Towards A Framework for Holistic Contextual Design for Low-Resource Settings

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Healthcare inequality is ubiquitous globally, but the effects are most striking in low-resource settings. In these settings, current methods for the design of medical devices are failing to address specific needs. The associated publications rarely describe how the context was studied at the front-end of design. There is a latent need for a holistic contextual framework for guiding the design decision-making process for devices in these complex contexts. We present results from a systematic literature review and expert interviews that informed the development of a framework for contextualized design for low-resource settings. The contextual factors identified are described and compared for different types of medical devices. This taxonomical framework aims to guide designers towards gaining a better understanding of the context of use when designing products for global challenges in low-resource settings.

Keywords **–** Design for Development, Context of Use, Frugal Innovations, Developing Countries, Healthcare.

Relevance to Design Practice **–** The study provides a comprehensive contextual framework to support design practitioners to gather, compile and analyse contextual information for the design of products for low-resource settings. The proposed framework is broad in scope to highlight under-appreciated and often neglected aspects of context, to aid decision-making at the earliest stages of product design and to avoid possible failures in "the last mile" of getting a product to market.

Citation: Aranda-Jan, C. B., Jagtap, S., & Moultrie, J. (2016). Towards a framework for holistic contextual design for low-resource settings. *International Journal of Design, 10*(3), 43-63.

Introduction

There are unacceptable health inequalities around the world. The conditions in which people are born, work and live, and the systems put in place to support healthy lifestyles determine many of these inequalities (The World Bank, 2015). Many argue that these socially determined inequalities are avoidable if these conditions are designed appropriately to reduce the risk of illness and disease (Manzini, 2014; Waddell, 2012). It is by design that we might begin to tackle the intractable global challenges of health inequity, poverty alleviation and development (Lawrence, 2014; Mulgan, Tucker, Ali, & Sanders, 2007).

Designing for Global Health Challenges

The design of medical devices has failed to deliver effective and efficient products to low-resource settings (LRSs). When visiting a healthcare facility in a developing country, the poor condition of healthcare technologies is evident. Facilities often contain obsolete or totally dysfunctional equipment (Free, 2004; Howitt et al., 2012; Malkin, 2007a, 2007b; Sinha & Barry, 2011). In other cases, expensive equipment lies dormant because there are inadequate skills and materials for its use, repair or maintenance. To adequately address global health challenges faced in LRSs, medical devices need to be designed to be sympathetic with the local conditions and context. Technologies need "to meet the needs of the world's poorest people" (Howitt et al., 2012, p.509) and be "good enough to meet the demands of customers who could not afford state-of-the-art technology" (Ibid., p.528). These technologies cannot merely replicate successful ones in the developed world, but should instead be designed to be cognisant of the local *context* (Arasaratnam & Humphreys, 2013; Free, 2004; Niemeier, Gombachika, & Richards-Kortum, 2014).

However, success stories are limited in the development of medical devices for LRSs (Sinha & Barry, 2011). Recently, numerous technology-based projects for global health have been funded, but information on their effectiveness is limited. Most of the medical devices designed for LRSs have been designed by people in developed countries and few have gone beyond being mere university projects (Garrett, 2007; Jagtap, Larsson, Hiort, Olander, Warell, & Khadilkar, 2014; Sienko, Sarvestani, & Grafman, 2013). The disconnection between the designer, her understanding of the context and the reality in the context might contribute to this systemic design failure. Challenges in understanding the context of use of products in LRSs have been reported as potential causes of failed designs (Free, 2004; Wood & Mattson, 2016). Indeed, developing appropriate medical

Received Jan. 11, 2016; **Accepted** Oct. 27, 2016; **Published** Dec. 31, 2016.

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devices can be more challenging when designing for LRSs than for developed countries (Bergmann, Noble, & Thompson, 2015). A reason behind this is that the task of gathering and interpreting contextual information in LRSs is hard, time-consuming and costly, particularly for less experienced designers (Castillo, Diehl, & Brezet, 2012; Mohedas, Daly, & Sienko, 2015).

Accurate collection of user requirements and contextual information has proven to be highly valuable in medical device design (Martin, Clark, Morgan, Crowe, & Murphy, 2012). When designing for LRSs, designers must have a deep understanding of the context of use at an early stage of device design (Castillo et al., 2012; Donaldson, 2006; Nakata & Weidner, 2012; Rodriguez, Diehl, & Christiaans, 2006). The inherent complexity of these contexts demands that designers devote a considerable amount of time to scoping the problem, gathering contextual information and defining design requirements (Jagtap et al., 2014; Jagtap, Larsson, Hjort af Ornäs, Olander, & Warell, 2013b). Often, however, designers overlook this complexity and consequently, products are poorly designed according to *expected* rather than *experienced* contexts (Donaldson, 2006).

A good definition of context is essential if a product is to be successful in the market (Mohedas, Daly, & Sienko, 2014a, 2014b; Nemoto, Uei, Sato, & Shimomura, 2015). Few frameworks exist to support designers, largely unfamiliar with the notion of context, to characterize the context in the design process of products for LRSs (Green, 2005; for instance, Green, Linsey, Seepersad, Wood, & Jensen, 2006). To our knowledge, no framework has focused on medical devices for LRSs. Recommendations for developing medical devices for LRSs are relatively common in the literature, but little guidance is available for designers regarding context and how to study context (Free, 2004; Malkin, 2007b; Wood & Mattson, 2014).

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James Moultrie has a background in industrial design and mechanical engineering. Before joining academia, James had an industrial career, where he was responsible for numerous projects, including metrology instruments and lenses for the movie industry for which he was awarded a 'Scientific and Technical Academy Award external link' (Oscar) in 2000. He is well known for his research investigating the 'value of design', including the 'Design Scoreboard' project, which developed an original comparison of national design capabilities. He was also a member of a European project, which established protocols for measuring the economic value of design. He is interested in design for manufacture and regularly works with companies to improve design for assembly. Current work includes activity exploring 'Design for Additive Manufacturing'.

Given the importance of context, it is surprising that the literature on medical devices for LRSs is limited in the definitions of the term. The World Health Organization [WHO] (2010) describes the context as the "aggregate of factors that influence the use of medical devices" (p.5) such as the characteristics of the healthcare facilities, the supply of devices, the organizational structure for the provision of care and the expectations of healthcare staff for the device. Likewise, Gauthier, Cruz, Medina, and Duke (2013) suggest that designing medical devices for LRSs should consider the characteristics of the device and the setting. The setting, in the view of Gauthier et al. (2013), includes the facilities available, population dynamics and conditions for implementation in the target country (standards, intellectual property, import/export policies).

A broad range of political, social, cultural and environmental factors determine the use and appropriateness of devices in LRSs (Bergmann et al., 2015; Free, 2004). Solely designing for a setting—mainly being the physical environment—has not ensured that devices satisfy the needs of the context. The compelling complexity of any LRS and their healthcare systems suggest the need for a new holistic approach to the context for designing medical devices for these settings. Contextual factors thus need to be holistically explored by designers. It is clear that definitions of context for medical devices for LRSs are falling short and must go beyond those provided by the WHO (2010) and Gauthier et al. (2013).

Definitions of the "Context of Use"

In the field of design, context of use has been given a number of different definitions (Hekkert, & van Dijk, 2011; Nemoto et al., 2015; Rosenman & Gero, 1998; Schifferstein & Hekkert, 2008; Stappers, Hekkert, & Keyson, 2007). In the Glossary of Human Computer Interaction, Soegaard and Dam (n.d.) describe the context of use as the set of "*actual conditions* under which a given artefact/software product is used, or will be used in a normal day to day working situation" [online]. Nemoto et al. (2015) define context as a "set of spatial-temporal elements related to the person or product" (p.43). Hekkert, and van Dijk (2011) consider that a "seemingly endless number of mechanisms […] co-determine what people are and need, and what products could and should provide" (p.15). These factors constitute the "context of use" of a product. Deconstructing or understanding this *context layer* is fundamental to the design process to characterise the product-user interactions as a pre-cursor to developing a design solution. The context layer does not describe the technical dimensions of a product, but rather contains ideas, views or other considerations about people, their lives, culture, nature, society and technology.

Rosenman and Gero (1998) propose a different perspective. They suggest that there are three *environments* that are fundamental for formulating a design problem statement and conceptualizing a solution for the design of an object.

These are the natural environment, the human socio-cultural environment and the artefact's techno-physical system. Objects are *intentionally* designed to serve a *purpose*. The purpose by the socio-cultural and the natural environments in which humans interact. Humans interpret the world within these environments and design needs are defined by both, whether generated by the physical world or perceived according to values and goals within the socio-cultural environment. The object is designed to *function* (serve a purpose) based on the *behaviour* given by the specific *structure* of the object. The object creates an artificial techno-physical environment. These three types of environments define the context by interacting with each other and the artifact acquires meaning through this context (Rosenman & Gero, 1998; Schifferstein & Hekkert, 2008).

For human-centered design, Maguire (2001) proposes that the analysis of the context should include the characteristics of the user, the characteristics of the task and the operating environment, both physical and organizational. Methods such as 'contextual analysis' will help to specify and evaluate user requirements. The context is the background against which design is taking place and provides an understanding of a product, its usability and safety. Specific to medical devices, the usability standard ISO/IEC 62366-1:2015 defines context in a more pragmatic way as the "actual conditions and settings in which users interact with the medical device" (Advancing Safety in Healthcare Technology, 2015, p. 11).

These definitions make it possible to extract three essential elements that define what the context of use means to designers. Firstly, the context of use is about the *users*. Users have certain characteristics (e.g., background, beliefs) that set the *expectations* of what the product is and how it achieves its goals, effectively and efficiently. For a product to achieve the intended goals, the user and the product interact with each other. The daily product-user *interactions and usability* define how the user experiences the product. Hence, the second element of the context of use is the *interactions*. Finally, interactions occur within a physical environment or *setting* (e.g., nature, workplace) as defined by the product-user interactions. The context of use is, therefore, the frame of reference in which a product interacts with and is fully understood by users.

