# The Use of Prototypes to Engage Stakeholders in Low- and Middle-Income Countries During the Early Phases of Design

by

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## List of Acronyms

| | |
|---|---|
| 2D | Two-Dimensional |
| 3D | Three-Dimensional |
| ABS | Acrylonitrile Butadiene Styrene |
| BDM | Becker-DeGroot-Marschak |
| CAD | Computer-Aided Design |
| CE | Conjoint Experiment |
| DCE | Discrete Choice Experiment |
| DfD | Design for Development |
| EAGER | EArly-concept Grants for Exploratory Research |
| EGD | Engineering for Global Development |
| E-waste | Electronic waste |
| GRFP | Graduate Research Fellowship Program |
| HIC | High-Income Country |
| LMIC | Low- and Middle-Income Country |
| NGO | Non-Governmental Organization |
| NICU | Neonatal Intensive Care Unit |
| NSF | National Science Foundation |
| RCT | Randomized Controlled Trial |
| RE | Requirements Elicitation |
| REU | Research Experience for Undergraduates |
| RMF | Rackham Merit Fellowship |
| SROP | Summer Research Opportunity Program |
| UN | United Nations |
| US | United States |
| WD4BoP | Westerners Designing for the Base of the Pyramid |

**Abstract**

Human-centered design processes have been leveraged to help advance solutions to the world's most pressing problems. Early and frequent engagement with stakeholders is a key activity of early-stage human-centered design processes that leads to better alignment of product requirements with the needs of stakeholders and the context of the artifact. There are many tools to support early stakeholder engagement. A subset of methods includes the use of prototypes – tangible manifestations of design ideas. However, prototypes are underutilized in early design activities to engage stakeholders, notably during cross-cultural design in Low and Middle-Income Countries (LMICs). In such contexts, prototypes have the potential to bridge contextual and cultural differences, which is especially critical when designing for LMICs where many proposed solutions have failed to meet people's needs. To investigate the roles of prototypes to engage stakeholders in LMICs, I used both qualitative and quantitative research methods emphasizing both engineering design and economics theory and methods. Specifically, I conducted an interview-based study with industry practitioners and investigated two prototype-based stakeholder engagement methods in practice in LMICs.

I conducted semi-structured interviews focused on the use of prototypes to engage stakeholders in early design stages with 24 medical device design practitioners from multinational and global health companies. Practitioners described the types of stakeholders, prototypes, and settings leveraged during front-end design and the associations of engagement strategies, stakeholders, prototypes, and/or settings. I further studied the practices of global health design practitioners working on medical devices for use in LMICs and described their approaches to tackle stakeholder remoteness, explore the environment of use, bridge cultural gaps, adjust the engagement activities to stakeholders, and work with limited resources.

My analysis of requirements elicitation interviews with 36 healthcare practitioners from two hospitals in Ghana revealed participant preferences when viewing three, one, or no prototypes. The findings indicate that stakeholders preferred interviews with prototypes and in the absence of a prototype, stakeholders referenced existing or imaginative devices as a frame of reference.

I investigated the preferences for, willingness to pay for, and usage of a novel tool for electronic-waste recycling with 105 workers in North-Eastern Thailand. Workers were assigned to one of two conjoint experiments that leveraged different prototype forms. Workers further completed baseline and endline surveys and participated in a Becker-Degroot-Marschak auction experiment. The results showed that the prototype form used in the conjoint experiment affected the valuation of product features. One-month evaluation of usage revealed that participants who received the new tool decreased their injury rates and increased productivity.

This research provides new insights into the practices and teachings of prototype usage for stakeholder engagement during early design stages, contributes to the developing body of literature that recognizes the unique design constraints associated with designing for LMICs, and advances approaches for promoting more inclusive design practices. The description of the types of stakeholders, prototypes, settings, and strategies leveraged by industry practitioners when engaging stakeholders in LMICs are potentially transferable to, and can have a broader impact on, other contexts in which prototypes are used to engage stakeholders. Furthermore, both applied studies illustrate the effect of using different numbers of prototypes and different prototype forms on the outcomes of the two commonly used stakeholder engagement methods – interviewing and conjoint analysis. The applied studies provide examples of stakeholder engagement methods with prototypes in LMIC settings in practice.

# Chapter 1 Background and Motivation

## 1.1 Introduction

Equitable access to health is a Sustainable Development Goal put forward by the United Nations [1]. But currently, the availability of health technology is inversely related to health need, meaning that existing healthcare technology mainly focuses on the needs of the wealthy [2]. Health technologies comprise all products and processes that can improve the health and wellbeing of individuals, including medical devices [3]. Health technologies are part of a comprehensive solution to address the burden of disease in Low- and Middle-Income Countries (LMICs), but many documented technology-based projects that have aimed to address this burden of disease, the majority of which have been initiated by Western designers, have failed. For example, many old medical devices from Western countries have been donated to LMICs [4] and designers have developed low-cost versions of medical devices for LMICs [5]. These efforts have resulted in medical device graveyards, piles of broken devices that clutter hospitals in LMICs [4].

One of the reasons health technologies have failed to reach their intended impact is that they are not contextually adequate [3]. Some examples of inadequacies include low reliability and durability, because devices are primarily driven by factors such as low cost, frequently resulting in limited to no customer support once purchased leading to inaccessibility of spare parts and inadequate power [6].

Many design efforts are failing at contextual design because the designed technology does not meet the needs of local people or does not correspond to the local context. Thus, there is a need for new and improved approaches for designing health technologies. Two particularly relevant recommendations for bettering the approach to designing health technologies include the additional use of iterative prototyping and field testing, and increased stakeholder involvement [7–11]. My dissertation work was focused on design for global health in LMICs, where stakeholder engagement with prototypes is a highly relevant topic.

## 1.2 Background

This section provides a brief history of the discipline of design and surveys the current literature on stakeholder engagement in design. Prototypes are then defined, and existing evidence of prototypes used to engage stakeholders is reviewed. The need for continued exploration of how prototypes can be leveraged for this purpose in front-end design is established. I further motivate the study of stakeholder engagement with prototypes in the context of design for LMICs, at the intersection of design, engineering, and economics.

### 1.2.1 Design processes

Design is the practice of following a process to solve ill-defined problems that are not understandable, universal, or consistent [12]. The discipline of design was developed from the discipline of artisanship after the industrial revolution. Mass manufacturing brought on by the industrial revolution radically changed our ways of making products, separating for the first time the planning and the making. The discipline of design has more recently evolved into a problem-solving approach, which requires identifying the right problem with which to start [13]. Design science has emerged as the science behind a design process, studying and creating fundamental knowledge and methods for designers.

Design processes have been broken down into phases in different ways by pioneers of the discipline. The traditional ISO 9001 lists the sequential design and development process steps as the following: planning, input, output, review, verification, validation, and control of design and development changes [14]. Starting in the field of software design, and by the 1990s, iterative and incremental processes had become widely popular [15]. Design processes are also increasingly interdisciplinary, as multi-disciplinary teams and interdisciplinary individuals have been shown to increase the chances of positive design outcomes [16].

Current design processes across fields have embraced an iterative approach and focus on user needs. The International Organization for Standardization human-centered design methods depicted in Figure 1, and the famous Design Thinking approach coined by IDEO in the 1990s [17] in Figure 2, are two examples of such processes. These novel processes emerged from changes in society: first, the development of personal computers which created the need for a design approach that focused on the needs of humans rather than focusing on the machine [18], creating the basis for human-centered design; and second, times of peace which invited reflection on what the purpose of design was in relation to society, humanity, and the planet [19–21].

Many depictions of a human-centered design process exist, and although they are all different, some key activities remain the same: getting to know the people and context relevant to the design; interpreting and synthesizing findings; exploring ideas (through creative processes); prototyping; testing; improving iteratively; and implementation [22]. Furthermore, there are also many principles and mindsets emulated by designers that accompany these processes, such as learning from failure, creativity, empathy, embracing ambiguity, fast iteration, [23], and divergent and convergent thinking [24]. Design research consists of rigorous research into the process of design and into design methods. These processes and principles have evolved and continue to change, informed by practice and research.

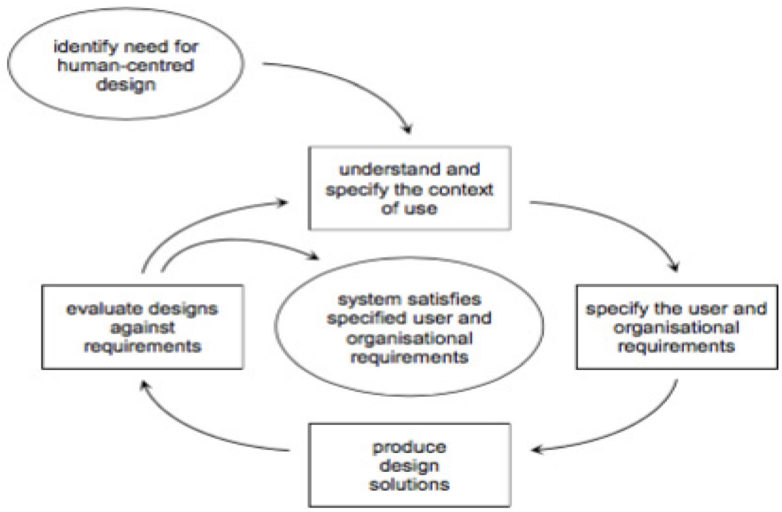


*Figure 1: ISO Human-centered design processes for interactive systems [25]*

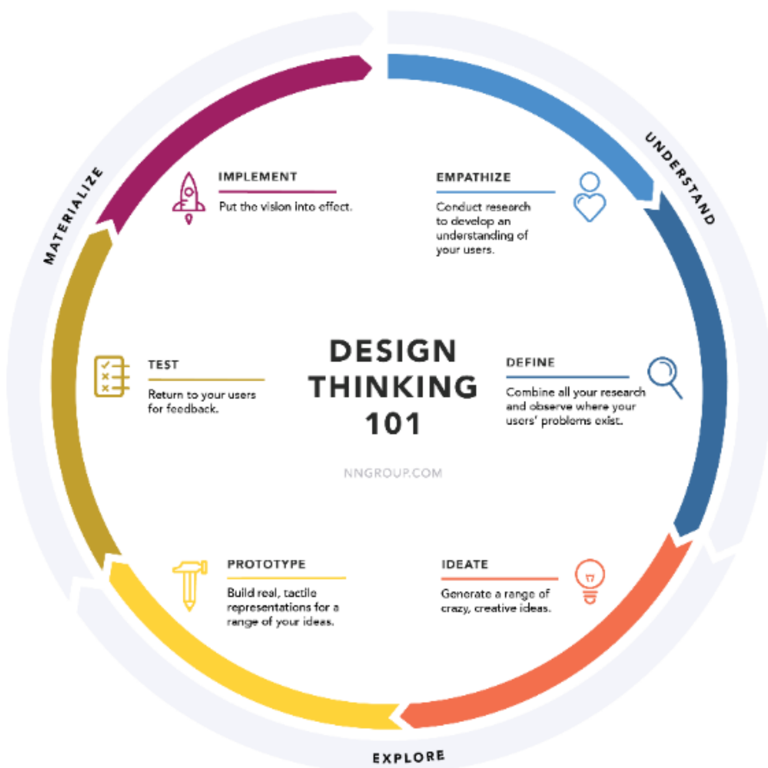


*Figure 2: Design Thinking iterative methodology [26]*

Modern design processes heavily emphasize the front-end of a design process (also called up-front or early phase). For example, in Figure 2, both the understand and explore steps could be considered front-end activities. Front-end design, which includes problem identification and definition, requirements elicitation, and idea generation, is an essential phase of any design process; if performed well, front-end design has positive effects on the success of a product [27–29]. The front-end has been described as ill-defined, ‘fuzzy’, uncertain, and ambiguous and a designer’s ability to navigate the front-end can determine project success [27,29–31]. The front-end is critical because it is the stage where the problem to be addressed is chosen. Buxton, 2010, discusses the difference between getting the design right and getting the right design, positing that true value stems from the latter, even though often, the former gets more attention [32]. Design Thinking processes focus designers’ attention on getting the right design. As Buxton, 2010, puts it: “Even if you do a brilliant job of building what you originally set out to build, if it is the wrong product, it still constitutes a failure (…). [Getting the design right] is one of the prime objectives of the up-front design phase [and] is the part that is too often absent in today’s practice” [32]. A central activity to front-end design is the engagement of stakeholders, through various methods such as interviews and observations, to understand their needs and define the right problem to address [33].

### 1.2.2 Stakeholder engagement in design processes

Stakeholders are defined as anyone who will affect or be affected by a design [34], or as “individuals or organizations who stand to gain or lose from the success or failure of a system” [35]. Stakeholders include the primary users of a design as well as many other players such as distributors, manufacturers, purchasers (who might not be the users). The BioDesign book proposes the stakeholder map for medical devices in Figure 3 [36].

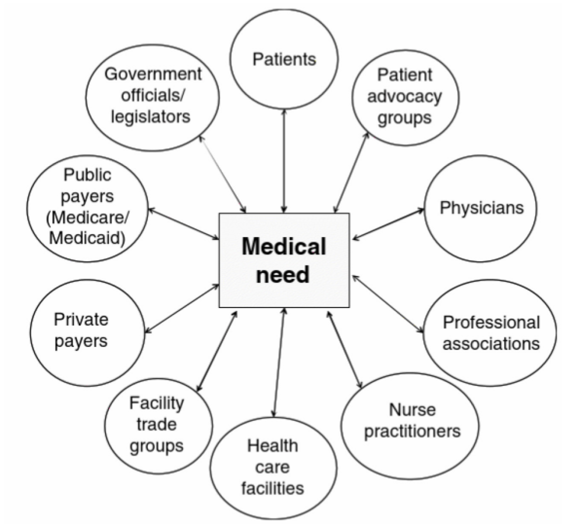


*Figure 3: Biodesign stakeholder map for medical devices [36]*

Engaging stakeholders enables designers to gather information to define the design problem and address stakeholder needs and expectations [34,37,38]. Stakeholder engagement helps designers generate insights about stakeholders' experiences and context [39,40], including stakeholders' behaviors, goals, values, and motivations [41,42], thereby broadening designers' understanding of a design problem [43]. Understanding stakeholder needs in the front-end can help mitigate the risks of product failures later in a design process, such as during product manufacturing and launch [44]. Indeed, downstream changes made later in a design process are more costly and difficult to implement [45].

Designers synthesize the information collected from stakeholders, generate design requirements and specifications (attributes that are solution independent and must be satisfied by the design, and specific and quantifiable characterizations of attributes, respectively), and iterate on the problem definition [46,47]. The synthesis of information is the foundation that will inform the detailed design and development of subsequent solutions [48,49].

Modern design processes have shifted from a focus on users (e.g., user-centered design) to a focus on stakeholders and context and include a wide diversity of stakeholders in design processes and activities [22]. Indeed, a project's success depends on the needs and wants of a variety of stakeholders, not only the end-users [34,47,50]. In many cases, the needs of various stakeholders are not aligned and may even oppose one another. Hence, stakeholder engagement methods are needed to gather diverse perspectives from different stakeholder groups that collectively impact a project's success.

Despite the demonstrated benefits of stakeholder engagement, challenges exist in carrying out such activities. Designer-stakeholder interactions occur across domain knowledge and expertise levels [35,51]. Many methods encouraging the involvement of stakeholders in front-end design have been studied in-depth, such as design ethnography, which includes interviews, focus groups, observations and contextual inquiry [31], surveys, use cases, role-playing, co-design and others [29,52]. A synthesis of stakeholder engagement methods is presented in Figure 4 from Sanders and Stappers, 2008 [53]. Some stakeholder engagement methods specifically enable designers to elicit needs and motivations from many stakeholders, such as Ortbal et al., 2016, who introduce a method based on personas and journey maps [54]. Designers then synthesize insights, balance the needs of various stakeholders, and reach a compromise [55,56].

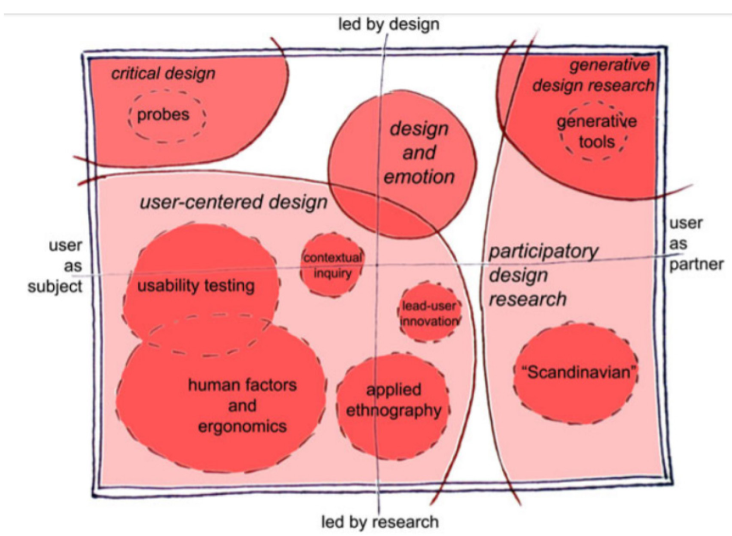


*Figure 4: Stakeholder engagement methods research map [53]*

Increasingly, information gathering methods with stakeholders in multiple product domains include the use of prototypes, notably during the elicitation of requirements in the design front-end [57,58].

### 1.2.3 Prototypes: a designer's tool to engage stakeholders

*"Prototyping may be simultaneously one of the most important*

*and least formally explored areas of design"* [59]

Prototyping is thought of as a critical activity in new product development [60]. Prototypes are often used throughout a design process to help designers develop requirements, generate concept solutions, communicate ideas to stakeholders, and verify design objectives [37–39]. The use of prototypes during a design process has been shown to lead to the production of a "greater number of functional ideas that solve the design problem" [45].

There are multiple and sometimes contradictory definitions of what a prototype is. However, contemporary definitions emphasize the communicative power of prototypes. Therefore, prototypes have a high potential as a medium to engage stakeholders in front-end design, and the role of prototypes in a design process has been evolving accordingly.

The Oxford dictionary defines a prototype as: "A first, typical or preliminary model of something, especially a machine, from which other forms are developed or copied." [61]. This definition remains general and non-specific to a domain.

Lauff et al., 2017, describes a prototype as a physical embodiment of critical elements of the design and an iterative tool to enhance and inform decision making throughout a design process [62]. This definition further supports the iterative nature of prototypes.

Ulrich and Eppinger define a prototype as "an approximation of the product along one or more dimension of interest" [47]. These dimensions of interest include the spectrum of "physical to analytical" and of "comprehensive to focused." Otto and Wood define a prototype as "a physical instantiation of a product, meant to be used to help resolve one or more issues during product development" [63]. They believe that prototypes are meant to minimize risk, demonstrate actions, check feasibility, and aid in modeling and manufacturability. Both these definitions point to the fact that a prototype is meant to embody [47] and help answer [63] a specific question or subset of questions about the design.

McElroy (2017) insists that "Everything is a prototype" [64] or rather, anything can be a prototype. McElroy describes prototypes as anything that makes visible to others an idea. This definition expands the traditional view that prototypes represent parts of the 'end product.' The terminology used ('visibility') implies the prototype is a medium through which the idea is shared (rather than using words and language to explain an idea). McElroy further defines prototypes as "a manifestation of an idea into a format that communicates the idea to others or is tested with users, with the intention to improve the prototype over time." I find here again the iterative nature of a prototype, with the objective of improvement. For example, a commercialized product becomes a prototype when a designer uses it for benchmarking with the intention of improving it. McElroy's definition focuses less on what the prototype embodies and more on the prototype's function: to communicate ideas, with the end-goal of improving on these ideas.

In the scope of this dissertation, I assume a broad definition of prototypes as "any representation of an artifact or of its use." This definition is meant to include all depictions of artifacts, whether representing potential solutions or other tangential artifacts; drawings; images; flow charts; or more traditional 3D objects. This definition enables me to consider the whole body of prototypes that designers use, so I can study a diverse set of prototyping behaviors.

More inclusive definitions of prototypes, such as early representations of ideas (including sketches and mock-ups), enable designers to use prototypes earlier in a design process, when design ideas are less formalized. Historically, prototyping was an activity that occurred later in a process [63,65]; more inclusive definitions of prototypes promote their use throughout a design process without necessitating their use during a single design phase. For example, the Center for Socially Engaged Design at the University of Michigan proposes a design process model where prototyping occurs at all stages (see Figure 5) [66].

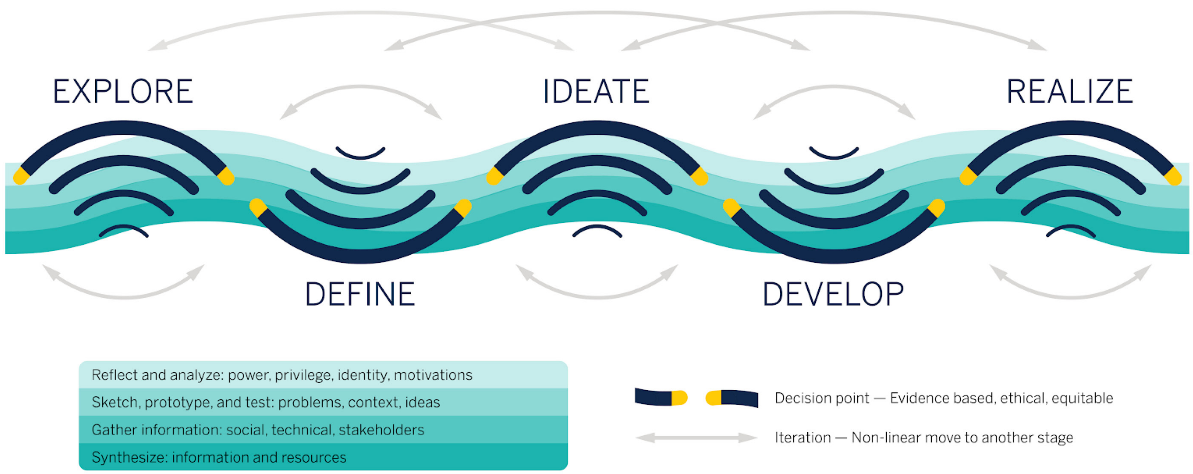


*Figure 5: Design process model from the Center for Socially Engaged Design [66]*

Prototypes have been studied extensively as a tool for exploring the technical 'feasibility' of the project and improving functionality and performance [59,67]. However, more contemporary definitions and prototyping frameworks that guide designers in the creation and use of prototypes broaden the scope of possible uses of prototypes. First, prototypes have taken a central role in informing decision making and as aids in learning [62]. Prototypes "act as decision variables in the optimization of product planning and development" [67]. Hence, prototypes are now central to project planning and decision making.

In recent years, there has been a proliferation of studies on prototyping, mostly focusing on prototyping frameworks and strategies [57,59,62,67–70]. Studies have focused on specific aspects of prototypes. For example, prototypes complexity [71], prototype fidelity, functionality, and prototype format in general [72–74], prototype fixation [45,75], and differences between novice and expert designers [62,76–78].

### 1.2.4 Prototype-based stakeholder engagement

Prototypes have also increasingly been used as a social tool, to understand (users, the problem), to communicate (with teams or with stakeholders to get feedback), to test and improve with users, and to advocate [64]. Prototypes enable more productive and deeper engagements between designers and end-users [67]. Kelley and Littman, 2001, talk about prototypes as "conversation pieces" [79]. A heavy emphasis has been placed on the role of prototypes as a communication tool for interdisciplinary teams in particular [62]. Prototypes are often considered as boundary objects, which enable communication across diverse groups of people, to create a shared mental model, generate feedback, negotiate, and persuade [64].

Prototypes have been recommended as tools to engage stakeholders in a design process. Some studies have highlighted the benefits of using prototypes in the early stages of design, especially to interact with stakeholders. Indeed, prototypes enable stakeholders to be more easily integrated into each step of the process [80]. Prototypes can encourage stakeholders to play a more active role in a design process [81]. The use of prototypes is particularly useful when the user would have trouble providing valuable information without a physical representation of the real product [82], notably when designing entirely new artifacts [81] with high uncertainty [68]. In their case study, Green et al., 2015, used concept prototypes during stakeholder interviews to "encourage discussion about, and gain insight into, the problem, and improve the general understanding" [83]. The prototypes were used as prompts to assist in uncovering the main functions of the system and to gain knowledge about the environment. "Prototyping and user testing are the best way to make valuable products that are impactful for your users." [64]. Prototypes support external stakeholder involvement, which leads to eliciting requirements in new product development [84–87]. Bjorgvinsson and Ehn Hillgren, 2010, and Buur and Matthews, 2008, make a case for engaging end-users with prototypes [88,89]. Sanders and Stappers, 2008, extend the invitation to other stakeholders with a more holistic approach to stakeholder engagement with prototypes [53]. Indeed, Design Thinking and similar human-centered design processes emphasize the early discovery of latent stakeholder needs while traditional approaches focus on quantifying stakeholder preferences for pre-defined product attributes and features [90].

However, the rigorous and systematic use of prototypes to engage stakeholders is under-utilized in early design [88,89]. Indeed, various fields have established robust methods for stakeholder engagement or the involvement of prototypes to engage during the later stages of a design process. Such methods include usability testing, a method used in the field of product design, which often requires a high-fidelity prototype [91].

In the marketing industry and in economics, discrete choice experiments (DCEs) provide a means of investigating relative preferences (trade-offs) across attributes of goods or services. Marketers have traditionally employed DCE techniques to assess consumer trade-offs [92,93]. DCEs that leverage prototypes often do so at later stages of a design process. Only recently have DCEs been explored as a tool for early stakeholder engagement to explore and define product requirements [94].

In economics research, field experiments such as randomized controlled trials (RCTs) are the new gold standard where groups of stakeholders are randomly assigned a different treatment condition (e.g., receive product version one, receive product version two, or do not receive a product), after which the outcomes of interest are measured (directly or through surveys) and compared across groups through statistical analysis [95,96]. While RCTs do not describe the treatment arms as ‘prototypes’, they do correspond to my definition of prototypes and could be described as pilots. For example, Dupas and Robinson, 2013, conducted an RCT where three products aimed at helping rural households to save for health expenditures were tested. After randomly distributing the different products to participants, the amount of money saved was measured [97].

A diversity of established prototype-based stakeholder engagement methods exists across fields. However, in the context of the design front-end, particularly the problem definition of a project, emerging stakeholder engagement methods for front-end design have grown in popularity. Low fidelity prototypes have been found to be very useful tools when engaging stakeholders in front-end design to create common ground between the stakeholder and the design [98] and have been used to evaluate core concepts [99].

Novel types of prototypes have also been shown to be useful tools in front-end stakeholder engagement. For example, “provotypes” are objects meant to provoke reactions from stakeholders and elicit feelings, experiences, and other intangible feedback, from the interaction with the object [100]. Other examples include ‘experience prototypes’ which are meant to help designers understand stakeholder experiences by prototyping temporal events rather than objects [84], and ‘live prototypes’ which are modified by stakeholders during the engagement and are a vector for co-ideation and iteration [101].

Some fields have developed methods for early stakeholder engagement, such as human factors engineering, which leverages user testing with both early non-functional prototypes and downstream functional prototypes, to shed light on user-device interaction issues as early as possible [102]. However, human factors research focuses on the engagement of users for the study of user-interface interaction.

Participatory design aims to include stakeholders throughout all phases of a design process. Hence, activities traditionally conducted by designers that involve prototypes (e.g., building prototypes, ideation) are carried out with stakeholders [53,103].

### 1.2.5 Application: design for LMICs

*"To understand design as an attitude and a method is to understand its fundamental significance and its enduring relevance. Although many of the processes and principles of design can be applied to any context, solutions are not universal when success is the outcome of a local and cultural context."* [104]

Designing for LMICs is particularly challenging because of additional constraints that these settings impose compared to high-income settings, which oftentimes constricts the solution space [105]. Some examples of the additional constraints faced by low-resource settings are affordability, lack of infrastructure, and weak supply chain [105,106], as well as performance, sustainability, regulations, and preference [107,108]. These constraints hinder the adoption and diffusion of innovations for LMICs, which seldom cross the "valley of death" between development and commercialization [106,109]. Obstacles that prevent technology from achieving more significant impact in low-resource settings are threefold: the non-existence of the technology (technology does not exist that is suitable for use in LMICs), the hindered access due to price, energy, and human resources inadequacy, and technology which is not culturally acceptable [3]. Some examples of reasons for product failings in LMICs include that the product does not solve the problem it intended to; it is too complex and introduces more problems [110]; low-profit margins; regulatory constraints; and incompatibility with the systems in place [111].

The emerging field of design for development (DfD) [112] has many names. For example, the terms humanitarian engineering [113], engineering for global development [114], design for developing countries, appropriate technology design, design for extreme affordability, and design for the base of the pyramid [115] have been used. The work in this field spans agriculture, water, poverty alleviation, energy, health, and sanitation [115]. Some fundamental aspects of the field include socio-technical thinking, at the intersection of various disciplines including engineering, sustainable community development, [113], and others. Increased interest in this field has prompted various universities to create programs related to DfD [116–118]. Dedicated journals have also been created in recent years to disseminate knowledge related to this type of work, such as the Development Engineering journal and the Journal of Humanitarian Engineering.

The field, which for the purposes of this dissertation will be called DfD, has developed in part from a Western-centric perspective, where designers are often designing products and services from High-Income Countries (HICs) for use in LMICs. In this dissertation, I will use the term "Western" when I want to bring focus to cultural and post- and neo-colonial aspects of DfD. Designing for people and settings different from oneself is complex and requires that one evaluates their own assumptions and biases [113], especially when there substantial geographical and cultural gaps. Remote design brings about cultural differences and a more significant divide between designer and end-user [112]. Furthermore, when designing for social impact to address issues rooted in a deep history of inequality and oppression, which is the case for many projects in LMICs, the power imbalances affect design processes and limit opportunities for sustained improvements in social justice [118]. One could argue that when products fail in LMICs, the impact is also more significant, and the benefits lost are more costly because the populations targeted by the field are typically marginalized and disadvantaged populations [112].

Kroll et al., 2013, argue that part of these problems could be solved if engineers had a better understanding of the underlying needs of the people for which they are trying to design [95]. Many of the research approaches and methodologies used in HICs are challenging to translate to and roll out in LMICs, such as choice experiments [119] that require infrastructure and acceptability of surveys [106]. Dupas et al., 2014, argues that because of the difficulty in implementing large scale quantitative methods that have been in use in HICs for decades in LMICs, it is harder to uncover the latent needs of communities in LMICs. Hence, the primary way designers and engineers have been collecting needs is through qualitative methods including focus groups and interviews, and sometimes surveys, which have been inadequate in and of themselves for fully capturing LMIC stakeholders' needs and wants. It is necessary to investigate methods that are specifically appropriate for LMICs, notably to engage stakeholders in the front-end design process, when needs are being uncovered.

Furthermore, when Westerners design in LMICs, cultural differences between engineering designers and stakeholders can create difficulties in the implementation of early design activities [8,10,120]. Frequently in such scenarios, cross-cultural design occurs remotely, which creates additional barriers to stakeholder engagement that prototypes might mitigate. Such barriers include: language barriers (native and/or disciplinary); different conventions around design processes and methods [119]; perceived hierarchy between designers and stakeholders [112]; and cognitive biases that influence designers' processes [121]. These barriers can lead to miscommunications between designers and stakeholders, especially during early design phases [122], further supporting the need to develop specific methods to support design activities within these settings.

An increasing number of design methods geared towards design for LMICs have been developed in recent years. These methods carry a business mindset following the movement for "business for the base of the pyramid," or carry a technology mindset, where designers are developing technology specifically to address the needs and constraints of LMICs [123]. Current design methods for low-resource settings are intended to help account for the added constraints of the setting in the design. Some aim to address the challenges of cross-cultural design [124], notably through design ethnography [125]. Aranda Jan, Jagtap, and Moultrie, 2016, pointed out the lack of tools to support contextual design and developed a framework to support designers in considering contextual factors in medical device design [126]. Other methods include the design for scarcity, design for scalability, design of simple solutions [127], design of appropriate training [7], and design for access, through affordability, availability, and adoption [128].

Furthermore, because traditional methods of stakeholder engagement fail to elicit useful information in some cross-cultural design settings, practitioners have developed methods specifically to tackle cultural differences [129]. Such methods include cultural probes [130], the Bollywood technique that consists of asking stakeholders to imagine they are in a television drama to encourage them to break with cultural traditions of "maintaining harmony" and "deferring to the group" [124,129], the Walking Havana method consisting of creating personas with the help of stakeholders by asking them to create protagonists of a television show that would take place in their local setting [131], as well as other recommended practices such as hiring local facilitators [129].

Among this array of potential design strategies for LMICs, there is a consensus on the benefits of increased stakeholder involvement for the successful design and implementation of appropriate medical devices [7]. The involvement of stakeholders, often members of the community one is designing for, is a key tenant of DfD [8,11,113]. The inclusion of contextual considerations such as socio-economic, political, cultural, historical, and environmental aspects are emphasized in DfD methods [10]. The simple consideration of stakeholder needs is not sufficient in DfD, and various sources suggest including stakeholders in a design process through participatory activities [8,11,132]. Extensive co-creation, where stakeholders are involved in each step of a design process, is now being widely encouraged for the design and development of medical devices for use in LMICs [7]. Strong local relationships with stakeholders [133] are also a crucial part of successful design for LMICs, along with user empowerment [134] and local ownership [135].

However, there is little practical guidance as to how to carry out design activities in these settings. The previously mentioned literature mostly suggests very general solutions, and little work has investigated specific design methodologies that are effective for designing medical devices for LMICs [126]. The absence of detailed investigation into stakeholder engagement methods in the field of DfD was proposed as a reason for why even experienced practitioners did not describe in-depth collaboration with stakeholders during an exercise working through a hypothetical scenario [113]. Although experienced designers were aware of the importance of involving various stakeholders in an DfD design process, they still were not able to articulate how they would involve them in a process [113].

Caldwell et al. 2011 recommended rapid prototyping and extensive field-testing when designing for low-resource settings [7]. Furthermore, participatory and co-creative activities suggest the use of prototypes to promote design with stakeholders in LMICs. There is therefore a movement towards the use of stakeholder engagement methods with prototypes and the body of work in this dissertation aims to contribute to the movement by investigating how to leverage prototypes to engage stakeholders in front-end design when designing for LMICs. Additionally, the use of prototypes in a cross-cultural design setting may support stakeholder engagement activities of Westerners designing in LMICs, by serving as a tool to aid in the “leveling of the playing field” between designers and stakeholders. However, prototypes could further intimidate stakeholders if not used properly. Hence, an investigation into the appropriateness of prototype usage for stakeholder engagement in LMICs is needed.

To make explicit the complex backdrop of the work of this dissertation, when referring to the design context of the studies, I will use the term Westerners Designing for the Base of the Pyramid (WD4BoP). The term aims to capture the identity of the designers implementing the methods studied in the work presented, and the population, which is the intended beneficiary of the product, namely disenfranchised communities in LMICs. The use of the strong and visible number 4 serves as a reminder that despite recommendations for participatory methods of stakeholder engagement, most methods studied in this dissertation remain one-sided.

### 1.3 Objectives and motivations

Engineering design methods for stakeholder engagement during the early phases of design have been predominantly based on ethnographic methods (e.g., observations, interviews). Ethnographic methods do not typically involve prototypes, although the use of additional materials such as probes and toolkits have been recommended [136]. Indeed, prototypes can support stakeholder-designer communication and help stakeholders formulate feedback [137]. Established methods of stakeholder engagement with prototypes include usability testing, conjoint experiments, and field experiments. Such methods traditionally leverage high-fidelity prototypes, later in a design process, which prevents their utilization during the early phases of design. However, the use of prototypes to engage stakeholders early during a design process has been documented in the literature, notably in other disciplines or sporadically throughout the engineering design literature. For example, usability testing has been conducted with early prototypes [138], notably in the field of human-computer interaction. While other fields have established and embraced early prototype-based stakeholder engagement methods (e.g., participatory design, methods from the field of human factors), the breadth of possible uses of prototypes for early stakeholder engagement has not yet caught on in engineering design [139] and has not yet been fully explored.

