our framework will help highlight critical areas where research is needed to improve the process and really support the development of technologies that are accessible, affordable and available to LRSs.

Described from top-to-bottom, the framework has three overarching phases: "identify", "invent" and "implement". Each major phase is composed of two stages, giving a total of 6 major stages and 29 activities required for designing a medical device (

Figure 2)

[Insert **Figure 2**]

Data coding and qualitative meta-analysis

The digital version (.pdf) of the studies was imported to MAXQDA. We established a two-level coding system based on the stages and activities of the analytic framework. Our first-cycle of coding used in-vivo and descriptive coding to capture details as described on the studies. Using the Quote Matrix function, we extracted the coded segments and corroborated coherence of the coding system. We mapped differences and similarities on each activity as they emerged from the studies, and transition to a second-cycle of coding that builds themes based on this comparison. We analysed the data using Crosstab, a mixed-methods function from MAXQDA that measures whether a code has been mentioned in a document. We used the number of studies as the unit of analysis. Because codes are not mutually exclusive, we used a multiple-code function that allows multiple codes to be assigned within a single document.

Results and discussion

Overview of studies and types of devices

The global public health field has driven innovations and transfer of technologies in areas such as pharmaceuticals and vaccines. This is largely because of the interest of practitioners in those fields to help to tackle the diseases of the most disadvantaged populations, their awareness of existing disparities of care provision between HIC and LMIC, and the challenges of bringing care services to people in LRSs (Sinha & Barry 2011; Garrett 2007; Piot 2012). Findings suggest that medical devices share a similar story since there is a greater interest in this topic in health-related than technology-related fields. Out of the 64 studies, the majority were published in

journals within the medical/clinical sciences (n=37), whilst a smaller number were published within other technical fields (n=24), or social sciences (n=2).

The rationale for designing a specific device is not clear for most studies in this review, but the type of care that devices target suggests an alignment to the wider the global health challenges (i.e. newborn and maternal health) (Sinha & Barry 2011). In Table 1, devices have been categorised by type of care. Using this categorization we do not intend to be prescriptive, but we hope to give a landscape of what has been done in the field.

[Insert Table 1]

The process for designing medical devices for LRSs

The field of medical devices for LRSs is characterised by being limited in peer-reviewed publishing, and often information about devices is found in the grey literature in the form of anecdotal reports (Thairu et al. 2012). Studies rarely describe how a solution, device or a prototype was achieved (Kuhr et al. 2013). Most of them provide a general description of the need (i.e. global health statistics), and final concept testing (Table 2). A very limited number of studies show how design methods were adapted to local conditions or contexts to address challenges in the design and product development processes (Hussain et al. 2012).

Using the stages of the Biodesign processes, we attempt to gain an overview of this design process. Due to the strategy of title and abstract screening and our interest in the initial stages of design (for context understanding), we anticipated that most of the papers identified in this review were going to describe the “identify” and “invent” phases, whilst only a few discussed

issues related to implementation. However, we captured as much detail as possible of each phase of the process.

[Insert Table 2]

Needs finding

The Biodesign process starts with the *needs finding* stage, which is when a designer defines the "strategic focus" or motivation to pursue a design project (Zenios et al. 2010). The strategic focus helps the designer define the criteria to embark on a project. In the studies analysed the strategic focus of the projects is not mentioned; however, there seems to be a strong alignment between the author's institutional affiliation and the type of care for which a device is being designe, particularly the case in the health-related studies. For instance, an anaesthetist may focus on redesigning an anaesthesia machine (Fenton 1989). This link is not so obvious in studies from other fields, such as engineering or social sciences.

With the strategic focus defined, engineers embark on identifying a problem inherent in that area of focus by directly observing a clinical setting, and gain understanding of the problem by directly experiencing a particular situation (Zenios et al. 2010). Passive or non-participant observation and key informant interviews are frequently used to gain understanding of the context in LRSs. Direct observation is generally conducted by someone external to the context (i.e. students from a foreign university, researcher, etc.) (n=12), who visits the context with the specific purpose of identifying challenges in the provision of services in facilities in LRSs.

[Insert Table 3]

Another approach, less common than direct observing and interviewing, involves the users and stakeholders as participants in the design process by identifying their own needs. A limited number of studies used this approach (n=6). For instance, Hussain *et al*. (2011) used participatory workshops for encouraging children in Cambodia to express their needs for the design of prosthetic legs.

