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Participatory Design, User Involvement and Health IT Evaluation

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Abstract. End user involvement and input into the design and evaluation of information systems has been recognized as being a critical success factor in the adoption of information systems. Nowhere is this need more critical than in the design of health information systems. Consistent with evidence from the general software engineering literature, the degree of user input into design of complex systems has been identified as one of the most important factors in the success or failure of complex information systems. The participatory approach goes beyond user-centered design and co-operative design approaches to include end users as more active participants in design ideas and decision making. Proponents of participatory approaches argue for greater end user participation in both design and evaluative processes. Evidence regarding the effectiveness of increased user involvement in design is explored in this contribution in the context of health IT. The contribution will discuss several approaches to including users in design and evaluation. Challenges in IT evaluation during participatory design will be described and explored along with several case studies.

Keywords. User-computer interface, software design, electronic health records, evidence-based practice.

1. Introduction

Work in health care has always been closely dependent on advanced levels of knowledge, and the way in which professionals work is not always apparent. Work may be interpreted differently and work descriptions do not reveal all aspects of work practices [1]. The late Professor Branko Cesnik of Monash University often used the slide in Figure 1 to express that the knowledge applied in health care activities arises from interaction rather than evidence. Instead of performing a literature search in e.g. Medline prior to making a decision to act, it is more common to discuss the issue with a co-worker, or ask a more senior colleague.

When designing or evaluating health IT systems it is essential to explicate the underlying knowledge that is determining the health care professionals' decisions to act. For this reason it is important to give the end users a prominent position particularly in design projects. However there are a multitude of methods to involve end users in design processes. In Figure 2 three of the dominant schools for involving users in IT sys-

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tem design are depicted. The three schools vary in the extent to which the user is involved in decision making about design.

> You can't **write** all that you say
> You can't **say** all that you know
> You often don't know what you know until you **need** to
> You often know how to **find** who does know
> Knowledge arises as much from **interaction** as from evidence

Figure 1. In performing health care work knowledge arises from interaction (from Professor Branko Cesnik, Monash University).

The *user-centered design* approach became widely used after Donald Norman and Stephen Draper in 1986 published their book: "User-Centered System Design: New Perspectives on Human-Computer Interaction" [2]. Two years later Norman published his seminal book "The Psychology Of Everyday Things (POET)" [3], which later was revised to "The Design of Everyday Things" [4], where he urged designers to study people, to take their needs and interests into account. The user-centered approach is also inherent in traditional usability testing and evaluation.[2] The methodological challenges for the user-centered design process are how to understand users' need and design for these needs. The user-centered approach acknowledges the importance of user input into design and the characteristics of user-centered design include: (a) an early focus on observing and understanding users and tasks in design, (b) empirical evaluation and measurement of user interactions, and (c) iterative design processes (involving cycles of design, evaluation and re-design) [5]. This may involve the designer/developer observing and making notes about user (e.g. health professional or eHealth consumer) preferences, interactions and needs (as depicted in Figure 2a) using a variety of methods ranging from usability testing to observational methods such as time-motion studies [6].

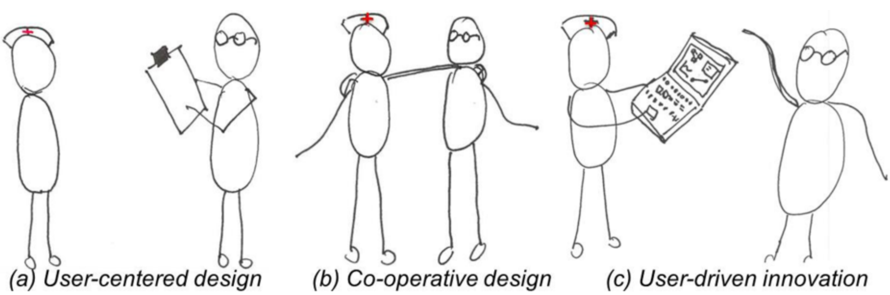

Figure 2. Three different schools of user involvement in IT design.

[2] See also: R. Marcilly et al., From usability engineering to evidence-based usability in health IT, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics 222, Stud Health Technol Inform, IOS Press, Amsterdam, 2016.

