Designing task shifting medical devices for low-resource settings

by

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On the shoulders of giants. This phrase sums up the support, advice, and mentorship I have received since first stepping foot onto the campus of the University of Michigan (UM) as a newly arrived young refugee from Iran in 2006. When I decided to pursue my doctoral degree, UM's Design Science Program enabled me to connect my interest in engineering, social sciences, and public health to improve the health of people living in low-resource settings. So, first and foremost: a big thank you to the University of Michigan for providing an enabling and empowering environment. Also, my work and my journey became possible because of the numerous individuals and institutions living and working in sub-Saharan Africa. I especially acknowledge the welcoming communities and individuals in Ghana, Uganda, and Ethiopia that facilitated my research and this thesis.

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I dedicate this work to my grandmother, Monireh, who passed on a few weeks before I completed this thesis. I would not be here today if it were not for her supportive and kind nature.

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Abstract

The availability and acceptability of many medical devices designed for use in low-resource settings is affected by many factors including unreliable energy and water supply, limited distribution and infrastructure, high product costs, and lack of spare parts and required consumable. One study found that 40 percent of medical devices used in low-resource settings were dysfunctional. Further, the limited availability of highly trained health providers is perhaps the most important obstacle to providing care in low-resource settings. For instance, Africa bears more than 24 percent of the global burden of disease, but has access to only 2 percent of the global physician supply. In fact, 47 percent of the World Health Organization's member states report having less than 1 physician per 1000 population. These pose a design challenge on how to develop task shifting medical devices that are simple enough to use that lay health providers can deliver or perform some of the more common and urgent health services and tasks previously undertaken by highly trained health providers.

This dissertation investigated the perceptions of stakeholders about task shifting and identified the attributes of task shifting medical devices by engaging with a wide range of stakeholders. Also, existing qualitative and quantitative methods for eliciting user requirements from diverse stakeholders were applied and analyzed; the research adopted a statistical approach to identify the requirements common, and conflicting, across stakeholder groups. Finally, a systematic design ethnography approach was used to develop an understanding of traditional male circumcision (TMC) in sub-Saharan Africa and inform user requirements for a device aimed at improving the safety of the procedure.

Ease of use was identified by our stakeholders as the most important characteristic that defines a task shifting medical device. This research also evaluated the effectiveness of open-ended, clustering, and discrete choice methods to elicit user requirements from a wide range of stakeholders, and used individual difference scaling analysis to further extend the analysis to further analyze the data from the clustering elicitation method. The requirements categories allowed an objective comparison of the requirements noted by the different stakeholder groups. Design ethnography techniques including focus group discussions, expert interviews, and direct observations were systematically applied to inform the design process of a device to mitigate the

adverse events of TMC in Uganda. The device's cultural acceptance and fit were measured through preference analysis of stakeholders and a clinical trial, respectively.

This dissertation made four contributions to the interdisciplinary field of design engineering, focusing on global health issues. First, it provided an understanding about diverse stakeholders' perceptions of task shifting medical devices. Second, it offered a set of methods by which requirements needed to develop a task shifting medical device can be elicited, and identified the necessary design requirements essential for designing easy to use mechanical task shifting medical devices. Third, it evaluated qualitative and quantitative user requirements elicitation and prioritization methods, and presented a methodology that indirectly identified the highest priority user requirement categories. Fourth, it developed a culturally acceptable and appropriate device, through interactions with local stakeholders based on design ethnography approaches, to make traditional adult male circumcision safer.

This work concludes with presenting a set of steps for product requirements elicitation, informed by an inclusive approach of involving multiple stakeholders and based on design ethnography approaches, to develop task shifting medical devices. The steps promote an iterative design process and repeated interactions between design engineers and target stakeholders to identify major categories of requirements, and then break them into measurable, objective sub-requirements. Future work includes the generation of a detailed and analytical user requirements elicitation method to inform a stakeholder-driven design requirements elicitation and engineering specification development process.

Chapter 1. Overview and motivation

1.1. Introduction

"The developing countries and all the rest of us must cooperate by combining simpler and small-scale approaches with new technologies, which for the first time make decentralized and human-size development feasible."

– Victor Papanek (Design for the Real World [1])

The availability, accessibility, and effectiveness of medical devices are vital in achieving the highest quality of care within health systems [2]. Medical devices, defined as "articles, instruments, apparatus, or machines that are used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose" [3], are a major part of health technologies (which also include vaccines and medicines), and an essential building block in any functioning health system [4]. The World Health Organization (WHO) indicates that there are over 10,000 types and brands of medical devices globally, ranging from basic stethoscopes to complex diagnostic imaging machines; it estimated that the global medical devices market was over $350 billion in 2011 [2]. However, historically, the overwhelming majority (~90 percent) of health technology sales have occurred within high- and middle-income countries [2,5].

Almost 80 percent of medical devices in low-income countries (LICs) are acquired by donation [6]. In addition to donations, medical devices are also acquired through technology transfer: local production of devices that resemble technology designed for use in high-income countries (HICs) or the low-cost sale of older models of devices originally designed for use in HICs [6,7]. However, use of medical devices in LICs that were originally designed for use in HIC are not entirely successful; one study noted that 40 percent of medical devices were dysfunctional in LICs versus less than 1 percent in HICs [8,9]. In LICs, constraints including unreliable energy supply and water, limited distribution and infrastructure, inadequate or untrained workforces, lack of spare parts, required consumables, and high costs affect the availability and acceptability of many devices [10].

The limited availability of highly trained health providers presents another extraordinary challenge in providing universal quality care. For instance, while Africa bears more than 24 percent of the global burden of disease, it only has access to 2 percent of the global physician supply [11]; or 47 percent of the WHO member states reported having less than 1 physician per 1000 population [12]. The mismatch reported between the number of commercially available medical devices and the projected global burden of disease, as well as the limited number of available devices designed for use in primary health care facilities by lay health workers (30 out of 358 medical devices) will challenge policymakers and the global health community to provide intellectual, financial, and regulatory support in order to develop the necessary technology in a timely manner [13]. Although it is not possible to separate the effects of medical devices from the effects of social, political, economical, and healthcare measures on mortality in LICs [8], availability and accessibility of medical devices are important and if part of a comprehensive solution, can positively impact global mortality and morbidity trends.

This poses a design challenge on how to develop medical devices that are simple enough to use that lay health providers can deliver or perform some of the more common and urgent health services and tasks previously undertaken only by highly trained health providers. This can have a tremendous implication for both developing and developed countries. Such, presumably task shifting, medical devices may benefit low-resource settings that have a limited access to highly trained physicians, and high-resource settings by informing the design and development of easy to use medical devices that may be suitable for home-based health care services.

This research, based on the outcome of qualitative and quantitative methods for continuous engagements with stakeholders in Uganda, Ethiopia, Ghana, and the United States of America, is motivated by the user-centered design challenge of medical devices. The major objective is to evaluate methods to engage with a wide range of stakeholders to elicit user requirements prior to the concept development stage in order to increase the likelihood of acceptance and approval of a device by end users. The second objective is to identify the key design requirements of task shifting medical devices. Finally, this research provides a pathway to designing and developing task shifting mechanical medical devices.

1.2. Research questions

This research provides a structured methodology to engage with wide range of stakeholders involved in health delivery so they can help inform the early phases of the design process of medical devices, knowing that stakeholder involvement throughout the design process leads to a higher likelihood of acceptance, and potentially increased uptake, by end users and stakeholders.

This dissertation poses the following research questions:

1. How can user elicitation methods of user requirements be used to capture and quantify subjective user requirements, such as ease of use?
2. What is the meaning of task shifting in the context of medical devices, and what are the primary design requirements for a device to be task shifting?
3. What are the design requirements that make a medical device easy to use?

This research encompasses the interdisciplinary field of "implementation engineering", which promotes the uptake of scientifically designed and tested products into routine healthcare in both clinical and policy contexts, by engaging stakeholders early in the design process. Engineering knowledge alone, however, is not sufficient for answering the three posed research questions. We will make use of findings, models and methods from several fields including behavioral and social psychology, decision-making, marketing, health care delivery, and health care systems sciences.

1.3. Aims, proposed methodology and chapter overviews

To inform the user-centered design process of medical devices, this research will identify some the most effective methods for eliciting stakeholder requirements. The elicitation of these requirements will also identify the design requirements that will enable less-trained health providers to deliver some of the care currently provided by well-trained personnel.

This dissertation uses a combination of qualitative and quantitative methodologies to address the general research questions and achieve each chapter's objectives. The final outcome, an introduction of series of steps to provide a structure for early phases of design process, will be informed by the mix methodologies described

Chapter two provides an overview of the current state of the art for early phases of the user-centered design process and reviews the literature on methods to elicit, prioritize, and

translate stakeholder requirements. This chapter also provides an overview of the existing knowledge of task shifting and medical device design processes for low-resource settings. The literature review is based on the current state of the art of the engineering design in conjunction with fields including marketing, psychology, and global public health. The following aims, associated with specific chapters, address different aspects of the three research questions.

Aim 1 (Chapter 3): To develop an understanding of the perception of task shifting medical devices for different stakeholders and generate a ranked order list of the design requirements necessary to develop a task shifting medical device

Chapter three investigates the understanding and expectations of stakeholders involved in health care delivery about task shifting medical devices. The chapter describes what a designer should know, based on the perception of stakeholders about task shifting medical devices, in order to facilitate design of task shifting medical devices. This chapter also validates the hypothesis that ease of use is the most important requirement to consider when designing a task shifting device. Consequently, the chapter elaborate on ease of use, as a subjective requirement, and defines it based on input from wide range of stakeholders.

The methodology to achieve these aims is a qualitative and quantitative based survey distributed to the different types of stakeholders providing health care, directly or indirectly, in low-resource settings. The qualitative approach includes, for example, open-ended responses, and the quantitative approach includes, for example, discrete choice.

Aim 2 (Chapter 4): To evaluate different user requirements elicitation and prioritization methods when engaging with different stakeholder groups

Chapter four compares the employment of three distinct qualitative and quantitative approaches to understand the needs of end-users and multiple stakeholders in Ghana. The chapter evaluates the outcomes of these three user requirement elicitation methods and suggests a structure for when, why, and how each should be used.

The methodology to achieve this aim is semi-structured interviews and statistical approaches that utilize individual difference scaling analysis. The chosen methodology serves two purposes: 1. To evaluate the quality of each elicitation and prioritization method, and 2. To assist in identifying the major groups of requirements expressed by each stakeholder group and

evaluate the similarity and differences across stakeholders through application of a novel statistical approach.

Aim 3 (Chapter 5): To demonstrate a method, based on design ethnography, to capture the qualitative input from stakeholders that will inform the quantitative specifications required to develop a medical device

Chapter five demonstrates the importance of understanding the needs of different stakeholders, especially the socio-cultural implications utilizing design ethnography. This chapter describes in detail how to engage with local communities and stakeholders when no prior systematically collected information and knowledge is available. The chapter elaborates on the importance of qualitative data to inform the early phases of the design process, especially when an engineering designer is new to a community or to a design context.

The deign ethnographic methodology combines cultural immersion, focus group discussions, interviews, and observations. The case study example is the design of a culturally acceptable device to reduce the adverse events of traditional male circumcision in Uganda.

Aim 4 (Chapter 6): To validate the effective translation of qualitative input to quantitative measures when designing a medical device: The case of ease of use in traditional male circumcision device

Chapter six presents a validation for methods to elicit design requirements and translation to quantifiable engineering specifications, with a focus on ease of use. The validation is presented through the design evolution process of a traditional male circumcision device. The chapter demonstrates how to translate the qualitative input presented in chapter five into numerical engineering specifications so that the device will have a higher likelihood of acceptance by its stakeholders.

The method follows the principles of user-centered design to develop a first-generation traditional male circumcision device. Through an iterative approach it will be shown how different qualitative input can be translated to numerical objectives to inform the early phases of the design process. Then, through interaction with stakeholders in Uganda the final design will be compared to the original design to evaluate the acceptability of the device. In addition to the stakeholder preference evaluation, to demonstrate the effective translation of qualitative

requirements to engineering specifications, this chapter also provides the outcomes of the clinical trial to validate the appropriate device fit and placement on target population in Uganda.

Chapter 7 summarizes the key findings, places them in the context of a broader literature, and suggests new directions for research.

1.4. Expected contributions

This work contributes to design science literature as follows:

1. It provides the first-ever understanding of task shifting medical devices.
2. It elaborates on and refines an ambiguous requirement (ease of use) to inform the design of mechanical medical devices based on input from wide range of stakeholders.
3. It provides a structure for eliciting qualitative user requirements from stakeholder groups and translating them into quantifiable engineering specifications.

The contributions of this dissertation extend beyond the fields of engineering and design. Public health, public policy, and all those fields involved with implementation and delivery of services and products to communities and individuals can benefit from this work by learning about requirements to develop a task shifting product and how to engage with different stakeholder groups, how to elicit their requirements, and how to translate those requirements into measurable objectives and specifications.

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Chapter 2. Background

The following sections provide a general review of the literature relevant to this work. However, each chapter also includes a relevant extended review the literature and current knowledge.

2.1. Medical devices for global health

Medical devices, defined by World Health Organization (WHO) as "article, instrument, apparatus, or machine that is used in the prevention, diagnosis, or treatment of illness or disease, or for detecting, measuring, restoring, correcting, or modifying the structure or function of the body for some health purpose" [1], have the potential to address critical global health needs, from rapid diagnostic testing to prevention and treatment. A recent survey of health workers in Africa and Asia shows significant gaps in the availability of essential health technologies to assist maternal and infant health in rural settings [2]. A report by the Lancet Commission on global health technologies states that "more frugal technology, specifically designed for the world's poorest people, is needed. Such technology also has the potential to be disruptive technology for health care in high-income countries" [3].

Supplying medical devices can involve the transfer of existing devices, termed "diffusion" of technology, from developed to developing settings in the form of low-cost sales or donations [4]. Almost 80% of health technologies in resource-limited settings are acquired by donation [5]. However, these transfers are not entirely successful [4]; one study notes that 40 percent of medical equipment is out of order in developing settings compared to less than 1 percent in high-income countries [3].

Given the current challenges with utilizing medical device in resources-limited settings with the models used so far (e.g., donation, direct transfer), there is a need to design and develop appropriate, and innovative devices that not only address a health care challenge, but also enable end-users and enhance the workforce capacity in the developing settings [3,6]. However, the developing world faces unique barriers regarding the design, development, procurement, and maintenance of medical devices.

Malkin *et al.* identify the lack of spare parts, required consumables, reliable power and water, and public infrastructure as major problems plaguing health care technology in the developing world [7]. In a closer look at medical devices, Malkin *et al.* find that even though the lack of spare parts impedes the delivery of appropriate care, capacity building and a focus on improving local workforce knowledge have the highest impacts on attaining full operational capacity [6]. Given these challenges, there is a clear need to design frugal, appropriate, and innovative devices via a process which considers the local limitations, cultural contexts, and stakeholder needs while enabling the end-users and enhancing the capacity of the local health care workforce [3,6]. However, decisions to introduce, purchase, design, and utilize medical devices for these settings need to be evidence-based and with careful consideration of the "real" needs and capacities of the end-users and stakeholders. For instance, Shah *et al.* show that users in any setting will quickly discard devices that do not fulfill their personal expectations, even though both manufacturers and healthcare professionals may consider that the end-users' requirements have been met [8]. Thus, a variety of organizations and experts recommend a user-centered approach as a viable method to create appropriate, sustainable health technology for developing settings [9,10].

2.2. Task shifting medical devices

By the end of the last decade, 57 countries faced chronic human resource shortages in the health sector [11]. Sub-Saharan Africa, which has 11 percent of the world's population but bears 24 percent of the global disease burden, has only 3 percent of the global health workforce and accounts for only 1 percent of global health expenditure [12]. The rapid increase in infectious and chronic epidemics globally and the accelerating human resource crises in low-resource settings now give task shifting major prominence and urgency.

Task shifting is a process whereby specific tasks are assigned, where appropriate, to less-qualified, less-trained health workers [11]. The process has two objectives: increasing access to health care among populations and in locations with limited availability of professional health care providers, and cost effectiveness [11,13-16]. Task shifting has been suggested, and practiced, to address the limited available human resources for delivery of quality and emergency health care services in low-resource settings.

In recent years there have been extensive systematic approaches in task shifting of health

care delivery services for maternal and newborn health and HIV/AIDS [17-21]. While almost all births in the developed world are supervised by skilled birth attendants, fewer than 50 percent of births in South Asia and sub-Saharan Africa receive such support [22]. Task shifting to address HIV/AIDS is a component of several voluntary medical male circumcision campaigns in eastern and southern sub-Saharan Africa [11,23,24], where voluntary medical male circumcision and HIV/AIDS testing counseling are being delegated to lay counselors, who are in greater supply than specialized physicians [24,25].

However, the role of medical devices in enabling task shifting and equipping lower cadres of health providers in task performance is underexplored. No systematic, evidence-based investigation has been undertaken to determine the key characteristics perceived by stakeholders that can be used in the design and development of successful devices.

2.3. Usability in the context of medical devices design

While the usability requirement (also termed easy to use, intuitive to use, usable, etc.) is repeatedly mentioned as a need for a medical device, there is limited rigorous scientific work to help define this requirement and inform the early stages of the medical device design process. In the requirements elicitation stage, many end-users and stakeholders will mention usability. However, usability's subjective requirements and heterogeneous definitions may be difficult to translate into engineering parameters and design attributes. Other than a few published works on the role of usability in infusion pump operations in order to decrease human error [26], there is limited knowledge about the concept of usability requirements to inform the early stage of medical device design. Moreover, there is limited work on understanding the role of multicultural factors when involving different user types in the design of medical devices [27]. Papanek states that "it is impossible to just move objects, tools, or artifacts from one culture to another and then expect them to work." [28] Thus, design engineers might interpret the usability requirement differently, since the stakeholders will exhibit diverse backgrounds, levels of expertise, perspective, and needs [29].

While there is limited work on the "usability" requirement in the context of mechanical (medical) devices, computer science and ergonomics have extensively investigated this notion. These studies tend to focus on human computer interfaces, or the post-design evaluation of

products in ergonomics. Software engineers break the concept of usability into five attributes [30]:

1. Learnability: The product/system must be easy to learn
2. Efficiency: The product/system should be efficient to use
3. Memorability: The use of the product/system should be easily remembered
4. Error: The product/system should have a low error rate
5. Satisfaction: The product/system should be pleasant to use

Back to medical devices field and involving users in design, Martin *et al.* propose the following specific benefits of involving users directly in the design process of medical devices [29,31]:

1. Improve safety of device
2. Improve usability of device
3. Reduce device recalls
4. Limit the need for ad hoc modifications
5. Improve efficiency of users
6. Improve patient outcomes and satisfaction

Shah *et al.*, who review the literature related to informing medical device design process by involving users, conclude that the major benefits of user involvement are the increased access to user needs, experiences, and ideas, and the increased functionality, usability, and quality of the devices [32]. Several studies note that resource issues, particularly time and funding, prevent the involvement of users in the development and evaluation of medical device technologies [31,32].

2.4. A case for design: making traditional male circumcision safer

Design of devices and tools to assist with male circumcision, which has been shown to reduce HIV/AIDS transmission among men by 60 percent, has been one of the objectives of global health organizations [33,34]. In sub-Saharan Africa, adult male circumcision occurs in both clinical settings and traditional ceremonies. Many ethnic groups throughout eastern and southern sub-Saharan Africa still consider traditional male circumcision (TMC) a rite of passage for boys between the ages of 10 and 18 [35]. Previous work has shown that the majority of ethnic groups will not give up TMC for cultural reasons [36], even though TMC is known to cause adverse events (as high as 48 percent) including excessive bleeding, excessive removal of

foreskin, infections, extreme pain, lacerations, erectile dysfunction, and even death [35-37]. Unfortunately, two relatively new medical devices for male circumcision, Shang Ring and PrePex, are not suitable for TMC due to their cultural inappropriateness, complexity, and cost.

2.5. User-centered design process: need for and challenges with

In the late 1970s and early 1980s, American and Japanese engineering design firms coined the terms, "voice of the customer" (VoC) and "design by customers", to help with identifying, structuring and prioritizing the needs of their customers [38,39]. Several empirical studies discuss the positive impacts of involving users, beginning with the earliest stages of the design process, i.e. needs assessment and establishing design requirement steps [40,41]. For instance, Burchil *et al.* demonstrate an iterative design process which involves users in the early stages of understanding the users' environment, converting the understanding into user requirements, operationalizing what has been learned through establishing functional specifications, generating early stage concepts, and finally, selecting the most desired concepts to develop a new product's successful path to market [42].

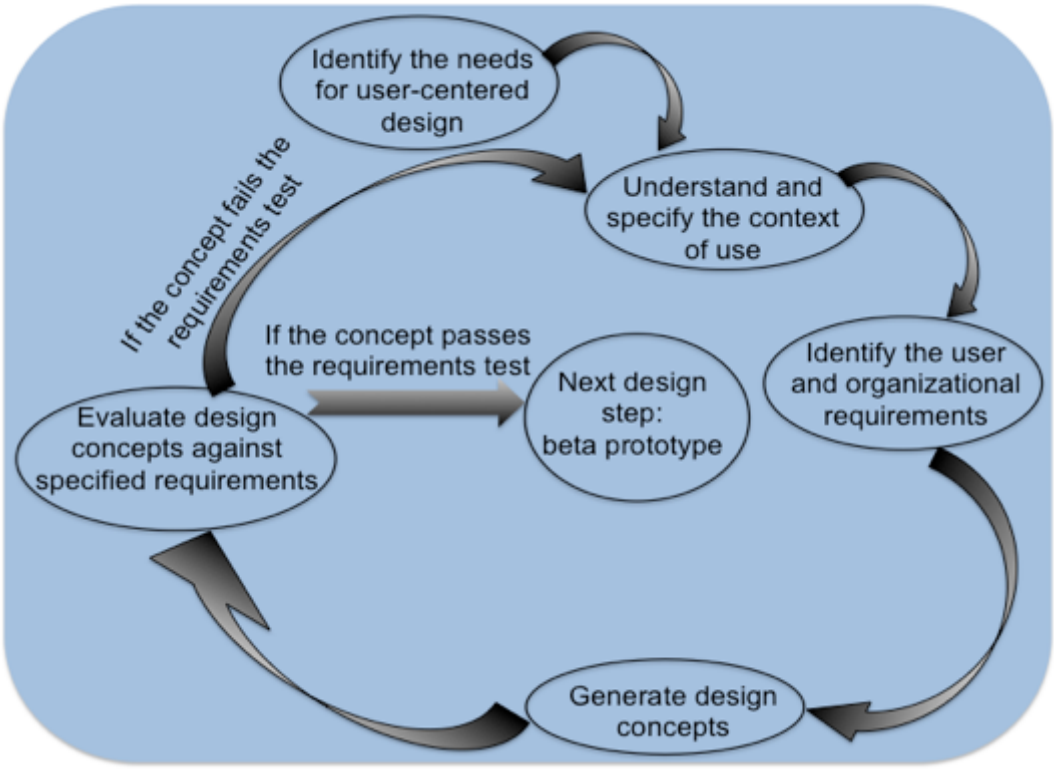

Figure 2.1: A typical iterative process of identifying needs and establishing user requirements in product design

New product development can originate either from new technologies or from new market opportunities. Ultimately, however, it is the customers and end-users who judge whether or not they adopt a new product [43]. Understanding the needs and specific requirements of potential customers has gradually become an "effective" practice [38,44]. The importance of conserving limited financial, material, natural, and human resources coupled with improved methods for capturing VoC techniques have introduced the concept of co-creative design, which views the *process* of design as a continuously evolving iterative pathway, ensuring that all stakeholders, be they end-users, purchasers, or decision-makers, will benefit from the final outcomes (Figure 2.1, adapted from ISO 13047 [45]). The following literature review discusses the current state of the art elicitation methods to capture the requirements desired, needed, and wanted by stakeholders, translation and prioritization of the elicited requirements to engineering parameters, and the implications for user-centered design processes of medical devices in low-resource settings.

2.6. Stakeholder involvement in the co-creative design process

Designed appropriately, the user requirements elicitation and its subsequent mapping to engineering attributes will fulfill the following objectives: ensure customer satisfaction with the product; ensure customer willingness to adopt, choose, or purchase the final product; and validate (value) customer participation. However, in reality, the co-creative process may not go as smoothly as envisioned by the design engineers. Using the field of health care technology as an example, the needs and wants of patients, health care workers, or physicians may conflict with those of insurance companies, regulators, or policy-makers. Kwong *et al.* assert the importance of identifying essential user requirements from heterogeneous stakeholder groups, prioritizing them, and addressing conflicting requirements at the early stage of the design process [46]. In another study, Witell *et al*. show how using different requirements elicitation methods within the same respondent groups can result in different outcomes [47]. Michalek *et al.* develop and adopt an analytical target cascading using AHP to explore the optimal decision-making process and address inconsistencies in inputs when designing a product [48]. Also, fuzzy set theory were used to prioritize the needs expressed by different user groups to create an optimized framework for a design process [49].

2.7. Requirements elicitation and engineering specification development methods

The field of requirements engineering has two major aims: reduce the ambiguity in user inputs and clarify the user requirements obtained [50]. The importance, need, relevance, and validity of engaging with users, establishing their needs, and eliciting their feedback, which have been studied and evaluated in computer science and software and information system design, have given rise to studies in human computer interaction (HCI), user-centered design (UCD), and human-machine interface (HMI) [44,51-55]. With the emergence of information technology–based services, such as the development of electronic communications and Web-based applications, the field of software engineering (SE) is expanding further to fully capture user requirements. For example, computer algorithm–based methods, interview servers and unified requirements elicitation frameworks, have been developed to elicit and manage user requirements [56,57]. Furthermore, to automate requirements elicitation, Kassel *et al*. identify user groups and domain experts and create an interactive central database facilitated by a requirements analyst [51].

Potentially, unified models of requirements elicitation and process automation should save time, reduce costs, and assist less-experienced designers, but there are several drawbacks to their use. For example, a "one size fits all" unified requirements model tends to capture requirements incompletely and overlook tacit assumptions [58]. Another problem is that user requirements are not set a priori, meaning that a designer cannot assume that the requirements remain the same across time and context [59]. Also, while subjective requirements can change continuously, depending on the stakeholder type, context, etc., the automation of requirements elicitation ignores specific questions that might be used to inform the overall process. These problems along with the reality that requirements are gathered from stakeholders having vastly different levels of knowledge, experience, and interests [60], complicate the management of requirements elicitation and the subsequent translation into quantifiable engineering specifications (attributes). Involving end-users and different stakeholder groups in the early stages of any new product development process is a critical success factor for any project [43,61,62]. Slater *et al.* observes that the central goal for any new product development (NPD) is to create a product with superior customer values so that customer needs will be satisfied [63]. Effective elicitation of user requirements and their translation to engineering specifications is associated with a transition process from "voice of customers" to "voice of designers" [64].