Conversely, findings show that direct observation is not always the approach used by engineers at this stage. In fact, the majority of the studies in this review (n=33) suggest that the need is identified based on broader technical challenges that medical devices face in LRSs. Some of these challenges may be infrastructure or technology-related (i.e. unreliable electricity, lack of supplies), whilst others are human resources or cultural-related aspects (i.e. inappropriateness due to cultural practices). The information on these challenges tends to be based on the authors' experience working in LRSs, or from the global health literature such as WHO reports, or global health statistics.

Technical specifications, when drafted for devices for specific use in LRSs, are also a starting point of the design process. For instance, Parati *et al*. (2010) describe the development of a oscillometric blood pressure measuring device (BPMD) for LRSs in which the design process started with a set of technical and physical specifications drawn up by experts. These specifications were given to manufacturers to design and produce the device. The two devices designed for this purpose, HEM-SOLAR and Microlife BP 3AS1-2, were not the result of directly observing clinical settings in in LRSs but of the experts' knowledge of the needs and the manufacturers' expertise in designing certain types of devices. Other examples in which

technical specifications seem to precede design include an autoclave (Cho et al. 2012), a syringe pump (Sung et al. 2011), a CPAP (Brown et al. 2011), and a passive-flow dialysis system (Gregory 2009). These are examples of devices where designs were based on pre-defined technical parameters adapted from technologies existing in the market to suit the conditions of the environment of use in LRSs.

Reverse engineering is also an approach used to design new devices. The goal is to make technologies cheaper but keeping the same technical parameters that technologies currently available have (Bravo & Salazar 2004; Amadi et al. 2007). Cost reduction seems to be the main trigger of reverse engineering. In a few cases, the adaptation is not only based on price, but also when an existing technology can be found to have new applications that fit needs in LRSs. This is the case of the Shakerscope, a hand-powered light source for an ophthalmoscope, that was the result of finding applications for a technology previously developed by a company (Williams & Dingley 2008a; Williams & Dingley 2008b).

Finally, another non-direct observation approach is when design requirements for the devices are drafted from general descriptions of a technology. For instance, Brown *et al*. (2011) presented the design and testing of a low-cost bubble continuous positive airway pressure (bCPAP) device suitable for low-resource settings. According to the authors, if intended to be used in developing countries, these systems need to have "(1) adjustable flow rates, (2) ability to mix oxygen into the flow stream; (3) mechanism to control the pressure delivered to the patient; (4) low cost; (5) safe; (6) durable; (7) easy to use and repair" (Brown et al. 2011, p.1). All of these are characteristics of a device that would be expected regardless of their intended market.

Needs screening

After identifying needs, engineers to gain a deep knowledge on the problem identified and filter needs before starting the "invent" phase (Zenios et al. 2010). During "needs screening" engineers scrutinise all essential areas of the problem, such as: understanding disease fundamentals, identifying treatment options available, and the stakeholders involved in the provision of treatment (across the cycle of care), identifying the market size, competitors and their technologies, and user requirements (Zenios et al. 2010). This phase ends with a needs statement that defines the criteria required for a solution to the problem (Zenios et al. 2010).

Starting with the fundamentals of a disease, studies show that researchers focus on global scale health statistics as a representation of the needs for a device (n=14). Similarly, global rather than local values are used for the identification of treatment options, and the stakeholder and market analyses. In identifying treatment options, studies evaluate how suitable existing technologies available on the market are for LRSs' contexts (n=15). Only a small proportion of the studies recognised the existence of technologies in a specific local context as a result of direct observations (n=10). Also the analysis of stakeholders is not very specific; only few studies mentioned relevant stakeholders surrounding the provision of care using a device (n=3). This tendency of looking at global values for understanding the needs in the context is interesting because the contexts in different LRSs are highly variable, possibly far more so than the context between high-resource settings (Arasaratnam et al. 2013; Patel et al. 2014). By looking at global values for screening needs, there is a possibility that context realities are being missed.