An increasing number of design methods that take into account the constraints and context of DfD have been developed, most of which focus heavily on stakeholder engagement as a factor of success. Indeed, when design for LMICs happens remotely, as it often does [112], a comprehensive characterization of context and stakeholders' needs and requirements is imperative and can better equip designers to address the constraints specific to LMIC settings [124,126]. Design approaches that consider local and regional constraints, cultural contexts, and stakeholder needs are particularly effective in LMICs [124]. However, there is little guidance as to how to implement stakeholder engagement methods in practice [126] and studies have shown that methods developed for use in HIC settings are not always directly transferrable to other cultures and contexts [124]. Therefore, there is an opportunity to study and formalize methods for using prototypes to engage stakeholders during early design phases within the field of engineering design and DfD, as depicted in Table 1.

*Table 1: Current literature and knowledge gaps related to stakeholder engagement with prototypes in early design, within the fields of engineering design and DfD. The highlighted cells were the focus of this dissertation.*

<table>
<tr><th>Stakeholder engagement methods…</th><th>Engineering design</th><th>DfD</th></tr>
<tr><td rowspan="2">… during early design phases</td><td>Methods adapted from the social sciences (e.g., design ethnography)</td><td>Established methods (e.g., participatory rural appraisal)</td></tr>
<tr><td colspan="2">User-based design processes (e.g., design thinking)</td></tr>
<tr><td>… with prototypes</td><td>Well established methods (e.g., usability testing, conjoint analysis)</td><td rowspan="2">Early and frequent prototype iteration in the field is recommended [7], but little guidance is provided [140]</td></tr>
<tr><td>… with prototypes during early design phases</td><td>Anecdotal descriptions of practice-based approaches</td></tr>
</table>

There is, therefore, a need to first understand how industry practitioners currently use prototypes during the design front-end to engage stakeholders in LMICs, and second, to investigate these methods in detail as they are applied in practice.

## 1.4 Research questions

The research presented therefore investigated the following research questions:

- During front-end design activities: what stakeholders are engaged with what prototypes, and in what settings?
- How do design practitioners designing for LMICs approach stakeholder engagement with prototypes during the front-end design of medical devices?

  I then chose to study the application of two early-stage prototype-based stakeholder engagement methods to a global health design setting. The research questions that guided the research are the following:

- How does the use of zero, one, or three prototypes during a cross-cultural requirements elicitation interview affect stakeholders?

- What is the effect of product representation on stakeholder preferences elicited from a conjoint experiment conducted in a low-resource setting in an LMIC?

These questions all explored how to get accurate and authentic feedback from stakeholders when engaging these stakeholders with prototypes. I conducted this research mainly in the field of medical device design for various reasons. Medical device design practitioners are mandated by regulations to engage stakeholders [141] through traditional and well-established methods such as usability testing [142]. Increasingly, regulations are requiring early stakeholder engagement through formative usability tests. However, stakeholder engagement in medical device design is not without challenges, notably with users [143]: users can be inaccessible and have conflicting needs, ethical regulations can be a barrier to engagement, users may have a limited understanding of design processes and have unrealistic expectations. Despite the regulatory requirements and demonstrated benefits of early stakeholder engagement, the industry of medical device design lacks formalized methods to integrate stakeholder input early in a design process [144].

### 1.5 Chapter overview

This section provides a brief overview of the chapters included in this dissertation. The first two studies built upon existing methods for engaging stakeholders in front-end design by describing the stakeholders, prototypes, and settings leveraged with strategies for stakeholder engagement with prototypes.

Chapter Two investigated current industry practices for prototype-based stakeholder engagement by examining the range of stakeholder groups engaged with prototypes, the types of prototypes used to engage stakeholders, the settings in which the engagement occurred, and the associations of stakeholders, prototypes, and settings with prototyping strategies. The findings provided insights into associations of stakeholder, prototype, setting, and/or strategy used by design practitioners to support front-end medical device design engagements.

Chapter Three investigated prototype-based stakeholder engagement practices in the context of design for LMICs. The study revealed objectives of global health design practitioners, such as stakeholder remoteness, exploring the environment of use, bridging cultural gaps, adjusting the engagement to the stakeholder, and working with limited resources. The study further detailed participants' approaches to prototypes-based stakeholder engagement for each of the objectives.

The last two studies dove into method choices designers must make when engaging stakeholders with prototypes – the number of prototypes and the prototype form – and their influence on the engagement and feedback collected.

Chapter Four investigated the application of stakeholder interviews to elicit early user requirements, for which the number of prototypes presented varied from zero to three. The findings revealed that participants used prototypes as a basis for answering designers' questions, and when they were not shown a prototype, they imagined a novel device concept or recalled a device from prior experiences during the interview.

Chapter Five investigated the application of conjoint analysis and a Becker-DeGroot-Marschak auction experiment to elicit stakeholder preferences for product attributes and willingness to pay for the product. The results suggested that changing the product representation affects the relative valuation of product attributes. Furthermore, a one-month post-auction endline survey aimed to capture the effect of receiving the tool on worker rate of injury and productivity.

**1.6 Research methods**

This dissertation's objectives were achieved through retrospective semi-structured interviews of design practitioners and the investigation into applied stakeholder engagement methods using both qualitative and quantitative research methods. In this section, I present the qualitative interview-based methods used in Chapters Two and Three, then I report on the research methods used in the subsequent Chapters Four and Five.

Qualitative research methods were 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, findings are not intended to be broadly generalizable [145]. However, a qualitative approach can enable the discovery of new phenomena and facilitate the generation of in-depth descriptions necessary for uncovering a more comprehensive understanding of phenomena. Qualitative methods can provide unique insights into engineering design processes, enabling new findings not obtainable via quantitative methodologies, and have been used in many studies of design processes and outcomes [146–149]. The qualitative methods leveraged in this body of work have enabled the elicitation of rich descriptions of the stakeholders, prototypes, and strategies leveraged by practitioners with minimal assumptions about who and what they were.

I chose to use the method of semi-structured interviewing, a tool to explore what, how, and why things happen. Semi-structured interviews are based on an interview guide containing a set of pre-determined questions [150]. In addition, semi-structured interviews allow the researcher to ask questions specific to each interview by deviating from the guide to pursue topics of interest with the interviewee. Semi-structured interviews are recommended as the most effective way to create rapport between the interviewer and the interviewee [151].

Both studies reported in Chapters Four and Five were implemented in a real-world context to study the application of two prototype-based stakeholder engagement methods. Such experiments allow for direct observations that enable researchers to check and verify results. While some elements are systematically controlled in the study's bounds, the real-life context introduces variables that researchers cannot control. Hence, such studies require large sample sizes to establish statistical significance and to establish generalizability of results.

To achieve the aims of Chapters Four and Five, I used both qualitative and quantitative methods. Quantitative methods are traditionally used in engineering design and economics and reveal complementary information to qualitative methods. In Chapter Four, I used inductive coding (qualitative) to study stakeholder preferences for seeing zero, one, or three prototypes during a requirements elicitation interview and I used deductive coding and statistical tests to find patterns in the data (quantitative). In Chapter Five, I used a conjoint experiment, a Becker-DeGroot-Marschak auction experiment, and regression analysis (all quantitative methods). I further used open-ended (qualitative) and multiple-choice (quantitative) questions in surveys to collect baseline and endline data from participants.

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## Chapter 2 Stakeholders, Prototypes, and Settings of Front-End Medical Device Design Activities

***Abstract*** – Successful medical device design requires an understanding of stakeholder-driven requirements early in the process to improve device safety and usability, and patient outcomes and satisfaction. Prototypes have been endorsed as tools for stakeholder engagement in the design front end. However, an understanding of medical device industry practices of front-end stakeholder engagement with prototypes is lacking. Through interviews with medical device design practitioners, this study explored the variety of stakeholder groups engaged by design practitioners, prototype forms used during the engagement, and settings in which engagements took place. This study defines the stakeholders, prototypes, and settings leveraged and describes salient choices of associations between engagement strategies, stakeholders, prototypes, and settings. These detailed industry practices could help broaden designers' stakeholder engagement practices.

***Keywords*** – Early Design Phases, Medical Device Design, Prototypes, Stakeholder Engagement

### 2.1 Introduction and background

Medical devices are part of the large array of health technologies that help increase access to healthcare [1]. A medical device is an instrument "intended for use in the diagnosis […], cure, mitigation, treatment, or prevention of disease […] and which does not achieve its primary intended purposes through chemical action" [2]. Throughout a design process, medical device designers engage and seek feedback from diverse stakeholders that are involved in the commercialization and use of devices. Stakeholders include healthcare practitioners, patients, professional and advocacy groups, government officials and legislators, payers [3], risk managers, clinical engineers, maintenance personnel, trainers, and supervisors [4,5]. The beneficiaries, users, payers, and purchasers of medical devices are often different people [6], potentially leading to conflicting needs [7]. Furthermore, medical devices are subject to a strict regulatory environment that mandates the use of prototypes to test concepts with users [8], through usability testing and clinical trials with fully functional devices [9].

Engaging a broad range of stakeholders throughout a medical device design process leads to more successful designs; it is particularly critical for designers to successfully engage stakeholders during the front end of design [10,11], which includes problem finding, identification of design opportunities, articulation of requirements and specifications, and idea development [12]. Stakeholder engagement provides design practitioners with insights into the design context and the values and behaviors of stakeholders [10], and leads to the elicitation of latent problems [13]. However, barriers also exist, such as the intense resources needed to engage medical device users, the limited availability of certain medical professionals and patient populations, and communication gaps between design practitioners and stakeholders [10,11].

Prototypes have been promoted as tools for engaging stakeholders during design processes [3,14], to elicit knowledge, needs, and requirements [15,16]. Prototypes are physical or virtual objects that represent design ideas and can have many forms such as sketches, digital models, and physical three-dimensional (3D) objects, representing ideas for the end product as well as sub-components, processes, and experiences [17]. For example, storyboards can be used to represent the process a user would go through to interact with a medical device interface [4] while virtual reality can be used to simulate a procedure involving a novel medical device [18].

Prototypes provide various ways for stakeholders to participate more actively in design activities [19,20]; notably, when stakeholders have trouble articulating knowledge relevant to the design without a representation of the product [21], i.e., when designing novel artifacts with high uncertainty [20]. Hence, prototype-based engagements facilitate the integration of stakeholders' input throughout the various stages of a design process [22] by centering the conversation around the prototypes [14]. Indeed, prototypes can support various designer-stakeholder activities, such as communicating a design concept [22], gathering feedback on a design concept, having stakeholders interact with a prototype [23], co-creating with stakeholders [24], helping to create a common language between designer and stakeholder, exploring the problem space, and eliciting requirements from the stakeholders [11].

Prototypes in medical device design have traditionally been leveraged to explore the technical feasibility of the project, to improve the device's functionality and performance [25], and in later design stages to verify specifications are reached and validate the fulfillment of the clinical need [8,26]. Some evidence suggests that medical device design practitioners often tend to use high-fidelity prototypes when seeking stakeholder feedback, causing design practitioners to obtain user information during the later stages of a design process [27]. Hence, stakeholder engagement practices are often defined in the context of usability studies meant to identify, quantify, and mitigate use errors [9,13]. Thus, prototyping is often seen as a phase that comes later in a design process [4] rather than as a tool that can also be leveraged at the onset of a design process.

Human factors, the field within which usability testing emerged, does emphasize the importance of early involvement of users in medical device design, particularly through observations, interviews, and focus groups [4]. Human factors and ergonomics research has shown that the integration of user-specific requirements early in the design process of medical devices leads to improved safety and usability of devices, improves patient outcomes and satisfaction, and reduces device recalls and the need for modifications later in the process [13]. Hence, human factors engineering has established methods for front-end user engagement consisting of user testing with both early non-functional prototypes and downstream functional prototypes, to shed light on user-device interaction issues as early as possible [4]. However, human factors research focuses on the engagement of users for the study of user-interface interaction. Therefore, the use of prototypes to engage a wide variety of stakeholders during the earliest phases of design is underexplored within the medical device field. In this paper, we explore which stakeholder groups are engaged by medical device design practitioners during front-end design, with what prototype forms, and in what settings.

Among the limited studies that have explored the effects of using specific prototype forms with specific stakeholders groups, several studies have found that the form of prototype used during user feedback sessions and usability testing affects the feedback received from stakeholders and the results of usability activities [28–30]. Hence, the choices of prototypes and settings leveraged to engage various stakeholder groups may influence the outcomes of the engagement. A description of what prototypes are used with what stakeholders in what settings should provide an understanding of choices for prototype-based stakeholder engagement, contextualized in medical device design practitioner experiences.

Through interviews with medical device design practitioners working in industry, we investigated the stakeholder groups engaged by design practitioners, the prototypes they used during the engagement, and the settings in which the engagement took place. We further investigate the associations among stakeholders, prototypes, and settings, within front-end prototypes-based stakeholder engagement. This study contributes to advancing the understanding of stakeholder engagement practices for industry and academic settings, for the improvement of front-end design processes.

## 2.2 Methods

### 2.2.1 Research aims

The following research question guided the research: During front-end medical device design activities: what stakeholders are engaged with what prototypes, and in what settings? The definitions of front end, prototype, stakeholder, and setting are provided in Appendix A.

### 2.2.2 Participants

Participants were recruited through existing contacts, cold emailing, networking at medical device conferences, and online searches. Potential participants completed a background questionnaire capturing their prior medical device design experience and their experience using prototypes to engage stakeholders during front-end design. Participant selection was further based on respondents' years of industry experience with mechanical or electro-mechanical medical device design (one or more years of experience required). This approach to recruitment led to the identification of key informants with the knowledge and expertise we aimed to elicit in this study [31]. Participants joined the study voluntarily, signed an informed consent document, and received $75 for their participation.

Twenty-two participants were interviewed (i.e., engineers, designers, design researchers, and technology officers) from sixteen medical device companies: five companies with over 1,000 employees, five companies with 10-200 employees, and six companies with 1-10 employees. While the majority of the participants worked for US-based companies, two participants worked for a company in Norway, and one for a company in India. Most companies were for-profit companies: eight were private for-profit companies, and five were public companies. Of the remaining companies, one company was a non-profit organization, one was a sole proprietorship, and one was a partnership. All participants had a Bachelor degree or higher, and 9 of the 22 participants were female. Ten of the participants worked for companies that specialized in the design of medical devices for global health applications. All other participants worked for multinational medical device companies. The median length of participants' design experience was nine years.

### 2.2.3 Data collection

Semi-structured interviews were conducted in person with five participants and via videocall with 17 participants. A semi-structured interview approach ensured that a standard set of questions were asked while allowing flexibility to pursue tailored follow-up questions [32]. The interviews lasted 87 minutes on average and ranged from 55 to 152 minutes in length.

The interview protocol was developed based on the literature related to the research questions following standard interviewing guidelines. These guidelines include initiating the interview with simple descriptive questions, writing open-ended questions rooted in the relevant literature and related to the research question, and supplementing interview questions with prompts and probing questions [33]. The protocol was revised iteratively as a result of 11 pilot interviews conducted with designers who had industry experience.

The definitions of 'front end', 'prototype', and 'stakeholder' were read to the participants to establish common ground between the interviewer and interviewee regarding the meaning of front-end design, prototypes, and stakeholders. The interview then began by asking participants to focus on a single prior project and describe instances when they engaged stakeholders with prototypes during front-end design activities in detail. Participants were probed about how they engaged stakeholders using prototypes, which stakeholders were engaged, what prototypes were leveraged, and the settings of the engagements. At the end of the interview, participants were encouraged to compare experiences of stakeholder engagement with prototypes across projects. Sample interview questions are included in Appendix B.

### 2.2.4 Data analysis

Interviews were transcribed and de-identified. Two graduate researchers, trained in qualitative research methods, read the transcripts multiple times to familiarize themselves with the data. Then, they applied a previously developed codebook and a deductive coding approach to identify front-end design prototyping strategies used to engage stakeholders; the 17 strategies from the codebook are shown in

Table 2. Although not a focus of this particular study, the codebook comprising the strategies served as an initial filter for extracting relevant excerpts to support a subsequent analysis of the types of stakeholders, prototypes, and settings intentionally leveraged by practitioners during front-end design activities.

Next, they used an inductive approach, where patterns were recognized across the data through continuous comparison of the data and to articulated patterns [34], to identify types of stakeholders, prototypes, and settings, within the identified strategy segments. Discrepancies were resolved through discussion. Then, through a process comparable to theoretical coding, where codes evolve based on input from the literature as described in Urquhart, 2013 [34], codes were refined using existing classifications of prototype forms [16,35–39] and stakeholder groups [3,5,13,40–46].

To study the associations among strategies, stakeholders, prototypes, and/or settings, transcript excerpts related to a specific prototype-based stakeholder engagement activity were grouped into engagement events. An engagement event, defined in [47], regrouped transcript excerpts that described a front-end activity where one or more strategies were used to engage one or more stakeholder(s) with one or more prototype(s) in a particular setting – all of which were explicitly named by the participant. Excerpts from a single engagement event could be contiguous or scattered throughout the transcript.

*Table 2: Prototype-based stakeholder engagement strategies of medical device design practitioners*

| ***Strategy*** | ***Label*** |
|---|---|
| Brief the stakeholder about the project and the prototype(s) shown | Brief |
| Encourage the stakeholder to envision use cases while interacting with the prototype(s) | Envision |
| Have the stakeholder interact with the prototype(s) in a simulated use case | Simulate |
| Introduce the prototype(s) to the stakeholder in the actual use environment | Introduce |
| Lessen a prototype's completeness when showing it to the stakeholder | Lessen completeness |
| Make prototype extremes to show the stakeholder | Extremes |
| Modify the prototype(s) in real time while engaging the stakeholder | Modify |
| Observe the stakeholder interacting with the prototype(s) | Observe |
| Polish the prototype(s) shown to the stakeholder | Polish |
| Present a deliberate subset of prototypes to the stakeholder | Subset |
| Prompt the stakeholder to select prototypes and prototype features | Select |
| Reveal only relevant information to the stakeholder specific to the prototype or its use | Reveal |
| Show a single prototype to the stakeholder | Single |
| Show the stakeholder multiple prototypes concurrently | Multiple |
| Standardize the refinement of prototypes shown concurrently to the stakeholder | Standardize |
| Supplement a prototype shown to the stakeholder with different prototype types | Supplement |
| Task the stakeholder with creating or changing the prototype(s) | Create |

As practice, two graduate researchers identified engagement events by reading the same transcript. This process established coding reliability and allowed the graduate researchers to resolve discrepancies through discussion. Both graduate researchers read half of the transcripts and identified and described engagement events. One graduate researcher then reviewed all engagements events to verify consistency across the data set. An average of six engagement events per transcript were identified, for a total of 127 engagement events (between 1 and 11 engagement events per transcript).

## 2.3 Findings

### 2.3.1 Stakeholder groups, prototype forms, and engagement settings for front-end prototype-based stakeholder engagement

#### *2.3.1.1 Stakeholder groups engaged with prototypes*

Across all prototyping strategies, participants engaged a wide range of stakeholders. We categorized these stakeholders into three groups: 1) users, 2) expert advisors, and 3) implementation stakeholders. Users (1) included active users, passive users, proxy users, and secondary-usage stakeholders. Broadly, participants described active users and proxy users as stakeholders who provided information on the clinical need being fulfilled and on the device design. Engaging passive users tended to reveal, according to participants, novel requirements that were not elicited during prototype usage on simulation models. Participants generally engaged secondary-usage stakeholders to ensure that the design of the device would meet relevant non-clinical based requirements (e.g., address storage and sanitation concerns). The next main category of stakeholders, expert advisors (2), primarily contributed information that supplemented the design team's knowledge, as perceived by participants. Lastly, implementation stakeholders (3), which included stakeholders such as manufacturing, marketing, and supply-chain stakeholders, typically revealed non-clinical requirements necessary for successful production and implementation of the device, according to participants. Definitions and examples of each stakeholder group within the medical device context are included in Table 3. Excerpts highlighted in grey are provided below the definition and examples, for each group.

*Table 3: Stakeholder group definitions, examples, and data excerpts*

| Stakeholder Group | Definition | Example(s) within medical device context |
|---|---|---|
| **User** | Uses the device and/or benefits from its primary function once the device is commercialized | |
| Active user | Operates the technology and uses the device's primary functionality; also called "primary user" | Patients who actively use medical devices, healthcare workers (e.g., doctors, nurses), and patients' caregivers, trainers and students |
| | *"I ran a couple focus groups with local nurses, based on ideas that our engineers had for upcoming products to see […] what needs the nurses had that weren't being fulfilled." (B)* | |
| Passive user | Is impacted by the outcome of the device but has little to no control over the use of it; also referred to as "incidental user" | Patients for whom a procedure was performed with a medical device, e.g., infants, children, adult patients, and prosthetic users |
| | *"When you are actually putting the prototype on the baby, the baby is not still." (C)* | |
| Proxy user | Shares similarities with the active user but is not an intended user of the device; leveraged when active users are not accessible | Healthcare practitioners who work in a setting that differs from that of the intended users, laypeople (e.g., friends, co-workers) or the designers themselves |
| | *"I got to the point I said: 'Who has the largest hands here? Who has the smallest hands here?' […] I'd go around and try [3D printed models] in different people's hands." (R)* | |
| Secondary-usage stakeholder | Interacts with the device outside of its primary function, throughout the product use-phase; also called "secondary user" | Technician, immunization manager, maintenance stakeholder involved in service and upkeep of the device (e.g., installation, charging, sterilization) |
| | *"We would get [the prototype]out in the hands of some service engineers and we would say, 'install this and align this tube […] and tell us what is weird about it.'" (S)* | |
| **Expert advisor** | Provides expertise on the device design and usage, and the problem space based on their professional knowledge and experience | Clinical experts, product experts, other medical device company employees, academics, professors, members of partnering organizations |
| | *"We can invite people with a special competence within materials or digital solutions that we don't have in our team." (I)* | |
| **Implementation stakeholder** | Is directly involved in the adoption of the device and influences the success of the device | |
| Supply-chain stakeholder | Influences the device supply-chain, could be an intended actor of the device supply-chain | Distributors, integration engineers, suppliers and vendors, quality verification |
| | *"[We engage] the supply-chain people who tell you what kind of [parts] are available." (P)* | |
| Community partner | Collaborates with the design team through a community organization partnership | Non-governmental organizations, offices and organizations in other countries, partner universities |
| | *"Before going to [a sub-Saharan country] I emailed several partners who work in family planning and I said, 'Listen I'm interested in visiting.'" (K)* | |
| Manufacturing stakeholder | Provides manufacturing expertise and insights into implementation constraints, could be the intended device manufacturer | Manufacturing stakeholders internal to the company, external manufacturers engaged as individuals or as companies |
| | *"When we are in the early phases of design and we are still in the concept generation of the product itself, we do include manufacturing in there, because we want to make sure that if we design something that the floor cannot currently produce, they tell us." (Q)* | |

| | | |
|---|---|---|
| Financial decision maker | Contributes money, materials, or goods to the project, engaged when raising funds or reporting progress | Internal board members, company leadership during a design review, external granters, project managers, donors |
| | *"During the concept phase, to go through each phase […] you need to go in front of a [board] and present what you have been doing during these different phases." (P)* | |
| Government stakeholder | Works in government agencies affecting the device implementation in the country | Ministry of health officials who purchase medical devices, members of regulatory bodies (e.g., FDA) |
| | *There were a few doctors from the government that we reached out to in the early stages of collecting feedback on the idea. We were […] showing them concepts on paper." (C)* | |
| Regulatory stakeholder | Provides expertise on the laws and regulations that govern medical devices | Research councils, regulatory experts employed by the company or a hospital to provide regulatory guidance on the device |
| | *"If we were to discuss regulatory risks with our consultants, what we would do, we would show them […] a very detailed description of what the product would do." (F)* | |
| Marketing stakeholder | Provides expertise on the market landscape, often working in a marketing or sales role | Stakeholders knowledgeable about the medical device market, stakeholders interfacing with users and customers to conduct market research |
| | *"Then you have marketing people coming in to say okay here are the market landscape and this is the trend. What are the popular and here's what people don't like about certain types of things. […] They want to see the [prototype] as it is." (P)* | |
| Customer | Purchases the device but is not the intended user or distributor | Hospital purchasing departments and hospital department heads |
| | *"Once you have something that is functional, that was when we started sending stuff to investors and to our customers, and then always getting evaluated." (H)* | |
| User influencer | Influences the use of the device by the active user | A mother's family whose beliefs impacted what devices could be used on an infant |
| | *"[What] was very important was the response of the others and the family. We realized that […] when you put something on a baby, it is not totally the mother's decision." (C)* | |

#### *2.3.1.2 Prototype forms for stakeholder engagement*

A variety of prototype forms were used by participants to engage stakeholders during front-end design activities. Prototypes predominantly represented device ideas or processes. We categorized these prototypes in three groups: 1) physical three-dimensional (3D) prototypes, 2) two-dimensional (2D) prototypes, and 3) digital 3D prototypes. Physical 3D (1) prototypes were typically described as tangible objects made of test-materials, integrated prototypes, existing products used as prototypes, or pilot experiments involving a physical prototype used in a real-world setting. Test-material prototypes were made very fast by participants, with readily available materials, parts, and rapid prototyping processes, and were often described as being used to test a subset requirement of an idea. In contrast, integrated prototypes were made with processes that more closely resembled that of a commercialized product.

2D prototypes (2) were 2D representations of a 3D object, made by hand, with digital tools, or a combination of both. 2D prototypes were also employed for stakeholder engagement during front-end design. For example, participants described using hand drawings to convey very early ideas; convincing stakeholders of the value of an early idea with photorealistic renderings or engineering drawings; and describing processes through storyboards to avoid biasing stakeholders with a solution.

Digital 3D (3) prototypes were also leveraged with stakeholders during front-end design, notably with more technical stakeholders or when showcasing the vision of the finished product to stakeholders. Definitions and examples of prototype forms in the medical design context are included in Table 4. Excerpts highlighted in grey are provided below the definition and examples.

*Table 4: Prototype form definitions, examples, and data excerpts*

| Prototype form | Definition | Example(s) within the medical device context |
|---|---|---|
| **Physical 3D** | A physical, three-dimensional representation of an idea | |
| **Test-materials** | A physical prototype made of test-materials that are readily available and quick to assemble; test-materials prototypes were often qualified as rough | |
| *Rapid prototyping* | A test-materials prototype made from a rapid manufacturing method, such as 3D printing, rapid machining or molding | A 3D printed prototype of a device outer shell made from stereolithography (ABS), a 3D printed functional prototype of a transportation device for medicine |
| | *"3D printing is more functional evaluation, I would say. Say, for example, [our device has] a space where we keep the [medication], we could organize the [medication], and we use trays to pull in, pull out, and stuff like that. That's more functional." (E)* | |
| *Constrained physical prototype* | A test-materials prototype made from materials with fixed form, such as hardware parts and modified existing products | Pliers handles used to mimic functional actuation, scrub brushes and other items with ergonomic gripping handles used to test grip when users are wearing bloody gloves |
| | *"They had ketchup bottles that you squeezed. It was whatever material that was available, and it had a power to tell to communicate if you put something on your body, and you can control these things. But it wasn't anywhere convincing as a final solution." (I)* | |

| | | |
|---|---|---|
| *Free form physical prototype* | A test-materials prototype made from easy-to-shape materials such as clay, foam, wood, and other craft materials | A versatile clay handle that could be molded into various shapes, a foam model to test the fit of the device concept in the laboratory space |
| | *"We use more foam to do aesthetic models when we want to do some styling of a product [we ask:] 'Does this product relate to the ruggedness of the product that you want?'" (E).* | |
| Integrated prototype | A physical prototype that has one or more refined aspects of the form or function, built using refined materials and processes | An aesthetically accurate but non-functional prototype of an injection device, a fully functional prototype of an infant treatment device with no aesthetic finish |
| | *"You would rather get a looks-like, feels-like prototype model in their hands, and describe how it's going to work." (G)* | |
| Existing product | A product on the market used as a prototype, to benchmark, to trigger memories and reactions, and/or to use as a reference in conversations | Existing body simulators brought to discuss the important anatomy to include in the product, current tools used in the operating room used as stimuli for conversation |
| | *"We did use some bigger syringes to actually give an example of what [the device] would look like, sometimes. […] So, usually, that was the replacement image that we would give so people would understand the general understanding of the operation." (F)* | |
| Pilot | A small-scale test where stakeholders use a physical prototype in its intended environment for multiple days | A functional training-device prototype used by teachers and students in a clinical setting for multiple days |
| | *"We'll leave a prototype behind in a facility for a month, then we'll go pick it up and we'll see what happened to it? […] Just to try to like see more about the lifetime." (K).* | |
| **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 | |
| CAD Model | A 3D CAD model, sometimes accompanied by computational tests | Center of gravity analysis of a handheld battery powered device, finite element analysis of a 3D model |
| | *"[For this project], we don't do a lot of hard prototypes. A lot of it is virtual prototypes. […] Very rarely do we build a full system and send it [to the hospital] just because that's like a million-dollar prototype." (Q)* | |
| Video recording of a prototype | A video recording of a physical prototype | A video of a heat test of a device |
| | *"We make a video of a prototype we're making and have one or two key questions or have Skype calls." (K)* | |
| Interactive rendering | A digital model that can be manipulated to move and mimic functionality through digital interfaces | A digital interface flow mock-up, a CAD model of a device manipulated on-screen to mimic function |
| | *"We had [stakeholders] program the [operation] on the tablet with the screen mocked up." (V)* | |

#### *2.3.1.3 Settings for prototype-based stakeholder engagements*

Participants engaged stakeholders with prototypes in various settings, which we categorized into four groups: 1) meeting spaces, 2) simulation settings, 3) real use environments, and 4) distant settings. Participants engaged stakeholders in various meeting spaces depending on the ease of finding stakeholders and their availability. When the type of engagement dictated specific activities such as usability testing, participants sometimes used special simulation environments. When possible, participants engaged stakeholders in real use environments to learn about the environment constraints and jog stakeholders' memory. Lastly, participants engaged distant stakeholders in real time or asynchronously. A definition and examples within the medical device context for each setting in which prototypes were shared are included in Table 5. Excerpts highlighted in grey are provided, below the definition and examples columns.

*Table 5: Setting type definitions, examples, and data excerpts*

| Setting type | Definition | Example(s) within medical device context |
|---|---|---|
| **Meeting space** | A face-to-face meeting environment that does not include elements of the real use environment of the device, real or simulated | |
| Designer's workspace | A space familiar to the design team | Designer's conference room or office |
| | *"When you do the testing, you actually invite nurses, or you have a van you reserve to have nurses come to this venue." (P)* | |
| Stakeholder's workspace or living space | A space familiar to the stakeholder | Hospital procedure rooms and hallways when interacting with clinical professionals, user homes, doctor's office |
| | *"We were interacting with [...] the head of the departments sitting in their offices." (C)* | |
| Neutral location | A space unfamiliar to both designer and stakeholder | A conference or convention, a networking event, a hack-a-thon |
| | *"We were at a little symposium conference or something where we had a booth, and we had our demo setup and all." (X)* | |
| **Simulation environment** | An environment made to resemble the user's environment | Cadaver lab, usability lab with anatomical models for demonstration and/or testing purposes |
| | *"We used simulation mannequins and the clinical simulation center at the hospital a lot when we would meet with users, so that they could try it out." (N)* | |
| **Real use environment** | An environment where the device would be used once commercialized | In the community or private home of the user, a hospital operation room or patient room, a training environment, a manufacturing floor |
| | *"So, when we interact the nurses it was actually in the ward next to the baby." (C)* | |
| **Distant** | A virtual online environment through which communication takes place | Skype call during which prototypes are demonstrated to stakeholders, sending prototype to stakeholder (via mail or email) and receiving feedback via email, phone call |
| | *"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?'" (E)* | |

### 2.3.2 Associations of stakeholder, prototypes, and settings for prototype-based stakeholder engagements

In the previous section, we defined the stakeholders, prototypes, and settings leveraged by participants when implementing one or more of the 17 strategies defined by author, year during front-end design stakeholder engagements. In this section, we present our analysis of the associations of strategies, stakeholders, prototypes, and/or settings.

Participants described how their choices of prototyping strategy(ies), stakeholder(s), prototype(s), and/or setting(s) affected and informed engagement decisions. These choices were the result of intentional decisions from participants, which related to the goals for the engagement and constraints associated with their respective design processes. We first present stakeholder-prototype-setting associations, depicted in Figure 6 by the region shaded with the black and white stripes. We then present in-depth descriptions of associations of stakeholders and prototypes for each strategy, depicted in Figure 6 by the region shaded with the checkered pattern. In Figure 6, the larger circle represents the engagement strategies within which stakeholders, prototypes, and settings were leveraged by participants during front-end medical device design. In the following sub-section, we denote associations of stakeholder, prototype, and setting with the following notation: stakeholder–prototype–setting.

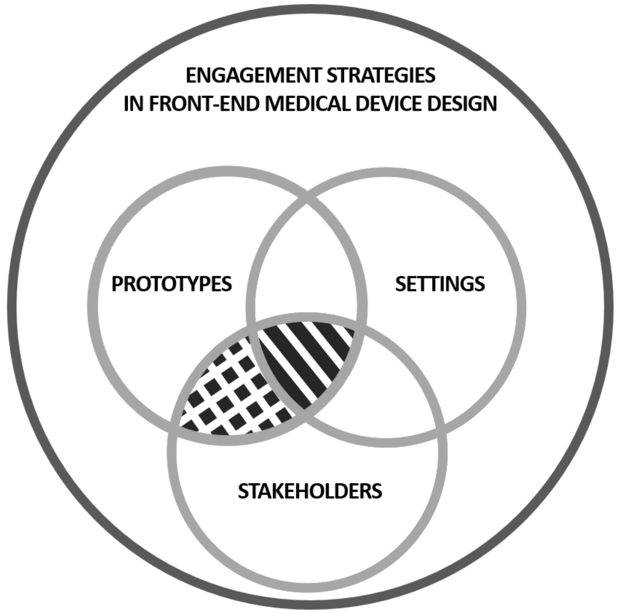


*Figure 6: Stakeholder engagement with prototypes during front-end medical device design, intersecting strategies, stakeholders, prototypes, and settings*

### *2.3.2.1 Stakeholder–Prototype–Setting Associations*

Participants described engaging stakeholders in settings which we categorized in four types: meeting spaces, simulation environments, real use environments, and in distant settings. Figure 7summarizes all the stakeholder–prototype–setting associations in a condensed form. For all figures in this section, including Figure 7, transcript level counts of associations are indicated for each association and the connecting lines thicken as counts increase.

*Users–prototype–setting*

All stakeholders, notably users, were most often engaged in meeting spaces where they could interact casually with the prototype(s) presented. Participants described meeting users most often in the user's own meeting space because of availability and time constraints, with various forms of prototypes. When engaging users in simulation environments, participants described only using physical 3D prototypes. Design practitioners replicated the conditions of use with supporting objects and artifacts used in the actual use environment. Some simulations were rough, using available materials to simulate the environment, some simulations were conducted in a cadaver lab, wet labs, or other high-fidelity simulation environments.

Participants asked users to perform tasks with the prototype within the simulated setting or demonstrated the prototype to users. Participants also described engaging users mainly with physical 3D prototypes in the real use environments of one or multiple stages of the product's lifecycle, to prompt the user to perform tasks with the prototype in the use environment. In two cases, 2D prototypes were used to supplement the physical 3D prototypes, such as a digital interface on a tablet which prototyped the programing interface of the device. To engage distant users, although 2D and digital 3D prototypes were easier to send to users, participants also sent physical 3D prototypes home with users to test over multiple days or sent physical 3D prototypes to distant users via mail, to then gather feedback on their experience.

