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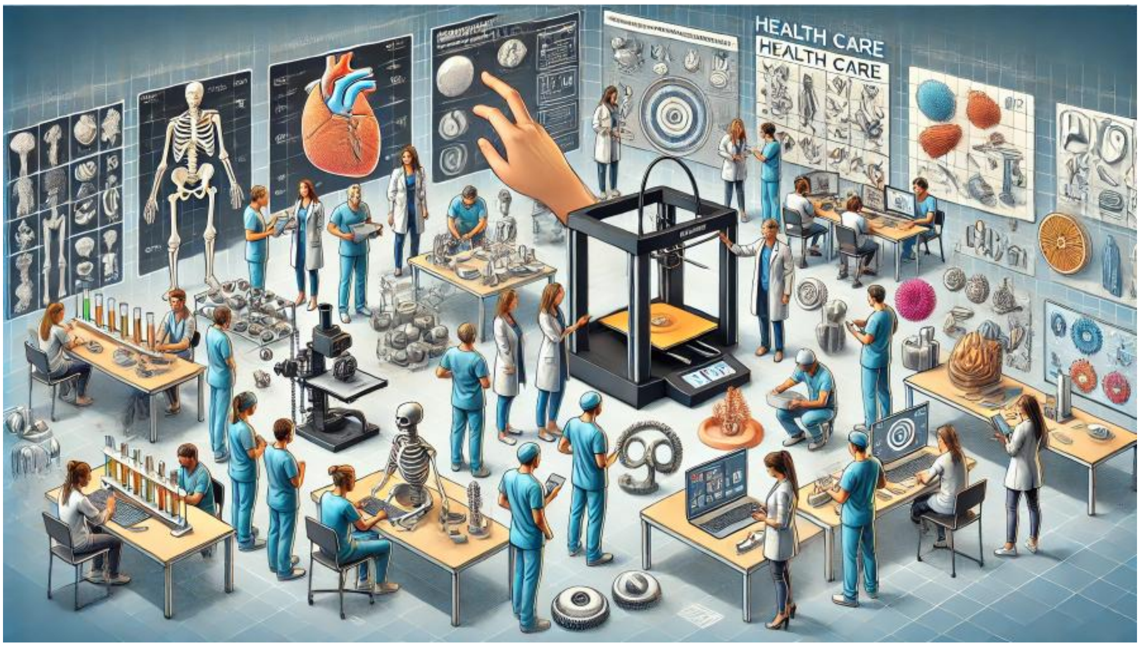
TECH HEALTH

Patient-Centered Participation Models for Implementation in 3D Printing-Based Digital Health Tools

A Guide for Vocational Education and Training - VET



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1. Definition of Patient-Centered Care

Patient participation represents an essential partnership between patients and healthcare professionals, in which both work together towards the common goal of achieving the best possible health outcomes (1).

The traditional model of health service delivery, where the patient is seen as a passive element and recipient of care, is insufficient to address the challenges of the healthcare sector (2). To overcome system shortcomings, it is necessary to adopt a more participatory, bottom-up, and open approach. The active participation of patients, families, and the community throughout the decision-making process, from identifying needs to implementing solutions, is clearly linked to success in developing health and well-being solutions (2,3).

