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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19 Abstract

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There is increasing recognition of the importance of user-centred design and testing in the 20 healthcare technology domain. Challenges associated with user and stakeholder involvement 21 in designing solutions for healthcare are recognized in the literature and need to be addressed 22 to facilitate the development of new technology that is usable and acceptable to the end-user. 23 The Devices for Dignity Health Technology Cooperative (D4D) has been involved in a range of 24 technology development projects with an underpinning approach of addressing unmet needs 25 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 26 processes; stakeholder and user recruitment and involvement; eliciting needs from users 27 regarding sensitive and personal issues; and interdisciplinary working. The paper will describe 28 some of the strategies that have been employed by D4D to overcome these challenges and 29 facilitate technology development. 30

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³²₃₃ **1. Introduction**

The importance of applying design approaches in healthcare 34 is increasingly accepted [1-6] with growing recognition of the 35 need for the NHS to embed user-centred and design thinking 36 approaches [7,8]. Health Design is a relatively nascent 37 interdisciplinary research area bringing together fields such 38 as design, healthcare, engineering, ergonomics, physiother-39 apy, occupational therapy, design, social research, etc. [9]. 40 User-centred design (UCD) is a development approach in 41 which end-users influence and are involved in design; it is 42 both a philosophy and variety of methods [10,11]. 43

The UCD approach typically involves identifying the 44 intended users of a device, then ascertaining and prioritizing 45 their needs and requirements, as well as the task require-46 ments; developing and testing prototypes; evaluating design 47 alternatives; analysing and resolving usability problems; and 48 testing the design and its features with users in an iterative 49 manner [11]. UCD can involve consulting users about their 50 needs and involving them at specific points during the design 51 process; or it can involve users being involved as partners 52 and co-designing throughout the development process 53 [10,12,13]. 54

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,

Keywords

D4D, health design, user-centred design

History

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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 96 use end-product increases effective usage, customer satisfac-97 tion and product sales [20]. Reviews by Bevan [21] and Bias 98 and Mayhew [14] explore the potential benefits and provide 99 statistics to support cost savings as well as the potential to 100 increase sales. Within a healthcare context, designs that are 101 usable and accepted by the intended user group increase the 102 likelihood of appropriate product usage encouraging healthy 103 behaviours and outcomes [22].

104 There are, however, challenges to undertaking user-centred 105 design [17,23] and particularly so in healthcare [1,5,24,25]. 106 Whilst some of the challenges are acknowledged in the 107 literature, there is a need for more discussion of these 108 challenges and how they can be tackled at a practical level 109 [26]. Therefore, this paper will build on the literature and 110 draw together some of the key issues that have been 111 experienced and addressed through D4D projects. 112

2. The D4D approach

The Devices for Dignity Healthcare Technology Co-operative 115 (D4D) brings together Industry, Academia and the NHS to 116 design and develop innovative technology solutions to support 117 people with long-term conditions [27–29]. To improve 118 independence and dignity, user willingness to uptake, 119 engage wit, and effectively use the resulting technology is 120

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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. 159 160 A project is initiated through an unmet clinical need or an idea of a device to address an unmet need. In order to 161 understand and validate that need, the user, stakeholder and 162 expert group related to the potential device will be 163 164 determined. Through that group, the need is validated and the requirements for the device will be established and 165 prioritized. This may involve research to understand the user, 166 tasks, experiences and context of use in detail, for example 167 though focus groups, observation and interviews. Goals for 168 169 the device will be established, for example in terms of usability, improved dignity, safety and design criteria. 170

The design and development process will then begin; in 171 some cases this may be from initial ideas and concepts, in 172 other cases D4D will have been presented with a device that is 173 already at the prototype stage. User and stakeholder involve-174 175 ment will be sought to inform and test ideas, concepts, mock ups and prototypes iteratively through the design process; and 176 then to evaluate against the established goals and require-177 ments. The UCD process sits within a wider D4D innovation 178 model which also supports the adoption and dissemination of 179 the resulting technology [27]. 180

3. UCD challenges

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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 organizsation, 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].

Projects are selected on the basis of an expert-led multi-205 criteria review process, ensuring that there is a clear unmet 206 clinical need as well as the potential for a technology-based 207 solution to enhance dignity and independence. Further project 208 definition and validation is undertaken through various 209 different formats, for example patient focus groups, meeting 210with clinicians and surveys through charities and patients' 211 associations. The impact on the end-user, the NHS and the 212 market to benefit are considered. Those selected will be 213 pursued through D4D pump-priming and commercial or 214 public funding. 215

3.2. Defining the user group, stakeholders and development team

Technology development is reliant on the right project team. 219 As well as having NHS Trusts, University and charities as 220 formally recognized partners; the D4D network aims to seek 221 out the right clinical, academic and commercial expertise on a 222 project-by-project basis. Appropriate multi-disciplinary 2.2.3 expertise and user and stakeholder involvement throughout 224 the project lifetime ensures complimentary expertise is in 225 place to develop and deliver projects [29]. 226