Better understanding the context of use is a much broader activity than just establishing product requirements. In design practice, however, methodological supports are lacking for this task (Braun, Benedict, Wendler, & Esswein, 2015). For medical devices, a review by Alexander and Clarkson (2000a) showed little practical guidance exists for designers to verify and validate design requirements. Taxonomic tools are proven supports for the collection, compilation, organization and interpretation of information at any stage in the design process (Manzini & Coad, 2015). Holistic taxonomical frameworks support designers throughout the design process to conceptualize, assess, develop, refine and implement their ideas in solving design problems (Roser & Walker, 2014).

This paper argues that a holistic framework may support the need to capture the complexity of the context of use of medical devices in LRSs. The framework aims to serve as a taxonomical structure to help designers unfamiliar with these settings to better explore, capture and document contextual information when designing medical technologies for LRSs.

Scope

For this study, we defined medical devices 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" (Moultrie, Sutcliffe, & Maier, 2015, p. 364). Due to our interest in hardware design, medicines, devices for home-care, vaccines, in-vitro diagnosis, mobile phones or other telecommunication systems applied to healthcare (mHealth or eHealth) sit outside our research scope. The term *low-resource setting* refers to a resource-constrained (human, economic and environmental) area, rural or urban, with limited infrastructure or basic services in a low- or middle-income country (LMIC) as defined by the World Bank. Used interchangeably, the terms *engineer* or *designer* describe an individual in the field of design of medical devices for LRSs, including product designers, engineers, innovators, students and researchers.

Aims and Methods

This study seeks to develop a holistic contextual framework for investigating and characterising factors defining the context of use of medical devices in LRSs. A qualitative approach was used to identify the contextual factors and a quantitative approach to evaluate their relevance.

Data Collection and Extraction

Systematic Literature Review

A systematic literature review was undertaken using sources from Pubmed, Scopus, Web of Knowledge and the IEEE Xplore Library for the proceedings from the Global Humanitarian Technology Conference and the Appropriate Health Technologies for Developing Countries Conference. Using Boolean operators AND and OR, the keywords *medical devices*, *medical equipment*, *low-resource settings*, *developing countries* and *low-income country* were combined. Only articles in English were included.

The literature searches resulted in a total of 971 titles from all the databases. The criteria for including studies, based on title and abstract review, were:

1. the study should refer to a medical device within the research scope, and
2. the design should target low-resource settings.
3. From the searches, 174 abstracts satisfied the criteria for full-text review, after removing 46 duplicates. Papers to be included in the full-text analysis were selected based on a third inclusion criterion:
4. the study should refer to the design process for the device being described, so that the case can be examined for content relating to the designers' understanding of context.

From the full-text review, 110 papers did not mention a stage in the product development process and were excluded. Hence, 64 journal articles were analysed. The Appendix 1 shows the decision process.

Expert Interviews

Additionally, semi-structured interviews were conducted with experts on designing medical devices for LRSs. A list of projects was compiled from: (1) presenters at WHO's Global Forum of Medical Devices in November 2013 in Geneva; (2) ASME presentations of appropriate medical devices in 2011; (3) Medical devices published in Appropedia (Sienko et al., 2013); (4) WHO's Compendium of appropriate medical devices; and (5) the Cooper-Hewitt Museum conference on *Design for the other 90%*.

When reviewing the projects, 191 medical devices were within the scope of the present study. This list of devices was filtered in two ways. Firstly, only commercially available devices were selected. Secondly, in order to understand perceptions of *context*, devices designed by people in developed countries were chosen. We worked with the assumption that designers in developed countries are less familiar with the context, but we acknowledge that this assertion could be contested. We consider that this filtering highlights particularly interesting experiences from the interviewees and allows us to understand their coping experiences in the process of learning about the context. Seventy devices resulted from these filters. From this list, organizations with more than one device were considered to have experts in the field. Fourteen organizations satisfied this criterion. We thus identified 34 potential interviewees after obtaining contact details from these organizations via academic publications, organizations' websites or LinkedIn.

The potential participants were contacted by email. A first invitation was sent introducing the research. A follow-up email was sent to those who did not reply after two weeks. In only one case, a phone call was made before the second email to confirm the interviewee's email address.

Interview Process

Eleven semi-structured interviews were conducted between February and July 2014. Table 1 describes the characteristics of the interviewees. Since interviewees were located in different parts of the world, interviews were conducted by telephone or Skype. Interviewees were informed that their anonymity will be rigorously maintained. Verbal consent was obtained from each of the participants at the beginning of the interview. Interviews lasted an average of 45 mins and included questions about project description (e.g., idea, motivation), the role of the interviewee in the project, the appropriateness of the device to LRSs, tools used to identify the need, validation of the design and the interviewee's perception of the LRSs context. Interview recordings were transcribed verbatim using MAXQDA11 for Mac and edited to ensure the participants' anonymity.

Data Management

All digital documents were imported to MAXQDA 11 and sets were created according to the type of device and type of data (literature or interview).

Data Analysis

Qualitative Analysis

In vivo and descriptive coding were used to analyse evidence from the literature and interview transcripts (Saldana, 2013). In vivo coding is the process of extracting text as found in the qualitative data record. Descriptive coding is the process of summarizing in a word or short phrase the meaning of the text extracted, requiring some interpretation. When a description of the context was identified, the fragment of text was highlighted and assigned a code. We refer to this fragment of text as a coded segment. Although we had an initial idea of the possible code categories based on literature review (e.g., technical, social, etc.), the factors were allowed to emerge from the data itself. Once all of the studies and transcripts were coded (in vivo and descriptive coding), a second iteration of coding was conducted.

Table 1. Details of interviewees' positions, device discussed during the interview and years of experience in the field (same or similar technologies).

I-x	*Position*	*Area of specialization*	*Experience*	*Background*	*Region of origin*
I-1	Managing director	Anaesthetic devices	≈ 11 years	Design	Americas
I-2	CEO	Hearing and communication aids	> 15 years	Business	Americas
I-3	CEO	Anaesthetic devices	> 30 years	Clinical	Europe
I-4	Designer/ Researcher	Assistive devices	≈ 5 years	Design/Engineering	Americas
I-5	Product development manager	Maternal and newborn health	≈ 14 years	Design	Europe
I-6	Designer	Newborn health, Drug delivery	≈ 18 years	Design	Americas
I-7	Designer/ Researcher	Maternal and newborn health	> 20 years	Design/Clinical	Americas
I-8	Designer/ Researcher	Assistive devices	> 10 years	Engineering	Americas
I-9	Designer	Maternal health	≈ 5 years	Design	Europe
I-10	Researcher	Maternal and newborn health	≈ 2 years	Engineering	Americas
I-11	CEO	Newborn health	NA	Business	Asia

The coded segments were grouped according to the similarity and meaning of the description using focused coding (Saldana, 2013). This procedure helped to identify a common ground for the first level of sub-codes—a *contextual factor*—that included several coded segments with similar meaning. For instance, interviewee I-3 mentioned: "It was 52ºC in [the operating] theatre. Well, if you put an ordinary anaesthetic machine into that, it is just not going to function." This segment was initially coded as *High Temperature*. Similarly, Sharp (1994) mentions that "it is customary in India to remove one's shoes on entering the house—or temple or mosque—and, in a hot climate, it is very much comfortable to wear sandals rather than closed shoes" (p.208). This segment of text was coded with multiple segments one of which was *Hot Climate*. During the second iteration of coding, Sharp's and I-3's segments would both appear in under a code named *Temperature*. Sharp's piece of text would also appear under the code *Religious and cultural beliefs*. That means that a single piece may contain a description of different contextual factors; in Sharp's example these are *Temperature* and *Religious and cultural beliefs*. Table 2 lists some examples of coded segments.

Contextual factors were grouped into *Category of Factors*, resulting in a two-layered coded system: code (Category of Factors) and sub-code (Contextual Factor). Using the Code Matrix function, the coded segments were extracted and the coherence of the grouping system was manually verified for each coded segment, sub-code and code.

Quantitative Analysis

To build the framework, we used the Mixed-methods function from MAXQDA to measure the frequency of each Contextual Factor by counting the number of coded segments in the set of documents (literature studies and interview transcripts). The Multiple-code option was used to count this frequency. By using the multiple-code function, the software assumes that the sub-codes are not exclusive of each other and counts the frequency of multiple sub-codes that have been assigned to coded segments in a file. Using the example above for the coded segment from Sharp (1994), the multiple-code function will count the segment twice, once for *Temperature* and once for *Religious and cultural beliefs*. Similarly, if another excerpt of text refers to *Temperature* again, that will be counted giving a count of two to *Temperature* in the total count in Sharp's text. Frequencies for each code (Category of Factors) and sub-code (Contextual Factor) were exported to Microsoft Excel to compare the factors across all types of medical devices.

Results and Analysis

Overview of the Types of Medical Devices

Initially, the journal articles (henceforth, also referred as design cases or studies) and interviews were categorized into 23 types of medical devices. After coding, five types of devices lacked contextual information and, therefore, were not analysed further (autoclave, non-pneumatic anti-shock garment, orthopaedic devices, dialysis machine and light source device for otoscope/eye scope). The remaining devices, designed with reference to some aspect of context and aimed at LRSs include anaesthesia machines, neonatal care devices (incubators, phototherapies and continuous positive airway pressure [CPAP] ventilators), assistive devices (hearing aids and prosthetics), patient monitoring devices (pulse oxymetry and blood pressure), patient transportation, suction devices, devices for surgery and surgical support, devices for drug delivery, waste incinerators and devices for anthropometric measurements (scales, mid-upper arm circumference [MUAC] measurement band for diagnosing of malnutrition).

