

Perspective

Co-Creation Facilitates Translational Research on Upper Limb Prosthetics

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Abstract: People who either use an upper limb prosthesis and/or have used services provided by a prosthetic rehabilitation centre, hereafter called users, are yet to benefit from the face-paced growth in academic knowledge within the field of upper limb prosthetics. Crucially over the past decade, research has acknowledged the limitations of conducting laboratory-based studies for clinical translation. This has led to an increase, albeit rather small, in trials that gather real-world user data. Multi-stakeholder collaboration is critical within such trials, especially between researchers, users and clinicians, as well as policy makers, charity representatives, and industry specialists. This paper presents a co-creation model that enables researchers to collaborate with multiple stakeholders, including users, throughout the duration of a study. This approach can lead to a transition in defining the roles of stakeholders, such as users: from participants to co-researchers. This presents a scenario whereby the boundaries between research and participation become blurred and ethical considerations may become complex. However, the time and resources that are required to conduct co-creation within academia can lead to greater impact and benefit the people that the research aims to serve.

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Introduction

The aim of the paper is to present a perspective of how *co-creation* can enable collaboration with multiple stakeholders throughout a research study. Within the field of upper limb prosthetics, we share our perspective on how co-creation can facilitate a transition from short-term laboratory-based testing, to long-term in-home trials. Also, we offer our broad perspective on the challenges and opportunities of how co-creation can contribute to the translational of academic knowledge into clinical practice.

Translating research into clinical practice for the benefit of users of upper limb prosthetics has been notoriously slow. As aforementioned, with the term “users,” we refer to people who either use an upper limb prosthesis and/or have used the services provided by a prosthetic rehabilitation centre. The last two decades have seen increased academic interest in prosthesis user needs and satisfaction [1]–[18]. However, proposed advancements that address the identified needs have not led to a reduction in device

abandonment, which has highlighted the gap between published research and its translation into clinical practice [6] [19]. Furthermore, evidence has highlighted that laboratory metrics and findings are not always consistent with clinical and/or outcomes of importance to users [20]. This exposes a limited understanding of how devices and/or systems fit within the daily lives and routines of users, for example: within a home environment where experimental constraints are relaxed [21]-[23]. The current rate of progress in addressing user needs poses an opportunity to explore how different research approaches can lead to advancement [24]. By incorporating user-centred information throughout all stages of research; new knowledge can be generated that may reduce the gap between academic developments and positive impacts on prosthesis users' experience in their everyday lives.

Background

In recent years, translational healthcare research, which aims to translate research into practice to reach patients [25], has experienced benefits of expanding the range of collaborative stakeholders [26]-[27]. Within pharmaceutical development, open innovation has enabled collaboration between researchers, industry agencies, users and policy makers [26]. Open innovation provides a framework that enables research teams to conduct external collaborations, by sharing information, resources and intellectual property [28]. Within healthcare, collaboration with patients and oncology nurses have resulted in studies that identify improvements for cancer diagnosis services, such as mobile applications [29]. Within assistive technology, studies have presented how using techniques to engage a range of stakeholders can assist in creating solutions that integrate into people's lives. For examples, rehabilitation advancement for people with multiple sclerosis [30], and technological innovation for people living with dementia [31]. Living Laboratories that monitor everyday activities of people within real-life scenarios have enabled researchers to evaluate the usability of healthcare technologies and assess health outcomes [32]. Participatory research methods implemented within Living Laboratories have provided an opportunity for users to share feedback and suggestions for solution improvements [32]. A consistent factor within these examples is the involvement of patients or users, as collaborators within the research process; and how their involvement informs research outcomes. Co-creation [Figure 1] can be an approach to facilitate such a form of collaboration, in particular between: researchers, users, and clinicians.

Co-creation is an approach that emerged from participatory design practice, with a focus on generating ideas with users as partners rather than subjects/participants [33]. The past two decades have seen an uptake of co-creation within many fields, which has led to variations of definition [33]-[34]. Figure 1 presents the definition of co-creation that the article will use, which seeks to assist in translating new knowledge into healthcare practice [35]. The definition presents four processes that facilitate collaboration with multiple stakeholders throughout a study, which can be applied to prosthetic research.

