Addressing barriers to the provision of custom assistive technologies

Fifteen policy recommendations accompanying a proposed digital design and manufacturing system

Jonathan Howard, Dominic Eggbeer, Sally Cloke and Katie Beverley

INTRODUCTION

Assistive technology (AT) has the potential to alleviate the impact of chronic health conditions on individuals, caregivers, healthcare services, and wider society. Up to 70% of AT is, however, prematurely abandoned since it does not meet user needs. Preliminary research has highlighted the potential of a co-design approach that prioritises the needs of the user, combined with a digital design and manufacturing system (DDMS). Evidence suggests that this method can deliver personalised AT with improved fit, functionality and aesthetic value. If implemented at scale, such a model could reduce premature AT abandonment and deliver significant social, environmental and economic benefits.

This policy document accompanies the Tidal Network+ project "Improving the efficiency of co-designing personal assistive technology through the use of digital design and manufacturing systems" (Howard et al., 2023). The project adopted user-centred design methods to engage with occupational therapists (OTs) and rehabilitation engineers to identify needs for a new digital design and manufacturing system to produce custom AT. During the study, our discussions revealed several policy-level barriers that would limit the effective implementation of such a system. This document discusses barriers that emerged in three key areas: **education and skills**; **funding**; and **regulation** and proposes policies that decision-makers in the healthcare sector should consider in order that the full benefits of such a system are realised.

POLICY AREA 1: EDUCATION AND SKILLS

Policy Recommendation 1: Conduct workflow analysis with occupational therapy and rehabilitation engineering teams to implement common processes for user need gathering.

The OTs taking part in our study indicated enthusiasm to be involved in parts of the digital design process for custom AT that aligned to their current practice – identifying and assessing client goals,

searching for solutions, testing and gathering user feedback and reviewing the use of the design with users. Some OTs also expressed interest in being involved in other parts of the custom AT process (generating design ideas, generating computer models of designs and manufacturing products) but cited a lack of time and staffing resources as a significant barrier to increased involvement in all parts of the process. This is in line with the findings of previous studies into barriers to the provision of custom AT (Hofmann *et al*., 2016; McDonald *et al.*, 2016; Slegers *et al*., 2022). As such, translating ideas into designs and producing devices usually falls to rehabilitation engineers. As we identified in our study, disparity in data gathering requirements and a lack of communication between healthcare teams in this early user needs phase can lead to duplication of effort in defining requirements for custom AT. A streamlined workflow and common processes for gathering user needs could go some way towards addressing this issue.

Policy Recommendation 2: Lobby to ensure that rehabilitation engineering is included in the UK Government's Shortage Occupation List.

Whilst a DDMS can go some way towards scaling up custom AT, it is not a panacea for the significant skills and workforce shortages that exist in occupational therapy and rehabilitation services. Occupational therapy is on the UK Government's Shortage Occupation List, which allows it to recruit overseas via the Health and Care Worker Visa. Currently, clinical engineering (including rehabilitation engineering) is not included on the list, despite there being a significantly higher number of people in the current workforce approaching retirement age and a limited capacity for existing staff to teach or to train new recruits (Institute of Physics and Engineering in Medicine, 2023). This is of particular concern since an ageing population and attendant increase in chronic diseases means that need for AT continues to grow. The WHO estimates that, by 2050, over 3.5 billion people will require at least one piece of AT (WHO, n.d).

Policy Recommendation 3: Work with Higher Education Institutions to develop and promote new occupational therapy programmes that frame the career as a problem-solving discipline and introduce skills that are relevant to future careers in both occupational therapy and rehabilitation engineering.