Developing A Holistic Contextual Framework

The studies analysed described the context inconsistently, with some authors providing more detailed descriptions than others. The studies tended to describe the context in a nonspecific way, mentioning aspects common to several LRSs, or any other context. For instance, Malkin and Anand (2010) mentions that "most phototherapy devices are too expensive for developing world hospitals, and the bulbs have a lifespan that is very short" (p. 38, coded as *Availability of spare parts*). Only a few studies referred to the characteristics specific to a place, country or healthcare facility. An example is given by Edwards (2008), who describes in detail the characteristics of the hospital and the community in Malawi where the Baoband project was implemented. Interviewees described the context more specifically, based on their own personal experiences. For instance, I-1 said:

> I was in an operating room in Ethiopia that had nine broken anaesthesia machines. And no functioning machines, before we showed up. (I-1, coded as *Functionality of donated equipment*)

Table 2. Examples of coded segments.

Contextual Factors	*Literature*	*Interview*
Temperature	Cancer diagnosis: "Recurrent problems such as overheating of the laptop due to high ambient temperatures and heat output from the light source caused us to lose at least some data from two patients" (Roblyer et al., 2007, p. S95).	Anaesthetic machine: "It was 52º in the [operating] theatre. Well, if you put an ordinary machine into that [room], it is just not going to function" (I-3).
Access to electricity and fuel	Pulse oximeters: "Its use [of pulse oximeters] in developing countries is limited by the cost, availability of existing devices and the lack of reliable power supplies" (Bezuidenhout et al., 2006, p. 158).	Anaesthetic machine: "The infrastructural problems that you would associate with that environment [are]: power outages, power shortages, not just outages but a lot of brown-outs. This is an issue wherever we go" (I-1).

The factors identified aim to cover a broader understanding of the context, a description of the user, setting and interactions. A total of 56 contextual factors were identified (from coded segments of text from transcripts and studies, N = 290) and classified in nine categories (as listed in Table 3): Geographical and Environmental Factors (number of coded segments for this category, n = 31), Institutional Factors (n = 68), Economic Factors (n = 12), Infrastructural Factors (n = 47), Public Health Factors (n = 30), Political Factors (n = 1), Manufacturing and Industrial Factors (n = 23), Socio-cultural Factors (n = 25) and Technological Factors (n = 53).

There was a large difference in the frequency of each contextual factor, some of which were mentioned only once and others of which were mentioned more than 15 times. To select the most relevant contextual factors, a second iteration of analysis was conducted. Contextual factors were ranked by relevance, based on a) total frequency, b) frequency of mention during interviews and c) frequency in literature cases. Factors cited once in the studies were excluded, whereas factors mentioned by interviewees once were included. This decision was made based on the idea to build a tool for design practitioners. Experts have first-hand experience of how the context influences success or failure of a device and can give valuable post-mortem knowledge that could be used for pre-mortem assessment of designs during scoping studies. As such, we prioritized designers' experience, particularly their design practice, over structurally written texts to the demands of academic publications. The second analytical iteration gave 44 contextual factors (N = 205). The decision process is shown in Appendix 2 and the Appendix 3 shows the factors ranked. The following sections present the categories of the holistic contextual framework.

Technical: *Industrial and Technological Factors*

Medical devices are designed to fulfil specific needs, for example, those concerning a treatment, diagnosis or prevention of a particular disease or illness. The early design stages will focus on identifying the technical criteria to satisfy that need. Traditional approaches to designing medical devices usually start with the identification of the system requirements, a rather techno-centric approach (Alexander & Clarkson, 2000a, 2000b, 2002; Chaturvedi, Logan, Narayan, & Kuttappa, 2015; Le Cocq, 1987). Medina, Wysk, and Okudan Kremer (2011) and Alexander and Clarkson (2000a) provide reviews of these traditional approaches to the design of medical devices. Although in developed countries *good design* principles exist for medical devices (i.e., DfX methods, Design for Manufacturing and Assembly, Design for Reliability, Design for Usability), most of these principles are often not applicable or conflict with the actual conditions in LRSs (Nimunkar, Baran, Van Sickle, Pagidimarry, & Webster, 2009; Wood & Mattson, 2014).

Of the total number of coded segments, these factors were divided into technological factors (n = 42) and industrial factors (n = 14). Technological factors refer to the design requirements that drive the technical aspects of the device and elements needed for adequate operability and functionality of the device. For instance, while the traditional good design practice ensures that medical devices satisfy their intended purpose and commercial aspects, when designing devices for LRSs, elements such as access to spare parts and consumables are also fundamental to ensure devices operate efficiently (Castillo et al., 2012; Wood & Mattson, 2014; WHO, 2010). Hence, designers need to simplify the design, for instance, reducing the number of parts may reduce the cost and increase the possibility that parts are available or reproducible in the country (Wood & Mattson, 2014). In our analysis, affordability (n = 13) was the most frequently mentioned technological factor, followed by availability of repair tools, spare and replacement parts (n = 7) and availability of consumables (n = 7). The relevance of these factors was highlighted by interviewees:

> Because sometimes there are existing products in terms of the design that might be available for use in developed countries, that might be unaffordable for low-income settings or the materials might be inappropriate or something like that. (I-7; coded as *Affordability*)

Table 3. Classification of categories of the holistic contextual framework.

Categories of contextual factors	*Definition*
Individual	
Socio-cultural factors	Factors defined by the individual's frame of beliefs, thoughts, lifestyle, and cultural characteristics.
Physical environment	
Infrastructural factors	Factors of the built environment (human-made) such as buildings, roads, electrification, etc.
Geographical and environmental factors	Factors of the natural environment such as temperature, humidity, rain, etc.
Technical	
Manufacturing and industrial factors	Factors external to the product but are required to produce/supply the product.
Technological factors	Factors specific to the design of the product (device requirements).
Systems and structures	
Institutional factors	Factors referring to social organizations and bureaucratic structures created for the functioning or delivery of specific services to the population (i.e., hospitals, healthcare system, institutions, etc.).
Public Health factors	Factors related to the health of the population and clinical practice, such as mortality, morbidity, sanitation, and hygiene.
Political factors	Factors referring to the political organisation of the context.
Economic factors	Factors referring to the economic aspects.

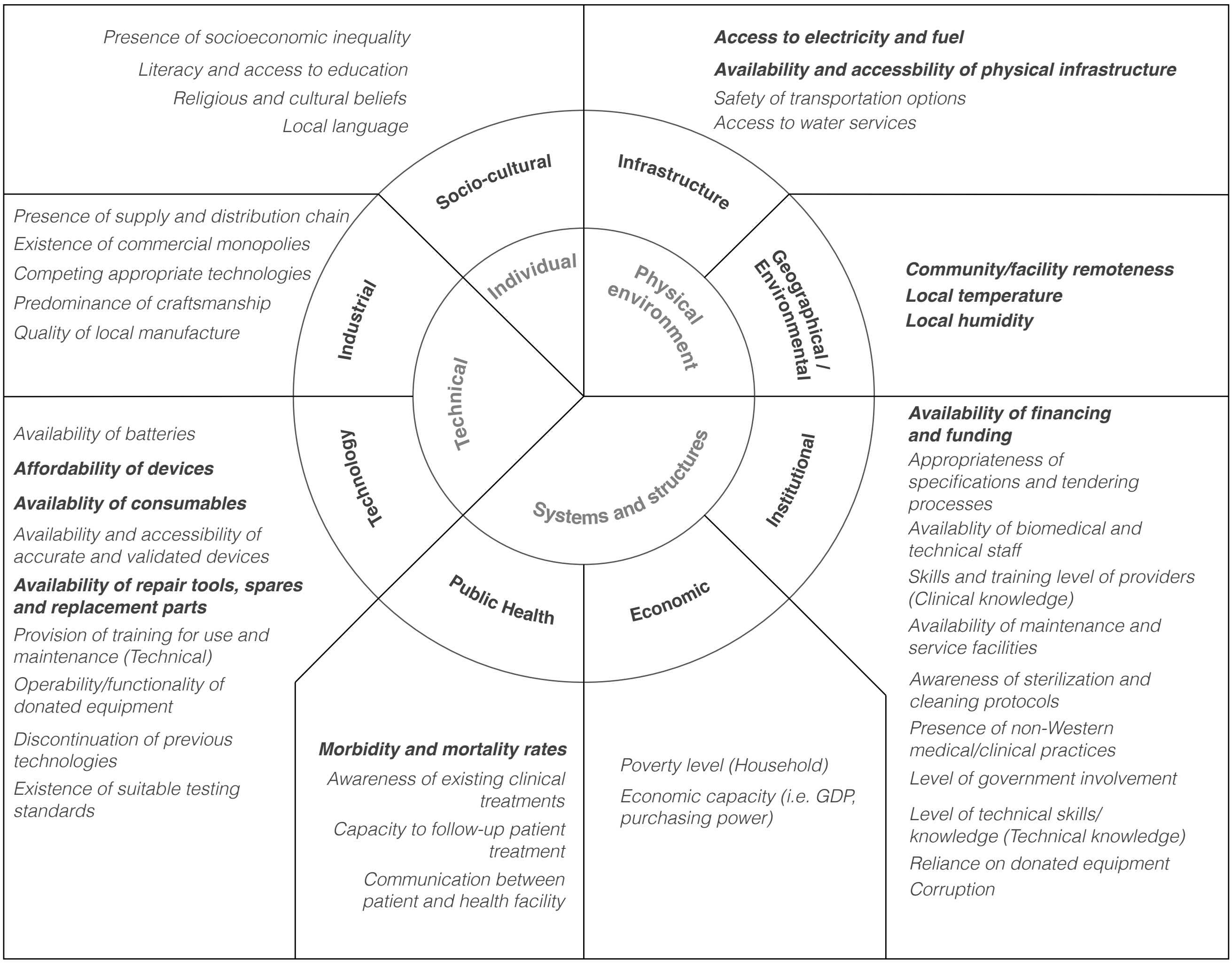

Figure 1. Overview of contextual categories. The most frequently mentioned factors are highlighted in bold.

