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Title. 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 [1]. Challenges associated with user and stakeholder involvement in designing solutions for healthcare are recognised in the literature [2] and need to be addressed to facilitate the development of new technology that is useable 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.

1 Introduction

The importance of applying design approaches in health care is increasingly accepted [1][3][4][5][6][7] with growing recognition of the need for the NHS to embed user-centred and design thinking approaches [8][9]. 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 [10]. 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 [11][12].

The UCD approach typically involves identifying the intended users of a device, then ascertaining and prioritising 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 [12]. 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 [11][13][14].

Whilst the approach has been criticised for the cost and time required to apply it effectively, the benefits are clear [12][15][16][17]. Studies report improved functionality, quality, usability and acceptability of resulting designs and therefore a reduction in product failure [2][12][16][18][19]. By detecting usability problems early in the development process and developing only relevant functionality the costs and time associated with redevelopment are reduced [15]. An easy to use end-product increases effective usage, customer satisfaction and product sales [20]. Reviews by Bevan [21] and Bias and Mayhew [15] 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 useable 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 [2][23] and particularly so in healthcare [1][6][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][28][29]. To improve independence and dignity, user willingness to uptake, engage with, and effectively use the resulting technology is 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 [11][14][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 prioritised. This may involve research to understand the user, tasks, experiences and context of use in detail, for example though focus groups, observation, interviews. Goals for the device will be established, for example in terms of usability, improved dignity, safety, and design criteria.

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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, 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 professionals can be time-consuming and challenging [2]. 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 stakeholder 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 5 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 user and stakeholders. The network facilitates the involvement of hospital and community settings and recognised 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][42][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][49][50][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 required REC review. Advice is sought from the local R&D departments involved to confirm the appropriate classification of projects.

3.3 Elicit and prioritise 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][54][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][57][58][59]. They may be reliant on carers to facilitate their transportation, access and participation. The organisation of user involvement sessions therefore takes into account participant's requirements and minimises 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 Prioritising 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 prioritising needs for a single device can be challenging. To ensure valid issues are being prioritised 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 prioritised user requirements helps to specify up-front in a design project exactly what the device needs to achieve for the specified group of users [2]. Where there are multiple stakeholders and users with variable needs, prioritisation 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 minimise bias and prioritise 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 prioritise 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 prioritise. The

D4D stakeholder and clinical expert involvement is essential to assess, prioritise 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 4 level 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 co-designing therefore varies as illustrated in the following examples.

Example 1: A D4D workshop was run to develop project ideas in the area of assistive technology. One of the projects to arise was looking at the design of the leg worn urine drainage bag. This led to an NIHR i4i grant to further explore user needs and potential design improvements. The data from this study provided many insights into design and functional limitations of currently available leg bags; the challenge was deciding which of the many issues to address. Here, requirements and design decisions were prioritised based on their impact on user dignity, in this case limiting the risk of accidental leakage and the discretion of the bag

under clothing. End-users came together to test and feedback on the usability of the prototypes developed by the design team before the designs were finalised [41][61].

Example 2 aimed to develop an innovative shower chair to meet the needs of the active, independent, self-purchasing wheelchair user allowing them freedom to travel and participate in sports. D4D consulted multi-disciplinary specialist clinicians at a Spinal Injuries Unit and groups of spinal-injured participants. Extensive feedback was collected on existing designs of mobile shower chairs and preliminary designs for the new prototype in terms of effectiveness, ergonomics, aesthetics, etc. It was interesting to explore the emerging requirements from the end-users and the clinicians in this project. The clinicians being more focused on minimising risk to the user; whilst the users themselves were more focused on their lifestyle and cost.