The *co-operative design approach* emerged as recognition that as work activities become complex, human activities involve coordination and co-operation among many individuals with different areas of expertise. When the number of people involved in a work process exceeds a few, the complexity of coordinating increases several times. CSCW (Computer Supported Cooperative Work) is a central research field to address how collaborative activities and their coordination can be supported by means of computer systems [7]. The main challenge for the co-operative design approach is how to co-operate with users in the design process. This is depicted in Figure 2b, where user and designer/developer work together to come up with designs and modifications to design. This may involve creating a "design process where both users and designers are participating actively and creatively, drawing on their different qualifications" [8]. Other aspects of this approach include creation of prototypes that can be shown to users and used to simulate future work situations or studied in real settings (i.e. "in-situ" simulations) or in real life. Use of prototyping and simulations[3] allow the users to explore and experience future work situations involving technology. This in turn supports discussion among the users and the designer/developers through a co-operative process. As an example, work by Jensen and colleagues, in development of a laboratory where clinical simulations are conducted with end users, has allowed for design and redesign of a wide range of clinical information systems [9].

User driven innovation is an example of participatory design where the basic idea is to engage the users to innovate and develop products themselves. Here the user becomes the central player on the design team and as shown in Figure 2c where key aspects of design decision making emanate from the user(s) themselves and the role of the developer becomes that of supporting and facilitating this creative user process. Participatory design involves direct involvement of users in the design of technologies [10]. Thus there is an emphasis on direct input of users in the design process and users are actively involved in decision making about design. It is not uncommon that users are the real source of innovations in an array of areas. Von Hippel studied this systematically and recommended that user driven innovation projects focus on "lead users" as the primary source of innovation [11]. A specific method to work systematically with the innovation process is described by Kanstrup and Bertelsen in their handbook on user innovation management [12]. This method involves application of a set of user innovation management (UIM) techniques to facilitate user innovation including stepwise approaches to understanding users and their contexts to generate design concepts from. As will be discussed, a major challenge for the user driven innovation approach is how to create space for user innovation, collect and sort out user-innovations, and transform these into new products.

2. Rationale for User Participation

There are two main rationales for participation of end users in design and evaluation of health IT. A pragmatic rationale is to increase IT system functionalities and service quality. This rationale stresses the need for users and developers to learn together through continuous mutual learning processes. The designers are responsible for point-

[3] See also: S. Jensen, Clinical simulation as an evaluation method in health informatics, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

ing out technological options, and the users are the source of knowledge about their practices and the use situation [10].

A second rationale is political and reflects a commitment to give voice to those whose future we are to design. The basic premise is to *empower*, *emancipate* and *enhance* the health professional, the patient and/or the citizens in relation to application of health IT systems [13]. Participation needs to happen, because those who are to be affected by the changes resulting from designing and implementing health IT systems should, as a basic human right, have the opportunity to influence the design and implementation processes [10].

The two rationales behind participation in design or evaluation of health IT cannot be parameterized to obtain evidence of their efficiency or effectiveness – from this perspective it is basically a matter of commitment and taking a stand. Healthcare has often been slow to empower users as equals and this has been a strong rationale for increased user participation in design of new healthcare systems and applications.

As described above, the degree of end user participation in design can be seen as being on a continuum from considering the user as a "subject of study" in user-centered design, to users playing a more collaborative role in co-operative design, to the move to users driving the design process itself in true participatory design. In the following section we will provide examples of design projects within health informatics that vary along this continuum of user involvement in design. This will be followed by a discussion of the evidence in the literature about the benefits of user involvement and also the challenges and issues that arise as the degree of user input and involvement in design is increased.

3. An Example of a User-centered Design and Evaluation Project

A key component of user-centered design is continual and iterative input from end users through the evaluation of user interactions with developing prototypes and system designs. Early work in this area in health informatics came from Kushniruk and colleagues who applied and extended usability engineering methods to the design and refinement of healthcare information systems such as electronic health records, decision support systems and patient clinical information systems [14].

The first work in this area involved classic usability testing methods whereby representative end users (e.g. physicians and nurses) were observed as they were asked to carry out representative tasks (e.g. entry and retrieval of information about medications) using early system designs and prototype information systems. This work involved video recording users as they interacted with the systems under study while verbalizing their thoughts (i.e. "thinking aloud").Thus the approach involved the designer/developers observing end users, noting their problems and issues through analysis of their observations, and refining system designs based on their analyses of end user interactions.

In a series of studies examining design of an electronic health record system (EHR) for use in clinical contexts, 16 physicians were asked to interact with a prototype version of the system and to think aloud while using it to carry out representative tasks (e.g. entering and retrieving patient data) using the system [14]. The screens were recorded as digital videos (using freely available screen recording software) and audio recordings of their thinking aloud were fully transcribed. In addition, physical actions can be recorded using an external camera (see Figure 3 for an example showing a health professional being recorded as she works with a computer system).Using a video coding scheme (described in [15]) the user interactions were analyzed at a fine-grained level to identify usability problems and potential inefficiencies and flaws with the design of the system. This resulted in identification of a range of specific usability issues, including user navigation problems, difficulty qualifying medical findings in the system, and difficulty in representing temporal sequences. The results were summarized and presented to the design team, resulting in a modified user interface, which was in turn tested again to ensure that the issues identified were resolved.