*Implementation stakeholder–prototype–setting*

Participants mentioned engaging implementation stakeholders with prototypes most often in meeting spaces. Because many implementation stakeholders were internal to the participants' companies, they were engaged in the designer's space. Reportedly, implementation stakeholders were seldom engaged in a simulation or real use environment. One participant gave a prototype to the customer to perform their own tests in a real use environment and one participant brought a physical 3D prototype to the manufacturing floor to gather feedback from manufacturing stakeholders on the manufacturing process. A subset of implementation stakeholders was engaged remotely, in a distant setting. Community partners in other countries were often engaged remotely, along with international supply-chain, manufacturing, government, and regulatory stakeholders, either through sending prototypes via email or mail, or showing prototypes via videocall.

*Expert advisor–prototype–setting*

Expert advisors were also cited as being mostly engaged in the designer's space or engaged in a distant setting when meeting in person was not possible, in which case using 2D and digital 3D prototypes became easier. If the advisors were clinical specialists, then they might have been engaged in a simulation environment to try out the prototype or witness a demonstration. No participant described engaging expert advisors with prototypes in the real use environment.

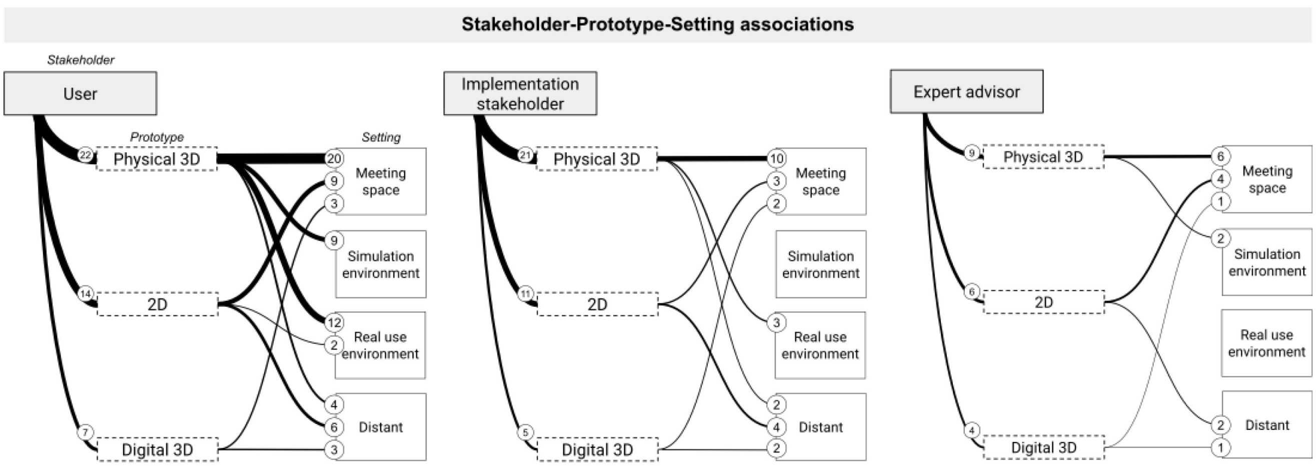


*Figure 7: Stakeholder-prototype-setting associations*

### *2.3.2.2 Stakeholder–Prototype–Strategy Associations*

*User–Prototype–Strategy Associations*

Users were most often engaged with physical 3D prototypes during front-end design activities, as described by participants. All strategies for stakeholder engagement were leveraged with users and physical 3D prototypes. For a subset of cases, a 2D prototype form achieved a strategy's goal. Digital 3D prototypes were used in presentations, to prototype an interface, to supplement other prototypes, or were sent to distant users. Figure 8 summarizes the user–prototype–strategy associations. The strategies are ordered alphabetically in all figures to support comparison across figures.

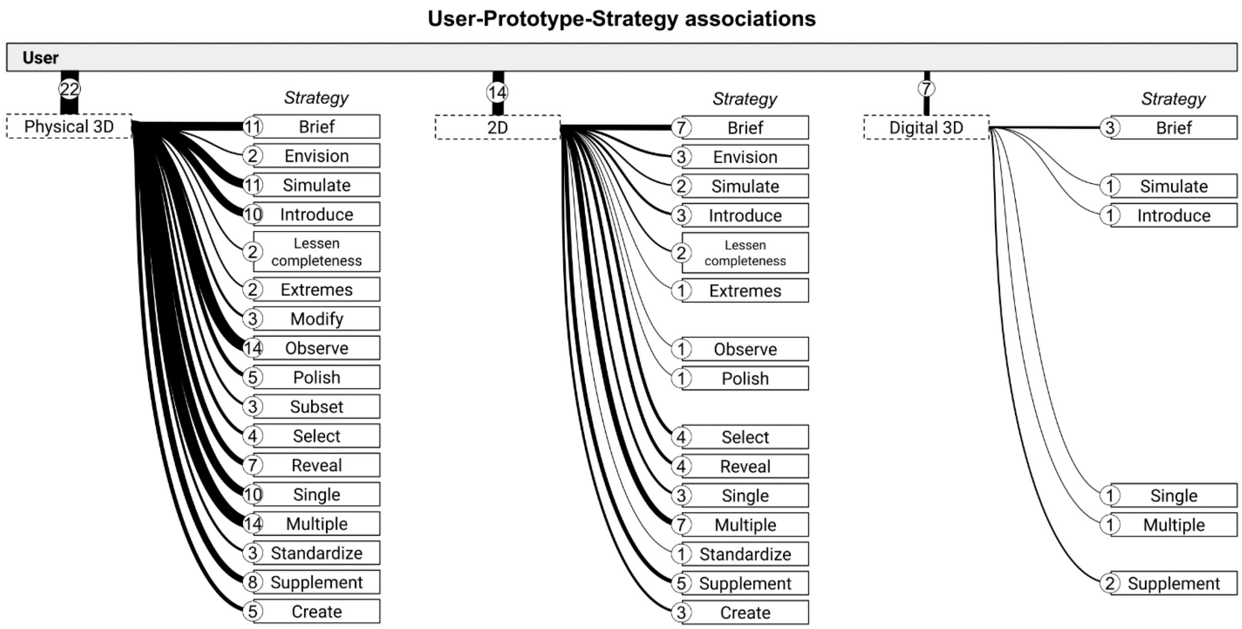


*Figure 8: User-prototype-strategy associations*

User–physical 3D–strategy

Participants discussed using physical 3D objects to engage users. For example, Participant N said she felt that users could not envision the idea through other prototype forms:

> *"Having something physical that they could hold and having something that they could move, and use made the quality of the interaction so much better because some people just can't imagine that next step."*

Participants F expressed that a physical 3D prototype generally led to 'better' feedback than other forms:

> *"A lot of those early, early 3D printed and machined prototypes, definitely for end-users over in [a sub-Saharan African country] got the best responses. […] With the physicians, there was a lot of interest around how some of the very specific features of the device and how it would apply to specific surgeries. A lot of the nurses were more focused on usability."*

User–physical 3D–create

Participants leveraged different forms of physical 3D prototypes for different strategies. To 'task the stakeholder with creating or modifying prototypes' (create), participants used test-material prototypes. For example, Participant N described making a rough handle prototype out of foam and asking users to shape it as they desired:

> *"We did a rough cut of how the handle shape would be and then we just let them shave it off how they think it would be good. [...] We used playdough to have them, you know, 'How would you want this built out? How big would you want it? Where do you want the thumb to sit?' sort of things."*

Engaging users as active participants by using malleable materials combined with a base prototype enabled the users engaged by Participant N to make quick and easy modifications.

User–2D–create

Other participants expressed using 2D prototypes to engage users with the create strategy. However, using drawings for active stakeholder participation was perceived as ineffective for Participant B, who described users' discomfort when asked to draw:

> *"We said, 'Here is a card, you can draw what you think the [device] would be, or you can write down characteristics that you would have in something that you would make. […] Only two [stakeholders] drew.'"*

User–physical 3D–polish

In other instances, participants described leveraging the strategy to 'polish the prototypes shown to the stakeholder' (polish) with physical 3D prototypes shown to users. For example, Participant A described removing less aesthetically pleasing and unfinished elements of a prototype to avoid distracting users:

*"[Users] can't help but focus on the unfinished aspects even though you know it's not really a concern at this point. So when I'm trying to put something out in the field, I'm trying to get it as finished as possible, even just aesthetically. I need to spray paint it or something because people will look at a 3D print and be like, why is it this color?"*

User–2D–lessen completeness

For a subset of strategies, physical 3D prototypes were not always chosen to engage users. For example, Participant N discussed using 2D prototypes, such as drawings, early on to not bias users with a more advanced prototype, following the strategy to 'lessen a prototype's refinement when showing it to the stakeholder' (lessen completeness):

*"So, sometimes we just tried kind of pencil and paper, […] just redraw what I had in CAD with pencil and paper because then people would give me more, like, 'Oh, she's early on, I can go ahead and give my input.'"*

User–2D–multiple

Participants also described using renderings, another form of 2D prototypes, to 'show multiple prototypes to the stakeholder concurrently' (multiple). Participant A described how renderings allowed different design concepts to be compared without creating multiple different physical 3D prototypes, hence saving resources:

*"Because you can do shading and stuff and make it look pretty good and it saves you from having to go through an actual producing of a 3D print or something like that which is not cheap."*

User–2D–envision

Another example was the use of 2D prototypes to “Encourage the stakeholder to envision use cases while interacting with the prototype(s)” (envision). 2D prototypes provided additional opportunities for participants to evoke use cases for Participant D:

> *“Showing this abstract device that’s floating in a white background, a lot of times people can mistake even understanding what the device does. […] We also did a version where we a little bit clumsily photoshopped it into a photo of a real person […] and tried to show where the device would go.”*

*Implementation Stakeholder–Prototype–Strategy Associations*

A wide variety of implementation stakeholders, such as manufacturing, marketing, and government stakeholders, were engaged during the front end. Participants’ associations of implementation stakeholder, prototype, and strategy aligned with the individual engagement goals for each group of implementation stakeholders. Physical 3D prototypes and 2D prototypes were used to a similar extent with implementation stakeholders, in contrast to participants’ leaning towards for physical 3D prototypes when engaging users. Digital 3D prototypes were sent to distant implementation stakeholders or were used during design reviews with financial decision makers. Figure 9 summarizes the implementation stakeholder–prototype–strategy associations.

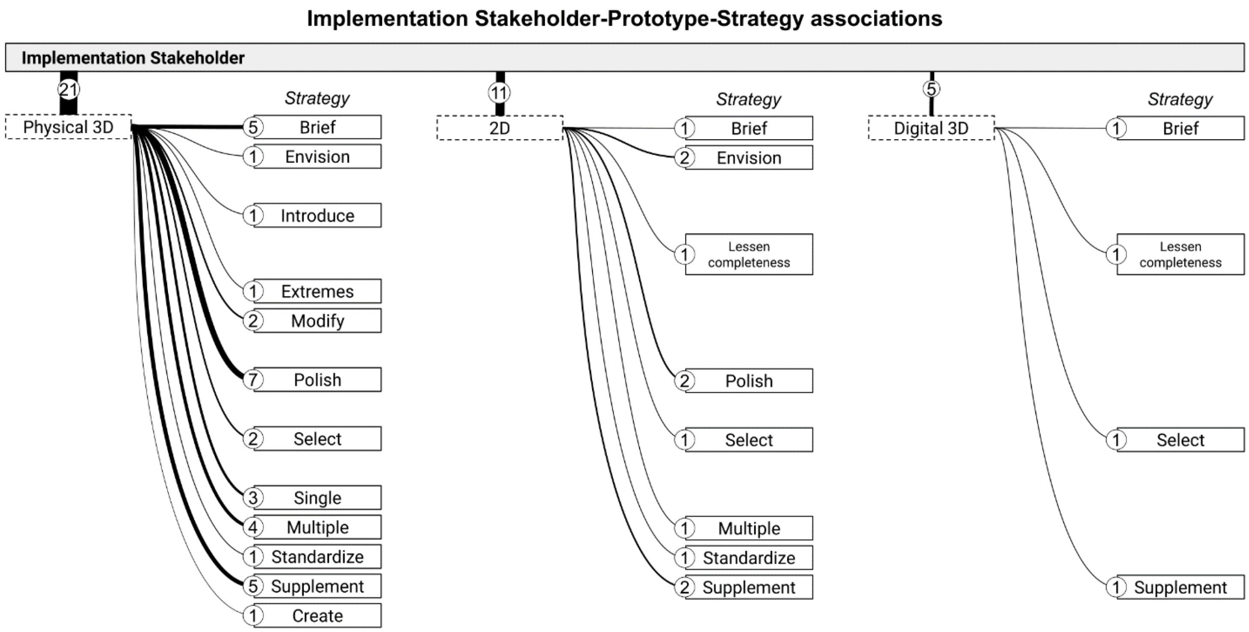


*Figure 9: Implementation stakeholder-prototype-strategy associations*

The following examples showcase choices of prototype and strategy for different implementation stakeholder groups.

Implementation stakeholder–physical 3D–polish

Participants showed polished prototypes to financial decision-makers. Participant A described polishing 3D printed prototypes when engaging financial decision-makers to impress and lend legitimacy to the project:

> *"For funding purposes, it would be the nicest looking, most functional device you had at any given time because you want to impress. You do not want to show them a bunch of junk."*

Implementation stakeholder–digital 3D–strategy

Participants described using digital 3D prototypes during design reviews when making design decisions with the company's internal financial decision-makers, as exemplified by participant Q:

*"Another stakeholder is like the leadership team, right? The people who are our leaders and guide the direction. With them, we would use a combination of the 3D models and finite element analysis to show them that the design is solid and fair."*

Implementation stakeholder–physical 3D

However, when engaging external financial decision-makers or customers, participants cited using physical 3D prototypes. Participant C, for example, chose physical 3D prototypes because they perceived them as more convincing than other prototype forms:

*"We were pitching our concept [to external financial decision-makers]. If we were showing things to them which were not real, if for example, if I'm showing a presentation or showing a booklet [...], that was less convincing as opposed to if I had this thing that I would actually demo in front of them."*

Implementation stakeholder–2D

Participant E described engaging government and regulatory stakeholders with 2D prototypes during front-end design to discuss device features and regulatory and manufacturing risks. Participant E described how these specific prototypes, including drawings and storyboards, were relevant to the concerns of this stakeholder group:

*"We would send them pictures of cross-sections, pictures of various parts involved, a more verbal description of what [each component did], and a very detailed description of what the product would do. That is [...] enough for regulatory people to comment, and come back and tell, or, 'You seem to have a reusable component. You seem to have a sterilizable product.' [...]*

*[For ministry of health officials] it does not make sense to take a huge foam mockup to them. They are more interested in what does it cost, and where are you manufacturing,*

*and what is the battery life [...]. You make really quick sketches or renders to just convey the idea. [...] They're not going to be fixated on the visuals [and] would just look at the bullet points [...] I think PowerPoint presentations with visuals of sketches, […] storyboards would be good enough."*

*Expert Advisor–Prototype–Strategy Associations*

Participants described engaging expert advisors with a variety of prototypes during front-end design but described leveraging fewer of the 17 strategies with experts than with other stakeholder groups. Advisors generally provided technical feedback, such as feasibility, based on their domain-specific knowledge. Hence, participants discussed showing advisors more technical prototypes, such as functional physical 3D prototypes, 2D prototypes of various concepts and device architectures for down-selection, and digital 3D prototypes, to collaborate with advisors. Some clinical advisors also provided feedback on ergonomics of physical 3D prototypes. Figure 10 summarizes the expert advisors–prototype–strategy associations.

Expert advisor–2D and physical 3D–supplement

One strategy most cited to gather feedback from advisors during front-end design was to 'supplement the prototype shown to stakeholders with additional representations' (supplement), with 2D and physical 3D prototypes. Participant W described bringing drawings and a physical mock-up to an engagement with an advisor:

*"In between user tests, we'd go to an [expert advisor] with a new idea or concept in mind, usually accompanied by a drawing or a really crude physical mock up that shows how it's supposed to work, and consult the [expert advisor] and get their feedback,*

*opinions about whether or not they thought that idea would work from a patient standpoint, make sure it would work from an anatomy standpoint."*

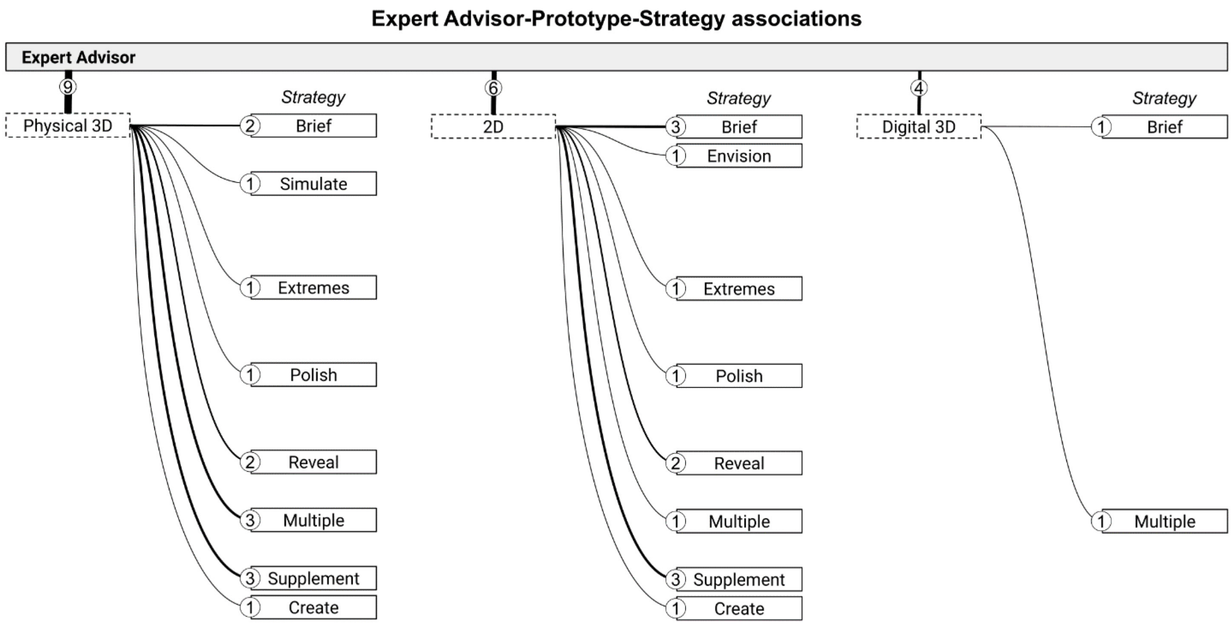


*Figure 10: Expert advisor-prototype-strategy associations*

## 2.4 Discussion

Our findings revealed that medical device design practitioners engaged a diverse set of stakeholders with prototypes during their front-end design processes. Although the stakeholder groups engaged by participants in this study have been reported in the literature (broadly, not specifically with respect to front-end design engagement supported by prototypes), only a subset of the stakeholder groups are currently represented in design frameworks. The stakeholder group users, including active and passive users, appears in multiple stakeholder frameworks [3,46,48]. The prominent presence of users in stakeholder frameworks aligns with literature tying user engagement to project success, notably during its earliest stages [4,49]. Other stakeholder groups reported in our study are less frequently incorporated into published stakeholder frameworks. For example, proxy users, secondary-usage stakeholders, and expert advisors, which were identified in our study, have only been described in individual medical device design studies [5,13,50], but are absent from the frameworks by Yock et al., 2015, USAID, 2017, and de Ana et al., 2013 and are seldom described as groups to engage with prototypes.

One stakeholder group reported in Yock et al., 2015, and USAID's Ready, Set, Launch, 2017, did not emerge in this study: trade groups and healthcare facilities (e.g., American Hospital Association, hospital department head). The latter group was mentioned several times by participants as the gatekeepers to healthcare practitioners (active users), but healthcare facilities stakeholders were not engaged with prototypes. The lack of healthcare facilities stakeholders mentioned in our study might have resulted from the types of medical devices discussed and/or because of the limited sample size.

A variety of prototypes were leveraged by the medical device design practitioners in our study to engage stakeholders during front-end design. Multiple classifications of prototype forms exist, but no single classification matched the breadth and/or depth of prototype forms described by participants. The list in this study most resembles taxonomies that described the materials and fabrication approaches for creating prototypes and these taxonomies were used to help define the codes [51–54].

Simple physical 3D prototypes were typically described by participants by the manufacturing methods used to fabricate them and/or the materials used to develop the particular form factors (e.g., 3D printed). However, when describing more complex physical 3D prototypes, created with multiple types of materials and/or manufacturing methods, participants tended to instead describe their functionality and/or aesthetic properties. Hence, the integrated prototype category emerged based on the work by Jensen et al. [36]. Houde and Hill [55] state that describing prototypes by the tools used to create them and their level of refinement can be distracting, and they propose that prototypes should be described by their goals rather than their form. While some participants did use ‘goal oriented’ language to describe early prototypes, e.g., ‘works like’, most did not. One can hypothesize that the materials of simple prototypes and the refinement of more complex prototypes may be salient characteristics that are easier to recall and thus used as descriptors, while the goals of the prototypes might not have been as easy to articulate and/or were not readily recalled by design practitioners’ during the interviews (i.e., might require specific interview prompts to elicit this information).

Furthermore, when making 2D prototypes, participants commonly described drawings of concepts or photographs of physical prototypes that were then enhanced through digital alterations. Hence, the distinction between paper and digital prototypes was blurred. Similarly, some CAD models (digital 3D prototypes) were used as a basis for renderings, and the actual CAD model was seldom shown to stakeholders. The advent of virtual and augmented reality prototyping technologies may increase the use of digital 3D prototypes in the future [56] and might further blend the lines between 2D, digital 3D, and physical 3D. Hence, a material-focused description of prototypes might be increasingly difficult to articulate as prototypes are created through mixed mediums to a greater extent.

Several settings were identified in this study for engaging stakeholders with prototypes during front-end design. Most front-end stakeholder engagements with prototypes happened in meeting spaces. In addition, early in their design processes, participants engaged users in simulation and real-use environments which aligns with regulatory guidelines for medical device development that mandate designers seek to understand the actual use environment of a device, through user feedback and observations [57]. The use of simulation environments is well reported in medical device design literature [9].

In addition to users, a few participants also engaged implementation stakeholders in real-use environments, such as on the manufacturing floor, to explore other parts of the lifecycle of the device. The high proportion in our sample of engagements conducted in real-use environments may have stemmed from the fact that half of the study sample designed medical devices for use in low- and middle-income countries (LMICs), and hence traveled to their users, with potentially limited access to usability labs in the LMIC, but with access to the real-use environment. Indeed, testing a prototype in its use environment is essential to uncovering previously unknown requirements [58]. Mattson and Wood, 2013, suggest integrating testing of the artifact in the real use environment throughout the whole design process rather than as a "final step" [59]. The advent of virtual reality may enhance the opportunities for designers to engage stakeholders in simulation environments, a resource intensive endeavor [60] and one not emphasized in our study sample.

Participants also leveraged distant environments, often when resources needed to visit stakeholders in person were too high. However, they also allowed for the testing of prototypes in the real-use environment for longer periods of time. Indeed, participants conducted small pilots by sending physical 3D prototypes to users to use in the real-use environment and provide feedback.

Our findings illustrate the broad combinations of strategy, stakeholder, prototype, and/or setting choices made by medical device design practitioners for stakeholder engagements with prototypes during front-end design. Particular combinations of choices appeared more frequently in our data set; for example, participants demonstrated a preference towards polishing prototypes as opposed to lessening the completeness of the prototype, specifically with implementation stakeholders rather than with users. This tendency might have been due to the commonly accepted practice of showing users low-fidelity prototypes to encourage preliminary feedback [61]. Furthermore, the strategy to supplement was common across all stakeholder groups and prototype forms, which might indicate that for many stakeholder engagement activities, a single prototype form does not adequately support the full range of stakeholder engagement activities.

On the other hand, expert advisors were not associated with a wide variety of strategies nor at high frequencies, which may result from a common disciplinary "language" shared between designers and advisors and/or the nature of the relationship between advisors and medical device companies, i.e., advisers may be perceived to be extended members of the design team and therefore the engagements might be less formal and result in less strategic pre-engagement planning work.

Participants highlighted associations of 2D and digital 3D prototypes with specific stakeholders, based on the technical background of stakeholders. For example, non-technical non-user stakeholders were often shown 2D prototypes (particularly government and regulatory stakeholders), while technical stakeholders (e.g., internal financial decision-makers), were shown CAD models. CAD models can communicate functional and technical aspects of the prototype and might be harder to understand when one is not familiar with CAD software, which could explain their limited use with stakeholders other than those interested in the technical feasibility of the project. Prior research in the automotive industry has shown that to convince stakeholders of the potential of a project, such as financial decision-makers, strategies comparable to supplement are leveraged, and physical 3D and 2D prototypes such as PowerPoint slides, and diagrams are used in conjunction with video recordings of mockup scenarios [62]. Video recordings are also used to send prototypes to distant stakeholders [62]. Additionally, external financial decision-makers were presented with physical 3D prototypes that were polished. Changing the engagement parameters based on stakeholders' technical background has been recommended by several authors in the software design space [63,64].

A subset of our findings aligns with associations that have previously been reported in the literature of various design fields. For instance, strategies leveraged primarily with users, such as simulate, observe, subset, and reveal, were strategies typically found in guidelines for usability testing and medical device design [3,9]. Participants described applying such best practices in very early informal testing for designers to better understand the requirements around usability and user preferences. Physical 3D prototypes were emphasized by participants as the most effective prototypes to engage users, an existing recommendation in engineering design texts [65].

### 2.5 Limitations

Limitations of the study include participants' open interpretation of what constituted front-end design activities. Indeed, although a definition was provided at the start of each interview, participants had varying expectations of what front-end activities constituted. Further, differences in device type and job role could have impacted the type of front-end activity participants had experience with. To mitigate such effects, the field of study was limited to mechanical and electro-mechanical medical devices. Participants filled out a background questionnaire before recruitment based off which a balance was struck between narrowing the participant pool and recruiting a diverse sample of the medical device industry. Participants were mostly from US-based companies, which further limits the generalizability of practices across countries.

The stakeholder groups emerged based on participants' descriptions of their roles and the feedback provided. However, some stakeholders could have belonged to multiple groups synchronously. For example, a clinician expert advisor or a community partner could sometimes act as a proxy user or active user. Hence, frequencies of stakeholder groups, along with prototype forms, setting types and associations, would have to be further studied to determine more specific prevalence.

## 2.6 Implications

Practitioners, both novice and professionals, can use the lists developed in this study to evaluate their stakeholder engagement plan and consider more diverse approaches to stakeholder engagement using prototypes. By developing general definitions of stakeholder, prototypes, and settings, the results may be applicable across industries and contexts. The domain specific examples we provide illustrate different stakeholders, prototypes, and settings with nuanced examples applicable to medical device design. The associations of strategy, stakeholder, prototype, and setting exemplify the various intentional choices of design practitioners to stakeholder engagement. High frequency associations can be used as a guideline for novice designers' awareness of ways of engaging stakeholders with prototypes. Lower frequency associations could inspire potentially novel stakeholder engagement approaches for seasoned professionals.

## 2.7 Conclusion

This study provides a comprehensive description of stakeholders (users, implementation stakeholders, and expert advisors), prototypes (physical 3D, 2D, digital 3D), and settings (meeting space, simulation environment, real use environment, and distant) leveraged for stakeholder engagement with prototypes during front-end medical device design activities. The breadth of stakeholders, prototypes, and settings illustrates the many ways practitioners conduct front-end activities (e.g., engaging proxy users and government stakeholders with prototypes, using constrained and free form physical 3D prototypes or photographs and video recordings of prototypes). The descriptions and categorizations of stakeholders, prototypes, and settings, as well as the rationales provided for using specific forms of prototype for engaging specific groups of stakeholders in certain settings, have the potential to enhance existing design frameworks and inform design practitioners' front-end prototyping practices with stakeholders. Future work should explore the transferability of these findings across industries.

## 2.8 Acknowledgements

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# Chapter 3 Global Health Front-End Medical Device Design: The Use Of Prototypes To Engage Stakeholders

***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.

***Keywords*** – Stakeholder Engagement, Prototype, Front-End, Low- and Middle-Income Countries, Medical Device Design

### 3.1 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 [1–3]. Numerous health technologies fail to reach scale due to a combination of factors including: cost, energy, and human resource constraints [1,4]; lack of cultural acceptability [1]; inability to address the core problem [5]; poor fit with existing systems and context [2,6]; additional regulatory constraints [1,2]; lack of training of health professionals [7]; maintainability challenges such as hindered access to spare parts and consumables [4,7]; low profit margins [2]; and limited monetary resources to support commercialization (e.g., venture capital) [4,5,7]. The confluence of these constraints specific to health technologies for development reduces the number of potential viable design solutions [8] and limits the adoption and diffusion of innovations in LMICs [9].

When design for LMICs happens remotely, as it often does [10], a comprehensive characterization of context and stakeholders' needs and requirements is needed and can better equip designers to address the aforementioned constraints [11,12]. For example, design approaches that consider local and regional constraints, cultural contexts, and stakeholder needs are particularly effective in LMICs [12]. Aranda Jan et al., 2016, developed a framework for the contextual design of medical devices that prompts designers to consider factors such as the infrastructural, industrial, and institutional contexts when designing 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 which can withstand harsh environmental conditions [1].

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 and specifications, and early concept generation [13] to better define product requirements that meet the needs of stakeholders [14,15]. Quality of execution of the front-end phases has been linked to the success of design projects [13,16]. 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 [17]. 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 [18].

Medical device stakeholders traditionally include users, such as doctors and nurses, as well as others who may impact or be impacted by the design [19], such as patients, caregivers, regulatory specialists, and public and private payers [20]. 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 [21]. Involving stakeholders during front-end design activities is especially important for designers whose target markets are LMICs [22]. Methods of stakeholder engagement such as design ethnography [23], which includes face-to-face interviews, focus groups, and co-design [24], have been encouraged when designing for LMICs settings [9,22,25]. 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 [12]. In multiple product domains, information gathering methods with stakeholders include the use of prototypes for the elicitation of requirements during the design front-end [21,26].

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 [27–29]. Prototypes are increasingly used to include stakeholders early in design processes because they can encourage stakeholders to play a more active role [30]. Prototypes provide a fundamentally different way of communicating around a shared space [31]. Users can articulate their needs by interacting with prototypes rather than doing so in the abstract [21,27]. Prototypes have therefore been leveraged in front-end design: during stakeholder engagement in the front end to communicate ideas [32]; during formative usability settings in the field of human-computer interaction [33]; during early co-design activities [34]; and during early requirement elicitation interviews [21,26].

However, although early and frequent prototyping in a design process has been recommended [35], limited research has focused on specific strategies for using prototypes during front-end stakeholder engagement, including within medical device design when designing for LMICs [22,36]. Some research has considered the impacts of prototype forms and quantity of prototypes shown on stakeholder feedback [33,37], 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 activities. Specifically, this study describes how the global health context influenced the decisions of stakeholder, prototype, and strategy leveraged during the stakeholder engagements with prototypes. Literature has demonstrated the value of rich descriptions of experiences collected through qualitative research methods [38,39], notably when studying design processes and strategies used within those processes [40]. 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 for the design of medical devices intended for use in LMICs.

## 3.2 Methods

### 3.2.1 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 [41]. 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 [11,40,42–44]. 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.

### 3.2.2 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 devices. The sample size for this study was similar to other interview-based qualitative studies in design [42–44]. 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 [41].

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 (US). 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. (st.dev. 3.0 yr.) and their average design experience was 8.4 yr. (st.dev. 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 healthcare technologies. The medical applications included treatment, diagnostics, preventative care, and training.

### 3.2.3 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 [45]. Following interview protocol development guidelines [41], the interview protocol began with rapport-building questions and transitioned to open-ended questions focused on particular experiences, finally follow-up questions were used to gain additional details [46]. 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 C. 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 D.

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.

### 3.2.4 Data analysis

#### *3.2.4.1 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 [41,47]. 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 [48]. 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 [19,20,49–56] and prototype form classifications [34,57–61] were used to refine the themes. For each analytic goal (stakeholder, prototypes, and strategies), the study team established a final set of themes for stakeholder group, prototype form, 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 6 (stakeholders), Table 7 (prototypes), and

Table 8 (strategies).

*Table 6: Stakeholders engaged by global health design practitioners with prototypes during front-end design. An earlier version of these emergent themes is reported in [62,63].*

| 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 directly involved in the adoption of the device and who strongly influences its success, such as people who intervene 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 the design process, such as students, hackathon participants, and translators. |

*Table 7: Prototypes leveraged by global health design practitioners to engage stakeholders during front-end design. An earlier version of these emergent themes is reported in [62,63].*

| Prototype form | Definition |
|---|---|
| **Physical 3D** | A physical representation of an idea that has a three-dimensional 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 representation of a three-dimensional 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 8: Strategies leveraged by global health design practitioners when engaging stakeholders with prototypes during front-end design. These strategies have been established and are further defined in [64-66].*

| 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) |

Data pertaining to the participants' team composition for the projects discussed was not collected. In this analysis, the researchers did not include interactions where designers used prototypes to engage other designers on the team (internal-internal stakeholder interactions [74]). 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.

### *3.2.4.2 Engagement events*

The following data analysis was performed only on the global health interview data. Upon completion of the thematic analysis, transcripts were partitioned into 'engagement events,' which regrouped all excerpts that pertained to a specific activity, as described in [67]. 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 where 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 was then partitioned, and each graduate researcher identified engagement events for half 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 E.

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 are representative of the larger sample and highlight commonly experienced global health challenges. Furthermore, the cases highlight how participants determined which stakeholders, prototypes, and strategies to leverage.

The participants whose excerpts are reported in the results worked in four different private US-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 F.

After the analysis was complete, 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 [68]. 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.

**3.3 Methods 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 6, Table 7, and Table 8. The transcript-level counts for each category are reported in Table 9. 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 were most frequent within the experiences that participants chose to share with the researchers, they do not suggest which stakeholders, prototypes, and strategies leveraged are the most used or the most useful for medical device design.

*Table 9: 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 |

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.

### 3.3.1 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 users (also nurses). The nurses who served as proxy users worked in the US 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 from 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 US based nurses but also nurses here in the US 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, in 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."*

### 3.3.2 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 since stakeholders could more precisely indicate preferences through pointing to elements of the prototype for example.

> *"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 around 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 US

> *"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 like 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."*

### 3.3.3 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 US and a foreign country to gather feedback; and described demonstrating the prototype to stakeholders in order to get buy in. Specifically, Participant C noted that she used different prototype forms for different groups of stakeholders.

First, 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 US and stakeholders in the LMIC, bringing to light the disconnect between the US-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 US, 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 US traditional design."*

In a different engagement event, Participant C engaged use-cycle stakeholders—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!'"*

Lastly, 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.

### 3.3.4 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. This was thought to more effectively communicate 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 specifically to engage government stakeholders, based on their interests 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—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.

### 3.4 Discussion

This study aimed to describe how global health design practitioners approach 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 (i.e., "the design of products to meet the needs of a user remotely located") with only short visits to the target regions [10], which is frequent in global health work. Despite the distance between designer and intended user, obtaining real-time feedback is crucial [22].

