

## DESIGN ETHNOGRAPHY AS AN ENGINEERING TOOL

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Currently the design, development, and implementation of medical devices insufficiently address health care needs in low-resource settings. Most existing medical devices are simple adaptations of devices designed for high-resource settings. However, the spectrum of needs in low-resource settings is often beyond the scope of such simple adaptations, resulting in products with limited impact.

To develop medical devices that address the complex challenges of global health, we have studied how conventional engineering design processes can be supplemented by methods derived from social science fields such as anthropology. Design ethnography, which encompasses processes for gaining a complete understanding of stakeholders' actions, behaviors, words, and thoughts, provides a framework for acquiring tacit information from stakeholders that would not be obtained through commonly used methodologies in engineering design and market research. Although this technique is applicable to a broad range of global health technologies, we chose to highlight its application to traditional adult male circumcision given the unique design context and constraints. This study, among others performed to date, indicates the need for engineers to understand the broader context in which a medical device will be used, as well as the need for global health design decision-making processes based on rigorous studies that generate quantitative outcomes rather than anecdotal evidence.

Male circumcision is a culturally significant procedure in many parts of the world. For instance, traditional adult male circumcision (TMC) is an important cultural practice in parts of sub-Saharan Africa, and a rite of passage for boys between the ages of 10 and 18.

Recently, several randomized clinical trials have shown that clinical adult male circumcision is an effective medical intervention for the prevention of sexually transmitted HIV, reducing the rate of transmission by 60 percent among heterosexual men [2, 3, 4]. This is an important result for sub-Saharan Africa, where more than two-thirds of the 22.5 million people in the world living with HIV reside [1].

Traditional adult male circumcision is not without risks. Cutters and their assistants, typically with limited or no formal clinical training, perform TMC in non-clinical settings. While evidence supports TMC's effectiveness against HIV transmission when adequate foreskin is removed, rates of life-threatening risks and health complications for this practice are as high as 48 percent [5]. Infection, delayed wound healing, glans amputation and injury, bleeding, loss of penile sensitivity, excessive removal of foreskin, and even death are the major complications reported [6].

There are medical devices that accommodate clinical adult male circumcision (AMC), but none of them are suitable for TMC due

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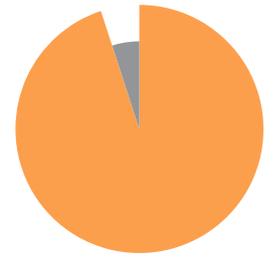
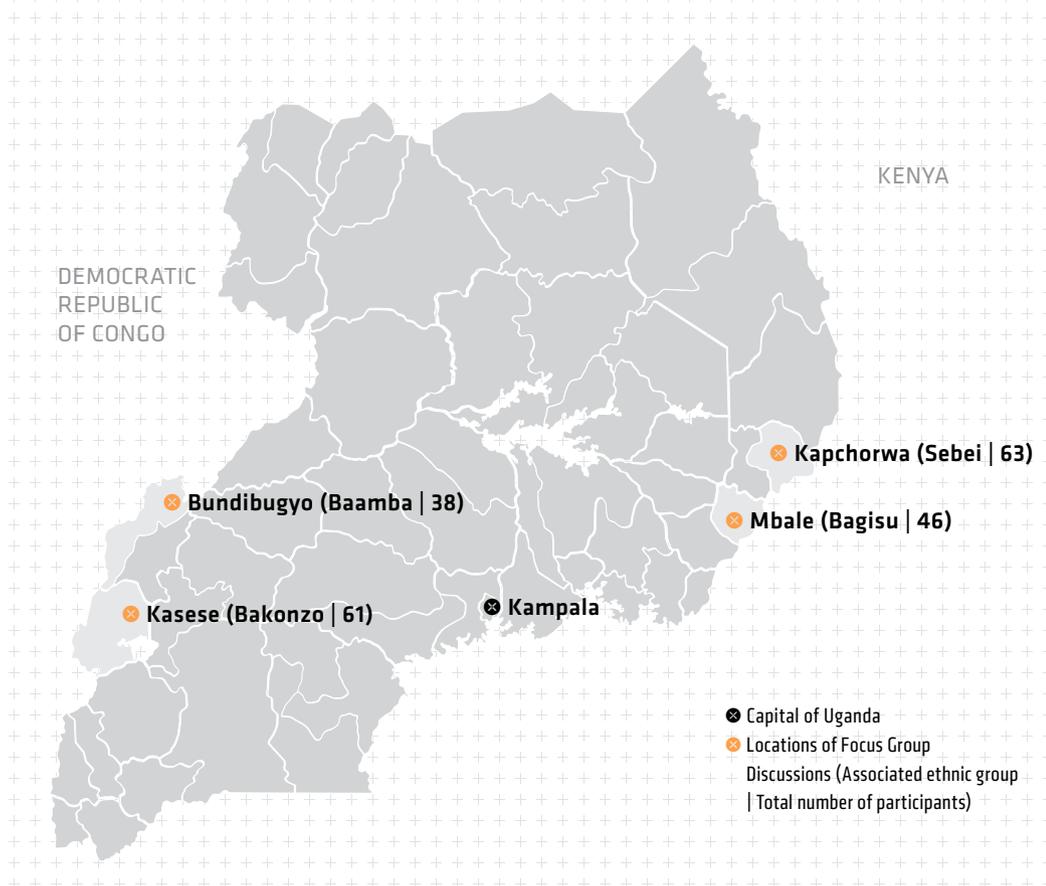