With this user-centered approach to design, users were involved in the process early on and their interactions with evolving prototypes and early system designs were recorded and analyzed. However, their direct input into design decision making was limited, with some direct user suggestions being incorporated into redesign, but the majority of "fixes" coming from results of empirical analysis of user interactions by the design and evaluation team. The approach was shown to be effective, and many subsequent usability studies following this iterative user-centered approach have shown substantial reduction of user problems from one iteration to the next in the design and implementation of systems such as EHRs in a range of clinical settings, with one evaluation project showing a ten-fold decrease in coded usability problems during one iteration [15]. The user-centered approach has also been effectively applied to the analysis of systems designed for use by patients and lay people [31]. In addition, the approaches to conducting such user-centered evaluation to feedback input into iterative cycles of redesign have been modified and packaged to become low-cost and rapid in their application [16], which is leading to increased dissemination of user-centered design methods in healthcare (see Figure 3).

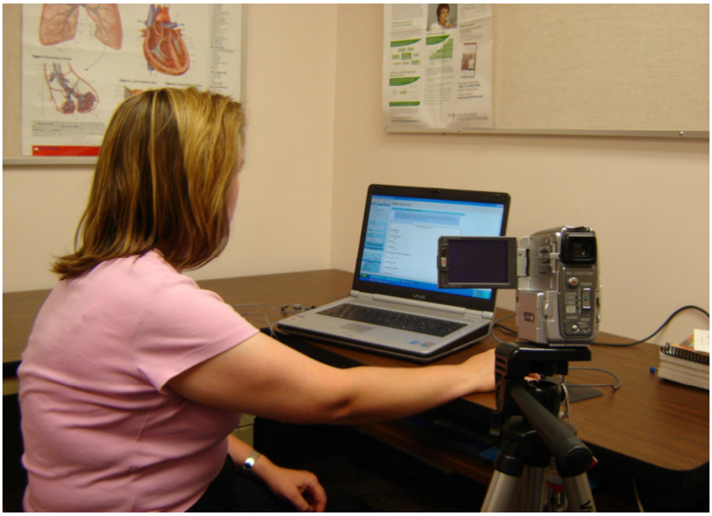

Figure 3. Example of low-cost rapid usability engineering set up for video recording health professionals as they work.

4. An Example of a Co-operative Design and Evaluation Project

As noted above, healthcare IT projects are recognized for being complex, typically involving multiple users and highly variable contexts of use. To address these issues we need to ensure systems are not only free from usability problems but that they serve to support and enhance complex healthcare workflow and practices [15].To address these issues evaluative projects have emerged that may include multiple levels of analysis to consider not only surface level usability problems, but also the impact of systems and technology on workflow, inter-professional collaboration, healthcare outcomes and patient safety. This has necessitated the application and development of new approaches in healthcare IT for supporting co-operative design. Along these lines low-cost methods for conducting evaluations involving multiple users in simulated as well as real life healthcare settings and contexts (i.e. "in-situ" methods) have emerged [16][18]. These methods extend the usability testing methods employed in user-centered design to include recording of users in real work settings and collaborative environments. Such work has been aimed at better understanding the complex interaction and interplay among multiple users (e.g. physicians, nurses, patients) in multiple contexts (e.g. hospital care, home care) of use. To carry out this type of design one approach has been the development of simulation laboratories [9], while other researchers have moved the study to the actual location(s) where the technology will be used (e.g. in a particular hospital or home setting).

In an extension of the work described above for user-centered design of an EHR, it was discovered that increased and new types of user input would be needed to determine how to effectively modify and extend the design of the EHR for use in real clinical practice (i.e. during use with patients present in the room during clinical consultations). Along these lines, the application of the "simulated patient" approach (used in medical education to assess resident-patient interactions) was extended to be including in clinical simulations that involved physicians interacting with prototype EHRs while interacting with actors playing the role of patients. This involved video recording not only the computer screens but also the full doctor-patient interaction (e.g. dialogue between the doctor and the patient). The earliest work along these lines in healthcare IT was able to detect how an EHR system affected doctor-patient interaction and clinician decision making through video analysis of the interaction during several clinical scenarios [17]. The results were used to modify the user interface of the EHR to include features that users desired (such as easier navigation through the system using a navigation map feature).

