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Global health front-end medical device design: The use of prototypes to engage stakeholders

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ABSTRACT

Availability, accessibility, affordability, and appropriateness are among several factors that significantly affect the adoption and diffusion of medical devices in low- and middle-income countries. Design processes that promote early and frequent engagement with stakeholders may increase the impact of medical devices aimed at addressing global health challenges by improving the uptake and sustained use of such devices. Prototypes are tools that can be leveraged to engage stakeholders during front-end design to define the problem, elicit requirements, and obtain feedback on early design concepts. Given the lack of literature that examines the practices for stakeholder engagement with prototypes during front-end design, this study was guided by the following research question: How do global health design practitioners approach stakeholder engagement with prototypes during front-end medical device design? Eleven design practitioners from industry were interviewed; transcripts were analyzed using thematic analysis to uncover prototyping behaviors. Transcript level counts of stakeholder groups, prototype forms, and strategies leveraged during stakeholder engagement with prototypes are reported. Based on the analysis of stakeholders, prototypes, and strategies, engagement events that reflect how the global health setting influenced decisions of stakeholder, prototype, and strategy are presented. Participants described challenges associated with: cross-cultural and remote design; the elicitation of contextual requirements; and limited access to resources. Participants devised approaches to overcome these challenges such as: engaging a wide range of stakeholders including proxy users and government stakeholders; developing long-term relationships with community partners; leveraging communication technologies; engaging stakeholders in the real use environment with physical prototypes; using prototypes to bridge the language barrier; 'polishing' prototypes; and inviting stakeholders to create and select prototypes. These results could impact approaches to practicing and teaching prototype usage during front-end design in a development setting.

1. Introduction

Health technologies contribute to multifaceted solutions aimed at alleviating the burden of disease in low- and middle-income countries (LMICs), but many existing health technologies, including medical devices, seldom reach their full potential to improve global health (Free, 2004; Howitt et al., 2012; Sabet Sarvestani and Sienko, 2018). Numerous health technologies fail to reach scale due to a combination of factors including: cost, energy, and human resource constraints (Howitt et al., 2012; Perry and Malkin, 2011); lack of cultural acceptability (Howitt et al., 2012); inability to address the core problem (Malkin and von Oldenburg Beer, 2013); poor fit with existing systems and context (Free, 2004; Schopman et al., 2013); additional regulatory constraints (Free, 2004; Howitt et al., 2012); lack of training of health professionals (WHO, 2010); maintainability challenges such as hindered access to spare parts and consumables (Perry and Malkin, 2011; WHO, 2010); low profit margins (Free, 2004); and limited monetary resources to support commercialization (e.g., venture capital) (Malkin and von Oldenburg Beer, 2013; Perry and Malkin, 2011; WHO, 2010). The confluence of these constraints specific to health technologies for development reduces the number of potential viable design solutions (Bergmann et al., 2015) and limits the adoption and diffusion of innovations in LMICs (Kroll et al., 2014).

When design for LMICs happens remotely, as it often does

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(Donaldson, 2009), a comprehensive characterization of context and of stakeholders' needs and requirements is necessary and can better equip designers to address the aforementioned constraints (Aranda Jan et al., 2016; Chavan et al., 2009). For example, design approaches that consider local and regional constraints, cultural contexts, and stakeholder needs are particularly effective in LMICs (Chavan et al., 2009). Aranda Jan et al., 2016, developed a framework that prompts designers to consider infrastructural, industrial, and institutional factors, for example, to support the design of medical devices for emerging markets. Design recommendations for development engineering include: focusing on local manufacturing to increase the maintainability of devices through the development of local support and expertise; designing device essential functions with fewer components and readily available parts; and designing devices that can withstand harsh environmental conditions (Howitt et al., 2012).

Studies have stressed the importance of engaging stakeholders during the front end of design (i.e., phases of product pre-development associated with problem definition including requirements elicitation, specifications formulation, and early concept generation (Khurana and Rosenthal, 1998)) to better define product requirements that meet the needs of stakeholders (Neale and Corkindale, 1998; Shah and Robinson, 2007). Quality of execution of the front-end phases has been linked to the success of design projects (Cooper, 1988; Khurana and Rosenthal, 1998). Eliciting and developing product requirements are key components of front-end design. Requirements form the base of any engineering design project by characterizing the attributes and features necessary for addressing diverse stakeholders needs (Hull et al., 2011). The steps of identifying stakeholders' authentic needs, eliciting product requirements, and translating them into engineering specifications are central to preventing disparities between stakeholders' needs and product attributes (Tseng and Du, 1998).

Medical device stakeholders traditionally include users, such as doctors and nurses, as well as others who may impact or be impacted by the design (Freeman, 2010), such as patients, caregivers, regulatory specialists, and public and private payers (Yock et al., 2015). To elicit product requirements, many methods have been published encouraging the involvement of stakeholders, such as interviews, questionnaires, contextual inquiry, use cases, role playing and others (Kausar et al., 2010). Involving stakeholders during front-end design activities is especially important for designers whose target markets are LMICs (Caldwell et al., 2011). Methods of stakeholder engagement such as design ethnography (Mohedas et al., 2014), which includes face-to-face interviews, focus groups, and co-design (Sanders and Stappers, 2008), have been encouraged when designing for LMIC settings (Caldwell et al., 2011; Kroll et al., 2014; Sarvestani and Sienko, 2014). Furthermore, some stakeholder engagement strategies have been developed specifically for use in LMICs, e.g., the Bollywood Method adapted cultural probes for engaging with stakeholders in India (Chavan et al., 2009). In multiple product domains, information gathering methods with stakeholders include the use of prototypes for the elicitation of requirements during the design front-end (Kausar et al., 2010; Maiden and Rugg, 1996).

Prototyping–the act of making physical or visual objects that represent a design idea–can support information gathering about stakeholders during the design front-end. Prototypes can be used throughout a design process to help designers develop requirements, generate concept solutions, communicate ideas to stakeholders, and verify design objectives (de Beer et al., 2009; Lauff et al., 2017; Yang, 2005). Prototypes are increasingly used to involve stakeholders early in design processes because they can encourage stakeholders to play a more active role (Aurum, 2005). Prototypes provide a fundamentally different way of communicating around a shared space (Lauff et al., 2020). Users can articulate their needs by interacting with prototypes rather than doing so in the abstract (de Beer et al., 2009; Kausar et al., 2010). Prototypes have therefore been leveraged in front-end design: during stakeholder engagement in the front end to communicate ideas (McElroy, 2016); during formative usability settings in the field of human-computer interaction (Tohidi et al., 2006); during early co-design activities (Sanders and Stappers, 2014); and during early requirement elicitation interviews (Kausar et al., 2010; Maiden and Rugg, 1996).