> Because a hearing aid battery costs about a dollar and lasts about a week, and obviously it is very expensive a dollar a week in Africa, and also very difficult to find a battery, outside of the capital city. (I-2; coded as *Affordability*)

Industrial factors describe the ecosystem in which the device will be produced and deployed. Closely linked to the technological factors, these refer to the capacity to manufacture, distribute and commercialize a device. One interviewee commented:

> It's really the lack of distribution and support networks in these countries that makes it so hard [for the device to be distributed]. (I-1; coded as Supply and distribution chains for devices)

Understanding industrial factors provides knowledge of market prices, existing supply chains and availability of consumables and spare parts. The existence of supply and distribution chains for the devices (n = 5) and the quality of the local manufacture (n = 5) were the most frequently mentioned industrial factors, followed by the reliance of the industrial sector on craftsmanship (n = 5) and the existence of competition (n = 3) or commercial monopolies (n = 1).

Physical: *Infrastructure, Geographical, and Environmental Factors*

The physical context defines the interactions occurring between individuals and objects. The exploration of the physical context is one of the first steps that designers embark on (Langdon, Johnson, Huppert, & Clarkson, 2013; Nemoto et al., 2015). The frameworks by WHO (2010) and Gauthier et al. (2013) refer almost exclusively to these factors, which include infrastructural, geographical and environmental factors.

Infrastructural factors are the most frequently mentioned within this category (n = 58). When infrastructure is poor or not readily available, devices fail to be deployed, distributed and used, ultimately hindering the purpose of the design. Infrastructural factors include the consideration of whether there is electricity or another power supply (n = 17) or whether infrastructure is accessible and available (n = 11), including access to buildings, water systems and transportation. As mentioned by an interviewee:

> The first stage is to look at its operating environment. And then look at what the logistical situation is in the area [the device] is going into. Are they going to be able to have access to compressed

> gases? Or do you have to provide something that will function without them? (I-3; coded as *Availability and accessibility of physical infrastructure*)

Geographical and Environmental Factors are important when designing medical devices. Environmental conditions can limit options for the use of certain materials and determine how the components of a device operate in a setting. Temperature (n = 10) and humidity (n = 8), as part of the local conditions, are important when considering the operation and lifespan of the devices. One interviewee said:

> I've been in sort of 28 different African countries with all sorts of environments. It is high humidity. You need someone that is experienced in that sort of environment before they can make decisions on what equipment is suitable. (I-3; coded as *Humidity*)

Oxygen concentrators, for instance, rely on the conditions of the environment during operation, delivering poor quality of oxygen concentration under high temperature and high humidity conditions (Peel & Howie, 2009). Other important factors include geographical remoteness (n = 7) and roughness of the terrain to access the facility (n = 6).

Individual: *Socio-Cultural Factors*

Design is a purposeful activity in which the socio-cultural and natural environments are translated into a techno-physical environment (Rosenman & Gero, 1998). User experiences of a product are defined by an individual's culture, knowledge, attitudes and behaviours (Leblanc, 2009; Nemoto et al., 2015; Stappers et al., 2007). Socio-cultural factors are thus essential to identify genuine problems that designed products need to address (Castillo et al., 2012; Cipolla & Bartholo, 2014; Huang & Deng, 2008; Lin, 2007; Rosenman & Gero, 1998; Stappers et al., 2007).

Socio-cultural factors refer to the characteristics of the users and beneficiaries of the device. Cultural beliefs around health, for instance, are part of the description of the characteristic of the setting in the WHO's (2010) framework. Designers should place as much attention on socio-cultural aspects as they do on physical and technical aspects (i.e., "look like a real foot", high-quality finishes). Religious and cultural beliefs (n = 5), literacy level (n = 4), socio-economic stratification (n = 2) and the local language (n = 1) are important considerations. When referring to these factors, an interviewee said:

> I think also the family environment, looking at not just the mother but maybe the husband and the kids, and family support in terms of infant health and what their priorities are. I mean, if they only have one day to go to the clinic and it is also the day they need to come into the city to do some shopping, what is more important? (I-10, coded as *Religious and socio-cultural beliefs*)

Systems and Structures: *Political, Institutional, Economic and Public Health Factors*

Healthcare rests within a system that comprises organized individuals and institutions who play specific roles in providing care. These organizational systems are forms of collaborative networks of different stakeholders working and communicating for the same purpose, assuring health care is given to the patient (World Health Organization, 2010). They involve individuals, devices, services and infrastructural spaces. The resources available to provide care depend on how the networks are institutionally, politically and economically structured. Being complex themselves, these systems and structures are crucial to facilitate the deployment, adoption and use of medical devices (World Health Organization, 2010). Equally, devices influence the overall performance of the systems (World Health Organization, 2010). If designers overlook these structures, the design might fail (Anderson & Markides, 2007; World Health Organization, 2010). The Systems and Structures category aims to capture these networks (n = 79) and has been divided into Institutional, Economic and Public Health factors.

The institutional factors categorise components of an organization or institution of care. These include knowledge of technology management within the hospital (n = 5), the availability of technical or biomedical technicians (n = 6), facilities and tools for maintenance of devices (n = 3), training for use of the devices (n = 4) and also funding and financing to operate the devices (n = 8). The economic factors refer to aspects such poverty level (n = 6) and a country's GDP (n = 2). The public health factors describe the systematic determinants of populations' health. The structure and organization of care provision and public health factors are mutually dependent (e.g., morbidity defining the type of care to be provided). Public health factors include morbidity and mortality indicators (n = 17), awareness of treatments (n = 4), adherence to treatment (n = 1) and communication mechanisms between healthcare providers and patients (n = 1).

A solid knowledge of systems and structures helps address questions of technology deployment, such as supply and distribution systems, and potential business models (Castillo et al., 2012). In most healthcare systems, equipment is purchased through tendering processes based on pricing and generic product descriptions that may not represent genuine needs in the setting. The problems of inadequate specifications and tendering processes (n = 7) were mentioned as barriers for introducing innovative technologies. One interviewee commented:

> The government has a subsidies program for wheelchairs […], but it's only for a wheelchair that is described as a wheelchair by the Indian Institute of Standards. […] So, in the long-term, I think we are going to have to apply and get approval from the Institute of Standards for our wheelchair [because] it's a different product. That is an issue. (I-4; coded as *Appropriateness of specification and tendering processes*)

Another interviewee mentioned the challenges of international standards and increase in the prices when purchases are done through tenders:

> If you make technical equipment to the international standards, it will not work in that location. […] The standards are a problem. […] Once you get into the international tender arena, to be honest, the costs go through the roof, […] medical equipment bought through tender increased the price 6-fold. (I-3; coded as *Appropriateness of specification and tendering processes*)

Relevance of Factors by Type of Device

The analysis included the relevance of contextual factors by type of technology. Figure 2 shows some of these differences. For instance, in the case of technologies for personal use (e.g., prosthetic devices), which are often purchased by the user, the Socio-cultural Factors are often cited as highly relevant. Some examples include the need for prosthetic limbs that support religious practices or productive activities such as farming and agriculture. Industrial aspects, especially questions about how to manufacture the technologies, were relevant for wheelchairs and prosthetic devices. For other technologies, such as surgical devices, patient transportation and suction devices, Infrastructural Factors are crucial. Institutional Factors are often more relevant for technologies primarily used in clinical settings than for other technologies. This group includes infant incubators, anaesthetic machines and ultrasounds. Though affordability and cost are often cited as key in frugal healthcare innovations, Economic Factors were not the most frequently mentioned factors for most technologies.

Example of Use

By raising awareness of otherwise underappreciated or even neglected contextual factors, the framework aims to support pre-mortem evaluations of contextually conscious designs and hopefully prevent avoidable failures in the later stages of bringing products into the market. To test the framework in the simplest possible way, we employed it to collect data from an unfamiliar context (Figure 3). In a desktop study on Tanzania, we proposed one or two exploratory questions for each contextual factor in the framework. We then collected data from online sources to help address these questions. Firstly, we visited websites from Government bodies or International Organizations, followed by websites from charitable organizations, academic institutions and news organisations. When data was lacking, we made notes on what needed further exploration through fieldwork for instance.

From the data collected, a preliminary analysis can be drawn to show the implications of the factors on two technologies: anaesthetic machine and prosthetic limb. The most important factors for these technologies are availability and accessibility of physical infrastructure, remoteness of the community and the healthcare facility, appropriateness of the technical specifications and tendering process, availability of spare parts and religious and cultural practices. As can be seen in bold in Figure 3, we focus on these factors for the purpose of this exercise.

Contextual factors influence design in many different ways. For instance, in Tanzania the average temperature and humidity levels in the country are high. Hence, the options for the materials to manufacture a prosthetic limb might be limited by environmental conditions. For the anaesthetic machine, these conditions demand a built-in ventilator to keep the device cool and operational, adding to the energy demands of the system. This is a potential challenge considering that access to electricity in households and healthcare facility is very limited (15.3% and 12.5%, respectively). Moreover, roads do not service most rural populations (only 24% of people live within 2 km of a road). The lack of access to paved roads may affect the distribution and supply of medical gases, spares and even the device itself. The lack of roads is also important for the design of the prosthetic limb. Considering socio-economic factors, most people in Tanzania work in agriculture (75% of labour) and nearly 30% of the population lives below the poverty line. Considering that most people practice a religion, the design of the prosthetic limb should be influenced by these practices (praying) as well as lifestyles (working in agriculture and the need to walk long distances).

