Use of Activity Theory-based Need Finding for Biomedical Device Development

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***Abstract*— Identifying the appropriate needs for biomedical device design is challenging, especially for less structured environments. The paper proposes an alternate need-finding method based on Cultural Historical Activity Theory and expanded to explicitly examine the role of devices within a socioeconomic system. This is compared to a conventional need-finding technique in a preliminary study with engineering student teams. The initial results show that the Activity Theory-based technique allows teams to gain deeper insights into their needs space.**

I. Introduction

According to a recent report from the United States Agency for International Development (USAID), the scale-up time for global health solutions such as medical devices can be up to two decades [1]. On the other hand, the scale-up time in the U.S for such solutions is on average five years. It is noteworthy that decreasing the scale-up time by even one year increases the potential impact of these solutions by 10% [1]. An IMS Health analysis indicates an effective introduction of a device into its intended ecosystem in the first 6 months can be highly crucial for its long-term success [2]. A successful introduction is only possible if an engineering design team completely understands clinical and technical needs of the stakeholders within the project's specific socioeconomic context. However, existing challenges with successful introductions indicate that it is worthwhile to examine and improve the design methodologies that engineering teams use to complete need finding.

During the initial stage of medical device development, designers perform need finding, during which they identify their stakeholders and investigate their problems to create a target product profile [1]. The idea-to-impact framework, developed by the USAID, suggests human-centred design techniques, such as contextual inquiry for need finding [1], [3][4]. The Stanford Biodesign Process is another highly referred method [5]. These two techniques are often used in the process of biomedical device development. They both emphasize the context of use and understanding parameters from multiple perspectives. However, we suggest the main challenge with these techniques is that the social context is not inherently included in the analysis; hence, they do not provide a framework for examining a socioeconomic system explicitly.

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To address this shortcoming, we are developing an extension to Cultural Historical Activity Theory ("Activity Theory") and propose its use as a need-finding technique in the design process. This psychological theory characterizes humans and their social behaviour by looking at the origin, structure and process of their activities [6], [7]. Our proposed technique extends the third generation of Activity Theory developed by Engestrom, and allows us to examine human activity in a social context with the role of technology as an added dimension [8].

As part of this work, we studied biomedical engineering student design teams using this new technique in comparison with a conventional technique used in the Stanford Biodesign Process. We hypothesize that the new Activity Theory-based method allows teams to develop an improved understanding of their design problem, as assessed by the diversity of themes in their work and participants' feedback. In this paper, the new Activity Theory-based method is described and elaborated via an example. Following that the study protocol and preliminary results are discussed.

II. Background

A. Overview of Biodesign Process

The Stanford Biodesign Process was developed through the Biodesign innovation training program at Stanford University [5]. Zenios, Makower and Yock leveraged the experience and insights of many engineers, physicians, entrepreneurs and design practitioners to develop their formulation. The process is divided into three main stages: identify, invent and implement. Fig. 1 shows the suggested need-finding method as part of the "identify" stage in the Biodesign process. Table 1 provides description of terms used in the Biodesign process.

Figure 1. The need finding technique in the Biodesign process

TABLE I. Definitions of Biodesign Need Finding Terms

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

The method outlined in this Biodesign process is specific to medical devices but also parallels other design processes.

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B. *Basics of Activity Theory*

In the last two decades, Activity Theory has been applied within a multitude of disciplines, including educational design [9], information technology [10] and human-computer interaction [11]. The initial formulation of Activity Theory, developed by Vygotsky and Leont'ev, describes the mediation of human activity by tools and how the activity is situated within a community [12], [13]. Engestrom expanded on this early work and developed a visual model of an *activity system*, which is a seven-element framework that describes a human activity at a given point in time, as shown in Fig. 2 [6]–[8]. Table 2 provides the definitions of its key elements and shows an example of an activity system.

