# EXPLORING ROLES AND RESPONSIBILITIES IN THE DESIGN OF 3D PRINTED PROSTHESES
# WHAT QUESTIONS NEED TO BE ASKED?

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## ABSTRACT

Prosthetic limbs are complex assistive devices that are made to augment and/or enhance the functional abilities of a person with a missing limb or limb difference. With emerging technology such as 3D printers and low-cost design software, functional prosthetics are being made and provided outside traditional prosthetic manufacturing/service provision settings. Alternatively, they are being made in the community by members who may not have the technical skills in prosthetic design. Further research is needed to evaluate the functionality and quality of these 3D printed prosthetic limb models and explore the feasibility of alternative prosthetic provisions that are available in the community. Can we create teams of prosthetic designers that utilise expertise of prosthetists, engineers, end-users and their caregivers? A methodology to evaluate team-based interactions in the design of prosthetic devices is discussed.

## LITERATURE REVIEW

Technology is meant to support and reflect the participation needs and preferences of persons across a lifespan. As the population trends predict, all families will eventually be touched by disability (Disabled World, 2016). Participation, social opportunities and economics will undeniably be impacted by the change in the population demographics (more people living longer and the rise of chronic disability). Research has shown that assistive technology (AT) can have a significant impact on the lives of families (Hammel, Lai, & Heller, 2002). As well, it has shown that the successful integration of assistive technology to meet the needs of a person with a disability is influenced by the family unit (Parette, VanBiervliet, & Hourcade, 2000). With this said few studies have centered families' voices and shared how a family with a member who has participation challenges becomes aware of, gains access to, or motivated to create their own assistive technology to meet their participation needs (Parette, & Brotherson, 2004). More information is needed about the daily lives of families impacted by participation challenges and how resources such as assistive technology can be designed and accessed to address a family's need. With current statistics reporting that 8 out 10 Canadians who identify as having a disability require some form of assistive aid to perform tasks of daily living and over 1.3 million persons with disabilities reporting not having the assistive technology when they need it; a viable solution to address this gap is needed (Statistics Canada, 2006; Statistics Canada, 2012). Is there a means by which we can increase access to expertise, equipment and materials to empower families to design and build individualized assistive technology thereby reducing some of the assistive technology demand?

A prosthetic limb is an example of a complex assistive device that is made to augment and/or enhance the functional capabilities of a person with a missing limb or limb difference. Accessing such a device has typically been in partnership with professionals within a health care setting. However, with emerging technology, 3D printers and low-cost design software, prosthetics are being made by community members who do not necessarily have professional training on how to design, build and fit prosthetics.

Families and end-users have an opportunity with emerging technology to participate more actively in making an assistive device. With instructions on how to create AT available online and with access to fabrication tools such as 3-D printers and creative spaces (i.e. Makerspaces) in the community, building and designing AT are seemingly more accessible than ever before (Scherer, 2002). However, studies have shown challenges in building functional AT using these resources (Hook, 2014). For example, Hook (2014) found that even though spaces and tools to build AT were available, these resources were not used because participants reported a lack of skill or confidence to build AT. Community made assistive technology is changing the rules and roles of how AT is made and by whom. The social implications of these changes influenced by emerging technology have yet to be fully examined.

If families are equipped with these skills and tools, could they meet their own assistive technology needs? Further to this, can functional assistive tools be created in homes and in the community? How would quality be assured? If so, how is the social pathway to gaining access to assistive technology changed? What are potential changes in technology that would further facilitate the design and building of assistive technology from non-commercial sources? Equally important, how is the industry of assistive technology and the training of future engineers, clinicians, and manufacturers of AT impacted? These are a few questions that such an endeavor generates.

## THEORETICAL APPROACH

Dewsbury, Clarke, Randall, Rouncefield, & Sommerville (2004) summarize the role of creating assistive technology within the perspective of the social model of disability as a human rights endeavor. The social model of disability defines disability as embedded in a disabling environment. The design of assistive technology should be informed by the lived experiences of the potential user (Scherer & Lane, 1997). This approach centers the experience of the user and not the designer. The theoretical framework of this research will be informed by the social model of disability, which maintains that disability is embedded in society rather than the biological impairment of a person. This framework situates this research in the body of knowledge geared to informing the design and modifications of the environment.

### Research Question

How can users of assistive technology and their families be supported to build assistive technology that fits, functions, and matches their needs?

### Specific Objectives

The objectives of this research are:

i) To engage end-users and families in the design and building of assistive devices using emerging technology);
ii) To centre the stories of end-users, families and people in support roles;
iii) To understand the personal, social, and ethical implications of designing and building AT;
iv) To determine how to leverage community resources to increase accessibility and allow for end-users to build and design functional AT.

## EVALUATING THE DESIGN AND BUILD EXPERIENCE

Developing a framework to support the building of AT requires observation and reflection of team players. Our model involves observing and evaluating the roles of end-users, engineers, families and clinicians when designing and building assistive devices. The resulting interaction framework will provide guidelines for teams to work cohesively in the development of functional AT.

### Hands-On Design Experience:

The hands-on design experience includes four phases: 1) Introduction; 2) Design and build; 3) Evaluation and training; and 4) Debrief.