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 [22], and building relationships with local stakeholders when designing remotely [10] has been documented in the development engineering literature. Further, participants used electronic communications, such as teleconferencing and email, to engage remote stakeholders by sending them 2D prototypes such as 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 [53]. However, most proxy users lacked knowledge of the specific design context, and their feedback was not always applicable or useful (Participant A). Participant C described how expert advisors from the U.S. provided feedback that contradicted local stakeholders, because they did not understand how disposable and reusable devices were perceived. These results are consistent with previously published studies that highlight the need to engage with stakeholders that have a deep understanding of local challenges [10,70]. Exploring and understanding the context of use is a central part of front-end medical device design [53] 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 [11,71]. 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 [11,71] with stakeholders using prototypes. Participants explored the environment of use in multiple ways. For example, they situated the prototype in its environment by adding picture elements in the background of 2D prototypes (Participant D). Participants also simulated the environment of use through fast and low-cost simulating elements (Participants A and B). Lastly, participants introduced physical prototypes in the environment of use during engagements (Participant B and D).

Mismatches between the device design and the environment of use contribute to the failure of medical devices in LMICs [11,72]. Because of multifaceted political, social, and cultural settings in LMICs, testing products in the environment of use throughout the design process rather than simply in the back-end of design is an essential part of developing products for LMICs [73,74]. 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 [10], 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" [67,75]. 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 (e.g., local inequalities, literacy and education, religious and cultural beliefs, and languages [11] 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 [11]. 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). Designers engaged government stakeholders with prototypes during the front end to gather background information about the healthcare context of an LMIC (Participant D) 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 [73]. In this study however, 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 (Participant D).

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. Indeed, critical information can be lost in translation (Boeijen and Stappers, 2011), as described in

Participant B's excerpts. A tactic to lessen this loss was to introduce a prototype during the engagement to provide a tangible object for discussion, which enabled stakeholders to more accurately and precisely communicate their viewpoints (Participant B). 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 [27,29].

Yet, 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 [37,76,77]. A prototype presented to different audiences can yield variable, and sometimes conflicting, feedback [23]. Mohedas et al., 2014, described a situation similar to the participants', 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 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) (Participant B). 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 [64]; this approach also contributed to building trust and establishing credibility with stakeholders, necessary aspects of co-creative design processes, especially when designing cross-culturally [78]. Our findings highlight that practitioners must approach the use of low-fidelity prototypes intentionally when engaging with stakeholders to take advantage of the aforementioned 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 [22,73] 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 [73]. Lastly, cultural gaps can lead to miscommunications, notably when a designer attempts to convey concepts to stakeholders by using the designer's cultural framework [78,79]. Presenting physical 2D prototypes (sketches and storyboards) and renderings with a relevant background picture depicting the environment of use or depicting a use case, diminished the risk of such miscommunications occurring (Participant D).

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 (Participant C). 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 [71], 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 [31], although in a global health context, funders were more often external to the company and provided support through grants. In a global health context, participants also used prototypes to gain endorsement from government stakeholders (Participant D). Hence, the stakeholders from whom global health practitioners must gain "buy-in" from appear to be somewhat specific to the global health setting (grant funders and government stakeholders).

Participants also described engaging support stakeholders (students and hackathon participants) to crowdsource design efforts and obtain university resources [22,80]. However, these types of partnerships are not without challenges (e.g., remote design [10], commercialization [81].

When participants lacked resources to build prototypes (Participant A) 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 [37], hence, design practitioners should carefully consider the appropriateness of the prototype form for the stakeholder engaged. A last 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 [33]. The smaller global health companies in the study's sample operated in price-sensitive markets that generated lower returns [82], two reasons that 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 medical device designs, user needs, and context.

## 3.5 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 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 the posed interview questions. Although most activities described were first-hand experiences, some were second-hand descriptions, which may have further altered the veracity of the descriptions. Additionally, while participants were probed to discuss front-end practices, the definition of front end was not bounded to problem definition and participants were free to interpret what they considered to be front-end design.

There are further limitations regarding the study sample. At the time of the interviews, all but one participant were working in a high-income country, designing for an LMIC. Therefore, this study does not accurately represent the practices of participants that design within LMICs. Furthermore, this study did not provide in-depth descriptions of the strategies, stakeholders, and prototypes. Lastly, further research is necessary to fully capture designers' behaviors with respect to strategic planning and execution of front-end prototyping behaviors with stakeholders, and how these behaviors transfer across industries, geographies, and design cultures.

## 3.6 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 designer practitioners engage 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 travelled 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 render lower quality feedback; feedback from stakeholders unfamiliar with the context can lead to the elicitation of less useful or incorrect information, whether proxy users or US 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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## Chapter 4 Stakeholder Perceptions of Requirements Elicitation Interviews With and Without Prototypes in a Cross-Cultural Design Setting

***Abstract*** – Using prototypes during design requirements elicitation (RE) interviews with stakeholders can encourage stakeholder participation. Stakeholder engagement and the quality of the feedback provided can be influenced by the format of the RE interview, especially in a cross-cultural design setting. Although the selection of design practices is typically motivated by designer preferences and design outcomes, deliberate consideration of stakeholder preferences and perceptions may lead to a more nuanced understanding of when and how to best leverage particular design practices. This study investigated the influence of the number of prototypes (here, assistive devices for removing subdermal contraceptive implants) presented during RE interviews on Ghanaian stakeholder preferences. The findings revealed that most participants (n=34, 94%) preferred the presence of one or more prototypes compared to no prototypes during the interviews because prototypes enabled participants to better understand the design space, provide accurate feedback, and evaluate ideas. Prototypes provided participants with a basis for answering designers' questions. When they were not provided with a prototype, participants explained that they imagined a novel device concept or recalled a device from prior experiences. Further, participants preferred the use of three prototypes versus a single prototype because multiple prototypes enabled them to compare across designs and make choices. These findings suggest that designers seeking requirements-related input from stakeholders at the problem definition stage should consider using one or more prototypes, unless they are interested in collecting design ideas from stakeholders.

***Keywords*** – Stakeholder preferences, prototypes, requirements elicitation, interview, cross-cultural design

## 4.1 Introduction

Health technologies can contribute to achieving the Sustainable Development Goals [1], but many existing technologies fail to affect global health issues because they do not meet the needs and context for which they are intended [2]. The success of a design process hinges on successful execution of its early phases [3]. Requirements engineering is a key component of early design phases, involving the iterative discovery, development, and management of requirements [4]. Requirements engineering supports designers in defining the wants and needs of various stakeholders of a project [5]. The development of quality user requirements and their translation into engineering specifications minimizes disparities between user needs and product attributes [6]. However, incomplete and unclear requirements can cause project failures [7].

Many methods facilitate the elicitation of requirements from stakeholders including interviews, focus groups, laddering, clustering, scenarios, contextual inquiry, and storytelling (e.g., [8]). Some studies have compared the relative effectiveness among methods. For example, Pitts and Browne showed that certain types of interview questions, such as procedural prompts which are based on typical reasoning patterns, lead to the elicitation of more meaningful requirements [9]. Davis et al. conducted a review of requirements elicitation (RE) techniques and concluded that structured interviews were the most effective [10]. Engelbrektsson studied the effect of showing different product representations (images versus a real-size functional model) to stakeholders on the feedback received during a focus group and found that different representations led stakeholders to focus on different parts of the design [11].

Interviewing is one of the most effective and widespread RE methods, often structured around pre-determined questions with the option to pose targeted follow-up questions with the potential to lead to open-ended discussions [10]. Interviews can be time- and resource-consuming and access may be a challenge with specific stakeholder groups [12]. There are a variety of approaches that can support effective interviews. The effectiveness of an interview depends on the quality of the interview questions, the experience of the interviewer, and on the expressiveness of stakeholders, i.e., their willingness to share their thoughts [10]. Several guidelines exist to increase the expressiveness of stakeholders. Such guidelines include building rapport and fostering conversation, asking open-ended questions, asking about experiences, encouraging storytelling, and asking probing questions (e.g., [9]).

A study by Wolgemuth et al. investigated the impact of various interviewing methods on the experiences of interview participants [13]. The authors showed that the space given to participants for reflection during the interview, the topic of the interview, and the number of times participants were interviewed impacted participants' perceptions of the interviews. However, these findings relied on interviews of disenfranchised populations and/or were about sensitive topics, rather than design interviews. To the best of our knowledge, there is no prior research that has investigated participant perceptions of design interviews. Understanding stakeholder perceptions and experiences of engagement methods can provide insight into the best methods to use.

Representations and artifacts can aid perceptual and cognitive processes and can be useful during interviews [14]. Prototypes—representations of an idea, such as drawings, physical models, or storyboards—are leveraged by designers throughout a design process to gather feedback from stakeholders [15]. Prototypes can be used to provoke discussion during an RE interview [8]. Prototypes can encourage stakeholders to "play an active role in developing requirements" [16].

The use of prototypes to elicit requirements has been documented. Prototypes have helped uncover "taken for-granted issues" and "unknown unknowns" and resulted in the discovery of knowledge about the primary function and environment of the system [17]. The tradeoffs from the perspectives of the interviewees of using or not using a prototype during RE interviews have not been described.

The use of prototypes during RE interviews may help overcome barriers to stakeholder engagement in cross-cultural design and Engineering for Global Development (EGD) settings. Indeed, in EGD settings, the following barriers to designer-stakeholder interactions include: language barriers (native and/or disciplinary) between designers and stakeholders; different conventions around design processes and design methods [18]; perceived hierarchy between designers and stakeholders that can hinder the ability of stakeholders to provide candid feedback [19]; and cognitive biases that influence designers' processes, including biases related to their background and experiences [20]. These barriers can lead to miscommunications between designers and stakeholders, especially during early design phases [21]. Miscommunications occur in cross-cultural design when designers convey concepts to stakeholders using their own cultural framework [22] and have been reported during feedback sessions [23].

Although the use of prototypes during interviews may serve as a tool to support the "leveling of the playing field" between designers and stakeholders [24], prototypes could further distance and intimidate stakeholders (e.g., similar to the negative impact caused by the use of technical jargon during a stakeholder interview) rather than empowering stakeholders to more clearly identify their wants and needs, if not used properly. Hence, an investigation into the appropriateness of prototype usage for RE interviews in a global health context is needed.

Furthermore, the use of multiple prototypes during usability testing has been shown to increase the quantity and quality of feedback received [25] and improve designers' abilities to act upon the feedback received [26]. However, no studies have investigated the effects of using multiple prototypes during RE interviews on stakeholder experiences or responses, despite their demonstrated benefits to designers during stakeholder engagement activities.

Hence, this study leveraged interview transcripts from 36 participants who participated in two RE interviews in a cross-cultural setting, each with zero, one, or three prototypes, to investigate stakeholder perceptions of RE interviews with and without prototypes. The study further investigated relationships between the presence of zero, one, or three prototypes on stakeholder responses. The preliminary results shed light on the effects of using prototypes as facilitation tools during early stakeholder engagement activities in an EGD context.

## 4.2 Materials and methods

### 4.2.1 Research aims

This study aimed to characterize participants' perceptions of prototypes during RE interviews and the effects of prototypes on participants' answers to RE interview questions. The RE interview questions used in this study were focused on three early stage medical device concept solutions aimed at supporting the removal of long-term contraceptive implants by healthcare practitioners in Ghana. The research questions motivating this study were:

- How do stakeholder perceptions vary as a function of the number of prototypes shown during a cross-cultural RE interview?
- How does the use of zero, one, or three prototypes during a cross-cultural RE interview influence how stakeholders answer questions?

#### 4.2.2 Participants

Thirty-six nurses, midwives, doctors, and biomedical engineering students from the Korle Bu Teaching Hospital in Accra, Ghana and the Komfo Anokye Teaching Hospital in Kumasi, Ghana were recruited for this study. Participants were interviewed after providing oral consent and received a small gift for their participation. Participants had between 8 months and 28 years of experience in their respective occupations (with the exception of the biomedical engineering students), and most participants had either performed, assisted, or seen the removal of a contraceptive implant. Two participants were not familiar with contraceptive implant removals and were shown a storyboard explaining the procedure. The study participants were largely representative of the target users of the device concepts discussed during the interviews.

Based on their experiences, participants were sorted into three groups: untrained participants had not been formally trained in contraceptive implant removal procedures; trained but not practicing participants had been formally trained but had performed fewer than five implant removal procedures; practicing participants had been formally trained and were performing implant removal procedures regularly (and had completed more than five at the time of the interview). The breakdown of participants into these three groups is presented in Figure 11.

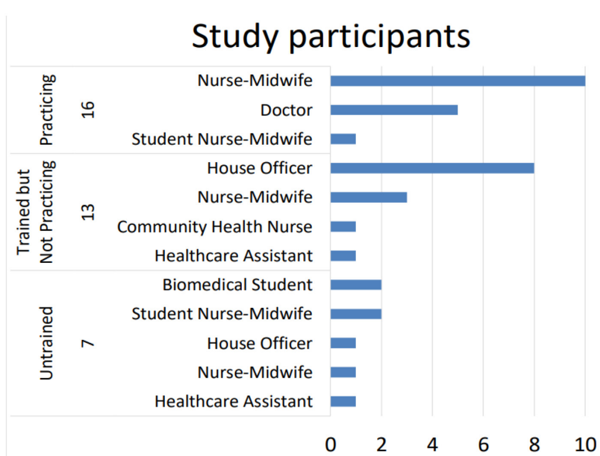



*Figure 11: Participant groupings and professions*

### 4.2.1 Data collection

Participants partook in two interview parts and answered reflection questions. Each interview part focused on one of three different contraceptive implant removal device concepts. Long term contraceptive implants are small rods that release hormones for three to five years and are inserted under the skin of a woman's upper arm. This method of contraception requires little maintenance, which makes it appealing in settings where access to healthcare is limited [27]. However, contraceptive implant removals are currently only performed by highly trained healthcare providers, hence limiting the widespread adoption of implants. The early stage device concepts used in this study aim to increase accessibility to contraceptive implants by enabling lesser-trained healthcare workers to remove implants.

The three device concepts used during RE interviews were:

- a device concept to help determine whether the depth of the implant is shallow—and therefore safe to remove—or deep—therefore requiring referral (relevant to all participants);
- a device concept to help remove palpable contraceptive implants that were properly inserted (relevant to all participants);
- a device concept to help remove deeply inserted implants, which is a result of an error at the insertion stage (relevant to practicing participants).

Each interview consisted of three parts:

- participants were interviewed about an initial device concept (referred to as part one);
- participants were interviewed about a second device concept (referred to as part two);
- lastly, participants were asked reflection questions.

The device concepts used during the interviews were chosen based on relevance to the particular stakeholder groups, and the order of the device concepts presented was randomized. Most interviews were conducted back-to-back. However, in a subset of cases, participants completed part two of the study at a later time, i.e., a few hours up to a few days, following the completion of part one of the study due to scheduling constraints. Three low-fidelity prototypes (i.e., non-functional, 3D prints or modified existing products) were developed for each of the three device concepts. The prototypes were developed to have a similar level of fidelity and are depicted in Figure 12. A subset of participants (19) had previously participated in student-designer led interviews focused on device concepts to help remove palpable contraceptive implants. In order to limit the effects of the previous interactions on this study, the researchers presented different prototypes from those previously shown as part of the student designer interviews.

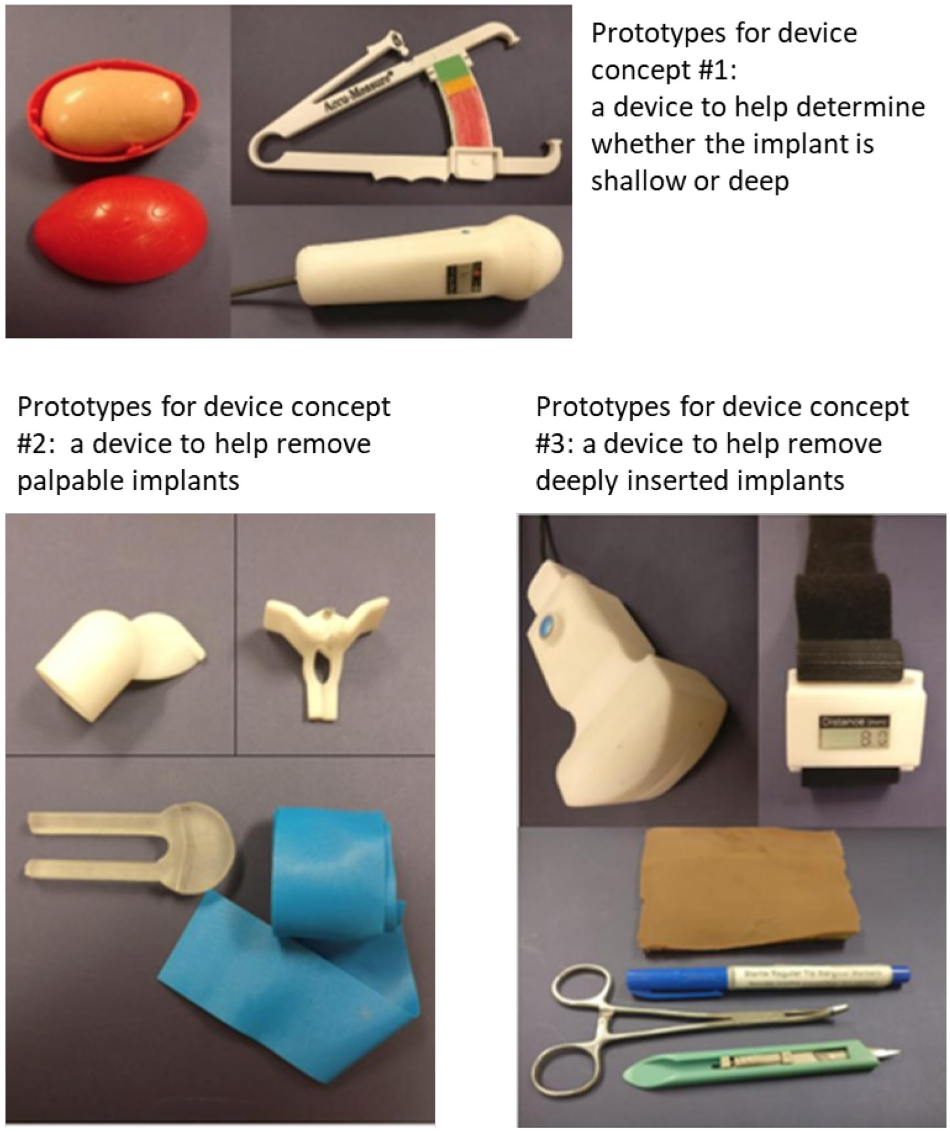



*Figure 12: Photographs of the nine low-fidelity prototypes used during RE interviews*

During each part (one and two) of the RE interview, participants were shown a different number of prototypes (zero, one, or three prototypes) following a minimization strategy to ensure even distribution among device concepts and the number of prototypes shown. When one or three prototypes were shown, the prototype(s) was/were first thoroughly described to the participants using scripted text. Participants were then asked 22 questions, the first two of which were tailored to the specific design concept being presented, while the remaining 20 were standard questions.

Questions included:

- *Who do you think should use the device? Why?*
- *Could you explain to me what you think an ideal device should do?*
- *What could cause the device to fail?*

The interview protocol was informed by Garvin's eight critical dimensions of quality (performance, features, reliability, conformance, durability, serviceability, aesthetics, and perceived quality) [28] and by a framework for contextual medical device design in low-resource settings [29]. Six pilot interviews were conducted prior to data collection. All interviews followed the same structured protocol and were performed by the same researcher.

At the end of part two, participants were asked the following reflection questions about the number of prototypes presented during parts one and two:

- *Was seeing prototype(s) helpful for answering the questions? Why or why not?*
- *What was the difference in the way you answered when you did not see a prototype versus when you saw one (or three) prototypes? (adapted for each participant)*
- *When conducting this type of interview, should I show your colleagues prototypes? Why or why not?*

#### 4.2.2 Data analysis

The interviews were audio-recorded, transcribed, and deidentified. To answer the first research question, we relied on the answers to the reflection questions posed at the end of part two. The responses to the reflection questions were coded inductively—a process during which the researchers established themes based on interpretation of the transcript data. The themes that emerged from the reflection questions were iterated on once and are reported in the results section.

To answer the second research question, the interview transcripts were analyzed following a deductive coding process whereby excerpts were categorized using pre-established categories.

The deductive codebook is presented in Table 10. The codes in Table 10 were developed to identify how prototypes were used by participants to answer questions (codes 1 through 4) and to gauge the level of engagement of participants during the interview (codes 5 and 6). To perform statistical tests, we grouped the interview parts during which one and three prototypes were presented into one treatment group because of the small sample size of the study. We performed t-tests to determine statistical significance among the counts for the codes in Table 10 when showing zero prototypes compared to showing one or three prototypes.

## 4.3 Results

### 4.3.1 How do stakeholder perceptions vary as a function of the number of prototypes shown during a cross-cultural RE interview?

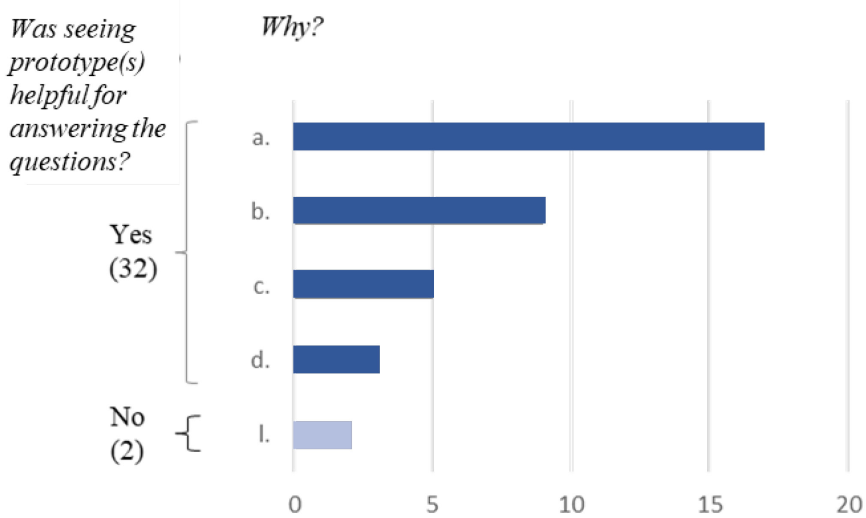
Most participants (n=34, 94%) preferred being shown prototypes to not being shown prototypes; and preferred being shown multiple prototypes over being shown only one. Participants shared a variety of reasons for why they liked being shown prototypes. In the following section, we report participants' responses for each reflection question.

When asked, *"Was seeing prototype(s) helpful for answering the questions? Why or why not?"* most participants (n=34, 94%) answered positively, and two participants answered negatively. The reasons given by participants are categorized in Figure 13.

Two participants (6%) did not think being shown prototypes was helpful to answer questions because they said they could rely on their experience. The first participant was a senior nurse-midwife who had started performing removals a year prior to the study, and the second participant was a doctor with six years of removal experience and 19 years of job experience.

*Table 10: Deductive codebook: codes, definitions, and example excerpts from the interview transcripts*

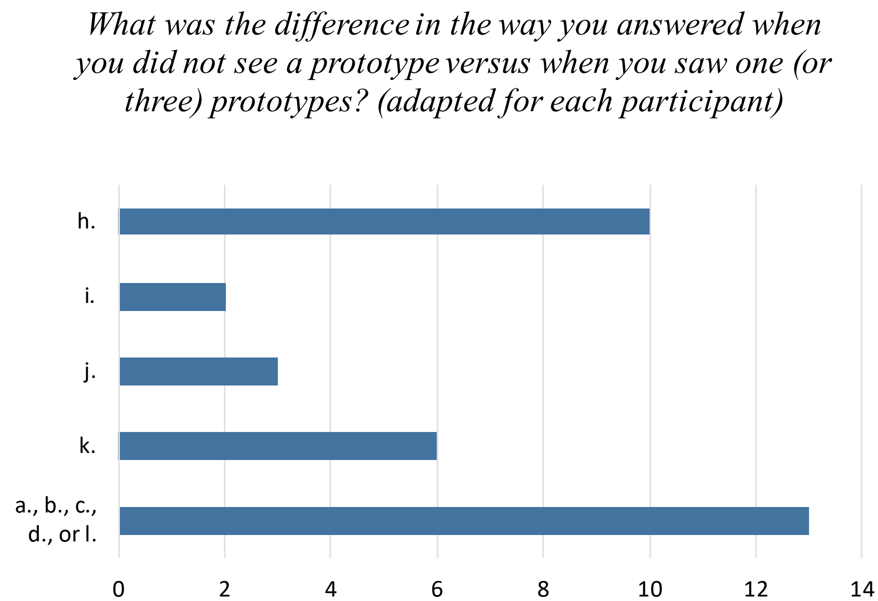
| **Codes** | **Definition** | **Example** |
|---|---|---|
| 1. The response was based on the prototype(s) shown | The participant referred to the prototype(s) shown or a part of the prototype(s) shown when answering. | *"I think we should use it once because it is made of plastic, so it should be disposable because if you cannot autoclave this, it will probably melt."* (participant 14, 1 prototype) |
| 2. The participant could not answer without more information | The participant said they could not answer the questions because they had not seen the device in question. | *"The device has not come so I would not know"* (participant 12, 0 prototypes)<br>*"I think we would have to try it first (short laughter)"* (participant 16, 1 prototype) |
| 3. The response was based on a previous prototype or device | The participant referred to a device previously brought by a University of Michigan student or a device they had knowledge of when answering. | *"The other one you came with (...), when you locate where the implant is, it exposes the tip, (...) so you could see that it makes it easier to remove it, (...), so that was what I was picturing when you asked me the question."* (participant 17, 1 prototype) |
| 4. The participant pictured a novel device | The participant described a device that is novel (and different than a prototype shown). | *"I am picturing ... it looks more like the artery forceps but has a longer edge such that it can go a bit deeper but does not cause much pain or injury to the person."* (participant 7, 0 prototypes) |
| 5. The participant asked a clarifying question | The participant asked a clarification question about the prototype(s), or about the question asked. | *"Are they disposable?"* (participant 1, 3 prototypes)<br>*"if you say medical device, meaning something that we put on the skin and is it going to take it out or…?"* (participant 5, 0 prototypes) |
| 6. The response was vague and/or did not address the question | The participant provided a vague answer that did not directly address the question asked. | *"I cannot think of anything"* (participant 15, 1 prototype)<br>*"the negative effect will be like the one who inserts, and it was so deep, the first provider who did the insertion is so deep for the client."* (participant 35, 1 prototype) |
| 7. The response was justified | The participant provided a justification for their answer | *"It [should not] last for long before doing it because when there is a difficult removal and we do not get any device to show, and it is going to take time, so it saves time and then it is easy, it makes even the client feels comfortable when it is easily removed."* (participant 29, 0 prototypes) |




a. Participants said they could understand what the device(s) looked like and how to use it (them).
b. Participants said it was easy to answer questions and give accurate answers.
c. Participants said they could judge if the device would be helpful or not.
d. Participants said they could understand what the designer sought to achieve.
l. Participants said that being shown prototypes was not helpful.

*Figure 13: Transcript-level counts of participant responses to the first reflection question*

When asked, *"What was the difference in the way you answered when you did not see any prototypes versus when you saw one (or three) prototypes?"* 13 participants justified their answers with similar themes that emerged as responses to the first question. However, other responses also emerged, categorized in Figure 14.




h. When being shown zero prototypes, participants said they had to imagine a device before they could answer the questions.
i. When being shown zero prototypes, participants said they recalled a device previously brought by students.
j. When being shown one prototype, participants said they imagined other devices to compare the prototype to.
k. When being shown three prototypes, participants said they compared and chose the best prototype. a., b., c., d., or l., Previously stated reasons.

*Figure 14: Transcript-level counts of participant responses to the second reflection question*

When asked, *"When conducting this type of interview, should I show your colleagues prototypes? Why or why not?"* most participants (30) answered positively, i.e., that it would be best to show prototypes to colleagues during an RE interview. The breakdown of the participant answers is summarized in Figure 15.

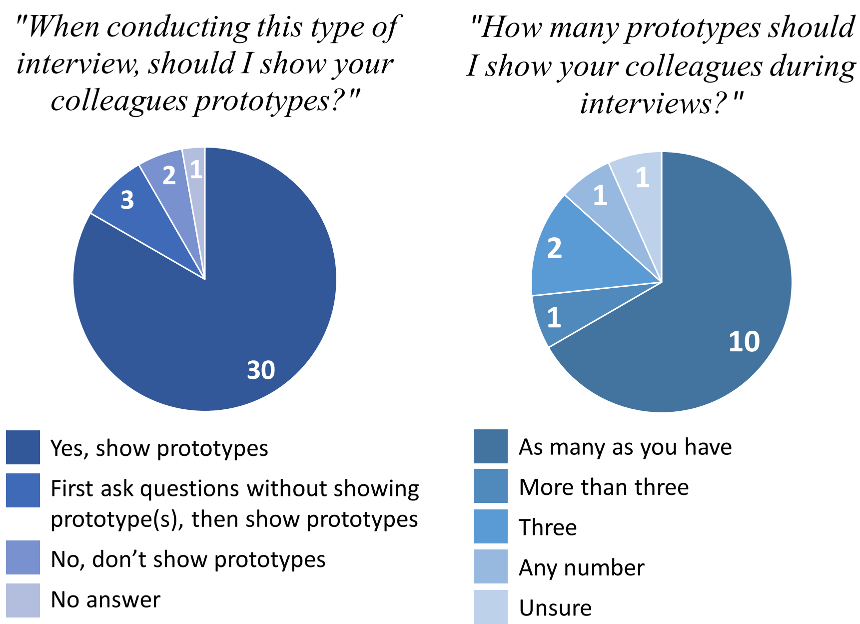



*Figure 15: Participant responses to the third reflection question*

Two participants responded that it would be best not to show prototypes to colleagues when conducting RE interviews. Three participants thought it would be better to first ask questions without showing a prototype, then to introduce prototypes. These five participants believed that designers should try to first elicit unbiased answers and ideas from the interviewees. One participant did not answer.

Participants who believed their colleagues would benefit from being shown one or more prototypes provided similar justifications to those provided for the first question (25). However, a new reason emerged: Participants said that prototypes helped them generate new ideas / expand their imagination (5).

A subset of participants (15) was asked how many prototypes should be shown to their colleagues during a similar interview. Their answers are also summarized in Figure 15. A summary of the participants' perceptions of RE interviews with zero, one, or three prototypes, as reported by the participants, is given in Table 11, along with illustrative examples and transcript-level counts of participants who cited the reason in response to any of the three reflection questions.

*Table 11: Participant answer categories to the reflection questions, illustrative examples, and transcript-level counts of each category*

| **Participant Answer Categories to Reflection Questions** | ***Example*** | **#** |
|---|---|---|
| a. When being shown one or three prototypes, participants said they could understand what the device(s) looked like and how to use it/them. | *"When you see it, it is easy to make a comment on it."* *"As you showed me the prototypes for detection, I had an idea as to how they look like."* | 19 |
| b. When being shown one or three prototypes, participants said it was easy to answer questions and give accurate answers. | *"It helped me answer the questions."* *"Seeing those would help […] better giving you the right answers."* | 13 |
| c. When being shown one or three prototype(s), participants said they could judge if the device would be helpful or not. | *"I think you should show them because seeing it will enable me to know whether it is going to be useful or not."* | 7 |
| d. When being shown one or three prototype(s), participants said they could understand what the designer sought to achieve. | *"Initially I did not have any idea it was about the removal, I just knew it was about implants, so my answers were not specific about the design. When I saw it, I understood it was not just about the depth; it was also about removing."* | 11 |
| e. When being shown one or three prototypes, participants said they gave answers based on the prototype(s) shown. | *" I was able to talk based on these ones that you showed me."* | 3 |
| f. When being shown one or three prototypes, participants said the prototypes helped them generate new ideas / expand their imagination | *"If you bring possible solutions, people can become more imaginative and critic and try to select and try to give suggestions to improve. (…) It is good to have prototypes instead of talking into the vacuum."* | 5 |
| g. When being shown zero prototypes, participants said they had to rely on their experience to answer questions. | *"Before I saw [the prototype], I was answering it based on my experience."* | 3 |
| h. When being shown zero prototypes, participants said they had to imagine a device before they could answer the questions. | *"If [the prototype] is not there, you need to picture, but I do not have anything in my mind now."* | 10 |
| i. When being shown zero prototypes, participants said they recalled a device previously brought by students. | *"I have seen some products the one you brought, so I was picturing that one."* | 2 |
| j. When being shown one prototype, participants said they imagined other devices to compare the prototype to. | *"Okay, if I see different types, it will help me to choose the ones that will best be useful."* | 3 |
| k. When being shown three prototypes, participants said they compared and chose the best prototype. | *"I had options with the three; I can actually tell that, okay, if it were me, I would go for the middle one. If you had given me only one, like this one, I would have based all my answers on this even though in my mind, I feel it is not durable."* | 12 |
| l. Some participants said there were no differences in the way they answered, or that prototypes were not useful to answer questions | *"My answers were more or less determined by the questions. […] I do not think [the different prototype numbers] really affected the answers so much."* | 5 |
| m. Non-informative responses | *" It was quite helpful in terms of the fact that we have had difficult removals, so anything that comes up is welcome."* | 9 |

### 4.3.2 How does the use of zero, one, or three prototypes during a cross-cultural RE interview influence how stakeholders answer questions?

To answer this question, we relied on the counts of the deductive codes, which are summarized in Table 12. Three results showed statistically significant differences between interview parts when zero prototypes were shown and interview parts when one or three prototypes were shown:

- the participant could not answer without more information when zero prototypes were shown versus one or three (code 2, $p<0.05$);
- the participant pictured a novel device concept when zero prototypes were shown versus one or three (code 4, $p<0.001$);
- the participant asked a clarification question when zero prototypes were shown versus one or three (code 5, $p<0.05$).

When one or three prototypes were presented, the participants used the prototype(s) as a basis for their response (code 1). Participants relied on the current prototype form to inform their answers and referred to the prototype(s) shown. However, when a prototype was not shown, participants responded in one of three ways: they could not answer the questions (code 2); they created a novel image of a device concept (code 4); they recalled past devices they had seen (code 3).

*Table 12: Counts of the deductive codes and p-values of the t-test comparing zero-prototype interviews with one-or-three-prototype interviews. Both the number of responses and the number of participants (in parenthesis) are reported.*

| | 1. The response was based on the prototype(s) shown | 2. The participant could not answer without more information | 3. The response was based on a previous prototype or device | 4. The participant pictured a novel device | 5. The participant asked a clarifying question | 6. The response was vague and/or did not address the question | 7. The response was justified |
|---|---|---|---|---|---|---|---|
| 0 prototypes (24 interviews) | 0 | 18 (6) | 6 (4/12) | 14 (14) | 37 (18) | 31 (15) | 24 (180) |
| 1 prototype (25 interviews) | 79 (25) | 4 (4) | 8 (7/13) | 5 (5) | 77 (23) | 49 (20) | 25 (201) |
| 3 prototypes (23 interviews) | 102 (22) | 2 (1) | 3 (2/14) | 2 (2) | 77 (21) | 37 (17) | 23 (175) |
| t-test (0 versus 1&3 prototypes) | N/A | p<0.05 | | p<0.001 | p<0.005 | | |

Nine participants said they could not answer the question without more information about the prototype (code 2, p<0.05). Of the nine participant, six participants said they could not answer when they were shown zero prototypes, while five participants stated that they could not answer the question without more information when they were shown one or three prototype(s) during the interview (two participants are double counted). In the instances when these participants were shown one or three prototypes, the participants communicated that they needed to see the prototype(s) in use or use the prototype(s) themselves to answer the question.

Eleven participants who had previously been exposed to a device concept presented by student designers recalled that particular device concept during a part of the interview (code 3).

There was no statistically significant difference between the number of recalls when zero prototypes were shown compared to when one or three prototypes were shown.