Our participants identified further "deterring barriers" (Iammarino *et al*. 2012) to participation in the design and manufacture of custom AT. The barriers have also been recognised by other researchers and include limited awareness of the potential of digital design and production methods (Aflatoony & Lee, 2020; Slegers *et al*., 2022), assumptions regarding the complexity of digital manufacturing processes (McDonald *et al.*, 2016; Slegers *et al*., 2022) and a perceived lack of skills and knowledge that limit the translation of user needs into viable product solutions (McDonald *et al*., 2016; Alharbi *et al*., 2020; Aflatoony & Lee, 2020; Slegers *et al*., 2022).

A recent study on diversity amongst OT students (Karaba Backstrom *et al*., 2021) recommended that undergraduate programme promotion should focus more on the role of occupational therapists as problem solvers, and that the scope of what is delivered within programmes should be broadened.

Building on this, framing occupational therapy as a problem-solving profession could enable the reimagining of future OT services. Digital design and manufacturing processes could be introduced as potential problem-solving skills in occupational therapy, ensuring that OT degrees and training opportunities reflect both emerging patient needs and potential new directions for the profession.

Policy Recommendation 4: Develop through-programme relationships with product design undergraduate degrees and rehabilitation engineering services to share skills and undertake projects.

There are multiple pathways that lead to a career in rehabilitation engineering. Recruitment may come from undergraduate degree programmes accredited to the Practitioner Training Programme, or graduate-entry level via the Scientist Training Programme or dedicated Masters' programmes, where a background in engineering, applied physics or mathematics is advised. We reviewed entry requirements to programmes and for entry-level jobs and noted limited opportunities for entry to the profession from product design programmes.

Although we acknowledge that health boards and universities may consider product design qualifications under the umbrella of engineering, this may not be obvious to product design graduates, who are likely to have become familiar with the principles of user-centred and usability design and design for 3D printing (also known as additive manufacturing) within their degree programmes. In addition, the design of task-based AT is a common application of the design process in many programmes. For example, the BA Sustainable Design programme at Falmouth University includes a compulsory second year module on inclusive and user-centred design. Students use modelling and 3D printing technologies to produce assistive devices for everyday living.

Another common feature of undergraduate product design programmes is live projects, where students respond to a design brief set by an external organisation, based on a real-world challenge they have encountered. Live projects may engage a whole student cohort on short projects within a module or may form the basis of a longer project for individual students. They are highly valued by students and academic staff as they give students the opportunity to experience the application of design in unfamiliar contexts. However, academics often struggle to find live projects for students. There is an opportunity to use live projects as a mechanism to engage with product design students who could bring skills relevant to the digital design of custom AT into rehabilitation engineering services.

Policy Recommendation 5: Explore opportunities for the development of new roles that bring user-centred design processes into rehabilitation engineering services.

Following on from the recommendation to engage more with undergraduate product design, we suggest that it may also be necessary to introduce new job roles that reflect the growing importance of user-centred design and design for 3D printing processes. A clinical technologist career pathway focused on the custom design of assistive devices would work in complementarity with current pathways in the rehabilitation engineering sector.

Policy Recommendation 6: Work with Higher Education specialists to develop short, asynchronous and low-cost continued professional development (CPD) programmes in design of custom assistive technology.

Now we turn from attracting new talent to the custom AT field to focus on capacity building amongst existing staff. For those OTs who do have an interest in becoming more involved in the making process, there are limited opportunities for them to develop design and production skills. Whilst our DDMS model aims to remove the complexity from this process, designing and making custom AT in accordance with standards and regulations (see Policy Area 3) may still be a desirable continued professional development opportunity for OTs. Our participants indicated that there is currently limited opportunity for OTs to engage in CPD. A similar situation arises in surgical and prosthetic design, where daily activities leave limited time for practitioners to take part in formal courses and there is little funding for professional development.

Recently, Eggbeer and team have been developing CPD-accredited video-based asynchronous training for healthcare professionals in the field of surgical and prosthetic design. Participants report the asynchronous approach as a positive step, with training supporting them to meet professional body requirements for skills development and career development. Meanwhile, the course delivery team has benefited as the training increases the reach and impact of previous research in line with the targets of the Research Excellence Framework. There may be opportunities to follow a similar model of training and development for healthcare professionals for the design and manufacture of custom AT.