Successful design should take into account the needs of, 227 and potential impact upon, a wide range of users and 228 stakeholders [34,35]. Device users are only one group of 229 stakeholders and usually wider involvement is needed [36,37]. 230 Carers and family, service providers, community and hospital-231 based clinicians, manufacturers, procurement agencies, etc., 232 all have an influence on the adoption of healthcare products 233 and services [38]. It is important, therefore, to consider which 234 users and stakeholders should be involved, in what way, and at 235 what point of the UCD development path. 236

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 240 251

241 professionals can be time-consuming and challenging [17]. 242 The UCD process is iterative and can be complex, lengthy, 243 constrained and expensive, so it is perhaps not surprising that, during product development, user and stakeholder consult-244 ation can be neglected [39]. There are often transport and 245 logistical issues to be addressed and funds need to be 246 247 allocated to this element of activity. Caregiver and healthcare professional priorities are the delivery of patient care and 248 informing a research or design project may be difficult for 249 them to allocate time and resources to. 250

252 3.2.2. Stakeholder and user groups and networks

253 If regular involvement of users and stakeholders is sought, the 254 time, logistics and financial implications have to be planned 255 carefully at the start of the project to ensure genuine 256 involvement is feasible and contributes to the technology 257 development needs. D4D projects tend to involve a stake-258 holder group from the outset to represent different perspec-259 tives, feedback throughout the development and potentially 260 influence final acceptance and use of a device [39].

261 This involvement is enabled through patient groups, 262 charities and Partner NHS Trusts. As project ideas are often 263 initiated by clinicians, this can offer a motivated source of 264 expertise and gatekeeper access to potential end-users. Being 265 based within Sheffield Teaching Hospitals NHS Foundation 266 Trust and with five partner NHS Trusts involved, there is local 267 access to the clinical setting and patient groups which relieves 268 some of the logistical, transport and financial challenges.

269 To further facilitate user and stakeholder involvement, D4D 270 has established a National Expert Network to engage users, 271 carers and clinicians. The network is comprised of established 272 user groups and a network of businesses, charities, academics 273 and NHS Trusts that enable rapid identification and involve-274 ment of users and stakeholders. The network facilitates the 275 involvement of hospital and community settings and recog-276 nized relevant experts. This has helped recruitment to studies, 277 guided the development process, as well as facilitating sharing 278 of the resulting technology with the wider community. 279

²⁸⁰ ²⁸¹ 3.2.3. Purchasing, procurement and health economics

Whilst the NHS advocates patient choice [40], the appliances, 282 products and devices available are limited to pre-selected 283 284 options and can vary widely. Those available are influenced by bodies responsible for purchasing for the NHS and 285 organizations with a role in influencing the adoption of new 286 products; cost is clearly a factor [41-43]. Whilst working 287 directly with manufacturers increases the likelihood of a 288 product getting to market, the uptake of the product within the 289 marketplace is also essential [44]. 290

For adoption, a device should be addressing a real NHS 291 challenge or unmet need that can be articulated in terms of 292 quality-of-life. Health technology is assessed and compared in 293 terms of QALYs (quality-adjusted life years). This provides a 294 295 common measure for assessing health gain and results and takes into account both the quantity and quality-of-life 296 297 generated by the healthcare intervention. When combined with the cost associated with an intervention, it is used to assess 298 relative worth from an economic perspective [45]. The cost per 299 300 QALY will influence an NHS purchasing decision.

D4D has included stakeholders from the NHS Supply 301 Chain, NHS Purchasing Consortium and NHS Prescription 302 Services, NHS Technology Adoption Centre, Life Sciences 303 Innovation and NHS National Innovation Centre to give 304 feedback on how a product would be assessed for its value to 305 the NHS and in identifying and addressing potential barriers 306 to the uptake of a product [39]. The constraint of item cost on 307 healthcare design is significant, so the importance of 308 involving purchasing and procurement as stakeholders in the 309 development process in defining requirements is becoming 310 increasingly clear. Equally the involvement of healthcare 311 economics expertise is important to ensure cost-312 effective development, evaluation and adoption of the D4D 313 portfolio [46]. 314

3.2.4. Ethical approval

Many D4D projects involve new materials, techniques or 318 testing ideas with users for the first time and are, therefore, 319 subject to ethical review to protect the interest of patients and 320 the public involved in the research. Where the project involves 321 NHS staff, patients and premises and is defined as research, 322 ethical approval will be sought through the National Research 323 Ethics Service (NRES) and granted by the Research Ethics 324 Committees (RECs) [47]. Local NHS R&D permission is also 325 sought with the collaborating NHS Trusts who review the 326 feasibility and logistics of undertaking the research locally, 327 undertake contract and budget negotiations, ensure compli-328 ance with legislation and issue Letters of Access or Honorary 329 Research Contracts for non-NHS research, e.g. academics. 330

Whilst the ethical review system has evolved, these 331 processes remain complex and time-consuming, particularly 332 when there are multiple centres involved which can result in 333 local variations in protocol [48–51]. There is a significant 334 level of administration and dependencies on the R&D 335 departments, occupational health and HR departments at the 336 Trusts for timely delivery [49]. 337