However, although early and frequent prototyping in a design process has been recommended (Kelley, 2007), limited research has focused on specific strategies for using prototypes during front-end stakeholder engagement, including within medical device design when designing for LMICs (Caldwell et al., 2011; IDEO.org, 2015). Some research has considered the effects of prototype forms and quantity of prototypes shown on stakeholder feedback (Deininger et al., 2019; Tohidi et al., 2006), but many questions remain regarding ways to strategically leverage prototypes to support fruitful and authentic information gathering from stakeholders early in a design process. Thus, this study aimed to describe the practices of global health design practitioners to engage stakeholders with prototypes during front-end medical device design activities. Specifically, this study describes how the global health context influenced decisions concerning the stakeholder groups to involve, prototypes to use, and strategies to leverage during stakeholder engagements with prototypes. Prior literature has demonstrated the value of rich descriptions of experiences collected through qualitative research methods (Hollway and Jefferson, 2000; Sandelowski, 1991), notably when studying design processes and strategies used within those processes (Daly et al., 2013). We selected excerpts from a qualitative research study of design practitioners to understand their practices and the rationales for such practices during front-end activities associated with the design of medical devices intended for use in LMICs.

2. Methods

2.1. Research aims and approach

This study investigated the practices of global health design practitioners for stakeholder engagement using prototypes during the front-end design of medical devices, guided by the following research question: **How do global health design practitioners approach stakeholder engagement with prototypes during the front-end design of medical devices?**

A qualitative research approach was selected to collect in-depth information about participants' front-end design practices. Qualitative methods enable the collection of rich data focused on specific contexts; thus, results are not intended to be broadly generalizable (Patton, 2014). A qualitative approach can enable the discovery of new phenomena and facilitate the generation of in-depth descriptions that are necessary for uncovering a more comprehensive understanding of phenomena. Qualitative methods can provide unique insights into the study of engineering design, enabling new results not obtainable via quantitative methodologies, and have been used in many studies of design processes and outcomes (Aranda Jan et al., 2016; Crilly, 2015; Daly et al., 2013; Stempfle and Badke-Schaub, 2002; Vincent et al., 2014). The qualitative methods leveraged in this study elicited rich descriptions of the stakeholders, prototypes, and strategies leveraged by practitioners with minimal assumptions as to who the stakeholders and what the prototypes and strategies were.

2.2. Participants

Participants included 11 design practitioners with prior experience engaging stakeholders with prototypes during front-end design phases while working on the design of mechanical and/or electro-mechanical global health medical devices. The sample size for this study was similar to other interview-based qualitative studies in design (Crilly, 2015; Stempfle and Badke-Schaub, 2002; Vincent et al., 2014). Participants were recruited through networks of the study team and through online searches. This approach to participant recruitment was guided by a qualitative research sampling strategy focused on identifying key individuals with the knowledge and expertise to describe particular phenomena (Patton, 2014).

Participants were recruited from eight global health design companies, four of which had 1-9 employees, three of which had 10-200 employees, and one of which had more than 200 employees. One company was situated in Norway, one in India, and the remaining six were headquartered in the United States (U.S.). Six companies were private, the remaining two were a non-profit and a partnership. All participants had a bachelor's or higher degree. Seven of the 11 participants were female. The average job tenure of the participants was 4.6 yr (±3.0 yr) and their average design experience was 8.4 yr (±5.3 yr). Participants' job titles included: product designer, project engineer, project manager, design consultant, chief technology officer, clinician advisor, and manager of strategic partnerships. The products discussed by participants were all mechanical or electro-mechanical medical devices. The medical applications included treatment, diagnostics, preventative care, and training. The study was reviewed by the University of Michigan Institutional Review Board and approved as exempt.

2.3. Data collection

Participants were interviewed in English using a semi-structured interview protocol. The semi-structured interview allowed for consistent questioning across participants as well as opportunities to seek additional detail and meaning through participant-specific follow-up questions (Barriball and While, 1994). Following interview protocol development guidelines (Patton, 2014), the interview protocol began with rapport-building questions, transitioned to open-ended questions focused on particular experiences, and ended with follow-up questions to explore additional details (Jacob and Furgerson, 2012). This protocol was guided by the research questions and literature on prototyping and was piloted 11 times, with different participants each time, to inform iterations to the interview questions and structure. The pilot participants included graduate students with prior industry experience in a design field (full-time and internships), a professor of practice, post-doctoral fellows, and university staff with experience in mechanical design of medical devices.

In the first part of the interview, definitions of front end, product, prototypes, and stakeholders were provided. The definitions are included in Appendix A. Next, participants were asked about a specific project that involved stakeholder engagement with prototypes during the design front-end, which involved speaking retroactively about their role in the design of a product developed within their company. Projects discussed by participants ranged from commercialized devices to novel projects currently in front-end design stages. In the last part of the interview, participants were asked to compare the practices they used across several of their projects. Example questions are given in Appendix B.

A subset of participants showed the interviewer examples of prototypes and/or shared images of prototypes during and/or shortly after the interview. These visuals were only used to provide context to the interviewer and were not used in the subsequent analysis, which is solely based on the interview transcripts.

2.4. Data analysis

2.4.1. Thematic analysis

Interviews were transcribed by a third-party service and checked for accuracy by two graduate researchers with formal training in qualitative research methods. The dataset of interview transcripts was then merged with a dataset of 13 other interviews of designers working in multinational medical device companies. The two graduate researchers, aided by an undergraduate researcher (trained to identify themes), analyzed the transcripts using a qualitative data analysis technique called thematic analysis. The process of thematic analysis comprises gaining familiarity with the data by listening to the interviews and reading the transcripts, searching for initial emergent themes across the transcripts, reviewing the themes, and defining and naming them (Braun and Clarke, 2006; Patton, 2014). Thematic analysis aims to 'encode' qualitative data with smaller units of meaning that set the stage for patterns to emerge and for interpretations to be drawn about the data (Coffey and Atkinson, 1996). In this study, the analysis focused on identifying patterns of:

- stakeholders engaged with prototypes during front-end design activities;
- prototypes used to engage stakeholders during front-end design activities; and
- strategies used by participants to engage stakeholders with prototypes during front-end design activities.

The study team iteratively repeated the process of searching for, reviewing, and defining themes multiple times, which improved their reliability (e.g., rating independently and comparing data excerpts with another experienced researcher until reaching full agreement). Existing stakeholder group frameworks (Alsos and Svanæs, 2011; Freeman, 2010; Fritz et al., 2018; Grech and Borg, 2008; Leonidou et al., 2018; Martin et al., 2006; Meissner and Blake, 2011; Montague and JieXu, 2012; *Ready, Set, Launch*, 2017; Yock et al., 2015) and prototype form classifications (Ciurana, 2014; Jensen et al., 2016; Mathias et al., 2018; Sanders and Stappers, 2014; Sass and Oxman, 2006; Ulrich and Eppinger, 2011) were used to refine the themes. For each analytic goal (i.e., stakeholders, prototypes, and strategies), the study team established a final set of themes for stakeholder groups, prototype forms, and strategy types. Because this paper focuses on design for LMICs, only the final themes found in the subset of global health participants' transcripts are reported in Table 1 (stakeholders), Table 2 (prototypes), and Table 3 (strategies).