[Insert Table 4]

Rarely do researchers discuss the market analysis for the devices. Generally, studies referred to larger statistics as representative of the need for a device. For instance, Kawaza *et al*. (2014) estimated the target market for the bCPAP using the proportion of global neonatal deaths in Africa. However, in LRSs people suffering from a disease tend to be marginalised and live in poverty. Depending on the device, it is likely that these people will not be the purchasers; therefore, the 'accessible' market depends on other factors. Governments, healthcare facilities or not-for-profit organisations usually provide the service and the market should be evaluated with these groups in mind. Interestingly, only four studies referred to the market specific to the context (i.e. region or country) (Malkin & V. Anand 2010; Israsena et al. 2013; Roblyer et al. 2007; Cho et al. 2012). By using large-scale values, rather than more specific market analysis of likely purchase and distribution capabilities, it is possible that potential purchasers are being poorly characterised resulting in a product that no one will pay for.

The final step is "needs filtering", where engineers compare and evaluate the needs identified against each other, to select the one that offers most opportunities for further development (Zenios et al. 2010). A score-based approach is suggested by Zenios *et al*. (2010), however, studies do not normally present their evaluation method for filtering needs. Only one study presented the method used for needs filtering. After initial explorations of the needs, Zurovcik (2011) used the peer-reviewed evaluation process to allow users and stakeholders to rank and prioritise their needs; interestingly, most of these stakeholders were located in clinical settings in HICs.

Predominantly, the needs screening process seems to be conducted by people outside of the context and it is a stage that tends to be strongly technically driven (i.e. specifications, costs, infrastructural considerations) (n=23). Even in Zurovcik's example, though the user ranked the needs, technical aspects were weighted highest in the ranking. In only one study was the needs selection completely driven by the user located in LRSs. Hussain and Sanders (2011), when identifying the needs for improving the design of prosthetic legs, described the use of participatory methods to allow children in Cambodia to express their needs and involve them in the design process. This is also the only example where user participation in the process was described in detail. Remarkably, in the rest of the studies, it is unclear how much input users and stakeholders from the context provide in this screening process.

Concept generation

Once the need is identified, solutions to the problem are generated (Zenios et al. 2010). This stage is the creative basis for product development (Elhafez 2012; Hsiao & Chou 2004; Howard et al. 2008; Liedtka 2011) and has two stages: ideation and brainstorming, and concept screening. Whilst brainstorming is a general method for conceptualization in engineering design (Cross 2008), there are also different creativity-based techniques and methods that could be used (Hsiao & Chou 2004; Gonçalves et al. 2014; Gero et al. 2013). The choice of techniques will vary depending on several factors: Is the designer working alone or in a team? (Liedtka 2011) Is the team multi-disciplinary or includes multiple stakeholders? Are computational tools or simulations being used? (Elhafez 2012; Sosa & Gero 2005).

[Insert Table 5]

None of the studies reviewed described how brainstorming happenend and whether it took place in the context with input from users and stakeholders, or independently outside of the context. This lack of description suggests that brainstorming happens within the design teams. For instance, when students explore the needs abroad in the context, they usually go back to their home university during this stage (Gerrard 2011). Sometimes this is even carried out by a different team to the one that identified the needs (Oden et al. 2010).

Although we could not identify the analytical methods used, concepts generated during brainstorming are then screened against a set of technical criteria (n=10). Some of these technical aspects are, for instance, cost reduction of the current design (Kawaza et al. 2014), the use of alternative energy sources (Williams & Dingley 2008b) or the goal of achieving a specific functional requirement based on technical specifications (Sung et al. 2011; Brown et al. 2011; Dennis 2008; Parati et al. 2010).

Similarly to the concept generation stage, screening of concepts seems to happen outside of the LRSs and is conducted by individuals foreign to the context (n=7). Only one study mentioned user and stakeholder involvement in the concept screening process. Hussain and Sanders (2012) describe workshops where mechanical engineering students and prosthetists from Cambodia ideated different solutions for a more suitable prosthetic leg for children, identified materials and technologies locally available for the production of the prostheses, and developed rapid-prototypes to express their concepts (Hussain 2011).

To generate concepts, understanding of the context is critical to avoid designing products that are impractical to implement. Despite this, there is a distinct lack of description of how this is

achieved in the literature found and reviewed here. It is therefore unclear how engineers gain, or utilise an understanding of context during concept generation and how much involvement there is of users and stakeholders.

Concept selection

From a pool of potential solutions, a concept is chosen for further development, based on IP/Patents registrations, regulations, reimbursement process, potential business model, prototyping and testing (Zenios et al. 2010). The importance of this step is to reduce the risk of anchoring too early to a single idea without full exploration of the other concepts.