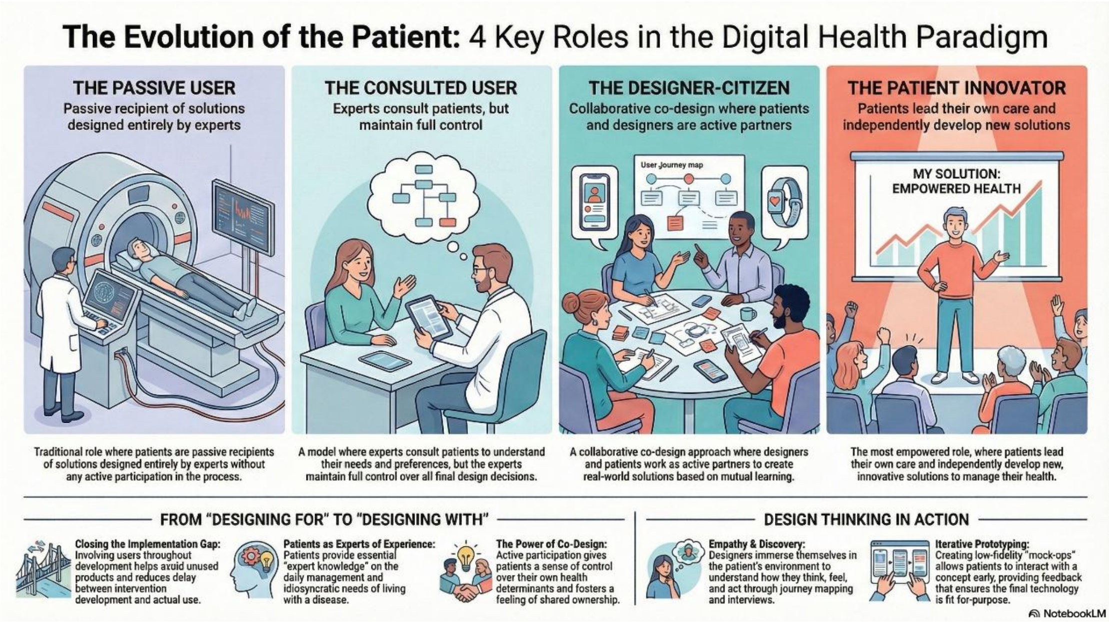
Patient participation in healthcare is an active and multifaceted process that involves close collaboration between patients and healthcare professionals. This process is designed to empower patients, giving them the knowledge, skills, and confidence necessary to make informed decisions about their health. Through a patient-centered approach, the healthcare system is adjusted to meet the unique needs and preferences of each individual, ensuring that they are active participants in their own care (4).

One of the fundamental pillars of patient participation is shared decision-making, which allows for direct collaboration between the patient and healthcare providers to jointly choose the most appropriate treatment options. This approach not only improves the quality of care but also reinforces patient autonomy and satisfaction with the healthcare process (5).

Patient participation is also reflected in promoting behaviors that support health and in the active self-management of chronic conditions. By involving patients proactively in their health, better disease management is facilitated, and a healthy lifestyle is promoted, which can positively impact clinical outcomes. This collaborative approach not only empowers patients but also contributes significantly to the effectiveness and efficiency of the global healthcare system (6).

The emerging transformation in the health sector involves a shift from passive patients to active or expert patients. This new figure, the patient, is no longer just a bearer of needs but a driving force for innovation in the healthcare sector. The expert patient can autonomously manage prevention and self-diagnosis and can actively collaborate with health professionals or the health system in their own care (2,7,8).

Research suggests that patient participation has positive effects, improving health outcomes, therapeutic compliance, self-efficacy, and return on investment, as well as other benefits, such as better treatment results and patient satisfaction. There are several levels of participation, ranging from consultation to collaboration. When patients participate as equal partners, value is created, and their contribution and collaboration are enhanced and validated (7, 9).



2. Patient participation in digital health

In the digital era, active patient participation is redefining the healthcare landscape, showing significant improvements in clinical outcomes across a variety of medical conditions. The integration of digital technologies into health management has enabled patients to play a more active and engaged role in their own care, which is essential for optimizing both treatment effectiveness and the patient experience (10).

High patient engagement in the use of digital health solutions has proven fundamental in improving treatment adherence and clinical outcomes in areas such as growth disorders and surgical interventions, including joint replacements and cardiac surgery. Moreover, this active participation is associated with reductions in surgical cancellations and hospital stays (11).

In terms of surgical procedures, patient involvement through digital tools not only enhances their satisfaction but also contributes to a more efficient recovery by reducing the overall use of healthcare services (12). In the management of chronic diseases such as diabetes, digital health has facilitated better self-management and promoted more consistent treatment adherence, which in turn significantly improves patients' quality of life (13).

The impact of patient participation also extends to the field of mental health, where greater interaction with digital interventions positively correlates with better mental health outcomes (14). Similarly, in metabolic diseases such as nonalcoholic fatty liver disease, well-structured digital health programs have led to significant improvements in weight loss and cardiometabolic health (15).

Digital health has also demonstrated significant benefits for older adults with multimorbidity, helping them monitor symptoms and well-being, which results in reduced symptom exacerbation and increased physical activity. This technology not only allows patients to better understand and manage their conditions but also facilitates greater autonomy and empowerment in their daily care (16).

