

APPLYING DESIGN ETHNOGRAPHY TO PRODUCT EVALUATION: A CASE EXAMPLE OF A MEDICAL DEVICE IN A LOW-RESOURCE SETTING

Mohedas, Ibrahim; Sabet Sarvestani, Amir; Daly, Shanna R.; Sienko, Kathleen H.
University Of Michigan, United States of America

Abstract

The use of design ethnography for the design of human-computer interfaces and computer supported cooperative work systems has become increasingly common both in industry and as a topic of study within the research community. However, as of yet, few studies have been performed where ethnographic techniques have been applied during the design of other products or services. Furthermore, of these studies, even fewer have provided the methodological detail necessary in order to understand how ethnographic techniques and data influenced the design or how these methods may be best implemented. This study sought to address this gap in the literature by using and methodically documenting the use of design ethnography during the design of a medical device (specifically for low- and middle-income countries). Below we detail the methodology used for data collection and analysis as well as present the findings from the ethnographic study and how it informed the revised device design. A discussion on the benefits and challenges of using ethnographic methods in this context is presented and recommendations for developing and implementing design ethnography during medical device design are given.

Keywords: Design ethnography, Biomedical design, Design methods, Requirements, Early design phases

Contact:

Ibrahim Mohedas
University Of Michigan
Mechanical Engineering
United States of America
imohedas@umich.edu

Please cite this paper as:

Surnames, Initials: *Title of paper*. In: Proceedings of the 20th International Conference on Engineering Design (ICED15), Vol. nn: Title of Volume, Milan, Italy, 27.-30.07.2015

1 INTRODUCTION

Successful products are well-adapted to the context and culture in which they will be deployed (Pralhad & Ramaswamy 2004). This requires designers to understand both the stakeholders who will interact with the product and the ultimate environment in which the product will be used. Design ethnography consists of methods that can be used to elicit and synthesize stakeholder and contextual understanding to inform design decisions. These techniques originated in the field of human-computer interaction and computer-supported cooperative work and have been well-studied within these contexts, however, the implementation of design ethnography in other contexts remains understudied. Developing a body of case study literature (where design ethnography is used in diverse contexts) would allow researchers to draw generalizations from cases and provide novice designers with many examples showing how to perform design ethnography. In this paper, we describe a case example where design ethnography was used to evaluate a medical device prototype for use in low-resource settings. The design of medical devices for low-resource settings provides an ideal context for design ethnography use because there are a variety of diverse stakeholders (clinicians, biomedical technicians, government officials, procurement agencies, regulatory agencies) and designers and stakeholders may not share a common culture (Martin et al. 2012; Malkin & Anand 2010). Below we detail the process of employing design ethnography to evaluate a medical device prototype in a low-resource setting, discuss how designers can use the resulting data to inform their device design, and explain the insights gained from this case example.

2 BACKGROUND

Design ethnography techniques evolved from the methodologies developed by anthropologists to understand unfamiliar cultures (Wasson 2000). The tools of design ethnography include observing stakeholders while they interact with products of interest or perform daily activities, interviewing stakeholders about their priorities, experiences, and preferences, observing a product's environment, developing genealogies and social maps, researching demographics, photographing, videotaping and documenting, researching archives, and "deep hanging out" (Salvador et al. 1999; Wax 1986; Werner et al. 1987). These tools are employed to better understand stakeholders' daily lives and preferences, their culture, and the environment where a product will function in order to make well-informed design decisions (Bucciarelli 1988; Salvador et al. 1999).

The first documented use of design ethnography in product development occurred at Xerox Palo Alto Research Center (PARC) during the 1980s, when Xerox PARC hired anthropologists to study how office workers used (and struggled with) copiers (Sanders 2002). Xerox applied the findings to design more usable machine interfaces. Recently, a host of other companies including Microsoft, Intel, and Motorola have begun to employ design ethnography. Today, design ethnography is most used and studied within the fields of human-computer interaction (HCI) and computer-supported cooperative work (CSCW), where studies have developed methods for integrating ethnography more efficiently into design processes (Iqbal et al. 2005; Ball & Ormerod 2000) and have investigated design ethnography's ability to support requirements development (Potts & Hsi 1997). Numerous case examples of the use of design ethnography have also been published within the fields of HCI and CSCW (Sperschneider & Bagger 2003; Diaz 2007). Despite growing interest in design ethnography, relatively few studies have investigated using the method outside the fields of HCI and CSCW.