In the studies, there was hardly any description of four activities in this stage (IP/patents, reimbursement, regulations and business models). No studies mentioned the role of purchasers during concept selection (or potential reimbursement mechanisms). Moreover, despite of the critical importance of patents and IP protection in the pipeline of product development (Malkin 2007a), a very small number of studies mentioned them (n=3). Edwards (2008) explored whether similar technologies have been patented, before the team embarked in the design of the device. Likewise, in the studies, reference to the regulations and standards were limited (n=2), despite their importance during the implementation phase. A lack of consideration for these steps at early stages of the design may mean that technologies face challenges later during diffusion and adoption (Malkin 2007b; Malkin & Oldenburg Beer 2013).

[Insert Table 6]

Prototyping

Prototyping aims to refine the material product against specific design criteria, and iterates until it gets to the near-final product to allow gathering of data for quality documentation and pre-manufacturing decisions. Studies tend to refer to these later-stage prototypes without providing much detail on how these prototypes were achieved. Only two studies offer a description of the rapid-prototypes as shown in pictures of studies conducted by Hussain (2012) and William & Dingley (2008a; 2008b).

Just as most studies define needs and developed concepts technically, prototyping is also presented in a technical manner. Often, studies are a technical analysis of performance of a prototype (generally, bench-testing outside the context of use) (n=16). In these cases, commonly, feedback from end-users comes at later stages in the design process, when a final concept prototype is being tested. For instance, Williams and Dingley (2008b) identified needs and constructed prototypes in the UK. Feedback from the users came later, after having been through a series of prototyping cycles and a company was hired to further redesign the prototype to improve its functionality and reduce costs of manufacturing. Spiegel *et al*. (2013) provide a similar example with the design of a dosing clip. In this case, a team of students received feedback from users in different countries after the device was designed. The concept was then redesigned and modified by a second group of students based on this feedback, who provided a second prototype of the product that was tested later (Oden et al. 2010).

Overall, studies do not describe their approach towards prototyping. For instance, in a study testing a redesigned blood-pressure monitor for LRSs, manufacturers were given technical

specifications for the device drafted by experts in the field (Parati et al. 2010). Yet, it is unknown how the manufacturers achieved the final product design. In the few studies where some hint of how prototyping was done, it seems that is the designer who develops the prototype and the process happens outside of the context of use (n=10).

Final concept selection/product design

While studies are not very descriptive of the other stages in the process, most of them do describe prototype testing to a certain extent (n=39). Generally, these studies are presented as clinical or technical trials. In this step, the device is tested in a clinical setting (to measure clinical outcomes or technical functionality) (n=34). The involvement of users and stakeholders seems to be limited to providing feedback to evaluate usability and acceptability of the device (n=22). Only three studies mentioned that the user selected the final prototype (Hussain 2011; Sethi et al. 1978; Sethi 1989). Researchers visit the context to test the devices they have designed and often an external researcher conducts the study.

Implementation: development strategy and integration

To overcome the failure of health technologies in LRSs it is important to consider factors that influence the design of the product, such as: (i) the characteristic of the market (needs, demands, procurement processes); (ii) creation of economic sustainability of the product and value creation; (iii) adaptation of existing products or platforms; (iv) management of intellectual property and regulatory processes; (v) management of partnerships (for designing, manufacturing and supply); (vi) validation of technologies; and (vii) development of technology policies (Free 2004). Innovations that are overly-specific and context-focused for LRSs rarely

scale-up, often because of a shortfall in resources, premature product launch, improper competitive analysis and insufficient market research (Soman 2014). All of these considerations are relevant to the implementation stage. It is in this "last mile" were projects face many challenges and tend to fail (Chao et al. 2014; Malkin & Oldenburg Beer 2013). However, descriptions of the implementation phase were limited in the studies. This may be the result of the search strategy used to select the studies or that demands for evidence-based studies in clinical and technical journals leave very little room for description of the process.

When a step of the implementation phase was mentioned (n=19), particular concerns were raised related to distribution and manufacturing of the technology (Pearlman et al. 2006; Malkin & V. Anand 2010; Sam et al. 2004; Sethi et al. 1978), purchasing of the consumables that the device uses (Kawaza et al. 2014; Brown et al. 2011), or integration into WHO recommendations (Rodgers 2012). Studies did not provide information with regards to how these implementation challenges influenced the design process and iterations.

