

User-centred health design: reflections on D4D's experiences and challenges

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RESEARCH ARTICLE

User-centred health design: reflections on D4D's experiences and challenges

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Abstract

There is increasing recognition of the importance of user-centred design and testing in the healthcare technology domain. Challenges associated with user and stakeholder involvement in designing solutions for healthcare are recognized in the literature and need to be addressed to facilitate the development of new technology that is usable and acceptable to the end-user. The Devices for Dignity Health Technology Cooperative (D4D) has been involved in a range of technology development projects with an underpinning approach of addressing unmet needs through user involvement. This paper provides practical examples of some of the challenges that occur at different stages during a user-centred design process including ethical approval processes; stakeholder and user recruitment and involvement; eliciting needs from users regarding sensitive and personal issues; and interdisciplinary working. The paper will describe some of the strategies that have been employed by D4D to overcome these challenges and facilitate technology development.

Keywords

D4D, health design, user-centred design

History

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1. Introduction

The importance of applying design approaches in healthcare is increasingly accepted [1–6] with growing recognition of the need for the NHS to embed user-centred and design thinking approaches [7,8]. Health Design is a relatively nascent interdisciplinary research area bringing together fields such as design, healthcare, engineering, ergonomics, physiotherapy, occupational therapy, design, social research, etc. [9]. User-centred design (UCD) is a development approach in which end-users influence and are involved in design; it is both a philosophy and variety of methods [10,11].

The UCD approach typically involves identifying the intended users of a device, then ascertaining and prioritizing their needs and requirements, as well as the task requirements; developing and testing prototypes; evaluating design alternatives; analysing and resolving usability problems; and testing the design and its features with users in an iterative manner [11]. UCD can involve consulting users about their needs and involving them at specific points during the design process; or it can involve users being involved as partners and co-designing throughout the development process [10,12,13].

Whilst the approach has been criticized for the cost and time required to apply it effectively, the benefits are clear [11,14–16]. Studies report improved functionality, quality, usability and acceptability of resulting designs and, therefore,

a reduction in product failure [11,15,17–19]. By detecting usability problems early in the development process and developing only relevant functionality the costs and time associated with re-development are reduced [14]. An easy to use end-product increases effective usage, customer satisfaction and product sales [20]. Reviews by Bevan [21] and Bias and Mayhew [14] explore the potential benefits and provide statistics to support cost savings as well as the potential to increase sales. Within a healthcare context, designs that are usable and accepted by the intended user group increase the likelihood of appropriate product usage encouraging healthy behaviours and outcomes [22].

There are, however, challenges to undertaking user-centred design [17,23] and particularly so in healthcare [1,5,24,25]. Whilst some of the challenges are acknowledged in the literature, there is a need for more discussion of these challenges and how they can be tackled at a practical level [26]. Therefore, this paper will build on the literature and draw together some of the key issues that have been experienced and addressed through D4D projects.

2. The D4D approach

The Devices for Dignity Healthcare Technology Co-operative (D4D) brings together Industry, Academia and the NHS to design and develop innovative technology solutions to support people with long-term conditions [27–29]. To improve independence and dignity, user willingness to uptake, engage with, and effectively use the resulting technology is

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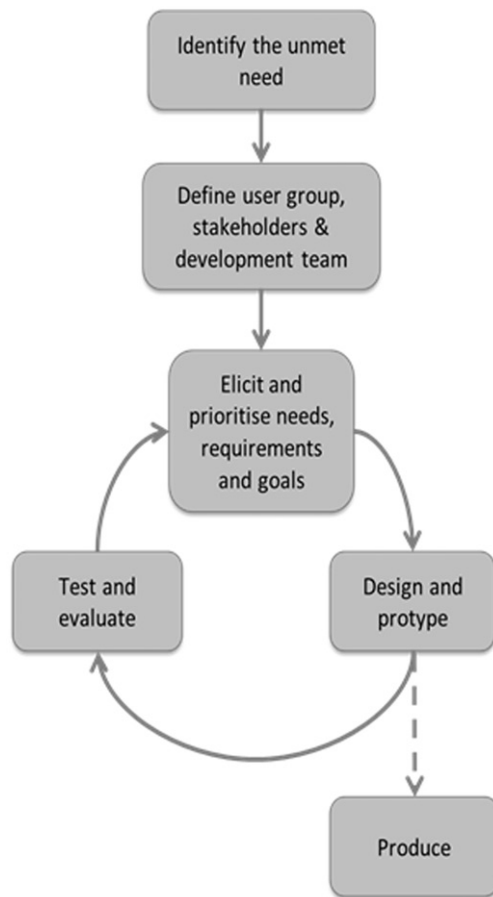


Figure 1. A UCD development process.

essential; it is argued that this is most successfully achieved by involving the user in the development process. The involvement of users and stakeholders as advisors, users, testers and co-designers ensures usable, acceptable and desirable solutions are developed that meet the needs of users with a diverse range of capabilities [10,13,30].