Data pertaining to the participants' team composition for the projects discussed were not collected. In this analysis, the researchers did not include interactions during which designers used prototypes to engage other designers on the team (internal-internal stakeholder interactions (Jensen et al., 2017)). Participant responses suggested that all participants worked on teams and shared responsibilities for prototyping and stakeholder engagement. Furthermore, all participants discussed making prototypes only in the country where their company was situated.

2.4.2. Engagement events

The following data analysis was performed only on the global-health-related interview data. Upon completion of the thematic analysis, transcripts were partitioned into 'engagement events,' which regrouped

Table 1
Stakeholders engaged by global health design practitioners with prototypes during front-end design. An earlier version of these emergent themes was reported in (Coulentianos et al., 2018, 2020).

Stakeholder group	Definition
User	A stakeholder who would use the device and/or would benefit from its primary function once the device is commercialized, such as doctors, nurses, patients, co-workers acting as users, and people responsible for cleaning and maintaining the device.
Expert advisor	A stakeholder who provides expertise on the device and the problem space based on their professional knowledge and experience.
Implementation stakeholder	A stakeholder who would be directly involved in the implementation of the device, such as people who participate in the manufacturing and supply chain of the device, community partners, financial decision makers, stakeholders in government, regulatory experts, and marketing stakeholders.
Support stakeholder	A stakeholder who supports and assists the designers in a design process, such as students, hackathon participants, and translators.

Table 2
Prototypes leveraged by global health design practitioners to engage stakeholders during front-end design. An earlier version of these emergent themes was reported in (Coulentianos et al., 2018, 2020).

Prototype form	Definition
Physical 3D	A physical representation of an idea that has a three-dimensional (3D) shape, such as models built with spare parts, craft materials and rapid prototyping methods; refined prototypes of the whole device; existing products; and pilot experiments with physical models.
2D	A static two-dimensional (2D) representation of a 3D prototype or of a process, created by hand and/or with digital tools, such as drawings, storyboards, photographs, renderings, and engineering drawings.
Digital 3D	A prototype created using Computer-Aided Design (CAD) software, viewed statically on screens or paper, or animated in a digital environment to simulate functionality, such as CAD 3D Models, interactive renderings, and video recordings of a physical prototype.

Table 3
Strategies leveraged by global health design practitioners when engaging stakeholders with prototypes during front-end design. These strategies have been established and were further defined in (Coulentianos et al., 2019; Rodriguez-Calero et al., 2020, in review).

Strategy
Brief the stakeholder about the project and the prototype(s) shown
Encourage the stakeholder to envision use cases while interacting with the prototype (s)
Have the stakeholder interact with the prototype(s) in a simulated use case
Introduce the prototype(s) to the stakeholder in the use environment
Make prototype extremes to show the stakeholder
Manage group composition and size
Modify the prototype(s) in real time while engaging the stakeholder
Observe the stakeholder interacting with the prototype(s)
Polish the prototype(s) shown to the stakeholder
Present a deliberate subset of prototypes to the stakeholder
Prompt the stakeholder to select prototypes and prototype features
Reveal only relevant information to the stakeholder specific to the prototype or its use
Show a single prototype to the stakeholder
Show progress of prototypes
Show the stakeholder additional prototypes to supplement a prototype of the same concept
Show the stakeholder multiple prototypes concurrently
Standardize the refinement of prototypes shown concurrently to the stakeholder
Task the stakeholder with creating or changing the prototype(s)

all excerpts that pertained to a specific activity, as described in (Montgomery and Duck, 1993). Each engagement event represented a specific interaction comprising a participant's use of one or more prototypes to engage one or more stakeholders during the front end of design. Multiple excerpts that described the same interaction, whether contiguous or scattered throughout the transcript, were grouped into a single engagement event. Hence, engagement events described front-end design activities during which an engagement strategy was used, and/or where a prototype and/or stakeholder were explicitly named. The graduate researchers practiced identifying engagement events on the same transcript to establish reliability. The data were then partitioned, and each graduate researcher identified engagement events for half of the transcripts. One graduate researcher then reviewed all engagement events to ensure parallelism between engagement events and any inconsistency was resolved through discussion. An example of an engagement event is included in Appendix C.

Each transcript contained between 6 and 14 engagement events, with an average of 8.4 engagement events per transcript. A total of 92 engagement events were identified. Engagement events during which participants described specific elements pertaining to design for an LMIC setting (e.g., travelling to an LMIC country to engage stakeholders with prototypes, describing perceived cultural differences and their effects on the engagement) were identified. All participants in this study were designing for a global health setting. However, in a subset of engagement events, participants described making choices as a direct result of the global health context for which participants were designing. Engagement events from four transcripts were selected by the study team as illustrative cases. The excerpts chosen represent decisions made by participants about stakeholders to engage, prototypes to use, and engagement strategies, and include participants' descriptions of how their decisions resulted from global-health specific challenges. The four cases presented below were selected because they were representative of the larger sample and highlighted commonly experienced global health challenges. Furthermore, the cases highlighted how participants determined which stakeholders, prototypes, and strategies to leverage.

The participants whose excerpts were reported in the results worked in four different private U.S.-based companies. Participants A, B, and C worked in companies with 1–9 employees and Participant D worked in a company with 10–200 employees. Additional background information relative to the excerpts presented in the results section are included in Appendix D.

After the analysis was completed, one of the graduate researchers sent the results section to the participants whose excerpts were included for member checking, a qualitative research practice where results are shared with study participants to verify their accuracy (Doyle, 2007). Each participant's specific excerpts were highlighted, and they were given an opportunity to edit their respective quotes if desired. During member checking, some participants adjusted the language in their quotes, but the meaning remained the same. The excerpts included in the results have been de-identified to protect participant confidentiality and smoothed from spoken word to make them more readable as text. All modifications are indicated with brackets.

3. Results

Participants engaged multiple stakeholder groups during early design activities, using a variety of strategies and diverse prototype forms. The stakeholders, prototypes, and strategies were leveraged during front-end stakeholder engagements with prototypes, for medical device design in global health settings. The stakeholder groups, prototype forms, and strategies described by the participants are given in Table 1, Table 2, and Table 3. The transcript-level counts for each category are reported in Table 4. The most frequently discussed stakeholders were *Users*, the most frequently discussed prototype form was *3D physical*, and the most frequently discussed strategy was to *show the stakeholder multiple prototypes concurrently*. While these stakeholder, prototype, and strategy were most frequent within the experiences that participants chose to share with the researchers, the frequencies do not suggest which stakeholders, prototypes, and strategies leveraged are the most used or the most useful for medical device design.

The following excerpts from four interviews provide exemplary cases of how global health design practitioners engaged stakeholders with prototypes during front-end design. These specific excerpts were selected to provide detailed descriptions of the use of prototypes to engage stakeholders during front-end design activities, including the stakeholders engaged, prototypes leveraged, and the strategies used.

3.1. Participant A: engaging active and proxy users with a polished 3D-printed prototype

Participant A discussed the front-end design of a device being developed for use by nurses and physicians in hospitals in LMICs. The objective of the engagement was to learn about the attachment mechanism for the device being designed. The engagement consisted of a focus group carried out in the participant's office space, for which Participant A brought a 3D-printed prototype. The stakeholders were invited to observe and interact with the prototype.