The nature of user-centred development means it does not 338 readily fit into the mould of a clinical trial. It can be 339 challenging to be specific about the prototype to be tested, the 340 way in which it will be used, participant sampling and 341 timeframes, prior to user needs research being carried out. 342 Multiple applications may, therefore, need to be made during 343 a project lifespan to cover user research through to evaluation. 344 From a project management perspective, D4D plan early and 345 where possible develop protocols for funding application that 346 will dovetail with NRES processes. The application process is 347 initiated as soon as funding is awarded to ensure approval 348 times do not hamper timely completion of the project. 349

Some D4D projects are not research related and can be 350 classified as audit, service evaluation or system/equipment 351 testing [52]. These activities involve minimal additional risk, 352 burden or intrusion for participants and are regulated outside 353 of NRES (Health Research Authority). The rationale for 354 consideration of technology development projects outside of 355 this sphere is where the aim is not new generalizable 356 knowledge. User requirements driven work for example, 357 involves assessing whether existing solutions are adequate 358 (service evaluation); whereas testing new solutions (i.e. 359 interventions not already in use) would be deemed research 360

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

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365 3.3. Elicit and prioritize needs, requirements366 and goals

³⁶⁷ D4D has focused on developing devices in areas of unmet
³⁶⁸ need in specialist areas [27]. Within these areas, users, their
³⁶⁹ needs and goals can be diverse, based on a variety of factors
³⁷⁰ such as the nature of the medical condition, age, gender,
³⁷¹ personal wants and needs, physical and cognitive capabilities,
³⁷² lifestyle choices and environment.

374 375 3.3.1. Discussing sensitive issues

Eliciting needs regarding sensitive and personal issues (for 376 example urinary continence) can be challenging, with 377 users reportedly being unwilling to discuss their experiences 378 [53–55]. The D4D network and relationships with clinical 379 specialists and charities provides access and builds relation-380 ships with users with conditions that they may usually be 381 reluctant to discuss. Our experience suggests that, once 382 recruited, participants are keen to engage and remain involved 383 in projects. They have the opportunity to talk and explain 384 problems and share their stories in a non-threatening envir-385 onment. Often in the case of urinary continence, it is a 386 condition users might 'keep secret' and problems they 387 assumed were their own, they are reassured to find are 388 'normal' within a similar population. This experience can be 389 empowering [56]. By focusing on unmet clinical needs, D4D 390 has benefitted from participation from users motivated to 391 improve their quality-of-life and the products they have to use. 392 393

394 3.3.2. Supporting complex needs

395 The users that D4D encourage design involvement from may 396 have complex needs and impairments affecting their mobility, 397 communication or ability to give informed consent to 398 participate [56-59]. They may be reliant on carers to facilitate 399 their transportation, access and participation. The organiza-400 tion of user involvement sessions, therefore, takes into 401 account participant's requirements and minimizes the chal-402 lenges as far as possible. 403

Research methods and facilitator style need to be flexible 404 to cope with user preferences and to ensure an empathic 405 approach [59,60]. Focus groups as well as interviews (face to 406 face and telephone) have been used, acknowledging the 407 participants needs and preferences and specific tools and 408 resources have been developed to aid user involvement and 409 facilitate discussion [58,59]. Carers have a role in supporting 410 user involvement, but are also secondary users that have a 411 voice to add [41,59]. The use of supplementary materials and 412 carer support may lead and influence the data collected, but it 413 is important to allow inclusion of users with diverse needs and 414 enable reflection on the carer perspective and requirements. 415

416 417 3.3.3. Prioritizing requirements

From the researcher and designer perspective, users sharingin-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 421 one user may not represent the views of many. Once the 422 designer/researcher has personally connected with the user, 423 the desire to solve their problems can be strong. Equally, there 424 may be a very diverse set of needs emerging, so eliciting and 425 prioritizing needs for a single device can be challenging. To 426 ensure valid issues are being prioritized and addressed, 427 consultation is undertaken with clinical specialists, relevant 428 charities and patient fora to verify findings are of significance 429 to a larger group. 430

Along with a design specification, a list of prioritized user 431 requirements helps to specify up-front in a design project 432 exactly what the device needs to achieve for the specified 433 group of users [17]. Where there are multiple stakeholders 434 and users with variable needs, prioritization may not be 435 straightforward and may be time-consuming in terms of data 436 analysis [38,62]. There is rarely a 'one size fits all' solution. 437 For example, a project looking to improve the usability of leg-438 worn urinary drainage systems highlighted the need for a 439 range of solutions to cater for a wide range of different 440 physical and cognitive capabilities and lifestyles [41,61]. 441

There is a need for methods to minimize bias and prioritize 442 requirements so that a design caters for most users or the most 443 severe problems. Consideration is also needed of materials 444 and manufacturing costs, as well as the complexity of device 445 regulation. There are methods and processes that can be used 446 to help inform these choices and prioritize requirements, for 447 example, Quality Function Deployment [63], Analytical 448 Hierarchy Process [64], Conjoint Analysis [65] and cost-449 value approaches [66]. Often in design, the decision-making 450 process is less formal and relies on consensus and the 451 experience and skills of a multidisciplinary team to prioritize. 452 The D4D stakeholder and clinical expert involvement is 453 essential to assess, prioritize and balance requirements. 454