Figure 1 illustrates a typical D4D UCD design process. A project is initiated through an unmet clinical need or an idea of a device to address an unmet need. In order to understand and validate that need, the user, stakeholder and expert group related to the potential device will be determined. Through that group, the need is validated and the requirements for the device will be established and prioritized. This may involve research to understand the user, tasks, experiences and context of use in detail, for example through focus groups, observation and interviews. Goals for the device will be established, for example in terms of usability, improved dignity, safety and design criteria.

The design and development process will then begin; in some cases this may be from initial ideas and concepts, in other cases D4D will have been presented with a device that is already at the prototype stage. User and stakeholder involvement will be sought to inform and test ideas, concepts, mock ups and prototypes iteratively through the design process; and then to evaluate against the established goals and requirements. The UCD process sits within a wider D4D innovation model which also supports the adoption and dissemination of the resulting technology [27].

3. UCD challenges

D4D has worked on a range of different innovations within its specialist focus areas (assistive and rehabilitation technology; renal technologies, urinary continence management and paediatrics). Some of the challenges that have been experienced are discussed with the aim of facilitating future end-user engagement in healthcare design.

3.1. Identifying the unmet need

NHS-based research can be challenging; the NHS is a large and complex organisation, with varying practises in different hospitals and wards, and an array of areas where design might be applied [26,31,32]. The principle for D4D was to create ‘technology pull’ into the NHS, targeting real user needs rather than being driven by technology or academic areas of interest [33].

The identification as well as the validation of unmet needs is important to determine whether a project should be pursued. Identifying needs is typically achieved through patient and public involvement, working with relevant charities and healthcare professionals. The D4D website also facilitates the submission of unmet needs by members of public, patients, carers, researchers, inventors, etc.

Projects are selected on the basis of an expert-led multi-criteria review process, ensuring that there is a clear unmet clinical need as well as the potential for a technology-based solution to enhance dignity and independence. Further project definition and validation is undertaken through various different formats, for example patient focus groups, meeting with clinicians and surveys through charities and patients’ associations. The impact on the end-user, the NHS and the market to benefit are considered. Those selected will be pursued through D4D pump-priming and commercial or public funding.

3.2. Defining the user group, stakeholders and development team

Technology development is reliant on the right project team. As well as having NHS Trusts, University and charities as formally recognized partners; the D4D network aims to seek out the right clinical, academic and commercial expertise on a project-by-project basis. Appropriate multi-disciplinary expertise and user and stakeholder involvement throughout the project lifetime ensures complimentary expertise is in place to develop and deliver projects [29].

Successful design should take into account the needs of, and potential impact upon, a wide range of users and stakeholders [34,35]. Device users are only one group of stakeholders and usually wider involvement is needed [36,37]. Carers and family, service providers, community and hospital-based clinicians, manufacturers, procurement agencies, etc., all have an influence on the adoption of healthcare products and services [38]. It is important, therefore, to consider which users and stakeholders should be involved, in what way, and at what point of the UCD development path.

3.2.1. Gaining and maintaining access

Gaining and maintaining direct access to healthcare technology users and their carers as well as clinical and healthcare

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professionals can be time-consuming and challenging [17]. The UCD process is iterative and can be complex, lengthy, constrained and expensive, so it is perhaps not surprising that, during product development, user and stakeholder consultation can be neglected [39]. There are often transport and logistical issues to be addressed and funds need to be allocated to this element of activity. Caregiver and healthcare professional priorities are the delivery of patient care and informing a research or design project may be difficult for them to allocate time and resources to.

