1 INTRODUCTION

Medical technology is one of the six essential building blocks of a health system as identified by WHO [WHO 2011]. The gap in the development of health technologies between High Income Countries (HIC) and Low and Middle Income Countries (LMIC) contributes to the current global burden of disease LMIC face. According to the 2004 report, Africa and south Asia count for 40% of the global population but have 54% of the global burden of disease. On the other hand, the investments and developments in healthcare technology show a reverse trend. The level of spending on research and development of healthcare technology is significantly higher in HIC as opposed to LMIC [WHO 2011]. This creates different dynamics for how medical devices are procured and maintained in HIC versus LMIC, ultimately impacting the quality of care delivered to patients in LMIC.

Medical device development is a well-established process within HIC. The medical device industry has grown significantly as physicians, government and investors started to realize the positive impact that healthcare technology can have in improving delivery of care, outcomes and cost. This has led to HIC creating appropriate political structures, monetary incentives, and regulatory systems to ensure that medical devices can be created, used and maintained safely where necessary. On the other hand, physicians and healthcare centres in LMIC often have a different approach to obtaining the necessary medical devices than that of HIC. The majority of medical devices in LMIC are either purchased from major companies in HIC or donated from various organizations globally [WHO 2010, 2011]. There are minimal local development and manufacturing resources in LMIC [WHO 2010, 2011]. Additionally, healthcare organizations in LMIC do not follow strict regulatory guidelines for obtaining or maintaining medical devices, and the governments in these countries often do not have a lot of resources dedicated toward monitoring and evaluating medical devices. The result is a graveyard of unused medical devices and a lack of appropriate equipment when needed. The WHO identified three main areas for improvement for addressing the challenge. Firstly, appropriate healthcare systems need to be established. Secondly, the market conditions and financing opportunities need to be enhanced for developers. Finally, there needs to be a comprehensive understanding of the design needs and requirements for medical devices in LMIC [WHO 2011]. This paper further investigates the third factor: challenge with understanding of design needs in LMIC.

WHO, the United States Agency for International Development (USAID), and other international organizations have recognized that needs are not appropriately understood in healthcare settings in LMIC [WHO 2011, USAID 2015]. According to the "Idea to Impact" report by USAID, the scale-up time (i.e., the time it takes to go from one initial prototype to having the devices disseminated where needed) is significantly higher in LMIC compared to HIC [USAID 2015]. The "Idea to Impact" guidelines identify that most companies do not have a comprehensive understanding of their problem space and that scale-up time could become shorter if design teams have a more holistic approach to need finding. Existing design methodologies have been primarily developed for design in HIC. There has only been a highly limited amount of work done in developing these appropriate techniques for LMIC [USAID 2015, WHO 2011].

This paper explores and addresses the challenge of understanding design needs for medical device development in LMIC. All design processes start with a needs-finding stage, and the author proposes and demonstrates the applicability of a new need finding technique based on Activity Theory. This novel needs-finding technique aims to provide the designer with a way of incorporating social, economic and political factors alongside the clinical and technical aspects necessary for a design challenge. The hypothesis of this concept is that the Activity Theory-based Needs Finding (ATNF) technique allows design teams to achieve an enriched understanding of their design problem and develop need statements that are more comprehensive and inclusive of the socioeconomic, clinical and technical factors. The ATNF technique is compared against a more conventional need finding technique used as part of the Stanford Biodesign Process, within a series of design workshops with biomedical engineering student teams. The paper describes the methodology and results of this study.

2 BACKGROUND

2.1 The Biodesign Process Needs Finding Stage

One of the best known modern biodesign processes was developed through the Biodesign innovation training program at Stanford University. Zenios, Makower and Yock leveraged the experience and insights of many engineers, physicians, entrepreneurs and design practitioners to develop their formulation [2010]. The process is divided into three main stages: identify, invent and implement. Figure 2-1 shows the suggested needs-finding method as part of the "identify" stage in the Biodesign process. Table 2-1 provides the description of terms used in the Biodesign process.