These examples highlight the crucial importance of patient participation in the implementation of digital health solutions. By empowering patients to take an active role in their treatment, digital health not only improves clinical outcomes and treatment efficiency but also elevates overall patient satisfaction and quality of life. This patient-centered approach illustrates the transformative potential of digital technologies in modern healthcare.

3. The participation of the patient in assistive technology created with 3D printing

3D printing offers numerous benefits for both patients and healthcare providers. For healthcare providers, it enhances surgical planning and execution, facilitates interdisciplinary collaboration, and offers potential cost savings and improvements in efficiency. For patients, it provides personalized medical interventions, improves surgical outcomes, and enhances patient education and engagement. These advantages underscore the transformative potential of 3D printing in modern healthcare (17).

Patient involvement in the context of medical 3D printing refers to the active process of engaging patients in decision-making related to their own medical care, especially regarding the design and manufacture of personalized medical devices such as prostheses, orthoses, or implants. This involves ongoing communication between patients and healthcare professionals to ensure that 3D printed products are tailored to the patient's individual needs, preferences, and expectations (18).

Patient involvement is crucial in medical 3D printing because it enables treatment to be customized at a level of detail that was previously impossible, thus increasing the effectiveness of treatments and medical interventions. In the field of prostheses and orthoses, this technology enables the creation of prosthetic limbs and orthopedic supports specifically designed for each patient, ensuring a better fit, functionality, and comfort (19). This not only improves aesthetic outcomes but also increases patient satisfaction; as in the case of 3D printed dentures, which present advantages such as better retention and comfort compared to conventional ones, with studies demonstrating that the retention of 3D printed dentures made from conventional and digitized molds is superior (20).

3D printing is redefining modern medicine by placing the patient at the center of the medical process. It transforms abstract medical data into concrete, personalized models, thereby improving communication, understanding, and treatment effectiveness. Additionally, 3D printing enhances patient education and engagement by enabling the visualization of conditions and procedures, improving patients' understanding of their treatment, with clinicians reporting a significant improvement in patients' comprehension of their procedure/disease (21).

In pediatric cardiology, for example, 3D-printed heart models have become an essential tool. These models allow young patients and their families to visualize cardiac anomalies and understand the necessary surgical procedures. This technique not only improves accuracy in surgical planning and execution but also empowers patients and their families by actively involving them in the decision-making process, helping them fully understand their medical situation and proposed interventions (22).

Similarly, in the treatment of spinal tumors, 3D-printed models visually explain the location and extent of the tumor, as well as the details of the planned surgery. This clear and tangible visualization significantly boosts patient confidence and fosters deeper engagement with the treatment. Patients can interact with models of their own anatomy, allowing for more open and detailed dialogue with their doctors, and therefore, more informed and collaborative decision-making (23).

In urologic oncology, 3D-printed prostate models used in robot-assisted radical prostatectomies offer a dual advantage: better patient preparation and increased surgical precision. These models not only educate the patient about the surgical procedure and the anatomy involved but also assist surgeons in performing more precise and safer interventions, resulting in better clinical outcomes and faster recovery (24).

The customization of implants and prostheses through 3D printing in ophthalmology and plastic surgery demonstrates another level of patient involvement. The ability to design prostheses that fit perfectly not only improves functionality and comfort but also meets patients' aesthetic expectations. This not only ensures better integration of the implant into the patient's daily life but also significantly elevates their satisfaction and quality of life (25).

By empowering patients with detailed knowledge and active participation in their medical procedures, 3D printing facilitates safer, more precise interventions tailored to individual needs, highlighting the transformative potential of patient involvement in the future evolution of healthcare.

4. Models of patient participation in 3D printing assistive technology

In the field of medical care, 3D printing has emerged as a crucial enabler for patient-centered care models, particularly in the creation of personalized assistive devices that significantly improve users' quality of life. The combination of user-centered design and 3D printing technologies shapes an innovative approach to the development of assistive technologies. This approach is based on continuous interaction among engineers, designers, occupational therapists, end users, and, in some cases, family members. This interactive process is essential during the initial design phases and throughout iterations to promote improvements between conceptual and functional prototypes (26).

Designing assistive technology with 3D printing requires a collaborative and multidisciplinary effort where technical knowledge and engineering tools are combined with a deep understanding of the user's therapeutic and occupational performance needs. This approach not only increases the functionality and accessibility of the developed devices but also encourages personalization and innovation in assistive solutions that truly address the users' specific needs.