The importance of stakeholder engagement during design and the potential for design ethnography to be effectively employed in this context have been discussed within the literature (Martin et al. 2006; Privitera & Murray 2009). Literature on the design process for medical devices has described the importance of engaging with stakeholders and properly defining product requirements and engineering specifications (Yock et al. 2015). A study of focus group use during the development of assistive devices for wheelchair users found that this form of stakeholder interaction effectively identified unmet needs (Batavia & Hammer 1990). Similarly, usability studies have allowed for the identification of end-user issues with devices that were only made apparent by observing end-users' interactions with products (Garmer et al. 2004).

As globalization propels companies to develop products for emerging markets, there is increased appreciation for design ethnography as a means of bridging the cultural gap between designers and stakeholders (Kim & Lee 2011). Within a globalized context, design ethnography allows designers to gain a deep understanding of stakeholders and a product's contexts of use even when the designers and

end-users do not share the same culture. Within universities, there has also been an effort to train students to employ design ethnography techniques as design programs targeted to particular end-users/contexts have become more common (e.g., resource-limited design, community-based design, etc.) (Sienko et al. 2014; Mohedas et al. 2014).

As the use of design ethnography becomes more widespread, the contexts in which we seek to employ these techniques are diversifying. While most studies of design ethnography have occurred within the fields of HCI and CSCW, design ethnography shows great potential as a design tool for medical devices and particularly in low-resource settings, and thus warrants additional study.

3 METHODS

The goal of this study was to perform a case analysis on how design ethnography could be used in the context of medical device design in low-resource settings. Through a richly detailed case, we demonstrate the relevance of design ethnography based on the significance of the data elicited. In this section, we introduce the design of the prototype being evaluated and present the design ethnography data collection and analysis methods used to evaluate the prototype.

3.1 Device Background

This case study focused on the design of a medical device created to assist healthcare workers in the insertion of subcutaneous underarm contraceptive implants, Figure 1. Subcutaneous contraceptive implants, one of the most effective forms of reversible long-term contraception, must be administered by mid- to high-level healthcare workers. This training barrier prevents their widespread adoption in rural areas of low- and middle-income countries. The contraceptive implants, which are inserted underneath the skin of a woman's non-dominant arm, must be placed accurately within the subcutaneous tissue. Inserted too deeply, the implant enters the muscle, causing significant problems during removal. The procedure involves first wrapping the device body against the patient's arm with a blood pressure cuff and then evenly applying pressure (by inflating the cuff). This pressure pushes the patient's skin and subcutaneous tissue into a cavity in the device body. Once the arm is pressurized, adapters slide along a guiding track inserting the implant at 1.7mm below the surface of the skin. The concept solution overcomes the problem of inaccurate insertions and could potentially reduce the training requirements necessary to insert contraceptive implants (a major barrier to access in rural areas).

Design ethnography methods were first used during the needs identification and requirements development design phases. We conducted fieldwork (authors IM and AS) over the course of three weeks during August 2013. Observations and interviews were performed at St. Paul's Hospital in Addis Ababa, Ethiopia. The need to reduce training requirements for the insertion of subcutaneous contraceptive implants was identified from these observations and interviews, and confirmed through discussions with Ministry of Health officials. After the need was identified, a mechanical engineering capstone design team, using input from clinicians at the University of Michigan and St. Paul's Hospital in Ethiopia, developed product requirements, engineering specifications, and designed the prototype shown in Figure 1.