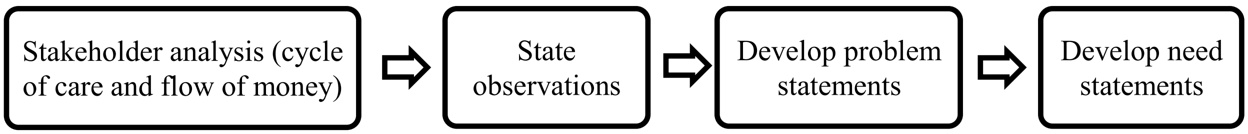

Figure 2-1 The needs-finding technique in the Stanford Biodesign Process

Table 2-1 Definition of Terms for Biodesign Needs-finding Technique

Cycle of care	The entire process of how care is delivered to the patient
Flow of money	A representation of sources, receivers and distribution of money
Observations	The data and information from field research
Problem statement	A statement highlighting the inadequacies or limitations derived from observations
Need statement	A statement that identifies a necessary change and includes a metric

The Biodesign process is a needs-driven design method and emphasizes that medical device development should correspond to a real need [Zenios et al. 2010]. Prior to needs finding, the design teams are required to learn as much as they can about their specific problem space [Zenios et al. 2010]. The needs finding in Biodesign starts with a stakeholder analysis by outlining the cycle of care and flow of money. Once the major stakeholders are identified, the design team notes all the observations that they have made through their ethnographic and secondary research. Once sufficient observations are made, the design team synthesizes the information and develops problem statements. Finally, the design teams develop a need statement corresponding to one or multiple problem statements [Zenios et al. 2010]. This technique emphasizes the importance of understanding the problems of the various stakeholders and transforming them into needs.

2.2 Activity Theory-based Needs Finding

To address the challenge with identification of design needs for medical device development in LMIC, the authors developed a novel needs-finding technique based on Activity Theory. The following sections provide a brief overview of Activity Theory and describe the Activity Theory-based Needs Finding.

2.2.1 Overview of Activity Theory

Vygotsky, Leontiev, and Engestrom have made significant contributions to the inception and development of Activity Theory. In Activity Theory (AT), an activity is a unit of analysis. Activity is described through a framework, an activity system. The entire activity system involves a subject (main agent) and multiple community members; it accounts for the role of the artefacts, the motivation of the actor, division of labour and socioeconomic norms [Engestrom 1984]. In the past, scholars and designers have incorporated Activity Theory in design methodology of information and communication technology [Karanasios et al. 2014] and human-computer interaction [Nardi et al. 2006].

2.2.2 Overview of Activity Theory-based Need Finding

The design process starts when the design team is aware of a problem. The ATNF has four main steps, as illustrated in Figure 2-2. The ATNF technique starts by identifying the main stakeholders and their activities within a problem space. The team needs to complete preliminary research and field observations before this first step. Then ATNF provides a framework for constructing an activity system as illustrated in Figure 2-3 and Table 2-2. The design team constructs an activity system by first identifying the subject, the objective, the outcome, the time and the community. Following that, the team develops a specific description of the instruments, rules and division of labour. Once a design team constructs multiple activity systems, they identify the contradictions (i.e., tension points) within or between various activities. Contradictions are points of conflict or tension within or between elements of one or multiple activity system [Engestrom 1984]. Finally, each of these contradictions is translated into need statements with a specific desired change and metric. The Biodesign process informed the ATNF definition and development of need statements. According to the Biodesign process, a need statement needs to express a desired change, target audience and a metric [Zenios et al. 2010]. A need statement should also have a specific scope and choices of words [Zenios et al. 2010]. A design team can develop a need statement by mapping a contradiction to the desired change and by deriving a metric based on the outcome of the activity systems. The design team can then refer to the activity systems and the contradictions to choose the specific scope and words for the need statement. A more detailed description of ATNF can be found in a previous publication [Rismani et al. 2016].