The multidisciplinary approach not only enhances the product development process but also ensures that assistive devices are more widely accepted by users, reducing the incidence of abandonment and increasing the efficiency in the use of resources. By centering the design on the user, 3D printing technology in the assistive field promotes greater independence and improves quality of life, making this integration a powerful tool in the evolution of personalized healthcare.

In the development of assistive devices, the integration of user-centered design from the early stages of conceptualization through to final production is of utmost importance. This includes the application of various design techniques and methods, such as: focus groups, user-centered design workshops (UCD), surveys and questionnaires, ethnographic studies, and Participatory Action Research (PAR); all of which enable the creation of prototypes and final products that are precisely tailored to the users' measurements and requirements (27)

Focus Groups: This technique brings together small groups of patients to discuss and explore their experiences and perceptions regarding the healthcare they have received. The group dynamic allows for in-depth discussion, revealing needs and expectations that might not be evident in a more formal setting or in individual interviews. Focus groups are especially useful for obtaining feedback on new service proposals or modifications to existing procedures (28)

User-Centered Design Workshops: These workshops directly involve patients in the design of healthcare solutions that affect them directly. Through interactive sessions, patients contribute their unique perspective, which helps designers and healthcare professionals create more intuitive and accessible services. This direct collaboration ensures that the final solutions are not only clinically effective but also welcomed by end users (29-34)

Surveys and Questionnaires: These quantitative tools provide data on patient preferences, behaviors, and satisfaction on a large scale. They are essential for assessing the quality of healthcare services and identifying areas for improvement. In addition, surveys and questionnaires can be designed for long-term follow-up, allowing healthcare institutions to measure changes and trends over time (30, 35, 36)

Ethnographic Studies: Through detailed observations and fieldwork, this methodology allows researchers to immerse themselves in patients' everyday lives. Ethnographic studies are particularly valuable for understanding how patients manage their conditions in their own environments, providing deep insights that may be invisible in a clinical context (37)

Participatory Action Research (PAR): PAR is a collaborative approach that involves patients not just as study subjects but as active co-researchers. This model fosters a symbiotic relationship between researchers and participants, enabling the development of solutions that genuinely reflect patients' needs and desires. PAR is particularly effective in communities where changes in healthcare can have significant cultural or social impact (38).

Implementing patient-centered care models not only improves clinical outcomes but also promotes greater patient involvement in their own care, which is essential in the modern era of personalized medicine. These methodologies ensure that healthcare is not only accessible and effective but also more humane and responsive to individual needs.

5. Strategies for Integrating Patient Participation: design thinking

Design Thinking is a human-centered problem-solving approach that aims to generate innovative solutions by integrating people's needs, technological possibilities, and the requirements for an organization's success (39, 40). It is defined as a practical, collaborative, and iterative process that prioritizes deep empathy with the user, teamwork in multidisciplinary groups, and rapid, action-focused prototyping. Unlike traditional linear approaches, Design Thinking allows us to tackle complex problems (or "wicked problems") where solutions are not obvious from the outset (41,42).

We can liken the design thinking process to the double diamond model, which is a visual representation of the design process that guides the way from discovering and defining a problem to developing and delivering a meaningful solution (43). Its structure is based on alternating phases of divergent thinking (expanding the focus to explore) and convergent thinking (narrowing the focus to decide) (40,43). This model is generally divided into two main diamonds (40,43,44):