Participant A described engaging active users (nurses) and proxy

Table 4
Transcript-level counts of stakeholder groups, prototype forms, and strategies leveraged by global health design practitioners when engaging stakeholders with prototypes during front-end design. Themes further discussed in the results are in boldface.

Stakeholder group	Transcript-level count
User	**11**
Implementation stakeholder	**11**
Expert advisor	**8**
Support stakeholder	**4**
Prototype form	Transcript-level count
Physical 3D	**11**
2D	**8**
Digital 3D	**2**
Strategy	Transcript-level count
Show the stakeholder multiple prototypes concurrently	10
Brief the stakeholder about the project and the prototype (s) shown	**10**
Observe the stakeholder interacting with the prototype(s)	8
Show a single prototype to the stakeholder	**8**
Introduce the prototype(s) to the stakeholder in the use environment	**7**
Have the stakeholder interact with the prototype(s) in a simulated use case	**5**
Manage group composition and size	5
Show progress of prototypes	5
Task the stakeholder with creating or changing the prototype(s)	**4**
Polish the prototype(s) shown to the stakeholder	**3**
Encourage the stakeholder to envision use cases while interacting with the prototype(s)	**3**
Show the stakeholder additional prototypes to supplement a prototype of the same concept	2
Reveal only relevant information to the stakeholder specific to the prototype or its use	2
Modify the prototype(s) in real time while engaging the stakeholder	2
Prompt the stakeholder to select prototypes and prototype features	**2**
Standardize the refinement of prototypes shown concurrently to the stakeholder	1
Present a deliberate subset of prototypes to the stakeholder	1
Make prototype extremes to show the stakeholder	1

users (also nurses). The nurses who served as proxy users worked in the U.S. and performed the same tasks as the intended active users but were unfamiliar with the technologies available in LMICs. The cost (time and resources) needed to engage the proxy nurses was lesser than it would have been to engage the active users who, in this case, were located in a different country than Participant A. However, Participant A noted that proxy users, who were sometimes engaged when active users were not accessible, provided less useful input because they were less familiar with the design context (i.e., the LMIC).

> *"I had to work on ways on how to attach [the device]. We got a collection of nurses, both U.S. based nurses but also nurses here in the U.S. but who had experience or were from other countries. (…)*
>
> *We sought people out that were familiar with [the domain of the device], and this was a challenge for us in this country. Pretty much all the nurses used [a higher-tech process], so they were already expecting a certain level of technology and a little sophistication. They weren't our intended users and customers for this device, so we struggled to find users that were familiar with [the domain of the device]. (…) The best interactions, the most useful ones came when we had a user that (…) understood that there was a need for this right away. Because then you could have a constructive conversation about how this would be useful to solve a problem they know about. The most frustrating ones we have are the nurses that work in the nice, well-*funded *hospital who don't understand the need for this. So, you end up spending half the time trying to explain to them why other people, not them, might need this device. The problem space is not familiar to them and it's hard for them to get over that. (…)"*

Across participants, proxy users included healthcare practitioners working in a different setting than the intended users, laypeople with similar characteristics to the intended user, such as family friends, co-workers, or the designers themselves acting as proxies.

Further, during the focus group, Participant A used a single polished 3D-printed prototype. Participant A explained that showing non-polished prototypes can fail to elicit useful feedback because some stakeholders, in his prior experience, were distracted by elements of the prototype that appeared unfinished. Hence, Participant A described polishing the prototype to avoid distracting or biasing the stakeholders.

> *"What we were putting in front of users was a little more polished (…). The problem with having a really rough prototype is that users can't get past the fact that it's not finished. They're like, 'oh it doesn't do this' and you're like 'I know, ignore that fact. Tell me other stuff.' So, you're always going to want to put the most polished thing in front of them that you can, because it prevents them from getting distracted by the shortcomings and focusing on the futures that you want to know about."*

Participant A described bringing a single prototype to the engagement because of resource constraints, even though he felt that showing multiple prototypes may have yielded better feedback.

> *"In general, just given our limited resources, most of the major stuff was done linearly and a single prototype iteration. If it becomes easy to try multiple styles at the same time and then I'm more than happy to do it and I try to do that every chance I get. (…) There are more options, so there's more questions about different things. If you show them one, it's like 'yeah, that's good' or 'this isn't good'. If you show them three, it kind of opens up their minds a little bit to other solutions. It's just more constructive feedback, if that makes sense."*

Resource constraints also prevented Participant A from engaging active users of the device as often as he would have liked.

> *"Ideally, if we had our way and we had unlimited funds, we would go and test in the exact locations where users would use this eventually at least half a dozen times. Every major design decision should come from that if it could. The reasons we did most of the testing the way we did was really just out of having very little money. (…) It's all about limited resources. Right now, it's sort of opportunistic where if we can get somebody, we'll do it. Whether that's, we bring them to the office here or we go visit them. We can't fly to Africa every time we have a question to ask."*

3.2. Participant B: engaging active users with modular prototypes

Participant B described engaging stakeholders with prototypes of a device for treating infants, during various front-end design activities. The active users were physicians and nurses. Participant B described engagement activities that took place in a hospital break room where participants interacted and performed multiple exercises with the prototype. Participant B carried out a front-end exploration of the interface requirements with paper prototypes, spare parts, and an early stage product-architecture prototype.

Participant B described working with a community partner, a non-governmental organization (NGO) from an LMIC, to facilitate access to active users (i.e., nurses and doctors) in a hospital in a Southeast Asian country and to other resources related to the device's use.

> *"At that point, we went abroad with the Alpha prototype to get feedback from hospital stakeholders in a country where we had an NGO partner at the time. The NGO had active connections to local hospitals."*

Participant B used several strategies while engaging stakeholders with prototypes, such as asking stakeholders to perform a task in a simulated use case, with the use of a toy doll.

"When visiting the hospitals, we'd bring out the prototype and then speak with a variety of stakeholders. We would invite [people] to engage with the prototype doing actions like pressing the button to see it turn on and off. We also brought a life-sized baby doll that stakeholders could use to pantomime different procedures."

Further, Participant B described how introducing the prototype into the real use environment, the neonatal intensive care unit (NICU), during the engagement was useful to uncover and reveal new requirements for the device. She described uncovering the requirement that the device had to fit in the existing baby cots, which was brought up because of the presence of a prototype in the real use environment.

"In one example, the participants tried placing the alpha prototype in an infant bed in the NICU, but it was too long to fit. If we had not brought any physical examples of the product, the topic of device size may not have come up. We may not have realized that the healthcare professionals would want to place the device in an infant bed and would not have sized it accordingly."

Participant B described the use of two strategies that actively involved the stakeholders in the design process: prompting them to select prototypes and tasking them to change the prototype. These strategies were leveraged across participants to bridge cultural gaps, in this case, translation hurdles. Participant B brought rough modular prototypes—prototypes with various pieces that could be assembled in different ways—and asked active users to modify the alpha prototype with the modules during the engagement.