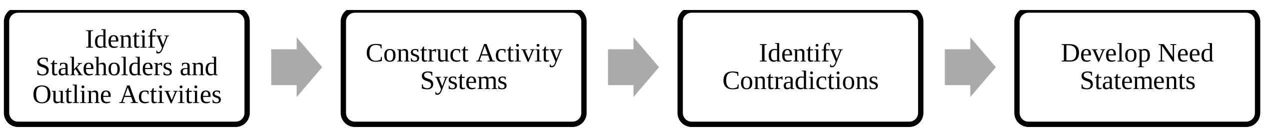

Figure 2-2 The Four Main Steps of the Activity Theory-based Need Finding (ATNF) Technique

Table 2-2 The definition of terms and example of the ATNF modified activity system

Term	**Definition (correspond to questions in** Error! Reference source not found.**)**	**Example**
Activity	Series of actions and interactions that a stakeholder can take within a specific context to reach their objective	A femur fracture fixation surgery performed by an orthopaedic surgeon in Uganda
Subject	A stakeholder who has the agency to participate in an activity to reach the objective	Orthopaedic surgeon
Objective	The motive of the stakeholder for engaging in the activity	To provide care to the patient
Time	The timeframe at which the activity is taking place	During the surgery
Outcome	The resulting changes after the activity	Femur of the patient is properly fixed
Community	All stakeholders who help the subject reach the objective	Nurse; Sterilization staff; Hospital admin
Physical instrument	All the tools and technology that the subject uses to accomplish the objective	Surgical drill, screws, plates, dressing, sutures
Non-physical instrument	The language, knowledge, and protocols that the subject uses to accomplish the objective	Surgical experience; Specific protocols in the operating room
Technical rules	All the constraints, conditions and regulations necessary for the optimal function of the physical instrument	The surgical drills need to be powered. The surgical drill needs to be sterilizable.
Non-technical rules	All the social norms, economic constrains and political system rules that influence the activity directly	Nurses often follow the orders of the physician; The hospital admin provides a limited amount of equipment based on limited financial resources
Division of labour with respect to technology	The role of the subject and community members with respect to the physical instruments	Scrub nurse prepares the drill for the surgeon The sterilization team needs to sterilize the drill
Division of labour	The role of the subject and community members in helping the subject reach the objective	Nurse ensures the surgeon is scrubbed in; The hospital admin allocates money and resources for the operating room