Policy Recommendation 7: Establish a nationwide Community of Practice that supports exchange of knowledge and experience between custom assistive technology practitioners.

Focusing on the custom AT skills that currently exist across health boards, there is little opportunity for the exchange of knowledge, skills and experience between practitioners in what remains an emerging area. This risks the duplication of effort and resources, and inefficient use of time. Progress in custom assistive technology is mainly reported at conferences and in academic journals once a project has been completed, but interactions during the design process between people who share a passion for custom assistive technology development are more limited. Community of Practice models have been shown to support social learning processes that happen at the edge of existing knowledge (Wenger, 1998), are widely used as support networks in healthcare (Seibert, 2015) and have been used to address perceived skills and workforce gaps in regional rehabilitation engineering activities (Gowran *et al*., 2016).

Policy Recommendation 8: Invest in research into the role of the open-source maker community in the hospital supported provision of custom AT.

Even with these policy measures, it is still important to note that there is a very small community of healthcare practitioners working in the digital provision of custom small devices. To rapidly upscale the

production of custom AT, it may be necessary to bring external skills into the system. In the ideation session, our participants discussed the potential role of maker communities. We will discuss the regulatory implications of this in Policy Area 3, but we propose that any Community of Practice could engage with the open source making communities to extend skills and production capacity. This will require research into community needs, skills and roles within the evolving service to avoid some of the pitfalls that were identified during the COVID-19 pandemic (Frazer *et al*., 2020).

POLICY AREA 2: FUNDING

Policy Recommendation 9: Raise awareness of the status of funding for small assistive devices through investment in research to understand the cost-benefit implications of providing such devices.

Our participants explained that there was no access to small aids through health services, explaining that typically small aids are bought by patients and their families. This has the potential to bring about inequalities for AT users in two ways: first, families living in poverty may be unable to purchase AT that could increase the quality of life for the user or, possibly, enable them to contribute economically; second, in the case of digitally-excluded groups, it may be difficult for them to identify the range of AT devices available and choose ones that meet the needs of the user. It is also challenging for OTs who reported purchasing small aids at their own expense to try with patients with complex needs. This has the net effect of putting an unfair financial burden on OTs while disempowering them, as they feel unable to offer good recommendations to people with limited resources to buy AT.

Whilst some charities (for example Scope and the MS Society) and the UK Government's "Access to Work" scheme offers funding for some devices, levels of funding, devices covered, and eligibility criteria differ. This creates a funding landscape that is difficult for both user and healthcare provider to navigate and contributes to the "postcode lottery" that is often cited as a serious issue for healthcare provision. Whilst the focus of our study is on custom AT, if funding for standard AT is not available there is a risk that OTs will turn to a new DDMS to fill the gap for their patients, rather than purchase off-the-shelf devices that could meet their needs in a more cost- and resource- effective manner.

Policy Recommendation 10: A programme of capacity assessment to quantify the potential size of the market for custom assistive technology, initially within a single health board, with the potential to extend the approach nationally.

Although some of our participants were aware that custom AT could be produced in-hospital by their health board, others were not. This is likely to have impacted referral numbers to date. Such limited awareness makes it very difficult to quantify the need for a service, to understand the potential costs and benefits to the organisation, and to determine the most appropriate business model to create value for AT use. A programme of capacity assessment could give a clear picture of the likely need and resource availability for custom AT, making it easier to plan for future service provision.

Policy Recommendation 11: A comprehensive technology assessment of custom AT.

Durocher *et al.* (2017) have argued that health technology assessment should be applied to determine where public funding should be directed towards AT. This involves considerations of the "effectiveness of the technologies, cost-benefit analysis, sustainability of the technology and its funding". In agreement, we suggest that such an approach should be extended to custom AT to support decision-making around funding the service.