[Insert Table 7]

Findings from studies show a limited interest in transforming these devices into marketable products. Business models for introducing, transferring and diffusion of the technologies were not frequently mentioned (n=2). It is not possible to know through the studies, if the devices reached the market successfully. This makes detailed comparative analysis of approaches impossible.

Integration of the context of use in the design process

The engineering design process is a complex series of tasks leading to the design of a product. The challenge increases further when contextual factors and the added complexity of healthcare systems in LRSs are included. It is notable that no studies were identified that analysed or assessed the different existing design approaches in this field and whether or not they are effective in understanding the context in LRSs and delivering technologies. The closest reference we found on providing detailed recommendations on how to appropriately design health technologies in LRSs, across the product development stages, was written a decade ago by Michael Free based on his experiences at the Program for Appropriate Technologies for Health, PATH (Free 2004). Other references provide recommendations on specific stages, especially on the implementation phase (Frost & Reich 2008; Malkin & Oldenburg Beer 2013; Dandonoli 2013; Malkin 2007b). In our analysis, we could not see these recommendations represented in an integral or systematic manner in any of the studies reviewed.

In this paper, we have described the different ways in which researchers proceed to design medical devices for LRSs. We were struck by the lack of reference to how researchers gathered information to understand the context in which the devices will be used. Although we used the Biodesign as a model for product development and framework of this review, it is still unclear how engineers currently adapt this for the unique challenges imposed by designing for LRSs, and if or how they integrate context-specific information throughout the product development stages. It is therefore impossible to propose a model characteristic for this process specific for this type of settings.

If we want to increase the number of devices that are not only adequate for the context in LRSs but also successfully reach the market and make an impact, it is important that the design and product development processes become more transparent in the literature. Clarifying how design decisions were made during the development of the devices, may allow studying the process to improve decision-making and outcomes. Further research should shed light on how this process could be improved, thus increasing the success rate of designing devices to improve health in these notoriously difficult-to-reach communities.

Limitation of the study

We recognise that a limitation of this study is that grey literature was not included. It is in the grey literature where organisations generally describe the design process followed to achieve medical devices for LRSs. However, grey literature is largely based on anecdotal information. Due to this reason, we decided to focus on peer-reviewed databases. We have analysed only information that could be identified in the included references, and we do not intend to lessen the work done by the authors of the studies to achieve the design of the devices.

Conclusions

The design of medical devices for low-resource settings is a fascinating problem. In theory, their development should be simple, but the reality of the situation in LRSs show that the challenges seem far greater than those faced when developing more advanced technologies for other sectors. So what are the key challenges? And does the available academic literature provide any clues as to how they can be overcome? This review concludes that the academic literature regarding how

medical devices for LRSs are designed is currently very limited. Whilst the research community must continue to pursue studies evaluating the effectiveness of devices for these settings, it is obvious that we also need to investigate the design process so that success can be achieved more frequently.

The field is currently characterised by its broad array of approaches, and outcomes that are hard to quantify. So far, the guiding processes for achieving effective design of devices and integrating the complexity of the context in LRSs into the product development pipeline are not well mapped out. The interaction between researchers, engineers and designers, users and stakeholders, and the flow of communication between them should be analysed and enhanced. This is particularly important considering that a large number of these studies is conducted by engineering students and researchers who are unfamiliar to the context in which the devices will be used. We may ask: how can we be better support them so that they can make more informed decisions during the engineering design process? In addition to strong engineering skills, these students, designers and researchers, need better guidance on methods and techniques for context understanding and decision-making that are required during the engineering design process. This could potentially improve the impact of engineering projects in the global health arena.

Recently, some people and organisations have started to look at LRSs as potential markets for developing context-specific healthcare innovations. This type of innovation has been particularly attractive for academic and non-profit organisations. Interestingly, design-oriented enterprises have emerged as spin-offs from some of these projects. Success stories in the field are limited and mostly found in the grey literature or public speeches. Perhaps by investigating and learning

from these practical experiences, we may be able to learn from them for a better integration of the understanding of the context of use in LRSs and make informed decisions throughout the engineering design process. This may result in designs of medical devices that are more inclusive of the needs in these regions of the world and can make a greater impact.

List of abbreviations

LRSs: Low-resource settings; HICs High-income countries; WHO: World Health Organization.

Competing interests

The authors declare no competing interests.