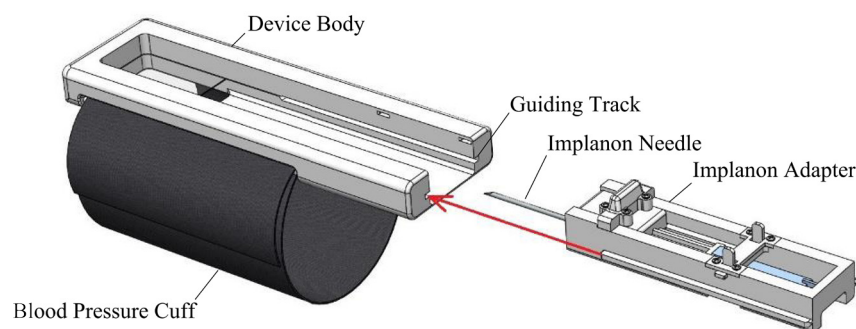


Figure 1: Assistive implant device prototype and its components

3.2 Design Ethnography Evaluation

We returned to Addis Ababa during May 2014 to evaluate the prototype design and gather input from stakeholders to inform future design iterations. Below we detail the use of design ethnography techniques during the evaluation of the prototype. We established two objectives for the use of design ethnography in prototype evaluation: gather feedback on the prototype that would inform modifications and/or additions to product requirements and engineering specifications, and to gain an understanding of the healthcare system (particularly in rural areas) and medical device development, manufacturing, and procurement processes in Ethiopia.

3.2.1 Data Collection

Fieldwork took place in and around Addis Ababa. A snowball sampling methodology was used to identify as many relevant stakeholders as possible and to use local stakeholder knowledge during sampling. Participants in the healthcare field included community health extension workers (CHEWs), physicians, nurses, and midwives. Participants in other fields included key policy stakeholders from the Ministry of Health, the Food, Medicine and Healthcare Administration and Control Authority (FM-HACA), and the Pharmaceutical Fund and Supply Agency (PFSA). Peripheral stakeholders with non-medical perspectives, such as biomedical engineers and biomedical technicians in charge of equipment maintenance were also included as participants. This study was reviewed by the Institutional Review Board of the University of Michigan and was determined to be exempt (exemption #2, 45 CFR 46.101(b)(2)). All participants provided consent prior to interviews.

Data collection took place through observations and semi-structured and unstructured interviews during May 2014. Observations were conducted in the family planning office of a referral level hospital in Addis Ababa, which receives many cases from surrounding smaller hospitals and health clinics. The goal was to understand how the implant procedure is performed and how the prototype can be incorporated into healthcare settings. Observations also guided the development of interview protocols for healthcare providers.

Semi-structured and unstructured interviews with more than 50 stakeholders took place at various locations and offices in and around the city. Interviews with healthcare providers focused on identifying the pros and cons of the concept solution as it related to implantation accuracy and ease of use. Interviews sought to generate actionable feedback that would have direct impact on the product requirements and engineering specifications. Interviews with government officials were used to better understand how community healthcare extension workers are trained and how the concept solution might be implemented within the Ethiopian healthcare system. Interviews with biomedical engineers and technicians focused on current medical technologies, maintenance practices, and how the prototype design might be modified to allow for ease of maintenance and repair. Interviews were also conducted with personnel at a small Ethiopian/American start-up attempting to manufacture medical devices within Ethiopia. Healthcare clinics in a small town outside of Addis Ababa were visited to assess the rural environment where the concept solution would be deployed.

Semi-structured interview protocols were developed for all interviews. Questions attempted to identify the positive aspects of the current concept solution (where the stakeholders saw value in the current design) and the negative aspects of the concept. Questions concerning the training of CHEWs and the context of use were asked in order to understand the environment in which the device would be used and adapting it for best fit. All interviews began with an overview of the interviewee's background and general questions (if applicable) about access to family planning in Ethiopia. We then demonstrated the prototype using a low-fidelity arm simulator and the interview focused on eliciting the positive and negative aspects of the prototype. Table 1 provides example questions asked of clinical and manufacturing experts as well as follow-up questions that were not formulated beforehand.