When answering question 19, "When I asked you this last question, were you picturing anything?" participants who were not shown a prototype broadly described novel device concepts that they pictured, at significantly higher rates (code 4, $p<0.001$) than when they were shown a prototype. When participants were shown a prototype, most explained that they relied on the prototype(s) presented when answering questions, while only a few said they imagined a novel or improved device concept.

We did not observe a significant effect of the presence of prototypes on the number of vague responses (code 6) and on the number of justified responses (code 7). However, the presence of a prototype increased the number of clarification questions asked by participants significantly (code 5, $p<0.005$). Participants mostly asked questions after the prototypes were presented to clarify their use.

### 4.4 Discussion

This preliminary study explored stakeholder perceptions and experiences during an RE interview in response to being shown zero, one, or three prototypes. The results revealed that a majority (n=34, 94%) of participants preferred being shown one or more prototypes during the interview. Prototypes enabled participants to: understand the device concept(s) and how to use the prototype(s) (Table 11, a.); understand what the designer sought to achieve (Table 11, d.); and answer the questions with ease and provide accurate feedback (Table 11, b.). Furthermore, prototypes aided participants in the evaluation of ideas. For example, participants noted that they could assess the utility of the device concept (Table 11, c.), and compare and select the best concept when they were presented with three prototypes (Table 11, k.). The presence of prototypes made participants feel like they were able to provide more useful responses. Most participants also preferred being shown multiple prototypes (Figure 13), because it enabled them to compare and select design ideas. Based on these findings, the incorporation of multiple prototypes into an RE interview may facilitate the active participation of stakeholders during the problem definition phase of a design process.

Furthermore, this study explored the effects of the presence or absence of prototypes on how participants answered questions. Participants asked significantly more clarifying questions when they were shown prototypes. The additional clarifying questions were often about the prototype(s), demonstrating a desire to better understand the device concept presented during the interview. Two additional significant outcomes emerged when no prototypes were shown: 1) participants could not answer without more information and 2) participants pictured novel devices. This study, however, did not reveal an effect of prototypes on the number of justified answers or the number of vague and irrelevant responses. We find overall consistent alignment between what stakeholders said when answering the reflection questions (research question 1, 3.1) with what they did during the RE interviews (research question 2, 3.2).

These results suggest that participants may benefit from having a mental model of a concept solution when answering design-related questions. Mental models are representations of the form and/or functions of the systems one interacts with, created to make sense of the world [30]. Indeed, when one or three prototypes were shown during the RE interview, most participants gave answers based on the prototypes(s) shown (code 1, Tables 1 and 3). Prior literature describes prototypes as tools for creating a shared mental model between parties. Representations in design enable all parties involved to access information and to contribute to the process, thereby influencing the design [31]. By externalizing an idea and representing it through a prototype, designers make the ideas accessible to others and "foster a shared mental model of the design object" [31], which participants relied on to answer questions. These results suggest that prototypes may alleviate some of the additional challenges of cross-cultural design (language barriers, different conventions around design methods, perceived hierarchy between designer and stakeholder, and cognitive biases) that can lead to miscommunications.

Additionally, stakeholders may rely on a different mental model when one is not provided for them. Results suggest that in the absence of a representation of the device concept, participants drew from other sources to create a mental model. For example, some participants stated that they imagined a device concept (Table 11, h.) or recalled a device previously presented by design students (Table 11, i.) prior to formulating a response. Likewise, when answering the reflection questions, three participants explained their need to picture a different device concept to compare with the single prototype shown (Table 11, j.). In these scenarios, participants may have created a new mental representation of a device concept or drew from past experiences with relevant devices if they were able to provide a response to the question posed. In some cases, in the absence of a prototype, participants could not answer the question (Tables 11 and 12).

Constructing mental models based on past experiences is an active and complex process [31]. The use of representations significantly increases the ability of someone to describe a mental model, the ability of others to understand it, and the ability to think of alternative options [32]. Without a representation, participants may have conjured a mental representation, a substantial cognitive task. Hence, presenting one or more prototypes may ease the mental load of stakeholders during stakeholder engagement design activities. Some studies investigated the effect of having a shared mental model in and across design teams [33]. However, limited studies have investigated related designer-stakeholder interaction applications. Instead, in the field of human-computer interaction, where user mental models are an essential consideration in designing interfaces, studies have investigated methods to elicit a user's mental model [34].

These results further suggest that the introduction of one or more prototypes at the beginning of an RE interview may negatively affect concept generation by stakeholders during the engagement, which has previously been observed by Sarvestani et al. [35]. Most participants who reported imagining a novel device concept were not shown a prototype during that particular part of the RE interview (Tables 1 and 3, code 4). Five participants suggested not showing prototypes to other stakeholders during an interview, or to begin the interview without prototypes and introduce them later during the interview in order to first gather stakeholder ideas. However, five participants noted that prototypes helped to expand their imagination, thereby facilitating concept generation during the interview (Table 11, f.). Although this sentiment was shared by a minority of the participants, it is important for the designer to consider the potential advantages and disadvantages of each approach (showing or not showing prototypes). If a goal of the interview is to gather stakeholder ideas, then starting an RE interview without a prototype might be advisable.

### 4.5 Limitations

A limitation of the study is that the majority of the two interview parts were conducted back-to-back, which may have affected the responses to the second device concept presented, during part two. However, the order in which participants were shown prototypes was randomized to minimize potential effects. Furthermore, the three device concepts used as a basis for the interviews were similar and sometimes caused confusion regarding the need being addressed. Hence, participants who were shown one or three prototypes during part one of the interview may have used one or more of the prototypes as mental models for part two of the interview.

## 4.6 Implications

This study has implications for design practice. The findings may impact how designers and engineers choose methods for engaging stakeholders during RE activities based on their objectives. The results also reveal how stakeholders may use product representations during interviews to create or support mental models, which, in turn, may affect the formulation of their responses. These findings can inform design processes for cross-cultural and remote design, notably in a global health setting, during which stakeholder engagement activities might be brief, infrequent, and for which communication is harder [19].

## 4.7 Conclusion

Current research lacks descriptions of how the presence of prototypes during cross-cultural stakeholder engagement activities affect the experiences of the stakeholders. To partially address this gap, this preliminary study described how the use of one or three prototypes influenced participants' experiences during an RE interview, as well as how it affected their responses to RE interview questions. The results revealed that a majority of participants found it helpful to be shown a prototype when answering questions, and that being shown three prototypes was preferable to being shown one prototype because three prototypes enabled participants to compare and choose. The findings suggest that the prototype(s) provided a shared mental model for the participants and interviewee, without which participants may have either created a new mental representation of a device concept or drew from past experiences with relevant devices if they were able to provide answers to the questions. To study the transferability of these findings, future research should explore the effects of using prototypes during early design phase interviews with different stakeholder groups for various design projects, both in cross-cultural and intracultural settings.

**4.8 Acknowledgements**

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# Chapter 5 Using Quantitative Stakeholder Engagement Methods with Prototypes to Inform the Design of a Novel Tool for Electronic-Waste Workers in North-East Thailand

***Abstract*** **–** In this chapter, we present two analyses of a research project carried out in Thailand between August and December 2019. The project was carried out in partnership with Mae Fah Luang University in Thailand. We aimed to design a novel tool for a community of electronic waste workers in North-Eastern Thailand. In Part 5.1, we present the results of a conjoint experiment conducted to elicit worker preferences. Based on the conjoint results, we designed and manufactured the tool preferred by participants. In Part 5.2, we present the results of a Becker-DeGroot-Marschak auction mechanism which elicited willingness to pay for the tool, and study the effect of receiving the tool on injuries and productivity one-month post-auction.

***Key words*** – conjoint analysis, product representation, Becker-DeGroot-Marschak auction mechanism, electronic-waste recycling

## 5.1 Product representations in conjoint analysis in an LMIC setting: comparing attribute valuation when three-dimensional physical prototypes are shown versus two-dimensional renderings

### 5.1.1 Introduction

Many products developed for low-resource settings with demonstrated benefits still retain very low adoption rates even when distributed for free. Examples can be found for water filtration devices [1], cook stoves [2,3], and bed nets [4], among others. Some studies have investigated and documented the reasons for low adoption, a main reason being the lack of good contextual design

[5]. Gathering reliable user data in developing settings may be challenging because of the lack of infrastructure usually relied on in developed countries such as receipts, web traffic, and household economic surveys [6]. Researchers are increasingly using diverse methods to understand consumer preferences and estimate demand curves in developing settings [6]. The main methods used to model consumer behavior are discrete choice experiments (DCEs) and conjoint experiments (CEs). While there is overlap between these two methods, in this paper we discuss rank-based (or rating-based) CEs, different from traditional choice-based methods in DCEs.

CEs provide a means of investigating relative preferences (trade-offs) across attributes of goods or services and are widely applied in marketing research [7,8]. Marketers have traditionally employed such methods to assess consumer trade-offs for product features in developed settings [9,10]. In addition, CEs have been commonly used in transportation, psychology, environmental valuation, municipal planning and others [11,12].

CE is a method for estimating consumer preferences for product or service attributes. Consumers are presented with alternative profiles with varying attribute levels and are asked to choose their preferred profile. Conjoint analysis assumes that consumers make choices based on the sum of utilities derived from specific attribute levels of a product or service. The goal of conjoint analysis is to estimate the utilities for each attribute [8].

CE is increasingly being used in Low- and Middle-Income Countries (LMICs). However, conjoint-based studies have mainly been studied in High-Income Country (HIC) settings; there have been very few studies reported of CEs applied in a LMIC setting [13]. In LMICs, CEs have been used in agriculture [14,15], for clean water initiatives [12], and in the transport and tourism sectors [16,17]. The use of CEs in LMICs has also been reported for health policy and planning questions, where it appears to be of growing interest [18,19]. Moreover, Baltussen and Niessen, 2006, argued that choice experiments, as a technique for undertaking multi-attribute analysis, should be used more routinely to guide resource allocation decisions in the field of global health [20].

The challenges of CEs in LMICs relate to different cultural or language settings, low levels of literacy, and the novelty of market research techniques [13]. The literature on CEs in LMICs suggests that participants can state their preferences on health service provision and areas for policy reform [13,18–21]. The results also suggest that the preferences are reasoned and deliberate. Hence, CEs seem to be a sensible choice of methodology for consumer preferences data collection in LMICs.

However, there is also concern over CE validity, since the outcomes of CE rely on participants being able to respond according to their true preferences [22]. The parameters of CE, such as the response format [23], the attributes and levels included [24], and the order of presentation of attributes [25], have been shown to affect participants' revealed preferences during a CE.

Product representation is one such parameter that has been shown to affect participant preferences [26]. Product representation concerns the way in which the attribute levels in a CE are presented. Typical representations of products or services in CE consist of verbal descriptions of the attribute levels, presented as a list, which might be complex and hard to understand [22]. Verbal descriptions could lead to misinterpretations, especially in a cross-cultural setting, where designers from HICs are conducting CEs in LMICs [27]. The use of pictures have been recommended when conducting CEs in LMICs [27]. However, using images could lead participants to focus on aspects of the product that are irrelevant to the CE [22]. Research in engineering design has also shown that a prototype form can impact the feedback received by stakeholders in other methods such as usability testing [28] and interviews in an LMIC setting [29].

Very few studies consider the population characteristics in which the CE is being performed and the impact that may have on the outcomes of using different CE designs [30]. We cannot assume that the research on product representation is transferrable to an LMIC context, where familiarity with the method of CE and local contextual factors could influence the outcomes.

In this study, we proposed to examine the impact of conducting a CE with 3D physical prototypes versus 2D renderings with verbal specifications and we analyzed the impact on participant responses. The present paper reported the results of two different representations on the estimated utilities of the attributes. This study contributes to the limited literature on the effect of product representation on CE outcomes in an LMIC setting.

### 5.1.2 Background: product representations in CEs

The impact of various product representation in conjoint analysis on the valuation of product features has been studied across product types. One might think that the ideal product representation would be a high-fidelity physical model. For example, Dominique-Ferreira et. al., 2012, used real water bottles to conduct a CE on bottle preferences [31]. However, creating physical products for a CE comes at a high cost in time, money, space, and logistics because of the number of product variations that need to be created [32]. Hence, creating physical prototypes for all product variations is often infeasible. Because of the high cost associated with creating physical models for every feature level association of most products, various studies examined the impact of product representation on the outcomes of CEs [32], with the goal of understanding what product representations can lead to reliable results at an affordable implementation price.

Some consensus exists around visual CE, where objects are represented with 2D images, as a way to accurately describe product aesthetic preferences while "effectively addressing the limitations of physical prototyping, focus groups, and traditional conjoint [with verbal descriptions]" [32]. However, research has also shown that introducing images in a CE may lead participants to evaluate 'accidental details,' a by-product of introducing imagery that carries more information that listing features and levels [26,33]. For example, showing physical prototypes that were not the final product led to a lower performing utility model due to the low-fidelity nature of the prototype regarding functional attributes, even when participants were asked to disregard those and concentrate on aesthetic evaluation [26]. Vriens et al., 1998, concludes that pictorial representations do improve participants' understanding of the attribute levels being tested as compared to verbal representations. However, verbal representations seems to make it easier for participants to make choices [34]. Hence, the use of rendering software to produce photorealistic images of products for CE still comes at a higher cost than using verbal descriptions [34] and might introduce bias into the attribute evaluation by participants.

Some studies have investigates experiential CEs, where participant experience part of the product they are evaluating, for example, through virtual reality [32]. CEs have also been used earlier in a design process to elicit customer preferences for experiences, by evaluating storyboard scenarios later translated in product features [35]. Other novel product representations include short videos [36], and a multimedia online buying environment meant to increase realism [37].

Much of the research on product representation in CE has examined the impact of product representation on aesthetics evaluation [38–41]. When designing in LMICs, different cultural and language settings, low levels of literacy, and the novelty of market research techniques [12] are reasons to hypothesize that the product representation may lead to misunderstandings and miscommunications between designers, marketers, and users, which will impact feature evaluation. Meyer and Rosenzweig, 2016, presented tools to use when conducting CEs in developing countries and recommend translating attributes into images [27]. Indeed, prototypes have been shown to be powerful communication tools and can aid stakeholders in understanding the concepts and ideas of the designer and actively participate in the design process [42]. Hence, showing prototypes in CEs could increase the mutual understanding between designer and user.

### 5.1.3 Methods

This study aimed to answer the following research questions: ***What is the effect of product representation in a CE in an LMIC low-resource setting on the estimated utilities for product attributes?***

A CE was conducted to better understand electronic-waste recycling (e-waste) workers' preferences for features of a new cutting tool. E-waste recycling involves the dismantling of various electronic components such as refrigerators, fans, washing machines, and televisions to retrieve and sell various materials including steel, copper, aluminum, plastic, PCB, screen, and cables. The informal e-waste sector is less regulated [43] and the rate of worker injury is much higher than in formal sectors [44]. Multiple stakeholder engagement activities over a year revealed increased risk when workers dismantle stators, depicted in Figure 16. Figures 16 and 17 also illustrates tools used by participants. E-waste workers in our sample bought their own tools and maintained them by regularly sharpening them. Hence, they were regularly making purchase choices and evaluating the tradeoffs in their choices for tools and were a good population for a choice experiment to reveal tool preferences. The preferences revealed through the CE then led to the design of an optimized tool, which was manufactured and distributed to half the sample through an auction experiment.

A total of 105 participants conducted a baseline survey and 83 participants conducted the 3D CE (i.e., with physical prototypes). Both activities were conducted during a field trip in August 2019. A subset (17) participants were not available to conduct the CE with physical prototypes at that time and instead conducted the 2D CE (i.e., with paper prototypes) during a following field trip in November 2019.

*Figure 16: E-waste worker dismantling a stator with a blade and hammer (left). Set of typical tools used to dismantle E-waste (right).*

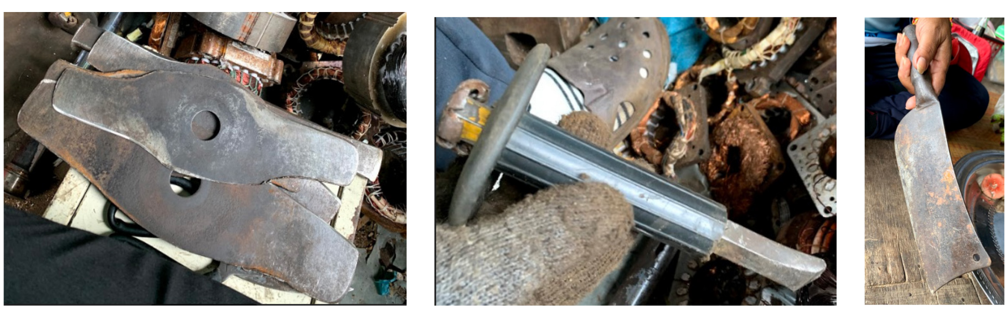

*Figure 17: Close-up of typical tools used to dismantle e-waste (from left to right: blade, chisel, knife)*

#### *5.1.2.1 Study design*

Multiple interviews with workers and feedback sessions on early tool designs were conducted prior to the beginning of the experiment. The goal was to establish which characteristics of the tool were important to the e-waste workers and which characteristics impact safety and productivity. Table 13 summarizes the attributes of the tool and their respective levels. The attributes were selected to represent the major design choices that would have a large impact on usability (mainly impacted by handle position, blade length), safety (guard), durability (blade thickness), and price (blade length, blade thickness, guard). The number of attributes and levels resulted in 24 different tool designs at 4 different prices for a total of 96 possible alternatives. A rank-order design was chosen, where participants were presented with a subset of five knives and were asked to rank-order the different alternatives. Participants were presented with a total of three sets of five knives. This CE design was chosen to gather more information in a short amount of time, given the field constraints. The sets of knives were randomly generated.

*Table 13: Tool attributes and respective levels. Prices in Thai currency, US$ 1 = THB 30.34.*

| **Attribute** | **Description** | **Levels and coding** | | **Expected coef. sign** |
|---|---|---|---|---|
| **Price** | Purchase price | Continuous variable in THB (100, 200, 300, 400) | | Negative |
| **Handle position** | Handle positioned at the top (mimicking a chisel design) or side of the blade (mimicking a knife design) | Top = 0<br>Side = 1 | | Positive |
| **Blade length** | Length of the cutting blade: short 4”, medium 7”, and long 9” | BL1 | Medium= 1<br>{Short, Long} = {0,0} | Positive |
| | | BL2 | Long = 1<br>{Short, Medium} = {0,0} | Positive |
| **Blade thickness** | Thickness of the cutting blade | Thin (0.8mm) = 0<br>Thick (3mm) = 1 | | Positive |
| **Guard** | Presence or absence of a hand guard to both protect from hammer hits and reduce vibrations | Absent = 0<br>Present = 1 | | Positive |

### *5.1.2.2 Estimation procedure*

Given that participants’ utility functions are not directly observable, we indirectly estimated aggregate utilities by observing participants’ ranks when presented with sets of five tools. The model results in an estimation of the influence of the product attributes on participant choices. We assumed that participants could rank possible alternatives in order of preference and follow a logical process of choosing options that were more desirable.

$U_{ij}$ is the unobserved utility of tool $i$ for participant $j$ which was posited to be some function of the product attributes. Because $U_{ij}$ is not directly observable, we decomposed the utility into two components,

$$U_{ij} = V_{ij} + \varepsilon_{ij}, \qquad i = 1, 2, \dots, k; \qquad j = 1, 2, \dots, n \tag{1}$$

In equation (1), $V_{ij}$ is the observable utility for individual $j$ for tool $i$. We introduced a stochastic element $\varepsilon_{ij}$ which captures the unobservable part of the utility [45]. We assume the weighting scheme was the same for all participants. The goal was to estimate the factors $V_{ij}$ given observations of participants' preference rank order for tools. We assumed that $V_{ij}$ is linear and that the parameters were additive. Hence, $V_{ij}$ was composed of a vector X of tool attributes and a vector Y of interaction variables that allowed for the preferences to vary depending on a set of participant characteristics.

$$V_{ij} = \beta * X_{ij} + \gamma * Y_{ij} \tag{2}$$

Because participants were given three choice sets of five tools, we applied a random effect logit model to account for variation between participants, modeled with $\upsilon_j$:

$$U_{ij} = V_{ij} + \varepsilon_{ij} + \upsilon_j \tag{6}$$

To analyze the data, we fit a rank order logit model also known as the exploded logit model [45], using the *cmrologit* function in *Stata* (Stata Statistical Software, College Station, TX: StataCorp LLC, 2019, release 16). This model is appropriate for the data because it uses rank ordered alternatives, it generalizes a version of McFadden's choice model in the case where alternatives vary for each participant, which is the case of our data (each participant saw different random sets of tools), and data from a same participant are linked together by a case ID variable.

#### *5.1.2.3 Testing the product representation effect*

Two methods of representation of the attribute levels were developed: 3D physical prototypes and 2D renderings made from Computer Aided Design (CAD) models, in order to compare the effect of representation on stakeholder preferences. The 3D prototypes were built using materials from a home-improvement store. The 2D renderings were displayed on a packaging sleeve that mimicked the current blade purchased by participants and provided the specifications of the tool at the bottom of the package rendering, in the same format as the benchmark tool. Examples of the two designs are shown in Figure 18 and a close up of the price representations in shown in Figure 19. We refer to the CE conducted with 3D physical prototypes as the 3D CE and we refer to the CE conducted with 2D renderings as the 2D CE.


*Figure 18: Example trial with five 3D physical prototypes (left) and five 2D renderings (right).*


*Figure 19: Price representation in the 2D rendering (left) and on the 3D prototype (right)*

We expected that the relative weighting of attributes would be affected by the different representations. Here, we formulated two specific hypotheses regarding the change in attribute weighting.

*H1: The weighting of the blade length and blade thickness attributes would decrease relative to the other attributes in the 2D CE.*

Indeed, 2D renderings were less effective at communicating size [46] and blade length and thickness might therefore been significantly less tangible in a rendering than in a 3D prototype representation. We hypothesized that participants will struggle to evaluate the different lengths and thicknesses accurately when shown a 2D rendering.

*H2: The weighting of the price attribute would increase in the 2D CE.*

The price attribute is more accurately represented in the 2D rendering, as it mimics the representation of the price of one of the blades that was used as a benchmark because it was frequently bought and used by participants.

To study the effect of product representation on attribute valuation in the analysis of the CEs, we included interaction variables ($Z_{ij}$ in Equation 2) where all attributes were multiplied by a binary variable (equal to 1 if the product representation is 2D; else 0). The statistical significance of interaction variable coefficients signified that the product representation impacted the valuation of that attribute.

#### *5.1.2.4 Auction experiment and endline survey*

We conducted a Becker-DeGroot-Marschak auction experiment to elicit participants' willingness to pay for the tool, which we present in more detail in Chapter Five, part II. During the auction experiment, 32 participants received the tool. One month later, we conducted an endline survey to measure participants' preferences for the tool, among other outcomes. We asked a subset of questions about tool preferences to both participants who did and did not receive the tool, the visual aids for these questions are included in Appendix G. These questions were based on design questions that remained after receiving some qualitative feedback during the auction experiment and in conversations with the manufacturer. The questions enabled us to further study how preferences evolved after using the tool for some time. A summary of the preference-related questions asked during the baseline, along with the answers to the questions, are included in Table 18 in the results.

#### 5.1.4 Results

In this results section, we first present demographics of participants. We present the random effect logit regression on the rank-ordered data collected from both 3D and 2D CE participants. We present in detail the regression results for the 3D CE and compare the 2D CE results to the 3D CE. Finally, we report the one-month post-auction preferences gathered in the endline survey.

Table 14 displays a summary of participant demographics. The full sample of 98 participants was made up of 42 workers (i.e., participants who were employed in an e-waste firm), and 56 owners (i.e., participants who owned and operated their own e-waste business). A total of 54 participants were male and the average age of participants was 46 years (st.dev. 11). Participants' average income was kTHB 8.7 (st.dev. 15). Only two respondents had never attended school, and 41% had attended secondary school or higher. A majority (61%) of participants stated that e-waste was their main job. The average family size was 4.7 people (st.dev. 2.1).

Participants available during the first field trip were assigned to the 3D CE, participants who were not available during the first field trip but were available during the second field trip were assigned to the 2D CE. We evaluated sample differences based on the available information collected in the baseline survey, including demographics and tool usage to account for potential self-selection of participants whose main job was not e-waste (hence, they were working elsewhere during the first field trip and could not be found) or other non-explicit reasons. The groups were balanced on all measures across participant groups except for age. Therefore, we investigated the effect of age as an independent variable on the regression output.

*Table 14: Group summary statistics by CE design (3D and 2D).*

| | 3D CE (83 participants) | 2D CE (15 participants) | T- or chi-2-test p value |
|---|---|---|---|
| Workers (%) | 42 | 47 | 0.75 |
| Men (%) | 55 | 53 | 0.88 |
| Age (yrs.) | 47<br>(10) | 40<br>(11) | 0.018** |
| Income (kTHB) | 10.6<br>(4.0) | 9.2<br>(4.5) | 0.32 |
| Number of people per household (person) | 4.7<br>(2.1) | 4.8<br>(1.8) | 0.89 |
| Education secondary or higher (%) | 40 | 40 | 0.99 |
| E-waste as a main job (%) | 59 | 67 | 0.58 |
| Tool usage (%) | | | |
| Blade | 72 | 73 | 0.46 |
| Chisel | 84 | 90 | 0.25 |
| Knife | 73 | 75 | 0.23 |

*p<0.1, **p<0.05, ***p<0.01, ****p<0.001
Table notes: Income was winsorized at the kTHB2 and kTHB15 levels, meaning income levels reported as below kTHB2 and above kTHB15 were counted as kTHB2 and kTHB15.

Table 15 reports the CE regression results. The estimates of utilities for the different attributes for 3D CE participants and 2D CE participants are reported in Part A, columns 1 and 2 respectively. To study the statistical significance of the utility estimate differences, we report the coefficients of the product representation binary variable interacted with all attributes, in Part B. of Column 1. The coefficients can be interpreted as utilities for each attribute level.

Furthermore, after running a regression with age as a coefficient interacted with all attribute levels and all 2D interaction regressors, we found that blade thickness interacted with age was a statistically significant predictor of preferences (p<0.01). Hence, we included age as a regressor interacted with 2D, blade thickness, and 2D*blade thickness. The results are reported in Part C. of Table 15.

*Table 15: Regression results for the multinomial logit model with all data*

| **A. Attributes** | **Coefficients (utilities)** 3D (1) | 2D (2) |
|---|---|---|
| Handle in the side position | 1.40**** (0.145) | 2.59**** (0.366) |
| Thick blade | 0.906**** (0.141) | 0.351** (0.147) |
| Blade length | | |
| 9 | 0.692**** (0.160) | 0.725*** (0.262) |
| 7 | 0.371*** (0.124) | 0.461 (0.286) |
| Guard present | 0.433**** (0.0919) | 0.932*** (0.298) |
| Price (continuous) | 0.000305 (0.000411) | -0.000783 (0.00135) |
| **B. Product representation (D)** | **D=2D** | **D=3D** |
| D | 1.43* (0.822) | 18.6**** (1.86) |
| D*Handle in the side position | 1.18*** (0.394) | -1.18*** (0.394) |
| D*Thick Blade | -0.555**** (0.204) | 0.555*** (0.204) |
| D*Blade length | | |
| D*9 | 0.0332 (0.307) | -0.0332 (0.307) |
| D*7 | 0.0904 (0.312) | -0.0904 (0.312) |
| D*Guard present | 0.498 (0.312) | -0.498 (0.312) |
| D*Price | -0.00109 (0.00141) | 0.00109 (0.00141) |
| **C. Age (centered around mean age of 46 years)** | | |
| D*Age | -1.74**** (0.0730) | 1.89**** (0.735) |
| Thick Blade*Age | -0.00405 (0.0128) | 0.0412**** (0.00878) |
| D*Thick Blade*Age | 0.0453*** (0.0155) | -0.0453*** (0.0155) |
| Observations | 1,401 | |
| Cases | 281 | |
| Respondents | 98 (83+15) | |
| Log-pseudo-likelihood | -1088 | |

*p<0.1, **p<0.05, ***p<0.01, ****p<0.001

*Table notes: Part A reports the attribute utilities. Column 1 presents the results with the 3D condition omitted. Column 2 presents the results with the 2D condition omitted. Part B reports the interaction terms between the attributes and product representation. A number of coefficients in Column 2 are reported in grey because they are simply the opposite number of Column 1. Part C reports the effect of Age. Age was centered around the mean age of 46 years, meaning that Age = 0 is equivalent to the participant's age being 46 years. Age = -10 is equivalent to the participant's age being 36 years. A subset of participants did not complete the full three sets of rank ordering when conducting the 3D CE. Hence, the number of observations does not equal the expected 98*15=1,470 observations. Results are clustered at the participant level.*

### *5.1.3.1 3D CE*

Participants saw the most value in the handle in the side position (coefficient = 1.35). Hence, if presented with two alternatives, a participant would choose a tool with the handle in the side position 80% of the time, with all other attributes being equal. A breakdown of probabilities for each attribute is given in Table 16.

*Table 16: Probabilities of choosing a tool with a specific attribute, all other attributes being equal*

| (in %) | 3D CE | 2D CE |
|---|---|---|
| Handle in the side position | 80 | 93 |
| Thick blade (age = 46) | 71 | 59 |
| Long versus short blade | 67 | 67 |
| Long versus medium blade | 58 | 57 |
| Medium versus short blade | 59 | 61 |
| Guard | 61 | 72 |

In order of importance, a thicker blade (utility = 0.906, 3mm compared to 0.8mm), a longer blade (utility = 0.692 for a 9-inch blade), a guard (utility = 0.433), and finally a medium blade (utility = 0.371 for a 7-inch blade), were all attractive attributes for participants. Price was not found to have a statistically significant effect on participants' preferences.

### *5.1.3.2 Comparing 3D and 2D product representation in CE results*

Looking at the attribute valuation of the 2D CE, we found that the order of importance of attributes had changed as compared to the 3D CE results. While the handle in the side position was still the most heavily weighted attribute (utility = 2.59), the guard came in as second most weighted attribute (coefficient = 0.942). The 9-inch blade and 7-inch blade lengths followed with coefficients of 0.676 and 0.486 respectively. The attribute of blade thickness had the lowest coefficient before price (coefficient = 0.351). Lastly, the utility for price, while not statistically significant, was negative. The difference in probabilities associated with each attribute between 3D and 2D CEs is reported in Table 16. For example, with all other attributes being equal, a participant of the 3D CE would pick the knife with a guard 61% of the time, while a participant of the 2D CE would pick the knife with the guard 72% of the time.

Furthermore, we found statistically significant coefficients of interaction variables (Table 15, Part B), namely *'2D * Handle position'* ($p<0.01$) and *'2D * Blade Thickness'* ($p<0.001$). These results implied that the product representation influenced the respondents' valuation of attributes. For blade thickness, the negative coefficient -0.555 signified that the 2D product representation decreases the relative importance of a thick blade by a factor of 1/2.6. In the case of the handle position, the positive coefficient 1.18 signified that the 2D product representation increased the relative importance of the handle in the side position by a factor of 1.9. A visual representation of the attribute utilities is included in Figure 20.

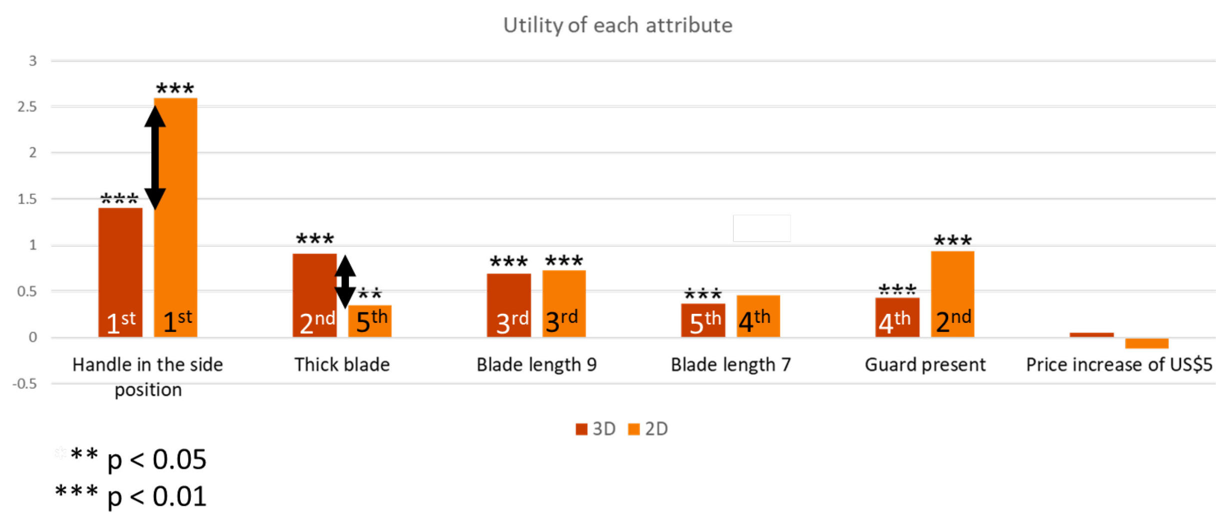


*Figure 20: Attribute utilities and rankings. The statistical significance of attribute valuation differences between 2D and 3D CE results are indicated with black arrows.*

### *5.1.3.3 Effect of age*

The effect of participant's age on the valuation of blade thickness was small and not statistically significant in the 3D CE (-0.00405) but was larger and statistically significant in the 2D CE (0.0412, $p<0.001$). The interaction coefficient between Age and Thick Blade was positive, which meant that as age increases, the valuation of a thick blade increases. For example, since age was centered around the mean of 46 years, a 20-year-old participant had a total utility of -0.720 for a thick blade, while a 60-year-old participant had a utility of 0.928 for a thick blade. Hence, older participants valued a thick blade (positive utility) and younger participants devalued a thick blade (negative utility). The age of 37 is the tipping point, at which utility for a thick blade is 0, and the change of the participant picking a tool with a thick blade over a thin blade is 50%. Hence, a 20-year-old participant would pick a tool with a thick blade over a thin blade 33% of the time, while a 60-year-old participant would pick a tool with a thick blade over a thin blade 72% of the time. Table 17 reports the utilities and probabilities of choosing a thick blade for various ages. On average, a 10 year increase in age results in a 10% increase in probability of choosing a thick blade.

*Table 17: Probabilities of choosing a tool with a thick blade when age is varied, all other attributes being equal*

| Age | Utility for a thick blade | Probability of choosing a thick blade (%) |
|---|---|---|
| 20 | -0.720 | 33 |
| 30 | -0.308 | 42 |
| 40 | 0.104 | 53 |
| 50 | 0.516 | 63 |
| 60 | 0.928 | 72 |

#### *5.1.3.4 One-month post-auction preferences*

We evaluated the aggregated participant preferences one month after the auction experiment (Table 18). We found that participants who had used the tool had significantly different responses than those who had not used the tool for one of the three preference questions asked in the endline survey. Indeed, while we failed to reject the null hypothesis that preferences for blade length were different, we found that participants who had received the tool during the auction preferred a thin a long blade, while participants who had not received the tool preferred a thick and short blade at significantly higher rates. In addition, the preferred width of the blade was also statistically different between participants who had received the tool and those who had not.

We anticipated such differences based off of qualitative evaluation of a video of an e-waste worker (not part of the study sample) who tested the tools before they were distributed in the BDM experiment. We observed that the blade was not wide enough compared to the width of the motor which prevented the worker to cut the motor from a single side. Rather the worker had to turn to motor around to cut from both sides. Furthermore, the blade seemed very thick compared to the space where a blade is typically inserted in a motor for dismantling.