Evidently, there are strengths and shortcomings associated with each requirements elicitation method [43]. Table 2.1 lists some of the widely used requirements elicitation methods and Figure 2.2 illustrates those deemed most suitable for each product type

Table 2.1: Some of the widely used methods of user requirements elicitation and associated strengths and weaknesses

Method	**Theoretical basis**	**Description and pros and cons**
Free elicitation (interview)	Theories of spreading activation [65]	1. Stimulus probes or cues (usually words) are presented to the participant 2. The potential end-users are asked to rapidly verbalize the concepts that immediately come to mind 3. The interview is generally recorded and transcribed for analysis 4. Results can be analyzed in a variety of ways **Pros**: Suitable for exploratory purposes; captures open-ended inquiries **Cons**: Results in subjective outcomes depending on context, etc.
Focus group discussion (FGD)	No specific [66]	1. A group of participants sits together for a series of open-ended discussions on a product or topic 2. A report summarizing the discussion draws inferences **Pros**: Suitable for exploratory projects; captures open-ended inquiries; has the potential for narrowing down the needs **Cons**: Results in subjective outcomes depending on context, etc.
Lead user technique	Diffusion of innovations [67,68]	1. The researchers identify lead users for a product of interest 2. Data is derived from lead users concerning their experience with novel product attributes and product concepts 3. The products developed by the lead users are evaluated by more typical users in the targeted market **Pros**: Faster response time to preliminary concepts **Cons**: Subjective based on user population group's feedback
Conjoint analysis (CA)	Experimental design [69,70]	1. Major attributes and their levels for a product are selected 2. Potential end-users are given a set of hypothetical design profiles and asked to rank or rate the stimuli 3. In data analysis part-worths are identified for the attribute

		levels to inform the evaluation of total utility of any given product profile **Pros**: Specific numerical attributes of the product are identified **Cons**: Resource (financial and technical) intensive
Empathic design	Theories of anthropological investigation and tacit knowledge [71,72]	1. A multi-functional team is established to observe the actual behavior and environment of the potential end-users 2. A record is made of the users interacting with their environment 3. The design team brainstorms to transform the observations into graphic, visual, and physical representations of possible solutions **Pros**: Suitable to identify end-users' problems and needs **Cons**: Potential outcomes could be limited to address minor needs; while needs are identified, their quantification could be problematic
Laddering	Means-end chain theory [73]	1. Each potential end-user receives a set of products and is asked to make distinctions between them 2. Each mentioned distinction becomes the starting point for a series of why-probes 3. When all interviews are completed, key elements of the interview are summarized by using standard content-analysis 4. The researchers produce a summary representing the number of connections between elements **Pros**: Suitable for exploratory purposes **Cons**: Results could be subjective given the context and user.

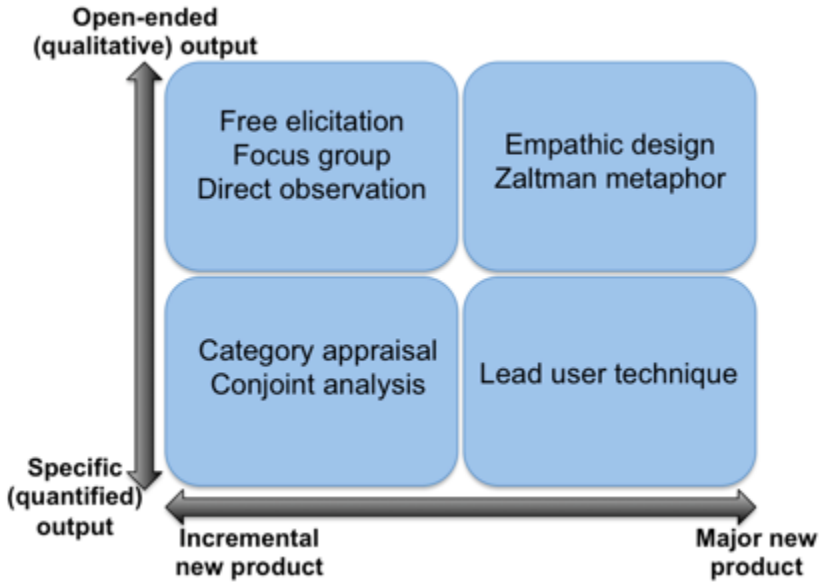

Figure 2.2: Methods to elicit user requirements and their relationship to product design type

2.8. Translation of (subjective) user requirements to (objective) engineering specifications

There are three keys to preventing a mismatch between customer needs and product attributes: identifying the "right" types of needs, eliciting "real" user requirements, and translating the requirements into "effective" engineering specifications (i.e., product attributes) [39]. Concurrent engineering, the systematic approach developed to integrated product development stages, emphasizes the responses by engineers to customer expectations and requirements [74]. Requirements management, in concurrent engineering, addresses issues such as communication, traceability, completeness, and consistency when eliciting user inputs [75]. Design engineering has developed several tools to map the acquired user requirements to quantified engineering specifications or attributes. For example, quality function deployment (QFD) is a tool that was developed in the 1970s to convert potential end-user and customer requirements to engineering attributes [76]. Most of the methods in Table 2.1 can be employed to identify customer requirements and then assess the relative importance weights via a Likert scale, pairwise or fuzzy pairwise comparison matrices, utilizing linear or non-linear programming tools, to inform the development of engineering parameters [77].

Design structure matrix (DSM) is another popular organizational and mapping tool. The literature describes the use of DSM to organize the engineering specifications' sequence on the correlation matrix between the items' (under evaluation) importance weight that are evaluated with QFD [78]. While it is especially useful for partitioning the tasks and items to be prioritized

within QFD, DSM's shortcomings include the uncertainties arising from the different levels of user expertise (both single user inputs and multiple group inputs), associated conflicts, and the resulting inability to capture the subjective requirements and issues [78].

In recent years, product engineering and marketing have begun to use conjoint analysis (CA) to identify and prioritize the engineering specifications based upon the data collected on user needs [69]. Pullman *et al.*, who compare QFD and CA, conclude that CA is easier to understand and administer and works well for designing product lines when optimizing for profits [79]. Pullman also finds that QFD captures certain engineering characteristics or design features that have both positive and negative aspects [79]. QFD also highlights the importance of starting explicitly with user requirements, regardless of which elicitation methodology is used [79]. The trade-offs between the two methods could point the way to "out of the box" solutions. These two methods can be complementary, i.e. if contradicting in any engineering specification outcome, CA conveys the customer's current preferences, whereas QFD captures what product developers believe will satisfy the customer's needs.

Taxonomy of information is useful for managing and classifying large and heterogeneous bodies of information. Its classification of user requirements adds order and clarity by creating distinctive categories which are mutually exclusive and exhaustive [80-82]. The obtained requirements can be ordered by end-user preferences, market requirements, regulatory requirements, technical requirements, and sub-categories, such as primary and secondary functional requirements [82]. Another requirements elicitation methodology, which utilizes taxonomy, Elicitation Knowledge (ELK), focuses on increasing the depth and breadth of the information acquired from lead users, which is mentioned in Table 2.1 [83].

Analytic hierarchical and neural network processes (AHP and NNP), from artificial intelligence field, can also be used to quantify user requirements [41]. Drawing from multiple criteria decision-making (MCDM) theory, these two methods apply mathematical analysis to map the complex interrelationships among decision elements, based on the elicited requirements, e.g., when multicultural factors disagree with technical needs, different levels of uncertainties, etc. AHP used in conjunction with QFD can decompose a problem into hierarchical levels, in which each decision element is considered to be independent [84,85]. One advantage of AHP is its use of pairwise comparisons with relative measurement scales. The relative measurement makes subjective judgment easier and more reliable than the use of absolute measurement. AHP

can easily model a modular product, because the nodes of the network model in the AHP can be specified at two different levels: clusters (modules) and elements (parts). However, both AHP and NNP make assumptions regarding elicited requirements on a case-by-case basis that cannot be expanded to other cases and conditions. Moreover, establishing AHP and NNP processes is often so complex that most designers prefer not to use them [86].

A review of the literature also reveals further challenges with inadequate methodologies for capturing complex requirements, the lack of expert guidance in eliciting and analyzing the requirements, and the application of quantitative evaluation for qualitative items [41]. These problems compound when the captured requirements are difficult to define and intangible. For instance, while customer may be able to explain and quantify some of the essential requirements such as "low-cost", they may run into difficulty explaining other requirements such as "aesthetically beautiful" or "user friendly". The difficulties stem from a term's subjective nature, based as it is upon each customer's diverse perspectives (knowledge, responsibilities, gender, experience, culture, etc.). Following is a description of few subjective requirements and the methods used to establish the associated engineering attributes.

For instance, to understand *environmental friendliness* it needs to be broken down to sub-requirements. Reid *et al.* evaluate users' environmental friendliness perception in auto industry based on vehicles' two-dimensional appearances [87]. Ersal *et al.*, quantify perception of *craftsmanship* in vehicle interior design using a functional dependence table and statistical analysis methods such as cluster analysis of craftsmanship's perceptions and multidimensional scaling [88]. In another study, evaluating *closeness* to customers is quantified and tested using multi-item scales [89]. Witel *et al*. use qualitative methodologies to evaluate the performance of an e-service and its *attractiveness* using taxonomy methods [47].

Users' emotions, another qualitative input, reflected for a design can be captured through Affective Design (AD), which attempts to identify emotional inputs based on user reactions and to define a design's physical parameters [61]. However, AD lacks the quantification rigor necessary to establish engineering specifications.

Some designers use the Kano model to understand and analyze user needs and their impacts on user satisfaction [77,90]. This model considers both the asymmetric and non-linear relationships between product performance and user satisfaction. For instance, Chen *et al.,* use it to evaluate the aesthetic preferences of customers [91]. Generally, the Kano model classifies

product attributes into five categories:

1. Must-be: Attributes taken for granted by customers; their presence does not create customer satisfaction (CS), but their absence or poor performance will result in high levels of customer dissatisfaction.
2. One-dimensional: CS is positively proportional to the fulfillment level of these attributes; the higher the level of fulfillment, the higher the CS and vice versa.
3. Attractive: Attributes not generally expected by customers; their presence will create high levels of CS, but their absence will not result in customer dissatisfaction.
4. Indifferent: Customers do not care about these attributes; their presence or absence will not affect levels of customer satisfaction or dissatisfaction.
5. Reverse: Their presence causes customer dissatisfaction, but their absence creates CS.

Kano classifications are identified via a Kano questionnaire, which contains a pair of questions for each product attribute [92,93]. The question pair includes a functional question that captures the user's perception if the product has a certain attribute, and a dysfunctional one that captures the user's perception if the product does not have that attribute. Figure 2.3, illustrating a generic Kano model, shows the impacts of the five attributes on a product's two-dimensional aspects (functionality and CS).

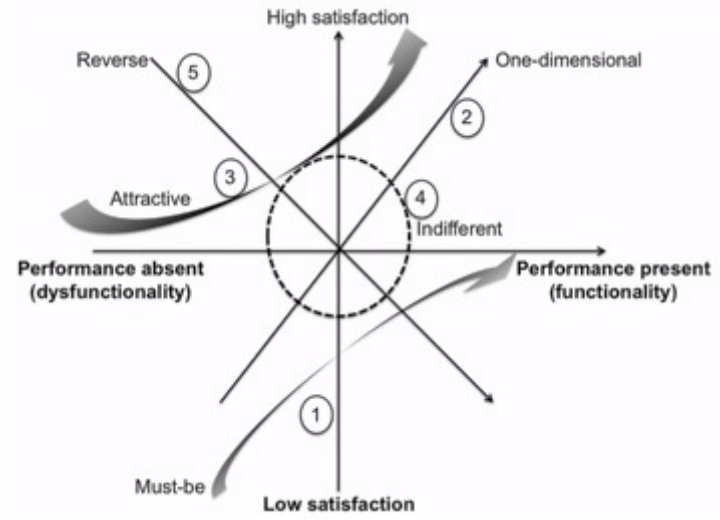

Figure 2.3: Illustration of a generic Kano model (circled numbers refer to the list at the page 22)

However, the Kano model does not provide a systematic and methodical quantification approach to translate user needs into measurable engineering parameters [77,92]. Hence, recent attempts to assess and estimate engineering parameters based on the outcomes of the Kano model have led to the development of an "analytical Kano" model [62,94], which is combined with QFD in some cases. This analytical Kano creates a series of criteria to classify user requirements and a configuration index that provides a decision factor for selecting the functional requirements that contribute to product attributes [94]. Even though the analytical

Kano model attempts to quantify the elicited requirements, the designer's subjective evaluation can still affect the quantification process.

Similar to the Kano model, Kansei Engineering (KS) has made considerable contributions to the "emotional" engineering design literature. KE is helpful in identifying the dimensions that a user may use to classify and comprehend the differences across existing products [95]. For example, using KE to inform the design of vehicle interior, designers can measure distances or quantify the shape of the instrument panel and the size of the instrument cluster based on the preference feedback of potential users using techniques from the social sciences and statistics, including multidimensional scaling (MDS), the semantic differential procedure, and advanced regression techniques [96]. However, questions remain about the methods to identify underlying dimensions that guide a user's perception and the inability to seek useful feedback from (potential) users when designing a new product, since users have limited to no knowledge about unseen novel product ideas.

2.9. Closing the knowledge gaps

Expanding the use of medical devices in task shifting continues to be hampered by the lack of a systematic and analytic approach to inform the user-centered design process. There are no studies of stakeholders' perceptions about task shifting medical devices and their design characteristics, and there is little knowledge about translating subjective user requirements, such as ease of use, into objective specifications. This work attempts to close the gaps in the design engineering literature by focusing on the process of designing a task shifting device for use in low-resource settings.

2.10. References

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Chapter 3. Stakeholder perception characterization and design requirements elicitation of task shifting medical devices for low-resource settings

3.1. Abstract

Background: Task shifting has been suggested as a solution to the problem of limited available human resources for delivery of quality and emergency health care services in low-resource settings. However, the role of medical devices in enabling task shifting practice and equipping less-trained health providers is not fully understood. This study investigates how health providers in low-resource settings perceive task shifting medical devices and identifies the key requirements elicited from stakeholders that designers can use to develop successful task shifting medical devices.

Methodology: A survey questionnaire including qualitative and quantitative questions was distributed to stakeholders who were directly or indirectly involved in health care delivery in low-resource settings. Respondent groups included medical doctors, nurses and midwives, community health workers, biomedical engineers and technicians, public health staff, and academic researchers. Themes and categories of responses were developed for qualitative responses. Rank ordering and comparison of choices between and within stakeholder groups were used for the quantitative responses.

Main Findings: There was strong support for the adoption and utilization of task shifting medical devices because the use of the devices enabled less trained cadres of health providers. Ease of use was found to be the most necessary design requirement in developing a task shifting medical device that was acceptable to end users. Primary design considerations to develop an easy to use device include the ability for the users to learn the device operation from their peers (peer-to-peer base learning), and the device should be maintainable by local technicians.

3.2. Introduction

Low- and middle-income countries (LMICs) as nations with the highest burden of health problems have been highly affected by the lack of trained and professional human resources to

provide quality medical care [1]. At the end of the last decade, 57 countries faced chronic human resource shortages in the health sector [2]. For example, sub-Saharan Africa, which has 11 percent of the world's population but bears 24 percent of the global disease burden, has only 3 percent of the global health workforce and accounts for just 1 percent of global health expenditure [3]. The rapid increase in infectious and chronic epidemics globally and the accelerating human resource crises in low-resource settings now give task shifting major prominence and urgency.

Task shifting is a process whereby specific tasks are moved, where appropriate, to less-qualified health workers with shorter training [2], or specific tasks are allocated to the least costly health worker capable of performing the task reliably [6].Task shifting has two objectives: increasing access to health care among populations and in locations with limited availability of professional health care providers, and cost effectiveness [2,4-7]. Task shifting has been suggested, and practiced, as one of the solutions to address the limited available human resources for delivery of quality and emergency health care services in low-resource settings. Prior to the introduction of task shifting, task substitution was used on a case-by-case basis to address the limited availability of human resources in health care delivery [8]. For instance, in 1969 Ghana introduced a medical assistant position that required a single year of training with a focus on the diagnosis and treatment of common disorders [6].

Task shifting typically involves four main cadres of health providers: medical doctors, non-physician clinicians (NPCs), nurses, and community health workers (CHWs) [1]. To enable successful implementation of task shifting, intervention factors such as clearly defined role distribution and scopes of practice, regulatory support, stakeholder involvement, training and supervision, effective referral systems, sustainable supplies and incentives should be considered [1]. In recent years extensive systematic approaches have been developed to promote shifting many basic health care delivery tasks for maternal and newborn health and HIV/AIDS [9-13].

While almost all births in the developed world are supervised by skilled birth attendance, fewer than 50 percent of births in South Asia and sub-Saharan Africa receive such support [14]. Consequently, there is an inverse association between neonatal mortality and the availability of skilled birth attendants [11]. Therefore, task shifting for maternal and newborn health related challenges has been pursued by global and national health organizations [2,4]. For example, a review of studies evaluating the effectiveness of lay health workers (similar to CHWs) in

delivering injectable vaccines and medicines via pre-filled auto-disabled devices in LMICs showed that the lay health workers successfully met the objectives and were motivated by positive responses from communities and increased social respect [10]. In another example, NPCs completing nine months of training were tasked to provide comprehensive emergency obstetric care in Tigray, Ethiopia [15]. A follow up evaluation found that even though the NPCs performed a significant proportion of emergency obstetric procedures (63 percent), the postoperative outcomes achieved under their care were similar to those attained by physicians. In rural Guatemala, training of auxiliary nurse-midwives to provide some services related to family planning actually increased the number of intrauterine contraceptive device users from 18.3 to 71.5 services per health center per month with only 0.6 percent complications [16].

An academic review of 82 studies to evaluate the effectiveness of CHWs intervention found that their utilization in providing primary health care services would promote immunization uptake and breastfeeding, improve TB treatment outcomes, and reduce child morbidity and mortality when compared to usual care [17]. A narrative synthesis of the literature from 2000 to 2011 found that task shifting related practices focused on specific clinical tasks (e.g., obstetric surgery, abortion, etc.) shifting between doctors, NPCs, nurses and midwives [11]. These findings suggest that the use of task shifting or sharing, as distribution of tasks among different cadres of health providers [1], for urgent and widely needed tasks may increase access to and availability of maternal and reproductive health services without compromising performance or patient outcomes and may lead to cost effective practices.

Task shifting and sharing have also been recognized as methods to address human resources needs during health services provision to address HIV/AIDS, especially for voluntary medical male circumcision campaigns in eastern and southern sub-Saharan Africa [2,18,19]. For examples, voluntary medical male circumcision and HIV/AIDS testing counseling can be delegated to lay counselors, NPCs, and nurses who are in greater supply than specialized physicians [19,20].

There are, however, potential barriers to effective implementation, such as possible adverse effects on patient safety, reductions in the authority of higher trained professionals, and lowering the standards of care [6,8,18]. Other barriers cited include poor clinical support and supervision, inadequate training, and haphazard implementation [7,11,12].

While task shifting has gained attention as a solution to address limited health workforce in low-resource settings, the role of medical devices in enabling task shifting and equipping lower cadres of health providers in achieving their newly defined tasks is underexplored. For example, only a few medical devices, such as PrePex and Shang Ring to assist with clinical male circumcision, and Uniject for vaccine and drug delivery, have been utilized in the task shifting process [9,10,13,21]. Expanding the role of medical devices in task shifting also requires a systematic, evidence-based investigation to determine the key factors expressed by stakeholders, needed to inform the design of successful task shifting medical devices.

This chapter investigates the perceptions of stakeholders directly or indirectly involved in health care delivery in low-resource settings about the role of medical devices in facilitating task shifting. Also, the chapter aims to elicit the characteristics that convert a device into a task shifting one and to define and clarify ease of use as a leading characteristic for designing a medical device.

3.3. Methods

A survey questionnaire, based on previous literature, consultation with experts and study team experience, was developed to elicit stakeholders' input and feedback on task shifting and medical devices. The University of Michigan's Institutional Review Board indicated this study as exempt since no personal identifiers were collected in the questionnaire. The questionnaire had three sections. Respondents could not revisit a question or section after completion and they could only view one question at a time.

3.3.1. Survey questionnaire development

Section one focused on stakeholders' general understanding of and preferences for task shifting in medicine and public health. The questions were:

1. Have you heard of task shifting in health care delivery? If so, what does task shifting mean to you in the context of your work (in health care delivery)?
2. Considering task shifting means "when feasible, healthcare tasks are shifted from higher-trained health workers to less highly trained health workers in order to maximize the efficient use of health workforce", do you agree with this definition? If not, please explain why.

3. Considering the definition of task shifting, list a few examples (procedures, devices, etc.) from your field that you believe can be considered as task shifting.
4. Under what conditions and pre-requisites do you think task shifting can happen?

The definition used for question two above was based on World Health Organization's (WHO) statement [2].

Section two focused on the necessary characteristics and product requirements that could lead to the development of a task shifting medical device. The questions were:

1. What does it mean for a medical device to be task shifting?
2. What design characteristics make a medical device task shifting?
3. What design characteristics make a medical device easy-to-use?
4. What are some examples of medical devices that can be considered as task shifting?
5. Rank order characteristics that make a medical device task shifting. Characteristics include:
    a. The device is easy-to-use.
    b. The device is widely available.
    c. The device is widely accessible (it can be delivered to users per their request).
    d. The device is low-cost (inexpensive).
    e. The device's operation is easy-to-learn (in less than a day).
    f. There is a policy in place for a device to become task shifting.
6. What other characteristics would make a medical device task shifting?
7. Would you consider a device easy to use, if it has any of the following characteristics:
    a. If its effective operation can be learned within three days.
    b. If its effective operation can be learned in less than a day.
    c. If its operation can be taught on peer-to-peer basis.
    d. If it is inexpensive (low-cost) compared to current practice.
    e. If is has an extensive operational manual written in the local language.
    f. If it has a brief operational manual in the local language.
    g. If it does not have an operational manual (no need for it).
    h. If it is portable (i.e., an average person can move/transport it without requiring assistance).
    i. If it reduces the current number of procedural steps for a given procedure.
    j. If it is easily cleaned by accessible or locally available cleaning products.

k. If it is single use (disposable after it is used once).
l. If it does not use electricity as its power source (powered mechanically).
m. If it is maintainable by local technicians.
n. If it is made from locally available materials.
o. If it is one size-fits-all.
p. If it is available in different sizes.
q. If it is culturally appropriate.
r. If it is safe for the intended patient.
s. If it is effective immediately.
t. If it is widely available.

8. What other design characteristics, if any, make a medical device easy to use?

The questionnaire explained that "design characteristics" referred to the tangible or intangible features that defined a medical device, and gave the example "device should be powered by mechanical source."

Section three focused on three medical devices, LifeWrap [22], Uniject [10], and condom catheter [23], used to address maternal and newborn health related challenges in low-resource settings. The rank order questions were:

1. Rank-order the devices in terms of their task shifting ability, and describe the logic used for your choices.
2. What is the minimum prior training level required to use the device?
3. What is the average training time required for a community (extension) health worker to learn how to use the device without any guidance?
4. What is the average time required by a community (extension) health worker to perform the task with this device?
5. What is the maximum risk to the patient if a community health (extension) worker operates this device?

The following descriptions for the three devices were also provided for the respondents.

> LifeWrap (Non-pneumatic Anti-shock Garment) for postpartum hemorrhage [22]:
> The LifeWrap delivers circumferential counter pressure to the lower body, legs, pelvis, and abdomen. The counter pressure reduces blood flow in the compressed

area, while the blood to the uncompressed area (core organs) is enhanced. The pressure applied by LifeWrap does not exceed 70 mmHg, hence avoiding potential ischemia or compartment syndrome. Compression decreases the radius of the blood vessels in the abdomen and pelvis, including the splanchnic plexus, which decreases blood flow. It is made of neoprene and Velcro™, with a foam compression ball that is placed over the abdomen.

Uniject (for vaccine and drug delivery) [10]: The Uniject is a single-use needle, designed with a pre-filled drug delivery container that cannot be refilled. This type of needle is effective in preventing needle sharing because it can only be used once and provides a sterile injection each time. It is also user-friendly in that medical personnel can be trained to use the Uniject in a short time. It is compact, convenient, easy to store and increases dosage precision.

Condom catheter balloon for postpartum hemorrhage [23]: A rubber catheter is used to insert a normal condom into the uterus. It is then inflated with 250-300 ml of isotonic saline solution until the bleeding is controlled. To retain the saline, the proximal end of the catheter is folded and tied with thread. Rolled gauze is packed in the vagina to keep the condom from moving.

3.3.2. Survey questionnaire distribution

The survey questionnaire was posted on an online platform using Qualtrics survey software. Online professional communities with members involved in health care delivery and technology development in low-resource settings were targeted, e.g., LinkedIn's Global Public Health, Global Public Health–Maternal and Reproductive Health, Global Public Health–Health Systems and Policy, Global Medical Devices, Medical Device Development, Marketing, and Sales, Global Health, Economic, and Education Development. The survey questionnaire was also distributed to members of the Global Health Delivery Online network (http://www.ghdonline.org) and emailed to members of the Global Alliance for Nursing and Midwifery Communities of Practice and the West African Health Informatics Fellowship Program and to the email list of the community of interest affiliated with WHO's Medical

Devices Unit. It was also distributed to health professionals and practitioners in Ethiopia, Ghana, and Uganda who had prior engagement with the research team. The survey was available online between June 15 and August 30, 2014 for public access.

3.3.3. Input analysis

Two study members trained in qualitative methods developed themes and categories based on the open-ended responses. One of the study members developed a themes codebook, and the other independently identified and categorized the themes. Rank ordering and comparison of choices between and within stakeholder groups were used for the quantitative responses. Statistical analysis software, SPSS V-20, was used to evaluate the quantitative input. Four randomly selected respondents received a $25 gift card or equivalent for completing the survey questionnaire.

3.4. Results

Of the 350 respondents who started the survey response process, 107 respondents completed it, giving a 30.6 percent completion rate. Three of the 107 respondents were removed for failure to complete the questionnaire properly, for a final total of 104 responses. The study team grouped the respondents into seven stakeholder categories based on professional position. Table 3.1 provides an overview of stakeholder categories and respondents' positions.

3.4.1 Section 1: General perception and feedback on task shifting in health delivery

Section one focused on eliciting perceptions, general understanding, and recommendations for task shifting in health delivery.

Task shifting definition and alternative suggestions: A total of 84 (81 percent) respondents had previously heard of task shifting in the context of health delivery services. Based on the responses, the study team identified 12 relatively distinct groups of definitions for task shifting. The most commonly given definitions aligned with WHO's definition. The following examples capture the definition given by the majority of respondents.