Co-Creation

"The generation of new knowledge that is derived from the application of rigorous research methods that are embedded into the delivery of a program or policy (by researchers and a range of actors including service providers, service users, community organisations and policymakers) through four collaborative processes:

- 1. generating an idea (**co-ideation**);
- 2. designing the program or policy and the research methods (**co-design**);
- 3. implementing the program or policy according to the agreed research methods (**co-implementation**),
- 4. the collection, analysis and interpretation of data (**co-evaluation**)."

Figure 1. Co-Creation Definition [34].

Collaboration with academic, clinical and industrial stakeholders throughout a study can lead to academic publication and intellectual property in the short term. Broadening the range of stakeholders to include users, policy makers and representatives from charitable and/or non-governmental organisations can facilitate the translation of knowledge into clinical practice in the long term [36]. This is especially evident when users directly contribute towards research studies by providing input based on their lived experiences [37]. Collaboration with users can lead to collecting real-world data, which can inform healthcare policy evidence [38]-[39]. The implementation of co-creation throughout the duration of research studies, can lead towards a significant step-change in how research practice develops within the field of upper limb prosthetics.

Application to Upper Limb Prosthetic Research

The co-creation approach presented in Figure 2 presents an example of how multiple stakeholders can collaborate flexibly throughout a prosthetic research study. The approach, based on Pearce [35], was developed to present an example of: (1) how the four collaborative processes of co-creation could occur over the duration of a research study, and (2) how a combination of stakeholders could collaborate throughout the approach.

All four collaborative processes of co-creation occur within each stage of prosthetic research, namely: research proposal development; experimental design; analysis of results; and dissemination of knowledge. In practice, research can be iterative, compared to the linear stages presented in Figure 2. However, Figure 2 presents an example of an adaptable reference point, based on the broad trajectory that research studies follow.

The core and peripheral stakeholders presented in Figure 2, document an example of how this approach could facilitate collaboration with a range of people throughout a study. The combination of stakeholders and their involvement in each collaborative process may vary at each research stage, depending upon the study [Figure 3]. Core stakeholders are integral to the work within a study stage, by providing knowledge, expertise and informed opinion. Collaboration with peripheral stakeholders occurs on an as-needed basis, with their participation contributing to the range of relevant opinions and expertise.

Based on the stakeholder combination presented in Figure 2: core stakeholders could be involved in the proposal stage, by developing a collaborative proposed programme of research. Within the experiment stage, core stakeholders could collaborate to develop experimental protocols. Within the analysis stage, users could influence future studies, by sharing their experience of the research, which could also inform published research within the dissemination stage. Figure 2 presents all stakeholders as core in the dissemination stage, as all parties can share research findings collaboratively, and within their own respective fields. Furthermore, the involvement of policy makers at each stage of the

approach enables research teams to create an on-going connection between research and policy. Figure 2, as aforementioned, is an example of a co-creation approach for upper limb prosthetics, other examples within the field are also documented, which present a range of collaborative stakeholders throughout a study [40].