Finally, Institutional Factors are relevant for both devices. The country relies heavily on donated equipment and the healthcare sector accounts for a large proportion of funds lost to corruption. Since the majority of purchases for public healthcare facilities are done through the Medical Store Department, devices need to be designed to be able to compete against donated equipment and also perhaps for the implementation of business models that can help tackle corruption.

The example shows how to use the framework as a taxonomical tool for data collection for problem scoping. Critically, it demonstrates how the information ascertained using the tool can have a real influence on the design itself, from material selection to functional characteristics. Deep knowledge of the context can only be gained through contextual immersion, but an initial extensive scoping exercise can be conducted with these contextual tools to gain a basic understanding of context during the ideation process.

Discussion

The year 2015 marked the end of the Millennium Development Goals. Unfortunately, global health equality remains a goal far from being achieved. Technologies and infrastructure are crucial for healthcare provision and to achieve universal healthcare coverage we will require appropriate technological advances. To support the most vulnerable and marginalized people of the world, the design of medical devices needs to account for the varied contexts in LRSs and to recognise their unique challenges from the earliest stages of design. In this paper, we present the development of a holistic contextual framework for medical devices in LRSs to assist in this process.

Recognising the Social and Organisational Aspects of Design

The challenge of the lack of access to medical devices in LRSs is a multifaceted problem that requires an understanding that goes beyond the mere characteristics of the users' interactions with the technologies. Designing medical devices for LRSs must also go further than designing for the basic concepts of frugality, simplicity, low-cost and scarcity. Although these elements are crucial for devices to reach healthcare facilities in LRSs, ranking highly in the framework, the design should also address a broader scope. This scope should include the complexity of the context and place technologies within dynamic contexts that set a problem in socio-technical systems (Bijl-Brouwer & Voort, 2014).

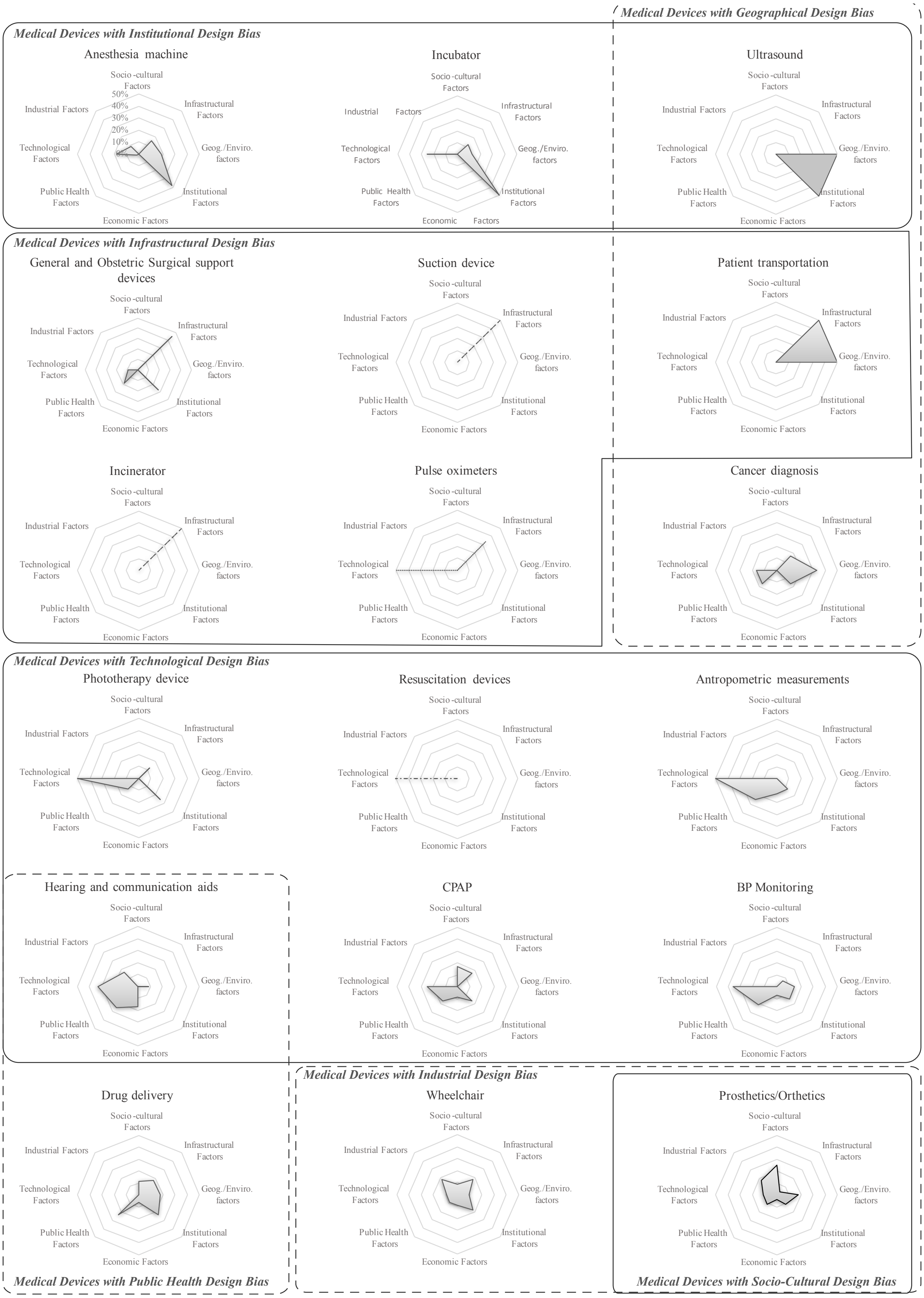

Figure 2. Relevance of contextual factors by the type of device (normalized). To facilitate visualisation, all graphs were fixed to show the percentage of mentions for each category to a maximum of 50% of the total per device. However, for the resuscitation device, suction device and incinerator, the dash-dot line indicates that factors within a single category were mentioned (100%). In the case of the pulse oximeter (dotted line), the technological factors accounted for 66.7% and the infrastructural factors accounted for the rest.

	Country: Tanzania Category: Least Developed country (World Bank, May 2016)	Questions (Exploratory)	Answers	Source	Notes	Anesthesia machine	Prosthetic limb
PE	Infrastructural Factors					√	√
1	Access to electricity and fuel	What is the population's access to energy sources?	15.3% of people with access to electricity in 2012	World Bank database: http://wdi.worldbank.org/table/3.7	**Fieldwork needed**: Explore specific situation of the healthcare system.	√	
		What is the access of energy in healthcare facilities?	12.5% of facilities have access to electricity or a generator with fuel	Service Provision Assessment (National Bureau of Statistics, 2006)http://dhsprogram.com/pubs/pdf/SPA12/SPA12.pdf			
2	Availability and accessibility of physical infrastructure	What is the conduction of the infrastructure for the provision of healthcare services?		Service Provision Assessment (National Bureau of Statistics, 2006)http://dhsprogram.com/pubs/pdf/SPA12/SPA12.pdf	**Fieldwork needed**: Explore and evaluate specific situation of the healthcare system.	√	
3	Safety of transportation options	What are the characteristics of public mobility in the country?	Access to public transportation is problematic in Tanzania	Kadobera *et al.*, 2012: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3495250/	**Fieldwork needed**: to learn about people's daily transportation options		√
4	Access to water services						
PE	Geographical and Environmental Factors					√	√
5	**Community/facility remoteness**	What is the average distance from the household to the health facility?	82.5% of people live within 5km of a healthcare facility in rural Tanzania	Klemick *et al.*, 2008: http://ageconsearch.umn.edu/bitstream/6178/2/wp080003.pdf	**Fieldwork needed:** Specific characteristics of geographic accessibility of facility and community	√	√
		How accessible is the community? How far it is from an urban area?	Unpaved and paved road quality in Tanzania is above the regional average. Only 24% of the rural population lives within 2km of a road.	World Bank, 2010: http://www.infrastructureafrica.org/system/files/Tanzania%20Country%20Report.pdf			
6	**Local temperature**	What are the characteristics of the temperature? (yearly averages)	19ºC (July)-23ºC (December)	Climate Change Portal. World Bank: http://sdwebx.worldbank.org/climateportal/index.cfm?page=country_historical_climate&ThisRegion=Africa&ThisCCode=TZA	**Fieldwork needed:** Specific characteristics of temperature and humidity. Investigate how they affect the equipment functionality.	√	√
7	**Local humidity**	What are the humidity conditions?	50mm (July)-200mm (December)			√	√
SS	Institutional Factors					√	√
8	Reliance on donated equipment	What percentage of medical devices in healthcare facilities come from donations?	Tanzania relies heavily on donated equipment.	Zomboko, *et al.*: http://www.researchersworld.com/vol3/issue4/vol3_issue4_1/Paper_06.pdf	**Fieldwork needed:** Understand how donation of equipment occurs for a specific facility, how partnerships work, country's donations guidelines.	√	
9	Availability of maintenance and service facilities	Are there existing maintenance and service facilities for medical equipment?	Inventories exist for expensive technologies. No information could be found about maintenance routines or protocols for medical equipment.	WHO, 2014: http://www.who.int/medical_devices/countries/tza.pdf	**Fieldwork needed:** Understand technology management and practices in healthcare facilities.	√	
10	Level of government involvement	What is the level of government involvement in management and procurement of medical technologies?	Hospitals within the public sector will depend on the government to purchase technologies.	Service Provision Assessment (National Bureau of Statistics, 2006)http://dhsprogram.com/pubs/pdf/SPA12/SPA12.pdf	**Fieldwork:** Understand how procurement systems work for the different triers of service provision. Explore the level of government involvement in all the different levels and types of care.	√	
11	Skills and training level of providers (Clinical Knowledge)	What is the quality of clinical training of healthcare providers?	Depending on the specific area of interest, the Service Provision Assessment contains information on the level and quality of training of healthcare providers.	Service Provision Assessment (National Bureau of Statistics, 2006)http://dhsprogram.com/pubs/pdf/SPA12/SPA12.pdf		√	
		Are users trained to use medical equipment?			**Fieldwork needed:** Understand users knowledge on the use of technology and frequency of training.		
12	Levels of Corruption	How does the country ranks in terms of procurement? What is the impact of corruption on the procurement of medical equipment?	In Tanzania, the public health sector has a 40% of leakage of public funds	World Bank, 2006: http://www1.worldbank.org/publicsector/anticorrupt/Corruption%20WP_78.pdf	**Fieldwork needed**: Explore how corruption affects and influences procurement of medical technologies.	√	
13	**Availability of financing and funding**	What is the budget for procuring and operating medical devices in Tanzania?	More than US$44mi invested in medicines in the public sector in 2008. No information was found for medical devices. 7.2% of the GDP is spent in the healthcare sector.	UNDP, 2011: http://www.undp.org.tt/News/UNODC/Anticorruption%20Methods%20and%20Tools%20in%20Health%20Lo%20Res%20final.pdf Brinda *et al.*, 2014: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3946236/	**Fieldwork needed:** Explore the different types of care providers and how they fund procurement and operations (i.e. consumable and staff) of medical equipment.	√	√
14	Appropriateness of specifications and tendering processes	Does the country have a procurement system with technical specifications for devices?	Procurement of medical equipment is done through the Medical Store Department (MSD), who set the specification and requirements for the equipment.	WHO, 2014: http://www.who.int/medical_devices/countries/tza.pdf	**Fieldwork needed:** For defining potential business model, it is important to understand the procurement system.	√	
15	Awareness of sterilisation and cleaning protocols					√	