3.2.2. Stakeholder and user groups and networks

If regular involvement of users and stakeholders is sought, the time, logistics and financial implications have to be planned carefully at the start of the project to ensure genuine involvement is feasible and contributes to the technology development needs. D4D projects tend to involve a stakeholder group from the outset to represent different perspectives, feedback throughout the development and potentially influence final acceptance and use of a device [39].

This involvement is enabled through patient groups, charities and Partner NHS Trusts. As project ideas are often initiated by clinicians, this can offer a motivated source of expertise and gatekeeper access to potential end-users. Being based within Sheffield Teaching Hospitals NHS Foundation Trust and with five partner NHS Trusts involved, there is local access to the clinical setting and patient groups which relieves some of the logistical, transport and financial challenges.

To further facilitate user and stakeholder involvement, D4D has established a National Expert Network to engage users, carers and clinicians. The network is comprised of established user groups and a network of businesses, charities, academics and NHS Trusts that enable rapid identification and involvement of users and stakeholders. The network facilitates the involvement of hospital and community settings and recognized relevant experts. This has helped recruitment to studies, guided the development process, as well as facilitating sharing of the resulting technology with the wider community.

3.2.3. Purchasing, procurement and health economics

Whilst the NHS advocates patient choice [40], the appliances, products and devices available are limited to pre-selected options and can vary widely. Those available are influenced by bodies responsible for purchasing for the NHS and organizations with a role in influencing the adoption of new products; cost is clearly a factor [41–43]. Whilst working directly with manufacturers increases the likelihood of a product getting to market, the uptake of the product within the marketplace is also essential [44].

For adoption, a device should be addressing a real NHS challenge or unmet need that can be articulated in terms of quality-of-life. Health technology is assessed and compared in terms of QALYs (quality-adjusted life years). This provides a common measure for assessing health gain and results and takes into account both the quantity and quality-of-life generated by the healthcare intervention. When combined with the cost associated with an intervention, it is used to assess relative worth from an economic perspective [45]. The cost per QALY will influence an NHS purchasing decision.

D4D has included stakeholders from the NHS Supply Chain, NHS Purchasing Consortium and NHS Prescription Services, NHS Technology Adoption Centre, Life Sciences Innovation and NHS National Innovation Centre to give feedback on how a product would be assessed for its value to the NHS and in identifying and addressing potential barriers to the uptake of a product [39]. The constraint of item cost on healthcare design is significant, so the importance of involving purchasing and procurement as stakeholders in the development process in defining requirements is becoming increasingly clear. Equally the involvement of healthcare economics expertise is important to ensure cost-effective development, evaluation and adoption of the D4D portfolio [46].

3.2.4. Ethical approval

Many D4D projects involve new materials, techniques or testing ideas with users for the first time and are, therefore, subject to ethical review to protect the interest of patients and the public involved in the research. Where the project involves NHS staff, patients and premises and is defined as research, ethical approval will be sought through the National Research Ethics Service (NRES) and granted by the Research Ethics Committees (RECs) [47]. Local NHS R&D permission is also sought with the collaborating NHS Trusts who review the feasibility and logistics of undertaking the research locally, undertake contract and budget negotiations, ensure compliance with legislation and issue Letters of Access or Honorary Research Contracts for non-NHS research, e.g. academics.

Whilst the ethical review system has evolved, these processes remain complex and time-consuming, particularly when there are multiple centres involved which can result in local variations in protocol [48–51]. There is a significant level of administration and dependencies on the R&D departments, occupational health and HR departments at the Trusts for timely delivery [49].

The nature of user-centred development means it does not readily fit into the mould of a clinical trial. It can be challenging to be specific about the prototype to be tested, the way in which it will be used, participant sampling and timeframes, prior to user needs research being carried out. Multiple applications may, therefore, need to be made during a project lifespan to cover user research through to evaluation. From a project management perspective, D4D plan early and where possible develop protocols for funding application that will dovetail with NRES processes. The application process is initiated as soon as funding is awarded to ensure approval times do not hamper timely completion of the project.

Some D4D projects are not research related and can be classified as audit, service evaluation or system/equipment testing [52]. These activities involve minimal additional risk, burden or intrusion for participants and are regulated outside of NRES (Health Research Authority). The rationale for consideration of technology development projects outside of this sphere is where the aim is not new generalizable knowledge. User requirements driven work for example, involves assessing whether existing solutions are adequate (service evaluation); whereas testing new solutions (i.e. interventions not already in use) would be deemed research

and would require REC review. Advice is sought from the local R&D departments involved to confirm the appropriate classification of projects.