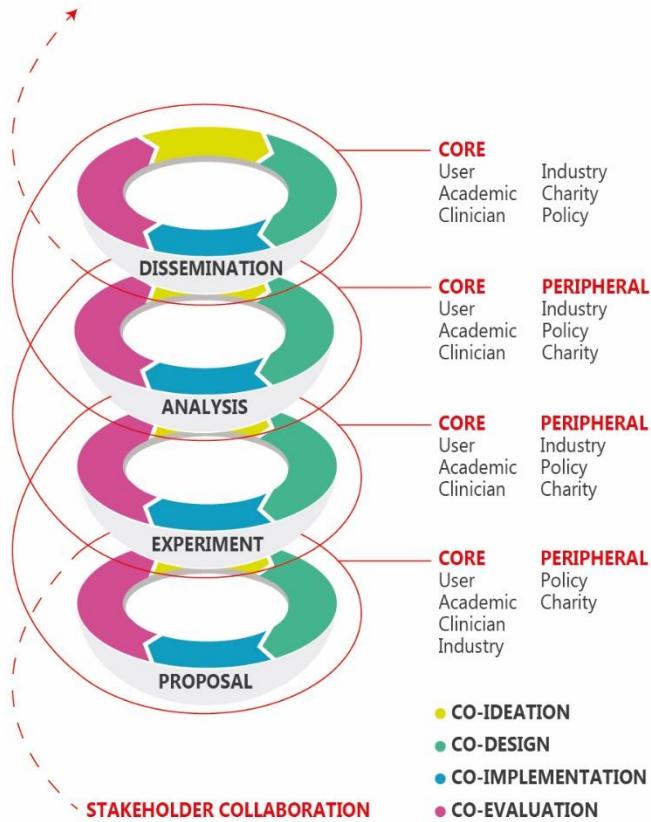


Figure 2. Co-Creation Model for upper limb prosthetics.

An emerging route towards clinical translation for upper limb prosthetics is in-home trials [41], which presents a scenario whereby research transcends the laboratory, entering into home environments. Whilst in-home trials are technologically feasible [22]-[23], [42]-[43], strategies that enable stakeholder collaboration within this context, are not currently documented within the literature. Co-creation can be used as an approach to enable such collaboration; an example of which is presented in Figure 3 that illustrates one way that user involvement could occur throughout an in-home trial. The four stages of research presented in Figure 3 are in linear form, however iteration across the stages, and within the collaborative processes of co-creation is possible in practice. For example, during the proposal stage, users can influence the proposed research, by providing feedback, and sharing experiences of using a prosthesis within the home. During the experiment stage, users can collaboratively develop experimental protocols, with a focus on the context of in-home trials, including opinions of remote data collection. The refinement of the protocol may require iteration, such as between co-ideate and co-evaluate within the experiment stage. Based on the experience of an in-home trial, users can influence the summary of findings within the analysis stage; including the identification of outcome measures are important in relation to the study. This can lead to forming recommendations for future studies. Furthermore, during the dissemination stage, users can contribute to peer-reviewed articles and conference proceedings as co-authors, and share research findings at outreach events.