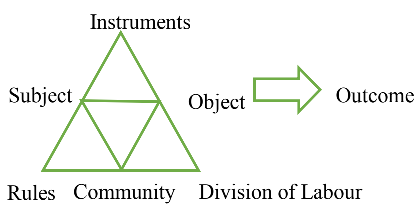

Figure 2. Basic Activity System developed by Engestrom

TABLE II. DEFINITION AND EXAMPLE OF A BASIC ACTIVITY SYSTEM AS DEVELOPED BY ENGESTROM

Terms	Definition	Example
Subject	Individual or sub-group whose agency is chosen as the point of view	Primary care physician
Object	"Raw material" or "problem space" at which the activity is directed	Patient with health problem and illness
Outcome	The object becomes the outcome once the transformation has taken place.	Intended recoveries and improvements in health as well as unintended outcomes
Instruments	The tools and signs used by the subject to transform the object into an outcome	X-rays, medical records as well as partially internalized diagnostic
Community	Multiple individuals and/or sub-groups who share the same general object	Staff of the clinic, collaborating clinics/hospitals
Rules	Refers to both the horizontal division of tasks and the vertical division of power and status between the members of the community	Use of time Measurement of outcomes Criteria for reward
Division of Labour	Explicit and implicit regulations, norms and conventions that constrain actions and interactions within the activity system	The task and decision-making powers of the physician, the nurse, the nurse's aide and other employee categories

Three key principles of Activity Theory [11] form the foundation of our design technique: (1) an activity system is the main unit of analysis; (2) activity systems are connected to each other and create networks of activities; (3) the contradictions within an activity system or between activity systems lead to changes within the network of activities.

III. EXTENSION OF ACTIVITY THEORY

In this research, we further modified and extended Activity Theory to develop a need-finding tool for biomedical devices, illustrated in Fig. 3, which is based on the three main principles mentioned earlier. In addition, the activity system constituents are expanded and defined at a more granular level.

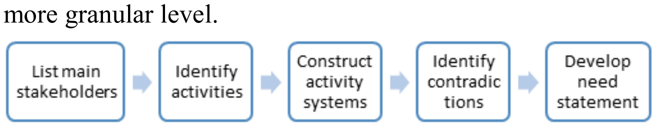

Figure 3. The proposed Activity Theory-based need-finding process

The technique starts with identifying stakeholders and their activities. Following that, activity systems can be constructed using the framework shown in Fig. 4.

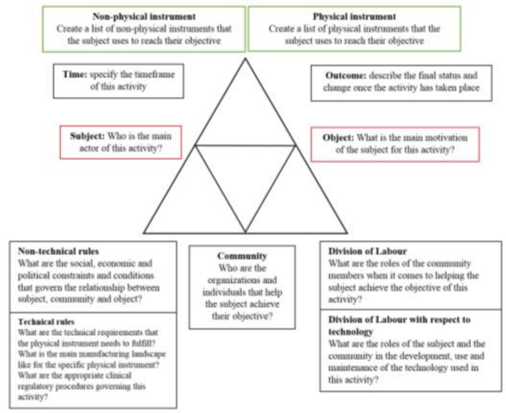

Figure 4. Extended Activity System

Once the activities are constructed, the contradictions within and between their elements are identified. Contradictions are network tension points and represent opportunities for change, which in turn can be expressed as need statements.

Steps 2 and 3 of this technique are built upon the first two principles of Activity Theory: the activity system is the unit of analysis, and activity systems are connected to each other in a network. Step 4 leverages the principle of contradictions and how they indicate desired change.

As illustrated in Fig. 4, there are four main changes to the activity system definitions and structure.

1. "Object" describes the motive for the subject to perform the activity as opposed to a problem space at which the activity is directed. By understanding the motives of the subject, a design team can gain a deeper understanding of the activity. In addition, this definition encourages a higher level of granularity in activity analysis [11].

2. "Instruments" is divided into "physical instruments" and "non-physical instruments. Non-physical instruments include language, signs and intrinsic knowledge [13]. This subcategorization encourages the design team to further examine the impact of each instrument within the context of the activity.