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UGANDA



## UGANDA

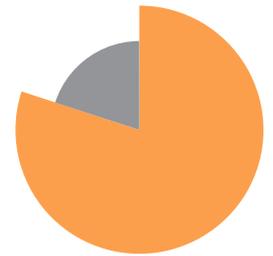


**95%**

APPROXIMATELY 95% of medical devices used in low- and middle-income settings are imported.

**40% - 70%**

OF IMPORTED DEVICES are dysfunctional (Howitt, 2012).



**80%**

MORE THAN 80% of health technologies in developing settings are acquired by donation.



**25,000,000**

HIV/AIDS HAS TAKEN OVER 25 MILLION LIVES IN THE LAST THREE DECADES and remains a major health challenge throughout the world, especially in sub-Saharan Africa, where about 68% of global HIV infection cases (22.5 million) reside.



**68%**  
22.5 MILLION

The African context: HIV/AIDS rates, medical devices and region of investigation

to their cultural inappropriateness, high cost, and complexity.

Based on a conversation with Family Health International 360's (FHI 360) Dr. David Sokal, with whom we partnered on this project, we raised the following questions: Was there a need for a culturally appropriate device to improve the likelihood of a safe outcome during traditional adult male circumcision? If a solution was

identified, would it be accepted? What is the process associated with designing such a device, given that we have no firsthand experience with the procedure or context?

Since funding wasn't initially available to tackle these questions through field-based studies, the project was offered to a team of undergraduate students within a section of the University of Michigan's Department of Mechanical Engineering Capstone Design

and Manufacturing course during the Winter 2009 semester. The students assigned to the unusual project—the course had never seen the likes of such a topic before—began work in a similar way to other academic design projects. They consulted the literature and interviewed clinical experts. We were surprised at the lack of data on traditional circumcision practice, which made the design of such a device extremely challenging. By

the end of the course, the students had generated a preliminary list of user requirements and associated engineering specifications, a concept solution and physical prototype, and preliminary validation results that enabled us to apply for external funding.

After applying for funding and receiving a Gates Grand Challenges Explorations Grant, we formed a multidisciplinary team that included engineers, clinicians, sociologists, and public health and business experts to further pursue the design. The funding enabled additional engineering analyses on the original prototype developed by the student design team, including fit and grip studies performed on cadavers at the University of Michigan's Anatomical Lab. Qualitative and quantitative measures were used in cadaver studies to assess the time required to apply and remove the device, the ease of application, the degree of glans protection, and the length of foreskin cut.

Most importantly, to gain much needed insight, we conducted fieldwork in Uganda, because of the country's multiple ethnic groups known to practice TMC, and because FHI 360 had a field office there with established relationships with the ethnic groups. In Uganda, as in many other sub-Saharan African countries, TMC has been practiced for centuries, particularly as an initiation ritual and rite of passage into manhood. Uganda's HIV prevalence rate is 6.5 percent, and approximately 10 percent (3.5 million) of the population belongs to ethnic groups that practice TMC [7].

### DESIGN ETHNOGRAPHY AS A GUIDING COMPASS

The prototype for the first functional TMC device satisfied the initial requirements established during the design course [8]. We had, however, many reservations regarding the validity of the device, given that there were no publicly available data detailing TMC practices in sub-Saharan Africa at the time. We also had no sense for local perceptions of such a device. Would anyone consider using it? Could it possibly be adopted into the practices of any of the ethnic groups?

Design ethnography provides a framework for acquiring tacit information from stakeholders, which would not be obtained through commonly used methodologies in engineering design and market research.