> *"Task shifting is a concept in which duties initially assigned to a given cadre are re-assigned to another cadre in order to improve on the effectiveness of*

performing such duties. It is a necessary concept that effectively deals with issues of reduced human resource, and for scaling up purposes." (Medical doctor)

"Task shifting helps increase the care provider to patient ratio by training lesser qualified health care workers on specialized tasks and allowing them to provide those basic services." (Medical doctor)

"Having appropriately skilled people doing the most advanced work for their skill level allowing regionalization and referral to optimize care." (Nurse-midwife)

"Shifting of some specialized task usually done by a highly trained health worker to a less specialized, skilled and trained worker following training due to lack of trained highly trained worker." (Medical doctor)

"It is the reallocation of tasks in healthcare setting usually performed by highly qualified personnel to less qualified staff."(Academic researcher)

The definitions given by 70 percent of medical doctors, 50 percent of nurse-midwives, 50 percent of biomedical engineers, 58 percent of public health officers, 86 percent of academic researchers, and 66 percent of community health workers aligned with the definitions above. A few definitions were too general (e.g., expanding health delivery) or too narrow (e.g., using specific location, personnel, or context):

"Task shifting is a low-cost solution to tackling gaps in health services gaps." (Biomedical engineer)

"Task shifting, for me, is using modern technology like modern medical devices that help to deliver the intended care efficiently and effectively." (Nurse-midwife)

Table 3.1: Demographics of the respondents

Stakeholder type	Numbers of respondents	Years of experience
Medical doctors (MDs)	30	<1: 1 1-3: 4 3-5: 2 5-10: 21 >10: 2
Nurse-Midwives (NMs)	26	<1: 0 1-3: 1 3-5: 6 5-10: 18 >10: 2
Biomedical engineers and technicians (BMEs)	16	<1: 2 1-3: 5 3-5: 3 5-10:2 >10: 4
Public health staff (PHs)	12	<1: 0 1-3: 0 3-5: 7 5-10: 4 >10: 1
Academic Researchers (ARs)	14	<1: 0 1-3: 4 3-5: 4 5-10: 5 >10: 1
Community health workers (CHWs)	3	<1: 0 1-3: 0 3-5: 1 5-10: 2 >10: 0
Others (involved in supply chain and NGO management)	3	<1: 0 1-3: 0 3-5: 2 5-10: 0 >10: 1

When asked whether they agreed with WHO's definition of task shifting, two medical doctors, three nurse-midwives, one biomedical engineer, one academic researcher, and two CHWs offered alternative or complementary definitions. The main point of disagreement raised by a medical doctor, nurse-midwife, and an academic researcher was that task sharing, rather than task shifting, should be the central point in expanding healthcare delivery services, for example:

> *"I would rather have the tasks shared than shifted because task shifting would reduce the dexterity of the more trained professionals." (Medical doctor)*

One CHW said that task shifting did not necessarily mean transferring the tasks from highly trained personnel to less trained ones:

> *"It doesn't necessarily have to be form higher to less highly, it can just be a restructured organization around one task." (Community health worker)*

Table 3.2: Task shifting procedure examples (blank cells indicate no response from the stakeholder group)

Example category	Sub categories	MDs (%)	NMs (%)	CHW (%)	BMEs (%)	PHs (%)	ARs (%)	Others (%)
General care (96)	Injections (immunization) – 19	27%	19%	33%	6%	8%	21%	
	Symptoms' management of already diagnosed patients – 1	3%						
	Management of common cases at the community level – 25	27%	19%		25%	33%	21%	
	Routine office visits and performing low-risk medical tests – 9	7%	4%	33%	19%		7%	33%
	Checking of medical tests – 5		15%		6%			
	Urethral catheterization – 3	3%	4%			8%		
	Pre-operation preparations – 1					8%		
	Basic surgical operations (suturing, wound care, etc.) – 9	7%	12%		6%	8%	14%	
	Prescribing some of the medications (simple diagnostic tests and medication admin) – 9	13%	15%				7%	
	Giving Anesthesia – 1	3%						
	Home-based care (e.g., management of diabetes, BP monitoring, etc.) – 3	3%	4%		6%			
	Taking vital sign – 3		12%					
	Feeding patients with assistive devices – 4		12%			8%		
	Sterilization – 1				6%			
Obstetric care (88)	Assisted delivery (vacuum extraction) – 5	7%	4%			8%	7%	
	Assisting in vaginal delivery – 19	23%						
	Removal of retained placenta – 1	3%						
	PPH care management/control – 6	7%	8%		6%	8%		
	Early detection of maternal and infant health related complications – 8	13%	23%		6%	8%		33%
	Assisted abortion (manual vacuum aspiration for abortion/termi) – 6	10%	4%				14%	
	C-section by midwives/trained surgical technicians – 12	23%	4%			8%	21%	
	Emergency obst care (e.g., oxytocin inj, MgSO4 admin by nurses) – 6		15%		6%	8%		
	Family planning services (e.g., IUD/ underarm implant insertion) – 17	23%	12%	33%	6%	17%	21%	
circumcision	Operation shift from clinical officers to nurses – 9	20%	4%		6%	8%		

	Using non-surgical MC devices – 1				6%			
	Early infant male circumcision (from med officers to midwives and…) – 3	10%						
Technology and medical devices (9)	Clinical engineering assistants setting up medical equipment and check on their operations – 1				6%			
	Portable devices for early diagnosis of diseases – 2				13%			
	Device for automatic analysis of a diagnostic image – 1				6%			
	Blood transfusion, from manual to automatic – 1				6%			
	EMR – 2				6%		7%	
	Vaccine patches or oral syringes – 1				6%			
	Uniject – 1						7%	
	Automated physiological signal analysis – 1						7%	
Public health and medical education (8)	Health education, preg related risk education – 6	3%	12%		6%	8%		
	Tutorial performed by teaching assistants rather than profs – 1						7%	
	Health education for parents re: congenital birth defects – 1							33%
Gynecological care (4)	Some of the gyn tests and minimal surgeries – 3	7%				8%		
	Cervical cancer screening – 1	3%						
Mental care (3)	Counseling from over-stressed doctors to trained psychologist and medical psychologist – 3	10%						
Vision care (3)	Vision tests and general care – from ophthalmology surgeon to optometrists, or in schools by teachers/CHWs instead of nurses – 2		4%			8%		
	Trachoma surgery – to integrate eye care workers – 1					8%		
Infant care (1)	Neonatal resuscitation by auxiliary midwives – 1						7%	
Dentistry services (1)	Dental therapist vs. dentists – 1						7%	

A nurse-midwife said that task shifting did not necessarily translate into maximizing the efficient use of healthcare workforce:

> *"This does not necessarily equal to 'efficient use of health workforce resources' rather risks creating an opposite outcome if effective supervision and mentor are (not) exercised." (Nurse-midwife)*

Examples of task shifting: Table 3.2 presents 40 examples of procedures, tasks, and uses of technologies that were shifted in the respondents' practice, or were candidates for task shifting. The majority of examples expressed were for general or primary care, obstetric care, and male circumcision.

Conditions required for task shifting: There were 18 distinct responses for "Under what conditions and pre-requisites do you think task shifting can happen?" The most commonly expressed (cited by at least 10 respondents) requirements were (number in parenthesis is the number of respondents giving the answer):

1. Availability of proper training, simplicity of the task, like following an algorithm, ease of teaching especially if accompanied with technology, in supportive conditions in which all parties are involved in the discussion and readiness of the working environment (47)
2. There needs to be a high public health demand, while there is a low number of trained health workforce (27)
3. Availability of proper (clear and continuous) supervision and follow up support with highly trained care providers (27)
4. Safe for the patient (11)
5. Availability of policies and guidelines to support task shifting (10)
6. Low-cost, especially for the patients, with appropriate (ease to use) devices available (10)

Other prerequisites included an uninterrupted supply chain to provide necessary materials for tasks, clearly defined tasks for shifting, ease of understanding and communicating the task, and acceptance of the task shifting by the patient population. A noteworthy response by one midwife

respondent stated that a group of health providers, for example midwives, could lose part of their sense of identity by shifting certain procedures (tasks) to other cadres, since both they and the patients had grown used to performing such work.

3.4.2. Section 2: Task shifting in medical devices

Section two asked the respondents to give the characteristics and specific design factors which they believed would enable developing task shifting medical devices.

Task shifting medical devices definition: Twelve categories emerged after the study team grouped the responses to "What does it mean for a medical device to be task shifting?" based on the themes identified (Table 3.3).

Table 3.3: Perception of stakeholders about task shifting medical devices

The device can be used… (frequency of mentioned)	MDs	NMs	BMEs	PHs	CHWs	ARs	Others
… by a less specialized health worker safely, and easily (50)	17 (57%)	5 (19%)	14 (88%)	5 (42%)	2 (67%)	7 (50%)	1 (33%)
… to do what skilled manpower would have done manually/requires fewer personnel in process (8)	2 (7%)	4 (15%)	2 (13%)				
… for purposes different than the intended design (3)	1 (3%)			1 (8%)		1 (7%)	
… for diagnostic procedures (2)	1 (3%)	1 (4%)					
… if it is replaced by a locally produced one with the same efficiency and safety (2)		1 (4%)		1 (8%)			
… if it assists, and supports the process (1)	1 (3%)						
… if its production is consistent with consistent with the developmental level of the community (1)	1 (3%)						
... if it assists with performing a duty and it can be maintained easily (1)		1 (4%)					
… if it assists with data collection that is otherwise done by a clinician (1)		1 (4%)					
… if it is a (more reliable) alternative replacing a technical equipment (1)					1 (33%)		
… if it can be used to screen, diagnose as well as treatment purposes (1)				1 (8%)			
… if it assists with timely operation (1)							1 (33%)
Unclear how these separate entities can go together (19)	6 (20%)	4 (15%)		4 (33%)		4 (29%)	1 (33%)

The two most common responses were (number in parenthesis is the number of respondents giving the answer):

1. The device can be used by a less specialized health worker safely and/or easily (50)
2. The device can be used to do what skilled manpower would have done manually/requires fewer personnel in process (8)

Nineteen respondents were unclear about the relationship between task shifting and medical devices or did not know how to respond to the question.

Sixty-seven characteristics emerged after the study team grouped the responses to "What characteristics make a medical device task shifting?" The study team then grouped them into seven major categories (usability, engineering design, performance, safety, cost, manufacturing and supply chain, and implementation and commercialization characteristics), Table 3.4.. The characteristics given by at least 10 respondents (number in parenthesis is the number of respondents giving the answer) were:

1. Be easy to learn how to use (68)
2. Be safe for patients (36)
3. Be made of locally available materials for ease of maintenance (29)
4. Be low-cost (28)
5. Be portable (18)
6. Have high accuracy, with reasonable specificity/sensitivity (17)
7. Be single use (13)
8. Accommodate alternative power sources (e.g., such as solar energy) (11)
9. Be multi-use (10)

The respondents cited 150 devices and technologies as examples of task shifting medical devices. However, only nine devices, or device types, were mentioned by five or more respondents (Table 3.5). The major justifications for considering devices as task shifting were:

1. A less-trained user, or even a person with no medical training can use it
2. It replaces a traditional user (e.g., physician) with a more readily available one (e.g., nurse)
3. It is easy to use with minimal risks to patient or user
4. It is light, or portable and suitable for point of care

Answering the open-ended question about the characteristics that made a medical device easy to use, 19 requirements were mentioned by at least five or more respondents (Table 3.6). The two most common were ease of learning the operation and easy to use.

The respondents were also asked to rank order the characteristics contributing to the development of a task shifting medical device. All stakeholder groups unanimously indicated "easy to use" as the most important characteristic. Six of the seven groups ranked "ease of learning operation" second. Five stakeholder groups ranked "having a policy in place" last. Table 3.7 presents the ranked characteristics by stakeholder group.

Section 2 of the survey questionnaire also listed 20 design requirements associated with ease of use. Table 3.8 provides an overview of the respondents' agreement with each requirement. More than 90 percent of respondents within each stakeholder group agreed that a device could be considered easy to use if its operation could be taught on a peer-to-peer basis. At least 80 percent of the respondents in each stakeholder group mentioned that a device should be maintainable by local technicians and that it should reduce the current procedural time.

Table 3.4: Characteristics perceived leading to development of a task shifting medical device (cell numbers indicate frequency of a characteristic mentioned by respondents in each stakeholder group)

Characteristics	MDs	NMs	BMEs	PHs	CHWs	ARs	Others
Usability and use(r) related characteristics (17)							
1. Easy to learn how to use, easy to use, simple	16	15	16	10	1	9	1
2. Clear results, findings, feedback reported – little interpretation required		2	3			1	
3. Single use/disposability	4	3	3	1	2		
4. Portable	8	4	1	2	2		1
5. Manually operated	6	1		1		1	
6. Easy to switch on/off	2						
7. Repeatability/ reusability	5	3	2				
8. Use should be appropriate for purpose	1						
9. Convenient/comfortable for use	2		1	1			
10. Can be adapted for the purpose	1						
11. Provides measurements that are easy to interpret	1						
12. Easy to assemble	1						
13. Does not require more than one operator/personnel	1						
14. Minimum operations, not too many functions	1						
15. Usable across all age population	1						
16. Consistent across sites of use						2	
17. Easy to teach from peer-to-peer base						1	

Engineering design characteristics (28)							
1. Power source – battery operated	2	3		2	1	3	
2. Power source – electrically powered	1		1				
3. Power source – use power source that goes with the setup	1						
4. Dual operating system (power source)				1			
5. Requires no or minimal accessories	1	2	2				
6. Culturally acceptable	4	2		1			
7. Durable	1	1	1			2	
8. Automate background complex tasks wherever possible	1						
9. Allows multitasking	1			1		1	
10. Artificial intelligence	1						
11. Open access		1					
12. Stylish		1					
13. Diagnostic	1	2					1
14. Calibration (well calibrated/programmed correctly)		2	2				
15. Stable at all temperature	1	1					
16. Ease of storage, for buffers and solutions	1						
17. Cable and/or wireless		1					
18. Not closely affect the doctor/nurse and patient relationship		1					
19. Not closely related to medical diagnosis or care		1					
20. Transaction record		1					
21. Includes concise instructions							2
22. Minimized the post-op visits	1						
23. No water source needed		1					
24. Accessible online/smart phone/ in-print				1			
25. Proper indications of how many times it may be used						1	
26. Supports transfer of skills and knowledge						1	
27. Similar to known devices						1	
28. Made of locally available materials, readily available easy to maintain	8	6	2	9	1	3	
Performance characteristics (2)							
1. High accuracy, or specificity, or sensitivity, or reliability	8	2	3	2		2	
2. Short procedure time/minimal steps		2	2	1		1	
Safety characteristics (8)							
1. Not harmful to patients	13	9	8	4		1	1
2. Less/non invasive	1	1	1				
3. Not a life supporting device		1					
4. Device is inserted inside the body		1					
5. Reduces human error			1				
6. Should protect the privacy of the user						1	1
7. Doesn't deploy if inappropriately in	1						

place							
8. Sterility of parts exposing in body – minimal possibility of cross contamination	1	1					
Cost characteristics (3)							
1. Reproducible, possible to scale up	3	2		1			
2. Cheap, cost effective, economical	8	5	4	5	2	3	1
3. Feasible	1						
Manufacturing and supply chain characteristics (3)							
1. Environmental friendly – limited waste	2	2	1	1			
2. Easy to dispense	1						
3. Appropriately installed		1					
Implementation and commercialization characteristics (6)							
1. Creates a sense of ownership			1				
2. Ready payer to pay for the device			1				
3. Priority of the health sector and strategy				1			
4. Should not put other employees out of work						1	
5. Standardization of procedure						1	
6. Easy access to guidelines to perform tasks	1	1					

Table 3.5: Top ten devices, or device types, mentioned as examples for task shifting consideration (the numbers in parenthesis indicate frequencies that each device was mentioned)

Device	**MDs (#)**	**NMs (#)**	**BMEs (#)**	**PHs (#)**	**CHWs (#)**	**ARs (#)**	**Others (#)**
Ultrasound (10)	4	1	1	1	2	1	
Glucometer (10)	5	3	1		1		
Male circumcision device (7)	2	2	2			1	
Uniject (6)	1			1		4	
Digital BP monitor (6)	2		3			1	
Thermometer (6)	2	2	1			1	
Automated BP cuff (5)		3	2				
Intrauterine device (5)	2	1			2		
ECG machine (5)	1	3				1	

Table 3.6: Design requirements that can lead to the design of an easy to use device (the numbers in parenthesis indicate frequencies that each requirement was mentioned)

The device is easy to use if…	**MDs**	**NMs**	**BMEs**	**PHs**	**CHWs**	**ARs**	**Others**
1. … it is easy to learn how to operate (41)	10	5	12	6	1	6	1
2. … if its operation manual and instructions are easily understood and readily available (23)	5	7	2	1	1	6	1
3. … if it is easy to apply (23)	9	7	2	3		1	1
4. … if it has few accessories with minimal complexity (21)	7	3	4	3		4	
5. … if it reduces the procedure time	2	4	5	5		2	

(18)							
6. … if it is easy to apply (18)	6	7	2	2			1
7. … if it provides results without need for interpretation (15)	2	4	5	2	1	1	
8. … if it is low cost (15)	6	3	3	1	1	1	
9. … if it is reliable, minimizing the likelihood of misuse (15)	4	6	3	1		1	
10. … if it is safe (12)	4	3	1	2		2	
11. …if it is portable (12)	3	2	1	1	2	1	2
12. … if it is available, or locally manufactured (12)	6	4	1	1			
13. … if it is easy to clean/sterile, if reusable (9)	3	2	2	2			
14. …if its operation and instruction manual is in local language (7)	2	3		1		1	
15. … if it is easy maintenance (7)	1	2	3	1			
16. … if it is safely assembled or disassembled (7)	2	1	1	2		1	
17. … if it is for single use, i.e., impossible to use twice (6)	3		1		1	1	
18. … if it is durable (5)	1	1		1		2	
19. … if it automates complex tasks, i.e., minimal manipulation by user (5)	1	1	1	1		1	

Table 3.7: Ranked order characteristics that can lead to development of a task shifting medical device; List of characteristics that respondents ranked is listed in the Methods section

Group	Rank 1	Rank 2	Rank 3	Rank 4	Rank 5	Rank 6
MDs	Easy to use	Easy to learn	Available	Low cost	Accessible	Policy
NMs	Easy to use	2. Easy to learn 2. Available	Accessible	Low cost	-	Policy
BMEs	Easy to use	Easy to learn	3. Low cost 3. Available	Accessible	-	Policy
PHs	Easy to use	Easy to learn	Policy	4. Available 4. Accessible	-	Low cost
CHWs	1. Easy to use 1. Available	Low cost	-	Easy to learn	Accessible	Policy
ARs	Easy to use	Easy to learn	Policy	Available	Accessible	Low cost
Others	Easy to use	2. Easy to learn 2. Low cost	Accessible	Available	-	Policy

Table 3.8: Stakeholder agreements with requirements leading to development of an easy to use device; The columns after the Requirement column indicate the percentage threshold that each stakeholder group agreed with the specific requirement

Requirement	90% and above	80% and above	70% and above	60% and above	50% and above
1. Learning time within 3 days	Others	MDs, Others	MDs, Others	MDs, PHs, CHWs, Others	MDs, BMEs, PHs, CHWs, Others
2. Learning time less than a day	BMEs	MDs, NMs, BMEs, PHs, CHWs, ARs	MDs, NMs, BMEs, PHs, CHWs, ARs	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
3. Taught peer to peer bases	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
4. Low cost	CHWs		MDs, CHWs	MDs, NMs, CHWs	MDs, NMs, CHWs
5. Extensive operational manual	CHWs	CHWs	CHWs	CHWs	
6. Brief operational manual	CHWs, Others	PHs, CHWs, Others	MDs, PHs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
7. No operational manual	CHWs	CHWs	BMEs, CHWs	BMEs, CHWs	NMs, BMEs, PHs, CHWs, ARs
8. Portable	PHs, CHWs	MDs, PHs, CHWs	MDs, NMs, BMEs, PHs, CHWs	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
9. Reduced procedural steps	MDs, NMs, PHs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
10. Cleaned by available materials	MDs, NMs, PHs, CHWs	MDs, NMs, PHs, CHWs, ARs	MDs, NMs, BMEs, PHs, CHWs, ARs	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
11. Single use				CHWs	MDs, NMs, CHWs, ARs
12. No electrical power required	CHWs	MDs, NMs, CHWs	MDs, NMs, CHWs	MDs, NMs, PHs, CHWs	MDs, NMs, PHs, CHWs, ARs
13. Maintainable by local technicians	MDs, NMs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others

14. Made from locally available materials	CHWs	MDs, NMs, CHWs	MDs, NMs, CHWs	MDs, NMs, CHWs, Others	MDs, NMs, PHs, CHWs, Others
15. One size fits all	MDs	MDs	MDs, NMs, ARs	MDs, NMs, BMEs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
16. Multiple size				MDs, NMs, PHs, CHWs, Others	MDs, NMs, PHs, CHWs, Others
17. Culturally acceptable	MDs, CHWs, Others	MDs, NMs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
18. Safe	NMs, PHs, CHWs, Others	MDs, NMs, PHs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
19. Effective immediately	MDs, CHWs, Others	MDs, NMs, PHs, CHWs, Others	MDs, NMs, PHs, CHWs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others	MDs, NMs, BMEs, PHs, CHWs, ARs, Others
20. Widely available		MDs, NMs	MDs, NMs	MDs, NMs, PHs, CHWs, Others	MDs, NMs, PHs, CHWs, ARs, Others

3.4.3. Section 3: Evaluation of task shifting medical devices

Section 3 asked respondents about the task shifting abilities and characteristics for three specific devices: LifeWrap, Uniject, and the condom catheter. Six of the seven stakeholder groups selected Uniject as the device with the most task shifting capability (Table 3.9).

Table 3.9: Task shifting ability ranking of each device (1: most task shifting, 3: least task shifting)

	LifeWrap (%)	Uniject (%)	Condom Catheter (%)
MDs (30)			
Rank 1	8 (27%)	16 (53%)	6 (20%)
Rank 2	15 (50%)	9 (30%)	7 (23%)
Rank 3	7 (23%)	5 (17%)	17 (57%)
NMs (26)			
Rank 1	11 (42%)	7 (27%)	8 (31%)
Rank 2	9 (35%)	6 (23%)	11 (42%)
Rank 3	6 (23%)	13 (50%)	7 (27%)
BMEs (16)			
Rank 1	2 (13%)	12 (75%)	1 (6%)
Rank 2	13 (81%)	2 (13%)	0 (0%)
Rank 3	1 (6%)	2 (13%)	15 (94%)
PHs (12)			
Rank 1	5 (42%)	5 (42%)	2 (17%)
Rank 2	4 (33%)	6 (50%)	2 (17%)
Rank 3	3 (25%)	1 (8%)	8 (67%)
ARs (14)			
Rank 1	4 (29%)	8 (57%)	2 (14%)
Rank 2	8 (57%)	5 (36%)	1 (7%)
Rank 3	2 (14%)	1 (7%)	11 (79%)
CHWs (3)			
Rank 1	1 (33%)	2 (67%)	0 (0%)
Rank 2	2 (67%)	1 (33%)	0 (0%)
Rank 3	0 (0%)	0 (0%)	3 (100%)
Others (3)			
Rank 1	1 (33%)	2 (67%)	0 (0%)
Rank 2	1 (33%)	1 (33%)	1 (33%)
Rank 3	1 (33%)	0 (0%)	2 (67%)

The choice aligned with the responses to the next question about the amount of minimum prior training, i.e., training level of CHWs (Table 3.10). Again, six of the seven stakeholder groups selected Uniject and indicated that it should take less than an hour to train a CHW (Table 3.11).

Table 3.10: Minimum prior training level required to be able to use the device properly

	Minimum prior training required to operate the device	LifeWrap (%)	Uniject (%)	Condom Catheter(%)
MDs (30)				
	1- CHW	19 (63%)	21 (70%)	6 (20%)
	2- Nurse/Midwife	11 (37%)	9 (30%)	15 (50%)
	3- Physician	0 (0%)	0 (0%)	9 (30%)
NMs (26)				
	1- CHW	13 (50%)	13 (50%)	5 (19%)
	2- Nurse/Midwife	13 (50%)	12 (46%)	18 (69%)
	3- Physician	0 (0%)	1 (4%)	3 (12%)
BMEs (16)				
	1- CHW	11 (69%)	14 (88%)	2 (13%)
	2- Nurse/Midwife	5 (31%)	2 (13%)	12 (75%)
	3- Physician	0 (0%)	0 (0%)	2 (13%)
PHs (12)				
	1- CHW	5 (42%)	11 (92%)	4 (33%)
	2- Nurse/Midwife	7 (58%)	1 (8%)	4 (33%)
	3- Physician	0 (0%)	0 (0%)	4 (33%)
ARs (14)				
	1- CHW	9 (64%)	14 (100%)	1 (7%)
	2- Nurse/Midwife	4 (29%)	0 (0%)	12 (86%)
	3- Physician	1 (7%)	0 (0%)	1 (7%)
CHWs (3)				
	1- CHW	2 (67%)	2 (67%)	0 (0%)
	2- Nurse/Midwife	1 (33%)	1 (33%)	2 (67%)
	3- Physician	0 (0%)	0 (0%)	1 (33%)
Others (3)				
	1- CHW	3 (100%)	1 (33%)	2 (67%)
	2- Nurse/Midwife	0 (0%)	2 67%	0 (0%)
	3- Physician	0 (0%)	0 (0%)	1 (33%)

Table 3.11: Average training time required for a CHW to learn how to use the device properly without guidance

	Average time required for training	LifeWrap	Uniject	Condom Catheter
MDs (30)				
	Less than one hour	9 (30%)	17 (57%)	5 (17%)
	Between one and five hours	16 (53%)	11 (37%)	11 (37%)
	More than a day	5 (17%)	2 (7%)	14 (47%)
NMs (26)				
	Less than one hour	7 (27%)	12 (46%)	3 (12%)
	Between one and five hours	14 (54%)	9 (35%)	13 (50%)
	More than a day	5 (19%)	5 (19%)	10 (38%)
BMEs (16)				
	Less than one hour	8 (50%)	12 (75%)	3 (19%)
	Between one and five hours	7 (44%)	3 (19%)	7 (44%)
	More than a day	1 (6%)	1 (6%)	6 (38%)
PHs (12)				
	Less than one hour	3 (25%)	6 (50%)	0 (0%)
	Between one and five hours	5 (42%)	5 (42%	6 (50%)
	More than a day	4 (33%)	1 (8%)	6 (50%)
ARs (14)				
	Less than one hour	4 (29%)	9 (64%)	0 (0%)
	Between one and five hours	7 (50%)	4 (29%)	4 (29%)
	More than a day	3 (21%)	1 (7%)	10 (71%)
CHWs (3)				
	Less than one hour	1 (33%)	1 (33%)	0 (0%)
	Between one and five hours	2 (67%)	2 (67%)	1 (33%)
	More than a day	0 (0%)	0 (0%)	2 (67%)
Others (3)				
	Less than one hour	1 (33%)	0 (0%)	1 (33%)
	Between one and five hours	1 (33%)	0 (0%)	0 (0%)
	More than a day	1 (33%)	3 (100%)	2 (67%)

All stakeholder groups agreed that it should take less than 15 minutes to use Uniject successfully (Table 3.12). When asked about the maximum possible risk to a patient if a CHW operated three devices, the majority of respondents in all stakeholder groups cited “no to medium risk” if a CHW used Uniject (Table 3.13).

Table 3.12: The average time required by a CHW to accomplish the task with the device

	Average time required to accomplish the task	LifeWrap	Uniject	Condom Catheter
MDs (30)				
	Less than fifteen minutes	14 (47%)	26 (87%)	11 (37%)
	Between fifteen and sixty minutes	15 (50%	3 (10%)	14 (47%)
	More than an hour	1 (3%)	1 (3%)	5 (17%)
NMs (26)				
	Less than fifteen minutes	9 (35%)	17 (65%)	13 (50%)
	Between fifteen and sixty minutes	10 (38%)	3 (12%)	8 (31%)
	More than an hour	7 (27%)	6 (23%)	5 (19%)
BMEs (16))				
	Less than fifteen minutes	9 (56%)	15 (94%)	6 (38%)
	Between fifteen and sixty minutes	6 (38%)	1 (6%)	7 (44%)
	More than an hour	1 (6%)	0 (0%)	3 (19%)
PHs (12)				
	Less than fifteen minutes	4 (33%)	11 (92%)	6 (50%)
	Between fifteen and sixty minutes	8 (67%)	1 (8%)	4 (33%)
	More than an hour	0 (0%)	0 (0%)	2 (17%)
ARs (14)				
	Less than fifteen minutes	4 (29%)	13 (93%)	2 (14%)
	Between fifteen and sixty minutes	10 (71%)	1 (7%)	9 (64%)
	More than an hour	0 (0%)	0 (0%)	3 (21%)
CHWs (3)				
	Less than fifteen minutes	0 (0%)	3 (100%)	1 (33%)
	Between fifteen and sixty minutes	3 (100%)	0 (0%)	2 (67%)
	More than an hour	0 (0%)	0 (0%)	0 (0%)
Others (3)				
	Less than fifteen minutes	1 (33%)	0 (0%)	1 (33%)
	Between fifteen and sixty minutes	2 (67%)	3 (100%)	1 (33%)
	More than an hour	0 (0%)	0 (0%)	1 (33%)

Table 3.13: Maximum risk to patient if a CHW operated the device

	Risk to patient if a CHW operates the device	LifeWrap	Uniject	Condom Catheter
MDs (30)				
	No risk	10 (33%)	15 (50%)	3 (10%)
	Medium risk	16 (53%)	14 (47%)	13 (43%)
	High risk	4 (13%)	1 (3%)	14 (47%)
NMs (26)				
	No risk	10 (38%)	7 (27%)	2 (8%)
	Medium risk	10 (38%)	13 (50%)	15 (58%)
	High risk	6 (23%)	6 (23%)	9 (35%)
BMEs (16)				
	No risk	9 (56%)	5 (31%)	1 (6%)
	Medium risk	4 (25%)	11 (69%)	8 (50%)
	High risk	3 (19%)	0 (0%)	7 (44%)
PHs (12)				
	No risk	3 (25%)	6 (50%)	1 (8%)
	Medium risk	7 (58%)	4 (33%)	4 (33%)
	High risk	2 (17%)	2 (17%)	7 (58%)
ARs (14)				
	No risk	4 (29%)	5 (36%)	0 (0%)
	Medium risk	5 (36%)	9 (64%)	4 29%
	High risk	5 (36%)	0 (0%)	10 71%
CHWs (3)				
	No risk	1 (33%)	0 (0%)	0 (0%)
	Medium risk	1 (33%)	3 100%	2 (67%)
	High risk	1 (33%)	0 0%	1 (33%)
Others (3)				
	No risk	2 (67%)	0 (0%)	1 (33%)
	Medium risk	1 (33%)	3 (100%)	1 (33%)
	High risk	0 (0%)	0 (0%)	1 (33%)

3.5. Discussion

Task shifting is facilitated and even expedited by utilizing medical devices expressly designed for this purpose. Therefore, it is essential to identify the generalizable design characteristics that can guide the design process for developing task shifting medical devices.