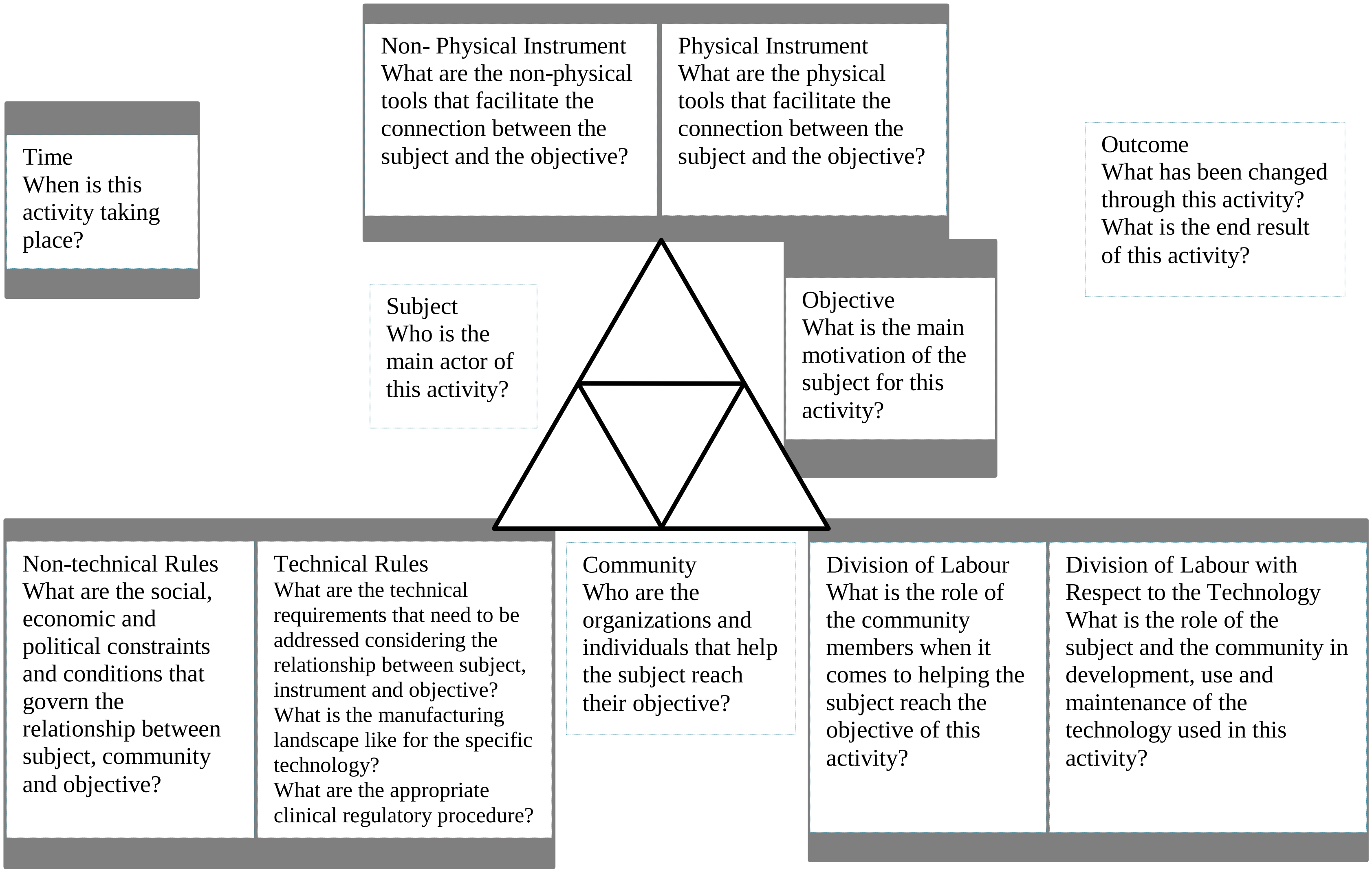

Figure 2-3 The Modified Activity System for ATNF – it includes the prompt questions that can be used by design team to develop the elements.

3 DESIGN STUDY METHODOLODY

The objective of this study is to compare the ATNF technique with a conventional needs finding technique. The author chose to use the needs finding technique used in the Stanford Biodesign process as the conventional method. This method provides an appropriate comparison for ANTF because it has been used for medical device development in both HIC and LMIC [Zenios et al 2010], indicating its versatility and adaptability. The two needs finding techniques are compared on the basis of process and outcome. The study has multiple goals. First, in order to assert efficacy of ATNF as a useful need finding technique in medical device design, it is important to understand how design teams adopt, apply, and use ATNF in their design practice. Can design teams apply the ATNF technique to develop need statements? If so, what do the design teams think about the process of developing these need statements? Second, to understand the quality of the ATNF technique, it is critical to study how the ATNF technique performs versus a prominent conventional technique such as the Stanford Biodesign process.

3.1 Study Design

The design teams were asked to participate in a 2-hour workshop, facilitated by the author. Each team came into the workshop with two design problems that they had researched previously. Each team started with applying one of the needs-finding techniques on one of their design projects. To avoid bias, the Biodesign needs-finding technique was referred to as Method A and the ATNF technique was referred to as Method B. The order of the techniques was randomly selected by the facilitator. From seven workshops, three of them started with Method A and the rest with Method B. Each team chose the order of the design problem. The workshop started with a brief 10-minute introduction of the research project, completion of the consent forms and overview of the workshop agenda. Following that the teams were introduced and facilitated through either one of the methods step-by-step. The facilitator tried to ensure that approximately 45 minutes was dedicated to each technique. However, it took anywhere from 30-60 minutes for each team to complete each technique. The teams were asked to record all of their work on flipchart papers, whiteboards or post-it notes. After completing the two needs-finding exercises, each participant was asked to complete a post-workshop questionnaire.

3.2 Data Collection

The author conducted an ethnographic study of the teams during the workshop and collected four data sources to capture the design process and its outcomes. The design artefacts and the post-workshop questionnaires were the two main sources of data. The design artefacts consisted of all the ideas that the teams wrote down throughout all the stages of needs finding on flipchart paper, post-it notes and board. Each team had one set of design artefacts for each of the needs finding techniques. There were in total 14 sets of design artefacts from the seven teams. The design artefacts captured the thought process of the teams about each of their design problems. Each one of the participants completed a questionnaire expressing personal opinions on each one of the needs finding techniques and its impact on the quality of need statements that were developed. The questionnaire consisted of five open-ended questions. The participants were asked to write about each one of the needs-finding techniques and compare them against each other. The participants also provided feedback about their overall experience in the workshop. All 30 participants filled out the post-workshop questionnaire.