"We also brought a make-your-own user interface kit. It included many pieces depicting buttons, displays, and LED read-outs made primarily from paper. Toward the end of an interview, after we had learned about the context and challenges, we would bring out the kit. First, we would ask which types of symbols participants preferred to communicate the device functions. (…) Then we asked healthcare professionals to use their preferred pieces to create a user interface on any surface of the device they desired. If it was a group interview, participants would discuss. (…) We would document the process with as many photos as possible to remember all the different options they considered."

Participant B described how designers' limited time with stakeholders rarely enabled them to create prototypes from scratch, hence the use of modular prototypes was conducive to the activity of having stakeholders modify the prototype.

Engaging stakeholders from LMICs required the assistance of a support stakeholder, a translator, which created issues for Participant B when trying to understand stakeholders' feedback. Participant B reported that the translator could not translate many voices speaking simultaneously or capture the complete reasoning of stakeholders, providing only the final consensus. Having a prototype during the engagement mitigated the issues created by the translation process because designers could observe what stakeholders did with the prototypes and could ask follow-up questions based on the observations. Participant B also felt the prototype made the responses more specific, for example, since stakeholders could more precisely indicate preferences through pointing to elements of the prototype.

"One benefit of having a make-your-own user interface prototype kit was to see the final version of the participants' ideal user interface and its location. If we were only speaking verbally with a translator about a theoretical user-interface and where it should be located on the device, the participants might say 'front panel' but then we would be left going through multiple languages to confirm we all mutually understood what 'front panel' means. Without prototypes, it would be easy to walk away having a mistaken idea of what participants wanted.

Prototypes are also an asset in cross-cultural interviews, where not everyone on the team will know the local language and the team may include a translator. (…) At many of these interviews, it was a large group of people all talking simultaneously and trying the prototypes, with the translator trying to communicate what multiple people were saying. Healthcare professionals' interactions with the prototypes would highlight additional aspects for inquiry beyond their final preferences and beyond what the translator was able to convey. For example, we could ask why they held some prototype buttons over the side panel area and ask why they discarded that idea. Viewing participants interaction with prototypes helped us generate useful follow-up questions."

Furthermore, Participant B described the challenge of using early prototypes (paper-based and spare parts) to engage stakeholders. She felt that stakeholders in LMICs were unfamiliar with low-fidelity prototypes and perceived the ideas represented with low-fidelity prototypes as low-quality. Communication issues about the form of the prototype (i.e., the visible shape or configuration of the prototype) were described to be especially salient in countries outside the U.S.

"In one country we visited, healthcare professionals did not have a lot of experience with the product design process or prototypes. (…) We would get feedback such as 'you obviously haven't thought through this product because this aspect of it doesn't work yet.' Luckily, once the concept of a prototype was explained, healthcare professionals were willing to give honest feedback."

To mitigate the challenge of showing stakeholders low-fidelity prototypes, Participant B explained the form of the prototype when briefing stakeholders about the project and the prototype at the start of the engagement. Briefing stakeholders also helped establish a comfort level so that the stakeholders felt like experts and felt that their knowledge, expertise, and feedback could be expressed freely.

"We often prep interview participants by saying 'This device isn't done yet, that's why we're coming to you. You are experts in what it is like to treat babies in the NICU. We would love to hear anything about the prototype that you think would work well and also anything that would not work very well, because there is still time for us to make changes."

The challenge of showing early prototypes to stakeholders was described by multiple participants, including both participants A and B. The above excerpts illustrate how two strategies helped limit the distraction of the stakeholder due to prototype form–explaining that the prototype was a work in progress while briefing the stakeholder and polishing the prototype to make it look closer to a final product.

Lastly, Participant B described relying on student teams (support stakeholders) to create the first prototypes. Engaging students was necessary to the business model of her non-profit company to help save resources.

"As a non-profit, [company name] works with different volunteers in order to design products. The first step was to engage a multi-disciplinary student design course. By the end of the semester, the students created (…) an Alpha prototype."

3.3. Participant C: engaging three different stakeholder groups with prototypes

Participant C discussed the front-end design of a device for a hospital setting in an LMIC. Participant C described conducting one-on-one interviews in both the U.S. and a foreign country to gather feedback and described demonstrating the prototype to stakeholders in order to get buy-in. Participant C noted that she used different prototype forms for different groups of stakeholders.

Participant C described engaging advisors and manufacturers with the objective of gaining knowledge of the design's technical feasibility.

Participant C used CAD models to engage expert advisors because they were familiar with such models. Participant C received conflicting feedback between advisors in the U.S. and stakeholders in the LMIC, revealing some misalignments between the U.S.-based advisors and the realities of the context for which she was designing.

> *"So, the CAD models and the drawings were usually chosen with some of the more engineering-oriented academic side (…) [The device] was designed to be single-use. And then every single user was like, 'No. We're not going to toss something that's over a foot long and three inches wide. We're going to re-use this.' Everyone in the U.S., engineers and other people, have said it should be single use (…). We wouldn't have gotten that if we hadn't interacted with users in [a sub-Saharan African country]. It would have been a single-use device that would have probably had some safety issues down the line if we had not really listened to them and made that leap, which, again, is a big departure from the U.S. traditional design."*

In a different engagement event, Participant C engaged use-cycle stakeholders (i.e., those who interact with the device outside of its primary function throughout the product lifetime) with a rapid 3D-printed prototype, to uncover requirements other than those related to the device's main medical functions, such as maintainability. Participant C described how the prototype helped the stakeholder imagine what could happen to the device in its lifetime at the hospital.

> *"[The prototype] allows [use-cycle stakeholders] to have a visual, and think of it as a tool that 'What could happen with this tool?' Now, I just keep thinking of this biomedical engineer at [the hospital in a sub-Saharan African country] who dropped a 3D-printed prototype, broke the handle off, and he's like, 'That could be a problem.' It's like, 'thank you, that's a drop risk!"*

In another engagement event, Participant C engaged financial decision-makers, referred to as funders, who were stakeholders who donated money, materials, or resources to the project. Participant C's objectives were to obtain economic support and update stakeholders about the progress of the device in a tangible way, for which she used a 3D-printed prototype. Participant C also polished prototypes to appeal to financial decision-makers and communicate concrete accomplishments.

> *"[A team member] was like, 'We need to bring a new shiny device to the board meeting.' So, with funders, it definitely helps for funding product development, to have a prototype. It lends a tangible realness to the venture and the products. We've had many different iterations of imagery for the product, (…) but nothing quite does it like something that you can see and hold in your hand."*

Hence, Participant C leveraged the prototype as a tool for persuasion and buy-in from financial decision-makers.

3.4. Participant D: engaging stakeholders with 2D prototypes

Participant D discussed using storyboards and renderings to engage government stakeholders, both during a one-on-one feedback session in a foreign country and through online interactions using communication technology, in the early stages of the design of a medical transportation device. Furthermore, Participant D discussed engaging stakeholders with prototypes in the real use environment.