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3.4. Design and prototype

457 In UCD, and demonstrated through D4D projects, user 458 involvement in the design and prototyping stages can be on 459 a continuum from informative through to participative [67]. 460 Druin [68] defines four levels of user involvement: (1) User: 461 tests a final concept to see how it works; (2) Tester: tests 462 prototypes once initial design work is complete; (3) 463 Informant: plays a part in the design process at various 464 stages determined by the designer; (4) Design partner: 465 throughout the whole design process. 466

3.4.1. Examples of user involvement in design

Ideally, involvement starts as early as possible to ensure that 469 the project is addressing an unmet need and involvement is 470 influential [69]. Close, and early user involvement ensures 471 accurate requirements and a better match between the 472 decisions of the design team and the needs and task of the 473 user. Concepts, mock-ups and prototypes are used to develop 474 and test out ideas before the design process has progressed too 475 far and it becomes more costly to make changes. However, in 476 some projects D4D may become involved relatively late in the 477 development of a device, so then the end-user may act as a 478 user or tester of a more developed concept. The level of user 479 involvement and extent to which users and stakeholder are 480

- 481 co-designing, therefore, varies, as illustrated in the following482 examples.
- 483 *Example 1*: A D4D workshop was run to develop project ٠ ideas in the area of assistive technology. One of the 484 projects to arise was looking at the design of the leg-worn 485 urine drainage bag. This led to an NIHR i4i grant to 486 487 further explore user needs and potential design improvements. The data from this study provided many insights 488 into design and functional limitations of currently 489 available leg bags; the challenge was deciding which of 490 the many issues to address. Here, requirements and 491 design decisions were prioritized based on their impact 492 493 on user dignity, in this case limiting the risk of accidental leakage and the discretion of the bag under clothing. End-494 495 users came together to test and feedback on the usability of the prototypes developed by the design team before the 496 designs were finalized [41,61]. 497
- Example 2: This was aimed to develop an innovative 498 • shower chair to meet the needs of the active, independent, 499 self-purchasing wheelchair user, allowing them freedom 500 to travel and participate in sports. D4D consulted multi-501 disciplinary specialist clinicians at a Spinal Injuries Unit 502 and groups of spinal-injured participants. Extensive 503 504 feedback was collected on existing designs of mobile shower chairs and preliminary designs for the new 505 prototype in terms of effectiveness, ergonomics, aes-506 thetics, etc. It was interesting to explore the emerging 507 508 requirements from the end-users and the clinicians in this 509 project. The clinicians were more focused on minimizing risk to the user; whilst the users themselves were more 510 focused on their lifestyle and cost. 511
- 512 Example 3: NIHR i4i grant funding was awarded to • further develop a prototype urinary catheter with a novel 513 deployment and retention mechanism. The inter-discip-514 linary development team involved clinical representation, 515 516 urinary continence research specialists, scientists, engineers, a manufacturer of continence products and a 517 usability specialist. The development process was itera-518 519 tive with three cycles of usability testing and re-design with clinical staff co-designing features of the device 520 [39]. Usability testing was undertaken on a Limbs & 521 Things Catheterization Trainer to enable repeated and 522 relatively realistic deployment of early prototypes with-523 524 out the ethical issues associated with testing on a patient. In this project it was a challenge of balancing the need to 525 have a tangible product to discuss, without having 526 invested too much on development to that stage. There 527 was a need to explain the limitations of the prototype 528 quality and the cost implications of significant design 529 530 changes. Over time a clear understanding of clinical and manufacturing priorities developed and supported the co-531 design process. 532
- Example 4: In collaboration with Frazer-Nash 533 • Consultancy, D4D aimed to design a paediatric wheel-534 535 chair that would improve independence, whilst incorporating complex equipment needs such as ventilators and 536 537 oxygen cylinders. A survey was undertaken to elicit needs and resulted in a surprisingly large and passionate 538 response over a 2-week period (114 wheelchair users, 539 540 190 carers and 164 professionals) [59] and wide ranging

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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

556 The process of user and stakeholder involvement in the design 557 process is rewarding to both the user and the research team. It 558 builds capacity, skills and is based on the premise of equal 559 value of expertise, whether that be design, health, academic or 560 personal experience. We have found useful design ideas 561 coming from different life experiences, for example a user 562 recommending a plumbing component with relevance to the 563 design of an incontinence product. Co-design activities build 564 empathy in the design professionals (designers, engineers, 565 material scientists, researchers, etc.) involved as they see the 566 perspective of the user more clearly and understand their 567 requirements; whilst it provides the user insight into design 568 processes, perspectives and methods. 569

3.4.3. Challenges of co-design

Whilst user and stakeholder involvement in co-design 572 activities is beneficial, there are a number of reported 573 challenges [17,69,70]. Co-design participants need to be 574 willing to share their experiences and ideas with new people; 575 help others have empathy with their condition; and have the 576 confidence to put forward their ideas. They may appear 577 resistant to change, be afraid to critique honestly, find it 578 difficult to convey their ideas, request significant changes 579 with little awareness of design constraints or fail to reach a 580 consensus [17,71]. Co-design workshops can be challenging 581 in terms of ensuring involvement through different activities; 582 balancing personality and confidence issues and differences in 583 work pace [60]. Equally, designers can be criticized for 584 adding unnecessary complexity, focusing on styling and use 585 of subject-specific language when working directly with end-586 users [17,71]. 587