3.3 Data Analysis

Four analysis methods were used to investigate the design artefacts and the questionnaire data. Firstly, the words in the needs statement were mapped to the words in the design artefacts. In this analysis the words from the need statement were mapped to the words in the design artefact. The idea was to understand what part of the needs-finding techniques contributed to the derivation of the need statement. Dictionary-based content analysis was done on the design artefacts. Phrases from the artefacts were divided into pre-determined dictionaries [Spinks 2015]. PESTLE, an analysis tool for understanding a certain environment, was used to determine the dictionaries. It asks the user to look at an environment from Political, Economic, Social, Technological, Legal, and Environmental aspects [USAID 2015]. For the purposes of this research, the author added "Clinical" as the 7th category. The aim of this analysis was to compare the percentage coverage of each dictionary for the design artefacts of the two methods. Sentiment analysis was done on the questionnaire responses to analyse the overall sentiment toward each technique. Sentiment analysis uses computational techniques to determine whether a certain phrase has a positive, negative or neutral sentiment [Medhat 2014, Ribeiro 2016]. A sentiment analysis tool by Lexalytics was used for this analysis [Medhat 2014, Ribeiro 2016]. Thematic analysis was done for both sets of data [Braun 2006].The data was coded by two investigators for all the thematic analysis.

4 RESULTS AND DISCUSSION

4.1 Mapping artefacts to needs statements

The number of words in the need statements that appeared in the design artefacts and the total number of occurrences of the need statement words in the design artefacts were used to investigate how closely the need statements reflected the ideas developed during the first three stages of each needs-finding technique. Two ratios were calculated for each set of design artefacts from the two techniques for all groups.

$$R1 = \frac{Number\ of\ words\ in\ need\ statement\ that\ appeared\ in\ the\ design\ artefact}{Total\ number\ of\ words\ in\ the\ need\ statement} \quad (1)$$

$$R2 = \frac{Total\ number\ of\ occurrences\ of\ the\ need\ statement\ words\ in\ the\ design\ artefacts}{Total\ number\ of\ words\ in\ the\ design\ artefacts} \quad (2)$$

The average value of R1 for the Biodesign and the ATNF method were respectively 25.8% and 29.8%. The average value of R2 for the Biodesign and the ATNF method were respectively 8.9% and 9.5%. The difference between the two techniques for each one of the ration is not statistically significant based a two-tailed paired t-test. These two ratio indicate the continuity of the ideas from the various stages of needs finding to development of the need statement. Both the Biodesign and the ATNF methods were equally successful in guiding the design team in developing need statements from the ideas developed in first three stages of each technique.

The Biodesign needs-finding technique is well-established and has been used by many design teams. The effectiveness of the needs-finding process for Biodesign is proven through its successful application. The novel ATNF technique allowed the teams to develop needs statements in this study. However, it is important to understand how the process of ATNF leads to development of needs statement. The two ratios (R1 and R2) that connect the words in the need statements to the words in the design artefacts are not significantly different between ATNF and Biodesign. This indicates that the needs statements developed by teams are equally connected to both ATNF and Biodesign needs finding processes.

4.2 Category-based and Thematic Analysis for Design Artefacts

Using the categories from the PESTLE technique and codes developed through thematic analysis the following coding structure was developed.