3. "Rules" is divided into "technical rules" and "non-technical rules". Technical rules are constraints and conditions in the design and maintenance of physical tools. Non-technical rules include social norms, economic constraints and political dynamics. The explicit differen-tiation between the rules helps the team understand how the technical rules interact with both the non-technical rules and the rest of the activity system.

4. "Division of labour" is separated into the "division of labour" and "division of labour with respect to technology". This distinction will again allow the team to understand how

tasks associated specifically with technology interact with other tasks and the system.

The main purpose of the modified activity system is to provide a more structured and detailed framework to medical device design teams to derive an improved analysis of needs.

IV. Example Case Study

To demonstrate the use of the proposed need finding technique in a real-world problem space, the technique was applied to the 3D-PrintAbility Project [14].

A. Project background

The 3D-PrintAbility Project is a collaboration between the University of Toronto, Christian Blind Mission and an institution in Uganda, CoRSU Rehabilitation Center. The team developed a 3D scanning and printing system for fabricating low-cost, fully customized, below-knee prostheses. One member of the research team conducted pilot observations of the 3D-PrintAbility Project at Kampala, Uganda in May 2015. For the purposes of this application, we analyzed CoRSU's prosthetics manufacturing process before the 3D-PrintAbility project was initiated. The common practice of CoRSU's orthopedic technologist was to use traditional plaster-casting methods to fabricate prostheses. The following stakeholders were identified from a preliminary Cycle of Care and Flow of Money analysis: patient, orthopedic technologist, caregiver, family members, hospital and government.

B. Constructing Activity Systems

For the purpose of this case study, we focused on two activities: "patient – to be able to do daily activities independently" and "orthopedic technologist – to provide the best possible care to the patient". The template in Fig. 4 was used to develop the two activity systems. The activity system of the patient is illustrated in Fig. 5.

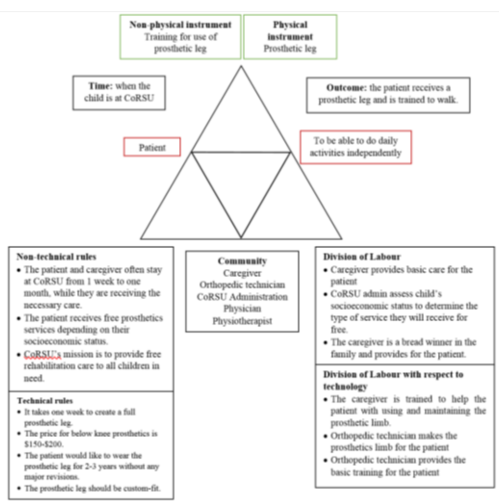

Figure 5. Sample Activity System of the patient

C. Identifying Contradictions

The following contradictions were identified between the two activities.

Contradiction between the rules in the patient activity:

a. CoRSU's budget is limited in its ability to provide prosthetics services. Even with the low cost of $150-$200 per prosthesis, with available funding they cannot afford to provide solutions to all children who need them. To maximize the number of children served, they conduct a socioeconomic assessment of their patients and offer free services only for patients who cannot afford to pay for their own prosthetics.

Contradictions between the two activities:

b. Caregivers are often the breadwinners in the family and therefore work to provide for their children (the patients). However, caregivers have to be at the hospital, often far from their hometown, and must stop working for approximately one month while the patient is being fitted with the prosthesis. This situation creates an extra financial burden on the caregiver and patient.

c. The prosthetic fit should be such that the patient is comfortable when wearing it daily for a period of 2-3 years. However, the prosthetics are made by hand, resulting in a high incidence of human error involved in their fabrication.