*Table 18: Preference-related endline questions*

| Question | Responses | All participants | Participants who received the tool (54) | Participants who did not receive the tool (51) | Chi-2 p value |
|---|---|---|---|---|---|
| What tool would you prefer? | Thin and long | 45 | 33 | 13 | 0.000236**** |
| | Thick and short | 42 | 21 | 38 | |
| Which blade length would you prefer? | Short | 1 | 0 | 1 | 0.771 |
| | Medium | 51 | 32 | 20 | |
| | Long | 27 | 15 | 12 | |
| | Extra-long | 8 | 6 | 2 | |
| How wide would you like the blade? | Small | 40 | 28 | 13 | 0.00496*** |
| | Medium | 36 | 15 | 21 | |
| | Large | 11 | 10 | 1 | |

*p<0.1, **p<0.05, ***p<0.01, ****p<0.001

We further asked participants to evaluate the safety and durability of the new tool compared to the past blades used on a likert-scale (1: very unsafe/very poor durability, 7: very safe/very durable). The results reveal a statistically significant difference in the safety assessment ($p<0.01$). Indeed, the new tool had a rank of 5.3 on the likert-scale (st.dev. 1.9) compared to 4.1 (st.dev. 2.0) for the prior tools used by participants. There was no statistically significant difference for durability.

### 5.1.5 Discussion

This paper investigated the methodological question of what product representation to use for CEs when eliciting participant preferences in a low-resource setting. Specifically, we investigated the differences in attribute valuation when 2D renderings were shown versus when 3D prototypes were shown. We found that the representation impacted participants' relative weighting of the attributes significantly. We further found that price had no statistically significant effect on participants' preferences.

#### *5.1.4.1 Hypothesis #1: The weighting of the blade length and blade thickness attributes would decrease relative to the other attributes in the 2D CE*

The first hypothesis was validated in part by our findings. The weight of the blade thickness attribute did indeed decrease, but we failed to reject the null hypothesis that the attribute weights are different for blade length (both 9-inch and 7-inch blades). If a designer was deciding which attributes to include in the tool based on priorities, they would have designed different tools if they used 3D versus 2D prototype form: based on 3D CE results, the two attributes with the highest utility were the handle in side position and a thick blade; based on the 2D CE results, the two highest ranked attributes were handle in side position and the presence of a guard.

The difference in relative importance of blade thickness may have been explained by the limitations of 2D renderings for conveying sizes [46]. Indeed, blade thickness was mainly displayed through the shading on the sharpened side of the blade, which might not have communicated the thickness appropriately. Instead, participants may have evaluated the size of the sharpened area rather than the thickness of the blade. Furthermore, the blade thickness specifications were given at the bottom of the rendering, but small measures such as 0.8 and 3mm can be harder to imagine than the larger measures associated with blade length (9-inch, 7-inch, 4-

inch). Blade length differences might also have been more apparent because of the use of empty space in the renderings.

Furthermore, the order of importance was different in the 2D CE compared to the 3D CE results for multiple attributes. For example, the guard attribute was the second most highly weighted in the 2D CE. The increased importance afforded to the guard might have resulted from the high-fidelity rendering in the 2D rendering, while in the 3D CE, the prototyped guards were made from existing tool guards that were cut open and re-fitted on the prototype tool handle, often leading to gaps which created an unfinished look and increased the circumference of the guard making it uncomfortably large. Some examples of the visual differences between the 2D rendering and the 3D prototypes are depicted in Figure 21.


*Figure 21: Examples of representation pitfalls of 2D renderings and 3D prototypes*

#### *5.1.4.2 Hypothesis #2: The weighting of the price attribute would increase in the 2D CE*

The second hypothesis was not validated. The representation of price more accurately resembled real-world prices in the 2D renderings as compared to the prices displayed on the 3D prototypes (see Figure 19 for an illustration of how the prices were represented in both CEs). Different price representations have been shown to impact price valuation [25,47]. However, we were not able to observe an effect of price on preferences. The fact that price had no effect on participant preferences impacted the usefulness of conjoint analysis as it prevented the estimation of willingness to pay for various features and thus, a cost-benefit analysis was not feasible.

The absence of the effect of price in the CE could have been due to the unexpectedly high willingness to pay for the tool estimated during the auction experiment. Indeed, the willingness to pay for the tool was estimated to be 3.5 times higher than the price of the benchmark tool (Chapter Five part II). Furthermore, in the conditions of incomplete information, price could have been used by CE participants as a proxy for quality [47].

#### *5.1.4.3 Other remarks*

The high weight of the handle position attribute was not surprising since the different attribute levels (side position or top position) changed the nature of the tool. For this pool of participants, a handle in the side position was preferred, indicating a preference for a knife-like tool rather than a chisel. We must note that our chisel-like design more radically parted with traditional use cases for chisels than the knife-like design did. Indeed, chisels traditionally have a very short blade, shorter than the handle itself, which was not the case for the chisel-like tools we presented. The knife-like tool more closely resembled tools that participants regularly used, as depicted in Figure 17.

The difference in preference for the tool between participants who had received the tool and those who had not, at the one-month post-use endline, suggested that preferences may change after an experiential evaluation of the product. In our 3D CE experiment design, participants were not allowed to use the tool prototypes. However, introducing an experiential task to the CE could increased the veracity of the CE outcomes. Therefore, we recommend that if any 3D objects are presented during a CE, participants be able to use them to perform common tasks, before stating their preferences.

The field of CE is also calling for more transparency in the methods leading to the selection of attributes and attribute levels. For example, Abiiro et. al., 2014, presented their approach to determining attribute levels through qualitative research methods in detail [48]. Indeed, primary data to establish attributes and levels was critical, because the CE results depend on how the program, product, or service attributes and levels were specified, which required a detailed understanding of the target populations' experience and point of view [12]. In our case, although the choice of attributes and levels were based on qualitative feedback collected during multiple stakeholder engagement activities over a year, some of which included the use of concept renderings, additional attributes to be tested emerged from qualitative feedback during the implementation of the CE. Furthermore, the results of the auction experiment revealed that the levels of the price attribute were not high enough to capture variation in preferences for price, which prevented us from evaluating the cost-benefit of individual attributes. More iteration and piloting of the CE design and materials could have prevented these failures.

### 5.1.6 Limitations

The sample size for the 2D CE was limited and there could have been self-selection into the 2D sample due to unobserved conditions. However, we aimed to reduce the impact of self-selection by testing the balance of participants across both CE groups based on information collected in the baseline survey. Furthermore, participants gave rank-ordered responses. The rank-ordered response format may have impacted the CE outcomes as compared to a traditional choice experiment design, as demonstrated by prior research [49]. However, both CEs were conducted with rank-ordering, mitigating the effect of response type on the evaluation of differences between the outcomes of the different CE groups.

### 5.1.7 Implications

2D renderings are low-cost to make in comparison to 3D prototypes which makes them attractive to use in CEs. However, they might not be adequate prototype forms to test specifications (e.g., thickness or length). On the other hand, low fidelity elements in 3D prototypes might lead to participants devaluing attributes (e.g., presence of a guard was devalued in the 3D CE and valued much higher in the 2D CE). Hence, we recommend levering 2D prototypes when evaluating product features, and using 3D prototypes when evaluating product specifications.

Indeed, if attributes regarding physical dimensions are being evaluated, levels that are very small (a few millimeters) or possibly very large (several meters) might be hard for participants to evaluate accurately. Furthermore, if some attributes are under-emphasized because of product representation, the weighting of other attributes may be over-emphasized, falsely representing participants' preferences. While the 'best' choice might be the same with either representation, the relative importance of the attributes could change, impacting the cost-benefit analysis a designer might conduct if not all preferred attributes can be included in the final product. We therefore recommend using a combination of 2D renderings and 3D product features to satisfy both the speed and low-cost advantages of renderings while enabling participants to have a better sense of product features.

Further investigation of more modular CE designs is needed, where choice alternatives could be presented with 2D renderings (because of the low-cost to create renderings) but that also include physical prototypes to help make the attribute more tangible and where an experiential task is proposed. The use of modular prototypes could also facilitate experiential evaluation of alternatives at a lower cost.

Lastly, the introduction of an attribute which fundamentally changed the use-case for the tool (i.e., handle position at the top or to the side) demonstrated the possibility of using CEs early on, before a product concept has been selected. Indeed, at the time of the CE, it was unclear whether a novel knife-like tool or a novel chisel-like tool would bring about more benefits to users.

### 5.1.8 Conclusion

This paper reports the outcomes of a CE study that investigated whether physical 3D prototypes of choice profiles versus 2D renderings generated differences in estimated utilities. The outcomes of the CE were twofold: they revealed participant preferences for tool attributes based on which we manufactured the best tool for our stakeholders; and we propose the hypothesis that 2D prototypes fare better when evaluating engineering requirements (such as the presence or absence of a guard), while 3D prototypes fare better for evaluating engineering specifications (such as blade thickness and length).

Indeed, using a tool designed for electronic-waste recycling as an example, we found significant differences in the estimation of utilities for three attributes (i.e., handle in the side position, thick blade, and guard). Blade thickness was weighted significantly differently, and the order of importance of guard and long blade attribute were inverted in the 2D CE compared to the 3D CE, which demonstrated a shift in prioritization of attribute levels between the two CE. These results indicate that product representation impacted participants' estimated preferences.

Furthermore, price was not found to have a significant impact on valuation. Such an outcome could have been very detrimental to designers trying to estimate cost-benefits of individual attributes. Hence, more piloting was needed to ensure the price levels and price representation were adequate. Lastly, we found that the aggregated preferences of participants one-month after having received the tool were different than those of participants who did not receive the tool, which illustrated the impact of experience using the tool on preferences.

The methodology presented builds upon existing research on CEs in LMICs to provide designers with new methods for gathering systematic reliable user data in developing settings based on efficient use of resources.

## 5.2 Eliciting and utilizing willingness-to-pay: evidence from field trials in North-East Thailand

### 5.2.1 Introduction

Electronic-waste recycling involves the dismantling of various electronic components such as refrigerators, fans, washing machines, and televisions to retrieve and sell various materials including steel, copper, aluminum, plastic, PCB, screens, and cables [50]. Many informal e-waste recycling firms operate in Southeast Asia, where countries not only recycle their own e-waste but receive huge quantities of e-waste from other countries [51]. The informal e-waste sector is less regulated [52] and the prohibition of informal e-waste recycling has yielded little positive results [53]. Hence, Chi et al., 2011, propose to improve working conditions of informal e-waste firms, among other policy-related strategies to incentivize the increased regulation of the e-waste industry [53].

E-waste dismantling is a difficult and arduous job, especially in informal markets where workers dismantle electronics in unsafe workshops with little protection. Dangers include health impacts due to the pollution of the local environment with heavy metals [54]. Workers also face risk of physical injury to hands and back due to working accidents and repetitive non-ergonomic work. Many e-waste workers use blades to cut parts for most of the day. In an informal e-waste recycling setting, the rate of injuries is high [50]. Many injuries stem from fatigue and from accidents when using tools [50]. Such injuries can impact workers' ability to earn and can impact a firm's revenue.

We set out to create novel tools for a community of informal e-waste workers in North-Eastern Thailand. Technology adoption in firms has historically been very slow [55,56], notably in the field of industrial technologies [57]. For example, Atkin et al., 2017, find that despite clear benefits of a new cutting technology that reduces waste, take-up was low in the study sample. Their findings support the hypothesis that a misalignment of incentives between employers and employees is at the root of the low adoption rate [58].

In our setting, e-waste workers are most often paid a daily rate, which does not create incentives for productivity optimization. The disincentive of workers to disclose how quickly they can work and to share methods to increase productivity has been reported [59]. E-waste firm owners, on the other hand, are paid by weight which creates an incentive for productivity enhancing tools. However, workers might be interested in a tool that reduces injuries that arise from accidents or fatigue-related issues, because it could increase the number of days one could work and earn an income.

Tailoring the design to satisfy safety and productivity requirements for both workers and firm owners could increase the rates of adoption of a new tool. Tailoring technology has been an increasingly used approach in numerous fields, especially in the field of health [60], with a focus on tailoring to racial minorities [61]. In the field of development, numerous technology projects have failed (e.g., cookstoves, water purification) due in part to the lack of tailoring of technologies [62]. Johnson and Bryden, 2014, emphasize the importance of developing technology that meets local needs and fit the local context [62].

Hence, we studied the demand for, and impact of, a new e-waste recycling tool, tailored to stakeholder preferences. The project was created through a partnership between Mae Fah Luang University in Thailand and the University of Michigan in the United States. We conducted a field experiment with 105 e-waste workers in rural Northeastern Thailand. A prior analysis of differences in preferences for a new tool to dismantle e-waste between workers and employers was conducted and we found few significant differences in preferences [63]. Therefore, we designed a single tool for both workers and firm owners. The tool consisted of a knife-like blade with a handle and guard that provided additional protection from accidents and from vibration-related fatigue.

After several design iterations through field work experiments, including design ethnography, feedback on early renderings, and conjoint analysis to determine preferred features, a knife design was chosen as the best tool to meet participants' needs. We conducted the Becker-DeGroot-Marschak (BDM) auction experiment in an alternate marketplace with play money that could be used to purchase either the tool or a selection of household goods. We gave participants a lump sum of play money to bid on the tool. After participants had placed their bids, we randomly drew a purchase price for each participant. If the participant had bid higher than the draw, they purchased the tool with the play money at the price drawn. Leftover money was spent on household goods. In this way, we randomized access to the tool. We conducted follow-up surveys one month after the sale to collect feedback on the tool and measure usage, injury rates, and productivity.

The study achieved two main goals. First, we measured the demand for a new tool in a population facing choices for tool purchases that affect their productivity and health. Second, we use exogenous variation in tool allocation provided by the BDM auction to estimate the causal effect of receiving the tool on injury rates and productivity.

### 5.2.2 Experimental setting and design

#### *5.2.2.1 Tool design*

An initial needs assessment revealed increased risk of physical injury when workers dismantle stators with a blade and hammer, depicted in Figure 15. The design team proposed multiple concepts of a tool meant to reduce such injuries. The team received feedback on their initial ideas which led to the design of a blade with a handle and hand guard to enable the user to have better control of the tool while distancing and protecting the user from the blade edge and hammer. Figure 22 further displays both current blades used for dismantling motors and the proposed new tool.

#### *5.2.2.2 Data collection and experiment design*

**Participants and Study Setting**

A total of 105 e-waste workers participated in the study. Written consent from all participants was obtained prior to participation. The participants were recruited by the local field team through convenience sampling by leveraging existing relationships in the community.

All participants conducted a baseline survey during a field trip in August 2019. During a following field trip in November 2019, 93 participants participated in the BDM auction experiment: 24 participants took part in a pilot auction experiment on the first day, 69 participants took part in the subsequent two days. One month later, 87 participants took part in the endline survey.

The study team set up headquarters at the local healthcare center and was aided by the healthcare workers in recruiting participants. The study activities were carried out either at participants' workplace or at the healthcare center. Participants were gifted a store-bought chisel (a tool used in the E-waste recycling process) to thank them for participating in the baseline and endline surveys. Participants were provided with lunch when conducting the BDM auction.

*Figure 22: Overview of E-waste tools of interest. Top left: E-waste worker dismantling a stator with a blade and hammer. Top right: Set of typical tools used to dismantle E-waste. Bottom left: Current blades used to dismantle stators. Bottom right: Proposed new tool, locally manufactured, next to a motor.*

### Baseline Survey

All participants (105) completed the baseline survey. Surveys were filled out by field workers for each participant on a printed paper form. Baseline questions consisted of demographic and employment information, common tools used and tasks performed during e-waste work, as well as health and injury information (e.g., general health, e-waste related injuries, severity of injuries). In addition, firm owners answered questions about the firm's finances and throughput, while employees answered questions about general e-waste work (e.g., salary, hours worked, quantities recycled).

**Tool sale**

We elicited participants' WTP through a BDM mechanism [64]. During the BDM experiment, participants stated their bid for the tool (i.e., the highest amount they were willing to pay for the tool). We then drew a random price. If the random price was greater than the participant's bid, the participant did not purchase the tool. If the random price was lower than the participant's bid, the participant purchased the product at the bid price rather than at their initial bid. The participants' utility maximizing strategy is to bid their true maximum WTP, because the stated WTP does not affect the price paid, only the probability of purchasing the tool. BDM field experiments allow for the elicitation of more refined WTP information than in other experimental models. However, BDM is a complex and mentally taxing experiment which might introduce errors. To maintain the relationship with the community, we decided to provide participants with play money (PM) that would be used to conduct the BDM experiment so they would not have to pay with money out of pocket. We created a market in which play money could be used to either buy household goods (e.g., coffee, milk, oil) or buy the manufactured tool. Hence, each participant received PM500 with which they could conduct the experiment. An example scenario is depicted in Figure 23 to illustrate how the BDM experiment worked.

Each sale began with a practice round in which we offered participants the opportunity to purchase a bar of soap with the BDM auction procedure, with provided PM in the amount of PM 50. After the practice round, we offered the manufactured tool using the same BDM mechanism, with PM 500 provided. PM 500 was valued higher than Thai Baht (THB), the Thai currency.

Indeed, on average, the play money prices of household goods available in the alternate marketplace were 25% below local market value. The upper bound was determine based on the average wage (THB 300 per day) and the price of the blade currently used by participants (THB 150).

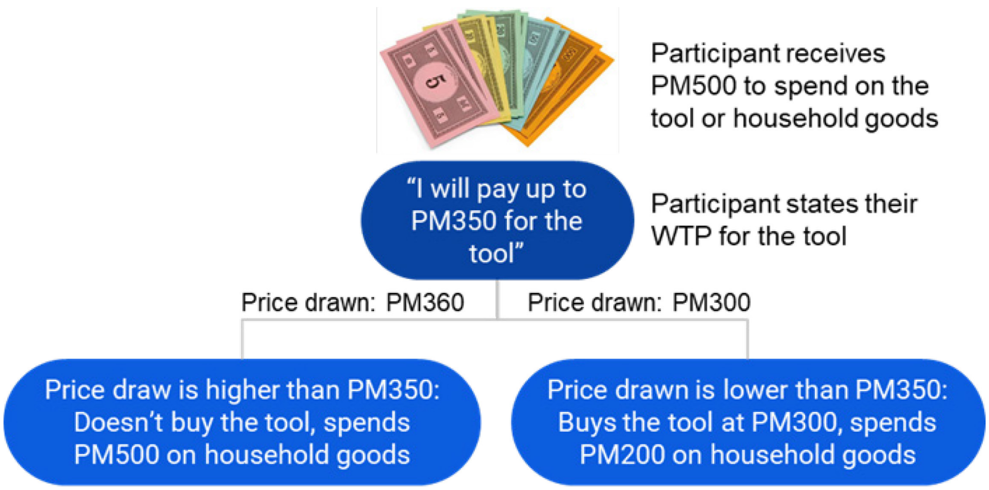


*Figure 23: Example BDM mechanism. Hasbro™ Monopoly Money used as play money in the BDM auction experiment is displayed at the top of the figure.*

If a sale resulted, the participant paid for the tool with the play money and received a manufactured tool. To maintain realism, we used physical bills of play money and exchanged money for goods, whether the tool or the household items.

**Endline survey**

Eighty-seven participants completed the endline survey. Surveys were filled out by field workers for each participant on a printed paper form. Participants answered similar questions to the baseline survey, excluding demographic information (i.e., employment information, common tools used and tasks performed, health and injury information, a shortened section on firm finances and throughput for firm owners, a shortened section on general e-waste work for employees). If they had received the tool during the auction experiment, participants answered additional questions about it. The additional questions related to the tool use (e.g., hours used) and the perception of safety features of the tool (e.g., was the tool perceived to reduce injury rates). All participants who had not received the tool during the auction were given the tool.

#### *5.2.2.3 Summary characteristics and balance*

Table 19 displays summary statistics, with the full sample in Column 1. The full sample was made up of 54 percent owners, 55 percent men, and the average age of participants was 46.3 years. The average household income of participants was THB10,300. Only two respondents had never attended school, and a total of 39 percent of respondents (41) had attended secondary school or higher. A majority (63 percent) of participants stated that e-waste was their main job. The average family size was 4.72 people. A total of 44% of participants had had an injury in the previous month before the baseline survey. Column 2 displays the characteristics of participants who took part in the BDM experiment.

Columns 3 and 4 display the characteristics of BDM participants who did not purchase the tool during the auction and who did purchase the tool during the auction, respectively. Column 5 displays the difference between both groups. Column 6 checks the differences between both groups through t-tests (for averages) and chi-2 tests (for counts) for each characteristic. There were no significant differences at the 0.1 level. In column 7, we check balance of the BDM draw by regressing the BDM draw on a subset of characteristics, including the BDM bid (income and family size excluded because of missing data for 30 participants). Of the five variables in the regression, none were significant at the 0.1 level.

*Table 19: Sample composition and descriptive statistics*

| | Sample composition | | | | Diff. | Regressions | |
|---|---|---|---|---|---|---|---|
| | Full Sample (1) | BDM (2) | BDM did not purchase the tool (3) | BDM purchased the tool (4) | Difference 3-4 (5) | t-test / chi-2 p value (6) | BDM draw reg. (7) |
| BDM bids | NA | 350 (108) | 289 (94.0) | 421 (75.5) | -132 | p<0.001 | p<0.001 |
| Number of bosses | 57, 54% | 35, 51% | 16, 43% | 19, 59% | -3, -16% | 0.181 | 0.261 |
| Men | 58, 55% | 37, 54% | 18, 49% | 19, 59% | -1, -10% | 0.373 | 0.182 |
| Age (yrs.) | 46.3 (12.8) | 46.4 (14.4) | 46.3 (16.7) | 46.4 (11.5) | -0.1 | 0.974 | 0.432 |
| Income (kTHB) | 10.3 (4.14) | 10.3 (4.27) | 10.6 (4.18) | 9.88 (4.41) | 0.72 | 0.537 | |
| Secondary education and above | 41, 39% | 29, 42% | 18, 49% | 11, 34% | 7, 15% | 0.231 | 0.195 |
| E-waste as a main job | 66, 63% | 43, 62% | 22, 59% | 21, 66% | 1, -7% | 0.598 | 0.292 |
| Family size | 4.72 (2.16) | 4.54 (2.18) | 4.20 (2.21) | 4.91 (2.23) | -0.71 | 0.264 | |
| Number of participants | 105 | 69 | 37 | 32 | 5 | | |
| **Health index baseline values** | | | | | | | |
| Injured in the past month at baseline | | 30, 43% | 18, 49% | 12, 38% | 6, 11% | 0.352 | |
| Injury index at baseline | | 8.72 (1.0) | 10.1 (10.2) | 7.28 (7.50) | 2.8 | 0.265 | |
| **Productivity index baseline values** | | | | | | | |
| Productivity at baseline | | 0.0 (1.0) | 0.049 (1.31) | -0.058 (0.42) | 0.11 | 0.671 | |

*Table notes: Columns 1 and 2 display sample means for the full sample and BDM participants, respectively. Columns 3 and 4 display sample means for the participants who did not purchase the tool and participants who purchased the tool during the auction, respectively. Column 5 displays the differences in means between participants who purchased the tool and those who did not (columns 3 and 4). Column 6 displays the results of a t-test or chi-2 test between characteristics of those who purchased and did not purchase the tool (columns 3 and 4). Column 7 displays the results of a regression of BDM draw on the listed characteristics. Standard deviation in parenthesis. * p < 0.10, ** p < 0.05, *** p < 0.01.*

### 5.2.3 Demand for the tool

This section describes the demand for the tool estimated through sales to households during the BDM auction experiment. Figure 24 shows the demand curve generated using all 69 BDM participants. In Figure 24, we plot for each price p the share of participants whose bid was greater than or equal to p. Participants were able to purchase common household good with the play money. The household goods were, on average, priced at 25% below market value (as observed in a local store). Hence, the value of PM 500 given to participant was equivalent to THB 667. The WTP for the tool was much higher than anticipated, based on the price of current tools on the market (the current market price for blades is THB 150). The median bid of PM 395, adjusted to THB 527, corresponds to 350 percent of the cost of the current blades used as a benchmark.

We further plot the price elasticity of demand in Figure 24. In both groups, demand at low prices is relatively inelastic. In fact, demand is price inelastic up to roughly the first quartile value (305) of the WTP distribution. An explanation for high demand could be that individuals may be less price sensitive when spending funds given to them, called the house money effect [65].

Before being told that participants would have PM500 to place a bid for the tool, 58 participants were asked how much they would pay for the tool out of pocket. The average stated WTP was THB 364 (st.d. 148). Without adjusting the play prices to the THB value, 28 participants bid the same amount they stated, 12 participants bid less than what they stated, 18 participants bid more than what they stated. When adjusting the play prices to market prices, 7 participants bid less than what they stated, 51 participants bid more. These results illustrate how stated WTP for a product can shift depending on the parameters of the experiment aiming to reveal WTP.

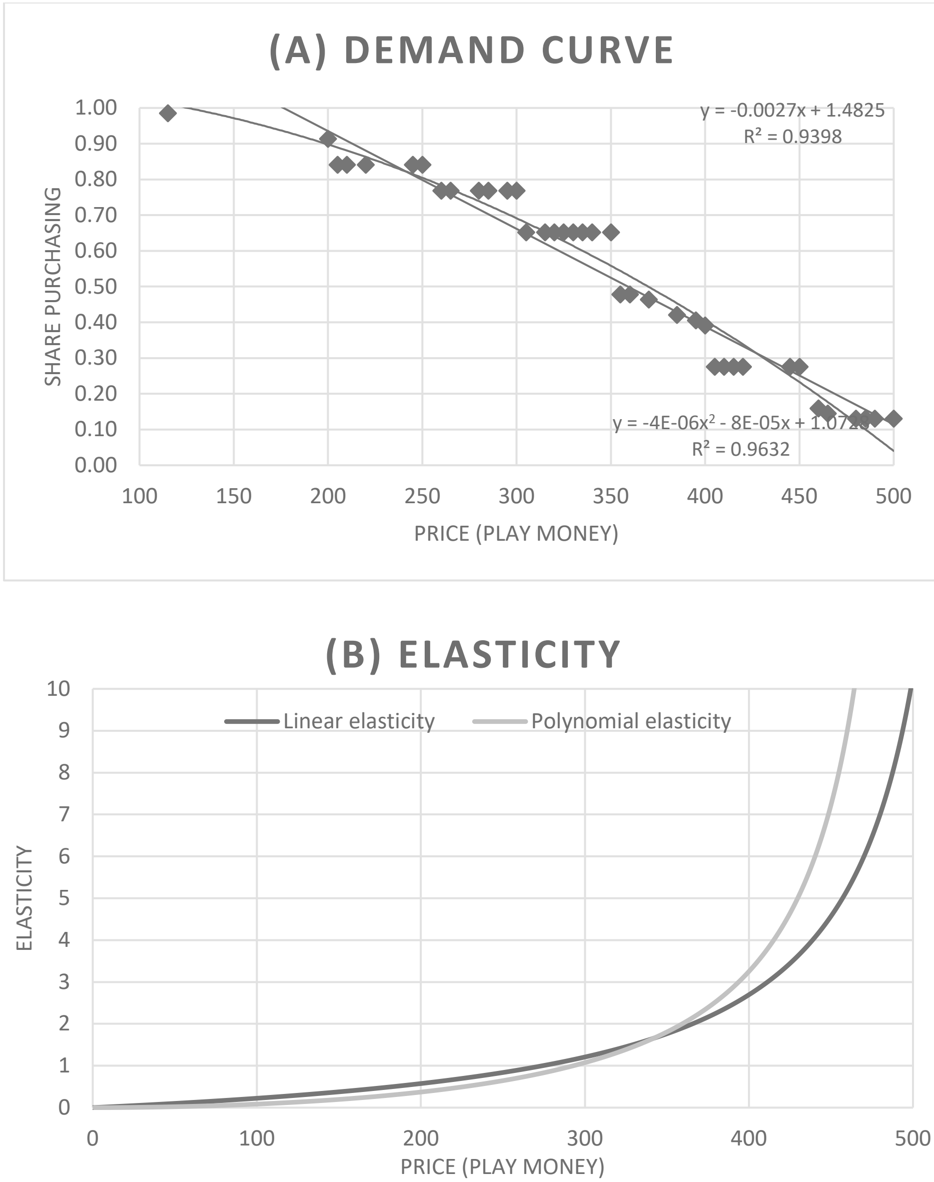


*Figure 24. (A) Demand curve. The data points represent the BDM demand at the randomly drawn prices, indicating the share of participants with a BDM bid greater than or equal to the indicated price. Total of 69 BDM observations. (B) Computed demand elasticities among BDM participants.*

### 5.2.4 Effects on injury and productivity

#### *5.2.4.1 Average effect on injury*

In this section, we look at participant responses regarding injuries related to e-waste work. First, we look at a binary outcome variable that was coded as 1 if the participant had an injury caused by e-waste work in the past month, and 0 otherwise. We also look at a summary injury index that summarized the number of general health issues, number of serious injuries, number of hand or finger injuries, number of near misses, incidents involving damaged property, all within the previous month. To create the summary injury index, we added the five aforementioned responses of participants. We created both an endline and baseline injury index. Participants had to have answered at least one of the endline questions and one of the baseline questions to be included in the sample.

We detail the equation for the treatment effect for the binary indicator for injury. The equation is the following:

$$Inj_{e,i} = \beta_0 + \beta_1 * T_i + \beta_2 * Inj_{b,i} + e_i \tag{1}$$

All variables are binary. $Inj_{e,i}$ indicates whether participant $i$ had one or more injuries in the month prior to the endline. $T_i$ indicates whether participant $i$ has received the tool. $Inj_{b,i}$ indicates whether participant $i$ had one or more injuries in the three months prior to the baseline. $e_i$ captures unobservable determinants of $Inj_{e,i}$. The coefficient of interest is $\beta_1$.

The first-stage equation that serves as an instrument for the treatment variable is the following:

$$T_i = \gamma_0 + \gamma_1 * Draw_i + \gamma_2 * Inj_{b,i} + v_i \tag{2}$$

$Draw_i$ is the BDM draw for participant $i$ and is random and uncorrelated with $e_i$, therefore, is a valid instrument for treatment.

The equation for the treatment effects on the summary injury index is the following:

$$II_{e,i} = \delta_0 + \delta_1 * T_i + \delta_2 * II_{b,i} + \zeta_i \tag{3}$$

$II_{e,i}$ is the endline injury index, $II_{b,i}$ is the baseline injury index.

The first-stage equation is the following:

$$T_i = \gamma_0 + \gamma_1 * Draw_i + \gamma_2 * II_{b,i} + v_i \tag{4}$$

Table 20 presents the results for both two-stage regressions on the binary indicator and on the health index. We ran a two-stage least squares regression in both cases.

*Table 20: Constant-effects instrumental variables estimates for injury.*

| **A. Second Stage Dependent Variable** | **Participant has had one or more injuries in the month prior to the endline** | **Summary injury index** |
|---|---|---|
| | *(1)* | *(2)* |
| Bought tool | -0.0892 | 0.190 |
| | (0.183) | (1.41) |
| Had one or more injuries in the prior three months prior to the baseline | -0.00715 | 0.00224 |
| | (0.143) | (0.0569) |
| Mean dependent variable | 0.47 | 2.9 |
| | | |
| **B. First stage Dependent Variable** | **Participant purchased tool** | |
| Draw (play money) | -0.00438*** | -0.00400*** |
| | (0.0005258) | (0.000549) |
| Had one or more injuries in the prior three months prior to the baseline | 0.167* | |
| | (0.0961) | |
| Mean of take up | 0.46 | 0.46 |
| Wald chi2 | 0.24 | 0.02 |
| Number of participants | 50 | 50 |

** p<0.10, ** p<0.05, ***p<0.01*

*Table notes: Table section A. column 1 displays the results of a two-stage regression of probability of injury in the past month at the participant level on tool purchase. Column 2 displays the results of a two-stage regression of the injury index on the tool purchase. For all regressions, tool purchase is instrumented by random BDM draw. B. displays the results of a probability model first-stage regression, where the dependent variable is an indicator for whether the participant purchased a tool and the independent variable of interest is a randomized price, and the instruments are as in A.*

The draw strongly predicts treatment, with a US$1 (PM 22, THB30) increase in draw price leading to a 9.6% decrease in the probability of buying the tool (from column 1 in Table 20). We use 10 PM = 13.33 THB = 0.45 USD [66]. The likelihood of an injury occurring in the month prior to the endline is reduced by 20% if the participant bought the tool (column 1 in Table 20). Our sample did not permit for statistically significant results. However, the negative value is in the right direction.

However, when investigating the injury index, the coefficient is positive, indicating an increase in probability of injury after receiving the knife (increase of 6.6% injuries when receiving the knife, column 2 Table 20). The conflicting directions suggest that further investigation is needed establish the impact of receiving the tool on injury rates.

Furthermore, further exploration is needed to rule out potential causes for an increased injury rate that are related to having received the tool but not related to the tool design, such as using the tool longer and paying less attention to safety when using the tool, which could have a detrimental effect on the rate of injury. Furthermore, participants who were planning for an increased workload could have had more incentive to place a high bid to receive the tool. Longer work hours increases the chance of getting injured.

#### *5.2.4.2 Average effect on productivity*

To study the impact of receiving the tool on productivity, we created summary productivity index that summarizes: the quantity of e-waste dismantled in the past 2 weeks; the quantity of motors dismantled in the past 2 weeks; the quantity of e-waste dismantled in an average day last month; the quantity of motors dismantled in an average day last month; and the quantity of motors that could have been dismantled in an average day if not limited by stock. To create the summary productivity index, we first normalized the responses to the five aforementioned questions to mean 0 and standard deviation 1. We then summed the responses into a baseline sum and an endline sum. We computed the ratio of endline over baseline sums and normalized the ratio to mean 0 and standard deviation 1. Participants had to have answered at least one of the injury questions in the baseline and in the endline to be included in the analysis. The results are reported in Table 21.

*Table 21: Constant-effects instrumental variables estimates for productivity.*

| **A. Second Stage Dependent Variable** | **Summary productivity index** |
|---|---|
| | *2SLS* |
| Bought tool | 0.871** |
| | (0.411) |
| Mean dependent variable | 0.00 |
| **B. First stage Dependent Variable** | **Participant purchased tool** |
| Draw (play money) | -0.00335*** |
| | (0.000540) |
| Mean of take up | 0.46 |
| Chi-2 | 4.5 |
| Number of participants | 65 |

** p<0.10, ** p<0.05, ***p<0.01*

*Table notes: The table part A. displays the results of a two-stage regression of a summary productivity index on the tool purchase. Tool purchase is instrumented by random BDM draw. Part B. displays the results of a probability model first-stage regression, where the dependent variable is an indicator for whether the participant purchased a tool and the independent variable of interest is a randomized price, and the instruments are as in A.*

The results suggest that receiving the tool increased productivity, the result is statistically significant. Because of the nature of the index, we are unable to interpret the magnitude of the index. Further research is needed to rule out behavior-related reasons for why receiving the tool might have increased productivity. For example, participants could have self-selected into receiving the tool by bidding higher if they knew they were going to have a lot of e-waste work in the next month, based on inventory for example.

### 5.2.5 WTP and use

We analyzed the use of the tool after one month. A total of 44 participants received the tool. One participant who received the tool did not complete the endline survey. 35 participants reported using the tool at least once. The reasons participants did not use the tool were that they did not have any e-waste work that month (5 participants) or they used old tools (1). Fifteen participants reported having stopped using the tool. Reasons participants stopped using the tool were that the tool was not suitable for their type of work (7 – too thick, not sharp, not smooth), the tool was chipping (2), the tool broke (6). On average, participants who used the tool at least once used the tool for 11 days (std 12.5), 5.5 hours/day (std 3.3), for an average of 81.5 hours total (std 97.5). Furthermore, we found that workers used the tool on average 91 hours more than firm owners over one month ($p<0.01$, 31 observations), which might be because firm owners have additional tasks other than e-waste dismantling, such as logistics, management, and paperwork.