Figure 3-1. Illustrative example of the practical use of the Contextual framework.
Test exercise conducted by one researcher to collect information following the contextual factors on the framework. The dark grey cells of the first column highlight the 10 most mentioned factors for all devices. Colours in the cells of the last two columns represent the relevance of the factors for each device: red, highly relevant; orange, relevant; yellow, slightly relevant; blue, little relevance; and white, not relevant. Within each category, the underlined arrows highlight the most mentioned factor from that category.

	Country: Tanzania Category: Least Developed country (World Bank, May 2016)	Questions (Exploratory)	Answers	Source	Notes	Anesthesia machine	Prosthetic limb
16	Availability of biomedical and technical staff	What is the existing availability of technical staff to maintain and repair the devices?	It is not possible to know availability of technical staff. However, in policy document from a Church-based hospital in Tanzania it is mentioned that maintenance of equipment should be provided by qualified staff.	Evangelic Lutheran Church in Tanzania, 2012:http://www.hcts.org/files/elct_maintenance_policy.pdf	**Fieldwork needed**: Identified where and how technical staff is trained. Explore the qualifications and training received by technical staff.	√	
17	Level of technical skills/knowledge	What is level and quality of the technical staff?			**Fieldwork needed**: Identified where and how technical staff is trained. Explore the qualifications and training received by technical staff.	√	
18	Presence of non-western medical/clinical practices	How acceptable are alternative medical practices in the country?	Traditional medicine practices are legal in Tanzania. Traditional medicine, however, is not incorporated in allopathic medical practices.	FAO, 2002: http://faolex.fao.org/docs/pdf/tan155105.pdf WHO, 2001: http://apps.who.int/medicinedocs/en/d/Jh2943e/4.42.html	**Fieldwork needed:** Explore how alternative medicines may influence the use and adoption of medical devices.	√	√
SS	Economic Factors						√
19	Economic capacity (i.e. GDP, purchasing power)	What is the country GDP?	Population of more than 44 million people. Agriculture contributes to 26% of GDP and employs 75% of labour force.	Atkinson & Lugo, 2010: http://eprints.lse.ac.uk/36376/1/Growth_poverty_and_distribution_in_Tanzania.pdf USAID, 2012: https://www.usaid.gov/tanzania/economic-growth-and-trade	**Fieldwork needed:** Explore how these factors may influence the use and adoption of medical devices.		
		What percentage of household income is destined to healthcare expenses?	Private expenditure on health as % of total expenditure of health: 60%.	WHO, 2014: http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_tza_en.pdf			
20	Poverty level (Household)	What percetange of people live below the poverty line?	28.2% of the population lived below the poverty line in 2012. Number of people under the poverty line has increased due to population growth. 67% of household dwelling floors are made of earth, sand or dung.	World Bank, 2015: http://www.worldbank.org/content/dam/Worldbank/document/Africa/Tanzania/Report/tanzania-poverty-assessment-05.2015.pdf USAID, 2012: https://www.usaid.gov/tanzania/economic-growth-and-trade UNDP, 2014: http://hdr.undp.org/sites/default/files/thdr2014-main.pdf	**Fieldwork needed:** For certain technologies, affordability at the household level may be more important than for others. Healthcare spending is important to understand the market.		√
SS	Public Health						√
21	Awareness of existing clinical treatments	How do healthcare providers train and/or keep up-to-date with clinical treatments and advancements? What is the role of the public health sector in this respect? What is the standard of care?			**Fieldwork needed**: Explore how this affects a particular device.		√
22	**Morbidity and mortality rates**	What is the country's life expentacy? What are the most common causes of death?	Male life expectancy: 59 years. Female life expectancy: 63 years. Top causes of death: HIV, Respiratory diseases, Malaria, Diarrhoea, Tuberculosis.	WHO, 2014: http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_tza_en.pdf CDC, 2013: https://www.cdc.gov/globalhealth/countries/tanzania/	**Information required**: Specific for a particular technology. Important for defining the strategic focus.		√
23	Capacity to follow-up patient treatment	What is the capacity of healthcare facilities to provide follow-up to patient treatment?			**Fieldwork needed**: Explore how this affects a particular device. Understand the capacity of health care providers to follow up patient's treatment.		
24	Communication between patient and health facility	What are the characteristics of the communication between the patient and the facility? (i.e. health education, follow-up, etc.)			**Fieldwork needed**: Explore how this affects a particular device.		
T	Technological Factors					√	√
25	**Affordability of devices**	How affordable are current technologies? What are the technological options available?			**Fieldwork needed:** Information about the cost of device is difficult to find online.		√
26	Affordability of operation	Are consumables/disposables needed for the operation of technologies? How much does it cost to run the equipment?			**Fieldwork needed:** Information difficult to find online. Exploration is needed in healthcare facilities to understand how expensive are certain technologies and how they fund their operation.	√	
27	Availability and accessibility accurate and validate devices	What is the status of current technologies?	Tanzania has a regulation on medical devices. The regulations have been recently reviewed by the WHO.	Sitta Kijo, 2013: http://www.who.int/medical_devices/Sat_pm_REG_6_KIJO.pdf TFDA, 2009: http://www.tanzania.go.tz/egov_uploads/documents/guideline_for_submission_of_documentation_for_registration_of_medical_devices_-_Now_sw.pdf	**Fieldwork needed:** To investigate more about regulations for specific devices. Devices are require to satisfy the government requirements:		√
28	Availability of batteries	Are batteries needed to operate the device? How affordable and accessible are they?			**Fieldwork needed:** Depending on the device of focus, batteries might be needed. Often batteries are problematic to access. Explore how the current situation of battery operated devices.		

Figure 3-2. Illustrative example of the practical use of the Contextual framework.
Test exercise conducted by one researcher to collect information following the contextual factors on the framework. The dark grey cells of the first column highlight the 10 most mentioned factors for all devices. Colours in the cells of the last two columns represent the relevance of the factors for each device: red, highly relevant; orange, relevant; yellow, slightly relevant; blue, little relevance; and white, not relevant. Within each category, the underlined arrows highlight the most mentioned factor from that category.

	Country: Tanzania Category: Least Developed country (World Bank, May 2016)	Questions (Exploratory)	Answers	Source	Notes	Anesthesia machine	Prosthetic limb
30	**Availability repair tools, spares and replacement parts**	What are the spares and parts needed to repair and maintain the device? Are they readily available?			**Fieldwork needed:** Information difficult to find online. Exploration is needed in healthcare facilities to understand how expensive are certain technologies and how they fund their operation.	√	
31	Operability/ functionality of donated equipment	What is the status of donated equipment? Is is functional? How do donated equipment reaches the facilities?			**Fieldwork needed:** Information difficult to find online. Exploration is needed in healthcare facilities to understand how expensive are certain technologies and how they fund their operation.	√	
32	Equipment obsolecense	What is the obsolescence status of equipment? What is the characteristic of the use of older technologies?			**Fieldwork needed:** Information difficult to find online. Exploration is needed in healthcare facilities to understand how expensive are certain technologies and how they fund their operation.	√	
33	Existance of suitable testing standards	How is functionality of technologies tested?				√	
34	Phase-out of previous technologies	Are there technologies being phased out that need new technological developments?			**Fieldwork needed:** Information difficult to find online. Exploration is needed in healthcare facilities to understand how expensive are certain technologies and how they fund their operation.		
35	Provision of training for use and maintenance	Is training provided for using and maintaining the devices?			**Fieldwork needed:** Information difficult to find online. Exploration is needed in healthcare facilities to understand how expensive are certain technologies and how they fund their operation.	√	
T	Industrial Factors					√	√
36	Existence of commercial monopolies	Do commercial monopolies exist in the medical devices sector?			**Fieldwork needed:** This is related to how equipment is procure and the existing corruption in the sector. Explore whether contracts are given to specific companies, posing a potential competitive threat.	√	
37	Quality of local manufacture	What are the characteristics of the manufacturing industry?	A manufacturing sector exists in Tanzania since the 1980s.	Mwaigomole, 2009: http://www.research.kobe-u.ac.jp/gsics-publication/jics/mwaigomole_16-3.pdf	**Fieldwork needed:** Investigate the specific manufacturing needs for a particular technology.		√
38	Presence of supply and distribution chain	Are there manufactures and/or distributors of medical devices in the country?			**Fieldwork needed:** Identify potential barriers for distribution and supply of medical devices.	√	√
39	Competing appropriate technologies	Are there any appropriate medical technologies in the country that function effectively and efficiently?			**Fieldwork needed:** Explore the devices currently found in the market, their functionality and how they may affect the introduction of new ones.	√	
40	Predominance of craftmanship	Does the country rely on craftsmanship for manufacturing technologies?			**Fieldwork needed:** Identify potential barriers for distribution and supply of medical devices.		√
I	Socio-cultural Factors						√
41	Local language	What are the local languages?			**Fieldwork needed:** Explore relevance of the local language for the operation and option of medical devices.		
42	Religious and cultural beliefs	What are the most relevant religious and cultural practices?			**Fieldwork needed:** Explore how cultural and religious practices may affect the use and adoption of technologies.		√
43	Levels of illiteracy and access to education	What is the country's literacy level?	73.2% of adult population are literate	WHO, 2014: http://www.who.int/countryfocus/cooperation_strategy/ccsbrief_tza_en.pdf	**Fieldwork needed:** Understand the characteristics of the users and how their literacy and education level may affect the use and adoption of a technology.		√
44	Presence of socioeconomic inequality	What is the wealth gap?			**Fieldwork needed:** Important to understand disparities on availability and affordability of devices.		√