In D4D projects these challenges have been addressed 588 through careful use of language, explanation of the process 589 and the development of tailored design tools. The use of a 590 facilitator has been found to be advantageous in resolving 591 conflicting views and when users may lack confidence or 592 need support contributing. The nature of the co-design 593 exercise and format is also important for adapting to 594 individual needs and styles; for some, smaller group or 1:1 595 sessions might be more appropriate. 596

Rapid prototyping and storyboarding tools are useful for demonstrating designs to non-designers. In our experience, users can find it hard to visualize a final product from a sketch or early prototype. Mock-ups and prototypes are useful to 600 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 608 presenting ideas, mock-ups and prototypes to support visu 609 ization so that users are not frustrated or disheartened 610 limited functionality and basic prototypes. The growth of 3 611 printing offers significant potential as it will become quick 612 easier and cheaper to provide realistic prototypes with great 613 potential for customization as the technology evolves [72,7 614 Briefings on the design process to educate users in the proce 615 and to set realistic expectations on what can be achiev 616 within the context of design constraints and competi-617 demands for resources is recommended. 618

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620 3.4.4. Interdisciplinary team working in design

621 The involvement of non-designers (SMEs, subject matt 622 experts, developers, scientists, etc.) in design can lead 623 challenges in terms of collaboration and shared understandi 624 and communication [70]. Members of D4D come from vari 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. 641

⁶⁴²₆₄₃ 3.5. Testing and evaluation

644 A user-centred approach is characterized by iterative testing and not just final evaluation [16] to ensure usability and cost 645 and efficiency benefits can be achieved by early identification 646 of issues in the development process [17,69]. Clinical trials 647 are used to study the impact of a device on clinical validity 648 649 and effectiveness [74]. User-centred methods such as heuristic evaluation and usability testing are better suited for exploring 650 barriers to usability, acceptability and willingness to use the 651 device, which will in turn determine healthy behaviours [11]. 652 A range of testing approaches is, therefore, valuable and it is 653 important to select the right level of testing for the questions 654 655 being asked, the user population and typical usage of the device [75]. Qualitative as well as quantitative approaches are 656 important to gain an in-depth understanding of device usage. 657 In a healthcare environment, ethical approval, funding 658 requirements and impact/research assessment can lead 659 towards controlled trials for generating credible evidence to 660

Table 1. Identified challenges of UCD of healthcare devices.	661
	(()

•	Gaining and maintaining access to users, carers and healthcare
_	Professionals Reaching and angaging 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
•	Rationalizing and prioritizing competing user and stakeholder
•	Minimizing bias in the prioritization 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

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

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

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- (5) Health economics and market analysis [76].
- (6) Clinical trials.

Where medical devices are developed, they are subject to 713 regulatory approval [74,77]. It may be necessary to carry out a 714 clinical trial in order to obtain CE marking for a medical 715 device and demonstrate that the device is compliant. This 716 topic is discussed more fully in another paper within this 717 special issue. The approach taken to testing, therefore, 718 depends on the stage of development and the context in 719 which the device will be used. 720

721 **4. Conclusions**

722 UCD in the healthcare context involves taking users on a 723 journey, involving them in the research and development 724 process, whilst offering the potential that the resulting device 725 will improve their dignity, independence and health. The final 726 product will always be a balance of competing demands 727 placed by a variety of stakeholders: the users, the healthcare 728 professionals, the buyers and purchasers, the regulators; and 729 constraints in terms of the cost of materials and manufacture. 730 However, it is important that, where possible, effective 731 solutions are delivered back to the user.

732 Involving a diverse range of users and stakeholders, is not 733 straightforward; but it is argued that working closely together 734 ensures that development is driven by real need and the final 735 product is one that is acceptable and usable. In order for the 736 UCD approach to be applied effectively, project planning 737 should take into account some of the challenges that face 738 UCD as it is applied in healthcare. Based on the experience of 739 embedding it as part of the D4D development process, some 740 of the key challenges are summarized in table 1. 741

The design of effective devices, products, systems and 742 services for healthcare requires expertise from diverse fields 743 and user and stakeholder involvement. As the benefits of 744 UCD are becoming widely accepted, research should focus on 745 strategies to reduce the challenges associated with designing 746 for health and finding practical working approaches to 747 facilitating user involvement. The design and usability of 748 technology should not be a barrier to healthy behaviours and 749 to the uptake and continued use of clinically-effective 750 products. 751

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758 Declaration of interest

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

763 **References**

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- Clarkson, P.J. Buckle, P., Coleman, R., Stubbs, D., Ward, J., Jarrett, J., and Lane, R., 2004, Bound Design for patient safety: A review of the effectiveness of design in the UK Health Service. *Journal of Engineering Design*, **15**, 123–140.
- Horne, M., Khan, H., and Corrigan, P., 2013, People Powered Health: Health for people, by people, with people (NESTA). Available online at: http://www.nesta.org.uk/library/documents/ PPHforpplbyppl2.pdf. Accessed 13 November 2014.
- Parker, S., and Heapy, J., 2006, The Journey to the Interface: How public service design can connect users to reform (London, UK: Demos). Available online at: http://demos.co.uk/publications/thejourneytotheinterface. Accessed 13 November 2014.
- Cottam, H., and Leadbeater, C., 2004, RED Paper 01 Health: Co-creating Services Available online at: http://www.hilarycottam.com/wp-content/uploads/(2010)/01/RED_Paper-01-Health_ Co-creating_services.pdf. Accessed 13 November 2014.
- 5. Buckle, P., Clarkson, P.J., Coleman, R., Ward, J., and Anderson, J., 2006, Patient safety, systems design and ergonomics. *Applied Ergonomics*, 37, 491–500.
- Furniss, D., O'Kane, A.A., Randell, R., Taneva, S., Mentis, H., and Blandford, A., 2013, HCI fieldwork in healthcare — Creating a