Table 1: Example interview questions for clinical and manufacturing experts and examples of follow-up questions not formulated prior to interviews

Example questions for clinicians:
Is this medical device filling a current need? Do other products already exist that accomplish the same functions?
Does this medical device facilitate task-shifting (is it appropriate for a CHEW)?
Is this medical device appropriate for use by a mobile health unit?
Example questions for manufacturers:
Are there any medical devices being produced locally?
Can this medical device be produced using a production line already in place for other devices/products?
What are the current challenges to manufacturing medical devices in country?
Example follow-up questions:
If you were to be the project manager, how would you move forward with this?
Is the Ministry of Health looking for a device that could help with the entire implant [insertion and removal] process? What kind of ideas do you have to overcome insertion and/or removal challenges?
Do you have a sense of what types of sterilizing methods the CHEWs have access to?

Observations and interviews were conducted in teams of two (or more). Observation notebooks were maintained by all researchers, and all notes were compared during and after observations. During interviews, one researcher asked the majority of the questions while the other researcher(s) took notes. The team format also allowed one of the researchers to consult interview protocols and ensure that no critical questions were missed while the principal interviewer was free to ask follow-up questions. Observational field notes and interviews field notes were compiled each night into digital format later analysis. Additionally, key interviews were recorded and transcribed for data analysis.

3.2.2 Data Analysis

Transcripts from all recorded interviews, observational field notes, and interview field notes from the three researchers were loaded into Nvivo 10 (Q.S.R.International Pty Ltd. 2012). A deductive coding scheme was developed to facilitate data organization and analysis (Creswell 2013). The coding scheme was derived from the original product requirements and engineering specifications, Table 2. The coding scheme allowed the compilation of all references made to each requirement and/or specification in the data. The final category, “Other,” in Table 2, was used to recognize data collected that did not fit into a previously defined code (i.e., it was not associated with a current product requirement or engineering specification). Originally, two additional coding schemes were used based upon 1) the various components of the device, and 2) a task analysis of the insertion procedure. However, the coding scheme in Table 2 allowed for more efficient organization of data and for insights to be gained more easily. After deductive coding was completed, an inductive constant comparative method was used within each code to identify patterns and discrepancies that elucidated if requirements and/or specifications needed to be modified or added (Creswell 2013).

Table 2: Coding scheme structured around the original user requirements and engineering specifications for the assistive device

Code Category	Code	Code Description
Accurate Implant Insertion	Depth	References to accuracy with respect to depth of implant in subcutaneous tissue.
	Min	References to how the device must ensure a minimally invasive procedure.
	Lateral	References to accuracy with respect to lateral implant location.
	Angle	References to accuracy with respect to angular implant orientation.
Safety	Cross	References to cross-contamination or sterility concerns.
	Accident	References to issues concerned with device sharps or accidental pricks.
	Biomat	References to biocompatibility of materials used in the device.
Ease of Use	Learnable	References to the learnability of the device by end-users.
	Train	References to the level of training needed by healthcare providers to operate the device.
	LowFail	References to the failure rate of the implant procedure.
	Time	References to the amount of time needed to perform the implant procedure.
Device Features	Accommodates	References to the need to accommodate multiple types of implants.
	Cost	References to the cost of the device.
	Power	References to the type/quantity of power needed to operate the device.
	Aesthetics	References to the aesthetics of the device.
Other	Other	References to the device or procedure that did not fit into any of the above codes.

4 FINDINGS

The synthesis and analysis of the design ethnography data led to major modifications and additions to the original product requirements and engineering specifications. Some of these modifications and additions would not have been evident without the use of a field-based inquiry method (design ethnography) and thorough analysis. Below we discuss three specific modifications and/or additions to product requirements that were either unexpected or contradicted our prior assumptions. The following modifications/additions, which are significant deviations from our original requirements, dramatically affected the current prototype design:

1. The device must accommodate delivery of anaesthesia (addition)
2. The device must address cross-contamination in a different manner (change)
3. The device must reduce patient fear of the procedure (addition)

4.1 Device must accommodate delivery of anaesthesia

The initial concept solution neglected to consider anaesthesia delivery within the product requirements, instead assuming that because CHEWs provide vaccinations, they would not have difficulty delivering the local anaesthesia necessary for the implant insertion. During our original design ethnography work, clinicians did not refer to any challenges associated with anaesthesia delivery, influencing our decision to not incorporate this procedure into our design.