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Figures and Tables

Figure 1 Decision flowchart for inclusion of papers in the analysis

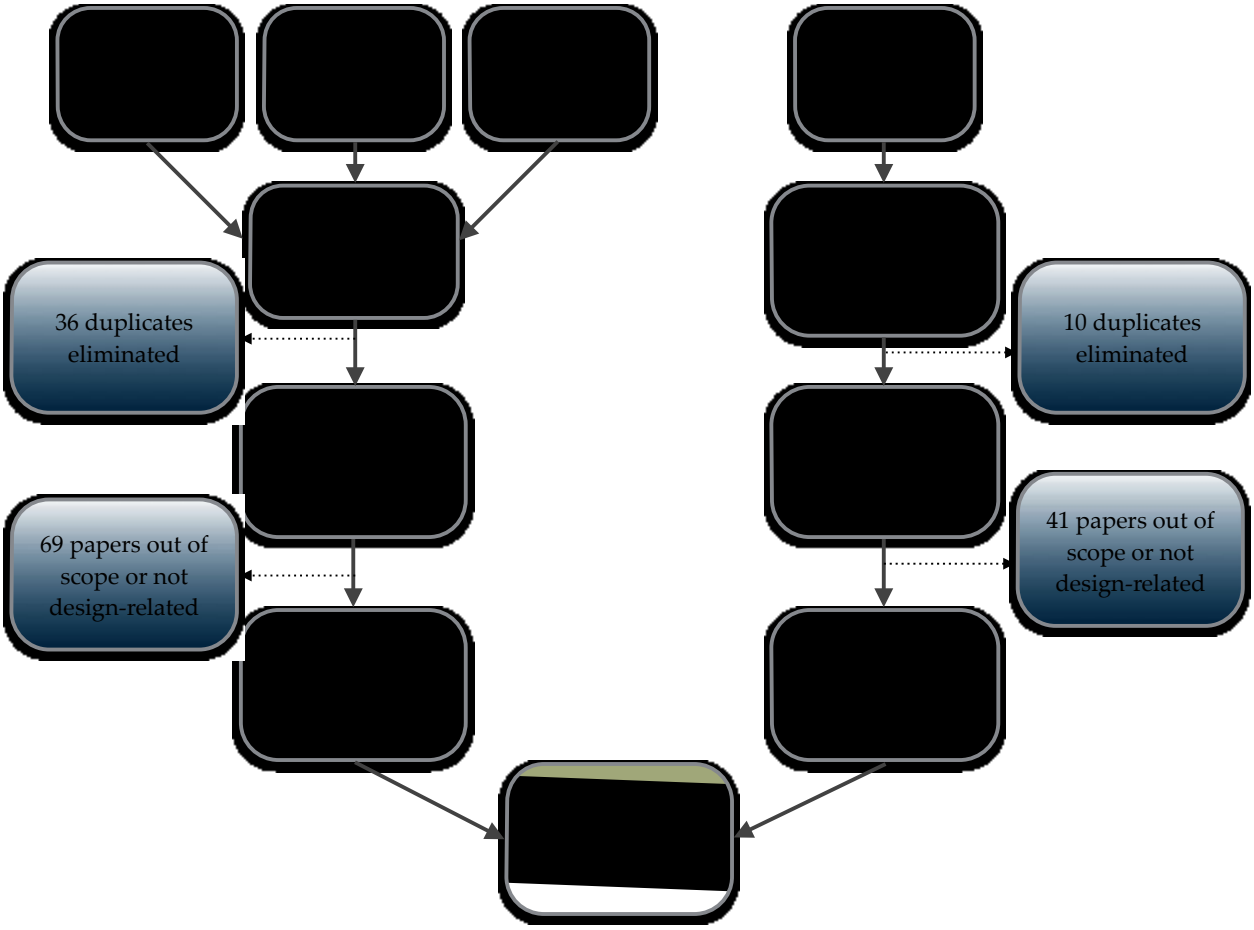

Figure 2 Stages in the Stanford Biodesign process (Source: (Yock et al. 2011) Reprinted with permission of the Stanford Biodesign program)