Participant D pitched his device idea to government stakeholders early in the design process by showcasing the value proposition of the device through storyboards, which represented use-case scenarios and enabled him to showcase the context of use of the device. He thought this approach more effectively communicated the device concept to the stakeholder. Participant D said that use cases conveyed additional information about how a device would be used in different scenarios and showcased its potential features without having to build a fully functional physical prototype. Adding contextual elements in a 2D image, such as a storyboard, was described as helping stakeholders envision the context of use more easily and helped establish an understanding between designer and stakeholder, in a cross-cultural context.

> *"We were trying to convey the message that, if they use our [finished product], they could save a lot of money, and also reduce wastage of [medicine]. (…) We depicted this by means of a use-case scenario and illustrations showing, 'This is a storage space. You have alarms and monitors to show you that, when there's a [performance] breach, you get a notification, and an alarm. Then, when you use our technology (…) in the clinic, you can use it this way, and then you could transport it this way on a motorbike, inside a car, inside a truck. (…)' All the features and value propositions of the benefits, we displayed it by means of use-case illustrations making the stakeholders realize the full potential of the product represented through various 'day-in-a-life' depictions."*

Participant D used storyboards to engage government stakeholders and described how other prototype forms would have been inappropriate. Government stakeholders were perceived as likely to influence the design process and eventual implementation or purchasing procedures.

> *"Say, for example, if it's a health ministry official, (…) he doesn't bother if the edges of the product are more rounded or sharp. (…) But he's more bothered in, 'How much power does it draw in a day if it runs on battery? What is the battery life?' Things like that. And, 'How much does it weigh?' If you had to make a foam mockup in this scenario, the healthcare ministry would lift a foam mockup and tell us, 'This doesn't weigh anything at all. Is it the real weight?'. (…) Storyboards would be good enough for ministry of health people."*

Further, in a different engagement event, Participant D created renderings (i.e., a virtual image created by software to make it appear 3D and realistic), and storyboards that depicted the product context, to enable email communication and discussion during teleconferences with remote stakeholders.

> *"So, we make a CAD model. We render them on software like KeyShot, Photoshop, to show them a photorealistic rendering, which is not actually made. We just show them, 'This is how it would look.' We use simple call out annotations to tell, 'This is the [functional element]. This is the way you [use the element],' with a series of images. Like, 'Step one, [describes step one]. Step two, [describes step two].' With those visuals, we send it to them, and then we get on a teleconference call, and tell, 'This is our new design. What do you think? Do you have any feedback?' We have done that in the past."*

In another engagement event, Participant D introduced a functional prototype to the environment of use with active users (healthcare workers) to investigate the context of use and uncover requirements related to the device's operation in the real use environment.

> *"In the past, we have spoken to healthcare workers who [work in a Southeast Asian country with the type of device we were designing]. (…) We gave them the working prototype, and they took it to their health clinic, and (…) they did like a dry run of how this product would be used in their context of use. That's in person in context. (…) My other teammate, he took the then [device prototype] without any ruggedized support to the field, and then that made him understand that, 'Oh, no. It cannot survive in this harsh environment without any kind of external support."*

By asking stakeholders to use a prototype in the real use environment, Participant D effectively conducted a pilot experiment, uncovering robustness and durability requirements.

4. Discussion

This study aimed to describe how global health design practitioners have approached stakeholder engagement with prototypes in the front end when designing medical devices for LMICs. The stakeholders, prototypes, and strategies used were varied, and some choices for engagement reflected the challenging conditions and constraints specific to designing cross-culturally and remotely for LMICs.

One challenge faced by participants was the remoteness of the stakeholders they engaged during front-end design. In the study's sample, all but one participant remotely performed the design work with only short visits to the target regions, which is frequent in global health work (Donaldson, 2009). Despite the distance between designer and intended user, obtaining real-time feedback is crucial (Caldwell et al., 2011).

Participants discussed different ways to gain access to international stakeholders in LMICs. Participants traveled to international stakeholders located in countries other than the design team's home country, where they engaged community partners to gain access to stakeholders and resources, exemplified by excerpts from Participant B. The importance of developing a network of community partners such as universities, professional organizations, NGOs, laboratories, healthcare facilities, and research centers, and building relationship with local stakeholder when designing remotely have been documented in the development engineering literature (Caldwell et al., 2011; Donaldson, 2009). Further, participants used electronic communications, such as teleconferencing and email, to engage remote stakeholders by sending them 2D prototypes. For example, Participant D sent stakeholders photographs of physical models and renderings (Participant D). Participants also described mailing physical prototypes to international stakeholders for rapid user testing, a practice reported in Caldwell et al. (2011).

Participants discussed using prototypes to engage proxy users (i.e., stakeholders who shared some characteristics with the intended users), which has been encouraged in medical device design (Martin et al., 2006). However, most proxy users lacked knowledge of the specific design context, and their feedback was not always applicable or useful, as evidenced by Participant A's case. Participant C described how expert advisors from the U.S. provided feedback that contradicted local stakeholders, because they did not know how disposable and reusable devices were perceived by locals. These results are consistent with previously published studies that highlight the need to engage with stakeholders that have a deep understanding of local challenges (Donaldson, 2009; Nieusma and Riley, 2010). Exploring and understanding the context of use is a central part of front-end medical device design (Martin et al., 2006) and participants prioritized engaging the most appropriate stakeholders to the extent possible.

Furthermore, the participants in this study devised strategies to elicit context-specific requirements when engaging stakeholders with prototypes during front-end design. Contextual factors for medical devices are defined as the physical environment, the systems and structures, the technical context, and the socio-cultural context (Aranda Jan et al., 2016; Eltringham and Neighbour, 2012). Frequently, participants described learning about new or changing requirements that emerged from exploring the physical environment of use (i.e., infrastructure, electrical supply, geographical and environmental conditions such as temperature, humidity, and dust as defined by Aranda Jan et al. (2016); Eltringham and Neighbour (2012)) with stakeholders using prototypes. Participants explored the environment of use in multiple ways. For example, Participant D situated the prototype in its environment by adding picture elements in the background of 2D prototypes. Participants A and B simulated the environment of use through fast and low-cost simulating elements, and Participant B and D introduced physical prototypes in the environment of use during engagements.

Mismatches between the device design and the environment of use contribute to the failure of medical devices in LMICs (Aranda Jan et al., 2016; Wood and Mattson, 2016). Because of multifaceted political, social, and cultural settings in LMICs, testing products in the environment of use throughout a design process rather than in the back end of design is an essential part of developing products for LMICs (Mattson and Wood, 2013; Murcott, 2007). Hence, having access to the environment of use (e.g., being able to test prototypes in the real environment) could improve the design of sustainable technology solutions for LMICs (Donaldson, 2009), which participants in the study's sample recognized. In addition, incorporating ways for stakeholders to consider the use context when giving feedback on prototypes allowed the participants to discover requirements that they had not previously anticipated, but that were relevant to the design. These types of requirements have been named "unknown unknowns" (Jensen et al., 2017; Sutcliffe and Sawyer, 2013). However, when testing in a real environment was not possible, participants devised strategies to explore the environment of use with stakeholders by portraying the environment in pictures and simulating elements of the environment.