Figure 3-3. Illustrative example of the practical use of the Contextual framework.
Test exercise conducted by one researcher to collect information following the contextual factors on the framework. The dark grey cells of the first column highlight the 10 most mentioned factors for all devices. Colours in the cells of the last two columns represent the relevance of the factors for each device: red, highly relevant; orange, relevant; yellow, slightly relevant; blue, little relevance; and white, not relevant. Within each category, the underlined arrows highlight the most mentioned factor from that category.

Unfortunately, the complexity of challenges in designing devices for LRSs tend to be poorly understood and is often overlooked (Hall, Matos, & Martin, 2014). In our research, we found that the practice of designing medical devices for LRSs is currently a highly technically-oriented task. Although the *Structures and Systems* category had the highest ranking individual factor (Morbidity and mortality rates), the *Physical* and *Technical* categories contained the majority of the other top ranking factors. Of the ten most frequently mentioned factors, five belong to the *Physical* category—energy, infrastructure and environmental conditions being the most frequently mentioned—and three to the *Technical* category. Many of these factors may be considered well understood, however, our approach highlights the relevance of less considered contextual factors, some of which may ultimately prove to be critical determinants of use.

When designing for LRSs, an approach inclusive of systems and organizations will encourage innovation processes that enable access to products and services for those most in need (Castillo et al., 2012). In areas such as design for sustainability, frameworks have successfully assisted designers to identify design solutions to problems in LRSs that are inclusive of the socio-cultural dimensions. Similarly, the present framework accounts for a broader range of contextual factors and places the technology within an organizational system in which healthcare is delivered. By looking at the context as a socio-technical system, designs may be able to achieve technological possibilities that will not only be technically-sound or frugal, but will also be adopted in communities by satisfying people's tacit and latent needs (Stappers, van Rijn, Kistemaker, Hennink, & Sleeswijk Visser, 2009). In practice, it is likely that more than one solution exists to solve these healthcare challenges, yet a purely technical approach is likely to fail to identify all possibilities (Bijl-Brouwer & Voort, 2014).

Contextual Framework as A Tool for Designers

A deep contextual understanding is required for designing, developing and commercializing products in LRSs (Castillo et al., 2012; Jagtap, Larsson, & Kandachar, 2013a). However, the identification of requirements and decision-making in the design process are generally unreported in the studies we have identified. Moreover, there is a lack of design-related tools to support these processes.

Frameworks, tools and methods to support designers in the initial phases of the design process are fundamental to better identify the needs for a product and understand its context of use (Chakrabarti, Morgenstern, & Knaab, 2004). Our framework aims to serve this purpose by providing a sound taxonomic tool to support designers to understand the context of use of medical devices in LRSs. The framework is not intended to be prescriptive and, as such, designers need to discern how information about these factors will affect the design of a device. As shown in the use example, the framework could be useful for the identification of needs and scoping of the problem at the early stages of the design process. The data collected by designers using this taxonomic framework could serve to inform, build and update the design of a product during later stages of the design process (e.g., validating and verifying design requirements) and may help to make the design decisions more explicit and transparent.

Conclusion

This research has used academic design cases and perspectives from experts in the field to explore the understanding of the context of use for medical devices in resource limited settings. Through systematically reviewing literature and conducting a qualitative analysis of data, the research resulted in a framework that we hope will help designers to inform their initial contextual explorations. We believe that the exercise of explicitly describing the identification and selection of factors is open to critique, but it is also an activity that should be encouraged by design researchers and practitioners. We hope that this research motivates similar research in the field. From the study, the main conclusions that can be drawn are:

- Contextual information is critical for problem understanding during the process of designing products for LRSs, particularly in the case of medical devices. Understanding and studying the context, however, poses several challenges for designers unfamiliar with this type of settings or with little experience designing. Not only do designers need to challenge their own assumptions and worldviews, but the task itself is costly and time-consuming.
- The framework in the study offers a taxonomical tool to support designers in the collection of data, thus making the initial exploration more efficient and effective. The framework provides guidance rather than prescriptive rules. The relevance of the factors varies depending on the type of technology being designed, but the context itself will determine the relevance of the factors (see, for instance, the example of use). The framework, however, does not aim to substitute contextual immersion, but rather to help designers during ideation and throughout the design process.
- As shown in the framework, the context of a technology goes beyond mere technical elements. Ultimately, whether a technology is adopted and diffused depends on the elements of the wider system that embraces technologies and their users. In this sense, we would like to highlight the relevance of the 'Systems and Structures' factors as elements that need to be considered by designers when designing medical devices for LRSs. These elements may be critical to whether a device will be purchased and used in healthcare settings, for example, organisational resources, procurement mechanisms, customs and traditions.
- Design researchers need to encourage more explicit ways to document the identification and selection of contextual factors. The study shows that academic publications offer a rather general description of the context, as opposed to the designer's approach to the description, this being often enriched by their own experience in the context and development of the product. This study has presented a comprehensive description of the decision-making process to build the framework in the hope of encouraging other researchers to do likewise. Learning from the methods used by other researchers in design will assist us to improve design practice to tackle the world's most critical challenges.

Implications in Research and Practice

Designers face challenges when designing medical devices for LRSs. In this regard, the framework may prove useful in engineering and industrial design education. Using the framework, students may start ideating by learning and becoming aware of the nature of problems faced in LRSs. The supplementary example of use in Appendix shows that understanding the context could influence the technical side of the design in multiple ways, for instance, how environment influences the selection of the materials or how road accessibility may influence the design of parts. We consider that the approach presented can help deliver more effective designs of medical devices for LRSs, with a greater chance of crossing the "last mile" of the product development process. This broader scope may thus offer new perspectives to tackle global health challenges.

Our contextual framework, based on the systematic literature review and empirical research, could be used by designers to collect contextual information. In design research, we believe this study will help researchers to rethink and question our conceptions and pre-conceptions of unfamiliar contexts. Although we are aware that this framework is one proposal to improve design success, we would like to invite designers and researchers to use it, adapt it and improve it with their own experiences and research in the field.

Limitations and Further Research

In its current state, the framework has been developed specifically for medical devices, one limitation being the focus on healthcare-related environments. Although the categorical factors may be applicable to other products, further research is required to explore the applicability of the framework to other product areas in LRSs. We believe that some minor adaptation to the framework may be required for that purpose.

We also acknowledge the lack of guidance on when and how to best use the framework at the different stages of the process as a limitation. Further research is needed to test the framework as a practical design support. Research may help to understand the usefulness of the framework in the design process and even understand the relevance of the categories at different stages of the process (i.e., is it useful to learn about a category in the early- or late-design stages?). We hope that this framework encourages similar approaches that can provide a starting point for an integrative approach towards designing effective and functional products for LRSs.

Acknowledgments

The National Council of Science and Technology (CONACYT) in Mexico supported this research.