The first diamond: The right problem

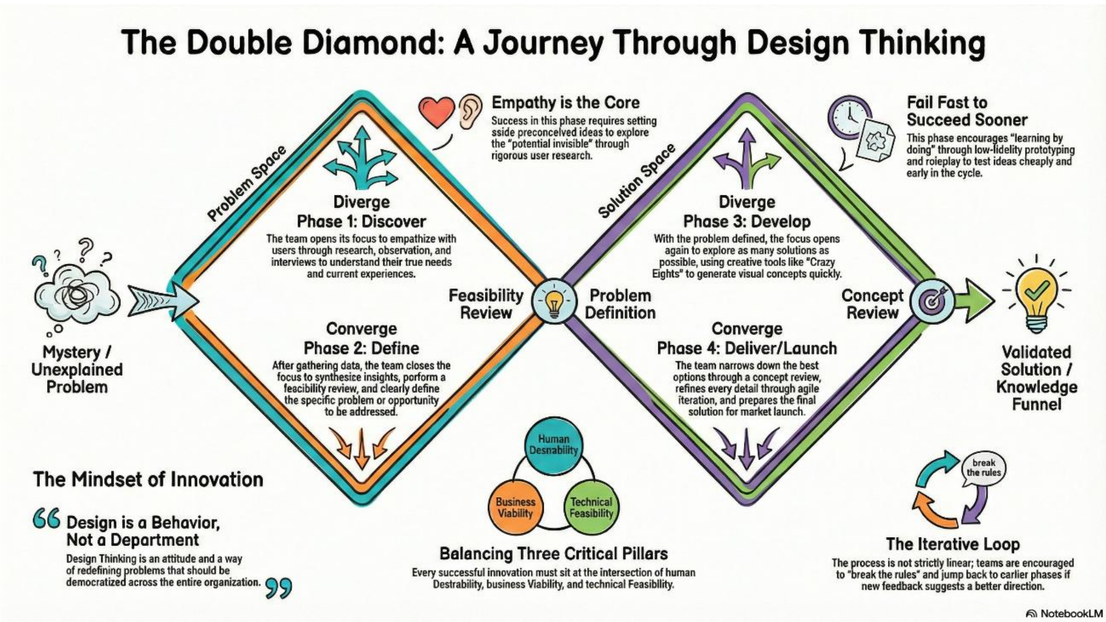
This segment focuses on thoroughly understanding the challenge before attempting to solve it.

- Discover (Divergence): This phase involves opening the focus to empathize with users, gather data, and observe their reality in order to understand their latent needs. In this stage, "mysteries" or unexplained problems are identified.
- Define (Convergence): The goal is to filter and synthesize the collected information to reach a clear definition of the problem or challenge statement, ensuring that the team is working on the right opportunity for both the user and the business.

The second diamond: The right solution

Once the problem is defined, the process repeats to find the best way to solve it.

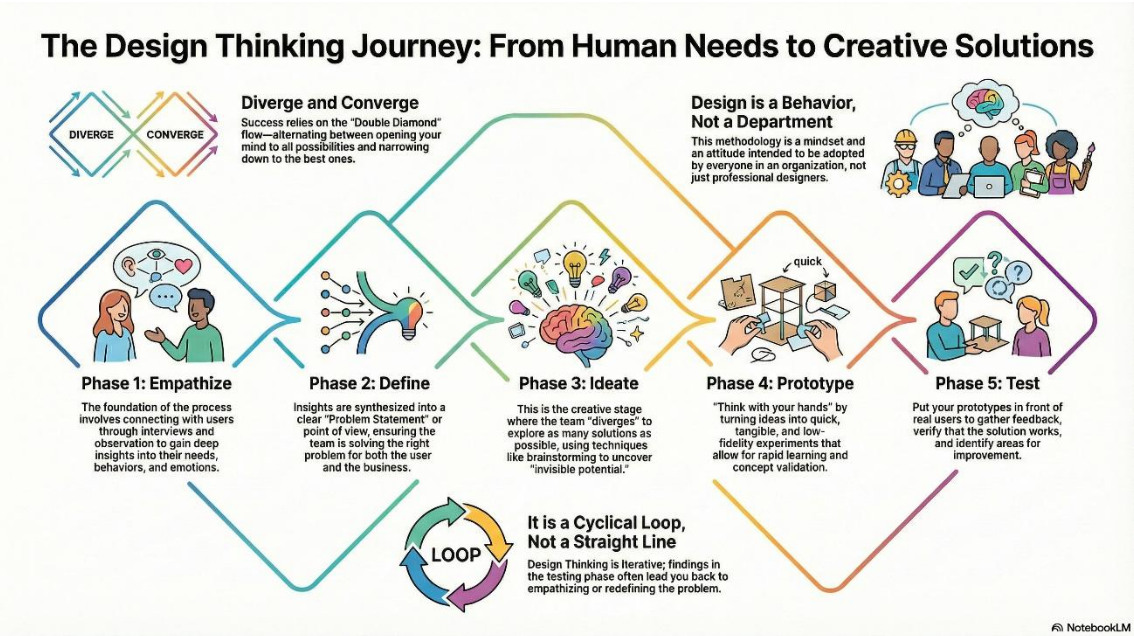
- Develop or Ideate (Divergence): The range of possibilities is opened again to generate as many creative solutions as possible, quick prototypes, and alternative concepts as possible, without judging them initially.
- Launch or Refine (Convergence): In this final phase, options are narrowed by selecting the ideas with the most potential, conducting user testing, and iterating to perfect all details before final implementation.