Participants discussed engaging stakeholders, such as use-cycle stakeholders and government stakeholders, to reveal requirements related to the socio-cultural context (i.e., local inequalities, literacy and education, religious and cultural beliefs, and languages, as defined by Aranda Jan et al. (2016) and the systems and structures (i.e., public health awareness and capacity, economics contexts of poverty and purchasing power, and institutional factors such as availability of skilled staff, government involvement, as defined by Aranda Jan et al. (2016)). Participants described that use-cycle stakeholders gave feedback related to healthcare management (e.g., where the device would be stored, charged, cleaned, and disposed of). Participant D engaged government stakeholders with prototypes during the front end to gather background information about the healthcare context of an LMIC and the existing systems and structures. In a review of examples of development engineering projects, researchers found that governments often had competing goals with designers (Mattson and Wood, 2013). In this study however, for Participant D, government stakeholders became key partners and their engagement increased the likelihood that government needs were met, and that the government's and participant's goals were aligned.

Participants had to bridge the cultural gaps existing between them and their stakeholders in LMICs. Participant B hired a translator to bridge the language gap, but detailed accounts of all stakeholder voices and their intermediate thoughts and deliberations were not translated. Critical information can be lost in translation (Boeijen and Stappers, 2011), as Participant B's articulated as well. Participant B tried to lessen this loss by introducing a prototype during the engagement to provide a tangible object for discussion, which enabled stakeholders to more accurately and precisely communicate their viewpoints. Observing stakeholders interacting with the prototypes provided non-verbal cues that also helped to sidestep the language barrier. These benefits of prototypes during stakeholder engagement have been documented in case studies (de Beer et al., 2009; Yang, 2005).

Introducing a prototype, specifically a low-fidelity prototype, also created new challenges. Participants discussed the difficulty of showing rough, low-fidelity prototypes to stakeholders from other cultures than their own. Low-fidelity prototypes have been shown to support establishing promising design directions, testing core concepts, and basic assumptions about the design and the user's mental models (Tiong, et al., 2019). In fact, low-fidelity prototypes can be especially useful to elicit requirements that are otherwise difficult for designers to elicit and stakeholders to articulate (Jensen et al., 2017). Even so, research has shown that some prototype forms may be suitable for specific tasks or audiences (Camburn et al., 2013; Deininger et al., 2019; Reid et al., 2013). A prototype presented to different audiences can yield variable, and sometimes conflicting, feedback (Mohedas et al., 2014). Mohedas et al. (2014), described a situation similar to the participants' experiences in this study, where student designers were unable to receive constructive feedback during their visit to a hospital in an LMIC because of the underdeveloped representation of the idea. One strategy used by Participant B to mitigate confusion or distraction caused by rough prototypes was to show stakeholders only polished prototypes, (i.e., a prototype that closely resembled the final device). Another way participants mitigated the rough form of the prototype was by explaining that the prototype was far from finalized when they briefed the stakeholder about the project and the prototype(s), as well as by setting expectations for the engagement (Coulentianos et al., 2019). This approach also contributed to building trust and establishing credibility with stakeholders, necessary aspects of co-creative design processes, especially when designing cross-culturally (Boeijen and Stappers, 2011). Our findings highlight that practitioners must approach the use of low-fidelity prototypes intentionally when engaging with stakeholders to take advantage of the benefits.

Participants discussed using the strategies of co-creation and co-selection of prototypes and concepts to give stakeholders more ownership to make critical decisions about the device design. "Co-design with people from the specific developing world context" is a key principle for design for LMICs necessary to expand the designer's knowledge of the need and the environment of use of the product being designed, and to increase stakeholders' ownership of the design and future initiatives (Mattson and Wood, 2013, p. 121403–2). Additionally, cultural gaps can lead to miscommunications, notably when a designer attempts to convey concepts to stakeholders by using the designer's cultural framework (Boeijen and Stappers, 2011; Rijn et al., 2006). By presenting physical 2D prototypes (e.g., sketches and storyboards) and renderings with a relevant background picture depicting the environment of use or depicting a use case, Participant D felt the risk of such miscommunications occurring was diminished.

Another salient challenge was the limited resources fueling global health design efforts in participants' companies. Participants described ways to manage limited resources during front-end design activities and how it affected their use of prototypes to engage stakeholders. Financial decision-makers were often external funders on whom the participants relied for capital and resources, for example in Participant C's experience. Notably, Participant C used "polished" prototypes as a tool to get "buy-in" and continued support from financial decision-makers. Since funders' priorities can be misaligned with the design requirements of medical devices for LMICs (Eltringham and Neighbour, 2012), designers must make an intentional effort to gain support. The use of prototypes to persuade financial decision-makers, such as company executives or external buyers, has been documented (Lauff et al., 2020), although in a global health context, funders were more often external to the company and provided support through grants. In a global health context, Participant D also used prototypes to gain endorsement from government stakeholders. Hence, the stakeholders from whom global health practitioners must gain "buy-in" from appear to be somewhat specific to the global health setting as they must focus on grant funders and government stakeholders.

Participants also described engaging support stakeholders (students and hackathon participants) to crowdsource design efforts and use university resources (Caldwell et al., 2011; Tucker, 2014). However, these types of partnerships with universities are not without challenges (e.g., remote design challenges (Donaldson, 2009) and commercialization challenges (Eltringham and Neighbour, 2014)).

When Participant A lacked resources to build prototypes or were constrained by travel, they discussed making prototypes that were easy to transport and easy to duplicate, such as 2D prototypes. However, 2D prototypes have been shown to elicit less valuable feedback from stakeholders than 3D physical prototypes (Deininger et al., 2019), hence, design practitioners should carefully consider the appropriateness of the prototype form for the stakeholder engaged. An option was to show a single prototype, even though participants recognized the benefit of showing multiple prototypes, which has also been documented in prior work (Tohidi et al., 2006). The smaller global health companies in the study's sample operated in price-sensitive markets that generated lower returns (Pitta et al., 2008), which might have constrained resources for participants.

This research may support design practitioners expanding their practices for engaging stakeholders with prototypes through intentional tactics to mitigate challenges that arise in a global health context. The outcomes of this research could contribute to reducing the number of devices that fail due to misalignments between the medical device designs and the user needs and context.

5. Limitations and future work

As part of this study, participants were asked to describe their front-end design work from a past project during retrospective interviews. Therefore, one limitation of the findings is that they are based solely on the self-reported practices of participants. Furthermore, the time between when the actual front-end design engagement and the study interview occurred ranged from months to years, which may have affected the accuracy and completeness of engagement event descriptions. Participants were encouraged to describe engagement activities that their colleagues may have executed if those activities were relevant to their descriptions. Although most activities described were first-hand experiences, some were second-hand descriptions, which may have further altered the accuracy of the descriptions. Additionally, while participants were probed to discuss front-end practices, participants could have strayed from the given definition of front-end design.