Example 3: NIHR i4i grant funding was awarded to further develop a prototype urinary catheter with a novel deployment and retention mechanism. The inter-disciplinary development team involved clinical representation, urinary continence research specialists, scientists, engineers, a manufacturer of continence products and a usability specialist. The development process was iterative with 3 cycles of usability testing and re-design with clinical staff co-designing features of the device [39]. Usability testing was undertaken on a Limbs & Things Catheterization Trainer to enable repeated and relatively realistic deployment of early prototypes without the ethical issues associated with testing on a patient. In this project it was a challenge balancing the need to have a tangible product to discuss, without having invested too much on development to that stage. There was a need to explain the limitations of the prototype quality and the cost implications of significant design changes. Over time a clear understanding of clinical and manufacturing priorities developed and supported the co-design process.

Example 4. In collaboration with Frazer-Nash Consultancy, D4D aimed to design a paediatric wheelchair that would improve independence, whilst incorporating complex equipment needs such as ventilators and oxygen cylinders. A survey was undertaken to elicit needs and resulted in a surprisingly large and passionate response over a 2 week period (114 wheelchair users, 190

carers and 164 professionals) [59] and wide ranging requirements. The analysis led to 10 key themes which were further prioritised and developed through a design workshop. Children and their carers took part in the co-design workshop, hosted by the charity Whizz-Kidz [33][59]. The participants gave feedback on some initial design concepts and reviewed existing technologies. They were then asked to build up a design for a new device using constituent parts from the solutions presented. One key challenge addressed through the workshop design was facilitating effective engagement and co-design from diverse participants including children [59]. The design output was reviewed by a stakeholder group who finalised the design to take forward.

3.4.2 Benefits of co-design

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

3.4.3 Challenges of co-design

Whilst user and stakeholder involvement in co-design activities is beneficial, there are a number of reported challenges [2][69][70]. Co-design participants need to be willing to share their experiences and ideas with new people; help others have empathy with their condition; and have the confidence to put forward their ideas. They may appear resistant to change, be afraid to critique honestly, find it difficult to convey their ideas, request significant changes with little awareness of design constraints, or fail to reach a consensus [2][71]. Co-design workshops can be challenging in terms of ensuring involvement through different activities; balancing

personality and confidence issues and differences in work pace [60]. Equally, designers can be criticised for adding unnecessary complexity, focusing on styling, and use of subject-specific language when working directly with end-users [2][71].

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

Rapid prototyping and storyboarding tools are useful for demonstrating designs to non-designers. In our experience users can find it hard to visualise a final product from a sketch or early prototype. Mock-ups and prototypes are useful to demonstrate the form of the device and to gain user feedback, but users can sometimes be distracted by the appearance and feel detracting from the focus on functionality and usability. Rapid prototyping has been used for example to produce valves for leg bags, and non-invasive ventilation masks. As it can be challenging to get the feel and final functionality right, it is important to manage user expectations.

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

3.4.4 Interdisciplinary team working in design

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

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

3.5 Testing and evaluation

A user-centred approach is characterised by iterative testing and not just final evaluation [17] to ensure usability, and cost and efficiency benefits can be achieved by early identification of issues in the development process [2][69]. Clinical trials are used to study the impact of a device on clinical validity and effectiveness [77]. User-centred methods such as heuristic evaluation and usability testing, are better suited for exploring barriers to usability, acceptability and willingness to use the device, which will in turn determine healthy behaviours [12]. A range of testing approaches is therefore valuable, and it is important to select the right level of testing for the questions being asked, the user population and typical usage of the device [74]. Qualitative as well as quantitative approaches are important to gain an in-depth understanding of device usage.

In a healthcare environment, ethical approval, funding requirements and impact / research assessment can lead towards controlled trials for generating credible evidence to establish new knowledge or clinical impact [74]. In contrast, in design, iterative testing is employed to explore how to develop and improve a design and to understand usability, user and market acceptance. This variation in approach can be a challenge in developing project plans and evaluation strategies for interdisciplinary projects [34]. A final product evaluation in the form a clinical trial will often require additional ethical approval processes and recruitment, and may be subject to additional funding beyond that secured for device development purposes. In contrast, iterative testing is more likely to be embedded within a project plan, funding, and ethical approval for the development of a device.