During prototype evaluation, however, analysis of the collected data revealed that healthcare providers viewed the anaesthetic injection associated with implant insertion as a more complex process than traditional injections (such as a vaccination), contrary to our original understanding. Through interviews with healthcare providers, we learned that the anaesthetic must be injected first at the insertion site and then subcutaneously throughout the path taken by the implant needle. In other words,

a healthcare provider must ensure that enough anaesthetic is applied to the entire area and that the anaesthesia needle follows the insertion path of the implant needle. Stakeholders reported that a vaccination is a simple injection requiring minimal accuracy and, thus, not a sound comparison. We also learned that delivering the anaesthetic correctly created what they termed a pilot hole, which they used to guide their implant insertion to the location where the anaesthetic concentrated. The prototype only allowed for approximate alignment of the anaesthetic delivery with the path of the implant needle. These reasons were not clear during the first design iteration, which is why we did not include a requirement related to anaesthesia delivery in our initial design.

4.2 Device must address cross-contamination in a different manner

During the original formulation of the product requirements and engineering specifications, we consulted physicians and healthcare providers to determine the accessibility of sterilization equipment (namely, access to autoclaves). Based upon these conversations, we decided that CHEWs would have access to autoclaves at their corresponding health centre (each health centre oversees five health posts run by CHEWs). However, during interviews with healthcare providers and Ministry of Health officials during prototype evaluation, concerns about the reusable nature of the device (which would be autoclaved after each use) were raised. One physician stated, “[community health extension workers] have no reason to go to the health centre and autoclave anything. But, my point is the health centre should have an autoclave.” It was a clear example of why we previously assumed that autoclaving after each use was viable, and why it would not work in practice. The physician mentioned that health centres do in fact have autoclaves where our device could be sterilized (as we had previously designed for); however, CHEWs do not currently have any need for traveling to the health centre regularly. Providing them a device that required autoclaving (and, therefore, required them to make regular visits to the health centre) would increase the likelihood that CHEWs would abandon the use of the device altogether. Physicians also told us that CHEWs only use disposable equipment (that have a reduced risk for cross-contamination), e.g., “they don’t use anything that is going to need sterilization.” This statement exemplifies the fact that as currently designed (requiring an autoclave) our prototype was likely to be resisted by end-users.

Some healthcare providers also thought that the safety and cleanliness of a reusable medical device for use in rural areas would be an issue for patients. After being told that the device was reusable and needed to be autoclaved after each use, a physician stated, “[patients] should be reassured that...[if the device] is going to be used in many patients, then at the same time, it is safe.” Many physicians were concerned with the reusable nature of the device, that autoclaving may not guarantee sterility, and that the sterilization procedures required would add to the heavy workload of CHEWs.

The issue of cross-contamination appeared frequently in the form of suggested design changes. For example, while many stakeholders thought that certain components of the device could be reused, they also thought that the specific components directly around the insertion site should be disposable. One physician mentioned that to ensure minimize "cross contamination, you could provide 10 to 15 caps that would be thrown away after each patient.” The caps would cover the insertion site and prevent bodily fluids from being transmitted between patients. Another healthcare worker mentioned providing “a new [end piece] for each patient...the end that could become contaminated.” The critiques of the reusable nature of the device coupled with the repeated indications that some components should be disposable provided enough evidence to dictate a major redesign to address cross-contamination concerns.

4.3 Device must reduce patient fear of the procedure

A key piece of feedback obtained from stakeholders was that the device needed to be redesigned to allay patient fears of the procedure. Inserting the implant requires using a large bore needle, which often leads to so much apprehension that many women choose short-term contraceptive methods because they are more familiar with simple injections or once-a-day pills. The large size of the original device was discussed by one physician, who stated that it needed to be as small as possible in order to “not terrorize the client.” Another healthcare provider said, “when you see this thing, I think it’s maybe big and huge.” Similarly, physicians mentioned that the device needed to be shorter, lighter, and smaller so that it would not intimidate patients and would comfortably fit the arm.