More than 80 percent of the respondents had heard of, or knew about task shifting. While the majority of definitions aligned with WHO's definition of task shifting, a few respondents favored task sharing, since they felt it could yield safer and more controlled practices. The respondents repeatedly cited availability of proper training, simplifying the task, high demand and urgent need when few care providers are available, continuous supervision, and safety considerations as the chief characteristics. required to facilitate task shifting. Other than these somewhat obvious prerequisites, lower cost of the procedure or task, uninterrupted supply chain for necessary instruments and devices, and ease of understanding and communicating the task to be shifted were cited. Each of these conditions will add to a designer's understanding of the requirements to consider when developing a task shifting medical device.

When asked about what they perceived as a task shifting medical device, the most common characteristics were ease of use and safe to use by less specialized health workers. Only 18 percent of respondents did not foresee how a medical device could be utilized to facilitate task shifting. When asked to give the design characteristics that could lead to the development of a task shifting device, 25 respondents (24 percent) mentioned ease of learning the device operation, safety when applied on a patient, ease of maintenance, and low cost. These characteristics point to the importance of designing simple devices based on sustainable usage cycles that can be easily taught to less trained providers, have minimal to no risk to patients and providers, and that can be repaired and maintained by the local workforce.

Among the options given to respondents for ranking of characteristics enabling task shifting, ease of use was the highest ranked characteristic required to consider a device as task shifting. The option aligns with two previously cited characteristics: ease of use and easy to learn. Six stakeholder groups ranked the latter as the second highest characteristic. Notably, five stakeholder groups ranked having a policy in place as the least important characteristic. The study team concluded that a medical device would not be perceived as task shifting simply because an institutional policy or guideline labeled it a task shifting device. In other words,

policy makers should help end users and stakeholders understand and accept the inherent task shifting nature of a device rather than imposing task shifting as a regulation or policy.

Recognizing that the ease of use requirement was a highly subjective one, the study team's survey questionnaire listed 20 specific design requirements associated with ease of use. Response evaluation showed that more than 90 percent of the respondents perceived that a device was easy to if its operation could be taught on a peer-to-peer basis, while more than 80 percent of the respondents perceived that the ease of use requirement also meant local maintenance and repair. Combining the characteristics would allow a designer to close the development loop of a task shifting medical device by enabling local users to train their peers and local technicians to maintain it.

Design engineers also need to consider learning time of less than a day and cultural appropriateness. Eighty-five respondents (80 percent) perceived reducing procedure time was important as a design characteristic. While reduced procedure time might lead to development of an easy to use device, it is doubtful that it would lead to development of a task shifting device. This shows that while there are requirements that could lead to development of an easy to use device, they might not be relevant to, or even oppose the requirements to develop a task shifting medical device.

Uniject was perceived as the best in task shifting of the three devices based on the device description provided or personal experience. Uniject's status was bolstered by real world usage in several LMICs [10]. Six stakeholder groups stated that its operation could be taught in less than 15 minutes, a finding that aligns with previous data showing that Uniject's operation could be taught in a short time [24].

The study's outcomes are somewhat limited, given the use of an online survey questionnaire. The study team could not confirm respondents' background information, thus leaving the possibility of inaccurate or biased responses. Evaluations of the three devices based on the written descriptions provided in the survey questionnaire limited or biased the responses. Only using English-speaking respondents who worked in low-resource settings undoubtedly limited the range of responses.

To our best knowledge this study is the first to investigate the concept of task shifting within the context of the design and development of medical devices for use in low-resource settings. It elicited the perception of stakeholders about task shifting medical devices. It also

investigated the necessary characteristics that designers could use as product requirements in developing successful task shifting medical devices. It captured the perceptions of a wide range of stakeholders involved in health care delivery in low-resource settings regarding the role of medical devices in facilitating task shifting.

Prior work in public health and health delivery in low-resource settings focused on developing an infrastructure for implementing task shifting has generally considered specific steps, such as providing training and referral systems, ensuring adequate recognition and remuneration, developing guidelines, engaging with regulatory frameworks and professional organizations, and exploring the potential for community support of task shifting. On the other hand, the work described in this study represents an opportunity to use an approach that includes the fields of public health, health care delivery, and design engineering. The study's findings demonstrate widespread support across the stakeholder groups involved in health care delivery in low-income settings to utilize task shifting medical devices. Medical device designers should consider ease of use as the most necessary design requirement in developing a task shifting medical device, followed by ability for peer-to-peer training, and local maintenance and repair.

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Chapter 4. Empirical evaluation of user requirements elicitation and prioritization methods for a medical device involving multiple stakeholders

4.1. Abstract

Involving stakeholders directly throughout the design engineering process can help to identify needs, elicit user requirements, and develop optimal solutions, particularly when the constraints are difficult to ascertain a priori. This study evaluates and discusses three user requirements elicitation and prioritization methods: open-ended, clustering, and discrete choice, to design a post-partum hemorrhage device for use in low-resource settings. We characterize each method's ability to elicit and prioritize user requirements and product preferences from four stakeholder groups involved in health care delivery. Open-ended, clustering, and discrete choice methods elicited user requirements and preferences of physicians, nurse-midwives, biomedical technicians, and public health officers (47 participants) in Ghana. The open-ended response method effectively captured the general requirements of a design concept, yet resulted in predominantly generic requirements, whereas the clustering and discrete choice methods were more useful for inferring in-depth user requirements and eliciting stakeholder priorities. The clustering method revealed that usability and affordability were high-priority requirements among all four stakeholder groups. An individual difference scaling analysis was performed using the clustering method outcomes and it indirectly identified ease-of-use, availability, and effectiveness as the priority UR categories. Stakeholders ranked ease-of-use as the highest-priority user requirement, followed by performance, cost, and place-of-origin requirements using the discrete choice method. Given the significance of the ease-of-use requirement, an analytical framework based on sub-requirements was developed for quantifying stakeholder needs. Lastly, we discuss the relative merits of the three elicitation approaches and their implications for use with different stakeholder groups.

4.2. Introduction

Engaging stakeholders with little or no engineering or product design background can be challenging in settings with limited methodical engineering design tradition and experience [1].

There have been many attempts to reinvent and refine engineering design culture and education in order to identify essential needs based on the voice of the customer and realize high impact solutions in practice [2-4]. Once the need for a new product is established, efficient and easy-to-administer methods that directly and systematically engage stakeholders to elicit user requirements, which define their need, are required. Hence, qualitative user requirements (URs) and their translation to quantitative engineering specifications are the major building blocks in an upstream product design process.

When designed appropriately, the elicitation process of URs and their subsequent mapping to engineering specifications should ensure customer satisfaction and willingness to choose, adopt, purchase, or use the final product. To achieve these objectives, there are three key strategies to preventing a mismatch between customer needs (requirements) and product specification: 1) identifying the "right" types of needs, 2) eliciting "real" URs, which may involve qualitative information, and 3) translating the requirements into "effective" quantitative engineering specifications [5]. Utilizing qualitative and quantitative approaches, engineers address these three key strategies by reducing the ambiguity in user inputs and clarifying the obtained URs through careful communication with stakeholders to achieve completeness and consistency of URs [6,7].

Ethnography, free association, open-ended responses, and clustering techniques are some of the qualitative methods used to elicit implicit and explicit URs. Ethnography, informed by research in anthropology, investigates tacit knowledge about the design subject [8,9]. To utilize ethnography for engineering design purposes, a multi-functional design team observes the actual behavior and environment of the potential end-users and records their interactions with their environment. This method is suitable to identify end-users' problems and needs, especially for designers who are new to an environment. In free association, elicitation stimulus probes or cues about requirements are presented to the end-users, who are asked to verbalize the concepts that immediately come to mind [10]. This approach is suitable for exploratory purposes and to capture open-ended inquiries. Open-ended responses ask questions to elicit feedback about users' preferences as informed by their background and professional role [2,9,11]. This approach is suitable when the design team is new to an environment or has limited background of a design task and is interested in capturing general information. Clustering methods identify how stakeholders perceive and represent URs, such as which ones are viewed as similar and which

are dissimilar. This approach is suitable for making comparisons across different stakeholder groups as well as individual users [12,13]. While these methods have their merits and are relatively simple to administer, their outcomes are often subjective, colloquial, context and linguistic dependent, and difficult to map to quantitative engineering specifications [14,15].

Quantitative methods have been developed to more systematically elicit, prioritize and translate URs. Conjoint analysis (CA), discrete choice, and quality function deployment (QFD) are among the most common quantitative methods used to elicit and quantify URs. CA, which follows standard principles from experimental design, is used by marketing specialists and engineers [16]. In this method, potential stakeholders and end-users are presented choice sets containing several product options that are defined in terms of their requirements. The levels (numerical values) of the requirements will vary across and within choice sets following experimental design principles. Users are asked to choose, rank or rate the products or options and their responses are evaluated in a computational model that assesses the "part worth" of each level of each requirement. While CA results in numerical outputs, it requires extensive resources to administer.

The discrete choice method, also based on preference structure modeling, involves the presentation of two design options with distinct numerical specifications to stakeholders to elicit their preferences. Through an iterative process UR rankings can be established and engineering specifications can be refined. This method, which allows estimation of the trade-offs between design features, can assist in prioritizing and quantifying URs [17].

Quality function deployment (QFD) is used to systematically identify all of the elements in the product development process and to create relationship matrices between the key parameters at each step of the process [18]. There are four steps to complete a QFD: 1) product planning, 2) part deployment, 3) process planning, and 4) production planning. Product planning, the first step of QFD, involves compiling and ranking URs and has a significant impact on the likelihood of product development success [15]. The qualitative URs, captured from the stakeholders using varying elicitation methods, are listed in the first column as part of the product-planning step. Then, the importance of these requirements compared to designated numerical specification(s) (design objectives) are ranked through a relationship matrix [18]. CA and QFD can be complementary. CA conveys the customers' current preferences, whereas QFD captures what product developers believe will satisfy the customers' needs [19]. Although

requirements can vary depending on the type, experience level, knowledge, and interests of stakeholders, and the user context, purely quantitative methods of eliciting URs may fail to thoroughly engage stakeholders in order to resolve conflicting input, reveal nuanced differences among stakeholder input, and inadvertently promote limited iterations with stakeholders to establish accurate translations of requirements to engineering specifications [20,21].

Given the current knowledge gap on how to effectively and efficiently capture, prioritize, and translate URs into engineering specifications, the objective of this study was to compare empirically the quality of outcomes of three UR elicitation and prioritization methods: a qualitative method based on responses to open-ended questions, an association method in which users cluster requirements according to their own criteria, and a discrete choice method. These three methods were used with multiple stakeholders and evaluated, with a real life scenario, using a medical device case study involving the design of a device to manage postpartum hemorrhage (PPH) in low-resource settings.

More than two thirds of the world's population reside in low-resource settings, where the high costs, difficulties in maintaining equipment and sourcing spare parts, and a lack of public infrastructure are major causes of the persistent disparities in access to effective health technology [22,23]. The development and eventual adoption and implementation of innovative health technologies in such environments require special attention and careful analysis of the needs and preference as expressed by the end-users and stakeholders involved [5,22]. For instance, a community health care worker in rural areas of a low-resource setting, with limited to no knowledge of engineering or technology development, can have a very different understanding of a medical device's use. Given that PPH, defined as excessive blood loss within 24 hours of childbirth, is the leading cause of maternal death globally and a major health concern in Ghana [24], the study here focuses on design of PPH control device.

4.3. Methods

Open-ended responses, clustering, and discrete choice methods were used to collect the preferences of four stakeholder groups in Ghana: medical doctor, nurse-midwife, biomedical engineering technician, and public health officer, for a total of 47 participants. Each stakeholder group was asked about its ideal device requirements to assist with management and treatment of PPH. The study participants either provided direct care for pregnant women or professionally

supported the care providers. Data collection used semi-structured interviews and survey techniques. Table 4.1 shows the stakeholder types, locations, numbers, and years of experience.

Table 4.1: Participants' background and demographics

Stakeholder Group by Type	Total Participants	Location	Years of Experience (mean)
Medical doctor	10	Komfo Anokye Teaching Hospital, Ghana Health Services (Accra)	1–20 (7)
Nurse-midwife	16	Komfo Anokye Teaching Hospital, Kumasi South Hospital, community health posts (rural northern Ghana)	2–30 (17)
Biomedical engineering technician	14	Komfo Anokye Teaching Hospital, Ghana Health Services (Accra), University of Ghana (Legon), Korle Bu Teaching Hospital	1–32 (8)
Public health officer	7	Komfo Anokye Teaching Hospital, Ghana Health Services (Kumasi)	1–19 (7)

The study was reviewed by the Institutional Review Boards (IRB) of the University of Michigan in Ann Arbor, Michigan, USA, which determined that it met US federal criteria for exemption. The study protocol was also reviewed and approved by the Ghana Health Services IRB committee in Accra, Ghana. Although the study was considered exempt, participants were fully informed about the nature of the study prior to each interview and were asked for their verbal and written consent. No form of identifier was collected from the participants.

The following description about PPH complications was provided at the start of each interview: "The leading cause of maternal mortality is obstetric hemorrhage, accounting for up to 44% of deaths in some areas. PPH is the most common type of obstetric hemorrhage, and the most common cause of maternal death in developing settings. Immediate PPH (heavy bleeding directly following childbirth or within the first 24 hours) is the most common type of PPH and can be caused by uterine atony (when the uterus fails to contract properly after delivery); retained placenta; inverted or ruptured uterus; or cervical, vaginal, or perineal lacerations. Hence, there is a need to develop a device for management and control of PPH in low-resource settings."

A study team member recorded the participants' responses to the open-ended questions described in Method I, and participants completed questionnaires for the study components described in Methods II and III. The time required by participants to complete each component

of the protocols described in Methods I-III was recorded. Two study team members digitized (using Microsoft Excel), reviewed, and crosschecked participant responses for accuracy.

4.3.1 Method I: Open-ended responses

For the open-ended (qualitative) method, the study team interviewed 12 out of the 47 participants: one medical doctor, eight nurse-midwives, two biomedical engineering technicians, and one public health officer. The open-ended responses method used in this study had two steps:

1. After reviewing the description of the PPH with the participant, he/she was asked: *"What are the user requirements and design characteristics of a device that could help to manage and assist with early control of PPH (indicate by whom and where the device could be used)?"*
2. After responding, the participant was asked to rank his/her requirement, and to give additional input to indicate how (s)he would quantify each requirement.

Following data collection, a study team member and a trained research assistant applied frequency analysis to the digitized stated requirements to identify the number of times a requirement was mentioned. Then, the study team grouped the URs with similar meanings, for example, easy-to-use and user friendly, and calculated the collective frequencies of requirements, regardless of stakeholders' affiliation, to infer the importance of each requirement.

4.3.2. Method II: Clustering

The clustering method required the participants to group requirements from a list of URs and to label each cluster. All 47 participants completed this portion of the study (see Table 4.1 for participant breakdown). The list was developed based on customary requirements in the device design literature [25] and supplemented by the outcomes of the open-ended responses described above. The labels, created by the participants for their self-identified clusters, provided insight regarding their representations of similarities among requirements.

The requirements clustering method had two steps:

1. After being given a list of URs (Table 4.2), the participants were instructed, *"Considering the different requirements of a device to address PPH, group your conceptual device's requirements into the categories that you think make the most sense. Note: Requirements can be clustered in as many categories as you see fit."*

2. After doing so, each participant was instructed to assign a descriptive label to each cluster. For example, a "low-cost" label could be assigned to the cluster of: maintainable locally, inexpensive, and widely available. The provided labels facilitate interpretation of the clusters.

Table 4.2: Generic list of user requirements, based on open-ended responses and design literature, for clustering method

The appropriate PPH device should be:
1. Easy to use
2. Inexpensive
3. Require minimal training time
4. Safe for patient and user
5. Effective immediately
6. Reduce the procedure time
7. Reduce the number of procedural steps
8. Widely available
9. Suitable for use in health posts (rural regions), district and regional hospitals
10. Suitable for use in district and regional hospitals
11. Single use
12. Auto-disable
13. Multiple uses
14. Made from locally available materials
15. Maintainable by local technicians
16. Reduce training time to less than a day
17. Require minimal post-operation visits
18. Cause minimal complication
19. Designed and manufactured locally
20. Designed and manufactured in the United States/European Union
21. Easily cleaned
22. Minimizes pain for the patient
23. One size fits all (adjustable size)
24. Available in different sizes
25. Portable
26. Fixable in the field
27. Powered mechanically
28. Powered mechanically and electrically
29. Culturally acceptable

Descriptive data were computed for the clusters. In addition, the UR clusters for all participants were analyzed using individual differences scaling analysis (INDSCAL), which is a weighted multidimensional scaling tool used to evaluate participant differences when making dis(similarity) classifications [26]. INDSCAL enables engineering designers to evaluate, approximate, and visualize the representation of URs from proximity matrices using Euclidean

distance [27]. INDSCAL reveals the optimal number of dimensions that participants considered when selecting their clusters. These dimensions represent the primary categories of URs that are not articulated directly by stakeholders but emerge from similarities in the data, in this case each participant's clustering. INDSCAL also provides information about how much each participant relies on a given dimension when judging similarity of URs. Here, INDSCAL was chosen over traditional multidimensional scaling in order to learn about the heterogeneity across the four stakeholder groups as well as across participants.

The data analyzed by INDSCAL were the proximity matrices representing each participant's (i.e., K_i, i=1-47) clustering of the URs (i.e., n=29) (Table 2). Thus the clustering procedure led to 47 distinct 29×29 binary proximity matrices. The similarity matrix for each participant was created based on the expressed UR clusters. For example, if five URs (1, 3, 5, 17, and 23 from the list of URs - Table 2) for participant K_4 were placed in the same cluster, then a "1" was entered in each cell of the 29×29 matrix representing all pairwise combinations of those 5 URs. For URs not in the same cluster, their pairwise entries in the 29×29 proximity matrix were "0". The binary proximity matrix for each participant was entered into the INDSCAL function (SPSS® V20, IBM Corp), using the nominal option. The stress value was used to compare model fits for different numbers of dimensions; the scree plot was examined for an elbow to determine the number of dimensions [26].

4.3.3. Method III: Discrete choice

This method determined the preference rankings of UR differences among the four stakeholder groups. All 47 participants completed this portion of the study. The study team gave each participant eight sets of paired-choices of hypothetical devices (A and B) with four requirements categories: performance, cost, ease-of-use, and place of origin, with two levels within each category (see Table 4.3 for experimental design). The paired-choices were carefully determined to help the study team infer orderings of utility differences from the preferences. Each paired-choice was printed on a separate card (Figure 4.1) and given to each participant. After being given a card for each of the eight pairs, the participants were asked to record their answers on a questionnaire:

"*Which one of the following devices, A or B, would you choose to assist with PPH control and management?*"

The study team assumed that higher performance, lower cost, ease-of-use, and locally made (made in Ghana) were the dominant levels of each of the requirements (the asterisks in Table 3). This paradigm allowed us to estimate preference order of UR differences separately by stakeholder group.

Table 4.3: List of user requirements and associated specifications for the discrete choice method; different combinations of specifications create hypothetical devices A and B. Careful construction of choice pairs permits inferring ordering of utility differences from choice

User Requirements	Specification	Levels
1. Performance	95% effective*	Level 1
	75% effective	Level 2
2. Cost	$10.00*	Level 1
	$50.00	Level 2
3. Ease-of-use	Used only by a trained physician	Level 1
	Used by less-trained health worker*	Level 2
4. Place of origin	US	Level 1
	Ghana*	Level 2

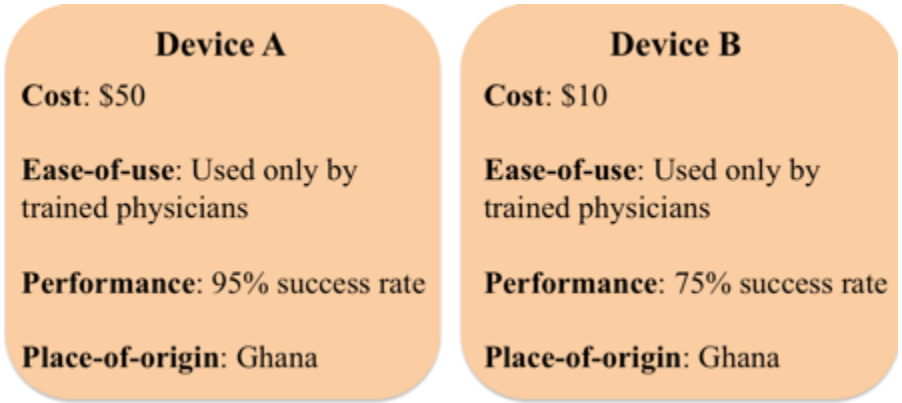


Figure 4.1: Options of hypothetical devices with specified requirements

Based on the principles of utility theory [25], the choice of an option was represented through a utility function U_j (j being an option). For example, in the case of devices A and B

presented in Figure 1, choosing device A is modeled as the utility of device A ($U_{(A)}$) being greater than that of device B for that participant, i.e., $U_{(A)} > U_{(B)}$.

The additive utility function, $U_{(A)}$, is represented as an additive combination of requirement-based utilities, v_j so we can drop requirements with identical values in a pair of choices. Hence, for the specific comparison between device A and B, where they share common values on two requirements, the utility ordering on the two remaining requirements that differ across those two devices is inferred from the choice (note: values for cost and performance used in the following equations are illustrative and only for demonstration purposes):

$$U_{(A)} = v_{cost}(\$50) + v_{performance}(95\%), \text{ and } U_{(B)} = v_{cost}(\$10) + v_{performance}(75\%)$$

The values for the other two URs are not shown because they cancel in the additive utility representation. Hence, the inference for the participant choosing device A over B is:

$$v_{cost}(\$50) + v_{performance}(95\%) > v_{cost}(\$10) + v_{performance}(75\%)$$

and this implies an ordering of utility differences across the two URs:

$$v_{performance}(95\%) - v_{performance}(75\%) > v_{cost}(\$10) - v_{cost}(\$50)$$

In this case, the choice model shows that if A is chosen over B, the difference between 95% and 75% on the UR performance is more important than the advantage of the lower cost $10 over $50 on the UR cost. All eight of the choice pairs had this structure and allowed us to order utility differences across requirements and to measure utility tradeoffs across requirements. The proportion of such orderings was tested across stakeholder groups using Fisher's exact test because of the relatively small sample size [29].

4.4 Results

4.4.1. Method I: Open-ended outcomes

Method I elicited 18 URs. Nine of the 12 participants cited inexpensive, easy-to-use, and task-shifting (a device facilitates a task to be performed by less trained health workers), as their desired requirements, whereas only four cited locally maintainable, immediately effective, and safe. The most number of requirements stated by a participant was 14 (by a medical doctor) and the fewest was 3 (by a nurse). The average time to elicit the requirements was approximately 10 minutes per participant.

The majority of URs for the PPH device were generic and universally applicable to any other medical device. Only two URs specific to the PPH device were cited by a medical doctor

("device must be fixable on the abdomen") and a nurse-midwife ("device must automatically detect PPH").

4.4.2. Method II: Clustering outcomes

The stakeholder groups assigned a total of 26 unique labels to their clusters of requirements. Medical doctors, nurse-midwives, biomedical technicians, and public health officers had combined totals of 14, 16, 15, and 13 labels, respectively. All groups cited affordability, usability, effectiveness, safety, and availability as cluster labels (Table 4.4). Usability and affordability were among the top three labels for all groups, whereas safety was the top level for only three groups. Not all participants used exactly the same titles for labeling, but the study team consolidated similar titles that had similar meaning. For instance, easy-to-use and user-friendly were categorized under usability, and low-cost and inexpensive were classified under affordability.

Table 4.4: Top (three) labels mentioned by stakeholder group using the clustering method (frequency % are indicated after each requirement)

Medical Doctor (*n*=10)	**Nurse-Midwife (*n*=16)**	**Biomedical Engineering Technician (*n*=14)**	**Public Health Officer (*n*=7)**
1. Usability (87.5%) 2. Affordability (62.5%, rank 2) 3. Effectiveness (62.5%, rank 2)	1. Usability (71.4%) 2. Affordability (57.1%) 3. Availability (35.7%)	1. Affordability (85.7%) 2. Usability (75.4%) 3. Safety (42.9%)	1. Affordability (64.3%, rank 1) 2. Effectiveness (64.3%, rank 1) 3. Usability (57.1%, rank 2)

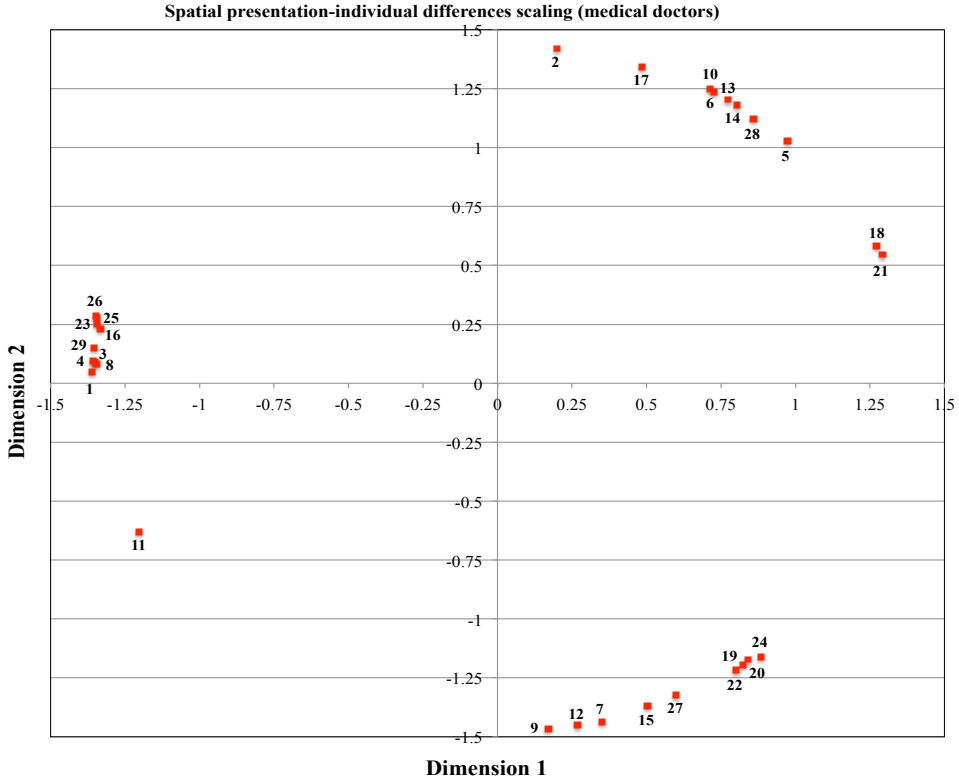
Other than usability, affordability, and safety, the other labels varied depending on each group's professional concerns, needs, and interests. The public health officer group had the greatest variety of labels (seven different labels ranked among the top three). Also, effectiveness was only mentioned by medical doctors and public health officers. Table 4 shows the frequency of participants' responses for each requirement cluster (top three) among the four stakeholder groups. The average time spent per respondent for this method was approximately 15 minutes.