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

1. User feedback: to gain iterative feedback on designs as they evolve, as well as a final prototype or device [33][76].
2. Expert assessment: drawing on networks of healthcare experts, scientists and academics to assess the solution against the clinical context [39][76]
3. Usability testing with end users: to assess ease of use and acceptability [39][76]
4. Heuristic evaluation: to assess and improve usability [12][39]
5. Health economics and market analysis [76]
6. Clinical trials

Where medical devices are developed, they are subject to regulatory approval [77][78]. It may be necessary to carry out a clinical trial in order to obtain CE marking for a medical device and demonstrate that the device is compliant. This topic is discussed more fully in another paper within this special issue. The approach taken to testing therefore depends on the stage of development and the context in which the device will be used.

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 stakeholder, 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 useable. In order for the UCD approach to be applied effectively, project planning should take into account some of 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 summarised below in

Table 1.

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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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6 Declaration of Interest sections

The author reports no declarations of interest.

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List of Tables and Figures

Figure 1. A UCD development process

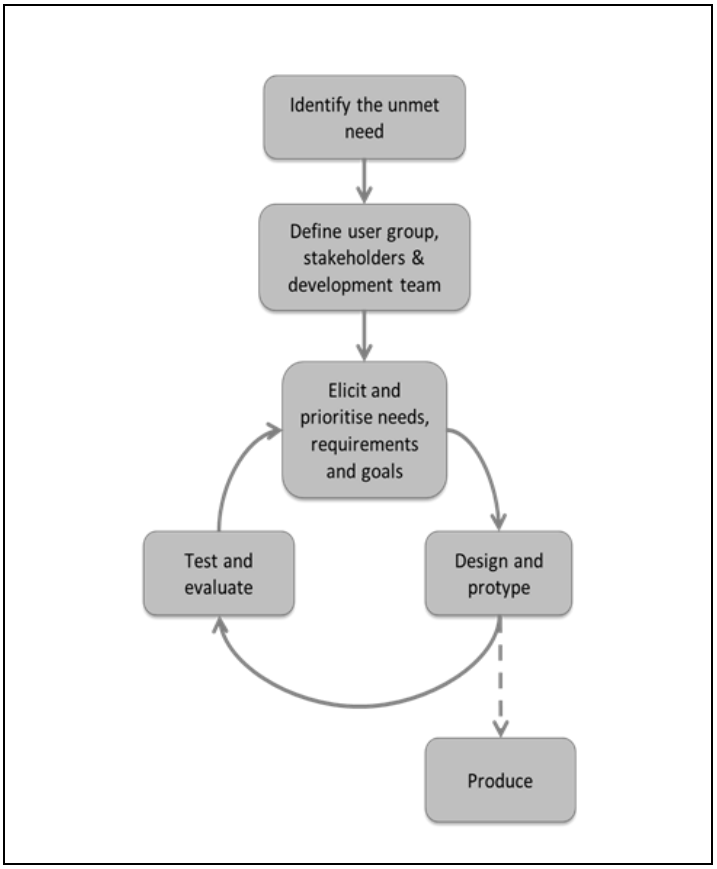

Table 1. Identified challenges of UCD of healthcare devices

A summary of UCD Challenges
• Gaining and maintaining access to users, carers and healthcare professionals • Reaching and engaging relevant stakeholders • Maintaining involvement • The time, logistics and resources required for involvement • Managing the ethical review and approval process for multi-stage design projects • Managing the regulatory frameworks for medical devices • Involving users at the early stages of the design process • Adapting methods to meet individual participation needs • Discussing and deriving user requirements on personal health issues • The time, logistics and resource requirements for managing the resulting data • Rationalising and prioritising competing user and stakeholder requirements • Minimising bias in the prioritisation of requirements • Cost as a significant design constraint • Differences in knowledge, working practises, language and ways of thinking, between disciplines • Communicating design thinking and ideas effectively to users and stakeholders • Devising testing and evaluation strategies to match ethical, funding and discipline expectations