3.3. Elicit and prioritize needs, requirements and goals

D4D has focused on developing devices in areas of unmet need in specialist areas [27]. Within these areas, users, their needs and goals can be diverse, based on a variety of factors such as the nature of the medical condition, age, gender, personal wants and needs, physical and cognitive capabilities, lifestyle choices and environment.

3.3.1. Discussing sensitive issues

Eliciting needs regarding sensitive and personal issues (for example urinary continence) can be challenging, with users reportedly being unwilling to discuss their experiences [53–55]. The D4D network and relationships with clinical specialists and charities provides access and builds relationships with users with conditions that they may usually be reluctant to discuss. Our experience suggests that, once recruited, participants are keen to engage and remain involved in projects. They have the opportunity to talk and explain problems and share their stories in a non-threatening environment. Often in the case of urinary continence, it is a condition users might ‘keep secret’ and problems they assumed were their own, they are reassured to find are ‘normal’ within a similar population. This experience can be empowering [56]. By focusing on unmet clinical needs, D4D has benefitted from participation from users motivated to improve their quality-of-life and the products they have to use.

3.3.2. Supporting complex needs

The users that D4D encourage design involvement from may have complex needs and impairments affecting their mobility, communication or ability to give informed consent to participate [56–59]. They may be reliant on carers to facilitate their transportation, access and participation. The organization of user involvement sessions, therefore, takes into account participant’s requirements and minimizes the challenges as far as possible.

Research methods and facilitator style need to be flexible to cope with user preferences and to ensure an empathic approach [59,60]. Focus groups as well as interviews (face to face and telephone) have been used, acknowledging the participants needs and preferences and specific tools and resources have been developed to aid user involvement and facilitate discussion [58,59]. Carers have a role in supporting user involvement, but are also secondary users that have a voice to add [41,59]. The use of supplementary materials and carer support may lead and influence the data collected, but it is important to allow inclusion of users with diverse needs and enable reflection on the carer perspective and requirements.

3.3.3. Prioritizing requirements

From the researcher and designer perspective, users sharing in-depth personal experiences is extremely valuable [61]. Processing these views and a large volume of qualitative data

can be difficult. A passionate view of significant issues for one user may not represent the views of many. Once the designer/researcher has personally connected with the user, the desire to solve their problems can be strong. Equally, there may be a very diverse set of needs emerging, so eliciting and prioritizing needs for a single device can be challenging. To ensure valid issues are being prioritized and addressed, consultation is undertaken with clinical specialists, relevant charities and patient fora to verify findings are of significance to a larger group.

Along with a design specification, a list of prioritized user requirements helps to specify up-front in a design project exactly what the device needs to achieve for the specified group of users [17]. Where there are multiple stakeholders and users with variable needs, prioritization may not be straightforward and may be time-consuming in terms of data analysis [38,62]. There is rarely a ‘one size fits all’ solution. For example, a project looking to improve the usability of leg-worn urinary drainage systems highlighted the need for a range of solutions to cater for a wide range of different physical and cognitive capabilities and lifestyles [41,61].

There is a need for methods to minimize bias and prioritize requirements so that a design caters for most users or the most severe problems. Consideration is also needed of materials and manufacturing costs, as well as the complexity of device regulation. There are methods and processes that can be used to help inform these choices and prioritize requirements, for example, Quality Function Deployment [63], Analytical Hierarchy Process [64], Conjoint Analysis [65] and cost-value approaches [66]. Often in design, the decision-making process is less formal and relies on consensus and the experience and skills of a multidisciplinary team to prioritize. The D4D stakeholder and clinical expert involvement is essential to assess, prioritize and balance requirements.

3.4. Design and prototype

In UCD, and demonstrated through D4D projects, user involvement in the design and prototyping stages can be on a continuum from informative through to participative [67]. Druin [68] defines four levels of user involvement: (1) User: tests a final concept to see how it works; (2) Tester: tests prototypes once initial design work is complete; (3) Informant: plays a part in the design process at various stages determined by the designer; (4) Design partner: throughout the whole design process.