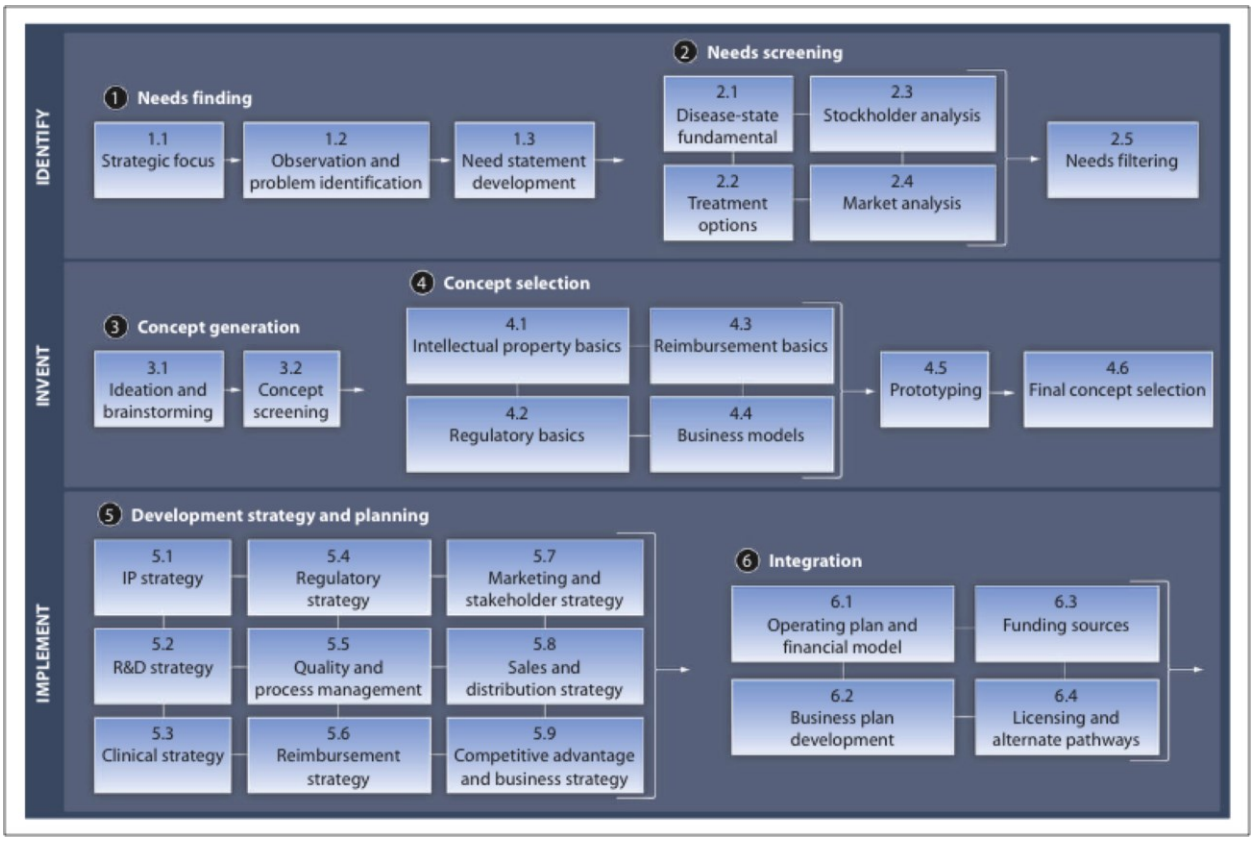

Table 1 List of devices for LRSs

Type of care	List of medical devices	Reference
Newborn care	Infant incubator	(Antonucci et al. 2009; Amadi et al. 2007)
	Phototherapy	(Malkin & V. Anand 2010)
	Bubble continuous positive airway pressure system (bCPAP)	(Kawaza et al. 2014; Brown et al. 2013)
Assistive devices	Lower-limb prosthetics	(Sethi 1989; Sethi et al. 1978; Sam et al. 2004; Sharp 1994; Hussain 2011; Arya & Klenerman 2008; Steen Jensen, Nilsen, Thanh, et al. 2006; Steen Jensen, Nilsen, Zeffer, et al. 2006; Jensen et al. 2004; Jensen & Raab 2007; Jensen &