guidebook. CHI '13 Extended Abstracts on Human Factors in Computing Systems, April 27-May 02, 2013, Paris, France. pp. 3203–83206.

- Buckle, P., Clarkson, P.J., Coleman, R., Lane, R., Stubbs, D., Ward, J., Jarrett J., and Bound, R., 2003, Design for Patient Safety: A System-wide Design-led Approach to Tackling Patient Safety in the NHS (London: Department of Health Publications). Available online at: http://www-edc.eng.cam.ac.uk/medical/reports.html. Accessed 5 November 2014.
 783
 784
 784
 785
 786
 787
- Clarkson, P.J., Buckle, P., Coleman, R., Stubbs, D., Ward, J., Jarrett,
 J., Lane, R., and Bound, R., 2004, Design for patient safety: A review of the effectiveness of design in the UK Health Service. *Journal of Engineering Design*, 15, 123–140.
- Yoxall, A., and Christer, K., 2013, Proceedings of the Second 791 European Conference on Design 4 Health 2013, 3 – 5 July 2013. 792 Sheffield Hallam University, Art & Design Research Centre, 793 Sheffield, UK. ISBN: 978-1-84387-373-0. 794
- Abras, C., Maloney-Krichmar, D., and Preece, J., 2004, User-Centered Design. In: Bainbridge, W., editor. Encyclopedia of Human-Computer Interaction (Thousand Oaks, CA: Sage).
- Nielsen, J., 1993, Usability Engineering. Morgan Kaufmann 797 (New York: Academic Press).
 798
- Robert, G., 2007, Bringing User Experience to Healthcare Improvement: The Concepts, Methods and practices of experience-based design (Oxford: Radcliffe Publishing Ltd).
- Sanders, E.B.N., and Stappers, P.J., 2008, Co-creation and the new landscapes of design, CoDesign. International Journal of CoCreation in Design and the Arts, 4, 5–18.
- Bias, R.G., and Mayhew, D.J., 2005, Cost-Justifying Usability: An Update for the Internet Age (San Francisco, CA: Morgan Kaufmann Publishers).
 803
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 804
 804
 804
 804
 805
- Mayhew, D.J., 1999, The Usability Engineering Lifecycle (San Francisco, CA: Morgan Kaufmann). pp. 1–15.
 Intermetional Operation for Standardization (ISO). Engenemica 807
- International Organization for Standardization (ISO), Ergonomics of human-system interaction—Part 210: Human-centred design for interactive systems ISO 9241-210:2010 ISO Standards. Available online at: http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=52075. Accessed 13 November 2014.
- Kujala, S., 2003, User involvement: A review of the benefits and challenges. *Behaviour and Information Technology*, 22, 1–16.
- Shah, S.G.S., and Robinson, I., 2006, User involvement in healthcare technology development and assessment. *International Journal of Health Care Quality Assurance*, 19, 500–515.
- Lee, S.H., 1999, Usability Testing for Developing Effective 816 Interactive Multimedia Software: Concepts, Dimensions and Procedures. *Educational Technology & Society*, 2, 1436–1440.
 818
- 20. Forrester Report, 2001, Get ROI from design (Cambridge, MA: Forrester Research, Inc.). 819
- Bevan, N., Cost benefits evidence and case studies Available online 820 at: http://www.usabilitynet.org/papers/Cost_benefits_evidence.pdf. 821 Accessed 05/02/15.
- 22. De Vito Dabbs, A.I., Myers, B.A., Mc Curry, K.R., Dunbar-Jacob, J., Hawkins, R.P., Begey, A., and Dew, M.A., 2009, User-centered design and interactive health technologies for patients. *Computers, 1nformatics, Nursing*, 27, 175.
- Marti, P., and Bannon, L.J., 2009, Exploring user-centred design in practice: Some caveats. *Knowledge, technology & Policy*, 22, 7–15.
- Martin, J.L., Norris, B.J., Murphy, E., and Crowe, J.A., 2008, 828 Medical device development: The challenge for ergonomics. 829 *Applied Ergonomics*, 39, 271–283.
 Paulson D. and Richardson S. 1008. USEDE: a framework for 830
- Poulson, D., and Richardson, S., 1998, USERfit–a framework for user centred design in assistive technology. *Technology and Disability*, 9.3, 163–171.
 832
- 26. Furniss, D., and Blandford, A., 2013, The challenge of doing 833 fieldwork in healthcare. *The Ergonomist*, **19**, 18.
- 27. Devices for Dignity Healthcare Technology Cooperative, Available online at: http://www.devicesfordignity.org.uk/. Accessed 13 November 2014.
 834
 835
 836
- Devices for Dignity Healthcare Technology Co-operative, 2014, Providing dignity and independence - linking, listening and learning through the pilot years 2008 to 2013. Available online at: http://www.devicesfordignity.org.uk/resources/news/247-d4dend-of-pilot-report-2008-2013. Accessed 26 November 2014.