The input provided by each participant for the clustering method was then further evaluated using INDSCAL to model the UR clusters. We first present the individual INDSCAL

findings for each of the four stakeholder groups, followed by the weights from a combined analysis of all 47 participants and their preference weights for each of the identified dimensions. The comparison of the stress metric revealed that two dimensions are appropriate for each of the stakeholder groups. All the stakeholder groups agreed on the first dimension, but there were differences across the groups on what constituted the second dimension.

Figures 4.2a-d demonstrate the spread of URs across two dimensions for each of the stakeholder groups. Ease-of-use emerged as the common UR category for dimension one for all the groups. The ease-of-use category, shown in dimension one, is an aggregate of URs including easy-to-use, minimal training time, and reduced procedure time. For medical doctors and public health officers a second dimension emerged as the effectiveness of the device, which was based on cluster labels such as effective immediately, minimal post-operation visit, and minimized pain. For the remaining two stakeholder groups, nurse-midwives and biomedical engineering technicians, availability of the device emerged as the second dimension. This term captured cluster labels such as suitable for health posts, district and regional hospitals, made from locally available materials, and inexpensiveness.

The INDSCAL procedure was also conducted for all 47 participants, as a whole. According to the stress metric, the two dimensional solution is the best fit for the UR space: dimension one was ease-of-use and dimension two was availability (Fig. 4.3a). INDSCAL also led to analysis of derived subject weights, which is a map of study participants' weighting on each of the two dimensions (Figure 4.3b). This presents the derived subject weights, demonstrating how much weight was given to each dimension when participants rated UR similarity. It appears that our participant pool did not rely heavily on only one dimension. While there was some variability across participants, it appears that both dimensions were weighted approximately equally across participants as indicated by the points in the weight plot being close to the identity line (Fig. 4.3b).


Spatial presentation-individual differences scaling (medical doctors)
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0.75
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-0.75
-1
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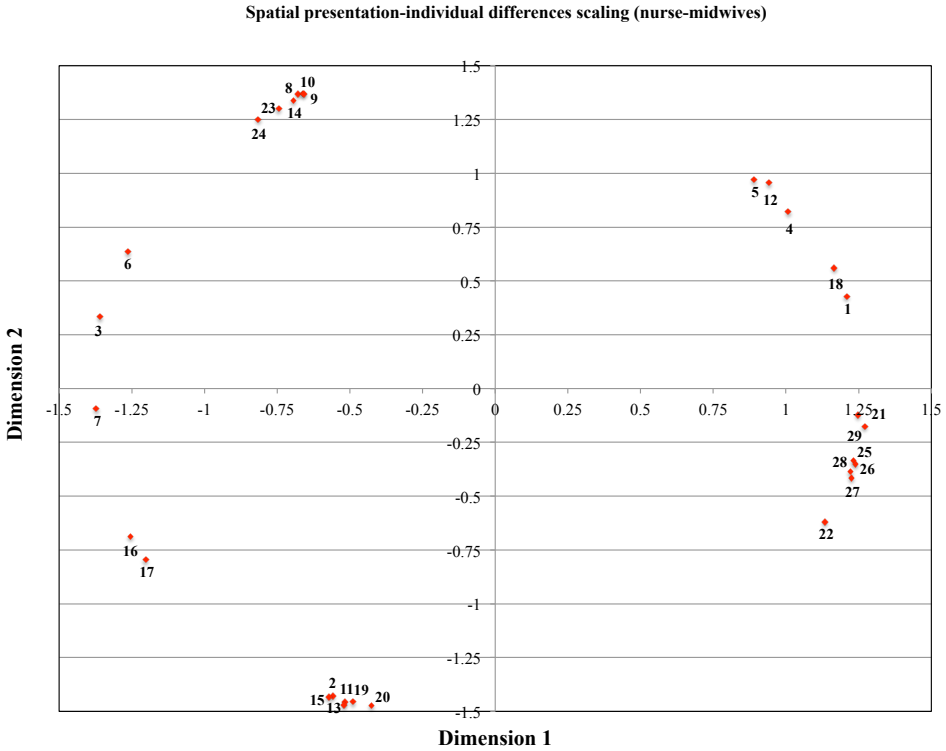
Spatial presentation-individual differences scaling (nurse-midwives)
Dimension 2
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-0.5
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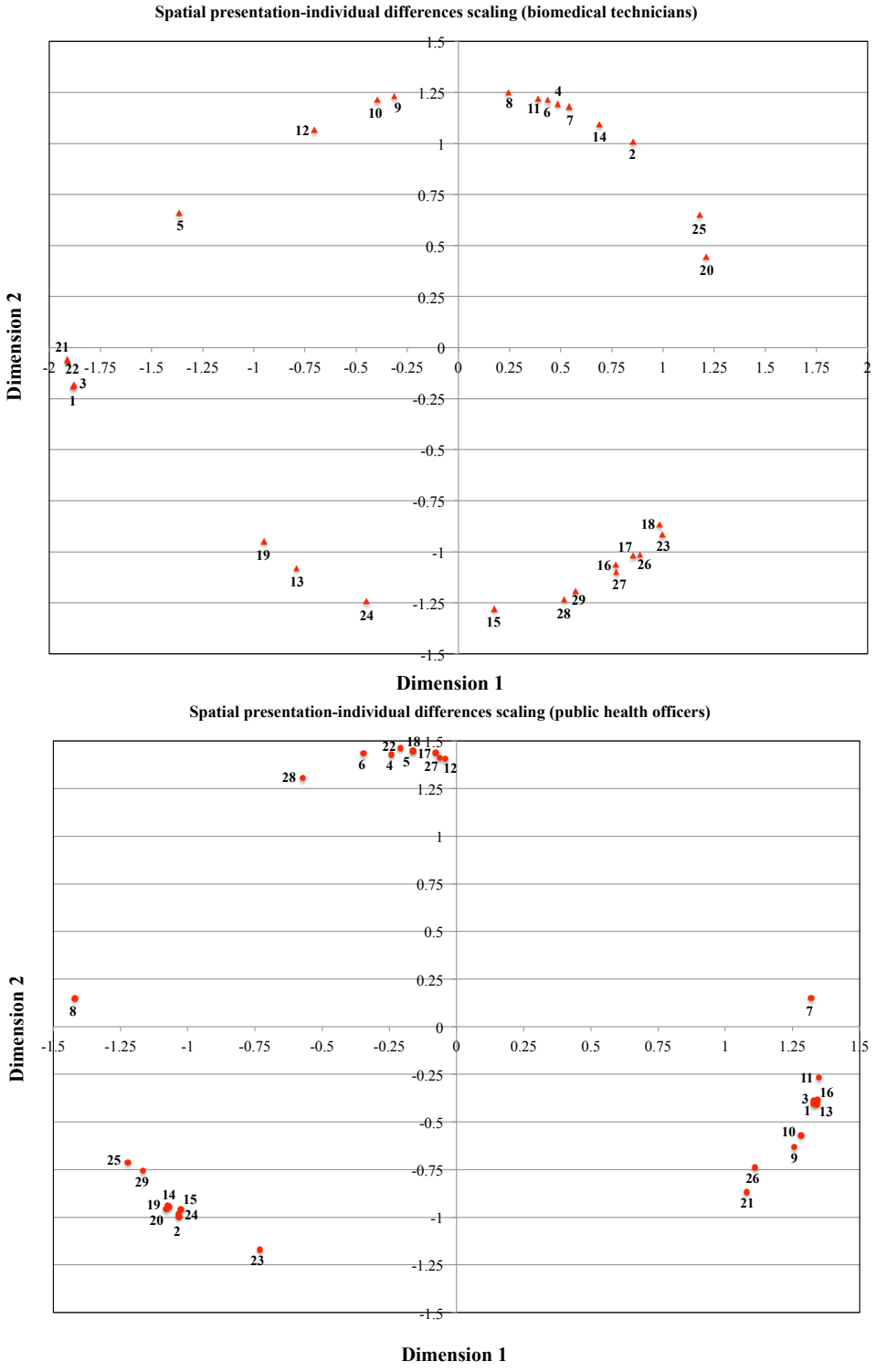
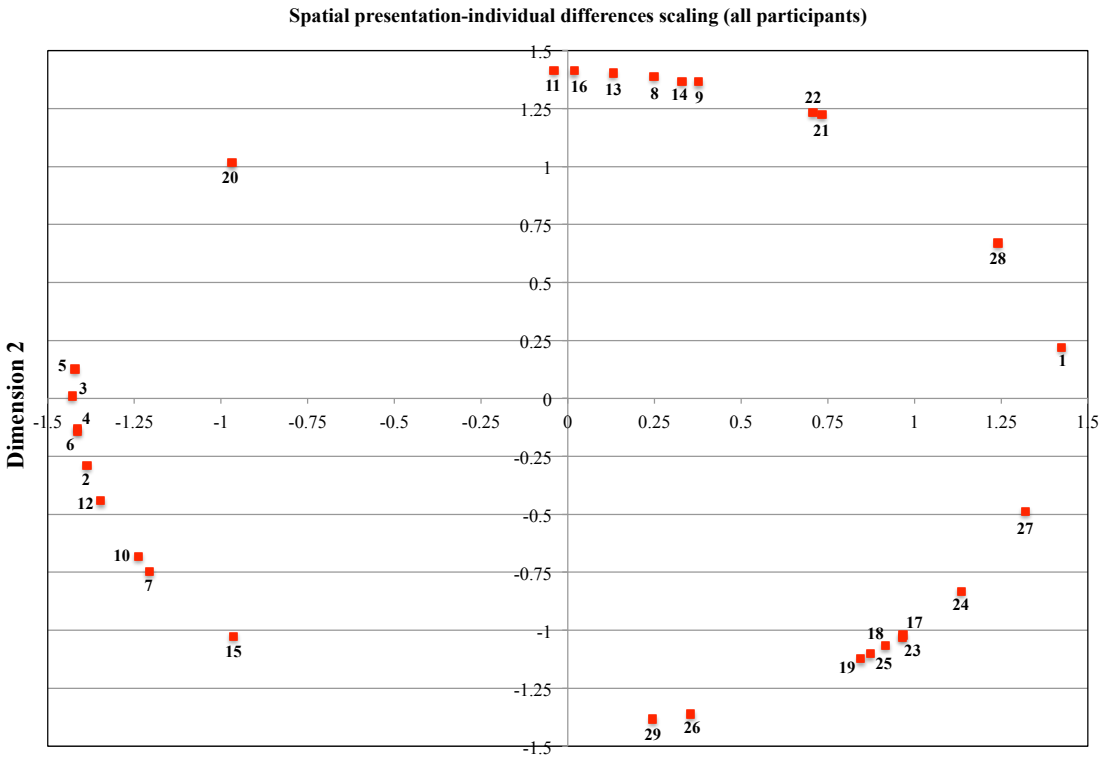


Figure 4.2: Visual representation of UR space across two dimensions based on the clustering method outcomes for each stakeholder group; Figure 4.2a (first from top, page 74): Medical doctors, Figure 4.2b (second from top, page 74): Nurse-midwives; Figure 4.2c (first from top, page 75): Biomedical engineering technicians, Figure 4.2d (second from top, page 75): Public health officers. Dimension 1 for all groups: ease-of-use; dimension 2 for MDs and PHs: effectiveness; dimension 2 for NMs and BMEs: availability.



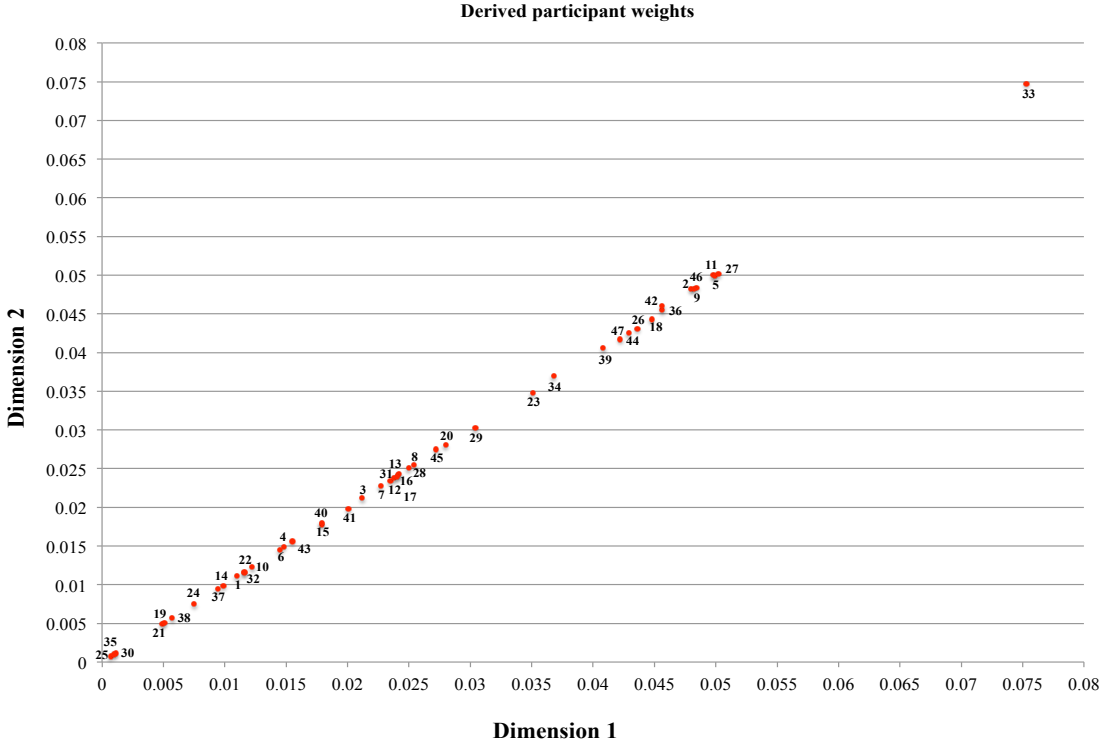


Figure 4.3a (first from top): Visual representation of UR space across two dimensions based on the clustering method outcomes for all the participants; dimension 1: ease-of-use; dimension 2: availability
Figure 4.3b (second from top): Each participant's weight, in determining the preference between the two dimensions

4.4.3. Method III: Discrete choice outcomes

The study team assumed that medical doctors represented the frontline of health care delivery and led the treatment process for PPH patients.

Table 4.5: Choice proportions by stakeholder group

Discrete Choice Question	Device Choice	Preferred characteristic	Medical Doctor	Nurse-Midwife	Biomedical Engineering Technician	Public Health Officer	Total
a	A	Performance	0.90	0.87	0.62	0.86	0.80
	B	Cost	0.10	0.13	0.38	0.14	0.20
b	A	Performance	0.70	0.81	0.64	0.57	0.70
	B	Cost	0.30	0.19	0.36	0.43	0.30
c	A	Performance	0.20	0.50	0.54	0.71	0.48
	B	Usability	0.80	0.50	0.46	0.29	0.52
d	A	Cost	0.40	0.33	0.43	0.43	0.39
	B	Usability	0.60	0.67	0.57	0.57	0.61
e	B	Place of origin (US)	0.0	0.21	0.21	0.14	0.16
	A	Usability	1.0	0.79	0.79	0.86	0.84
f	B	Performance	0.30	0.57	0.29	0.57	0.40
	A	Usability	0.70	0.43	0.71	0.43	0.60
g	B	Place of origin	0.20	0.21	0	0.14	0.13
	A	Cost	0.80	0.79	1	0.86	0.87
h	A	Place of origin	0.10	0.07	0.07	0	0.07
	B	Performance	0.90	0.93	0.93	1	0.93

Hence, Fisher's exact test was used to compare preference proportions (Table 4.5) between this group and each of the other three groups. In the language of statistics, the medical

doctors were treated as the "reference group." The use of this test to compare preference proportions showed no statistically significant comparisons between medical doctors and each of the other three stakeholder groups across all 8 choice pairs (*ps*>0.05). We also examined the discrete choice responses combined to detect the specific preferences when looking at the participant groups collectively. Table 4.5 shows the proportion of responses within each stakeholder group for preference differentiation between devices A and B.

Overall, the outcomes of the utility preferences showed that stakeholders were most interested in the ease-of-use requirement, followed by performance, cost, and place-of-origin (Table 4.6 – last column). Table 4.6 shows the lists of rank-ordered requirements by stakeholder group. Although there was disagreement about the order of the first two device requirements, ease-of-use vs. performance, all groups agreed about the order of the last two, cost and place-of-origin. The average time spent for this method was approximately 5 minutes per participant.

Table 4.6: Ranked order device requirements from the discrete choice analysis from inferred rank order of utility differences by stakeholder group

Medical Doctor	**Nurse-Midwife**	**Biomedical Engineering Technician**	**Public Health Officer**	**Total**
1. Ease-of-use	1. Performance	1. Ease-of-use	1. Performance	1. Ease-of-use
2. Performance	2. Ease-of-use	2. Performance	2. Ease-of-use	2. Performance
3. Cost	3. Cost	3. Cost	3. Cost	3. Cost
4. Place of origin	4. Place of origin	4. Place of origin	4. Place of origin	4. Place-of-origin

4.5. Discussion

It is generally recognized that stakeholder involvement throughout the medical device design process is preferable to interaction during select phases of design. Increased stakeholder involvement has been shown to increase the likelihood of developing products that are safe, usable, clinically effective, and appropriate to the cultural context [26,27]. Historically, medical device industry interactions with stakeholders have predominantly occurred during the prototype and post market evaluation stages of the design process, given a technology- versus need-driven approach [26]. Lack of stakeholder involvement during the establishment and refinement of URs and translation to engineering specifications can lead to engineers making assumptions.

Therefore, it is particularly important to capture stakeholder input when defining and prioritizing URs and engineering specifications to increase the likeliness of developing solutions that are superior in functionality, usability, and quality [5,28]. However, there are tradeoffs that exist among the various qualitative and quantitative methods for eliciting such UR input, yet there have been limited studies that compare the effectiveness and efficiency of such techniques [27]. This study compared the requirements elicited and their prioritization from multiple stakeholder groups using three methods.

The primary finding of this study was that open-ended responses effectively captured general requirements, whereas the clustering and discrete choice methods were most useful for eliciting detailed requirements and stakeholder priorities (Table 4.7). While the clustering method was effective in capturing tacit and poorly articulated URs, the discrete choice method was the easiest for the stakeholders to perform, considering the time to complete the task.

Administering the open-ended response method was time consuming while yielding limited results, given most of the elicited requirements were generic. Also, URs elicited through this method became repetitive after engaging with fewer than ten participants. Providing input with this method was challenging for most of the participants, demonstrating the difficulty of expressing URs for a hypothetical design in the absence of a physical model or prototype to assist with the articulation of their thoughts [29]. Although the open-ended response method did not take as long to perform as the clustering method, the clustering produced more PPH-specific design requirements than the open-ended responses. Therefore, the open-ended response results suggest the need for a guiding mechanism to elicit and establish more specific URs.

The clustering method revealed participants' preferences and concerns for a hypothetical PPH device directly, by clustering and labeling each cluster, and indirectly, using an INDSCAL. It also identified the requirements in the form of cluster labels defined by each participant, and primary requirement categories in the form of dimensions revealed in INDSCAL. However, its administration was the most time consuming. A comparison between the outcomes of the open-ended responses and the clustering methods identified low-cost and usability (here: easy-to-use and task-shifting) as the two most important requirements. However, the stakeholder groups showed different orderings in the frequency of labeling them (Table 4.4).

Table 4.7: Overview of three elicitation and prioritization methods' outcomes

Does the method have the ability to…	Open-ended responses	Clustering	Discrete choice
… elicit general user requirements?	Yes	Yes	No
… elicit specific user requirements?	No	Yes	No
… prioritize requirements?	No	Yes	Yes
… elicit requirements and prioritize in a simple fashion (easy to administer)?	No	No	Yes
… elicit tacit requirements?	No	Yes	No

An INDSCAL was used to model the participants' representations of URs categories, indicated as INDSCAL dimensions. Ease-of-use was the common UR category among all stakeholder groups. Availability, for nurse-midwife and biomedical engineering technician groups, and effectiveness, for medical doctors and public health officers, were the second identified dimensions.

INDSCAL outcomes provide a visual representation for each participant's preference on primary URs (dimension) based on his/her expressed clustering of the 29 URs. These outcomes provide engineering designers with an opportunity to utilize an indirect approach in identifying participants' primary UR categories and their evaluations. Participants may not be able to articulate UR categories with open-ended responses for a specific design challenge, but as in this study they may be able to understand individual specific URs and cluster them based on similarity. When the clustering is complete they can assign labels to their own clusters. In this way, the designer can have a better understanding of the primary UR categories because they consist of more specific, and sometimes actionable, items. INDSCAL can also provide information about how different stakeholder groups represent URs. As revealed in this study, all groups agreed on ease-of-use as a major UR category, but groups did not agree entirely on the second dimension (availability vs. effectiveness).

Multidimensional scaling techniques such as INDSCAL take symmetric proximity matrices, such as those collected in this study, and perform analyses similar to singular value decomposition. Each additional dimension is analogous to adding another eigenvector to the representation. The goal is to have a parsimonious description of the proximity matrices with as few dimensions as possible; the stress metric essentially evaluates the residual between the observed proximity matrix and the model-implied proximity matrix, similar to residuals in the

context of regression analysis. A solution with the same number of dimensions as there are rows and columns in the proximity matrix will produce a perfect fit as assessed by stress. This is analogous to an eigenvector decomposition that uses all eigenvectors can reproduce the original matrix. For an example of how multidimensional scaling techniques can be adapted to quantitative engineering design see [30].

Administering the discrete choice method was simple and short. Given that this method is implemented to assess tradeoffs between two potential devices, and prioritize preferences, the outcome was a set of utility orderings that are useful in defining engineering specifications and design constraints. When studying and developing products for multiple stakeholders, a major challenge is how to incorporate and translate different, sometimes conflicting URs, into the design outcome. The discrete choice method was used to demonstrate how differences between stakeholder preferences can be investigated. Given the small sample sizes, the statistical power in our study can only detect relatively large differences in proportions. Implementation of this method requires careful attention to the construction of choice pairs so choice data can lead to ordering of utility differences. In this study, the eight choice pairs for the discrete choice method were selected in advance (i.e., we hypothesized the four URs and selected the levels). However, it is possible to inform the selection of major URs and levels from the outcomes of the clustering method.

The carefully selected choice pairs in this study allowed for an easy to deliver method to elicit URs, which is less computationally intensive and complex to perform compared to conjoint analysis. While our procedure did not permit computation of part worths, because the eight choice pairs were carefully selected we were able to find orderings of utility differences for each of the four stakeholder groups. Hence, the discrete choice method is suitable for a faster prioritization and analysis of URs, especially when access to software and complex tools are limited.

Engineering designers tend to rely on tools such as QFD to translate URs (from qualitative to quantitative) to define engineering specifications that may overlook users' inputs [31]. Ease-of-use emerged as the most important requirement expressed by all of the stakeholder groups. However, its translation to a quantitative measurable feature is still challenging.

To quantify ease-of-use, we can break the concept down to more specific sub-requirements with more likelihood for quantification, and then recombine the evaluations of the

sub-requirements to provide an overall quantification for ease-of-use. For example, ease-of-use can be represented as a function of given requirements f_i that are functions of device specifications x (e.g., prior required training, user type, etc.). Ease-of-use can then be defined by an index "C" that is weighted sum of attributes.

$$C = \sum_{i=1}^{\kappa} \omega i \, fi$$

$$fi = fi(x)$$

$$x = (x_1 \; x_2 \; x_3 \ldots x_n)^T$$

ω_i is a weight that determines how much specification f_i contributes to ease-of-use, with a total k number of design requirements and n number of specifications.

In cases where the sub-requirements are already known, a discrete choice study, as outlined here, can provide information on the ordering of utility differences for each of the f_i, whereas if sub-requirements are not known in advance, then a clustering procedure could be conducted first to find such requirements that can then be included in a discrete choice study. The weights for (ω_i) can be set with further investigation to determine the importance of given sub-requirements to define ease-of-use. Future research can extend this model by allowing heterogeneity to account for individual differences in a relevant stakeholder group or to account for variability within and between different target markets. The choice method used in this study for inferring ordering of utility differences can be extended to the case of sub-requirements, so choice data could be used to put further restriction on the f_i. Finally, if the design team has additional resources, then more involved discrete choice methods such as conjoint analysis can be used to provide additional information beyond ordering of utility differences.

The limitations of this study included a small number of participants per stakeholder group and a limited number of stakeholder groups. Specifically, it was challenging to recruit healthcare providers due to their clinical commitments. The small sample size prevented us from applying more complicated statistical models. Furthermore, stakeholders such as patients and community health workers were not recruited and therefore not represented. Their involvement could have potentially expanded the quantity and quality of the URs, with respect to cultural and societal considerations, gathered during the open-ended responses. Even though no significant differences among group preferences using the discrete choice method were observed, this does

not imply that differences will not exist among stakeholder groups for other design scenarios. We note that in many real-world design scenarios, the sample sizes may be even smaller than those used in this study. So while this sample size is not ideal from the perspective of statistical power, it is analogous to non-research based design tasks.

The benefits and limitations of three UR elicitation and prioritization methods were characterized using a case study approach. The qualitative methods yielded general requirements, while the quantitative method produced prioritized, detailed requirements. Each method elicited similar high-priority general requirements among all stakeholder groups. Despite the differences in URs elicited applying the three distinct methods, each individual method or their use in combination, may benefit any given design undertaking. Engineering designers, who are new to a setting or unfamiliar with the stakeholders' needs can benefit from starting their URs elicitation process with an open-ended response method study. Open-ended responses' outcomes can be used to establish a list of URs for use in a clustering method study. The clustering can be analyzed descriptively as well as with algorithms such as INDSCAL. Clustering and INDSCAL evaluations can then provide categories of URs that can be used in a choice based method study. Of course, designers should be cognizant of the quality of output they will obtain given the method they choose to use.

Such evidence-base methods, as presented here, may benefit from emerging interdisciplinary fields such as implementation engineering, which promotes uptake of scientifically designed and tested products into routine healthcare in both clinical and policy contexts, by engaging stakeholders effectively in the design process as early as possible [32].

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Chapter 5. Design ethnographic approaches to guide design process: the case of Traditional Male Circumcision in Uganda[1]

5.1. Abstract

Background: The growing body of evidence attesting to the effectiveness of clinical male circumcision in the prevention of HIV/AIDS transmission is prompting the majority of sub-Saharan African governments to move towards the adoption of voluntary medical male circumcision (VMMC). Even though it is recommended to consider collaboration with traditional male circumcision (TMC) providers when planning for VMMC, there is limited knowledge available about the TMC landscape and traditional beliefs.

Methodology and Main Findings: During 2010-11 over 25 focus group discussions (FGDs) were held with clan leaders, traditional cutters, and their assistants to understand the practice of TMC in four ethnic groups in Uganda. Cultural significance and cost were among the primary reasons cited for preferring TMC over VMMC. Ethnic groups in western Uganda circumcised boys at younger ages and encountered lower rates of TMC related adverse events compared to ethnic groups in eastern Uganda. Cutting styles and post-cut care also differed among the four groups. The use of a single razor blade per candidate instead of the traditional knife was identified as an important and recent change. Participants in the focus groups expressed interest in learning about methods to reduce adverse events.