It was obvious that stakeholder input was required to establish the need for such an intervention and to generate the data necessary for informing key design decisions. With the input of social scientists skilled in qualitative research, we used principles of design ethnography that focus on the broad patterns of daily life that pertain to the conception, development, and implementation of new products in a given society. Design ethnography, which encompasses processes for gaining a complete understanding of stakeholders' actions, behaviors, words, and thoughts, provides a framework for acquiring tacit information from stakeholders that would not be obtained through commonly used methodologies in engineering design and market research [9].

We traveled to Uganda in 2010 to learn about the cultural implications of TMC and generate data needed to refine and justify our design decisions [11]. Together with FHI 360, we identified major stakeholders and planned for semi-structured focus group discussions (FGD) and interviews. We also planned for direct observation of TMC and contextual inquiry about the practice.

Stakeholders that we engaged with at this stage of the project included clan and cultural leaders, traditional cutters, assistant cutters, public health officials, and

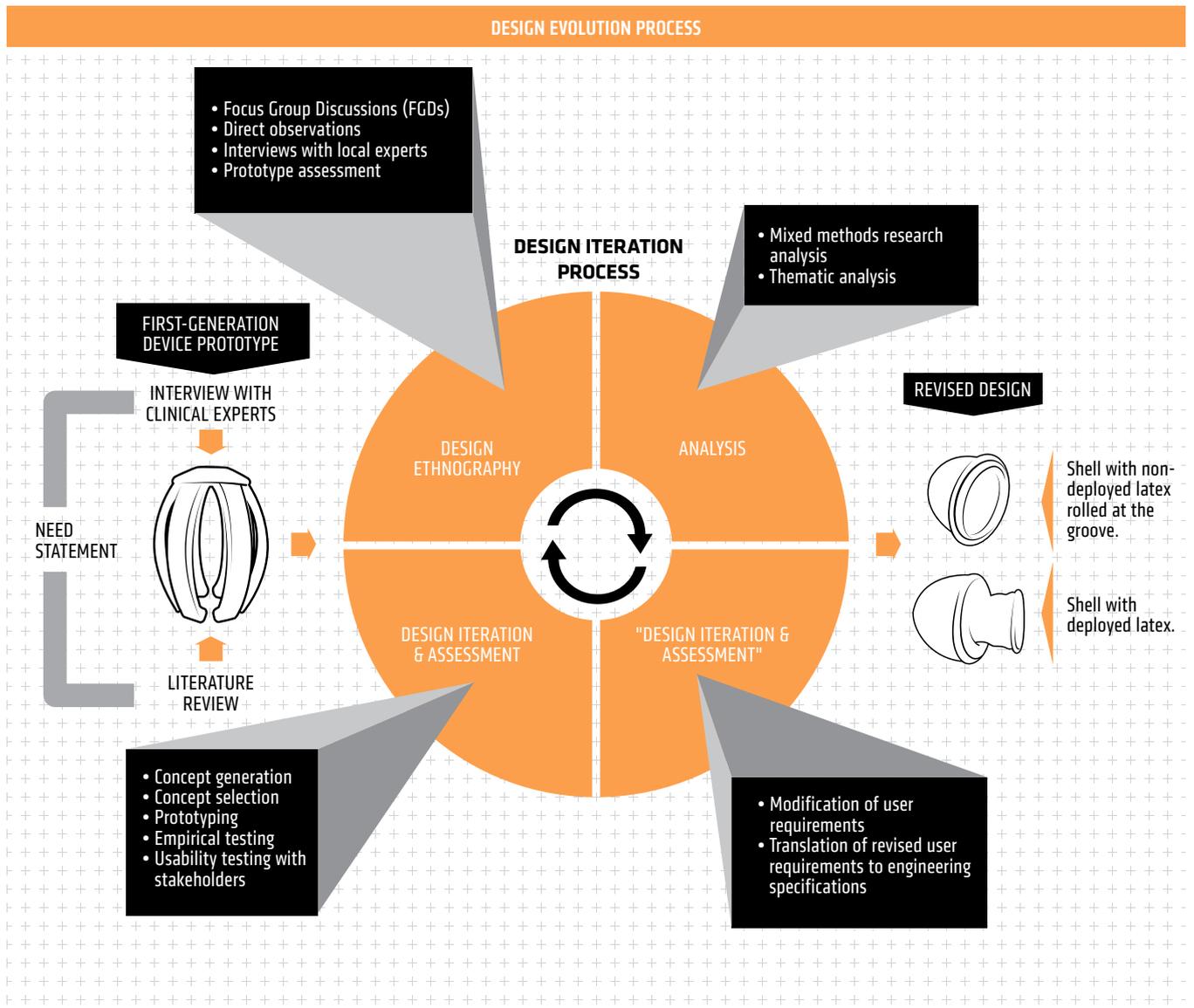
staff of international and national organizations promoting and implementing clinical male circumcision.