- 8 L. Moody
- 841 29. Heron, N., Tindale, W., and Hawley, M., 2010, Devices for Dignity;
 842 A Healthcare Technology Co-operative (AAATE). pp. 31–32. Available online at: http://www.aaate.net/sites/default/files/ AAATEworkshopSheffield(2010)_proceedings.pdf#page=31.
 844 Accessed 19 November 2014.
- 845 30. Norman, D., 1998, The Design of Everyday Things (MIT Press).
- 31. Campbell, N.C., Murray, E., Darbyshire, J., Emery, J., Farmer, A., Griffiths, F., and Kinmonth, A.L., 2007, Designing and evaluating complex interventions to improve health care. *British Medical Journal*, 334, 455–459.
- 849 32. Hewlett, S., Wit, M.D., Richards, P., Quest, E., Hughes, R., Heiberg, T., and Kirwan, J., 2006, Patients and professionals as research partners: Challenges, practicalities, and benefits. *Arthritis Care & Research*, 55, 676–680.
- Robertson, Z., Hawley, M., and Heron, N., 2010, Devices for
 Dignity in Practice Collaborative working to achieve technology
 transfer (AAATE). pp. 72–75. Available online at: http://www.aaate.net/sites/default/files/AAATEworkshopSheffield(2010)_
 proceedings pdf#page=72_Accessed 19_November 2014
 - proceedings.pdf#page=72. Accessed 19 November 2014.
- 856 34. Pagliari, C., 2007, Design and evaluation in eHealth: Challenges and implications for an interdisciplinary field. *Journal of Medical Internet Research*, 9, e15.
- 35. Eason, K., 1987, Information technology and organizational change (London: Taylor and Francis).
- Solution 2010 Sector 2010 Sec
- 37. Curry, A., Stark, S., and Summerhill, L., 1999, Patient and stakeholder consultation in healthcare. *Managing Service Quality*, 5, 327–336.
- 865 38. Vink, P., Imadac, A.S., and Zinkd, K.J., 2008, Defining stakeholder involvement in participatory design processes Applied Ergonomics, 39, 451–526.
- 867 39. Moody, L., Long, A., and McCarthy, A., 2014, Design for Health and Dignity: User and Stakeholder Involvement in Design for Urinary Continence. *Advances in Human Aspects of Healthcare*, 3, 58–63.
 870 40 58–63.
- 40. Department of Health, 2011, Operational guidance to the NHS:
 Extending Patient Choice of Provider.
- 41. Moody, L., and McCarthy, A., (), Experiences of leg bag users and emerging design priorities. *Journal of Wound Care, Ostomy and Continence*, , E. (In press).
- 42. Appleby, J., Harrison, A., and Devlin, N.J., 2003, What is the real cost of more patient choice? (London: King's Fund).
- 876 43. Drug Tariff. Available online at: http://www.nhsbsa.nhs.uk/
 924.aspx. Accessed 20 November 2014.
- 44. John, L., Ross S., McLeod, C., and Gildiner, A., 2003, Measuring the impact of health research. *Journal of Health Services Research* & *Policy*, 8, 165–170.
- Phillips, C., What is a QALY? Available online at: http://
 www.medicine.ox.ac.uk/bandolier/painres/download/whatis/
 OALY.pdf. Accessed 5 February 2015.
- 46. Dixon, S., Palfreyman, S., Shackley, P., and Brazier, J., 2011, What is dignity? A literature review and conceptual mapping. Discussion Paper. (Unpublished). Available online at: http://eprints.whiterose.ac.uk/43280/. Accessed 19 November 2014.
- 47. Health Research Authority, Available online at: http://www.hra.nh-s.uk/about-the-hra/. Accessed 13 November 2014.
 887 48 Thompson A G 1 and France E E 2010 One stop or full stop?
- Thompson, A.G.1., and France, E.F., 2010, One stop or full stop?
 The continuing challenges for researchers despite the new streamlined NHS research governance process. BMC Health Services Research, 13;10, 124.
- McDonach, E., Barbour, R., and Williams, B., 2009,
 McDonach, E., Barbour, R., and Williams, B., 2009,
 Reflections on applying for NHS ethical approval and governance
 in a climate of rapid change: Prioritising process over principles.
 International Journal of Social Research Methodology, 12, 227–241.
- Alberti, K.G., 2000, Multicentre research ethics committees: Has
 the cure been worse than the disease? But idiosyncrasies and
 obstructions to good research must be removed. *British Medical Journal*, 320, 1157–1158.
- 51. Lux, A.L., Edwards, S.W., and Osborne, J.P., 2000, Responses of local research ethics committees to a study with approval from a multicentre research ethics committee. *British Medical Journal*, 320, 1182.