		Treichl 2007)
	Orthopaedics	(De Ruyter & Lelieveld 1984)
	Solar hearing aids	(Israsena et al. 2013)
	Communication panel for deaf people	(Bravo & Salazar 2004)
	Wheelchair	(Authier et al. 2007; Guimaraes & Mann 2003; Owens & Simonds 2010; Golding & Nathan 1987; Chavarriaga et al. 2014)
General care	Blood pressure measuring	(Kewalbansing et al. 2013; Parati et al. 2010; de Greeff et al. 2008; Baker et al. 2012)
	Light source for otoscope	(Williams & Dingley 2008a; Williams & Dingley 2008b)
	Pulse oxymeter	(Bezuidenhout, Woods, Wyatt & Lawn 2006a; Bezuidenhout, Woods, Wyatt & Lawn 2006b)
	Anthropometric measurements	(Mullany 2006; Edwards 2008; Ghosh et al. 2011)
	Stretcher	(Guha & S. Anand 1989)
Surgery or critical care devices	Anesthesia machines	(Tully & Eltringham 2008; Neighbour & Eltringham 2012; Eltringham & Varvinski 1997; Bailey et al. 2009; Eltringham 2004; Eltringham et al. 2002; Eltringham 2000; Dobson & Neighbour 2008; Fenton 1989)
	Suction devices	(Battinelli et al. 2012; Zurovcik et al. 2011)
	Non-pneumatic anti-shock garment (NASG)	(Miller et al. 2007; Rodgers 2012)
	Drug delivery devices	(Gerrard et al. 2012; Spiegel et al. 2013; Ching et al. 2004; Sung et al. 2011)
Supporting	Autoclave	(Cho et al. 2012)

devices	Medical waste incinerator	(Picken & Bennett 2002; Picken & Bennett 2000)
	Motorcycle ambulance	(Dennis 2008)
	Surgical supporting devices	(Kalechstein et al. 2012; Ijaduola 1986; Noor 1988)
Maternal care	Ultrasound	(Kobal et al. 2004)
Other specialised care	Cancer diagnostic devices	(Pierce & Richards-Kortum 2010; Roblyer et al. 2007)
	Dialysis	(Gregory 2009)

Table 2 Summary of the number of studies that mentioned at least one activity of each stage

Stage	#Studies (n=)
Needs finding	44
Needs screening	39
Concept generation	21
Concept selection	48
Development and strategy	12
Integration	10

Table 3 Number of studies with information on the Needs identification stage

Needs finding stage	#Studies (n=)
Observation and problem identification	
Identified by experts	5
General statistics or technical need	33
General description of the context	10

External agent as an observer	12
Identified by user (i.e. co-design)	6

Table 4 Number of studies with information on the Needs screening stage

Needs screening stage	#Studies (n=)
Disease fundamentals	
General or global values	14
Needs filtering	
User filter their needs	2
Filtering based on technical requirements	23
Market analysis	
General statistics, values or descriptions	10
Specific to the context	4
Treatment options	
General treatment options identified	14
Direct observation of options available	10
Recognised existence of other treatment options in the context	15
Stakeholder analysis	
External observer analyses stakeholders	3

Table 5 Number of papers describing the "Concept generation" stage

Concept generation phase	#Studies (n=)
Brainstorming	
Concept generated based on technical requirements	15
Users participate in ideation	0
Ideation happens outside of the context	4

Concept screening	
User/Stakeholders screens concepts	1
Concepts are screened on technical basis	10
Screening of concepts happens outside of the context	7

Table 6 Number of studies describing the broader areas of the Concept selection stage

Concept selection stage	#Studies (n=)
IP/Patents	3
Reimbursement	0
Regulations	2
Business models	0
Prototyping	
Test prototypes in the lab/Bench-testing	16
Rapid prototyping	2
User/Stakeholder involved in prototyping	2
Developed by people external to the context	10
Detailed prototype	9
Final concept selection	
Later involvement of users or stakeholders	22
Selected based on guidelines, technical aspects	9
User involved in selection of the concept	1
Clinical or technical trials/testing of the device	34

Table 7 Number of studies describing the "Implement" stage

Development and strategy	#Studies (n=)
Research and development strategy	2
Regulation strategy	1

Competitive advantage	0
Sales and distribution strategy	1
Healthcare facilities are customers	1
Governments are the customers	2
Need for champions in the field	1
Barriers to distribution	1
Subsidies	1
Donors and non-profits are customers	4
Marketing and stakeholder strategy	0
Integration	#Studies (n=)
Funding sources	4
Business plan	2
Licensing	0
Manufacturing partner	5
Design partner	3
Partner with distributor	3
Operating plan and financial model	3

Supplementary material

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