We conducted 10 interviews with various experts during this initial visit, and held 12 FGDs with about 100 participants with the four ethnic groups that practice TMC in Uganda—the Sebei, Bagisu, Baamba, and Bakonzo. While the circumcision rate in Baamba and Bakonzo men is unknown, it is estimated that 80 percent of Sebei and Bagisu men are circumcised.

Each FGD consisted of 6 to 12 participants and was run by trained American and Ugandan study team members, who remained the same across the focus groups, with the assistance of translators, who varied. Predetermined themes, such as TMC's cultural importance, logistics of the practice, cutters' training procedures, and tools used during TMC were selected prior to holding the FGDs.

The FGDs were recorded, and we transcribed all the files verbatim and cross-checked the transcription results with research assistants to ensure accuracy. Transcripts were reviewed, and reoccurring themes based on the five topics were identified to develop a codebook. After an in-depth review of the transcriptions and cross-analyses of the four ethnic groups and different participants, additional codes were derived for further characterization. Hence our 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.

The focus group participants agreed that TMC is a major milestone in the process of becoming a man among the different ethnic groups. It is a traditional part of the cultural belief system to such an extent that those who are not circumcised traditionally are strongly stigmatized within their communities. Participants in all of the FGDs and medical doctors identified the most common TMC adverse events: excessive bleeding, prolonged wound healing, infection,



glans injury and amputation, and unfinished cuts requiring additional cuts.

In order to design a device that could accommodate all the ethnic groups practicing TMC, we needed to understand their cutting styles. While there is no single style practiced among the four groups, the majority of cutters in the Sebei and Bagisu groups share a similar method. A candidate for circumcision is called to the center of the area designated for the ceremony. The boy 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 as hard as possible 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 through a radial cut using the same knife.

Cutters do not dress the wound with any medical supplies, but use herbs, clay and other products.

There have been some important recent changes and modifications to the TMC practices. Most significantly, while custom, ritual and cutting methods vary by ethnic group, the Uganda Ministry of Health mandated the use of one traditional knife or razor blade per candidate during circumcision. The change was implemented in early 2000 across all ethnic groups. Eastern groups still use a traditional

knife while the Baamba and Bakonzo groups use razor blades.

At the end of each FGD, we showed the participants the original TMC design to stimulate discussion among the stakeholders. Three out of four ethnic groups expressed without hesitation that they would be willing to use the device as soon as it is provided to them. They did, however, provide numerous suggestions to improve the design's form and function.

#### DESIGN INFORMED BY ETHNOGRAPHIC RESEARCH

Based on the data gathered during our first visit to Uganda, we revised the original list of user requirements and engineering specifications as well as their associated ranks. Three particular user requirements and associated engineering specifications are worth highlighting:

**> Fast Cut:** Traditional cutters and ethnic leaders unanimously expressed their desire for a quick procedure. They emphasized that cutting should not last more than 10 seconds. Reducing the cutting time requirement from the original time suggested by clinical experts consulted (three minutes) to less than 10 seconds had significant implications during the design iteration.

**> Safe Cut:** We knew that our device must protect the head of the glans against the circumcision cut. However, our "safe cut" specification was informed by the guidelines developed by the World Health Organization for clinical male circumcision, which specify only partial coverage of the glans since the foreskin cutting technique suggested by WHO is not consistent with the "guillotine cut" used in cultural procedures. However, after meetings with stakeholders, we realized that the device must cover the penile glans fully in order to provide complete protection against any cutting style variations.

**> Device Size:** The original concept assumed that a one-size-fits-all solution would be desirable. This made intuitive sense and was supported by clinical experts and available literature. However, when

ORIGINAL REQUIREMENTS	ORIGINAL ENGINEERING SPECIFICATIONS	REVISED USER REQUIREMENTS	REVISED ENGINEERING SPECIFICATIONS
1. Fast cut	120 sec	1. Fast cut	Cutting time < 10 sec
2. No. of procedural steps	10	2. Safe cut	Full (100%) glans protection
3. No. of parts	3	3. Strong grip	No displacement while cutting
4. Adjustable diameter	15-41 mm	4. Low cost	Final cost < \$1.00
5. Glans coverage	50%	5. Three sizes	Small (2.5 cm), Medium (3.0 cm), Large (3.5 cm)

Original and revised lists of user requirements and engineering specifications

we presented the original concept to the stakeholders in Uganda, they unanimously expressed that they'd prefer three sizes for the device. They mentioned that this is how they were accustomed to purchasing items such as t-shirts, and that it didn't make sense to them that one device could fit the perceived range of penile sizes. This is a good illustration of the fact that a low-cost, effective device will not always be embraced by its target community. There are cultural norms that will impact the adoption and implementation of such devices.