Table 4-1 Categories and Themes for Design Artefacts

Themes	**Economic**	**Social**	**Environmental**
Supply chain Low-resource setting System level issues Access to healthcare	Financial support/funding sources Market condition Economically feasible/cost of device Economic status of buyer/receiver of care	Social norms Communication Family and friends	People Physical Time
Political	**Technology**	**Clinical**	**Legal**
Healthcare provider Non-governmental or non-profit organizations Government Hospital	Quality/reliability of Technology Manufacturing Training Developers Specific instrument Use Maintenance Technical design requirements	Training Medical condition Physician Other clinical staff Patient	Device Regulation Laws/general regulations

The coding scheme, including definition of each code was used to co-code by two researchers. The coders ensured to keep the coding mutually exclusive between the categories. If a phrase was coded as economic, it would not be coded into any other category. The percentage agreement between the coders is 97.09% and the kappa coefficient is 0.34. The percentage agreement is high; however, the kappa coefficient indicates only a fair agreement between the two separate analyses [Viera 2005].
The percentage coverage of each category was calculated for each set of design artefacts for both techniques. Table 4-2 shows the average percentage coverage for each category for all the focus groups for each needs finding technique. After a two-tailed paired t-test, it was clear that the difference between the percentage coverage is not statistically significant for any one of the categories.

Table 4-2 Average Percentage Coverage for each Category for Design Artefacts

Percentage Coverage (%)	**Clinical**	**Environmental**	**Political**	**Technological**	**Economic**	**Legal**	**Social**
ATNF	18.9	7.8	8.4	19.8	8.7	2.8	7.1
Biodesign	24.5	8.7	5	24.7	9.3	0.4	6.1

4.3 Sentiment Analysis for Questionnaire

Semantria by Lexalytics was used to conduct a sentiment analysis on the questionnaire responses. The sentiment scores for the feedback on the Biodesign technique was compared to the sentiment scores for the ATNF technique. Table 4-3 summarizes the results from the sentiment analysis. The average sentiment score is higher for the ATNF technique is higher across all the questions. After applying the Bonferroni Correction for multiple comparisons, the p-value needs to be less than 0.01 for a two-tailed paired t-test. The difference is statistically significant for Q1 and Q4. The average sentiment score is not statistically significant for Q2 and Q5. However, considering the Bonferroni correction is highly conservative, it can be said that the average sentiment towards ATNF is positive.

Table 4-3 Average Sentiment Score for Questionnaire Response for Biodesign and ATNF

Question	**Biodesign Technique Average Sentiment Score**	**ATNF Technique Average Sentiment Score**	**p-value**
1. How did you use each one of the tools to identify the appropriate scope for your need statement?	0.104	0.467	0.003
2. How did you use each one of the tools to come up with context-specific words for your need statement?	0.117	0.276	0.02
3. How well did each one of the tools help you define an appropriate metric?	0.126	0.240	0.3
4. How well did each one of the tools help you define a desired change for your need statement?	0.0809	0.390	0.0001
5. Do you have any other comments about the two need finding techniques? Please elaborate.	0.140	0.399	0.02

The participants had a positive sentiment toward both of the techniques for questions 1 and 4; however, they thought that the ATNF technique was more effective in developing an appropriate scope and identifying a desired change. The participants mentioned that the ATNF technique allowed them to think through more information and integrate it to arrive at an appropriate scope. They also thought that the ATNF technique was more helpful in identifying a desired change through determining existing contradictions. The thematic analysis of the participant feedback thoroughly explains why the participants had a more positive opinion toward the ATNF technique on scope and the desired change. Based on the responses for question 2, the participants had a more positive sentiment toward the capability of both methods to help them find context-specific words for their needs statements. The responses indicate a more positive trend toward the ATNF technique; however, there is not a statistically significant difference. The thematic analysis elaborates on how each technique allows the design teams to derive context-specific words. Question 3 on the development of a metric has a relatively low sentiment score for both of the needs-finding techniques, indicating that it was the most challenging part of writing a need statement. This is also highlighted in the results from the thematic analysis. Both of the techniques did not have an explicit means of defining a metric, and this could be considered for future improvements of the ATNF method.

4.4 Thematic Analysis for Questionnaire

The thematic analysis was done by two coders using a coding scheme that was initially developed by one of the coders and then further improved through discussion. The key themes that came through the questionnaire responses are highlighted in the following table. The percentage agreement between two coders is 96% and the kappa coefficient is 0.73, indicating a high level of agreement.