Further, at the time of the interviews, all but one participant were working in a high-income country designing for an LMIC. Therefore, this study did not represent many practices of participants that design within LMICs. Furthermore, this study did not provide definitions of the strategies, stakeholders, and prototypes. Lastly, further research is necessary to examine the transferability of designers' behaviors across industries, geographies, and design cultures.

6. Conclusions

This study identified a variety of front-end design prototyping approaches used by global health design practitioners to engage stakeholders when designing medical devices for use in LMICs: the stakeholders engaged, the prototypes used, and the strategies leveraged during the engagements. Excerpts from four interview transcripts were reported illustrating global health specific challenges and how participants tackled them, which represented participant experiences across the study sample. The excerpts from four participants depict a variety of the ways in which global health design practitioners engaged stakeholders with prototypes in a global health setting. Engagement activities included focus groups and one-on-one interviews with prototypes; active creation, modification, and selection prototypes; remote engagements with virtual prototypes; and engagements in the real use environment with prototypes. When engaging stakeholders with prototypes in the front end, the objectives of participants, grounded in the evidence presented in this paper, included: tackling stakeholder remoteness; exploring the environment of use; bridging cultural gaps; adjusting the engagement to the stakeholder; and working around the constraints of limited resources.

To tackle stakeholder remoteness, participants in this study traveled to local settings where they partnered with community organizations to access stakeholders; used communication technology to connect with stakeholders remotely using 2D prototypes; and engaged proxy users who were more readily available. Caveats included the fact that: travel to a foreign location involves a lot of resources; 2D prototypes can generate low quality feedback; feedback from stakeholders unfamiliar with the context can lead to the elicitation of unhelpful or incorrect information, whether proxy users or U.S. based experts.

To explore the environment of use, participants in this study: added elements of the environment into 2D prototype backgrounds; simulated the environment of use with various low-cost objects; and introduced a physical prototype in the environment of use during an engagement. These behaviors triggered stakeholders to react to the juxtaposition of the prototype and elements of the environment and led to the elicitation of "unknown unknowns".

To bridge cultural gaps, participants in this study: relied on the prototype as a communication bridge to counteract the information lost in translation; engaged a wide variety of stakeholders (including government and use-cycle stakeholders) to reveal requirements that might affect uptake but are not directly related to the user; and empowered stakeholders to act on the design by asking them to choose between prototypes and change modular prototypes to their liking.

To adjust the engagement to the stakeholder, participants in this study: showed polished prototypes to stakeholders less familiar with low-fidelity prototypes; briefed stakeholders by explaining the prototype form and put the stakeholders at ease; used prototypes as a persuasion tool to get buy-in from certain stakeholders; and showed different prototype forms to different stakeholders (e.g., 2D prototype to government stakeholder, 3D digital prototype to an expert advisor, physical 3D prototype to a user-cycle stakeholder).

To work around constraints of limited resources, participants in this study: leveraged support stakeholders (e.g., hackathon participants and students) to aid in generating ideas and developing prototypes; used 2D prototypes which are easier to transport and to make prototype variations from; and showed a single prototype to stakeholders.

These results contribute to the developing body of literature that recognizes the unique design constraints associated with LMICs and the need for context-specific design methodologies for LMICs.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Definitions of front end, product, prototypes, and stakeholders provided to participants at the start of the interview

Term	Definition provided
Front end	Phases of product development associated with problem identification/needs findings, problem definition (e.g., requirements and specifications development), background research, concept generation, early prototyping, and concept selection.
Product	The designed artifact. The prototype could represent a process (the procedure), a system, or a sub-part of the designed artifact.
Prototypes	Include mockups, CAD models, drawings, scenarios, and other representations of the product or its use.
Stakeholders	Anyone who will affect or be affected by the artifact at some point, including end-users, colleagues, manufacturers, clients, policy makers/ministry officials, technicians, procurement officers, etc.

Appendix B. Excerpts of the interview protocol

Interview topic	*Example questions*
Project context	*Can you select a project that you would say is the best example of a project you worked on where you used prototypes in the design front-end to engage stakeholders? Can you briefly tell us what the goal of the project was?*
Types of stakeholders	*Who were the stakeholders you engaged during your project?* *Did you interact with any additional stakeholder groups we did not mention yet? How?*
Types of prototypes	*Could you go over the different types of prototypes you used during the front-end phases of the project to engage with stakeholders?* *Did you use different types of prototypes when you were in a different setting with different stakeholders? Why did you use this particular prototype with this stakeholder?* *What are other prototypes you used that did not represent the artifact/product itself, but you used to engage stakeholders?* *Across your projects, are there other types of prototypes you have used that we haven't yet talked about yet?*
Interactions with stakeholders	*Can you tell me how you used these prototypes to engage with different stakeholders?* *Could you describe the interactions in more detail?* *What made an interaction (with stakeholders) easy? What made an interaction hard?*
Design activities	*Could you focus on a requirement that was really informed by the use of a prototype(s) with stakeholders? One that you might not have uncovered had you not had the prototype?* *Why was the prototype crucial in the discovery? Who was the stakeholder? Where did the interaction take place?* *What strategies did you employ to get stakeholders to be more precise in what they were telling you?* *In the project you described, did you engage with stakeholders using prototypes to co-create concepts and new ideas?*
Prototyping strategies	*How did the interactions with stakeholders using only one prototype changed from the interactions using more than one prototype?* *When did you move on from having multiple prototypes to only one prototype you iterated upon?*

Appendix C. Example of an engagement event

Interview data excerpt:

"I had to work on ways on how to attach [the device]. We got a collection of nurses, both U.S. based nurses[1] but also nurses here in the U.S. but who had experience or were from other countries[2]. (…) What we were putting in front of users was a little more polished[3]. It was stereolithography print in ABS[4] and it sort of had titer tolerance dimensioning and it contained a battery and everything like that. Then I had my own overlays made that would put on the front, so they were pretty good-looking prototypes[5] by the time we were getting the really detailed user feedback at that point."

Engagement event: Participant conducts an engagement activity with [1]proxy users (stakeholder group) and [2]active users (stakeholder group), where the [4]3D-printed prototype (prototype form) used in the engagement is [3,5]polished (strategy type).

Any additional interview excerpts pertaining to this stakeholder engagement event were associated to this engagement event. For example, the participant described the composition of the engagement room later in the interview, which was then associated to this engagement event.

Appendix D. Background information relative to the excerpts from four participants presented in the results section

Participant code	Medical application	Types of interactions	Product type
A	Treatment	• Focus group with a prototype in the designer's office space: participants observe and interact with the prototype	Electromechanical, including a digital interface
B	Treatment	• Group discussion in a hospital break room: participant interact and perform multiple exercises with the prototype	Electromechanical
C	Treatment	• One-on-one feedback session in the U.S. • One-on-one feedback session in country • Demonstration of the prototype to stakeholders	Mechanical
D	Preventative care	• One-on-one feedback session in foreign country • Distant engagement with digital prototypes • Engagement in the real use environment during which stakeholders can use the prototype	Electromechanical, including a digital interface

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