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Based on feedback from Ugandan ethnic groups, public health officials, and medical practitioners, as well as our cadaver testing results, we generated over 20 additional device concepts. We then fabricated prototypes of the top five concepts and performed additional experimental tests on

cadavers to evaluate each prototype against the revised engineering specifications.

We selected a second-generation prototype composed of two parts: a strong solid shell that provides complete protection of the glans against the cut, and a latex sleeve that covers the shell and anchors the device to the glans (see illustration).[11] The non-deployed latex sleeve, resembling a condom in its material, shape, and usability, rolls up so that it sits on top of a groove at the end of the shell. After the shell is placed over the glans, the foreskin is retracted and the latex sleeve is deployed by rolling it 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 pulled over the shell. Also, latex provides an auto-disable-like feature for the device; as it is removed from the device by the cut, the reuse of the device would be difficult.

To increase functionality, a medical-grade elastic band, which can be applied over the foreskin and against the device's groove, helps hold the foreskin in place and provides a visual cue to guide the cutter. The applied compression to the foreskin also minimizes blood loss.

Three shell sizes were designed to accommodate adult glans diameters ranging from the 5th to the 95th percentile. Careful testing on fresh cadavers showed that this revised design provided 100 percent glans coverage during a cut, could be applied and removed in approximately five seconds, and provided excellent grip on the glans.

We returned to Uganda in 2011 with the revised design and met with the same ethnic groups with whom we had originally visited. We held 15 additional FGDs with the same stakeholder groups (the individuals differed) and interviewed over 30 leaders in circumcision policies and practices. These interactions were used to gauge community interest in the revised design among TMC practitioners and establish the extent to which Ministry of Health officials and clinical surgeons supported the design and associated procedure. To evaluate the preferences among stakeholders, we asked FGD participants to compare the original and revised prototype designs using a Likert scale.

We found that 80 percent of cutters and their assistants and 97 percent of clan leaders chose the revised device over our original design for its simplicity, ease of use, and perceived increased protection. When asked if they would use and/or support the revised device if public health officials supported its usage and the TMC cutters were properly trained, 74 percent of cutters and assistant cutters and 88 percent of clan leaders strongly agreed that they would do so.

We are currently conducting a study in Uganda to collect anthropometric data on penile sizes and evaluate the ability of the device to grip the penile glans.

## UNDERSTANDING STAKEHOLDER VIEWPOINTS

The design ethnography techniques we used in our design process provided many

Design ethnography is an enabling methodology that can be used in product design when limited information is available.

critical insights. The techniques were key to establishing and confirming the need, which had a significant cultural load associated with it. They also helped us understand the stakeholders' viewpoints and concerns, and provided data used to generate justifiable user requirements and associated engineering specifications.

Indeed, there were no publicly accessible data available about TMC practices in Uganda and sub-Saharan Africa—at least not specifically detailed data necessary to base design decisions on. Therefore we, as engineers, needed to take the initiative to collect the data. This involved the use of both qualitative and quantitative techniques inspired by tools used by ethnographers.

The data garnered through this work would have been impossible to obtain in a conventional laboratory setting. For example, we learned that while the ethnic group participants had general knowledge about the effectiveness of AMC against HIV transmission, they preferred TMC due to cultural reasons. We found out about the potential role of churches and mosques with respect to the promotion of safe TMC and their religious leaders' interest in supporting the development of an intervention, as well as the recent formation of a “cutters union” among the Bagisu to preserve TMC's cultural

significance. These data were directly used to inform the establishment of stakeholder-driven user requirements.

Our experience demonstrates the value of an iterative, process-focused, design ethnography approach that actively engages stakeholders to confirm needs, drive the establishment of user requirements and engineering specifications based on rigorous studies that generate quantitative outcomes rather than anecdotal evidence, and provide continuous feedback on early stage design iterations. Design ethnography is an enabling methodology that can be used in product design when limited information is available. The methodology is especially useful when designing for low-resource settings, where financial, social, and cultural constraints impose challenges on designers developing affordable, accessible, available, and culturally appropriate devices.

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