Conclusion: This work reaffirmed the strong cultural significance of TMC within Ugandan ethnic groups. Outcomes suggest that there is an opportunity to evaluate the involvement of local communities that still perform TMC in the national VMMC roll-out plan by devising safer, more effective procedures through innovative approaches.

5.2. Introduction

HIV/AIDS remains a major health challenge throughout the world, especially in sub-Saharan Africa, where it accounts for 68% (or 22.5 million) of global HIV cases [1]. The use of male circumcision as an efficacious biomedical intervention against HIV transmission has been

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demonstrated in three randomized controlled clinical trials [2-4], which show a consistent protective effect of approximately 60% risk reduction among heterosexual men. More than 35 epidemiological studies [5-6] reinforce the results of the controlled trials. Faced with such evidence, the governments of most sub-Saharan countries are adopting policies and programs to "roll-out" voluntary medical male circumcision (VMMC) with the support of international public health organizations such as the World Health Organization and USAID [7]. In 2009, the Ugandan Ministry of Health (MoH) began to discuss a national plan for voluntary mass circumcision of adult males [8].

In many of these countries, traditional male circumcision (TMC) has been practiced for centuries, particularly as an initiation ritual and rite of passage into manhood [9]. As scale-up plans for clinical male circumcision are being considered as a strategy against HIV/AIDS by sub-Saharan African Ministries of Health, traditional providers will continue to function as an important source of service [10]. In fact, many international public health organizations believe that clinical male circumcision will never completely replace traditional practices due to both the cultural implications and the human resource constraints pending in the near future [9, 11]. Typically, providers with limited or no formal clinical training perform TMC in non-clinical settings. While some evidence supports TMC's effectiveness against HIV transmission [12-13], the life-threatening risks and health complications of its practice are alarming. Studies evaluating the complications due to TMC have found rates varying from 35% (Kenya) to 48% (South Africa) [5, 14]. Infection, delayed wound healing, glans amputation and injury, bleeding, loss of penile sensitivity, excessive removal of foreskin, and death are the major complications reported [5, 14-17].

Uganda's HIV prevalence rate is 6.5%, and almost 70% of Ugandan males remain uncircumcised [18]. Approximately 10% (3.5 million) of the population belongs to ethnic groups which still practice TMC [18]. The Ugandan National Safe Male Circumcision policy, a roadmap for implementation of an effective male circumcision program, acknowledges the importance of understanding TMC and its associated cultural aspects when devising methods to make TMC safer. Two suggested approaches, based on experiences in other countries, include the integration of TMC into official health care systems and the intensive training of traditional providers [5, 19-20]. Considering both the limitations of implementing VMMC in areas traditionally practicing circumcision and the promise of TMC for reducing infection transmission, the objective of this

paper is to characterize TMC practices in Uganda and the cultural implications by using a comprehensive focus group discussion (FGD)–based qualitative analysis. Ultimately, such information can inform the strategies to make TMC safer and to fully utilize the resources available to support Uganda's gradual transition towards VMMC.

5.3. Methods

To our best knowledge, this study is the first countrywide FGD-based qualitative analysis to understand the culture, traditions, and customs of TMC in Uganda.

5.3.1 Ethics statement

The study was reviewed by the Institutional Review Board (IRB) of the University of Michigan in Ann Arbor, Michigan, USA, which determined that it met US federal criteria for exemption, including not more than minimal risk to subjects (exemption #2 (45 CFR 46.101(b)(2)). The University of Michigan's IRB informed the Uganda National Council of Science and Technology about this study and its exempt status. All study team members received training in the ethical conduct of human subjects' research. There were two data collection periods (2010 and 2011) utilizing focus groups. Although the study was considered exempt, participants were fully informed about the nature of the study prior to each FGD and were asked for their verbal consent. Also, they were able to leave at any time during the discussions; however, none of the participants opted to leave prior to the completion of the focus groups. Participants during the 2010 data collection sessions also provided written consent. For the focus groups conducted in 2011, the consent process was also audio recorded. No form of identifier (name, age, living location, clan) was collected from the participants. During FGDs, participants were assigned numbers or responded anonymously.

5.3.2. Focus group discussion settings

In Uganda, Sebei, Bagisu, Baamba, and Bakonzo ethnic groups practice TMC. The Sebei and Bagisu ethnic groups reside in eastern Uganda, while the Baamba and Bakonzo people reside in the western region. The HIV rate for Bagisu and Sebei men is 3.5%, while that of Baamba and Bakonzo men is 5.7% [18]. It is estimated that 80% of Sebei and Bagisu men are circumcised. The circumcision percentage of Baamba and Bakonzo men is unknown [18]. The

study team held 26 FGDs (total of 208 participants) from August 2010 to June 2011. Each focus group consisted of 6–12 participants and was run by trained US and Uganda study team members, who remained the same across FGDs. Focus groups were held in local health clinics in Kapchorwa and Mbale districts (eastern Uganda) and Bundibugyo and Kasese districts (western Uganda), as indicated with red stars in Figure 5.1, and lasted for approximately 1 hour.

Figure 5.1: Map of Uganda, Stars indicate locations of FGDs; Source: Central Intelligence Agency World Factbook

They were conducted in the local language and translated simultaneously into English by an interpreter from the same ethnic group, who was trained in social science research and familiar with TMC. The participants were paid 10,000 Ugandan Shillings (UGX), or about USD 3.75, to reimburse their transportation expenses and time of participation.

5.3.3. Participants

Three primary groups participated in the FGDs. Group one included traditional senior cutters responsible for cutting procedures. Group two included assistant cutters or guardians who help prepare boys (candidates) for circumcision, assist during the procedure, and advise candidates on post-operative care. Group three included clan leaders, who serve as community gatekeepers responsible for preserving the cultural aspects, such as TMC, of their respective ethnic groups. Each primary group attended a separate FGD designated by specific ethnicity. Table 5.1 shows the location, number of participants, and the groups' degree of involvement in the FGDs.

Table 5.1: Participant background and demographics

Ethnic Group	FGD Location	Cutters	Assistant Cutters/Mentors	Clan Leaders	Total (%)
Sebei	Kapchorwa	20	21	22	**63 (30.3%)**
Bagisu	Mbale	14	16	16	**46 (22.1%)**
Baamba	Bundibugyo	11	10	17	**38 (18.3%)**
Bakonzo	Kasese	22	21	18	**61 (29.3%)**
Total (%)		**67 (32%)**	**68 (33%)**	**73 (35%)**	

5.3.4. Focus group discussion topics

Focus groups were structured around the following topics:

1. Cultural and traditional significance of TMC.
2. General information on TMC.
3. Roles, responsibilities, and training processes for cutters and assistant cutters/guardians before, during, and after TMC.
4. Cutting techniques and handling of TMC adverse events.
5. Recent changes in TMC, and views and suggestion on how to make TMC safer.

5.3.4. Qualitative data collection and management

Predetermined themes, such as TMC's cultural importance, logistics of the practice, cutters' training procedure, and tools used during TMC were selected prior to holding the FGDs. Several experts reviewed the planned themes and associated questions. The FGDs were audio and video recorded. All files were transcribed verbatim by two of the study team members. Study team members also cross checked the transcription results to ensure rigor and accuracy. Transcripts were reviewed, and reoccurring themes based on the five topics above were identified to develop a codebook. After an in-depth review of the transcriptions and cross-analyses of the four ethnic groups (Sebei, Bagisu, Baamba, Bakonzo) and different participant groups (clan leaders, traditional cutters, assistant cutters) additional codes were derived for further characterization. Hence, the codebook, which was initially based on predetermined codes, evolved through an iterative process with the emergence of new information, which was either unique to a given ethnic group or common across all groups.

5.4. Results

5.4.1. Cultural and traditional significance of TMC

In order to understand the cultural and traditional importance of TMC in each ethnic group, open-ended questions such as the following were asked:

1. What are the traditions, customs, and rituals associated with male circumcision in your ethnic group?
2. What are the reasons parents decide to circumcise their sons traditionally?

All participants agreed and even emphasized that traditional male circumcision is a major milestone in the process of becoming a man.

> *"It [circumcision] is the time when a boy is initiated to become a man, to become his own per son, when he has to take responsibilities. Traditionally, if a boy not cut traditionally will not be allowed to inherit and always will be called coward. Once he is born, family knows he must be cut traditionally. He is raised with that mentality and prepared for that important day [sic]."* (clan leader – Bagisu)

"Once the boy is born, they know that he must be circumcised traditionally. So boys are brought up knowing they have to be circumcised in a traditional way [sic]." (clan leader – Bagisu)

"The process begins with dancing. The initiate goes around inviting his relatives and friends to attend the ceremony. Until the last day that is called the eve of the circumcision. That's when some rituals are done and in the morning the cutting is done [sic]." (clan leader – Sebei)

The Bugisu region (eastern Uganda, Bagisu ethnic group) is considered the birthplace of TMC in Uganda. Common belief holds that the first male circumcision was performed in the region centuries ago. Even today at the start of each circumcision season, the first cohort of candidates is circumcised in the Bugisu region. This tradition is part of the cultural belief system to such an extent that those who are not circumcised traditionally are strongly stigmatized within their communities.

"There is a big difference between a person circumcised at the hospital and one circumcised at home. Reason being that if you were circumcised in the hospital then you will never be an heir. And also if a child is going to be circumcised, you cannot advise because you did not go through a normal circumcision. When you are circumcised in the hospital, people look down upon you and know you are not as strong as others [sic]." (clan leader – Bagisu)

In the Sebei and Bagisu ethnic groups, candidates announce their decision to be circumcised by dancing publicly in their villages a few days prior to the day of circumcision. They visit the homes of their relatives and invite them to the circumcision ceremony. During this time, they receive gifts from their relatives and help their parents prepare food and brew beer for the ceremony.

In the Baamba ethnic group, to ensure the safety of the procedure, sometimes a male relative of the candidate, typically a maternal uncle, stands behind the cutter, armed with a spear and ready to strike the cutter if the cut injures the boy in an unexpected way.

> *"Family head stands behind the senior cutter holding the spear. The reason for it is that, if in any case, the procedure was done badly leading to death, then he would hit the cutter [sic]."* (clan leader – Baamba)

When asked if there were reasons for TMC beyond cultural beliefs, some participants from different ethnic groups cited health benefits.

5.4.2. Candidate's age, TMC's season, cost, cutting time, and number of traditional cutters

Sample questions to stimulate discussion on the logistics and operations of TMC included the following:

1. What is the age range of the boys when they are circumcised?
2. What time of year is TMC performed?
3. How many circumcisions, on average, does each cutter perform during this time frame? How many traditional cutters are associated with your ethnic group?

Table 5.2 shows the candidates' age range, ethnic group, season, and the associated cost. The highest number of TMCs occurs in August and December due to school holidays. In eastern Uganda TMC is performed only in even years, while in western Uganda TMCs can be performed at any time depending on demand.

There is no fixed age limit in any of the ethnic groups, but the age range for eastern Ugandan candidates is relatively older (14-18 years) than that of western Uganda (2-15 years). The cost of TMC varies from UGX 5,000 to 40,000, or approximately USD 2.00 to 16.00 (Uganda GDP per capita is USD 1,300.00). The candidate's parents are responsible for the payment, although the price is negotiable and depends on the family's financial ability. Cutters performing procedures in the Sebei ethnic group are given a chicken and 20–40 liters of locally brewed beer in addition to the cash payment. Almost half of what a cutter receives must be given to his assistant.

When asked about the number of cutters in active practice, the Sebei, Baamba, and Bakonzo indicated about 20 cutters and the Bagisu indicated about 1000 cutters. This very high number is due to the Bagisu's growing population, the historical importance of TMC, and the social emphasis on training more cutters to meet demand. The average number of cuts performed by each cutter in each season is 170 (Sebei), 90 (Bagisu), and 200 (Baamba and Bakonzo). Cutting time is significantly shorter in the Bugisu and Sebei regions (Table 5.2).

Table 5.2: General information on TMC for the four ethnic groups studied

Ethnic Group	Age Range (yrs)	Circumcision Season	Cost Range	Cutting Time (sec)	Active Cutters
Sebei	14 – 18	Every even year, months of August and December	UGX 20,000 – 40,000 (USD 8 – 16)	10 – 50	20
Bagisu	14 – 18	Every even year, months of August-September and December-January	UGX 5,000–15,000 (USD 2.0 – 6.0)	5 – 10	1000
Baamba	5 – 15	Every year, months of August and December	UGX 5,000 (USD 2.0)	120 – 180	20
Bakonzo	2 – 15	Every year, months of August and December	UGX 5,000 – 15,000 (USD 2.0 – 6.0)	120 – 180	20

5.4.3. Role, responsibilities, and training process for cutters and assistant cutters/guardians, before, during, and after TMC

The following open-ended questions were asked to learn about the role of senior and assistant cutters and to understand whether they underwent any systematic training:

1. Can you describe your role (as a cutter/assistant cutter) during the traditional circumcision in detail?
2. What do you do to prepare the candidate before and after TMC?
3. What makes one cutter better than another?
4. What type of training, if any, is required to become a cutter or assistant cutter/mentor?

The Sebei did not have a traditional cutter of their own until the mid-1980s; instead they asked Bagisu cutters to perform the procedure. However, in the last 20 years, the Sebei trained their cutters by shadowing those of the Bagisu group.

> *"We thought of the money they [Bagisu cutters] were making. We thought why are we losing this money? That is why we started performing circumcision [sic]."* (clan leader – Sebei)

A Sebei cutter's role is simply to perform the actual cut of the foreskin.

> *"A good cutter is the one who cuts fast, but does not hurt the head of the penis." "[a good cutter is determined] based on the size of the wound. The quicker it heals means the person who circumcised is better in cutting." "A good cutter is one who cuts and no [foreskin] part is left. So, during the healing process the mentors have been able to identify these cutters and let the community know [sic]."* (cutter – Sebei)

Most Sebei cutters lack formal training, other than occasional meetings with others involved in TMC to talk about their experiences, and shadowing elders.

> *"In some cases they [cutters] have seminars among themselves that's coordinated by their seniors, those who have been cutting for a long time and have been training them [sic]."* (cutter – Sebei)

Sebei cutters who attended the FGDs had been practicing on average for 10.5 years. Assistant cutters in Sebei are referred to as "guardians or mentors" and are responsible for coaching the candidate, preparing him for the cut, and advising him on post-operative care for the wound. Guardians also ensure that a clean knife is used for each candidate and that cutters wash their hands before the procedure.

"Mentors assist cutters to make sure that candidates have been circumcised very well [sic]." (clan leader – Sebei)

A good mentor is one whose candidates do not fear the procedure and whose recovery periods are one week or less. On average, Sebei guardians who participated in the FGDs had 14 years of experience.

Notably, only the Bagisu group has formed a union of cutters and assistant cutters and registered the organization with the local government. Not everyone within the Bagisu group can become a cutter, since the journey is a spiritual one that is not afforded to many. The process typically starts with the onset of a mysterious sickness, during which the individual dreams of ancestral spirits which encourage him to become involved in TMC. When the individual falls ill and does not respond to traditional or modern medicine, he is taken to the elders of the community. Depending on the situation and the individual's background and circumstances, the elders decide if he is ready to become involved in TMC. If accepted by the elders, the individual begins to shadow a senior cutter as an assistant.

A few days before each circumcision season, the local district health office in the Mbale District holds training sessions for TMC cutters and their assistants that provide instruction on safe and hygienic practices and adverse events management. Cutters must obtain a certificate from the district health office upon finishing the training session before they can perform that season. Cutters in the Bagisu group are solely responsible for the circumcision cut and the assistant cutters are responsible for preparing the candidate. A good Bagisu cutter should hold strong ties to the community and know how to make a fast cut without complications. Senior cutters attending the FGDs had been working as senior cutters on average for 13 years.

Assistant cutters take instructions from senior cutters. The assistants manage and control the crowds, which typically gather at the circumcision ceremony, ensuring that the cutter and candidates are not disturbed. They also care for the wound following the procedure. The Bagisu group requires its assistants to shadow senior cutters extensively before the seniors and clan leaders determine whether they are ready to graduate to senior cutter. Bagisu assistant cutters who participated in the FGDs had been working as assistant cutters on average for 11 years.

Among the Baamba and Bakonzo, TMC is considered a family business. Cutters and assistant cutters from both ethnic groups who participated in the FGDs said they were involved

in TMC because of their fathers and grandfathers. No formal training exists in either ethnic group. Rather, a good cutter typically performs a consistent cut, leaves a minimal amount of foreskin, and uses a new razor blade for each candidate.

> *"In order for somebody to become a senior cutter, it is about consistency and speed in the [cutting] procedure [sic]."* (cutter – Baamba)

A senior cutter must learn to effectively manage complications. To prevent possible complications, Bakonzo cutters frequently visit candidates post-procedure to clean the wounds and advise parents on proper care. In the Baamba and Bakonzo groups, cutters who participated in the FGDs had been working on average for 40 and 24 years, respectively.

Assistant cutters in both ethnic groups hold young candidates on their laps while the cutter performs the circumcision. In the Baamba ethnic group, assistant cutters remain with the candidate for a few hours post-procedure to care for the wound and manage potential complications. A Baamba assistant cutter explained:

> *"We wash the wound after cut with water. We also stay around for few hours to take care of the boy to make sure he is fine. Then, we hand him to his parents [sic]."* (assistant cutter – Baamba)

Assistant cutters in the Bakonzo remain with the candidate for a half hour post-procedure. Assistant cutters in the Baamba and Bakonzo who participated in the FGDs had been working on average for 10 and 22 years, respectively.

5.4.4. Cutting techniques and handling of TMC adverse events

To obtain information about cutting techniques unique to each ethnic group, their associated adverse events, and the view of local communities on potential changes to make TMC safer, the following questions were asked:

1. What are the techniques used for traditional circumcision cuts in your ethnic group? Is there any variation among cutters' methods? How much foreskin is cut?

2. Have you ever heard of a circumcision that has resulted in an adverse event? If yes, what was the reason? Who is to blame if an adverse event happens?

While it should be acknowledged that there is no set TMC "style", the majority of cutters in the Sebei and Bagisu groups share the same method. That is, a candidate ready to be circumcised is called to the center of the area designated for the circumcision ceremony. The boy stands and holds his hands up as the cutter removes his clothing to expose the penile shaft. The cutter pushes the glans inside and pulls the foreskin forward. The pushing and pulling sequence is performed three to four times While pulling the foreskin, he places his thumbnail where he can feel the glans. He uses his nail to mark where the glans ends and to protect it against the cut. While the foreskin is pulled, the cutter uses a traditional knife to cut through it. After the first cut, the assistant cutter holds the glans as the cutter removes the remaining foreskin (inner layer) through a radial cut using the same knife. Cutters do not dress the wound with any medical supplies. Clan leaders attending the ceremony are responsible for supervising the process.

> *"Cutting method depends on the length of the foreskin. During the cutting ceremony clan leaders stand by the candidate and advise if there is too much or less skin cut. They also make sure the cutter acts responsibly if a complication happens [sic]."* (cutter – Sebei)

> The major difference between Sebei and Bagisu cutting styles is that the Sebei do not cut some of the skin from the inner layer whereas the Bagisu cut the entire foreskin.

> *"In compare to Bagisu, Sebei cut less amount of foreskin because cutting too much makes healing process complicated [sic]."* (cutter – Sebei)

Figure 5.2 and Table 5.3 summarize the cutting techniques used by the four ethnic groups. As shown for the Sebei and Bagisu, the first two cutting steps are identical. But for the second cut, Sebei cutters leave some foreskin intact. The final row of images shows the outcome of the traditional cut. The pink area shown is a layer of inner foreskin. The red area depicts the open wound caused by the cut.

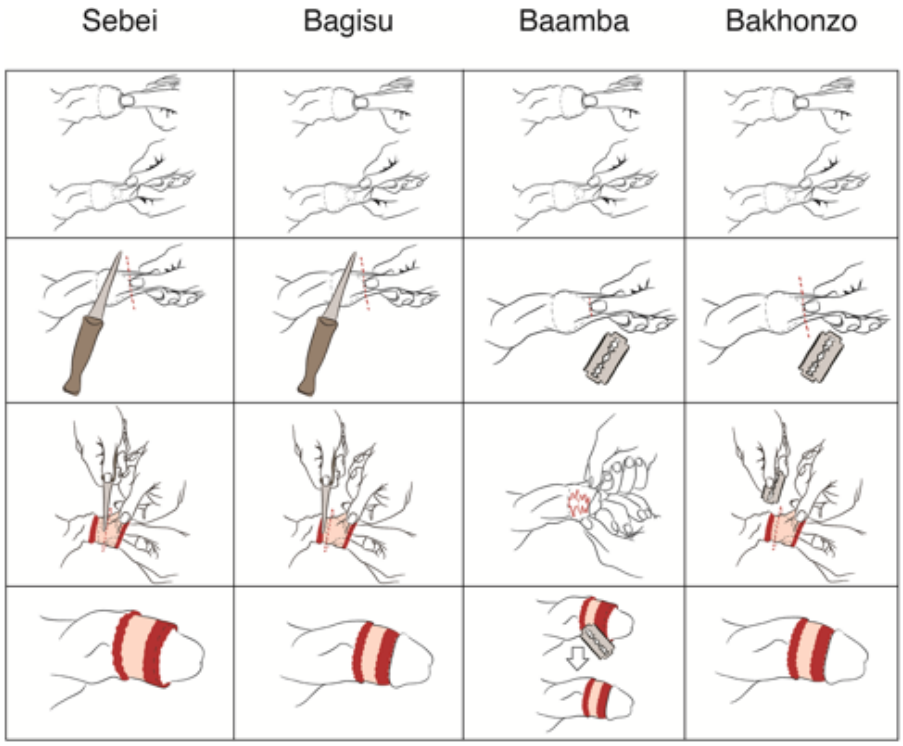

Figure 5.2: Illustration of traditional circumcision cutting techniques by ethnic group; Columns depict TMC cutting techniques per ethnic group; Rows show cutting process steps (row 1: pull foreskin and push glans; row 2: initial cut; row 3: secondary cut; row 4: circumcised penis)

Table 5.3: Circumcision cut style and performer per ethnic group

Ethnic Group	**Cut Performed by**	**Cutting Style**
Sebei	Cutter	1. Push the glans in. 2. Pull the foreskin forward. 3. Cut through foreskin with a traditional knife. 4. Hold the glans and perform a radial cut. Leave some amount of foreskin uncut.
Bagisu	Cutter	1. Push the glans in. 2. Pull the foreskin forward. 3. Cut through foreskin with a traditional knife. 4. Hold the glans and perform a radial cut. Remove the foreskin fully.
Baamba	Cutter with assistant cutter	1. Push the glans in. 2. Pull the foreskin forward. 3. Make an incision through foreskin with a razor blade. 4. Tear apart the foreskin by hand. 5. Cut any remaining foreskin through a radial cut with a razor blade.
Bakonzo	Cutter	1. Push the glans in. 2. Pull the foreskin forward. 3. Cut through the foreskin with a razor blade. 4. If the cutter feels the inner layer is long, perform a radial cut.

In the Baamba ethnic group, a candidate arrives at the designated cutting area and the cutter strips him down. If too young to stand alone, the boy is held by a male family relative or by the assistant cutter. After exposing the penile shaft, the cutter pulls the foreskin to measure the amount to be cut. Similar to the process followed by the Bagisu and Sebei, the cutter uses his thumbnail to indicate where the cut should be made. A razor blade provided by the parents of the candidate is used to make a small incision to allow the cutter and his assistant to tear apart the skin. Once the incision is made, the assistant cutter tears the skin by pulling it apart up to the penis corona. Finally, the cutter uses the razor blade to cut away any remaining skin (Fig 2). After the cut, the assistant cutter washes the penis with clean water, but does not use medical supplies to dress the wound. Cutters in Bakonzo explained their method as a simple pull on the foreskin followed by a cut through it with a razor blade (Fig 2). If they feel the inner layer is too long, they cut it radially around the penile shaft, otherwise the first cut suffices. In this technique, the cutting style depends on candidate's age. If the boy is younger than five years old, the cutters usually perform an initial cut and a radial cut. If the candidate is older, one vertical cut is enough to consider the boy circumcised.

Participants in all of the FGDs identified excessive bleeding, prolonged wound healing, infection, glans injury and amputation, and unfinished cuts requiring additional cuts as the most common adverse events. Sebei and Bagisu participants also mentioned the risk of deafness due to excessive festivities with loud music and crowds.

> *"Complications happen due to rushing and the speed of the process. There will be inaccuracy and imperfect cutting by the cutter [sic]."* (clan leader – Sebei)

One Bagisu cutter complained about the uncontrollable and crowded public who surround the candidate and cutter to watch the ceremony:

> *"Sometimes the complications they [candidates] are getting is because of the rowdy crowd. Sometimes they become so crowded and they push you [sic]."* (cutter – Bagisu)

No focus group participant would identify the party responsible for an adverse event, although a few cutters blamed their assistant or the candidate, citing the failure to adequately care for the wound. Assistant cutters and clan leaders mostly blamed the cutters, claiming that it was their responsibility to ensure the candidate's safety.

5.4.5. Recent changes in TMC, views, and suggestions for making it safer

To capture recent changes to the traditional circumcision ceremony and to explore the potential for additional future changes to make TMC safer, the following questions were asked:

1. Have the traditions, customs, and rituals associated with circumcision in this region changed over time? If yes, how? Why?
2. Would you support changes in TMC practice to make it safer? What type of changes would you considering?

As mentioned, custom, ritual and cutting methods vary by ethnic group. However, the use of one traditional knife or razor blade per candidate during circumcision is one of the most significant changes mandated by the Uganda MoH. The change was implemented in early 2000 across all ethnic groups. Eastern groups still use a traditional knife whereas the Baamba and Bakonzo groups use razor blades.

> *"Due to country's development of change of time, now we have changed some customs and rituals. Now, we use one-time use razor blades and have made the cutting procedure and ceremonies more decent [sic]."* (cutter – Baamba)

> *"Cutters nowadays must have different [separate] knives per candidate [sic]."* (clan leader – Bagisu)

Another change is connected to the spread of organized religions in Uganda. For instance, Muslims prefer to circumcise their sons at an early age (typically 7 days old). Catholics and Anglicans oppose the excessive festivities surrounding TMC, the over-consumption of alcohol, and promiscuity. Hence, an ethnic group's religious preference can motivate a change in TMC practice.

"For some people, due to their modern religious beliefs, they don't participate in dancing ceremonies. They just cut traditionally and leave it at that [sic]." (clan leader – Bagisu)

"Initially we were using traditional knives, just very sharp and small. There is now a razor blade per candidate. Each candidate is also provided with his own water. After circumcising him, we wash the fresh cut with clean water [sic]" (cutter – Baamba)

Although there have been changes in custom and rituals, a Bagisu cutter expressed:

"No matter what has changed around circumcision, the bottom line and the most important factor is that the boy must be cut traditionally [sic]." (cutter – Bagisu)

Participants were also asked about potential reforms in TMC that can help reduce its adverse events.

"We accept promoting other tools for circumcision. When we are looking at how the world has been in the past and now, there have been many complications [with TMC], so we are positive to adopt scissors and razor blades for the procedures, as long as it reduces the risks to the circumcision [sic]." (clan leader – Sebei)

"In villages lack the equipments, so if there is a way, a tool, that specifically can reduce the pain and maybe fast healing, we can welcome it very well [sic]." (clan leader – Bakonzo)

The majority of the FGDs emphasized that information on the importance and health benefits of circumcision should be provided and that families should be informed about what to look for when selecting a cutter.