3.4.1. Examples of user involvement in design

Ideally, involvement starts as early as possible to ensure that the project is addressing an unmet need and involvement is influential [69]. Close, and early user involvement ensures accurate requirements and a better match between the decisions of the design team and the needs and task of the user. Concepts, mock-ups and prototypes are used to develop and test out ideas before the design process has progressed too far and it becomes more costly to make changes. However, in some projects D4D may become involved relatively late in the development of a device, so then the end-user may act as a user or tester of a more developed concept. The level of user involvement and extent to which users and stakeholder are

481 co-designing, therefore, varies, as illustrated in the following
482 examples.

- 483 • *Example 1:* A D4D workshop was run to develop project
484 ideas in the area of assistive technology. One of the
485 projects to arise was looking at the design of the leg-worn
486 urine drainage bag. This led to an NIHR i4i grant to
487 further explore user needs and potential design improve-
488 ments. The data from this study provided many insights
489 into design and functional limitations of currently
490 available leg bags; the challenge was deciding which of
491 the many issues to address. Here, requirements and
492 design decisions were prioritized based on their impact
493 on user dignity, in this case limiting the risk of accidental
494 leakage and the discretion of the bag under clothing. End-
495 users came together to test and feedback on the usability
496 of the prototypes developed by the design team before the
497 designs were finalized [41,61].
- 498 • *Example 2:* This was aimed to develop an innovative
499 shower chair to meet the needs of the active, independent,
500 self-purchasing wheelchair user, allowing them freedom
501 to travel and participate in sports. D4D consulted multi-
502 disciplinary specialist clinicians at a Spinal Injuries Unit
503 and groups of spinal-injured participants. Extensive
504 feedback was collected on existing designs of mobile
505 shower chairs and preliminary designs for the new
506 prototype in terms of effectiveness, ergonomics, aes-
507 thetics, etc. It was interesting to explore the emerging
508 requirements from the end-users and the clinicians in this
509 project. The clinicians were more focused on minimizing
510 risk to the user; whilst the users themselves were more
511 focused on their lifestyle and cost.
- 512 • *Example 3:* NIHR i4i grant funding was awarded to
513 further develop a prototype urinary catheter with a novel
514 deployment and retention mechanism. The inter-discip-
515 linary development team involved clinical representation,
516 urinary continence research specialists, scientists, engi-
517 neers, a manufacturer of continence products and a
518 usability specialist. The development process was itera-
519 tive with three cycles of usability testing and re-design
520 with clinical staff co-designing features of the device
521 [39]. Usability testing was undertaken on a Limbs &
522 Things Catheterization Trainer to enable repeated and
523 relatively realistic deployment of early prototypes with-
524 out the ethical issues associated with testing on a patient.
525 In this project it was a challenge of balancing the need to
526 have a tangible product to discuss, without having
527 invested too much on development to that stage. There
528 was a need to explain the limitations of the prototype
529 quality and the cost implications of significant design
530 changes. Over time a clear understanding of clinical and
531 manufacturing priorities developed and supported the co-
532 design process.
- 533 • *Example 4:* In collaboration with Frazer-Nash
534 Consultancy, D4D aimed to design a paediatric wheel-
535 chair that would improve independence, whilst incorpor-
536 ating complex equipment needs such as ventilators and
537 oxygen cylinders. A survey was undertaken to elicit
538 needs and resulted in a surprisingly large and passionate
539 response over a 2-week period (114 wheelchair users,
540 190 carers and 164 professionals) [59] and wide ranging

requirements. The analysis led to 10 key themes, which 541
were further prioritized and developed through a design 542
workshop. Children and their carers took part in the co- 543
design workshop, hosted by the charity Whizz-Kidz 544
[33,59]. The participants gave feedback on some initial 545
design concepts and reviewed existing technologies. 546
They were then asked to build up a design for a new 547
device using constituent parts from the solutions pre- 548
sented. One key challenge addressed through the work- 549
shop design was facilitating effective engagement and 550
co-design from diverse participants including children 551
[59]. The design output was reviewed by a stakeholder 552
group, who finalized the design to take forward. 553

3.4.2. Benefits of co-design 554

The process of user and stakeholder involvement in the design 555
process is rewarding to both the user and the research team. It 556
builds capacity, skills and is based on the premise of equal 557
value of expertise, whether that be design, health, academic or 558
personal experience. We have found useful design ideas 559
coming from different life experiences, for example a user 560
recommending a plumbing component with relevance to the 561
design of an incontinence product. Co-design activities build 562
empathy in the design professionals (designers, engineers, 563
material scientists, researchers, etc.) involved as they see the 564
perspective of the user more clearly and understand their 565
requirements; whilst it provides the user insight into design 566
processes, perspectives and methods. 567