Some feedback from stakeholders related to the theme of reducing patient fear during the discussion of other features. For example, speaking about the need for anaesthesia delivery to be incorporated into

the design of the device, one physician stated “what patients fear is pain, so anaesthesia delivery remains necessary.” He talked about how the device, in its current form, would not be seen as an improvement by patients, because the design would not reduce their fear of the procedure. Nurses who worked in the family planning office spoke about the challenges of counselling women about long-term contraceptive options when they were fearful of the procedures (e.g., the large bore implant needle). These discussions made clear that future device iterations would need to account for patient concerns of the entire procedure and not focus solely on the technical requirements of the procedure.

5 DISCUSSION

The findings from the use of design ethnography guided significant modifications and additions to the product requirements and engineering specifications of the assistive device. Some of the changes would not have become evident through evaluations performed outside the field (e.g., in a laboratory setting). For example, during the original needs assessment (August 2014), healthcare workers repeatedly made clear that a reusable device would help keep costs low and would be a positive feature of the device. However, during evaluation of the prototype through design ethnography, healthcare providers expressed concerns that a reusable device was less likely to remain sterile and could lead to cross-contamination issues. By showing the physical prototype to stakeholders, we learned of several issues that had not been raised previously and, as shown in previous work, which greatly improved our ability to obtain feedback about requirements and specifications (Yock et al. 2015; Martin et al. 2012).

While prior work on design ethnography has focussed mainly on data collection (Wasson 2000), our goal was to demonstrate the complete process and provide detail about the methods used during data analysis. The deductive coding scheme used to organize and analyse the data collected was critical to informing modifications and additions to product requirements. Use of this coding scheme was easily employed because design ethnography was being used in the evaluation of an already-developed prototype; thus, the requirements and specifications were already fully developed. While prior literature has emphasized the role of inductive methods to analyse data collected through design ethnography, we believe that the combination of inductive and deductive methods might be opportune during later design phases as it focuses data analysis on product requirements and/or engineering specifications, highlighting necessary changes and modifications (Blomberg et al. 2009).

Another key realization that emerged from use of design ethnography was that assumptions were made during the original requirements and specifications formulation. During the original design process, we assumed that CHEWs were the primary end-users/stakeholders and therefore we designed to their known and perceived needs and wants. We failed to give adequate consideration to patients, because we assumed that women would make contraceptive choices based purely on the merits of the contraceptives themselves and not on the method of delivery or equipment involved. Only during the prototype evaluation phase did our use of design ethnography make it clear that the original design would negatively affect uptake of contraceptive implants, because it may add to women's fears of the procedure. Challenging designers' assumptions of stakeholders or the context of use is an important benefit of design ethnography use (Bidwell et al. 2010; Skaggs 2010).

In addition to the goal of modifying product requirements and engineering specifications to better reflect the true needs and wants of stakeholders, we also sought to understand medical device development, manufacturing, and procurement processes within Ethiopia to ensure that our approach would be synergistic with processes currently in place. While the information gained as part of this goal did not directly lead to modifications/additions to product requirements or engineering specifications, it will be important when evaluating future iterations of the design. Interviews with the operator of a small start-up attempting to develop medical devices in Ethiopia provided valuable information. For example, producing medical devices in country is advantageous when seeking to win government contracts (e.g., devices manufactured at least 35% locally receive a 30% bidding advantage over imported devices). This information, which was not directly added to the product requirements or engineering specifications, will be considered during future concept evaluation (e.g., a design that could be produced within Ethiopia might be favoured over a design that would prove difficult to manufacture in a low-resource setting).

The design ethnography conducted to evaluate the prototype (Figure 1) led to significant changes in the product requirements and engineering specifications of the device. These changes, in turn, led to a

dramatic redesign of the device as shown in Figure 2 (Mohedas et al. 2015). The significant changes emphasize the actionable nature of the feedback generated through data collection and the conclusions drawn from data analysis.