### 5.2.6 Conclusion

In this study, we used a BDM auction mechanism to elicit WTP for a new tool for informal e-waste workers in North-East Thailand, designed according to participants' preferences. We studied the impact of receiving the tool at the one-month mark on injury rates and productivity. We find that WTP for the tool was high, corresponding to 350 percent of the cost of a benchmark blade. Under standard neoclassical assumptions of full information, complete markets, and efficient households, a high WTP indicates that the tool has a high effect on worker welfare. Tailoring technology that improves health outcomes to worker and firm owner preferences might help increase interest in the tool (as measured through WTP) and adoption rates.

#### *5.2.6.1 Limitations*

The study limitations include the difference in valuation of the play money as compared to the Thai Baht, which could have introduced additional cognitive load on participants when trying to state their true WTP during the BDM experiment. Furthermore, the results of the analysis of the effects of receiving the tool on injury rates and productivity were based on self-reported data with high variances and a limited sample size. Per the current analysis, we are not able to confidently assess the impact of receiving the tool on the injury rates and productivity of the e-waste workers.

#### *5.2.6.2 Implications*

Throughout this project, we leveraged stakeholder engagement methods to gather feedback from the target users of the tool (e.g., design ethnography activities, surveys, conjoint experiments). Through these activities, we developed a relationship with the local community and tailored the tool to their preferences. Participatory design principles are based on increasing stakeholder participation in a design process [67] with the goal of increasing stakeholder ownership of the project, especially in Design for Development (DfD) [68]. Active participation in the design of tailored technology solutions could be a way to increase adoption.

Furthermore, we used complimentary tools from Engineering Design and Economics to develop a tailored product and study its impact. By leveraging interdisciplinary methods, we propose an approach to early quantitative technology evaluation which could help designers working in DfD to evaluate the benefits of a technology early on and communicate on such benefits to increase adoption.

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### 5.4 Acknowledgements

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# Chapter 6 Discussion: Contributions, Implications, and Future Work

## 6.1 Chapter summaries

### 6.1.1 Chapter Two summary: stakeholders, prototypes, and settings of front-end medical device design activities

The goal of the study presented in Chapter Two was to characterize the prototypes, stakeholders, and settings leveraged by design practitioners for prototype-based stakeholder engagement in front-end design, in the context of medical device design. The study further examined the associations of stakeholders, prototypes, settings, and engagement strategies employed by practitioners. This study aimed to address the following research question: During front-end design activities, what stakeholders are engaged with what prototypes, and in what settings?

Chapter Two reported on a study based on interviews with medical device design practitioners. Twenty-four participants were interviewed, 11 were from medical device companies working specifically to address needs in LMICs, referred to as 'global health' companies. Participants worked in 16 medical device companies, a subset of nine companies were global health companies. Of the seven global health companies, four were small (1-9 employees), and three were medium (10-200 employees). Of the remaining nine general medical device companies, two were small, two were medium-sized, and five were large (1,000 and more employees).

This study explored the variety of stakeholder groups engaged by design practitioners, prototype forms used during the engagement, and settings in which engagements took place. The detailed categories of stakeholder, prototype, and setting are summarized in Figure 25. The findings in Chapter Two further provided insight into associations of stakeholder, prototype, setting, and/or strategy used by design practitioners to support front-end medical device design engagements.

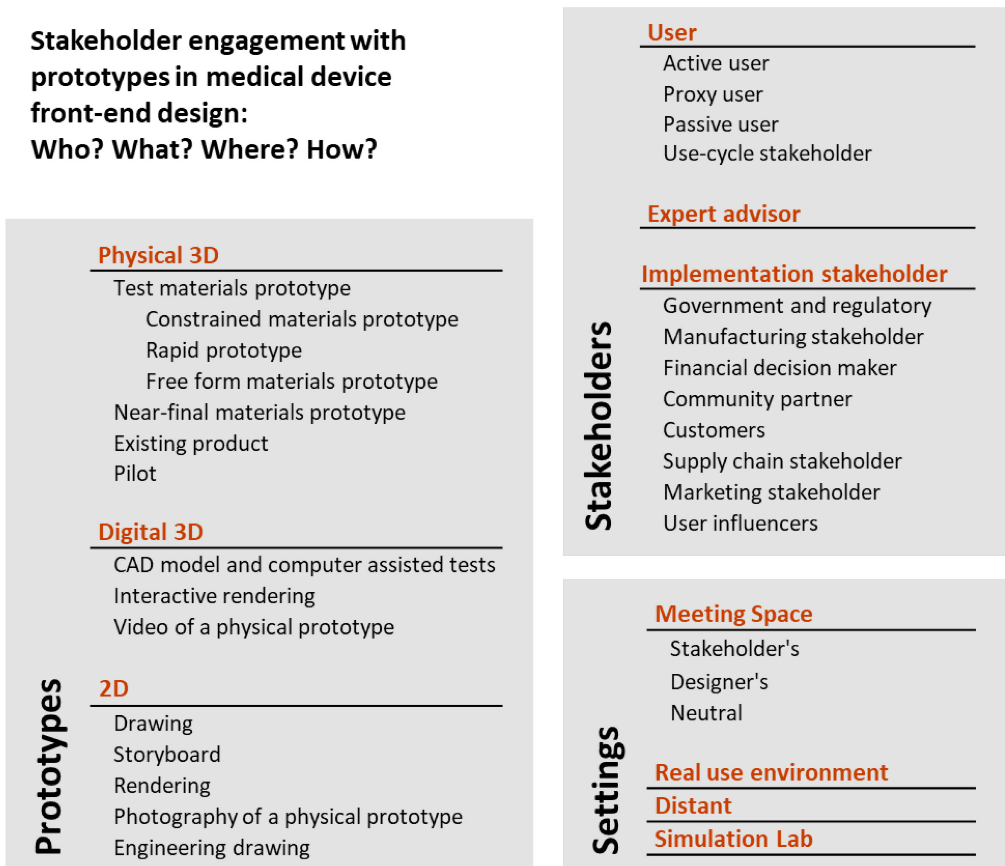


*Figure 25: Stakeholders, prototypes, setting, and strategies leveraged by design practitioners in front-end medical device design*

### 6.1.2 Chapter Three summary: global health front-end medical device design: cases of prototype use for stakeholder engagement

The goal of the study presented in Chapter Three was to examine the practices for stakeholder engagement with prototypes during front-end medical device design in LMIC settings, through four illustrative cases, based on the subset of interviews of global health design practitioners. This study aimed to address the following research question: How do global health design practitioners approach stakeholder engagement with prototypes during front-end design? Of the eleven design practitioners interviewed, all but one worked in an HIC, designing for an LMIC. Engagement events that reflected how the global health setting influenced decisions of stakeholder, prototype, and strategy were extracted and presented as illustrative cases.

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.

The challenges faced by participants and the respective approaches undertaken to address these challenges are summarized in Table 22 (below).

*Table 22: Summary of practitioner approaches to overcome challenges to prototype-based stakeholder engagement in LMICs*

| Objective of participants | Approaches to prototype-based stakeholder engagement |
|---|---|
| Tackling stakeholder remoteness | • Traveling to local settings and partnered with community organizations to access stakeholders<br>o Challenge: Travel to a foreign location involved a lot of resources<br>• Using communication technology to connect with stakeholders remotely using 2D prototypes<br>o Challenge: 2D prototypes could render low-quality feedback<br>• Engaging proxy users who were more readily available<br>o Challenge: Feedback from stakeholder unfamiliar with the context could lead to the elicitation of incorrect information |
| Exploring the environment of use | • Adding elements of the environment into 2D prototype backgrounds<br>• Simulating the environment of use with various low-cost objects<br>• Introducing a physical prototype in the environment of use during an engagement |
| Bridging cultural gaps | • Relying on the prototype as a communication bridge to counteract the information lost in translation<br>• Engaging a wide variety of stakeholders (including government and use-cycle stakeholders) to reveal requirements that might affect uptake but are not directly related to usage<br>• Empowering stakeholders to act on the design by asking them to choose between prototypes and change modular prototypes to their liking |
| Adjusting the engagement to the stakeholder | • Showing polished prototypes to stakeholders less familiar with low-fidelity prototypes<br>• Briefing stakeholders by explaining the prototype form and put the stakeholders at ease<br>• Using prototypes as a persuasion tool to get buy-in from certain stakeholders<br>• Showing 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) |
| Working around the constraints of limited resources | • Leveraging support stakeholders (e.g., hackathon participants and students) to aid in generating ideas and developing prototypes<br>• Using 2D prototypes that are easier to transport and to use in making prototype variations<br>• Showing a single prototype to stakeholders. |

### 6.1.3 Chapter Four summary: stakeholder perceptions of requirements elicitation interview with and without prototypes

The goal of Chapter Four was to investigate a strategy for prototype-based stakeholder engagement that was salient in Chapters Two and Three studies: engaging stakeholders with multiple prototypes. Current research lacks descriptions of how the presence of prototypes during cross-cultural stakeholder engagement activities affect the experiences of the stakeholders. Hence, Chapter Four partially addresses this gap by understanding how stakeholder perceptions vary as a function of the number of prototypes shown during a requirements elicitation interview. The second study goal was to examine how the number of prototypes shown influences how stakeholders answer questions. I explored these questions in a cross-cultural interview setting, where I, as a Western designer, interviewed stakeholders in an LMIC, in Ghana. The use of prototypes in cross-cultural settings could help alleviate some of the additional barriers to effective stakeholder engagement, leading to miscommunications between designers and stakeholders that prototypes may help dampen.

The findings revealed that most participants (n=34, 94%) preferred the presence of one or more prototypes compared to no prototypes during the interviews because prototypes enabled participants to better understand the design space, provide accurate feedback, and evaluate ideas. Prototypes provided participants with a basis for answering designers' questions. When they were not provided with a prototype, participants explained that they imagined a novel device concept or recalled a device from prior experiences. Further, participants preferred seeing three prototypes versus a single prototype because multiple prototypes enabled them to compare across designs and make choices. Overall, the number of vague responses and the number of justified responses, which were both proxies for quality of responses, was balanced across participants. However, the presence of a prototype significantly increased the number of clarification questions asked by participants, which might suggest additional engagement in the interview from participants. Furthermore, when no prototype was presented, some participants could not answer a significant portion of the interview that pertained to the device specifically.

There is, therefore, a tradeoff that designers must make between trying to uncover stakeholders' ideas without biasing them with prototypes while still empowering them to give feedback during a requirements elicitation interview. These findings suggest that designers seeking requirements-related input from stakeholders at the problem-definition stage should consider using one or more prototypes unless they are interested in collecting design ideas from stakeholders.

### 6.1.4 Chapter Five summary representations in conjoint analysis for development engineering applications: comparing attribute valuation when three-dimensional physical prototypes are shown versus two-dimensional renderings

Chapter Five reports on a study conducted in North-East Thailand with electronic-waste (e-waste) workers over the period of August to December 2019. The goal of the study was to design a novel tool for e-waste workers, according to their preferences as elicited through a conjoint experiment (CE), to measure their willingness to pay (WTP) for the tool through a Becker-DeGroot-Marschak experiment (BDM), and to study the effect of receiving the tool on injury rates and productivity through a one-month post-auction survey.

In Part 5.1, I examined how physical three-dimensional (3D) prototypes and 2D renderings with written specifications of attribute profiles in CEs generated differences in estimated utilities. Two independent CEs were run with each representation form, a total of ninety participants across both experiments each ranked three sets of five alternative tool concept solutions from most to least preferred. The results suggested that providing physical 3D representations affected the relative importance of different product attributes. The differences in the relative importance of product attributes may have been explained by the limitations of 2D renderings for conveying sizes. Based on our findings, I recommend careful consideration for product representations – specifically, how well the representations convey all product attributes being evaluated – in conjoint analysis, notably in a cross-cultural context. The results of the conjoint analysis led to the manufacturing of an optimized tool, which was then distributed to half of the sample through a BDM auction experiment.

In Part 5.2, using the BDM mechanism, I estimate the WTP for, and impact of, the manufactured tool. WTP is high relative to the price of other tools usually purchased by workers. The results are non-conclusive with regard to the impact of the tool injury rate. I show, however, that receiving the tool might have a positive effect on productivity. This study investigates the use of quantitative stakeholder engagement tools to support the design of tailored technology that could improve the welfare of disenfranchised populations.

## 6.2 Discussion

### 6.2.1 Differences between global health and general medical device design practitioners

Chapter Two presented the results from the analysis of interview data from medical device design practitioners for firms that design with a focus on both HICs and LMICs. Chapter Three presented the results from the subset of practitioners that design medical devices for LMICs. While both groups leveraged most strategies, stakeholders, prototypes, and settings, some differences emerged, supporting the claim that prototype-based stakeholder engagement approaches change as a function of the context for which one is designing.

Challenges to stakeholder engagement related to their implementation in DfD settings, or low-resource settings, have been reported [1]. These include challenges in getting stakeholders to engage with the design activities, such as in interviews and focus groups, or more participatory activities, such as storyboarding and card sorting [1]. These challenges to stakeholder engagement in low-resource settings have been reported in numerous other studies, where stakeholders defer to the designer and do not feel empowered to meaningfully contribute [2–5]. This challenge was notably observed when carrying out interviews with healthcare practitioners in Ghana, both in cases with and without prototypes (Chapter Four).

Corsini et al., 2019, compile a list of challenges faced by practitioners when applying participatory design principles in DfD settings [1]. The list overlaps with the one reported in this dissertation (Chapter Three) to some extent. Indeed, challenges around building relationships with stakeholders, bridging language and cultural barriers, familiarizing stakeholders to design methods, accessing users, and encouraging stakeholder participation were present in both studies. Corsini et al., 2019, proposed approaches to overcome these challenges based on a case study [1], in the same way that the study in Chapter Three proposes approaches to overcoming challenges with prototype-based stakeholder engagement in LMICs based on the retrospective interviews of 11 global health design practitioners. Other researchers have investigated stakeholder engagement methods specifically adapted to LMIC contexts, such as the Bollywood method discussed in Chavan et al., 2009 [6].

Some differences that emerged from the studies in this dissertation are discussed henceforth. The strategy to "downplay the fidelity of a prototype shown to stakeholders" was never reportedly used by the global health design practitioners. The strategy to "supplement the prototype with additional artifacts and representations" was seldom used by the global health design practitioners, perhaps because of the additional time and resources needed to create additional artifacts and representations. On the other hand, the strategy to "manage group composition and size" was more often leveraged by global health design practitioners, perhaps because when engaging with stakeholders from LMIC countries, they did not have as much control over who was in the room and hence managing the focus group participants was more salient to them, which might also be due to the need to “flatten the hierarchy” [1], a well-reported objective of designers engaging in design for low-resource settings [3,4,7–16].

The stakeholder group engaged by global health practitioners and general medical device practitioners were also somewhat different. Indeed, global health design practitioners engaged more proxy users, community partners, government representatives, and support stakeholders, while multinational participants engaged marketing and internal stakeholders at higher rates. These differences might be due to the setting in which each group operated. Proxy users were engaged when active users were not locally available, which would be the case when a global health design practitioner is designing in her home country for LMICs.

The differences might also be due to firm size. Most global health companies were small or medium size (under 200 employees), and most general companies were a medium-size or a large-size (up to 10,000 employees). When engaging stakeholders in an LMIC setting, global health design practitioners engaged community partners to access users in local hospitals and to gain information locally. At the same time, general firms often had a lot of stakeholders in-house as compared to global health practitioners. For example, manufacturing stakeholders engaged by general practitioners tended to be from the firm’s manufacturing floor, while global health practitioners venture out to find manufacturing stakeholders. Many expert advisors were also hired by general practitioners, while global health companies had to engage academics and external advisors. Internal stakeholders were defined as stakeholders actively employed by the firm developing the device but were not part of the device design and development team.

Finally, general design practitioners used more digital 3D prototypes than global health design practitioners to engage stakeholders, perhaps because the stakeholders engaged were more familiar with CAD models. Global health design practitioners engaged stakeholders in the stakeholders' spaces more often than general practitioners, which might be driven by the amount of travel done by global health design practitioners. Indeed, the latter group engaged many international stakeholders, while no general design practitioner mentioned engaging an international stakeholder. The practice of engaging stakeholders in their space has been reported to reduce the burden on stakeholders [11]. However, proper compensation for time is necessary when expecting enthusiastic engagement in design activities [1].

Overall, the strategies, stakeholders, prototypes, and settings leveraged by practitioners were not drastically different. Some differences could be explored further to understand if the context of the firm drives differences (e.g., size of the firm) or the setting the practitioners are designing for (e.g., domestic, international, LMIC). The small sample size of data used in Chapters Two and Three does not allow for a robust statistical analysis of the differences. However, as seen in Chapter Three, some of the practices described by global health design practitioners were directly related to global health-specific challenges they encountered during their design process.

### 6.2.2 Using zero, one, or multiple prototypes when engaging stakeholders

In this body of work, I investigated the use of zero, one, or multiple prototypes and described trade-offs. Not showing any prototypes can prompt stakeholders to generate more original ideas (Chapter Four), but showing at least one prototype can help create a common mental model between designers and stakeholders and avoid miscommunications while putting the stakeholders at ease to answer questions (Chapters Three and Four). Showing multiple prototypes enables stakeholders to compare across options and can inspire them to generate even more ideas (Chapters Three and Four), but making many prototypes can come at a cost (Chapters Three and Five). These results can help design practitioners decide how many prototypes to use when engaging stakeholders, depending on the engagement goals.

Showing stakeholders multiple prototypes is a documented prototyping practice and has been shown to enable designers to explore a diversity of design concepts and improve their designed solutions [17]. In particular, showing stakeholders multiple prototypes has been shown to support stakeholders in giving feedback [17,18]. While many studies have investigated parallel versus sequential prototype development, these studies tend to investigate the choice of a latter strategy based on resources and project timeline rather than on stakeholder engagement strategies and goals [19,20].

Design practitioners in Chapters Two and Three expressed various reasons for why using multiple prototypes was beneficial in stakeholder engagements, including to provide stakeholders with tangible representations of design ideas that would help them to articulate feedback, to compare various options with either different concept prototypes entirely or different features of a prototype, to showcase that the project was far from final and that stakeholders could make meaningful contributions of design ideas for future iterations of the designs. These results support the findings from Chapter Four: healthcare practitioners liked seeing prototypes when answering questions because it helped them answer, and healthcare practitioners liked seeing multiple prototypes to compare across prototypes. Showing multiple prototypes to stakeholders has been shown to help designers interpret the stakeholders' feedback [21]. The novelty of this work is in describing how showing multiple prototypes to stakeholders helps them formulate feedback.

When they were not shown a prototype, most healthcare practitioners in Chapter Four imagined a novel device or thought of a previously known device to answer questions. Hence, some healthcare practitioners suggested asking several questions without showing stakeholders prototypes to first gather their ideas. On the other hand, some healthcare practitioners said that seeing multiple prototypes helped them generate even more ideas. In Chapter Three, design practitioners described doing some creative exercises with participants such as drawing or assembling prototype parts in the desired way, always with a prototype. Furthermore, a creative exercise that required stakeholders to draw a device from scratch was described as having little success. Hence, perhaps even when participating in creative exercises, the presence of one or multiple prototypes as a basis can encourage stakeholders to generate ideas. For a subset of stakeholders who have an inclination for idea generation, showing prototypes might have the opposite effect of biasing them with the designer's ideas.

Furthermore, design practitioners also reported using multiple prototypes to evaluate which needs were more important to stakeholders by having device concepts that addressed different needs, to determine which features to include by depicting various feature combinations through different prototypes and reported using multiple prototypes with small variations of a given feature to determine the exact specification for that feature. Hence, the use of multiple prototypes in stakeholder engagement extends beyond requirements elicitation interview activities to design activities that precede and succeed traditional requirements elicitation activities.

### 6.2.3 Prototype form matters when engaging stakeholders with prototypes

The study in Chapter Five showed that the prototype form impacted the valuation of product features by stakeholders, which could be attributed to the limitations of the prototype forms. 3D prototypes enable the evaluation of features in a more tangible way than 2D prototypes, but they can be more resource-intensive to build, and their fidelity level can impact stakeholders' perceptions of the prototypes (Chapters Three and Five), illustrating the tradeoffs between different prototype forms for stakeholder engagement. While design practitioners attempt to build 'just right' prototypes – in terms of form and fidelity – for specific stakeholder groups, their designer context also influences the prototypes they create for stakeholder engagement purposes

(Chapter Three, [22]). More research is needed to better understand what prototypes to use with what stakeholders, which also considers the designer context.

Findings from other research support the result that prototype format influences stakeholder feedback [23–26]. Indeed, in Chapter Five, the 2D rendering of the knife did not allow us to convey the accurate length or width of the knife blade. Although the information on the length and width was given in specification form (in inches and millimeters), the fact that participants could not experience those specifications through the prototype changed their valuation of those features: a thicker and longer knife was less valued when 2D prototypes were shown. Indeed, virtual prototypes have been shown to have several limitations for stakeholder engagement, including the difficulty to assess scales, the force needed to operate a device, and comfort [27,28]. Deininger et al., 2019, found that some stakeholders were unfamiliar with virtual prototypes and had trouble evaluating virtual models presented to them during a feedback interview [29].

When participants saw a 3D prototype, because of its rough form, the participants criticized the bolts that were used to hold the knife and handle together (which would be replaced by a weld in the manufactured product) and criticized the size of the grip (which was forcefully fit on a large handle and was therefore expanded from its original size). Although the critiques of the 3D prototype did not create a measurable difference in valuation of features as compared to the 2D prototypes, it does illustrate how low-fidelity elements of prototypes are noticed by stakeholders and may be important to them when evaluating a prototype, even if the design tries to draw attention away from such low-fidelity elements. However, Deininger et al., 2019, found that stakeholder gave more usable responses when they were shown physical prototypes during a design interview, and that high-fidelity prototypes resulted in more usable feedback as well [29], making a case for the use of high-fidelity physical prototypes when engaging stakeholders.

The episodes analyzed in Chapter Two revealed that participants were intentional about what prototypes to show which stakeholder group, with what strategy, and in what setting. For example, in the real use environment or a simulated environment, design practitioners would engage stakeholders with physical 3D prototypes to create meaningful interactions between the prototype, the stakeholder, and the environment. Both studies in Chapters Two and Five, therefore, add to the literature that demonstrates that prototype form matters and that design practitioners should be intentional about their choices of prototypes to show stakeholders.

In Chapter Three, design practitioners expressed limitations around prototyping flexibility based on the resources available to them and the constraints of the field in LMICs. Deininger et al., 2017, also reports on prototyping limitations of novice designers in Ghana, who had little access to resources to build physical prototypes and mostly built virtual prototypes, as low-cost scrappy prototypes were perceived as low quality [30]. Deininger, 2018, further points out some aspects of the Ghanaian culture that could explain an aversion for un-refined, un-finished prototypes, such as dress and artistic culture, as well as the newness of some engineering sub-disciplines that involve prototyping [31]. Hence, not only does the perception of the stakeholder matter, but the perception and context of the designer also influence the type of prototype that is built. Establishing which prototyping practices are effective for different stakeholder engagements can help designers prioritize prototype forms when limited resources are available, which this work contributes to doing.

### 6.2.4 Interdisciplinary design for global health: tailored technology-based interventions

Many products developed for low-resource settings with demonstrated benefits still retain very low adoption rates even when distributed for free. Examples can be found for water filtration schemes, cookstoves, and bed nets. Some studies have investigated and documented the reasons for this, the main reason being the lack of good contextual design [6]. Engineering design processes propose methods to design tailored technology based on qualitative assessments of stakeholder needs and requirements (Chapters Two, Three, Four). Development economics proposes methods to elicit willingness to pay and to evaluate the effect of a technology on outcomes of interest (Chapter 5). Interdisciplinary uses of prototypes to engage stakeholders could lead to a better understanding of the needs of stakeholders and their context, by combining needs and requirements elicited through engineering design methods and consumer data based on quantifiable interest and impact assessments, to inform design processes early on and make go / no go decisions.

It is much harder for designers and engineers to gather reliable user data in developing settings because of the lack of infrastructure usually relied upon in developed countries such as receipts, web traffic, household economic surveys, and others [32]. Researchers are starting to use new innovative methods to understand consumer demand curves in developing settings such as user-centered design – including ethnography [33] and usability testing [34], discrete choice experiments [35], field experiments [36], and even big data and sensing devices [32]. In particular, human-centered design methods are increasingly popular in global health work [37].

Working at the intersection of engineering design and economics, I was able to explore methods from various fields in the context of global development. In Chapter Five, I used methods from engineering design, economics, and public health. Engineering design methods included CAD, functional testing, surveys, design ethnography (interviews and observations, active participation), video data, task log, rapid prototyping, interviews with prototypes, and ideation, a number of which are rooted in human-centered design processes. Methods from economics included a conjoint experiment, a Becker-DeGroot-Marschak auction experiment, surveys, and a

Randomized Controlled Trial evaluation. Public health methods included surveys and environmental valuation (measures of air quality and noise levels). By combining methods from engineering design and economics, I designed a novel tool tailored to our user needs, evaluated the impact of receiving the tool on workers' injury rates and productivity, and elicited information on participants' willingness to pay.

The two latter outcomes (i.e., impact evaluation and willingness to pay elicitation) are uncommon in traditional technology-based approaches to global health projects. Indeed, in DfD, very few studies use choice experiments or field experiments during the design process to understand the value of features and attributes of a product or the impact of a technology on the users. Jagtap and Santosh (2019) advocate for integrating methods to measure project outcomes in DfD [38]. The few examples that leverage field experiments in design for low-resource settings by Das and colleagues and Dupas and Robinson do not offer any evidence that the results were used to inform the design of bed nets in one case and of saving products in the other [36,39]. Other studies that use field experiments mostly assess the value of existing products, rather than a product under development. For example, Albert et al., 2010, aims to understand preferences for already commercialized point-of-use water treatment technologies, which are filtering and/or disinfecting products like chlorine tablets, and factors that influence adoptions [40].

On the other hand, the first outcome (i.e., a novel tool design that is tailored to user needs) is less common in traditional health interventions in development economics. For example, Nyqvist et al., 2017, created an intervention where a 'sales agent' was recruited locally and trained to conduct community health work such as conducting home visits, advising on health issues, and selling health products [41]. The intervention was random so as to study the impact of such services on infant mortality. In another example, Fujiwara, 2015, studied the impact of introducing visual aids during voting in Brazil and finds an impact on health service utilization and better health at birth for babies of less-educated mothers [42]. The methods used in the prior two papers focus on measuring outcomes and viability of the intervention, with little focus on the appropriate design of the intervention.

Dupas advocates for the use of a field experiment approach to answering the question: what new product/technology is needed to solve a specific problem that the poor face? She advises to first ask people what problem they face and to design a few products with varying features and attributes that meet their needs. Then, one observes adoption by conducting a “bottom-line” experiment where free vouchers for the products or service are handed out – or the equivalent of a voucher depending on the context – which will enable one to determine which product attributes are valued. Once the product is defined, one can move on to determine the willingness to pay [43]. The process proposed is at the intersection of engineering design methods and methods from economics. The approach is applied in [36], where three products aimed at helping rural households save for health expenditures were tested. Qualitative surveys revealed the main issues faced, and the solutions tested each solved one, two, or all three issues. Das et al., 2007 also propose an interesting example of using a combination of methods from economics and engineering design to understand user preferences for bed net textures, colors, and size, through surveys and focus groups, after trial periods of 7 days [39]. The works by Rao et al., 2019, and McCoy et al., 2017, are additional examples of integrating human-centered design approaches and economics methods in global health contexts [44,45].

The next generation of Global Engineers should, therefore, have an interdisciplinary approach [38] and learn from development economics [46]. The combination of engineering design and economics methods in a design process could help designers understand the outcomes and impact of their designs early on. Furthermore, methods for stakeholder engagement traditionally leveraged by economists with fully developed or even commercialized products could be implemented earlier in a design process.

#### 6.2.5 Positionality statement

In the studies presented in this dissertation, I, a white cis-gendered heterosexual woman who was born, raised, and educated in Western countries (France and the US), conducted the interviews in Chapter Three and the studies in Chapters Four and Five. (The interviews in Chapter Two were conducted in part by a collaborator.) Even in the cases where local field researchers administered survey instruments, I was present for many of the study tasks. My identity granted me unquestioned access to many spaces during my research, whether I was reaching out to designers in the US or abroad, or reaching out to healthcare practitioners in Ghana. These outreach tactics included my asking to interview busy doctors whom I did not know and to whom I was not introduced. Healthcare practitioners found time in their very busy schedule to sit down for an interview with me, in exchange for a meal or a small token of gratitude.

I used English in my interviews with healthcare practitioners in Ghana. Because most Ghanaians in the hospitals I was working in spoke English, as reported by a Ph.D. student who had done research in the same setting before, I did not think it necessary to hire a translator to facilitate an interview in the stakeholders' first language. I did not think about the impact of conducting an interview in English, whom it would exclude as interviewees, or how it might impact the answers I got. I saw the discomfort of more than a few participants when I asked a long question formulated in a dry standardized way. Many participants asked to skip questions altogether, and did so with a lot of discomfort, despite my best efforts to make them feel like they were the experts in the room. In Thailand, Thai field workers conducted interviews and study activities with participating stakeholders. When I was present on the field trips, I was always greeted politely and invited in, asked to sit in a chair while most people sat on the ground, and complimented on my skin. The presence of the US team in the field had to have an impact on the study, although it was less visible by the US team because of language barriers.

To describe this body of work as design for LMICs would be to ignore the differences between design by LMICs for LMICs and design by HICs for LMICs. I was and remain an outsider to the settings for which I was designing. Although many designers do not design for themselves, cultural differences, the history of colonization, neo-colonial aid systems, and the like [47] are inherently a part of design by HICs for LMICs that impact design processes and outcomes. Hence, I would describe this work as an exploration of prototype-based stakeholder engagement methods in a WD4BoP design context, meaning a Western design team designing for a disenfranchised population in LMICs. The goal of this research was to explore stakeholder engagement methods with prototypes in WD4BoP design, to uncover specific details of how these methods work or do not work in a WD4BoP context, to characterize how the WD4BoP context influenced the methods, and to start formulating recommendations.

I have recently signed the sidekick manifesto [48], which is framed around the following message: “Local leaders with local solutions to local problems will end poverty. I will not.” The manifesto invites all people working to end poverty to be “sidekicks to the story.” In this regard, I hope that Western designers working in DfD can learn from the research performed in this dissertation and can use it to be a sidekick. I wish to make sure I am more of a sidekick in any future work, which I have failed to do in the two studies where methods were applied to a real-world problem with real stakeholders. For example, I failed to identify local leaders who could make the best decisions for the community’s outcomes, rather than centering research outcomes.

For example, when designing the knife, I collected some informal qualitative feedback in addition to the formal conjoint but did not consider that qualitative feedback when making design decisions because the feedback was informal and could not easily be reported in a research paper. Furthermore, I, as a Westerner, made most of the design decisions, ‘checking’ when possible with local people. I held on to the spotlight rather than ceding the power to local people, which I could have done.

Therefore, to critically evaluate and reflect on the prototype-based stakeholder engagement methods explored in this dissertation, I propose to map a subset of prototype-based stakeholder engagement activities to the ‘spectrum of engagement’ or the ‘spectrum of public participation’ [49]. A proposed map of a selection of prototype-based stakeholder engagement behaviors by three different graduate researchers is presented in Table 24, based on the definitions in Table 23. While the researchers did not agree fully on where different behaviors would fall, based on their interpretation and experience with the behavior, the exercise helped the group reflect on the practices and framed a discussion about design experiences as they relate to power-sharing. Full collaboration or empowerment might not be feasible for every project, or at every stage of a project. However, this mapping practice could help designers and Global Engineers ensure that wherever the activity lands, it is an intentional decision that was taken with or by the community members whom one is working for.

*Table 23: Spectrum of engagement from the Intranational Association for Public Participations, adapted from Nelimarkka et al., 2014 [49]*

INCREASING IMPACT ON THE DECISION

| | INFORM | CONSULT | INVOLVE | COLLABORATE | EMPOWER |
|---|---|---|---|---|---|
| PUBLIC PARTICIPATION GOAL | To provide the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solutions. | To obtain public feedback on analysis, alternatives and/or decisions. | To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered. | To partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution. | To place final decision making in the hands of the public. |
| PROMISE TO THE PUBLIC | We will keep you informed. | We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how public input influenced the decision. We will seek your feedback on drafts and proposals. | We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision. | We will work together with you to formulate solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible. | We will implement what you decide. |



*Table 24: Mapping of prototype-based stakeholder engagement activities with the spectrum of engagement*

| **Stakeholder engagement activities** | Researcher #1 | Researcher #2 | Researcher #3 |
|---|---|---|---|
| Demonstrate the prototype to the stakeholder | **Inform** | **Inform** | **Inform** |
| Show incremental progress done on prototypes/build rapport | **Inform** | **Inform** | **Inform** |
| Conduct interview and focus groups with stakeholders using prototypes (e.g., usability test) | **Consult** | **Consult** | **Consult** |
| Observe stakeholders perform a task with the prototype | **Consult** | **Consult** | **Consult** |
| Gauge the emotional reaction to the prototype from stakeholders | **Consult** | **Consult** | **Consult** |
| Select prototypes or prototype features with stakeholders | **Involve** | **Consult** | **Collaborate** |
| Engage in co-creation using a prototype | **Involve** | **Involve** | **Collaborate** |
| Negotiate product requirements with the stakeholder using a prototype | **Collaborate** | **Involve** | **Involve** |
| Makerspaces | **Empower** | **Empower** | **Empower** |

### 6.2.6 The role of prototypes in engineering for social justice

Prototypes can facilitate collaboration with local communities in a design process, by making it easier to carry out design activities with local partners and by equalizing power imbalances that might exist because of the different social identities and cultures of the design team and local community. Hence, stakeholder engagement with prototypes can contribute to achieving the social justice objectives of DfD, in a WD4BoP context.

Riley, 2008, proposes the following as the main themes of social justice: "the struggle to end different kinds of oppression, to create economic equality, to uphold human rights or dignity, and to restore right relationships among all people and the environment" [50]. The author proposes a roadmap for engineers to take part in social justice, on issues spanning politics, class, capitalism, racism, sexism, homophobia, ableism, and particularly relevant to my dissertation work: colonialism and globalization, or global development engineering. Other authors have since then investigated the relation of engineering and social justice (e.g., [51,52]). A major failure of engineering is the assumption of neutrality [50]. The traditional assumed neutral stance of engineering has meant that engineers have perpetuated the injustices of society. Some skills necessary for engineers to contribute to achieving social justice goals include ethics, reflection, communication, collaboration, and valuation of other forms of learning and knowledge [50].

As engineers strive to contribute to positive change and social justice goals, current engineering design methods and processes still fail to lead to the desired outcomes. In this section, I will reflect on how stakeholder engagement with prototypes can help engineers address and reflect on some of the major failures of DfD in the context of WD4BoP.

A salient failure in DfD is the non-inclusion of local communities in a design process. Inclusive design is difficult to do, from a logistical perspective, when designing from HICs for

LMICs because of barriers related to travel, time, language, among others [51]. Additionally, a significant fraction of WD4BoP work is conducted within university settings, which predominantly involves novice designers with competing educational workloads that can impede community involvement, which can be extremely time-consuming. As exemplified by the case study presented by Nieusma and Riley, 2010, community-engagement is often de-prioritized in technology-based development more generally [51]. The establishment of stakeholder engagement methods in general, and of stakeholder engagement with prototypes specifically, can help formalize community engagement activities in a design process. Today, prototyping is an inevitable part of a design process, where unfinished and unrefined representations of ideas are created. We must make stakeholder engagement activities as inevitable as prototyping, for example, by associating a majority of prototype-based activities with stakeholder engagement.