**Participants:** The participants will include a clinician (orthoptist/prosthetist), an engineer, an OT, end-users and their families/caregivers who wish to design and build their own AT.

### Phase 1: Introduction, Space, Tools, Roles, and Expectations

Families and end-users will come with different skills and interest on what role they want to play in the design and build of their AT. They will have the opportunity to learn what a 3D printer does, understand design software that can be used to print images, and we will gauge their level of support needed in using the technology and designing their AT. The creative space provided will be one that can actively respond to this variety. The research will provide an opportunity to discover what resources would be optimal to support families and end-users with a variety of skills and roles they want to engage in the process of "making" functional AT. Training protocols in learning how to use tools, resources in creative space and the functionality of the newly built AT will be established.

### Phase 2: Design and Build Focus - 3D Printed Prosthetic Hand

As a case study in the development of this framework, a prosthetic hand will be developed. 3D printed prosthetic hand designs are noted as one of the most downloaded designs for 3D printable images. (Buehler, Branham, Chang, Hofmann, Hurst & Kane, 2015). In the design phase, the team will work together to develop the specific attributes and design specifications. If the end-user is sufficiently comfortable with creating their own model (computer assisted design CAD model), the family can "virtually test" their own designs before the building of the device occurs.

Once the virtual design has been created, the team will work together in ensuring that the correct protocols exist for the building of the prosthesis. If many parts are required, the team will work together in assembling them. This will ensure that everyone involved understands how the parts are put together, how accurately the design represents the final model and how to fix the prosthesis if a specific part becomes unusable or is broken.

## Phase 3: Evaluation and Training with Assistive Technology

Assessing the functionality of the device can be accomplished using outcome measures. Formal evaluation and safety protocols will be established to ensure that the device is functional, properly tested, and effective training by the occupational therapist is conducted. This study will utilize outcome measures that have gone through rigorous testing for reliability, validity and clinical utility to assist in evaluating prosthetics. Wright (2006) suggests the use of multiple outcome measures be used when prosthetics are prescribed to determine their impact. This study will utilize outcome measures with sound psychometric properties to ensure that the analysis of the information gathered reflects what was intended be measured. In particular, research has shown that outcome measures cover particular aspects of prosthetic provision, which include: evaluating the function of the device, the functional gains made by user using the device, and the impact the device has made on self-reports of quality of life.

Three outcome measures will be used to assist in informing the functional performance of the prosthetics made during the iterative design process. The outcome measures were chosen to reflect setting goals for the prosthetic, determining the functional strengths and limitations of the device and of the user when using the tool. The outcome measures include: COPM: The Canadian Occupational Performance Measure (COPM) is an individualized, client-centered measure that assists in establishing goals in AT use. It has also been shown to detect change in a client's perceived performance and satisfaction of their performance over time (Law, Baptiste, McColl, Opzoomer, Polatajko, & Pollock, 1990). UNBN**:** The University of New Brunswick - Test of Prosthetics Function is a test that score's a user's ability to use a prosthetic during functional training (Sanderson & Scott, 1984). PUFI**:** The Prosthetic Upper Extremity Functional Index (PUFI) is an outcome measure that specifically provides a way to evaluate a user's use of prosthetic during daily activities, and provides a measure to determine ease of task performance with and without prosthetic. The PUFI also includes a test for perceived usefulness of prosthetic (Wright, Hubbard, Jutai & Naumann, 2001).

## Phase 4: Debrief

The impact of the process will be discussed in greater detail. Critical reflection of the process and the outcome will explore the meaning behind the experience. Members of the design team will be interviewed with questions such as: How has the experience shaped their understanding of AT and their needs? How were they able to meet their AT needs? How have views changed of what is possible to access at the community level to support making AT? How supportive was the space in encouraging active participation by end-users and families?

## Data Collection and Analysis

Time spent in all phases will be *video-recorded* and then transcribed to understand the social exchanges and dynamics of engaging in the process. *In-depth Individual and Group Interviews* will be used to uncover and describe a specific aspect and opinions of the experience – guided by phenomenological interviewing. Phenomenological interviewing entails gathering and compiling observations and conversations to discover meaning in the experience (Bevan, 2014). Collection and interpretation of the data will be guided by the following structure of phenomenological study. 1) Contextualization: reconstructing contextual narratives of personal experiences; 2) Descriptive narrative context questions as mentioned above; 3) Reflexive: descriptive and structural questions of modes that are individual and/or shared; 4) Descriptive and deconstructive modes: establish these through active listening and varying the structure of questions.

## CLINICAL SIGNIFICANCE OF RESEARCH

This research aims to develop a framework of team interaction through an understanding of the social context, lessons learned, skills, and resources needed to design and build functional AT. It will provide a better understanding of why families and end-users choose to build, and the skills and resources needed in making "designing and building" functional AT more accessible to end-users and families. It will help inform knowledge and practice. The personal, social, and ethical implications in gaining access to creative spaces and having the opportunity to create tools to shape how one can experience and participate in the world has yet to be fully realized. Exploration is needed to discover the possibilities. Creative spaces and emerging technology have a major role to play actualizing this further.

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