Figure 2: Device redesign based on design ethnography findings

Despite the large benefits gained by using design ethnography to evaluate the concept discussed above, several issues presented barriers to the implementation and utility of design ethnography. Data collection presented several such challenges. For example, our access to CHEWs (the primary end-user) was difficult because they were spread throughout rural areas. This made visiting CHEWs challenging and we were unable to speak with the number we had targeted. Preparation for interviews also proved challenging due to the diversity of stakeholders involved and our lack of information about particular interviewees beforehand. We found it necessary to create separate interview protocols for physicians, nurses, biomedical engineers, Ministry of Health officials, FM-HACA officials, PMFSA officials, etc. Prior to our interviews, we did not always know a stakeholder's area of expertise (e.g., some officials from the Ministry of Health specialized in training CHEWs, while others dealt with biomedical equipment issues). Thus, we had to prepare ourselves to talk about a range of topics for any one interview. Creating an interview binder containing all interview protocols was necessary to ensure proper preparation for all interviews. Data analysis also presented a challenge, specifically finding an appropriate coding scheme that facilitated the identification of necessary modifications and additions to product requirements and engineering specifications. While the coding scheme used in this study might not be as easily implemented during earlier design phases (e.g., prior to the develop of product requirements and engineering specifications), a modified version could prove equally beneficial. For example, use of Garvin's eight dimensions of quality (performance, reliability, durability, serviceability, conformance, perceived quality, aesthetics, and features) could provide a foundation for data analysis during earlier design phases (Garvin 1987). Future work could focus on developing more versatile coding schemes when implementing design ethnography during other design phases.

6 CONCLUSION

This paper detailed the use of design ethnography when evaluating a medical device prototype in a low-resource setting. We conclude that design ethnography is particularly applicable to the design of medical devices in low-resource settings, because: 1) appropriate consideration of stakeholder needs and wants is critical to medical device design, and 2) the technique helps to close the cultural gap that can exist between designers and stakeholders. We note that the challenges associated with the use of design ethnography emphasize the need for more research on both data collection and analysis.

ACKNOWLEDGEMENTS

The study team thanks Dr. Fisseha and our clinical collaborators in Ethiopia, Dr. Dilayehu, Dr. Lia, Dr. Malede, and Dr. Balkachew. We thank our device design team, Corey Bertch, Tony Franklin, Adam Joyce, Jacob McCormick, and Michael Shoemaker. We also thank Dr. Prashant, Dr. Adhvaryu, and Dr. Johnson for their support and Colin Delaney for help with data collection. This work was supported by the National Science Foundation's Graduate Research Fellowship Program, the Ethiopia-Michigan Platform for Advancing Collaborative Engagement, and the University of Michigan Global Challenges for Third Century Team Development Grant.