Policy Recommendation 12: Explore social business models that can share risk and value between funders and health boards.

Exploring the extent to which charities or other funders are aware of the potential for the provision of quality assured, robust and effective custom AT produced in-hospital goes beyond the scope of this work. Thus, we recommend that, once a capacity assessment exercise (Policy Recommendation 10) has been conducted, the role that alternative funders may play in custom AT is explored, acknowledging the restrictions in funding that currently exist and the need to create value for all partners through social business model innovation (see, for example, Chirarini *et al.,* 2023).

POLICY AREA 3: REGULATION

Three main areas of concern emerged through the project regarding regulation: compliance with Medical Device Regulations; issues of intellectual property management in the event of distributed production systems; and data protection.

Policy Recommendation 13: Lobby UK government to address the barriers to custom assistive device design and manufacture in future medical device regulations.

Our OT participants discussed how the Medical Device Regulations have affected their existing practice, reducing their willingness to adapt equipment to meet user needs:

"*OTs are less able to adapt equipment nowadays compared to previously as [there are] more restrictions on not being able to adapt outside of manufacturer instructions."*

"[I] have been asked in the past to adapt things. Due to the MDR, we may not be able to adapt things any more as a profession, due to liability issues."

Both OTs and rehabilitation engineers described the application of the Medical Device Regulations to small custom assistive devices as "a grey area" and, in a naturally risk-averse environment, this is a significant barrier to innovation. A recent scoping study of legal and data protection issues in medical 3D printing (Pettersson *et al*., 2023) has identified: non-standard and vague terminology for production processes and for the act of customisation; a lack of clarity over who in the value chain is designated a manufacturer and how liability might be assigned for product failure (of particular importance for

distributed systems); and the legal status of Computer Aided Design (CAD) files. There is an urgent need to resolve these issues. Post-Brexit, the UK Government is reforming regulation around medical devices, and this provides an opportunity to raise the challenges faced by the custom assistive device innovation ecosystem.

Policy Recommendation 14: Include discussions about intellectual property from the beginning of the DDMS development, involving relevant legal experts.

Once there is clarity around roles and liability within the regulations, the opportunities for distributed manufacturing and the potential inclusion of open-source maker communities can be explored. This brings with it governance and regulatory issues as identified by Srai *et al*. (2016), including questions of ownership and intellectual property management. Pettersson *et* al. (2023) identify the lack of a legal definition for CAD files in the Medical Device Regulations as a particular point of concern, as it is currently unclear whether there is any legal protection afforded to them. They also express concern over the legal issues that may arise if in-hospital production begins replicating existing devices, rather than adopting a fully customised approach. At this time, we are unsure what the most appropriate approach to IP management would be, given the full range of actors in the DDMS is not yet clarified. However, we note with interest the work of Esmaeilian *et al.*, (2019), who have explored the potential of Blockchain technologies for managing IP between multiple partners and managing the risk of unregulated devices or those that infringe existing intellectual property entering the market.

Policy Recommendation 15: Engage with healthcare data protection specialists to understand the data management risks of the DDMS throughout its development.

In a distributed manufacturing system (in which the new product development process may be geographically dispersed) that deals with patient data, there are obvious concerns over data security that must be addressed to avoid its malicious use. These become particularly important when the possible future role of maker communities is considered, given the principles of data sharing that underpin the open-source movement. Rigid compliance with existing data protection laws (such as General Data Protection Act (GDPR) or UK GDPR) will be necessary, but there may be other data protection issues that come to light as the DDMS develops. Pettersson *et al*. (2023) also identify potential risks for in-hospital production that are not well-addressed by existing Electronic Health Records and Picture Archiving and Communication Systems. Exploring the data management implications of the DDMS is beyond the scope of this project, and outside the knowledge of the research team, but it is critically important that this is done prior to its implementation.

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