D. Identifying need statements

The contradictions were translated into need statements by identifying the desired change and target audience. The need statements that correspond to the above contradictions are:

a. A method to provide affordable and quality prosthetics to patients with a challenged socioeconomic status.

b. A method to provide more accessible prosthetics services to patients living in remote areas.

c. A method to develop prosthetics with a more accurate and a custom fit for patients such that the prosthetic can be used for a longer period of time

Our extension of Activity Theory was based on the observations made in the context of a severely resource-limited medical device deployment environment. We sought to validate this formulation with a series of human-subjects trials with biomedical engineering students involved in university-based design projects. Methods and results are presented in the next section.

V. Study Design and Methodology

A. Objective

The aim of this study is to compare the use of two need-finding design techniques, the Biodesign and the modified Activity Theory techniques, as used by biomedical engineering student teams. The two techniques were compared qualitatively for the purposes of preliminary analysis. We expected that modified Activity Theory would provide a more structured approach to need finding and it would allow the design team to understand the scope of the problem more holistically.

B. Study Protocol

For this study, the research team collaborated with a graduate-level design course, Engineers-in-Scrubs (EiS), at the University of British Columbia [15]. The study protocol was approved by UBC's Behavioural Research Ethics Board, and participants provided written informed consent.

EiS teams were asked to take part in a 2-hour need-finding workshop, in which they were facilitated through the two design techniques. The teams brought two problems that they wanted to investigate to the workshop. The workshop started with a 10-minute introduction, and then teams were facilitated through an exercise with the two techniques, each for 45 minutes. The session concluded with a 15-minute post-workshop questionnaire. Biodesign and modified Activity Theory were referred to as Method A and Method B during the workshop. The order of the methods was random.

C. Data collection and analysis

All three of the EiS teams participated in this study, for a total of 12 participants. The three teams were different in size: 5, 4, and 3 students. The collected data include video recording of the sessions, design artefacts (e.g., post-its and flipchart paper), post-workshop questionnaires and facilitator notes. In addition to the facilitator's observations, a preliminary thematic analysis of the design artefacts and the post-workshop questionnaire was completed.

VI. Preliminary Results and Discussion

The workshops proceeded as expected for all of the three teams, resulting in a large amount of discussion and artefacts. Based on the facilitator's observations, the teams were able to use both of the techniques effectively; however, modified Activity Theory required a longer explanation than Biodesign. Modified Activity Theory was more novel for the participants and required them to use more advanced terminology. The facilitator also observed that teams ended up focusing solely on a single solution or medical device when employing the Biodesign technique. The same tendency existed for modified Activity Theory; however, the teams appeared to incorporate a wider set of design parameters when using this method. This was also validated by the observation that the participants generated diverse questions about their problem space using modified Activity Theory.

The coding scheme for this thematic analysis included the following categories: political, economic, technical (design, training and maintenance), social and clinical (treatment and diagnosis). Artefacts from the modified Activity Theory process covered all categories of the coding scheme, and the political, economic and social codes were used as frequently as the technical and clinical codes. However, Biodesign predominantly included technical and clinical codes.

A thematic analysis was also done on the post-workshop questionnaires. The coding scheme fit under four major categories: developing the need statement, the Biodesign process, Activity Theory-based method, and general feedback. The participants thought that both of the techniques allowed them to investigate the needs space. Overall, the participants thought it was more intuitive to implement Biodesign because they were more familiar with it. However, they highlighted that modified Activity Theory allowed them to delve "more in-depth" and think "outside of the box". The participants mentioned that they had a higher level of detail and had to be more explicit with modified Activity Theory as opposed to Biodesign.

VII. Conclusion and Future Work

This paper describes the development of the Activity Theory-based technique and its application using a case study. Preliminary qualitative analysis of the study indicates that the Activity Theory-based technique is a promising need-finding tool in biomedical device development. The results suggest some expected advantages of this technique. Teams covered a broader spectrum of issues and went more in-depth with their analysis. The new technique was more difficult to use; however, we anticipate that teams will become more proficient with exposure and training. Further data collection and quantitative data analysis are necessary for more thorough evaluation of this technique.

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