REFERENCES

- Ball, L.J. & Ormerod, T.C., 2000. Putting ethnography to work: the case for a cognitive ethnography of design. *International Journal of Human-Computer Studies*, 53(1), pp.147–168.
- Batavia, A.I. & Hammer, G.S., 1990. Toward the development of consumer-based criteria for the evaluation of assistive devices. *Journal of Rehabilitation Research and Development*, 27(4), pp.425–436.
- Bidwell, N.J. et al., 2010. Designing with mobile digital storytelling in rural Africa. In *Proceedings of the 28th International Conference on Human Factors in Computing Systems (CHI '10)*. April 10-15. Atlanta, Georgia: ACM Press, pp. 1593–1602.
- Blomberg, J., Burrell, M. & Guest, G., 2009. An ethnographic approach to design. In J. A. Jacko & A. Sears, eds. *The human-computer interaction handbook*. Mahwah, New Jersey: Lawrence Earlbaum Associates, pp. 965–984.
- Bucciarelli, L.L., 1988. An ethnographic perspective on engineering design. *Design Studies*, 9(3), pp.159–168.
- Creswell, J.W., 2013. *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* 4th ed., Thousand Oaks, CA: Sage Publications.
- Diaz, A.E., 2007. The challenge of dealing with cultural differences in industrial design in emerging countries: Latin-American case studies N. Aykin, ed. *Usability and Internationalization HCI and Culture*, 45559, pp.57–64.
- Garmer, K., Ylven, J. & Karlsson, I.C.M., 2004. User participation in requirements elicitation comparing focus group interviews and usability tests for eliciting usability requirements for medical equipment : a case study. *International Journal of Industrial Ergonomics*, 33, pp.85–98.
- Garvin, D.A., 1987. Competing on the 8 Dimensions of Quality. *Harvard Business Review*, 65(6), pp.101–109.
- Iqbal, R., James, A. & Gatward, R., 2005. Designing with ethnography: An integrative approach to CSCW design. *Advanced Engineering Informatics*, 19(2), pp.81–92.
- Kim, D. & Lee, K.-P., 2011. Ethnographic Research of User Behavior of Mobile Devices of China , Korea , India , and The Netherlands. In A. Marcus, ed. *Design, User Experience, and Usability. Theory, Methods, Tools and Practice*. Berlin: Springer-Verlag, pp. 294–302.
- Malkin, R. & Anand, V., 2010. A novel phototherapy device. *IEEE Engineering in Medicine and Biology Magazine*, (April), pp.37–43.
- Martin, J.L. et al., 2012. A user-centred approach to requirements elicitation in medical device development: a case study from an industry perspective. *Applied Ergonomics*, 43(1), pp.184–90.
- Martin, J.L. et al., 2006. Capturing user requirements in medical device development: the role of ergonomics. *Physiological measurement*, 27(8), pp.49–62.
- Mohedas, I. et al., 2015. Assistive device for the insertion of subcutaneous contraceptive implants. In *Proceedings of the Design of Medical Devices Conference*. Minneapolis. April 13-16.
- Mohedas, I., Daly, S.R. & Sienko, K.H., 2014. Design Ethnography in Capstone Design: Investigating Student Use and Perceptions. *International Journal of Engineering Education*, 30(4), pp.888–900.
- Potts, C. & Hsi, I., 1997. Abstraction and context in requirements engineering: Toward a synthesis. *Annals of Software Engineering*, 3, pp.23–61.
- Prahalad, C.K. & Ramaswamy, V., 2004. Co-creating unique value with customers. *Strategy & Leadership*, 32(3), pp.4–9.
- Privitera, M.B. & Murray, D.L., 2009. Applied ergonomics: Determining user needs in medical device design. In *31st Annual International Conference of the IEEE Engineering in Medicine and Biology Society*. September 2-6. Minneapolis: IEEE, pp. 5606–5608.
- Q.S.R.International Pty Ltd., 2012. Nvivo qualitative data analysis software, Version 10.
- Salvador, T., Bell, G. & Anderson, K., 1999. Design Ethnography. *Design Management Journal*, 10(4), pp.35 – 41.
- Sanders, E., 2002. Ethnography in NPD research: How “applied ethnography” can improve your NPD research process. *Visions Magazine*, April/May, pp.1–5.
- Sienko, K.H. et al., 2014. Obstetrics-based clinical immersion of a multinational team of biomedical engineering students in Ghana. *International Journal of Gynecology and Obstetrics*, 127(2), pp.218–20.
- Skaggs, P., 2010. Ethnography in product design - looking for compensatory behaviors. *Journal of Management and Marketing Research*, 3, pp.1–6.
- Sperschneider, W. & Bagger, K., 2003. Ethnographic fieldwork under industrial constraints: Towards design-in-context. *International Journal of Human-Computer Interaction*, 15(1), pp.41–50.
- Wasson, C., 2000. Ethnography in the field of design. *Human Organization*, 59(4), pp.377 – 388.
- Wax, R., 1986. *Doing fieldwork: Warnings and advice*, Chicago: University of Chicago Press.
- Werner, O., Schoepfle, G.M. & Ahern, J., 1987. *Systematic fieldwork: ethnographic analysis and data management (Vol. 2)*, Newbury Park, CA: Sage Publications.
- Yock, P.G. et al., 2015. *Biodesign: The process of innovating medical technologies* 2nd ed., United Kingdom: Cambridge University Press.