Following this scheme, the Design Thinking process unfolds through the following phases:

- **Empathize:** This phase involves deeply immersing in the user's world to understand their experiences, feelings, motivations, and challenges (40, 42). Tools such as open interviews, contextual observations, and empathy maps are used to uncover needs that users themselves may not be able to express (40, 45).

- **Define:** The goal is to analyze and synthesize the information gathered in the empathy phase to identify the central problem (42). The challenge is reframed from the human user's perspective, creating a clear, specific, and actionable "problem statement" or design challenge (39,40).
- **Ideate:** This stage encourages a massive generation of creative solutions without initially judging their feasibility (39,42). Techniques such as collaborative brainstorming or "Crazy Eights" are used to explore a large number of ideas, moving between divergent and convergent thinking (39,40).
- **Prototype:** Selected ideas are transformed into tangible, visible, and low-cost representations such as sketches, cardboard models, storyboards, or simulations (40,42). The aim is to create something the user can interact with to quickly learn from mistakes before making major investments (39,40).
- **Test:** Prototypes are tested with end users in their real environment to gather feedback (42,46). This phase is not the end of the process but rather an opportunity to learn, refine the solution, and, if necessary, return to previous stages to adjust the design based on what truly works for the person (39,47).



In the hospital and healthcare context, low-cost prototyping (or low-fidelity prototyping) is a fundamental phase of Design Thinking that aims to turn ideas into tangible and affordable representations in order to "fail fast and cheap" before making major investments. 3D printing is one of the digital technology tools that enables this rapid and low-cost prototyping, so using it together with the user offers many advantages (48)

6. Case Studies

The following table shows some examples in which design thinking techniques have been used to co-create assistive devices with users, using 3D printing to prototype solutions.

Author	Theme	Empathize	Define	Ideation	Prototype	Test
Aflatoony, 2021 (29)	Co-designing 3D printed assistive technologies (AT) with occupational therapists (OT), designers, and end-users	PW 1: comprehensive clinical assessment of the user´s abilities. Limitations goals, OTs identified off-the-shelf AT solutions that meet user´s needs.	PW2: Low Fidelity DIY 3 D printing prototyping. End users collaborate with OT in co-design AT prototypes	PW 3: Industrial designers act as technical facilitators to translate prototypes into tangible AT solutions	PW 4: Designers as "design thinkers" to actively contribute ideas to identify needs, brainstorm a wide variety of possible solutions an develop custom AT prototypes	Experiences, strengths and weaknesses: focus groups and semi-structured interviews. Device utilization outcome: legibility of end user´s handwriting
Benham, 2023 (35)	Mobile device accessibility with 3D printed devices for individuals with physical disabilities	Initial interviews and analysis of previous AT use.	Initial interviews: Self-identified accessibility needs of the mobile device	Choice of designs from catalogue and customization with the team	In 1–2 weeks, the device was custom-made and 3D printed with Crealty Ender-3: 3D-printed supports, styluses, and mounts	Quebec User Evaluation of satisfaction with assistive device (QUEST 2.0). Canadian Occupational Performance Measure (COMP)
Dressen, 2017 (49)	A FabLab as facilitator for personal fabrication of tools to self-manage diabetes	Insights of day-to day issues: Participants with type 1 Diabetes mapped their experience of using self-care and self-management tools daily, together with designers.	Participatory observations and interviews with endocrinologist provided further understanding	Designers and participants collaboratively built scenarios to tackle specific issues. Scenarios were translated into videos and used as an input for FabLab.	Two 3D printed prototypes: system to roll up the thread of the catheter and a clip system to attach toll to the body, through PD workshops with participant with several iterations	Tests in the user's daily life
Higgins, 2022 (33)	Creating 3D Printed Assistive Technology Through Design Shortcuts	Real users worked with teams of PT students to model and design devices	Translating clinical needs into design challenges and communicate with makers	Student-led ideation with real users, using clay models and paper forms	3D printing prototypes (Pencil grips, wrist splints, cylindrical weights for strengthening, and cutlery adapters	Direct feedback on the comfort and functionality of the final 3D printed AT.
Howard, 2024 (30)	Assessing the use of co-design to produce bespoke assistive technology solutions within a current healthcare service	Identification of everyday problems with users in the community by OT and physiotherapists	Prioritization of challenges for activities of daily living	Ideation of solutions with users through sketches or low-fidelity prototypes	Functional prototypes through device development iterative design loop	Quebec User Evaluation of satisfaction with assistive device (QUEST 2.0). Psychosocial Impact of Assistive Devices Scale (PIADS)
Thorsen, 2019 (50)	From patient to maker. A case study	The participant illustrated her impairments and the challenges thy posed, and me a list of ADL task for which she would have liked to become autonomous	Analysis of difficulties in ADL using the Individually Prioritized Problem Assessment (IPPA) questionnaire	Remote co-design editing CAD in real time	Ergonomic handle printed in TPU	Individually Prioritized Problem Assessment (IPPA)
Thorsen 2024 (51)	From patient to maker. People with cerebral palsy	Observation of participants' daily activities through videos	Videos about movement patterns, gripping methods, and eating habits	Digital manufacturing method involving CAD software service, slicing program, 3D printer and a videoconference application. Several iterations	Spoon/fork holder	Individually Prioritized Problem Assessment (IPPA) Quebec User Evaluation of satisfaction with assistive device (QUEST 2.0).