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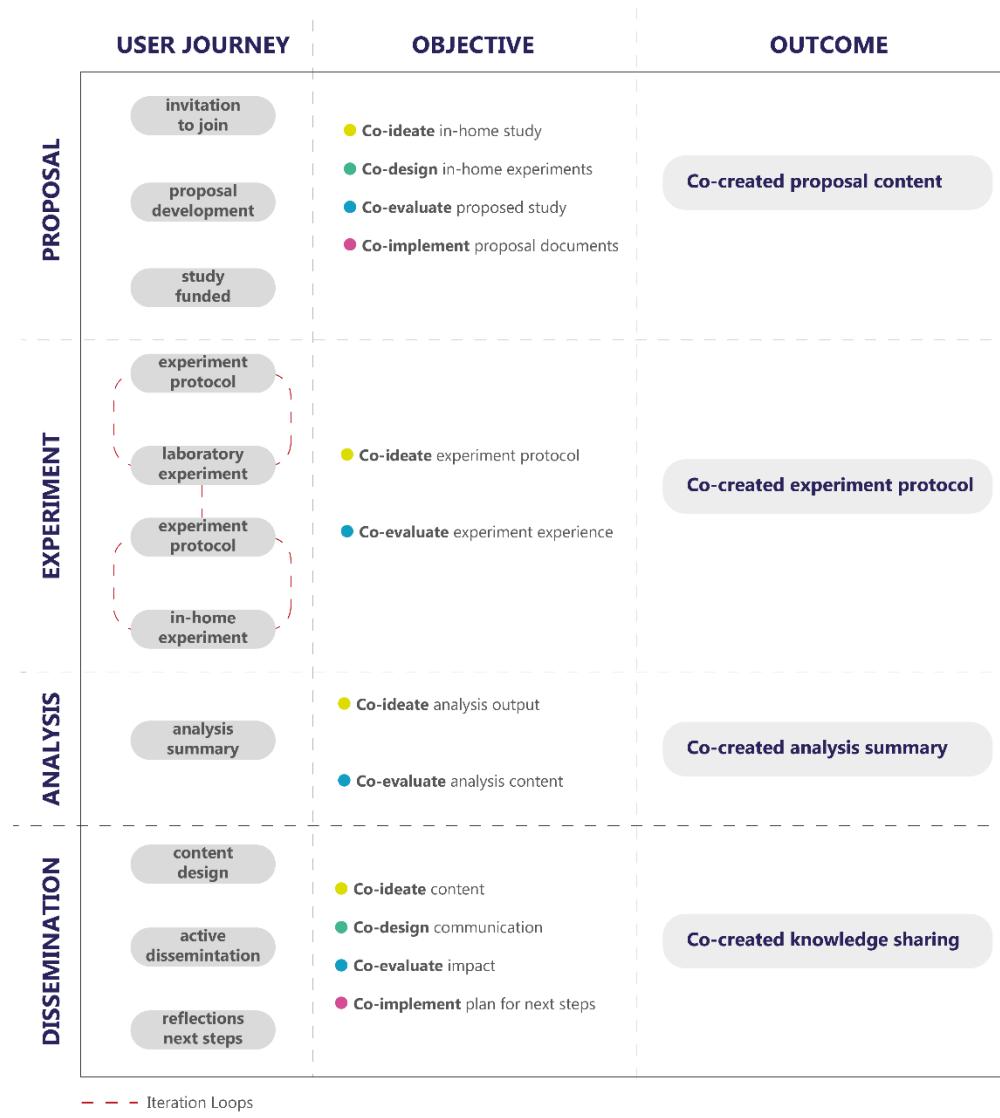


Figure 3. Co-creation for an in-home trial - a potential user journey map.

Recruitment of users to in-home trials can be achieved through building relationships with existing research participants or forming new relationships through avenues, such as social media or connections to rehabilitation centres. Communication methods between researchers and users is key within the recruitment process. To that end, a variety of methods can be conducted, for example: project videos, text and pictorial documents, and phone and/or video conversations. Accessibility considerations are key within the recruitment process, ensuring that chosen mediums are accessible to all involved. Identifying clear inclusion criteria is beneficial when recruiting users to such studies. Given the longitudinal nature of in-home trials, which can run over several years, researchers and users can benefit from establishing how to work together and build relationships over a long-term basis. Initially, this can be addressed by defining stakeholder roles and responsibilities from the study onset.

Building collaborative relationships between researchers and users is based on forming trust through ensuring transparency between both parties and conducting ongoing informed consent [44]. Conducting research with users that incorporates user input from an early project stage can assist in forging strong relationships between stakeholders and lead to an effective research experience for all involved [40]. The key aspect of the model presented in Figure 2 is the identification of users as core stakeholders within all four study stages and the range of core stakeholders at the dissemination stage. This range of

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collaborative stakeholders can lead to greater success in translating academia research into clinical practice. 171
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Challenges and Opportunities 173

The scenario presented above illustrates a transition in defining user involvement within research: from participants to co-researchers. Such an approach comes with risks; for example, the blurring of the boundaries between research and everyday life could have a negative impact on users. Ethical considerations can therefore become more complex. For example, ensuring that meaningful, informed consent is obtained throughout the study [44]. In addition, the design of blinded experiments in collaboration with users is a pertinent consideration, such that biases are addressed. A key principle to be addressed and re-visited throughout the duration of a co-creation study is *power sharing*, which identifies research as jointly owned through neutral understanding [45]. Adopting an approach that involves users as core stakeholders will be challenging [37]. However, resources are available to assist the exploration of ethical considerations in collaboration with stakeholders throughout the course of a study, such as The Ethical Roadmap [46]. Furthermore, existing examples demonstrate that including users can lead to capturing new knowledge and experience that is vital in conducting meaningful, impactful research [47]. Therefore, it is timely to establish how co-creation can successfully work in practice. 174
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Suggestions for the field 191