- Health Research Authority, Defining Research Available online at: http://www.hra.nhs.uk/documents/(2013)/09/defining-research.pdf. Accessed 13 November 2014.
- Dickson-Swift, V., James, E.J., Kippen, S., and Liamputtong, P., 2007, Doing sensitive research: What challenges do qualitative researchers face? *Qualitative Research*, 7, 327–353.
- 54. Garcia, J.A., Crocker, J., and Wyman, J.F., 2005, Breaking the Cycle of Stigmatization: Managing the Stigma of Incontinence in Social Interactions. *Journal of Wound, Ostomy & Continence Nursing*, 32, 38–52.
 908
- 55. Kavanaugh, K., and Lioness, A., 1998, 'Not as bad as it could have been': Assessing and mitigating harm during research interviews on sensitive topics. *Research in Nursing & Health*, 21, 91–97.
 56. Joss, N., and Oldenburg, B., 2013, Costs and benefits of end user 912
- Joss, N., and Oldenburg, B., 2013, Costs and benefits of end user engagement in disability research: A snapshot review. ISCRR 913 research report for WorkSafe/TAC. 914
- 57. Scott, W.D., Woodcock, A., and McDonagh, D., 2015, An investigation of the methods used by designers to engage with users that have Specific, Critical, Additional Needs (SCAN).
 916 International Journal of Design Management and Professional 917 Practice, 8, 1–13.
- Judge, S., and Townend, G., 2010, Users' perceptions of communication aid design - D4D project report. Devices for Dignity.
- 60. Thieme, A., Vines, J., Wallace, J., Clarke, R.E., Slovák, P., 925 McCarthy, J., and Parker, A.G., 2014, Enabling empathy in health and care: Design methods and challenges. CHI 2014 Extended Abstracts on Human Factors in Computing Systems. ACM, , 139–142.
 61. Moody L. and McCarthy A 2011 Improving the design of leg 929
- Moody, L., and McCarthy, A., 2011, Improving the design of leg 929 bags. BB&F: The Journal of the Bladder and Bowel Foundation, 7, 930 12–13.
- Berander, P., and Andrews, A., 2005, Requirements prioritization.
 Engineering and managing software requirements (Heidelberg: Springer Berlin). pp. 69–94.
 931
 932
 933
- Akao, Y., 1988, Quality Function Deployment: Integrating 934 Customer Requirements into Product Design (Productivity 935 Press).
- 64. Saaty, L., 1980, The Analytical Hierarchy Process (New York: McGraw-Hill).
- 65. Ijzerman, M.J., Van Til, J.A., and Bridges, J.F., (1), A comparison 938 of analytic hierarchy process and conjoint analysis methods in assessing treatment alternatives for stroke rehabilitation. *The Patient-Patient-Centered Outcomes Research*, 5, 45–56.
- Karlsson, J., and Ryan, K., 1997, A cost-value approach for prioritizing requirements. *IEEE Software*, 14, 67–74.
- Damodaran, L., 1996, User involvement in the systems design process-a practical guide for users. *Behaviour & Information Technology*, 15, 363–377.
- Druin, A., 2002, The role of children in the design of new 945 technology. *Behaviour and Information Technology*, 21, 1–25. 946
- 69. Wilson, S., Bekker, M., Johnson, P., and Johnson, H., 1997, Helping and hindering user involvement—a tale of everyday design. *Proceedings of the ACM SIGCHI Conference on Human factors in computing systems, ACM*, Ⅰ, 178–185.
- Wilson, S., Bekker, M., Johnson, H., and Johnson, P., 1996, Costs 950 and benefits of user involvement in design: Practitioners' views. 951 People and Computers XI (London: Springer). pp. 221–240.
- Vilich, R.S., Zimring, C.M., Zhu, X., DuBose, J., Seo, H., Choi, Y., et al., 2008, A review of the research literature on evidence-based healthcare design. *Health Environments Research & Design*, 1, 954 61–125.
- 72. Lipson, H., and Kurman, M., 2013, Fabricated: The new world of 3D printing (John Wiley & Sons).
- Giannatsis, J., and Dedoussis, V., 2009, Additive fabrication technologies applied to medicine and health care: A review. 958 *International Journal of Advanced Manufacturing Technology*, 40, 959 116–127. 960

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922

923

928



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- MHRA. Available online at: http://www.mhra.gov.uk/ Howweregulate/Devices/Classification/. Accessed 20 November 2014.
- 963 75. Heathfield, H., Pitty, D., and Hanka, R., 1998, Evaluating
 964 information technology in health care: Barriers and challenges.
 965 British Medical Journal, **316**, 1959–1961.
- 76. Dymond, E., Long, A., McCarthy, A., and Drake, M.J., 2012, Developing a new treatment device: How to get an idea to the marketplace. *Neurourology and Urodynamics*, **31**, 429–436.
- European Medical Device Directive (93/42/EEC). Available online at: http://ec.europa.eu/enterprise/policies/european-standards/ harmonised-standards/medical-devices/index_en.htm. Accessed 24 November 2014.
- Mangera, A., Marzo, A., Heron, N., Fernando, D., Hameed, K., Soliman, A.H.A., and Chapple, C., 2014, Development of two electronic bladder diaries: A patient and healthcare professionals pilot study. *Neurourology & Urodynamics*, 33, 1101–1109.