However, traditional prototypes could exacerbate power imbalances by putting the designer's expertise at the forefront. When prototypes are used to engage stakeholders, they affect the designer-stakeholder relation, which is riddled with power imbalances [53], especially in WD4BoP settings. Introducing a prototype inescapably introduces an object that is in the domain of expertise of the designer who made it. Hence, the designer becomes the expert of the prototype, which was illustrated when healthcare practitioners in Ghana answered some questions by saying that I should answer that question because I am the designer and I will be making the medical device we were talking about (Chapter Four).

Indeed, stakeholders often feel apprehension (i.e., feel as if they cannot contribute anything of value) during an ethnographic interview [54]. Making the stakeholder feel less apprehensive may become more challenging with the introduction of the prototype, because the prototype could be perceived as solely within the domain expertise of the designer, which may, in turn, further distance the stakeholder. As introduced in the background section, other barriers to genuine designer-stakeholder interaction arise in WD4BoP settings. These barriers can be more exacerbated based on the extent to which the designers' and stakeholders' social identities differ. For example, healthcare practitioners in Ghana whom I interviewed about the design of a medical device had more identities that were similar to mine (e.g., higher education) compared to electronic-waste workers in Thailand whom I engaged with through Thai research assistants and field workers. Power imbalances need to be examined and addressed in development assistance projects [51]; hence, I propose some tactics to counter the potential power-imbalancing effects of prototypes described above. These tactics were collected from literature, from conversations with other designers, and from my own experience.

Tactic: Making fuzzy, low-fidelity, and early prototypes that are clearly not finished so stakeholders feel like they can still contribute. This tactic has been reported by designers, notably in Chapters Two and Three. However, early prototypes can also create distrust on the part of the stakeholder when they expect a more polished product. Hence, strategies where multiple prototype representations are used to engage stakeholders during the same engagement, both early representation and more refined representation, may enable a discussion where stakeholders feel like the prototype can still be modified while being confident in the designer's ability to deliver a refined product.

Tactic: Framing the prototypes. Designers can take time at the start of an engagement involving a prototype to make stakeholders feel like they are experts and have valuable information to share [55]. Designers can ask questions in ways that prompt wary stakeholders to provide criticism throughout the engagement [55]. Deininger et al. (2019) showed that the questions posed by designers when engaging a stakeholder with a prototype can influence the quality of feedback elicited and discussed how the phrasing of the interview question accompanying the presentation of the prototype may serve to either empower or intimidate stakeholders [29].

Tactic: Let stakeholders see their impact on a prototype. This tactic can be achieved through a variety of ways, immediately or asynchronously. For example, by co-creating or co-selecting features with stakeholders, by modifying a prototype in real-time based on a stakeholders comments and suggestions, or by showing stakeholders updated versions of a prototype that includes changes that they suggested (Chapters 3, 4, and [55]).

Tactic: Make prototypes locally. Hiring local people to make prototypes to be used during engagements with stakeholders from the same setting can lead to the creation of artifacts that are based in the local culture and are more familiar to stakeholders. For example, storyboards or renderings would leverage the aesthetics of local media to represent people, and objects would use local materials and fabrication processes. Sabet Sarvestani et al., 2013, illustrated how pictorial cards made to assess maternal health history in Ghana were misunderstood when they were designed by a Western team, and more clearly conveyed maternal symptoms when the cards were redesigned by local illustrators [56]. Furthermore, the perception of foreign objects can introduce additional biases; for example, expectations of quality can depend on the provenance of the artifact, which might influence the willingness of stakeholders to engage with early prototypes if the expectation is that objects from the US must be refined and of high quality.

Tactic: Leave the room. Stakeholders sometimes think there are good and bad answers to give during a design interview, despite a designer's best efforts to combat such perceptions through communication. Hence, stakeholders can be apprehensive about answering questions or about engaging with a prototype, which I was able to observe directly during my study in Ghana and which has also been related to me by other designers. Increasingly, methods to gather information on product usage happens automatically, without an observer present [32]. Hence, by ‘leaving the room’ and allowing stakeholders to interact with a prototype without feeling like they are observed (even if sometimes they are) could allow for more genuine interactions. A one-way mirror in a usability laboratory might be one way of discretely observing stakeholder interactions without being in the room. One could also leave a prototype behind and collecting feedback after a day, or a week (if no safety risk is involved). These practices can resemble an early-stage pilot, where prototypes (if they are safe) are given to stakeholders to use for some time as they see fit, as exemplified by Boer and Donovan, 2012 [57].

Tactic: Using non-traditional artifacts. Non-traditional artifacts can be used as objects to facilitate designer-stakeholder interactions while bypassing some of the issues that arise with more traditional forms of prototypes. For example, by using existing products as prototypes, the issues of fidelity can be bypassed while still imagining new creative use cases and scenarios. Cultural probes are artifacts in which stakeholders can take ownership.

Tactic: Be the learner. I have observed the ease with which stakeholders have shown me what is familiar to them. For example, a Ghanaian nurse demonstrated an implant removal procedure and a Thai work demonstrated how to dismantle a motor. I have also observed a higher willingness to engage if I present myself as a student rather than as a researcher. If instead of teaching healthcare stakeholders how to use a prototype on a simulator, I had asked them to teach me how they would use it, the interaction may have been more genuine.

While designers’ and engineers’ minds might be in the right place when developing projects in a WD4BoP context, the potential for increased harm is high [58]. This potential for harm places an added responsibility on engineering design practitioners to reflect and question their design processes and practices, and to recognize the many root causes of power structures stem from neocolonial economic policies of Western nations. The mapping of design practices to the spectrum of engagement, presented in the previous section, and the pathway to stakeholder engagement, presented in the following section, are elements that have emerged from the work in my dissertation, which attempts to facilitate reflection on prototype-based stakeholder engagement practices, especially on power structures.

While the field of DfD is growing, and the opportunities to develop engineering-based projects in LMICs are multiplying, I find myself questioning the role of a Westerner Designing for the Base of the Pyramid. All of our efforts seem vain and superficial if we have not dismantled the systems of oppression that are the root cause of the problems we attempt to solve. While I was working on a safer and more effective tool for electronic-waste (e-waste) workers in Thailand, I wondered about preventing waste from HICs being dumped in LMICs, which would remove the need for informal e-waste work. I wondered about addressing capitalist overconsumption which leads to piles of electronics needing to be recycled. And I wondered about the e-waste workers and what their livelihood would look like if we removed their current income source. I do not know if work at all of these levels is needed, or where to prioritize the work – a quick design of a new tool with limited impact or a fastidious lifelong battle against overconsumption. I do know that recognizing the complexity of the issues engineers are currently trying to address in LMICs is a necessary step to answering these questions. Prof. Nick Tobier gave me two pieces of advice that have shaped my reflection on the role of WD4BoP, which I will share with you to end this section.

*"We don't need a new chair, we need to rethink how we sit together."* Prof. Nick Tobier, University of Michigan

*"The beauty of that little trim tab is that it elegantly demonstrates the answer to the question: What can individuals do to change the world? […] Not only does it demonstrate that a little device can steer a very large system, it shows us that the absolutely highest leverage spot in steering the system of that ship is perhaps where one would least expect it, at the very trailing edge of the rudder, at the very back (i.e., stern) of the ship."* Jaime Snyder 2009 introductory essay to Ideas and Integrities and Education Automation [59].

### 6.3 Pathway for stakeholder engagement with prototypes in front-end design

Here, I synthesize a process for preparing stakeholder engagement activities with prototypes in early design stages, depicted in Figure 26. This decision-making process can potentially serve as a guide to stakeholder engagement with prototypes during the front-end design. After establishing the goals of the engagement and selecting the stakeholder(s) best suited to answer the design questions, participants chose prototypes, strategies, and settings for the engagements. These choices were driven by the engagement goals, the stakeholder type chosen for the engagement, and constraints (e.g., monetary, geographical, time [15]). This process underscores how choices of prototype(s), setting(s) and strategy(ies) influence each other, and how these choices are based on the intent of the engagement, the stakeholder(s) chosen to fulfill the intent, and constraints on the design process. Furthermore, establishing the intent for the engagement (the 'why'); aligning the choice of stakeholder with the intent (the 'who'); and managing the prototypes (the 'what'), settings (the 'where'), and strategies (the 'how') for the engagement, were the result of intentional decisions from participants.

While design practitioners did not explicitly lay out this particular process, it emerged as a result of analysis of the whole body of interview data from Chapters Two and Three. Design practitioners intentionally selected which stakeholders to engage, which prototypes to use, and which strategies to apply for a given setting. In practice, practitioners did not always make choices in this order, and there were times when choices of certain parameters were unavailable, omitted or unintentionally ignored by practitioners. The importance of the intentional choice for each characteristic may have also varied. Hence, this proposed process can help novice design practitioners develop thoughtful stakeholder engagement activities and invite them to think about the various parameters that could influence the effectiveness of the engagement.

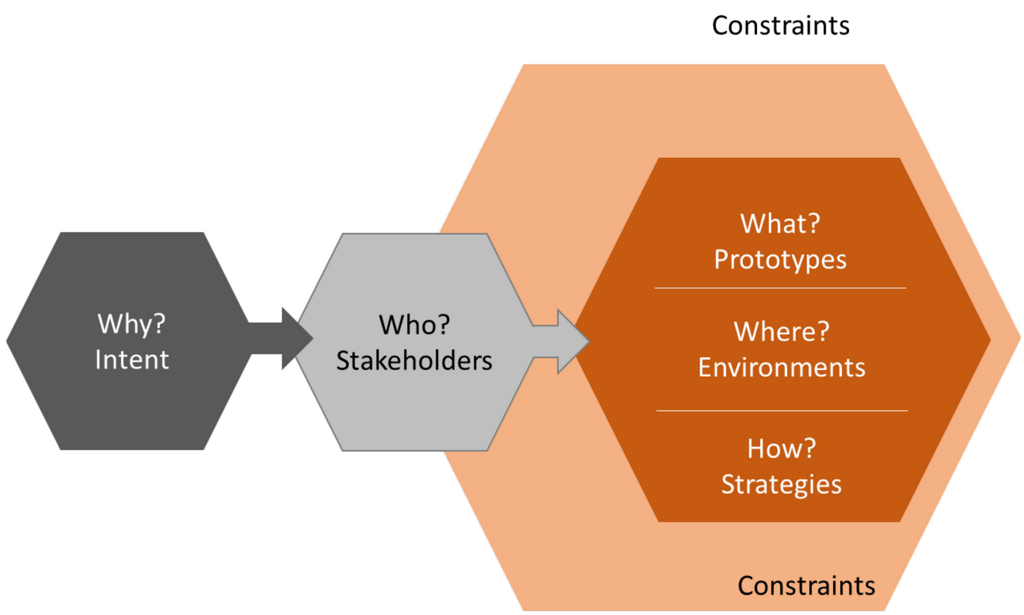


*Figure 26: Pathway for stakeholder engagement with prototypes during front-end design*

### 6.3.1 Design intent

Before choosing a stakeholder, prototype, and setting for the engagement, participants first set the goals of the engagement, which would guide their subsequent choices. Participants intentionally decided which design questions had to be answered for a given design stage and set clear objectives for the engagement of the stakeholder with the prototype. For example, participants N and O described the importance of setting engagement goals. Participant N described how her team would select a specific goal for the engagement:

*"It all just comes down to your end goal, like what particular piece of information you want to get out of each interaction. We were very specific." (Participant N, Chapter Two)*

*"Before we ever [engage stakeholders], we have multiple meetings to prepare for it. We put our goals very clearly on the wall, on a whiteboard usually, and say, 'What is our number one goal?'" (Participant O, Chapter Two)*

This first step of determining the intent is an essential step that is commonly forgotten before building prototypes, and in particular, when prototyping for stakeholder engagement [60,61].

### 6.3.2 Choosing a stakeholder group

Based upon the engagement goals, participants then tended to select the most appropriate stakeholders for obtaining the type of information and feedback needed to meet the goal; they considered stakeholder groups and other stakeholder characteristics such as the experience and location of stakeholders. Their stakeholder selection procedures aimed to limit biases, gather diverse perspectives, and select stakeholders that were familiar with the problem at hand. Participant T emphasized the importance of engaging the right stakeholder to meet the goals of the engagement:

*"We were trying to pick people who had more of an innovative mindset, so they could picture what things would be like in the future rather than maybe focusing on what today's problems were […]. The first and foremost is in the selection of those stakeholders […]. It'll typically be [that] you're picking them from a certain demographic—'Oh we want young physicians' because we want people that don't have much experience to see [if] what we're developing is something to make it easier for someone who's learning to use a device." (Participant T, Chapter Two)*

### 6.3.3 Choosing prototype forms, engagement settings, and strategies

After selecting the stakeholder(s), participants typically discussed navigating the choices of prototype type, setting for the engagement, and strategies for engagement. These choices were driven by the engagement goals, stakeholder type chosen for the engagement, and constraints (e.g., money, geography, time). These intersecting choices are illustrated in the following quotes. Participant N described selecting the most appropriate form factor for the prototype to answer the specific questions with the stakeholder:

> *"So we just tried to really be pointed about one piece of information or two pieces of information that we really wanted to walk away with and so whatever form factor was best to get rid of all the distraction, and just focus on those things is kind of how we did it." (Participant N, Chapter Two)*

Participant X discussed how the setting of the engagement would influence the choice of prototype shown to stakeholders, which is an example of the setting and prototype choices overlapping and influencing one another.

> *"So again it goes down to the goal, what we are trying to get accomplished, what we want them to see. So the setting very much has to do with that. If we are going to [the stakeholders'] offices or something, we are going to bring a more minimal version, like show the main components but maybe not have it fully usable or at the fully usable prototype with us." (Participant X, Chapter Two)*

Indeed, the location of the engagement influenced the amount of control participants had over the setting. For example, the number and size of prototypes were constrained by transportation based on the location of the engagement setting. Participants described using photographs and videos of physical prototypes to engage distant stakeholders. Distant stakeholders were also engaged in real-time through Skype or on the phone.

Participant A employed the strategy to *"polish the prototypes"* shown to stakeholders (defined in prior collaborative work: reference [66] from Chapter Three). Indeed, Participant A described using this strategy to mitigate the fact that some users could not get past certain unfinished elements of a prototype.

> *"The problem with having a really rough prototype is that users cannot get past the fact that it is not finished. They are always distracted by the shortcomings of a prototype that you are aware of as an engineer. (...) So you are 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, Chapter Two)*

These associations of strategy, stakeholder, prototype, and setting are explored in detail in the first study (Chapter Two).

### 6.3.4 Constraints

As set forth in the discussion section, the availability of resources can influence the various stakeholders, prototypes, settings, and strategies leveraged by medical device design practitioners during a design process. Examples include difficulty engaging patients [62], having little time to spend in local contexts especially relevant in WD4BoP design settings ([1] and Chapter Three), and limited access to materials and manufacturing tools to build physical prototypes ([30] and Chapter Three). Further exploration of how resources affect stakeholder engagement capabilities is necessary to better describe the process of planning stakeholder engagements with prototypes during front-end design and to understand the current perceived cost-benefit of stakeholder engagement, especially in the medical device industry which faces challenges to stakeholder engagement due to regulations and reduced accessibility of patients and healthcare practitioners [11].

### 6.3.5 Example application of the pathway to stakeholder engagement with prototypes

To illustrate the application of the proposed pathway, I used the empirical studies in Chapters Four and Five and mapped the various parts of the pathway to the prototype-based stakeholder engagement activities I studied, as displayed in Figures 27 and 28. The figures display in red the aspects of the activity that I varied to study the effect of different choices on the engagement. This exercise can facilitate reflection on study design and the other choices that might have affected outcomes.

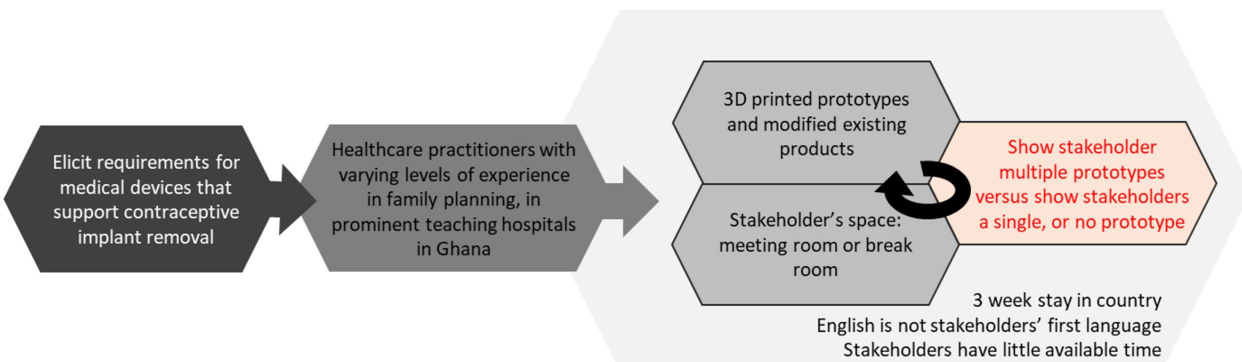


*Figure 27: Chapter Four prototype-based stakeholder engagement pathway*

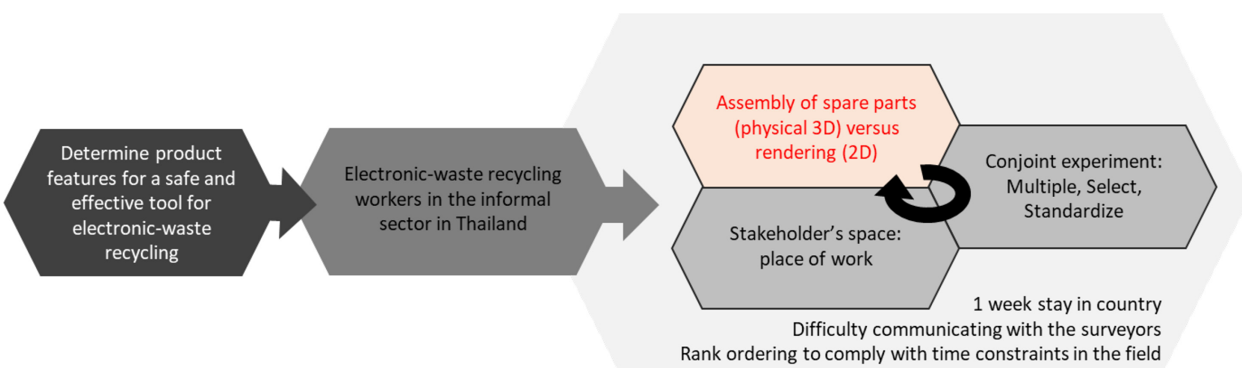


*Figure 28: Chapter Five prototype-based stakeholder engagement pathway*

### 6.4 Limitations and future work

While this body of work contributes to describing practices for prototype-based stakeholder engagement in LMICs, further research is necessary to fully capture designers' behaviors with respect to strategic planning and execution of front-end prototyping behaviors with stakeholders, and how these behaviors transfer across industries, geographies, and design cultures.

The work presented in this dissertation was based, in large part, on qualitative methods. While there are limitations to the generalizability of the findings from qualitative work, these methods were chosen because they allow the analysis of deep and rich data with few assumptions of what will be uncovered. As a first step to the detailed description of prototype-based stakeholder engagement practices, qualitative research methods were appropriate. Future work could attempt to validate the findings across a wider range of stakeholders and contexts. For example, the findings from Chapters Two, Three, and Four relied on studies in the medical device field specifically, and findings from Chapter Five relied on a study based on a consumer product related to health. While some of the findings of this work might be applicable to other contexts, future studies could apply the methods described and studied in this body of work to other design contexts and with more diverse participants. Especially when studying industry practitioners, I found that prototype-based stakeholder engagement might be practiced by people with job descriptions beyond those included in this work, such as marketing professionals who are very customer-facing. As specific next steps, I suggest conducting retrospective interviews with marketing professionals in medical device design and conducting observations of a medical device design process in a large company (200 + employees).

Additionally, the body of work is based on information related to us by participants, including retrospective interviews of design practitioners (Chapters Two and Three) and answers to questions that elicit reflection from study participants (Chapter Four). To support the findings from participants' answers to reflection questions, Chapter Four leveraged the analysis of responses to structured interview questions. Future studies could use the findings from this work as a basis for other research studies using methods such as systematic surveys with large samples or observations to investigate the generalizability and transferability of the findings. For example, one could conduct a survey across industries about the stakeholders, prototypes, settings, and strategies leveraged by design practitioners when engaging stakeholders with prototypes in early design stages.

Another limitation of this work relates to the absence of qualifications of the effect of various stakeholder engagement methods on the outcomes of the projects. The study presented in Chapter Five proposes a study model where longer-term impacts of early design decisions can be evaluated with the use of methods from economics. Such practices could help evaluate project outcomes that leverage different stakeholder engagement methods with prototypes and would allow one to gain a better sense of the effect of the stakeholder engagement methods on the project outcomes. This could be studied first in a 'laboratory' setting or in a capstone class where students work on the same problems, but a subset of groups is taught about interviewing stakeholders with multiple prototypes, while other groups are taught to use a single prototype, or no prototype.

As a Western and white designer conducting research in LMICs, I most likely unintentionally introduced bias into the research methods and analysis. Future work that intentionally considers the identity of the researcher and the participants when investigating design methods, especially when conducting empirical research in the field, could help make visible the cultural and identity-driven biases in the field of engineering for global development. Prototype-based stakeholder engagement methods could, therefore, be investigated in LMIC-to-LMIC contexts. Future research could compare LMIC-to-LMIC and WD4BoP design to make visible the biases introduced in the latter and steer the field in a non-Western-centric direction. For example, a study could compare a large sample of technologies meant to achieve the same goal, which were invented and developed in an LMIC setting versus in a HIC setting, and do a deep dive into a subset of technologies by conducting retrospective interviews with the design teams.

Stakeholder engagement has been shown to be a crucial part of a successful design process, especially when designing in and for an LMIC setting. While this work contributes to the growing literature that studies and proposes a detailed methodology for prototype-based stakeholder engagement, increasing or refining the methodologies used by designers might not be enough to radically increase the success rate of development projects. The future of design-stakeholder interactions may lie in increased designer-stakeholder collaborations. As described in the spectrum of engagement [49] parallelism, and as exemplified in the growing field of participatory design, stakeholders could be empowered to become the leaders of a design project. Pushing this idea to the extreme, through the model of maker spaces for example [49], future studies could investigate designer-stakeholder interactions where stakeholders create prototypes to engage designers and gather feedback, rather than the other way around.

### 6.5 Contributions, implications, and recommendations

The body of work presented in this dissertation characterized stakeholder engagement methods with prototypes during front-end design by describing the stakeholders, prototypes, and settings leveraged by design practitioners in the field of medical device design (Chapter Two). This work further characterized the associations of the stakeholders, prototypes, and settings with prototyping strategies (strategies established in prior collaborative work), driven by intentional decisions made by design practitioners (Chapter Two). These practices were then examined in the context of WD4BoP design for global health. Chapter Three described how design practitioners leveraged prototype-based stakeholder engagement practices in response to global health-specific challenges. To my knowledge, this work is the first description of prototype-based stakeholder engagement practices with this level of detail about the parameters of the engagement: the stakeholders, prototypes, setting. This work also described the choices of associations between the parameters (stakeholders, prototypes, and settings) and strategies, in a WD4BoP design for global health context.

Two subsequent studies provided examples of applications of stakeholder engagement methods with prototypes in early design. First, a study of requirements elicitation interviews with healthcare practitioners in Ghana examined the differences between conducting the interview with and without prototypes (Chapter Four). Second, a study of a conjoint experiment to elicit electronic-waste workers' preferences for a new tool in Thailand examined the differences in attribute valuation when 3D physical prototypes were shown versus 2D renderings of the tool (Chapter Five). These two studies provided concrete examples of how prototyping choices (whether in number or form) can impact stakeholder engagement activities in a WD4BoP design setting. The studies further provided some indication of the ways in which prototypes can impact the outcomes of stakeholder engagement activities.

My graduate research, as represented in this dissertation, contributed to the advancement of a foundational understanding of how prototype-based stakeholder engagement is implemented, notably in a remote and cross-cultural WD4BoP global development setting. This research provided detailed descriptions of such methods that can be used to support the creation of targeted design tools and pedagogy for both students and practicing global development designers. Below, I outline the contributions made to engineering design education, design for global development in a WD4BoP setting, and interdisciplinary design practice.

### 6.5.1 Implications for engineering design education and practice

Our findings can help support the development of educational tools that promote and scaffold intentional and reflective stakeholder engagement practices with prototypes within the discipline of engineering (such as capstone design courses). The proposed pathway could be a stepping-stone to developing a formal tool to guide novice designers in preparing and carrying out stakeholder engagement activities with prototypes in early design phases. These results can support novice designers in planning stakeholder engagements with prototypes and considering a wide variety of ways of doing so. The proposed pathway can potentially serve as a bridge between theory and practice, by demonstrating how specific cases approach planning and decision making; theory that might otherwise be hard for students to find applicable to their design setting. For example, the fact that prototypes are defined based on materials and manufacturing methods rather than more abstract names found in other frameworks (e.g., 'looks like' and 'works like' prototypes [63]) can help students explore the breadth of prototype forms that can be used to engage stakeholders.

Indeed, engineering design courses at several institutions include early phase design activities to explore the needs of stakeholders. The findings of this work, notably the ones summarized in the proposed pathway for stakeholder engagement with prototypes (Figure 26) and the stakeholders, prototypes, setting leveraged by design practitioners (Figure 25), have already been integrated into University of Michigan Center for Socially Engaged Design workshops (i.e., in the core workshop on Prototyping and in a workshop titled Prototyping for feedback).

The proposed pathway could also be used as a reflective tool for practitioners to evaluate their more successful and less successful practices and processes. Furthermore, combined with the comprehensive lists and associations of stakeholders, prototypes, and settings, along with strategies derived from collaborative work, this work can help practitioners think of ways to expand their current practices to include other practices not previously considered.

### 6.5.2 Implications for engineering for global development

In a WD4BoP setting, the constraints associated with a given design process or targeted design outcome might be different than the constraints in other settings (e.g., HIC-to-HIC and LMIC-to-LMIC). This research complemented the existing literature by providing rich descriptions of specific constraints and hurdles faced by practitioners in WD4BoP settings. My research also reported specific prototype-based stakeholder engagement methods used by practitioners in response to those constraints, and empirically studied variations of specific methods for prototype-based stakeholder engagement in real-world settings. Indeed, there is little guidance for designers as to how to engage stakeholders in LMICs when working on global development projects [1]. The findings of this work aimed to partially address this gap by providing detailed descriptions of expert practices to tackle additional constraints faced by designers in WD4BoP settings, that could be leveraged by both novices and professionals working in such settings.

This work could be incorporated into workshops focused on preparing interdisciplinary students for fieldwork, notably student teams doing fieldwork in the medical device design space in a WD4BoP setting, such as the Global Health Design Initiative at the University of Michigan, or the BLUELab and MHEAL student organization. This body of work offers concrete examples of how a design process can be affected by the WD4BoP setting and encourages students to think critically about the specific barriers they will face while proposing concrete approaches to tackle the barriers faced. Not only does this body of work propose a plethora of alternative methods for prototype-based stakeholder engagements, but the studies also give examples as to how to choose different methods based on practitioner testimonies and empirical results.

For example, when introducing stakeholder interviews as a method to gather requirements, students can be encouraged to consider bringing a prototype to the interview and crafting an interview guide that incorporates one or multiple prototypes during the interview. The findings from Chapter Four can provide guidance as to how to make these choices based on the goal of the interview and the stakeholders engaged in a WD4BoP setting.

Indeed, the results from this research show that the different ways of using prototypes (i.e., zero, one, or three prototypes presented during interviews; 2D or physical 3D prototypes during a conjoint experiment) impacted the outcomes of the activity, which implies that designers, both novice and expert, should give careful consideration to the choices they make when conducting stakeholder engagement activities.

### 6.5.3 Implications for interdisciplinary design for global development

The case study research in Chapter Five captured how quantitative methods of prototype-based stakeholder engagement, which are also typically used in economics and marketing research, can be applied during early design stages in a WD4BoP setting. The case study can serve as a resource for designers who want to apply similar methods to their own design process. Furthermore, the case study exemplified the benefits of implementing conjoint analysis and auction experiments and offers methodological insights. For example, despite the lesser resources needed to make product renderings instead of physical prototypes, the case study provided examples of how some attributes were harder to depict in a 2D drawing which might cause participants of a conjoint experiment to value those attributes differently if shown images as opposed to physical prototypes. Providing an example of how the methods of conjoint and auction experiments were used in an engineering design process for LMICs provides further evidence that these methods should not be simply associated with marketing and economics, but should be more broadly applied to engineering design for global development.

#### 6.5.4 Conclusions of implications

The research presented in this dissertation contributes 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. These results could impact approaches to practicing and teaching prototype usage during front-end design in WD4BoP settings. The goal of this research is to promote early and frequent engagement with stakeholders when designing global health technologies, which could improve the uptake and sustained use of such technologies.

The findings of this work provide a foundation for the development of pedagogical tools that could be incorporated into design curricula. These tools could have value for both novice designers and industry practitioners. Multiple figures and tables were created as a result of synthesizing the collection of findings throughout this dissertation, which can subsequently serve as guides for both novice and experienced designers. These figures and tables include the list of stakeholders, prototypes, settings, and strategies (Figure 25); the objectives and approaches of global health design practitioners (Table 22); the proposed pathway for stakeholder engagement with prototypes in front-end design (Figure 26); and the spectrum of stakeholder engagement (Table 24).

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## Appendices

### Appendix A: Definitions framing the research question

*Table 25: Definitions framing the research question (Chapter Two)*

| Word | Definition |
|---|---|
| Front-end design activities | Front-end design activities are activities including problem identification and needs findings, problem definition (e.g., requirements and specifications development), background research, concept generation, early prototyping, and concept selection. Participants were further instructed not to discuss evaluative design activities (e.g., clinical trials, requirement verification, summative usability testing). |
| Prototype | A representation of a process (the procedure), a system, or a sub-part of the designed product, such as mock-ups, CAD models, drawings, scenarios, and other representations of the product or its use. |
| Stakeholder | Anyone who will affect or be affected by the [product] at some point, including end-users, colleagues, manufacturers, clients, policymakers/ministry officials, technicians, procurement officers." |
| Setting | Locations where an interaction between a designer and a stakeholder occurred using a prototype during the front-end activities of medical device design. |

## Appendix B: Sample interview questions

*Table 26: Sample interview questions (Chapter Two)*

| Theme | Example question |
|---|---|
| Stakeholder groups | Who were the stakeholders you engaged during your project? |
| Prototype forms | Could you go over the different types of prototypes you used during the front-end phases of the project to engage with stakeholders? |
| Associations | Did you use different types of prototypes when you were in a different setting with different stakeholders? Could you describe these choices?<br>Can you tell me how you used these prototypes to engage with the different stakeholders? Could you describe the interactions with stakeholders in more detail? |
| Engagement event exploration | 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?<br>Why was the prototype crucial in the discovery?<br>Who was the stakeholder?<br>Where did the interaction take place? Was the context important to this discovery? |

## Appendix C: Definitions of front-end, product, prototypes, and stakeholders provided to participants at the start of the interview

*Table 27: Definitions of front-end, product, prototypes, and stakeholders provided to participants at the start of the interview (Chapter Three)*

| 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 D: Excerpts of the interview protocol

*Table 28: Excerpts of the interview protocol (Chapter Three)*

| 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 E: 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 US based nurses[1] but also nurses here in the US 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 F: Background information relative to the excerpts from four participants presented in the results section

*Table 29: Background information relative to the excerpts from four participants presented in the results section (Chapter Three)*

| 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 US<br>• One-on-one feedback session in country<br>• Demonstration of the prototype to stakeholders | Mechanical |
| D | Preventative care | • One-on-one feedback session in foreign country<br>• Distant engagement with digital prototypes<br>• Engagement in the real use environment during which stakeholders can use the prototype | Electromechanical, including a digital interface |

## Appendix G: Visual aids for endline preference-related questions regarding the tool

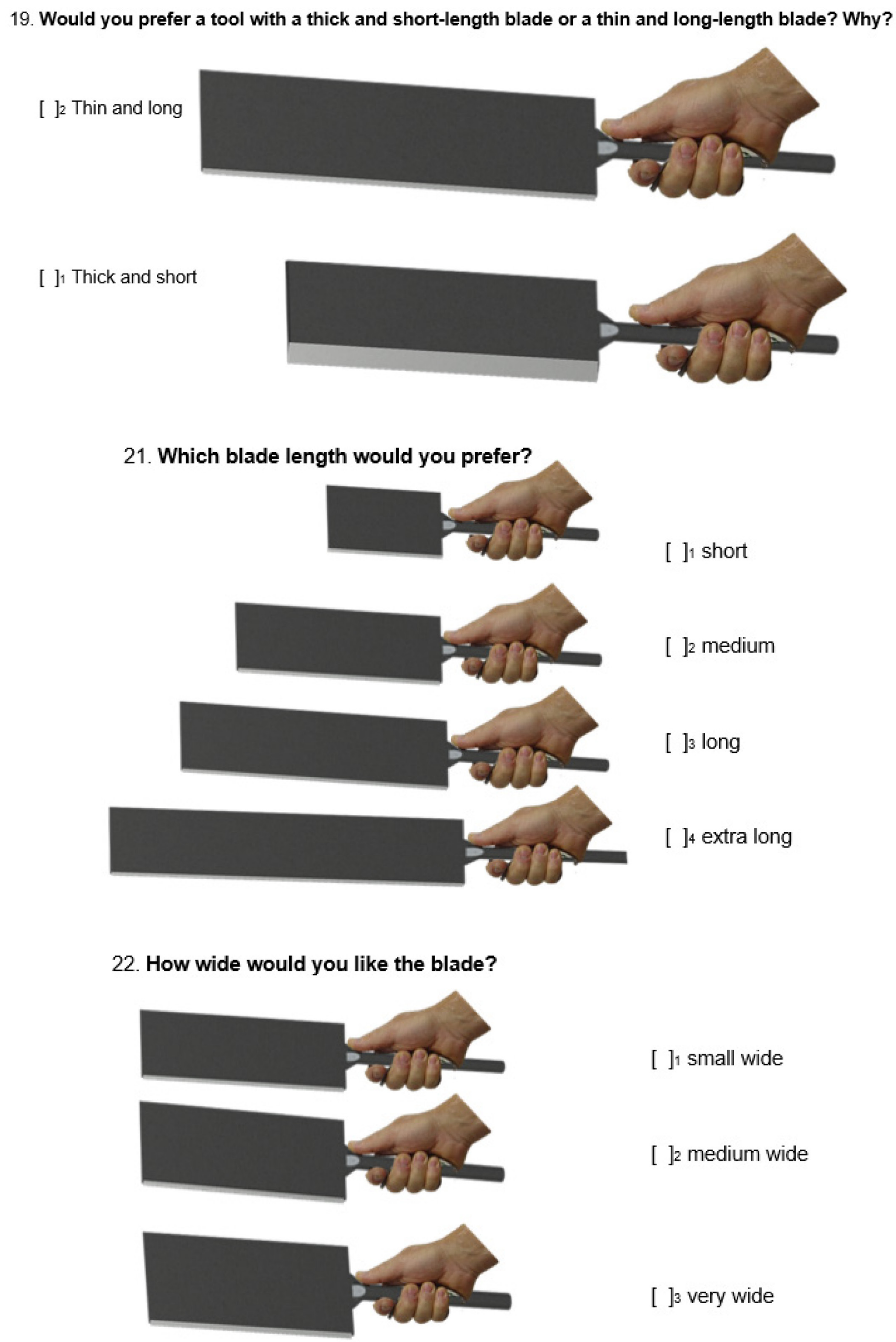


*Figure 29: Visual aids for the endline preference-related questions regarding the tool (Chapter Five)*