Table 4-4 Thematic Codes for Questionnaire Responses and their Description

Code	**Description**
Familiarity with technique	Use if response indicates familiarity with the need finding technique
Ease of use	Perspective on how easy it was to apply and use each one of the need finding techniques
Bringing in stakeholders	Perspective on how stakeholder input is brought in the technique
Bringing in context	Perspective on how context is analysed and understood
Time	Perspective on how long it takes to go through each technique
Thinking style	Perspective on how the participants thought through the problem
Structure of analysis	Perspective on overall structure and steps that the participants follow for this need analysis
Level of analysis	Perspective on depth understanding they achieved
Use of previous knowledge	Any references to use of previous knowledge in the analysis

Contrary to the Biodesign technique, which focuses more on stakeholder involvements, the ATNF technique also explicitly incorporates elements of context-aware design as highlighted in the thematic analysis. The ATNF technique has a more structured approach, which allows designers to have a more comprehensive understanding of the needs. The Biodesign technique is more linear and less structured, which means that the participants brainstorm and discuss to come up with the need statement. The Biodesign technique is easier to learn and use. However, the cues and frameworks for the ATNF technique were helpful in facilitating the thinking process for the design teams.

5 CONCLUSION AND RECOMMENDATION

The comparative study of the two needs finding technique illustrated that the novel ATNF technique is a viable technique which can be used by engineering design teams working on healthcare challenges in LMIC. The current study showed that the design artefacts from both ATNF and Biodesign techniques allowed for exploration of issues from political, clinical, environmental, economic, legal, social and legal perspectives. However, there was no significant difference between these categories for these techniques. The participants thought that the ATNF method was more effective in developing appropriate scope, identifying words for need statements and identifying the desired change. The ATNF method provided a more systematic way of analysing the information and it allowed the design team to think "outside of the box" and "explicitly consider some implicit issues". The analysis of the responses supports that the ATNF technique is more effective in understanding the design problem more comprehensively. The analysis of the design artefacts does not support this conclusion. However, the study showed that ATNF has distinct strengths for needs finding for MDD in LMIC. Further design studies with more engineering teams is recommended to better understand and improve this novel technique.

REFERENCES

Kaptelinin, V. & Nardi, B., 2006. Acting with Technology: Activity Theory and Interaction Design, Cambridge, MA: The MIT Press.

Zenios, S., Makower, J. & Yock, P., 2010. Biodesign: The Process of Innovating Medical Technologies, New York: Cambridge University Press.

Engestrom, Y., 1984. Developmental studies of work as a testbench of activity theory : The case of primary care medical practice.

Karanasios, S., 2014. Framing ICT4D Research Using Activity Theory : A Match Between the ICT4D Field and Theory ? , 10(2), pp.1–17.

USAID, 2015. Idea to Impact: A Guide to Introduction and Scale of Global Health Innovations. Available at: www.usaid.gov.

World Health Organization, 2010. Landscape analysis of Barriers to Developing or Adapting Technology for Global Health Purposes.

World Health Organization, 2010. Medical devices : Managing the Mismatch Barriers to Innovation in the Field of Medical Devices.

Spinks, N. & Canhoto, A.I., 2015. Quantitative content analysis. , pp.1–9.

Ribeiro, F.N. et al., 2016. SentiBench - a benchmark comparison of state-of-the-practice sentiment analysis methods. EPJ Data Science, 5(1).

Anon, Sentiment Analysis | Lexalytics. Available at: https://www.lexalytics.com/technology/sentiment [Accessed January 3, 2017].

Medhat, W., Hassan, A. & Korashy, H., 2014. Sentiment analysis algorithms and applications: A survey. Ain Shams Engineering Journal, 5(4), pp.1093–1113. Available at: http://dx.doi.org/10.1016/j.asej.2014.04.011.

Rismani, S., Ratto, M. & Loos, H.F.M. Van Der, 2016. Use of Activity Theory-based Need Finding for Biomedical Device Development. , pp.4341–4344.

World Health Organization, 2011. WHO Global Forum Medical Devices : context, outcomes and future actions.

Braun, V. & Clarke, V., 2006. Using thematic analysis in psychology. Qualitative Research in Psychology, 3(May 2015), pp.77–101.

Viera, A.J. & Garrett, J.M., 2005. Understanding inter-observer agreement: Family Medicine, 37(5), pp.360–363.