It should be noted that during design sessions, the users who had interacted with the EHR system during the simulations were also included in design discussions to provide direct input and feedback into modifications of the system. Thus the roles of users in the project included interacting with the prototype and system being developed, as well as directly interacting with the design team during debriefs and design meetings to provide their continual input in a co-operative design process. This hybrid approach to user involvement (i.e. involving both observation of users, and also their direct input and feedback into design decision making) has since proven useful in a wide range of projects [18], including in the design and evaluation of a medication information system, and in the study of personal health records where users worked closely with designers in verbalizing and documenting their information needs during post-task interviews and cued-recall sessions after interacting with a health information system [19].

5. An Example of User Driven Innovation

User driven innovation is an excellent example of participatory design. In user driven innovation, the key issue is to create the space for *users* to be able to innovate and to transform these innovation ideas into new products or usable systems. The innovations should be grounded in user's needs, values, and knowledge.

Kanstrup and Bertelsen have outlined three central themes for organizing and conducting user-driven innovation and presented a set of techniques to support user-driven innovation processes [12]. First a co-operation between the users and the designers must be established – participating users must be carefully selected and a plan made for the innovation process. Second the context of the innovation has to be explored by gaining insight into current problems and needs, and also generating visions for future solutions. Thirdly ideas for the possible futures should be sketched and presented to decision makers. The second phase can be particularly challenging in the health care domain as health care institutions and facilities constantly are short of resources and taking clinicians away for design activities always means taking their time away from patient care. However, design games can be an activity that makes participating in innovation projects achievable as it has a high output using little clinician time for participating.

In the early 1990's design games were introduced to provoke development of a shared understanding among users and designers [20] and to form dialogue that supported mutual learning of the current practice and generate new design ideas [21]. Kanstrup and Christensen point out that the opening of the mind that gaming generates can be explained by Bateson's reflection on fun and seriousness, fantasy and games [22-23]. When playing games we are moving down unknown paths and thereby discover new aspects and generate new ideas. In games you can challenge the rules of current work practice by adding randomness to achieve a certain degree of "muddle". In Bateson's metalogues[4] he makes the point: "If we didn't get into muddles, our talks would be like playing rummy without first shuffling the cards" [23, p. 26]

In the European project PSIP (Patient Safety through Intelligent Procedures in medication), which aimed to identify and prevent adverse drug events (ADE), a participatory design approach using design games was employed. The main objective of the project was to develop innovative knowledge based on data mining results and to deliver to professionals and patients a contextualized knowledge fitting the local risk parameters in the form of alerts and decision support functions. The design of these decision support functions was targeted by a design game approach. A PSIP design game was constructed to create space for clinician users to participate with their design ideas for clinical decision support functions [24]. The game was played by two teams (green team and blue team) each consisting of two nurses and two physicians (see Figure 4). They had the following items available:

- A box called "the PSIP machine" was made as a physical artifact that they could point to, hold, discuss the functionality of – a machine they could attribute any ability they wanted.
- A set of laminated scenarios for situations with medical errors for focusing and situating discussions and designs against medical errors.

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[4] A metalogue is a conversation about some problematic subject.

- Printed cards describing pre-made functionalities for clinical decision support plus blank cards for the group to describe newly invented functionalities.

The task for the competing teams was to build machines that could help to prevent the errors in the scenarios. There were no limits to the ability of the machines, they can do whatever the participants can imagine. The rules of the game were:

- Participants have two minutes to read the scenario.
- The team has 10 minutes to discuss the scenario and design a "PSIP machine" using the functionality cards or the blank cards.
- The teams have two minutes to present their machine to each other.
- After one hour the designed machines were evaluated and scored by the competing group.

The PSIP design game included three principles: Focus, produce, and prioritize. The scenarios presenting the problems to solve were derived from the database of reported ADEs, they made the participants focus on a very specific task. The competitive elements and the time limits stimulated the creativeness to produce results, and the evaluation and scoring prompted a prioritization among the solutions.

The game process, the evaluation and scoring were documented with video photos and notes by the facilitators. The teams designed eight different machines for clinical decision support preventing medical errors. The machines presented what the teams found most important in order to prevent medical errors. In the succeeding debriefing the design principles were derived from the central themes – see table 1.

This design game provided central knowledge and ideas for future design of clinical decision support systems based on negotiations among expert clinical users about complex practices. The game resulted in eight different machines derived through discussions and priorities for further design that the players pointed out. The two-hour workshop occupied only very little clinician time but produced a very important outcome for the further input into the design process.

Figure 4. The PSIP design game.

Table 1. Central themes and design principles from the played game [24].