Collaboration between academics and users is central to co-creation, which is supported by the definition of patient and public involvement: researching with people, rather than for people [48]. Conducting academic research with patients and/or the public has been facilitated by recent changes to ethical review mechanisms, which are proportionate to the level of risk within the study [49]. National and international research funders publish calls that require patient and public involvement within studies that are proposed. In addition, pairing schemes that provide opportunities to build knowledge of how policy is informed by research evidence can provide a platform to develop collaboration between academic and governmental partners [50]. However, a top-down approach can influence the challenges that are addressed by academic research, in addition to the research methods that are utilised. This is in contrast to a bottom-up structure whereby a population, such as a user group, defines a challenge, and the methods that could be used to conduct research within that field. Consequently, a top-down approach can lead to tokenism, which may not result in co-created research that address the needs of a population [51]. Furthermore, the time required to implement co-creation can be deemed impractical, especially for early career researchers, due to contract duration and lack of career incentives for this area of research [52]. Given the multi-disciplinary nature of co-creation; from a broad perspective, academic institutions may benefit from assessing how studies are facilitated by current structures and career progression routes. Academic institutions can adopt a phased approach, which could be initiated by re-addressing incentives for conducting public involvement [52]. 192
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The rapid growth of online collaborative platforms during the Covid-19 pandemic has provided new possibilities to address the challenges of allocating time and identifying convenient locations to bring stakeholders together throughout a project. This is especially beneficial to users who require a flexibility and balance of their own work and personal responsibilities, alongside their contribution to academic research. In addition, technological capabilities of connecting multiple people through internet enabled devices, termed: the Internet of Things, has provided remote methods of user interaction with clinical and academic teams within the field of rehabilitation [53]. Advancement in technology has enabled such forms of engagement within research, however, there are people who are 215
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digitally excluded from such studies, based on internet and device accessibility, and digital literacy [54].

Collaboration between academics and clinicians, as presented in Figure 2, can provide a bridge that connects researchers with users [55], which forms a collegiality whereby users can contribute throughout the research process.

Conclusion

The growth of user-centred studies within healthcare research generally presents an opportunity to identify approaches that can enable collaboration with multiple stakeholders throughout a study. Co-creation has the potential to aid in realising this opportunity, by identifying users as core stakeholders. Given the dynamic range of input that each stakeholder provides, the future of co-creation depends, in-part, on forming an inclusive approach that nurtures collaboration, especially between researchers and users. Now is the time to implement co-creation and frame its contribution towards enabling academic knowledge to translate into long-term user benefits and positive impacts, through the advancement of upper limb prosthetic devices and the overarching ecosystem of clinical care.

Author Contributions:

All authors have contributed to the formation of the presented co-creation approach for translational research for upper limb prosthetics. Specifically, HJ, SigridD, and KN conceptualized the co-creation approach and the methodology outlined within the paper. TE-C, DM, and ES contributed to the development of the presented approach, based on their experience of using an upper limb prosthetic device and receiving clinical care. HJ, SigridD, and KN created the visualization of the co-creation approach. HJ produced the original draft preparation. HJ, SigridD, KN, DD, MD, GW, and HW contributed to the writing – review and editing. All authors have read and agreed to the published version of the manuscript.

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Dedication

The authors wish to dedicate this paper in memory of Edward Small, who contributed to the original article, in shaping the idea of how co-creation can enable research to be conducted with users.

Conflicts of Interest: The authors declare no conflict of interest.

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<https://doi.org/10.1007/s12008-019-00641-z> Supplementary Materials: The following are available online at www.mdpi.com/xxx/s1, Figure S1: title, Table S1: title, Video S1: title.