AT: assistive technologies; OT: occupational therapists; PW: participatory workshop; DIY: Do it yourself; PD: Participatory design; PT: Physical therapy; ADL: Activities of daily life; CAD: Computer-aided design; TPU: Thermoplastic Polyurethane

7. Challenges and Solutions:

The use of 3D printing (or additive manufacturing) in the co-creation of assistive technologies (AT) represents a paradigm shift, enabling the move from generic solutions to personalised devices. Nevertheless, its implementation on a larger scale within healthcare services faces significant challenges that require structured, both technical and organisational, solutions (37, 38).

Technical challenges faced in the implementation of 3D printed assistive technologies include printing errors and material limitations, which were overcome by refining the design process and improving material selection. Economic implications, such as the high cost of 3D printing technology, represent an initial challenge; however, these costs are often offset by reduced operating room time and improved surgical outcomes. Additionally, the lack of standardized protocols and regulatory guidelines remains a challenge that requires future research and collaboration to establish best practices and regulatory frameworks to ensure the safe and effective use of 3D printing in medical applications (52).

The integration of 3D printing technology into medical practice has demonstrated remarkable success in improving patient-specific treatments and outcomes. Addressing technical, economic, and regulatory challenges through continued research and innovation will further enhance the capabilities of 3D printing in the healthcare field (53).

Challenges in the use of 3D printing and co-creation

- Technical skills gap: Many therapists and healthcare professionals lack the necessary training in computer-aided design (CAD) and digital manufacturing. This limits the complexity of devices they can create and generates uncertainty about their safety.
- High abandonment rates: Devices are often abandoned if the user's opinion is not considered, if performance is poor, or if they exhibit a stigmatizing "medical" aesthetic that makes the home resemble a hospital.
- Time and resource pressures: The co-design process can be complex and time-consuming for clinicians, increasing personnel costs. In addition, healthcare systems often operate under limited budgets and staff shortages.
- Regulations and responsibility: There is considerable uncertainty and difficulty in navigating regulatory frameworks for medical devices. Professionals fear assuming legal responsibility in the event of device failure, especially if it has been modified or created by themselves.
- Technical limitations of 3D printing: Processes such as fused deposition modelling can generate substantial waste from supports and require prolonged post-processing. Poor quality in the final finish can discourage the user.

Proposed solutions

- Structured design methodologies: The use of models such as Design Thinking or others is proposed, which systematises the process into phases, integrating designers, healthcare professionals, and users, with a continuous evaluation process.
- Digital platforms and repositories: Creating centralised, user-friendly databases that allow sharing of existing designs. This facilitates reuse and modification of previous models, dramatically reducing design time and associated costs.
- User empowerment (User-centred design): Involving the patient from the outset to establish goals and manage expectations. This creates an emotional bond with the device and increases motivation during the adaptation period.
- Software simplification: Developing more intuitive CAD tools for "non-designers" and establishing validated procedures to ensure printed parts are mechanically safe and meet hygiene standards.
- Comprehensive evaluation: Combining qualitative assessments with technical tests of strength and functionality to ensure the therapeutic quality of the device before its final delivery.

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