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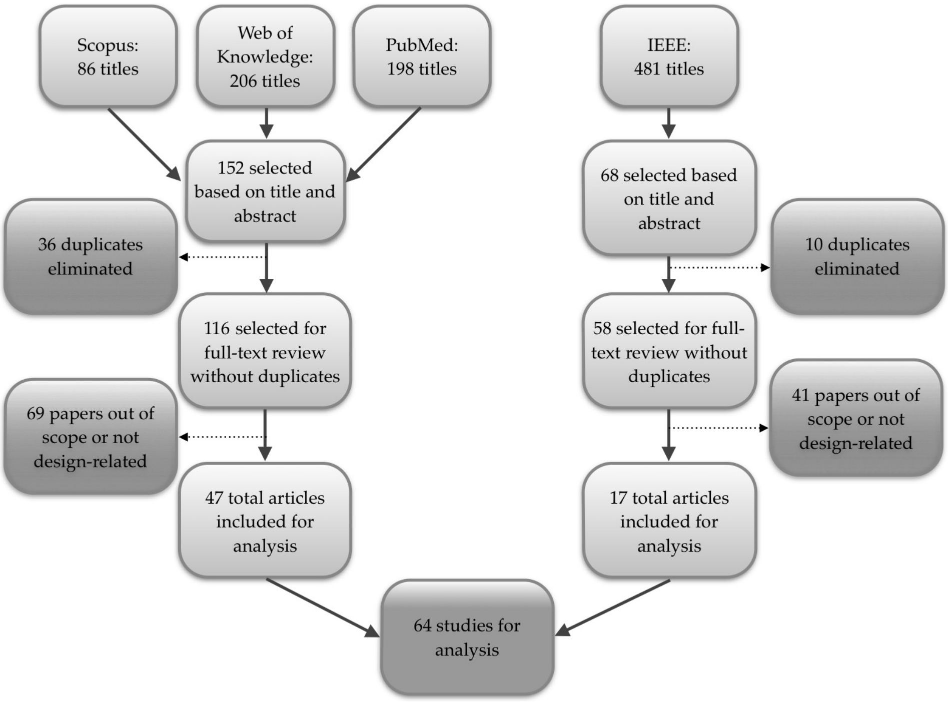
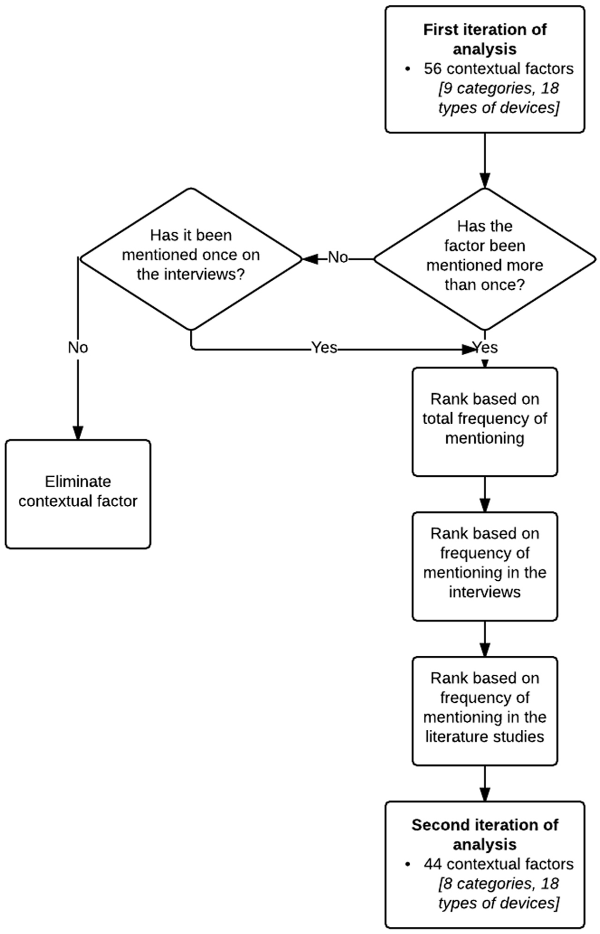
Appendix

Appendix 1. Decision tree for inclusion of studies (Aranda-Jan, Cruickshank, & Moultrie, 2015).



Appendix 2. Decision tree for inclusion of contextual factors.



Appendix 3. Holistic Framework (Ranked Factors)

Contextual factor	*Category*	*Literature*	*Interview*	*Total*	*Rank*
Morbidity and mortality rates	Public Health	14	3	17	1
Access to electricity and fuel	Infrastructural	13	3	16	2
Affordability of devices	Technological	7	6	13	3
Availability and accessibility of physical infrastructure	Infrastructural	8	3	11	4
Local temperature	Geographical and Environmental	7	2	9	5
Local humidity	Geographical and Environmental	6	2	8	6
Availability of financing and funding	Institutional	6	2	8	7
Community/facility remoteness	Geographical and Environmental	6	1	7	8
Availability of consumables	Technological	6	1	7	9
Availability of repair tools, spares and replacement parts	Technological	5	2	7	10
Appropriateness of specifications and tendering processes	Institutional	2	5	7	11
Availability of biomedical and technical staff	Institutional	5	1	6	12
Poverty level (Household)	Economic	4	2	6	13
Religious and cultural beliefs	Socio-cultural	4	1	5	14
Availability and accessibility of accurate and validated devices	Technological	4	1	5	15
Presence of supply and distribution chain	Industrial	3	2	5	16
Knowledge of technology management	Institutional	2	3	5	17
Rough terrains	Geographical and Environmental	4	0	4	18
Skill and training level of providers (Clinical knowledge)	Institutional	4	0	4	19
Awareness of existing clinical treatments	Public Health	3	1	4	20
Literacy level and access to education	Socio-cultural	3	1	4	21
Quality of local manufacture	Industrial	2	2	4	22
Availability of maintenance and service facilities	Institutional	2	1	3	23
Awareness of sterilization and cleaning protocols	Institutional	2	1	3	24
Presence of non-Western medical/clinical practices	Institutional	2	1	3	25
Operability/functionality of donated equipment	Technological	2	1	3	26
Level of government involvement	Institutional	0	3	3	27
Level of technical skills/knowledge (Technical knowledge)	Institutional	2	0	2	28
Economic capacity (i.e. GDP, purchasing power)	Economic	2	0	2	29
Safety of transportation choices	Infrastructural	2	0	2	30
Predominance of craftsmanship	Industrial	2	0	2	31
Presence of socioeconomic inequality	Socio-cultural	2	0	2	32
Discontinuation of previous technologies	Technological	2	0	2	33
Reliance on donated equipment	Institutional	1	1	2	34
Existence of suitable testing standards	Technological	1	1	2	35
Corruption	Institutional	0	2	2	36
Competing appropriate technologies	Industrial	0	2	2	37
Provision of training for use and maintenance (Technical training)	Technological	0	2	2	38
Access to water services	Infrastructural	0	1	1	39
Capacity to follow-up patient treatment	Public Health	0	1	1	40
Communication of patient and health facility	Public Health	0	1	1	41
Existence of commercial monopolies	Industrial	0	1	1	42
Local language	Socio-cultural	0	1	1	43
Availability of batteries	Technological	0	1	1	44

Appendix 4. Technical Factors (Industrial and Technological). Numbers refer to the number of times each contextual factor was mentioned.

Contextual factor	*Literature*	*Interview*	*Total*	*Included in the Framework?*
Technological Factors				
Affordability of devices	7	6	13	Included
Availability of repair tools, spares and replacement parts	5	2	7	Included
Availability of consumables	6	1	7	Included
Availability and accessibility of accurate and validate devices	4	1	5	Included
Operability/functionality of donated equipment	2	1	3	Included
Provision of training for use and maintenance (Technical training)	0	2	2	Included
Existence of suitable testing standards	1	1	2	Included
Discontinuation of previous technologies	2	0	2	Included
Availability of batteries	0	1	1	Included
Affordability of operation	1	0	1	Excluded
Equipment obsolescence	1	0	1	Excluded
Transportability	1	0	1	Excluded
Industrial Factors				
Presence of supply and distribution chain	3	2	5	Included
Quality of local manufacture	2	2	4	Included
Competing appropriate technologies	0	2	2	Included
Predominance of craftsmanship	2	0	2	Included
Existence of commercial monopolies	0	1	1	Included
Accuracy on needs identification	1	0	1	Excluded

Appendix 5. Infrastructural Factors. Numbers refer to the number of times each contextual factor was mentioned.

Contextual factor	*Literature*	*Interview*	*Total*	*Included in the Framework?*
Availability and accessibility of physical infrastructure	13	3	16	Included
Access to electricity and fuel	8	3	11	Included
Access to water services	2	0	2	Included
Safety of transportation choices	0	1	1	Included
Workplace safety	1	0	1	Excluded

Appendix 6. Geographical and Environmental Factors. Numbers refer to the number of times each contextual factor was mentioned.

Contextual factor	*Literature*	*Interview*	*Total*	*Included in the Framework?*
Local temperature	7	2	9	Included
Local humidity	6	2	8	Included
Community/facility remoteness	6	1	7	Included
Roughness of access terrains	4	0	4	Included

Appendix 7. Socio-cultural Factors. Numbers refer to the number of times each contextual factor was mentioned.

Contextual factor	*Literature*	*Interview*	*Total*	*Included in the Framework?*
Religious and cultural beliefs	4	1	5	Included
Literacy level and access to education	3	1	4	Included
Presence of socioeconomic stratification	2	0	2	Included
Local language	0	1	1	Included
Family traditions	1	0	1	Excluded
Presence of discrimination and stigmatization	1	0	1	Excluded
Demand	1	0	1	Excluded

Appendix 8. Structures and Systems Factors. Numbers refer to the number of times each contextual factor was mentioned.

Contextual factor	*Literature*	*Interview*	*Total*	*Included in the Framework?*
Economic Factors				
Poverty level (Household)	4	2	6	Included
Economic capacity (i.e., GDP, purchasing power)	2	0	2	Included
Equal access to job opportunities	1	0	1	Excluded
Cost of labor	1	0	1	Excluded
Health economics indicators (i.e., QALYs)	1	0	1	Excluded
Institutional Factors				
Availability of financing and funding	6	2	8	Included
Appropriateness of specifications and tendering processes	2	5	7	Included
Availability of biomedical and technical staff	5	1	6	Included
Knowledge on technology management	2	3	5	Included
Skills and training level of providers (Clinical knowledge)	4	0	4	Included
Level of government involvement	0	3	3	Included
Availability of maintenance and servicing facilities	2	1	3	Included
Awareness of sterilization and cleaning protocols	2	1	3	Included
Presence of non-Western medical/clinical practices	2	1	3	Included
Levels of Corruption	0	2	2	Included
Reliance on donated equipment	1	1	2	Included
Level of technical skills/knowledge (Technical knowledge)	2	0	2	Included
Public Health Factors				
Morbidity and mortality rates	14	3	17	Included
Awareness of existing clinical treatments	3	1	4	Included
Capacity to follow-up patient treatment	0	1	1	Included
Communication of patient and health facility	0	1	1	Included
Political Factors				
Sociopolitical movements (i.e., armed conflicts)	0	1	1	Excluded