"Better is that to make people educated to know how to have circumcision safe. Unless we educate them about that complications will continue [sic]." (cutter – Bagisu)

Most participants also stressed the need to inform people about adverse events. When asked about venues to disseminate such information and by whom, the participants cited: churches and mosques (religious leaders); radio talk shows (clan leaders); and schools (teachers). Other suggestions included stocking health clinics with wound-dressing supplies, clean gloves, and sterile razor blades for cutters to purchase for a minimal fee.

5.5. Discussion

In Uganda, as in most other sub-Saharan African countries where TMC is practiced, traditional circumcision marks the entry to manhood. However, there are variations in the logistics and performance of TMC among Uganda's four ethnic groups. For instance, eastern groups tend to circumcise at an older age than those in western Uganda. There are also variations in cutting styles. For example, even though Sebei cutters are trained by their Bagisu counterparts, they leave some of the foreskin intact unlike the Bagisu, who cut the entire foreskin. The side effects of such cutting style variations include longer healing times and potentially different protection levels against HIV/AIDS transmission; a report from the Forum for Collaborative HIV Research recommends leaving less than 3 mm of foreskin (although this is an on-going area of research) in a clinical circumcision for the most effective protection [21]. Complications cited by several focus group participants are consistent with the adverse events identified in previous studies [9]. They revealed that rapid cutting methods are effective in reducing instant pain but can increase the risk of glans injury and amputation and cause larger wounds and scarring. Participants from the Baamba and Bakonzo ethnic groups recalled fewer adverse events, which we attribute to the younger age of their candidates, the fact that Baamba assistant cutters remain with the patient for a few hours post-cut, and that Bakonzo cutters perform a follow-up visit a few days later.

For the Bagisu group, TMC represents a sense of pride. Unlike the three other groups, the Bagisu had formed a union comprised of cutters and assistant cutters to determine how to best

preserve TMC's cultural significance in an era when festivities, elaborate dances, and other forms of celebration centered around TMC have been greatly reduced. In western Uganda, celebrations are rare and in the east they are shorter and less well attended. Focus group participants from various backgrounds emphasized that they would not completely abandon TMC, even if the side-events that typically accompany the ritual disappear. From a policy perspective, local communities' willingness to detach from some traditions signals a potential opportunity to discuss how to make TMC safer, but only if the local leaders are included in the planning and implementation.

Focus group participants offered several reasons for preferring TMC over clinical circumcision, such as cultural significance, low cost, and individual's resistance to the modern health care system. Although some participants were aware of the positive impact of circumcision in reducing HIV transmission, it is unclear whether traditionally circumcised males will experience the same level of protection from HIV transmission [12-13].

We suggest that a reliable clinical infrastructure providing voluntary mass medical male circumcisions by trained individuals using appropriate equipment is the best long-term solution to reduce circumcision-based HIV transmission rates in sub-Saharan Africa. However, a number of significant barriers identified by the African Ministries of Health and emphasized in our paper make it unlikely that the VMMC vision for Uganda will be realized in the near future [22]. Among the critical issues cited for the slow scale-up of clinical male circumcision are a shortage of human resources for programming and service delivery; a lack of buy-in from social gatekeepers such as traditional clan leaders and key decision leaders; and a poor understanding of how policy-makers might engage Ugandans in order to influence behavioral change [22]. The strong cultural significance of TMC reaffirmed through the FGDs demonstrates the reluctance of local communities to partake in the government's mass VMMC roll-out plan. However, timely changes in TMC practices, such as minimizing the TMC related festivities, using one knife/razor blade per candidate, and acceptance of local health staff supervision in some cases in Bagisu (e.g., mandatory training certificates by local health office for all cutters) demonstrate the possibility of acceptance in the future. Indeed, changing attitudes at the community level may open the door for health care providers, key decision-leaders, and policy-makers to explore a hybrid model that standardizes cutting style and ensures effective protection against HIV/AIDS transmission. Sharing responsibility between the trained health care provider who is responsible

for the cut and caring of the wound and the local cutter who is responsible for cultural rituals might also mitigate the risks of excessive bleeding and glans damage, and reduce overall healing time.

The limited information about the effectiveness of TMC against HIV/AIDS suggests the need for both a systematic evaluation of TMC's role in HIV prevention and the creation of innovative approaches to reduce adverse events. While the initial attempt should focus on making TMC safer, communities that still practice TMC need to be made aware of VMMC's health benefits. For men who are already circumcised traditionally, the educational campaigns should provide information about the limited protective effects of TMC against HIV/AIDS to adjust for risk compensation behavior. The results of the FGDs support these and earlier suggestions to engage local communities that perform TMC in the planning and execution of an effective, safe mass male circumcision roll-out plan [22]. A meeting of NGO representatives and sub-Saharan African Ministries of Health officials who met in 2009 to discuss their progress with the mass scale-up of VMMC and to evaluate the common challenges, states that "it is important to maintain engagement with traditional circumcisers and to avoid alienating them and to use this opportunity for promoting safer traditional practices." [22]. This is especially true in communities where TMC provides status and a source of revenue. Traditional cutters can be involved by educating them about sterile, hygienic practices and methods to manage complications and risks. The FGD results also demonstrate an opportunity for gradual transition of TMC practicing communities to accept VMMC. To implement such transitions and innovative approaches, collaboration can be undertaken with local religious and community leaders, and information about the importance of VMMC and the methods to reduce adverse events of TMC can be disseminated to Uganda's media, schools, and public venues.

This chapter represents the first attempt to demonstrate the landscape of TMC in Uganda. However, the findings reported here should be considered with specific limitations. While the study team made great efforts to include a wide range of informed stakeholders, it is possible that the final study does not reflect the full spectrum of beliefs and opinions about TMC in Uganda. Nevertheless, considering the number of participants from different ethnic groups and the quality of the data collected, saturation was achieved and no new information emerged during the final FGDs. Opinions presented in the FGDs represent the knowledge, assumptions, and understanding of the participants. While the participants are considered experts in this field, their

opinions may not reflect the most accurate facts about TMC. Furthermore, there may be minor grammatical (real-time translations reported herein without modification) and contextual related issues associated with translating the FGD participants' responses from their local languages to English. Finally, this work on four ethnic groups that practice TMC in Uganda may not be relevant for other communities in sub-Saharan Africa that also practice TMC. We conclude, however, that, communities' attitudes and reactions to change, common adverse events, and the challenges associated with making TMC safer are expandable concepts.

We suggest that our research is an important factor in developing both a safe TMC program and the educational and informing methods required for an effective national mass male circumcision roll-out. Further studies should be undertaken to evaluate the adverse events of TMC in Uganda and its potential effectiveness for public health purposes, and to identify the potential methods and approaches needed to convince local communities to adopt safe practices and potentially transition to VMMC.

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Chapter 6. Design evolution of a traditional male circumcision tool[2]

6.1. Abstract

Background: Randomized clinical trials have proven that clinical adult male circumcision can reduce the HIV/AIDS transmission rate between heterosexual men by 60 percent. Some ethnic groups in eastern and southern sub-Saharan Africa, however, still practice traditional male circumcision (TMC), despite a high rate (as much as 48 percent) of reported adverse events. This study introduces a culturally appropriate tool, the design of which is based on the continuous feedback of stakeholders involved in traditional and clinical male circumcision practices in Uganda. It also reports the outcomes of a clinical trial that collected the penile anthropometric data used to inform the tool's design and to evaluate its fitness and placement on the penile glans.

Methodology: The first generation design was based on input from clinicians practicing clinical male circumcision. Next, the design was introduced to stakeholders in Uganda (ethnic leaders, traditional cutters, etc.) including individuals from ethnic groups that practice TMC. Design feedback obtained through ethnography (observation of TMC, 25 focus group discussions, and over 20 interviews) was used to develop alternative designs that were tested analytically and experimentally (cadaver testing).

Main Findings: Three of the four ethnic groups stated that they would use the final design tool that reduced TMC's adverse events if proven effective and approved by authorities. In fact, 97 percent of the clan leaders and 80 percent of the traditional cutters preferred the final tool to other alternative designs. The final tool accommodates a fast cut, as practiced in TMC, provides full coverage of the penile glans, and anchors securely as the foreskin is pulled in tension. The study members participating in the clinical trial "strongly agreed" or "agreed" that the tool anchored securely on the penile glans as the foreskin was pulled over it. When asked about the

[2] Parts of this chapter have been published in *American Society of Mechanical Engineering's Journal of Medical Devices (2013) and DEMAND - Global Development Review (2014)*

level of pain when the tool was applied over the glans, 96 percent of the participants reported minimal to none.

Conclusion: Ethnic groups in Uganda support using tools, which are proven effective in reducing TMC adverse events and are designed with their input. A stakeholder driven process for obtaining design requirements and defining engineering specifications can result in end-users' higher levels of design acceptance. The presented anthropometric data and qualitative feedback based on a clinical trial can inform future designs of culturally and socially acceptable clinical male circumcision devices.

6.2. Introduction

6.2.1. Importance of male circumcision

Globally in 2012, an estimated 35.4 million people were living with HIV, and sub-Saharan Africa hosted 70 percent of all new HIV infections [1]. The recent series of randomized clinical trials showing that clinical adult male circumcision reduced the HIV transmission rate by 60 percent among heterosexual men [2-4] led the World Health Organization to conclude that clinical male circumcision is the only proven efficacious biomedical intervention for the prevention of sexually transmitted HIV infection in adult men [5]. Consequently, most of the ministries of health in sub-Saharan Africa are developing educational campaigns and rolling out plans for implementing mass male circumcision with the support of key global public health organizations [6].

6.2.2. Traditional male circumcision: significance and challenges

In sub-Saharan Africa, adult male circumcision occurs in both clinical settings and traditional ceremonies. Many ethnic groups throughout eastern and southern sub-Saharan Africa consider traditional male circumcision (TMC) a rite of passage for boys between the ages of 10 and 18 [7]. However, the practice is associated with adverse events (as high as 48 percent) including excessive bleeding, excessive removal of foreskin, infections, extreme pain, lacerations, erectile dysfunction, and even death [7-9]. For example, in Uganda where the HIV prevalence rate is 6.5 percent, approximately 10 percent (3.5 million) of the population belongs to ethnic groups that practice TMC.

Even though two relatively new medical devices, ShangRing and PrePex, enable less-trained health workers to perform clinical adult male circumcision [10,11], they are not suitable

for use in traditional settings due to cultural inappropriateness, complexity, and cost. Hence, there is a need for a culturally appropriate and locally acceptable approach to address the adverse events of TMC.

6.2.3. Making TMC safer

Previous work has shown that ethnic groups practicing TMC will not give up this tradition easily given its cultural significance [9]. As long as TMC continues to be practiced, an innovative intervention is needed to ensure safer and healthier outcomes. This work describes the development of a culturally and physically appropriate tool intended to reduce TMC's high rate of adverse events, by using a stakeholder driven process for obtaining design requirements and defining engineering specifications. The work also reports the outcomes of a clinical trial that identified penile anthropometric data, evaluated the first generation tool's fitness and placement, and gathered additional feedback that improved the final design.

6.3. Methods

6.3.1. First generation design of a TMC tool: need finding and design validation

The study team began the design process by establishing a list of user requirements, which were the desired design features as expressed by users, and the engineering specifications, which were the numerical and measurable translations of the user requirements based on the literature and elicited in interviews with Kenyan and American surgeons. The complete methodology and outcomes of the design of the first generation tool were previously presented at [12]. Qualitative and quantitative measures were applied to evaluate the validity of the most important user requirements and engineering specifications, e.g., time required to apply and remove the tool, ease-of-application, degree of glans protection, and length of foreskin cut. The study team used male cadavers at the University of Michigan's Anatomical Laboratory to evaluate the validity of some requirements.

Due to the lack of available rigorously collected knowledge about TMC's sociocultural importance, the study team sought out end users and stakeholders, local practitioners, and beneficiaries in Uganda, to learn about TMC practice. The team conducted fieldwork on TMC's cultural and social aspects and researched related local and national policies. The design ethnographic methods included 12 focus group discussions (FGDs) with traditional cutters and ethnic group leaders, and more than 15 interviews with local and national public health officials

and clinical experts. The fieldwork had two objectives: 1. Understand the sociocultural implications of TMC, and 2. Confirm the need for a tool to make TMC safer, obtain feedback about the first-generation design and revise the original user requirements. The outcomes were previously published in [9].

6.3.2. Intermediate designs

Mechanical and anatomical evaluation of the first-generation tool and the ethnographic findings from the stakeholders were used to revise the list of user requirements and engineering specifications (Table 6.1). Twenty-five concepts were developed using hand-drawn images along with descriptions of their presumed functions and their favorable and unfavorable features. The new concepts were either refinements of the first-generation tool or were new ideas.

Table 6.1: Original and revised user requirement and engineering specifications

Original Requirements	Original Engineering Specifications	Revised User Requirements	Revised Engineering Specifications
1. Fast cut	120 sec	1. Fast cut	Cutting time < 10 sec
2. Number of procedural steps	10	2. Safe cut	Full (100%) glans coverage
3. Number of parts	3	3. Strong grip	0 incident of falling the tool while cutting the foreskin
4. Adjustable diameter	15.2-40.6 mm	4. Low cost	Final cost < $1.00
5. Glans coverage	50%	5. Three sizes	Three diameter sizes for the opening of the hard shell: Small: 1.5 cm; Medium: 1.75 cm; Large: 2 cm.

Three study team members reviewed the new design ideas and used prioritization methods such as go/no-go feasibility tests, Pugh Charts, and parameter analyses to down-select the top five concepts. The five selected concepts were developed further using 3D software (SolidWorks V'11). Simulation-based mechanical analysis and anatomical evaluation were used to compare the top five designs against the revised list of requirements and specifications.

6.3.3. Final design and follow-up fieldwork

The final design was selected based on the revised list of user requirements and engineering specifications and the results of the team's anatomical validation tests on cadavers.

After selection of the final design, the study team performed additional fieldwork in Uganda during 2011-2012. The fieldwork had two objectives: 1. Perform usability analysis on the final design, and 2. Elicit stakeholders' preferences when comparing the original and final designs. The fieldwork included 15 FGDs, 30 interviews, and observation of TMC practice. FGDs participants included traditional cutters, their assistance, and religious and community leaders from the four ethnic groups practicing TMC. Interviews were conducted with the national and local public health officials, clinical experts, and organizations involved in rolling out plans for implementing clinical male circumcision. The team also attended a series of TMC practices in Masaba Land with Bugisu ethnic group. A partial report of the fieldwork and stakeholder preference elicitation was published in [13].

6.3.4. Clinical trial

After confirming stakeholders' approval of the final design, a clinical trial was conducted to:

1. Collect anthropometric penile measurements of the target population to further refine the final design of the tool based on target users' penile sizes, and to use when designing future clinical male circumcision devices.
2. Evaluate the final design tool's fit and placement to validate protection of the penile glans during a TMC cut.

The trial was performed at the Rakai Health Sciences Program in Kalisizo in March and April 2014. Men with congenital or acquired genital abnormalities were excluded. Each participant was reimbursed 5,000 Ugandan shillings (about US $2.00) for his time and 12,500 Ugandan shillings (about US $5.00) for transportation. The fees were set based on national standards determined for similar clinical trials in Uganda. Table 2 lists the demographic information of the participants. A full description of the clinical trial performance and outcome is provided in the appendix.

6.4. Results

6.4.1. First-generation design of a TMC tool

The first-generation design had six compliant arms that embraced the penile glans and were intended to protect the penis during the cut (Fig. 6.1). Engineering analyses were performed

to characterize the relationships between arm dimensions (length, width) and geometries (radius of curvature), and to find the optimum number of arms and various dimensions needed to control the removal of an adequate amount of foreskin. The complete description of this design was previously published in [12].

Figure 6.1: First-generation prototype

Because there was no systematically collected data on the sociocultural importance of TMC in Uganda, the study team conducted 12 FGDs and over 15 interviews. FGDs involved ethnic and religious leaders, traditional cutters, assistant cutters, and parents of young men from the four ethnic groups that practice TMC. The interviews involved public health officials and clinical experts caring for patients with TMC-related complications. A complete description of TMC practice in Uganda and feedback on the first-generation design were previously published in [9,13,15].

Three of the four ethnic groups stated without hesitation that they would be willing to use the tool as soon as it was provided, if proven effective and approved by responsible authorities. After 12 FGDs and over 15 interviews between 2011 and 2012, the original list of user requirements and engineering specifications was revised to include more specific numerical targets for fast cut, full coverage of the glans during circumcision, secure fit to the penile glans while the foreskin was being pulled in tension, and three measurement sizes.

Traditional cutters and ethnic leaders unanimously wanted a quick procedure. They emphasized that cutting should not last more than 15 to 20 seconds. One traditional cutter from the Bugisu ethnic group said that in some ceremonies a coconut is thrown into the air, and by the time it hits the ground the cut must be finished. This change in cutting time requirement, from the original time expressed by clinical experts (three minutes) to less than 10 seconds had significant implications during design iterations.

The original specification for “safe cut” requirement was informed by the literature that was published by the World Health Organization to develop devices for clinical male circumcision. Hence, the protection of glans, in that literature, meant partial coverage, since cutting the foreskin should not require a “guillotine cut”, which is sometimes practiced during TMC. FGDs revealed that the tool needed to fully cover the penile glans to provide complete protection against variations in cutting styles [9].

The first-generation design assumed a one-size-fits-all solution to eliminate measuring confusion by end-users. The solution made intuitive sense and was supported in interviews with clinical experts. However, after presenting the first-generation tool, all stakeholders said they only wanted small, medium and large size, as it made sense to end-users that there should be different tool sizes to fit a range of penile sizes.

6.4.2. Intermediate designs

Based on feedback and cadaver testing outcomes, the study team generated 25 additional design concepts. The concepts were either modified versions of the first-generation tool or were designed without reference to prior models. The team then selected the top five design concepts.

Intermediate design I: A modified version of the first-generation tool with four one-directional arms. Once the tool is applied over the penile glans, the traditional cutter (user) closes the arms so that they fully embrace the glans. Advantages: 1. Impossible to reuse due to one-directional arms; 2. Easier placement over the glans using only one hand; and 3. Adjustable size due to movable arms. Disadvantages: 1. Glans is not fully covered; 2. Unlikely to finish cutting in less than 10 seconds.

Intermediate design II: A modification of the first-generation design with three flexible arms and a hole at the end of the tool to allow placement with a guiding (placement) rod. Advantages: 1. Flexible arms allow for easier placement over glans; 2. Rod also guides placement. Disadvantages: 1. Glans is not fully covered; 2. Unlikely to finish cutting in less than 10 seconds.

Intermediate design III: A modification of the first-generation tool with more flexible arms supported by an elastic band that presses the arms against the glans to provide tight closure over the glans. Advantages: 1. Flexible arms allow for easier placement over glans; 2. Elastic band assists tighter closure of the arms over the glans. Disadvantages: 1. Glans is not fully covered; 2. Unlikely to finish cutting in less than 10 seconds.

Intermediate design IV: A cylindrical tool with ridges on its external body and three small arms that only move inward.. When the cylinder is applied over the glans, the grabbers close in on the foreskin. The cutter pulls up on the cylinder, which also pulls up the foreskin. The cut is made against the body of the cylinder while the glans is fully protected. Advantages: 1. Cylinder provides full glans protection; 2. Three grabbers pull foreskin completely and

accommodate a maximized level of foreskin cut. Disadvantages: 1. Requires more time to apply due to cylindrical shape; 2. Not easy to use.

Final design (Fig. 6.2): Hard plastic shell and a flexible latex sleeve. The user places the hard shell over the glans and retracts the foreskin. User then rolls the latex over the glans until it covers the coronal sulcus. Latex was chosen as the sleeve material due to its ability to firmly grip and anchor the device to the penis while the foreskin is being pulled over the shell. Three shell sizes were designed to accommodate the 5^{th}-95^{th} percentile adult glans diameter based on previously published data on the non-African male population [16]. Advantages: 1. Using latex roll is like using a condom; 2. Simple to apply and remove; 3. Glans fully covered; 4. Tight grip over the glans.

Figure 6.2: Final design prototype

6.4.3. Stakeholders' feedback on final design

The team demonstrated the final design prototype in 15 FGDs and asked the participants to compare the original and the final designs (Fig. 6.3). A Likert scale found that 80 percent of cutters and their assistants (n=51) and 97 percent of clan leaders (n=44) chose the final design based on simplicity, ease of use, and amount of protection. Asked if they would use and/or support the revised device if proven effective and approved by the authorities and with proper training by cutters, 74 percent of cutters and assistant cutters and 88 percent of clan leaders "strongly agreed" they

Figure 6.3: Focus group discussions with ethnic leaders in Uganda to evaluate design prototypes

would do so.

6.4.4. Clinical trial outcomes

The clinical trial collected anthropometric data, validated coverage of the glans by the final tool, and assessed its fit and placement. A total of 103 males (ages 12 to) from eight ethnic groups across Uganda participated. Full details and findings of the clinical trial are presented in the appendix.

The trial's outcomes indicate that applying and removing the tool took about 5 seconds, a significant improvement compared to the study team's prior design concepts. Therefore, this design addresses the need for a tool that accommodates a fast cut. In addition, the study team members input regarding the tool's ease of application was collected. In 99 percent of the cases, the study team member "strongly agreed" or "agreed" with the statement: "I was able to easily apply the tool over the glans easily." In 90 percent of the cases, the study team member "strongly agreed" or "agreed" with the statement: "I was able to fully roll the foreskin over the glans." In 98 percent of the cases, study team members agreed that the participants did not need help applying the tool over the glans. In 97 percent of the cases, study team members "strongly agreed" or "agreed" with the statement, "It was easy to remove the tool." In 95 percent of the cases, study team members "strongly agreed" or "agreed" with the statement, "The tool stayed over the glans without losing its grip while the foreskin was pulled over it."

Over 67 percent of respondents were fully satisfied with the current design. The remaining respondents mentioned two issues: shell design and potential inclusion of lubricant to apply the tool. In five cases team members expressed the need for a smaller size tool to accommodate extra-small size penile glans. In 18 cases the study team members noted that using a narrower curvature for the shape of the tool's shell would improve conformance around the glans. In five cases, the study team members mentioned that lubricated latex would assist with easier application of the tool over glans.

6.5. Discussion

TMC has been practiced in eastern and southern sub-Saharan Africa for centuries. However, its high rate of adverse events indicates a need to make the cultural practice safer. This study described the evolution of a design that incorporated feedback from end- users and

stakeholders. The authors believe that the collection of anthropometric penile data for Ugandan males is the first of its kind.

The study asked two questions: 1. Would end-users and stakeholders accept a tool to make TMC safer? 2. What user requirements and engineering specifications would make a tool culturally acceptable and appropriate? Due to the lack of data and systematical studies, the study team interacted extensively with stakeholders and end-users about TMC and the likelihood of tool acceptance [9].

Rapid cutting methods as practiced by traditional cutters are effective in reducing instant pain, but increase the risk of glans injury and amputation, and cause larger wounds and scarring. The final design is able to accommodate a fast cut as it was shown that the time required to apply and remove it is about five seconds. During TMC, glans injury, amputation, and infection are among the most cited adverse events. The final design both accommodates a fast cut and provides full coverage to prevent injuries. Strong placement and grip of the tool addresses the issue of displacement of the previous designs when foreskin was pulled into tension, which in turn could increase procedure time and decrease protection due to ineffective placement and an inability to control for a consistent cut. Producing this tool in different sizes, as requested by stakeholders, should be inexpensive given it is made of only two simple parts.

The final design's physical structure, using latex roll, builds on the end-users' familiarity with condom use. This design consideration, taking into account prior and existing knowledge of end-users, provides an opportunity to design and develop products that are more likely to be accepted and used. Since the final presented design met the revised user requirements and engineering specifications, there is no need for substantial redesign. To address size variety, however, additional sizes of the tool with more conforming shell curvature should be considered. Providing lubricated latex is another design consideration for overall design improvements.

The outcomes of the clinical trial (presented in appendix) include anthropometric measurements of penile dimensions for Ugandan men. General penile measurements align with a recent study of Tanzanian male [17]; however, more glans-specific data with a focus on a specific circumcision tool was collected for this work. The anthropometric and tool-related findings should inform the future development of clinical male circumcision devices. The results of the clinical trial are not necessarily generalizable to other sub-Saharan African countries due to variations based on age, race, ethnicity, and environmental and nutritional factors. The clinical

trial's outcomes show that the majority (90 percent) of the participants' coronal sulcus diameter fall between 3.25 cm and 4 cm. This diameter informs the necessity for adding more variety to the tool's opening diameter. This finding and the data on glans shape should be used to refine the shell's curvature and the conformation of the penile glans into the shell; however, further evaluation is needed to obtain precise shell curvature.

Design ethnography provides a framework for acquiring tacit information from stakeholders that otherwise would not be obtained from commonly used methodologies in engineering design and market research. Design ethnographic methods were essential in developing an effective TMC tool that was accepted by end-users. In this study, design ethnographic methods such as FGDs led to qualitative and quantitative outcomes that provided necessary background to understand TMC and assisted with eliciting user requirements for an acceptable design and feedback from stakeholders on alternative design concepts.

Limitations included a smaller than ideal number of participants for the clinical trial due to funding. This limitation potentially contributed to the study team's inability to detect a significant difference across age groups. Even though participants for the clinical trial were from eight ethnic groups in Uganda, they did not represent the four ethnic groups that currently practice TMC. While this work presents an approach to make TMC safer, traditional circumcision's effectiveness against HIV transmission is not fully investigated.

This research demonstrated the practical application of an ethnographically based design framework to develop a medical device for a cultural practice while addressing a public health challenge. The framework can be adapted for other types of product development challenges to increase the likelihood of success and acceptability by engaging primary stakeholders throughout the design process.

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Chapter 7. Conclusion: Contributions, implications, lessons learned from the field, and future work

Successful medical device design processes for low-resource settings should consider the broader context of the design during the early phases of device development, rather than after validation or production [1,2]. Therefore, novel medical device design frameworks that consider both diverse stakeholder needs and wants and downstream factors such as regulatory and manufacturing pathways during the front-end phases of design (e.g., development of user requirements and engineering specifications) are needed [3,4].

The concept of user-centered design considers the design process as a continually evolving, iterative process that enables stakeholder engagement to elicit the right needs that will lead to the most appropriate engineering specifications [5,6]. While it is commonly believed that this process should yield a higher likelihood of the device's acceptance and adoption, there is a lack of evidence to demonstrate how designers should engage systematically with a wide range of stakeholders to elicit and translate their design requirements. The engagement with stakeholders when designing medical devices for low-resource settings is even more vital when the designers are otherwise unfamiliar with the cultural context. This work has argued convincingly to adopt methods that engage stakeholders in early phases of the design process. It has also offered a context for task shifting medical devices and presented the requirements necessary to design such devices.

7.1. Summary

Chapter three provided a context for task shifting medical devices and identified the characteristics needed to enable health providers with less training or educational background to perform urgent or specialized medical needs. Over 100 individuals were categorized into seven stakeholder groups that provided health care directly or indirectly in low-resource settings. All stakeholders identified ease of use as the most important characteristic that defined a task shifting medical device. Surprisingly, the requirement of having a policy or law in place to mandate task shifting was considered the least important by four (physicians, nurse-midwives, community health workers, and biomedical engineers) of the seven stakeholder groups. The

finding demonstrated that when there is an urgent need for a task or procedure to be performed, availability and accessibility of an enabling task shifting device could precede policies and guidelines. Subjective requirements such as ease of use could have different meanings to different stakeholder groups. However, the wide range of stakeholders participating in the work concurred that first and foremost a medical device is easy to use if: its operation can be taught on a peer-to-peer training basis, it reduces the procedural (current task) time, and its repair and maintenance can be performed by local technicians. Each stakeholder group also identified other user requirements leading to the design and development of task shifting medical devices.