3.4.3. Challenges of co-design 568

Whilst user and stakeholder involvement in co-design 569
activities is beneficial, there are a number of reported 570
challenges [17,69,70]. Co-design participants need to be 571
willing to share their experiences and ideas with new people; 572
help others have empathy with their condition; and have the 573
confidence to put forward their ideas. They may appear 574
resistant to change, be afraid to critique honestly, find it 575
difficult to convey their ideas, request significant changes 576
with little awareness of design constraints or fail to reach a 577
consensus [17,71]. Co-design workshops can be challenging 578
in terms of ensuring involvement through different activities; 579
balancing personality and confidence issues and differences in 580
work pace [60]. Equally, designers can be criticized for 581
adding unnecessary complexity, focusing on styling and use 582
of subject-specific language when working directly with end- 583
users [17,71]. 584

In D4D projects these challenges have been addressed 585
through careful use of language, explanation of the process 586
and the development of tailored design tools. The use of a 587
facilitator has been found to be advantageous in resolving 588
conflicting views and when users may lack confidence or 589
need support contributing. The nature of the co-design 590
exercise and format is also important for adapting to 591
individual needs and styles; for some, smaller group or 1:1 592
sessions might be more appropriate. 593

Rapid prototyping and storyboarding tools are useful for 594
demonstrating designs to non-designers. In our experience, 595
users can find it hard to visualize a final product from a sketch 596
or early prototype. Mock-ups and prototypes are useful to 597
600

601 demonstrate the form of the device and to gain user feedback,
 602 but users can sometimes be distracted by the appearance and
 603 feel, detracting from the focus on functionality and usability.
 604 Rapid prototyping has been used, for example, to produce
 605 valves for leg bags and non-invasive ventilation masks. As it
 606 can be challenging to get the feel and final functionality right,
 607 it is important to manage user expectations.

608 Going forward there is a need to further consider tools for
 609 presenting ideas, mock-ups and prototypes to support visual-
 610 ization so that users are not frustrated or disheartened by
 611 limited functionality and basic prototypes. The growth of 3D
 612 printing offers significant potential as it will become quicker,
 613 easier and cheaper to provide realistic prototypes with greater
 614 potential for customization as the technology evolves [72,73].
 615 Briefings on the design process to educate users in the process
 616 and to set realistic expectations on what can be achieved
 617 within the context of design constraints and competing
 618 demands for resources is recommended.

619 3.4.4. Interdisciplinary team working in design

621 The involvement of non-designers (SMEs, subject matter
 622 experts, developers, scientists, etc.) in design can lead to
 623 challenges in terms of collaboration and shared understanding
 624 and communication [70]. Members of D4D come from varied
 625 backgrounds—health and care providers; academic research-
 626 ers; charities; health commissioners; health technology
 627 industry. The range of disciplines will vary on a project-by-
 628 project basis. The differences in working practises, methods,
 629 language and communication, ways of thinking and the desire
 630 to problem-solve and innovate between disciplines have to be
 631 negotiated [34].

632 However, as a result of multi-disciplinary collaboration
 633 D4D projects are very closely informed by appropriate
 634 expertise. The involvement of a range of disciplines brings
 635 together novelty, freedom and creative expertise with tech-
 636 nology and condition-specific knowledge and experience.
 637 Effective facilitation and sharing of working methods and
 638 approaches is important to ensuring that involvement is
 639 effective, supports ideas generation and balances conflicting
 640 demands from the specialisms involved.

642 3.5. Testing and evaluation

644 A user-centred approach is characterized by iterative testing
 645 and not just final evaluation [16] to ensure usability and cost
 646 and efficiency benefits can be achieved by early identification
 647 of issues in the development process [17,69]. Clinical trials
 648 are used to study the impact of a device on clinical validity
 649 and effectiveness [74]. User-centred methods such as heuristic
 650 evaluation and usability testing are better suited for exploring
 651 barriers to usability, acceptability and willingness to use the
 652 device, which will in turn determine healthy behaviours [11].
 653 A range of testing approaches is, therefore, valuable and it is
 654 important to select the right level of testing for the questions
 655 being asked, the user population and typical usage of the
 656 device [75]. Qualitative as well as quantitative approaches are
 657 important to gain an in-depth understanding of device usage.