Chapter four evaluated the quality of outcomes of different user requirement elicitation and prioritization methods (open-ended, clustering, and discrete choice) and developed a methodology to indirectly identify the major categories of user requirements by applying statistical analysis methods combined with stakeholder interview and preference data. A qualitative, open-ended response method provided a gateway to understand the stakeholders' general need and wants. Even though the information obtained was limited, it proved useful in compiling a list of requirements that could be applied when using the clustering method. The individual difference scaling (INDSCAL) analysis used to further analyze the outcomes of the clustering method produced more specific user requirement categories, consisting of sets of user requirements. The categories provided an objective comparison of the requirements expressed by different stakeholder groups; for example, identifying specific requirements that would lead to develop an easy to use device. The requirements categories resulting from an INDSCAL analysis can be used to produce the levels required for a discrete-choice method to prioritize selected user requirements and establish engineering specifications. The outcomes of the three methods also demonstrated that ease of use was the most important requirement expressed by the majority of stakeholders. This finding was consistent with the conclusion reached in chapter three, that ease of use is the most important design characteristic when developing a task shifting medical device for use in low-resource settings. This study's methodology, consisting of elicitation methods and their implementation, will allow engineers designing for low-resource settings to communicate with a wide range of stakeholders and to capture and prioritize user requirements in a timely and cost efficient manner.

Chapter five presented a systematic approach employing design ethnography to learn about the cultural practice of TMC in Uganda. The findings from this chapter were used to design a medical device to minimize the likelihood of adverse events during the cutting procedure. Given the lack of publicly accessible data about TMC practices in sub-Saharan Africa, design ethnography techniques, such as focus group discussions, expert interviews, and direct observation, were utilized, in addition to the three methods described in chapter four.

Chapter six validated some of the user requirements elicitation and prioritization methods investigated in the previous chapters. The requirements gathered from the stakeholder groups were translated into quantitative engineering specifications to inform the design process of a TMC device. Device acceptance (cultural and anatomical appropriateness) was assessed using qualitative research methods. Fit and function feasibility studies were performed with 103 Ugandan men (ages 12-32). As shown by the example of designing a device for safer practice of TMC, the use of design ethnography can reveal knowledge and information that most design engineers are not trained to identify. However, while some findings can be expanded across ethnic groups in a given setting (district, region, country), but designers should be careful that such generalizability is not always appropriate.

7.2. Contributions and implications

This work achieved the following aims:

1. Investigated the definition of task shifting medical devices as expressed by stakeholders involved in health delivery, directly or indirectly, in low-resource settings.
2. Identified primary design requirements to develop task shifting medical devices.
3. Elaborated on the definition of ease of use as expressed by stakeholders involved in health delivery.
4. Developed an understanding of how to effectively employ user requirements elicitation and prioritization methods by involving different stakeholder groups to inform the design process of medical devices.

This dissertation makes several contributions to the interdisciplinary field of design engineering. First, it provides an understanding about diverse stakeholders' perceptions of task shifting medical devices. Second, it identifies the most important requirements needed to develop a task shifting medical device, with results applicable to easy to use mechanical medical devices

as well. Third, it evaluates qualitative and quantitative user requirements elicitation and prioritization methods, and presents a methodology that indirectly identifies the highest priority user requirement categories. Fourth, it develops a culturally acceptable and appropriate device, based on design ethnography methods, to make TMC safer.

This work contributes to the user-centered design literature by investigating methods and approaches for involving stakeholders as co-designers during the early phases of the design process. Ease of use is a subjective user requirement that may carry different meanings for different stakeholder groups and/or individuals. The establishment of a well-defined list of requirements for task shifting medical devices is beneficial to designers, as well as health providers, public health experts, and policy makers responsible for setting up and developing the requisite systems, programs, and products.

Depending upon the setting and available resources, "usability" and "ease of use" can have different meanings. In high-resource settings, for example, usability in the context of medical devices often is the attributes identified by stakeholders that make a device safe for its users, reduce device recall, result in patient satisfaction [7,8]. Although in low-resource settings, usability in the same context has not been as well defined, this study found that the meaning broadened to include attributes such as peer-to-peer training, and local maintainability and reparability with local materials.

This dissertation focused on the attributes of task shifting medical devices and the perceived roles of task shifting medical devices. In other words, this work was design centric, and therefore one might assume that the creation of new task shifting medical devices drives the creation of complementary task shifting clinical procedures. However, the creation of new task shifting clinical procedures may also drive the creation of complementary task shifting medical devices. Also, designers need to consider the extent to which the clinical procedure should be shared, or in the extreme case, shifted to a healthcare provided with less training. In the case of the procedure driving the design of the device, the complexity of the device may depend on the extent to which the clinical procedure is shared/shifted. Likewise, complexity may be inversely correlated with ease of use; as the complexity of the device increases (perhaps to accommodate a complex procedure that is being shifted), the ease of use may decrease. The design should take into consideration contextual factors, such as local culture, urgency of need, available resources, and health providers' prior training and education levels.

The lessons learned from designing task shifting devices for use in low-resource settings may also extend to high-resource settings. For decades, the perception has been that innovation flows from high-resource or high-tech environments to low-resource settings [9]. However, reverse innovation processes also occur. For example, a pocket-sized ultrasound originally designed for use in rural India, has been adopted by clinicians in Europe and North America [10]. It is also plausible that, depending on the medical condition, patients (users) in high-income countries (HICs) may directly benefit from task shifting medical devices designed to support healthcare delivery in low-income countries. Given the increase in life expectancy in HICs, devices designed for use by individuals with minimal healthcare training in low-income countries may support the development of telerehabilitation (i.e., home-based use of devices by patients) in HICs.

This work empirically presented the value of engaging with different stakeholder groups by augmenting traditional quantitative approaches with qualitative approaches to elicit user requirements. The suggested order for applying the various requirements elicitation methods described in chapters four and six should aid novice designers and engineering design students with limited knowledge about the broader context of the design problem. For instance, the requirements gathered to develop the TMC device would have been impossible to obtain without multiple engagements with the Ugandan stakeholders.

Development of design ethnography techniques is useful in informing early phases of engineering design process. Design ethnography is especially critical when designing for low-resource settings, where financial, social, and cultural constraints impose challenges on designers trying to develop affordable, accessible, and culturally appropriate devices. The overall findings demonstrate the value of an iterative, systematic, design ethnography focused process that actively engages stakeholders to confirm needs and establish user requirements. Based on the methodologies used during this research and subsequent learnings, the following steps are suggested for eliciting user requirements for medical device design in low resource settings:

- Step 1: Perform literature reviews and generate a list of initial user requirements based on proxy stakeholders if you don't have access to appropriate stakeholders (i.e., context-specific stakeholders).
- Step 2: Generate preliminary concepts based on initial requirements for future use in fieldwork-based protocols with the appropriate stakeholders.

- Step 3: Use open-ended interviews and focus group discussions with appropriate and diverse stakeholders to understand the broader context of the design problem.
- Step 4: Identify key thought leaders within each appropriate stakeholder group.
- Step 5: Use semi-structured interviews and focus group discussions with physical protocols to inform additional user requirements elicitation methods and to promote a co-creative design process. Ideally, the physical prototypes should be introduced after an attempt is made to elicit requirements in a more general manner. Multiple prototypes are recommended to avoid fixation on particular device features and to prompt conversations that compare pros and cons.
- Step 6: Identify downstream factors that may affect implementation and incorporate findings into user requirements.
- Step 7: Modify user requirements to incorporate fieldwork outcomes and generate new concepts.
- Step 8: Iterate steps 5-7.

The recommended steps can be performed over several weeks for a novice designer and over a shorter period of time for an expert. Regardless of a designer's level of expertise, the steps are especially applicable for low-resource settings, where financial, social, and cultural constraints impose unique challenges. More important, process is superior to collecting data by working only within a laboratory or research facility setting. The steps allow a design engineer to directly and easily communicate with appropriate and targeted stakeholders in an expeditious fashion, identify their major categories of requirements, and then break them into measurable, objective sub-requirements as explained in chapters three, four, and six.

This work adds to ongoing efforts to develop medical devices in conjunction with intellectual and financial investments by international foundations, academic, and non-profit organizations, such as the Programs in Appropriate Technology in Health, and accelerate design, development and commercialization for low income countries (LIC) [11-13]. The medical device industry may also benefit from this work given that two-thirds of the world's population resides in developing settings, and medical device design to date has focused primarily on high-income settings. Also lessons learned from developing innovative low-cost health technologies devices for LICs may be appropriate and relevant for HICs [3].

7.3. Thirteen lessons learned from the field

During the past five years of fieldwork in Ethiopia, Ghana, and Uganda, studying the engineering design process of medical devices for low-resource settings, and collaborating with the World Health Organization's Medical Devices Unit, I have learned the following 13 lessons [14-18]. I believe these lessons could be useful for designers that aim to employ design ethnography as part of their design approach and to inform engineering design pedagogy.

1. Broader context: Consider the broader context of the design problem. Designing for low-resource settings is not only about developing low-cost devices. Good design considers factors that form broader contexts, such as end-users' previous training, available local resources, and cultural and social constraints that would also impact the eventual adoption and acceptance of the product. These can assist designers to understand what potential factors impact a device's adoption and acceptance by stakeholders.

2. Mission statement: Have clear, well-articulated mission and introduction statements when entering a new community, and engaging with stakeholders. Do not assume that that everyone knows the role of an engineer and/or engineering designer. Many times after introducing myself as an engineering designer interested in learning about a given health challenge, I was asked to fix equipment or devices I knew nothing about. I discovered that having introductory statements helped both with achieving my objectives and managing the stakeholders' expectations.

3. Interview skills: Apply the following four techniques to improve the quality of stakeholder interviews:
    i. Communicate clearly, whether by repeating the questions in different forms or speaking slowly
    ii. Do not ask complex questions
    iii. Do not assume any prior knowledge about the question being asked
    iv. Do not interrupt or try to finish the response for the stakeholder, because it can lead to biases and sometimes wrong outcomes [19,20].

4. Managing expectations: Actively manage stakeholder and personal expectations. The host community or local stakeholders might expect a design team to deliver a functional and validated medical device, especially if the designer did not explain the mission and expected outcomes of the fieldwork beforehand. For instance, ethnic leaders in Uganda might have expected a fully functional device in my second trip, if the goals and objectives of the fieldwork were not clearly communicated. I used to believe that my educational environment and skills equipped me with the ability to develop technological solutions for all challenges, including those arising in low-resource settings. Of course, after my first fieldwork experience, I realized this was not the case. Hence, I learned that exercising humility and patience are essential in conducting fieldwork. Either when I conducted fieldwork by myself, or when I was part of a research team, I learned the importance of managing my own expectations and my peers' expectations, well before entering the field.

5. Design ethnography: Employ the following steps for a effective design ethnography practice.
    i. Prepare fieldwork plans and study protocols well in advance to fieldwork (at least 45 days). Circulate the plan among team members, advisors, and local hosts to obtain feedback. Create protocols that will generate data that can contribute to generalizable knowledge. In many cases, the data generated during the interviews and focus group discussions concerning the broader context of design will be in and of itself a contribution to the field and publishable.
    ii. Obtain appropriate Institutional Review Board approvals.
    iii. Be flexible when planning the logistical aspects of the fieldwork. Plan on spending the first several days at the fieldsite to make initial connections and logistical arrangements.
    iv. Identify the gatekeepers, the community leaders or locals with intimate local and design problem specific knowledge. Seek introductions to community and stakeholder gatekeepers by individuals that are familiar to both parties.
    v. Identify the champions, or collaborators, within the stakeholder groups, such as public health officials, health care providers, biomedical engineers and technicians, non-governmental organization staff, government administrators, patient population representatives, etc.

vi. Identify a reliable translator, who is knowledgeable about the local context. The designer should familiarize the translator with the design topic.

vii. Prepare a concise, specific mission statement to help communicate the goals of the fieldwork and overall project to gatekeepers and stakeholders. The statement clarifies the expected outcomes and manages expectations of study team members and stakeholders.

viii. Ask follow-up "why-based" questions during the fieldwork (interviews, focus group discussions, observations) to uncover more detailed information about the context [21].

ix. Incentivize the participants and local partners to express input by providing them with a small token of appreciation and make efforts to help them feel more connected with the process.

x. End interviews and focus group discussions with requests for introductions to or contact information for individuals and organizations that might provide feedback or input about the design.

6. Improvise: Be able to think on your feet and be flexible. I used to follow a strict plan of action when I was in an unfamiliar setting or designing for an unknown context. However, my attitude changed after completing several fieldwork experiences. Many different factors can affect the plan and agenda. I have learned the importance of improvising a plan and using critical thinking and creative problem solving skills.

7. Continuous communication: Maintain consistent contact with stakeholders. Another lesson learned is the value of openness and continuous engagement with the target community, the end-users, and stakeholders. Stakeholders, including non-governmental organizations, government officials, physicians, and patients can provide critical feedback and support during the implementation and adoption phases of the process. Hence, communications with local stakeholders about the status of the project is extremely valuable. As shown by the TMC device design process, respectful collaboration with stakeholders, some of whom would not be considered experts based on (developed world) standards or prejudice, elicited feedback and input otherwise unavailable in a laboratory setting.

8. Local peers: Engage local peers throughout the design process, especially in its early phases. Local peers such as engineering students, also benefit by feeling "ownership" and involvement in a device that could have positive impact on the health of local populations.

9. Co-designers: When possible, return to the host communities, because they are your co-designers. For example, some of the host communities in Uganda and the physicians in Ghana never believed me when I told them I would return and continue to work on a design. After I returned, they were much more interested in the design task, and believed in the value of their involvement throughout the design process.

10. Implications: Articulate and communicate clearly the implications and benefits of the fieldwork and overall project. The expected outcomes should be made clear to all stakeholders, whether they are a participant in a focus group or a local peer involved in the design process.

11. Local etiquette: Be aware of local etiquette. A design engineer should have a general understanding of factors that are considered cultural norms or those that might be considered insulting. Consideration of local culture and behavioral etiquette is fundamental to successful fieldwork and effective engagement with stakeholders. Regardless of the objectives, this applies to foreigners arriving in Uganda to learn about traditional male circumcision or domestics entering an obstetric ward in an American hospital.

12. Physical prototypes: Use prototypes during the requirements elicitation process. It is usually frustrating, both for designer and the stakeholder, to discuss the need or requirements for a hypothetical product [22]. Another main learning from the field is the value of having multiple (2-4) physical prototypes or mock-ups to show in order to facilitate discussions that elicit information about user requirements. Visiting the local market to identify, and potentially purchase, available materials for building simple mock-ups is also valuable. Be aware, though that there is a fine balance between biasing the stakeholders with a specific object versus promoting open-ended discussions.

13. Record keeping: Keep detailed records and maintain a running list of contacts throughout the fieldwork [23]. Also, back up the data from the fieldwork in case of unpredicted events.

7.4. Future work

Chapter three was based on the input and perceptions of selected stakeholders who responded to an online survey, but semi-structured interviews can also obtain more details about perceptions and needs. The latter method could be supplemented with a mathematical model to measure a stakeholder's preference when choosing between device prototypes with different task shifting characteristics.

Chapter four could be extended to include an analytical conceptual framework for a systematic user requirements elicitation methodology. This framework, incorporating the data of the three evaluated elicitation and prioritization methods and the design ethnography techniques, could expedite the requirements capturing process and assist with the accurate translation of the requirements to quantitative engineering specifications. The framework could be developed to accommodate designers' different levels of experience and knowledge about the design task.

The author plans to investigate the potential tradeoffs between developing task shifting medical devices to enable health providers to perform a task versus training them to perform it without the device. While the necessity for task shifting always must be confirmed on a case-by-case basis, it is important to understand at what point it is reasonable to spend time and financial resources to shift a task via adoption of a device versus additional training of the user.

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Appendix – Clinical trial report: Penile anthropometric data collection and fit and placement evaluation of the traditional male circumcision tool

A clinical trial at the Rakai Health Sciences Program's facility evaluated fit and placement of the traditional male circumcision (TMC) tool (chapter 6). Additional anthropometric data were gathered, and quantitative objectives including penile circumference, glans diameter, linear distance along the dorsal side of the penis, and time required for tool application and removal were measured.

The trial was performed at the Rakai Health Sciences Program in Kalisizo in March and April 2014. Men with congenital or acquired genital abnormalities were excluded. Each participant was reimbursed 5,000 Ugandan shillings (about US $2.00) for his time and 12,500 Ugandan shillings (about US $5.00) for transportation. The fees were set based on national standards determined for similar clinical trials in Uganda. Table A.1 lists the demographic information of the participants.

Table A.1: Participants' demographics

Number of participants and age range	103 participants 12–34 years (mean: 20.9, stdev: 4.9)				12-17 years: 16 participants 18+ years: 87 participants			
Represented ethnic groups (number of participants)	Madi (1), Mufumbira (6), Muganda (38), Mukiga (11), Munyankole (41), Munyarwand (4), Muteso (1), Muziba (1)							
General physical evaluation								
	Weight (kg)				Height (cm)			
Age range	Min	Max	Mean	SD	Min	Max	Mean	SD
12 – 17	34.0	65.0	46.5	8.1	142.0	177.0	158.0	9.8
18+	41.0	71.0	56.5	6.4	150.0	195	170.5	46.9
Total (all ages combined)	34.0	71.0	54.9	7.6	142.0	195.0	168.5	43.4

The anthropometric measurements and tool-related evaluations were performed by physicians and trained medical officers with experience in clinical male circumcision. They attended a one-day training and orientation on data collection methods.

The study was reviewed and approved by the Institutional Review Board of Uganda's National Council of Science and Technology, Uganda Virus Research Institute, and the

University of Michigan, USA. All clinical study team members received training in the ethical conduct of human subjects' research. The participants were fully informed about the nature of the study prior to each data collection session and were asked for their written consent. A parent or guardian of participants younger than 18 years of age had to provide written consent prior to the start of the data collection. Participants could leave at any time; however, none opted to leave prior to the completion of the data collection. No form of identifier was collected from the participants.

A customized plastic measuring tape was used to measure length and circumference of the penile glans (Fig. A.1a). The tape was identical to one used to evaluate the safety and efficacy of a clinical circumcision device in a previous trial [14]. A plastic template with 15 cm diameter and 0.5 cm thickness with seven varying diameter holes was used to measure the diameter of the glans (Fig. A.1b). The templates were fabricated at the University of Michigan's Medical Innovation Center's prototyping facility on an Objet Connex500 3D printer using VeroWhite, a white, ABS-like resin.

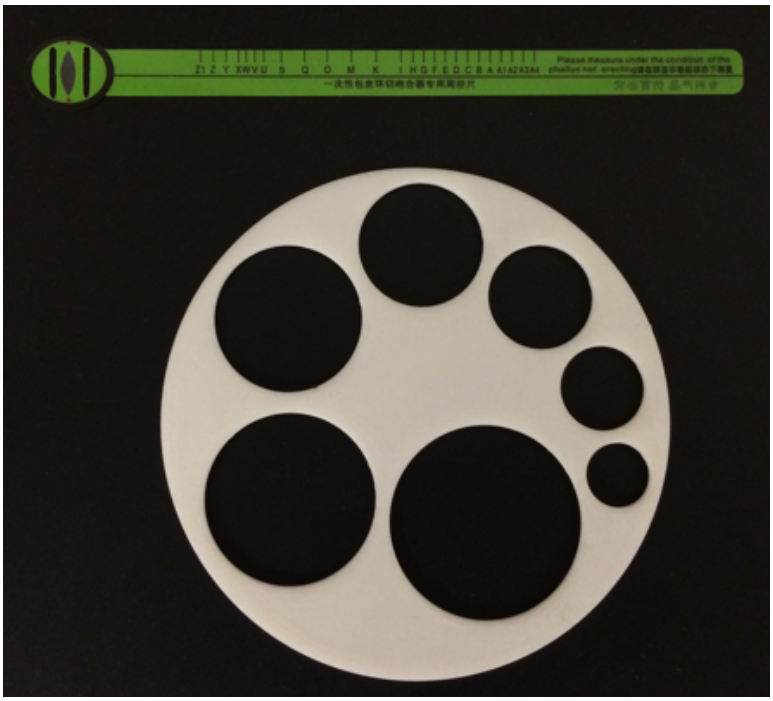

Figure A.1a (top): Measuring tape; Figure A.1b (below): Circumference template

The hard, curved shells of the final tools were fabricated at the Medical Innovation Center in three small (opening diameter: 2.5 cm), medium (opening diameter: 2.8 cm), and large

(opening diameter: 3.2 cm) sizes using a 3D Systems Viper Si2 Stereolithography Apparatus (SLA) with Accura 60, a clear, polycarbonate-like resin. The latex roll part of the tool was made from finger cot latex (Interstate Group Inc., CA, USA). The rolls were available in small (diameter: 1.5 cm), medium (diameter: 1.75 cm), and large (diameter: 2 cm). The tools' sub-parts (hard shell and latex roll) were assembled at the Rakai Health Sciences Program's clinic.

Each trial was performed in a private room. Other than the participant and the study team member, no one was allowed entry, with the exception of the parents or legal guardians of young participants (ages 12 to 17). Room temperature was held constant between 20-25°C. A new measuring tape and template were used for each participant. The larger reading mark was selected when a measurement reading fell between two sizes on the tape. The study team member used a stopwatch to record the time required to apply and remove the tool. At the end, the study team member separated the latex part from the hard plastic shell and discarded the parts and examination gloves in a trash bag marked as medical waste.

After the consent process, the study team member recorded the participant's age, height, and weight. The penile glans was cleaned with an alcohol swab and the following measurements and tool-related feedback were recorded (note: units in cm):

1. Glans length from tip to corona sulcus at normal state.
2. Penile circumference at penile shaft when foreskin was retracted.
3. Linear distance along the dorsal side of the penis extending from tip of glans to coronal sulcus during flaccid and fully stretched modes.
4. Glans diameter based on the best fit with and without foreskin in the measurement template; the glans was inserted into the hole having the least resistance so that the template stayed on the glans without external help and discomfort.
5. Shape (dome- or bullet-shape) of glans.

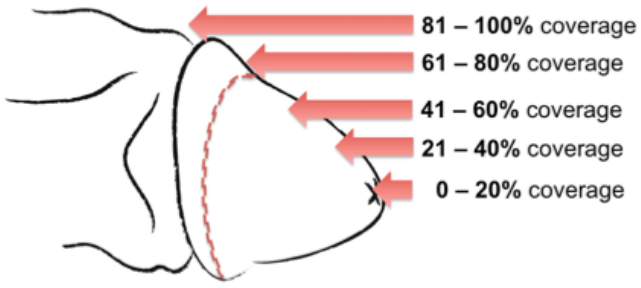

Figure A.2: Amount of coverage provided by the tool

6. TMC tool size selection: small (diameter < 2.5 cm), medium (2.5 cm < diameter < 3.25 cm), and large (diameter > 3.25 cm).

7. Time (in sec) needed to roll the latex sleeve up to the back of the penile corona sulcus after applying the tool over the glans.
8. Amount of coverage provided for the glans by the tool shell (%) using the visual aid example (Fig. A.2).
9. Linear distance across the dorsal side not covered by the tool shell.
10. Amount of foreskin pulled over from corona sulcus, i.e., the amount of foreskin that would be removed during TMC cutting.
11. Time (in sec) needed to remove the tool.

Study team members also recorded comments by participants about application and removal and their observations about the tool's design.

The mean, median, and standard deviations for continuous variables and the frequency and percent for categorical variables were calculated. Participants' ages, heights, and weights were examined for correlations with penile measurements. Originally, the results were analyzed by age category (12 to 17 years; 18 years and above), but the final analysis included all ages because there was no significant difference across age groups. Statistical analysis was performed with SPSS, V20 (IBM Corp, Armonk, USA).

Trial's outcomes

The clinical trial collected anthropometric data, validated coverage of the glans by the final tool, and assessed its fit and placement. A total of 103 males (ages 12 to 34 including 16 participants between ages 12 and 17) from eight ethnic groups across Uganda participated (Table A.1). The final analysis included all ages because there was no significant difference across age groups. The team measured glans length, penile circumference, dorsal side measurements, glans diameter fit (at coronal sulcus) in the measurement template, glans shape, tool size, tool application and removal times, level of coverage provided by the tool, glans uncovered distance, and amount of foreskin pulled over glans when the tool was applied (Table A.2). Small and medium tool sizes were used for 93 percent of the participants. Also, it was found that the general shape of the penile glans was more dome shaped, rather than having a bullet-like profile.

The trial's outcomes indicate that applying and removing the tool took about 5 seconds, a significant improvement compared to the study team's prior design concepts. Therefore, this design addresses the need for a tool that accommodates a fast cut. In addition, the study team

members input regarding the tool's ease of application was collected. In 99 percent of the cases, the study team member "strongly agreed" or "agreed" with the statement: "I was able to easily apply the tool over the glans easily." In 90 percent of the cases, the study team member "strongly agreed" or "agreed" with the statement: "I was able to fully roll the foreskin over the glans." In 98 percent of the cases, study team members agreed that the participants did not need help applying the tool over the glans. In 97 percent of the cases, study team members "strongly agreed" or "agreed" with the statement, "It was easy to remove the tool." In 95 percent of the cases, study team members "strongly agreed" or "agreed" with the statement, "The tool stayed over the glans without losing its grip while the foreskin was pulled over it."

When participants were asked about the level of pain when the tool was applied over their penis, 79 percent reported no pain, while 17 percent reported a minimal to mild pain. The new tool provided more than 60 percent coverage for more than 95 percent of the participants, and more than 80 percent coverage for 70 percent of the participants.

Over 67 percent of respondents were fully satisfied with the current design. The remaining respondents mentioned two issues: shell design and potential inclusion of lubricant to apply the tool. In five cases team members expressed the need for a smaller size tool to accommodate extra-small size penile glans. In 18 cases the study team members noted that using a narrower curvature for the shape of the tool's shell would improve conformance around the glans. In five cases, the study team members mentioned that lubricated latex would assist with easier application of the tool over glans.

Table A.2: Penile anthropometric and final design related measurements

Measurement Category	**Outcome**		
Glans length – from glans tip to corona sulcus	Mean: 3.1 cm; SD: 0.3 cm		
Penile circumference at penile shaft	Mean: 8.8 cm; SD: 0.4 cm		
Linear distance-dorsal side (flaccid mode)	Mean: 2.9 cm; SD: 0.3 cm		
Linear distance-dorsal side (stretched mode)	Mean: 3.4 cm; SD: 0.4 cm		
Glans diameter with foreskin (based on template fit)	**Hole # (diameter)**	**Number of participants**	**Percent**
	1 (1 cm)	1	1.0%
	2 (1.75 cm)	3	2.9%
	3 (3.25 cm)	40	38.8%
	4 (4.0 cm)	53	51.5%
	5 (4.75 cm)	6	5.8%
Glans diameter without foreskin (based on template fit)	**Hole # (diameter)**	**Number of participants**	**Percent**
	1 (1 cm)	1	1.0%
	2 (1.75 cm)	3	2.9%
	3 (3.25 cm)	44	42.7%
	4 (4.0 cm)	50	48.5%
	5 (4.75 cm)	5	4.58%
Glans shape	**Glans shape**	**Number of participants**	**Percent**
	1 (Dome shape)	82	79.6%
	2 (Bullet shape)	21	20.4%
Tool size (small, medium, large)	**Size**	**Number of participants**	**Percent**
	Small	47	45.6%
	Medium	49	47.6%
	Large	7	6.8%
Time to apply the tool	Mean: 5.9 sec; SD: 0.3 sec		
Level of coverage tool provided (%)	**Coverage (%)**	**Number of participants**	**Percent**
	41-60%	4	3.8%
	61-80%	29	28.2%
	81-100%	70	68%
Distance of the dorsal side uncovered by the tool	Total – Mean: 0.4 cm; SD: 0.04 cm		
Amount of foreskin pulled over the tool	Mean: 3.9 cm; SD: 0.4 cm		
Time to remove the tool (sec)	Mean: 5.3 sec; SD: 0.3 sec		