658 In a healthcare environment, ethical approval, funding
 659 requirements and impact/research assessment can lead
 660 towards controlled trials for generating credible evidence to

Table 1. Identified challenges of UCD of healthcare devices.

A summary of UCD challenges	
• Gaining and maintaining access to users, carers and healthcare professionals	664
• Reaching and engaging relevant stakeholders	665
• Maintaining involvement	666
• The time, logistics and resources required for involvement	667
• Managing the ethical review and approval process for multi-stage design projects	668
• Managing the regulatory frameworks for medical devices	669
• Involving users at the early stages of the design process	670
• Adapting methods to meet individual participation needs	671
• Discussing and deriving user requirements on personal health issues	672
• The time, logistics and resource requirements for managing the resulting data	673
• Rationalizing and prioritizing competing user and stakeholder requirements	674
• Minimizing bias in the prioritization of requirements	675
• Cost as a significant design constraint	676
• Differences in knowledge, working practises, language and ways of thinking, between disciplines	677
• Communicating design thinking and ideas effectively to users and stakeholders	678
• Devising testing and evaluation strategies to match ethical, funding and discipline expectations	679

683 establish new knowledge or clinical impact [75]. In contrast,
 684 in design, iterative testing is employed to explore how to
 685 develop and improve a design and to understand usability,
 686 user and market acceptance. This variation in approach can be
 687 a challenge in developing project plans and evaluation
 688 strategies for interdisciplinary projects [34]. A final product
 689 evaluation in the form a clinical trial will often require
 690 additional ethical approval processes and recruitment and
 691 may be subject to additional funding beyond that secured for
 692 device development purposes. In contrast, iterative testing is
 693 more likely to be embedded within a project plan, funding and
 694 ethical approval for the development of a device.

695 The D4D approach has focused on collecting different
 696 forms of evidence to support the further development or
 697 production of a device, as well as looking to demonstrate
 698 clinical benefit. The following provide examples of various
 699 testing methods that have been employed:

- 700 (1) User feedback: To gain iterative feedback on designs
 701 as they evolve, as well as a final prototype or device
 702 [33,76]. 703
- 704 (2) Expert assessment: Drawing on networks of healthcare
 705 experts, scientists and academics to assess the solution
 706 against the clinical context [39,76]. 707
- 708 (3) Usability testing with end users: To assess ease of use
 709 and acceptability [39,76]. 710
- 711 (4) Heuristic evaluation: To assess and improve usability
 712 [11,39]. 713
- 714 (5) Health economics and market analysis [76]. 715
- 716 (6) Clinical trials. 717

718 Where medical devices are developed, they are subject to
 719 regulatory approval [74,77]. It may be necessary to carry out a
 720 clinical trial in order to obtain CE marking for a medical
 721 device and demonstrate that the device is compliant. This
 722 topic is discussed more fully in another paper within this
 723 special issue. The approach taken to testing, therefore,
 724 depends on the stage of development and the context in
 725 which the device will be used. 726

4. Conclusions

UCD in the healthcare context involves taking users on a journey, involving them in the research and development process, whilst offering the potential that the resulting device will improve their dignity, independence and health. The final product will always be a balance of competing demands placed by a variety of stakeholders: the users, the healthcare professionals, the buyers and purchasers, the regulators; and constraints in terms of the cost of materials and manufacture. However, it is important that, where possible, effective solutions are delivered back to the user.

Involving a diverse range of users and stakeholders, is not straightforward; but it is argued that working closely together ensures that development is driven by real need and the final product is one that is acceptable and usable. In order for the UCD approach to be applied effectively, project planning should take into account some of the challenges that face UCD as it is applied in healthcare. Based on the experience of embedding it as part of the D4D development process, some of the key challenges are summarized in table 1.

The design of effective devices, products, systems and services for healthcare requires expertise from diverse fields and user and stakeholder involvement. As the benefits of UCD are becoming widely accepted, research should focus on strategies to reduce the challenges associated with designing for health and finding practical working approaches to facilitating user involvement. The design and usability of technology should not be a barrier to healthy behaviours and to the uptake and continued use of clinically-effective products.

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The author reports no conflicts of interest. The author alone is responsible for the content and writing of the paper.

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