Theme	Design Principle
Risks related to lack of integration of information	**Design for integrated information:** If physicians are to gather information from several different information systems, the risk that some information will be missing is high. Hand written information is dangerous and must be avoided.
	Integrated information must be used intelligently for clinical alerts, i.e. in cases of interaction.
Risks related to misreading and analysis of measurements and test results	**Design graphical diagrams for visualizing measurements and lab results**: Diagrams, e.g. a curve, will at a glance reveal if a measurement is out of normal range.
Risks related to rigid information system	**Design for optimizing prescription:** Information systems experienced as rigid and a disturbance (vs. a support) of the clinical work tend to lead to bad data discipline and workarounds.
Risks related to interruptions	**Design for calm working environments when prescribing dispensing and administering medicine.**
Risk related to misreading of medicine	**Design for barcode readings** or other types of scanning for verification.

6. The Benefits of User Participation

In the general IT literature lack of user input during design has been identified as being the single biggest contributing factor in the failure of complex IT systems to be adopted by users [25]. This finding has been found to hold in a number of different domains and is nowhere more salient than when considering complex healthcare IT projects, which have been associated with a high failure rate internationally [15]. Thus there is clear evidence that lack of user input is detrimental to the likelihood of system success and end user adoption.

Regarding the impact of varying degrees of user involvement in design, Kujala [6] as well as Damodaran [26] have collated results of studies from a number of different areas. Reported benefits of increased user involvement during design (particularly from participatory design) have included: (a) improved system quality as a result of better and more accurate user requirements gathering, (b) greater likelihood of inclusion of features users actually want, while avoiding addition during design of costly features users did not want, (c) higher levels of user acceptance of the resultant system developed with greater user input, (d) improved understanding of the resultant system by end users leading to lessened training needs and fewer usage issues, and (e) a higher level of participation in decision making by users in the organization to which they belong.

7. Selecting Tools and Techniques for User Participation

Regarding the issue of selection of tools and techniques for supporting greater user involvement in design of healthcare IT, a growing body of literature has documented an array of design and evaluation methods that can be employed [10]. Muller and colleagues [30] have characterized participatory design practices along several dimensions in creating a taxonomy of methods that can be used for selecting an appropriate approach for a particular design project. Along one dimension there is a range between designers participating in the user's world, which includes ethnographic observation[5] and contextual inquiry and sessions envisioning future solutions (e.g. which could be held for example in an eHealth consumer's home or a health professionals' clinical environment). Other types of studies may be conducted in simulated environments (i.e. usability and simulation laboratories) using mock-ups, prototypes and theatres for design, where users may directly participate in design activities using computer supported tools, prototypes and methods.[6]

Also, the point in time along the system development life cycle where the product being developed is located is another important dimension, with methods such as use of design games, envisioning exercises, ethnographic methods and contextual inquiry being potentially very useful during the early phases of design. Methods particularly applicable later in the design process include co-operative prototyping, co-operative evaluation, participatory analysis of usability data and participatory customization of healthcare IT. Issues that cut across all phases of the life cycle include decisions regarding location of design and evaluation activities, the selection of user participants and the assessment of the appropriate user participant group size [10].

Evaluation methods used include many used in traditional system development. However, they differ fundamentally in the extent to which the boundary between designer and user is crossed and the degree, extent and nature of the user input into design. Therefore, evaluative methods such as focus groups, interviews, observation and methods adapted from usability engineering such as clinical simulations are applicable for evaluation during participatory design [10]. In addition, participatory and interpretive evaluative methods may also be applied, borrowing from advances in areas such as contextual inquiry, participative ethnographic methods, and video ethnography.

8. Issues and Challenges

Despite the reported benefits of greater user involvement in the design process, the issues of *how* (i.e. what methods to use), *when* (i.e. when during the system development life cycle) and *where* (e.g. in laboratory settings, real-world settings etc.) to engage users in design have remained active research questions, with varying evidence about the optimal approaches to bringing users into the design process in healthcare IT development [27]. In particular, the issue of assessing how representative the users (selected or volunteered to be involved in design process) are of the projected user population becomes a complex question when designing large scale systems (i.e. systems such as public health systems, which may have hundreds of thousands of users and a great many categories of different user types).

This has led Pilemalam and Timpka to discuss a need for a third generation of participatory design in healthcare (with the first generation being focused on the ideology of collective system design, and the second generation of participatory design shifting

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[5] See also: B. Kaplan, Evaluation of people and organizational Issues – Sociotechnical ethnographic evaluation, in: E. Ammenwerth, M. Rigby (eds.), Evidence-Based Health Informatics, Stud Health Technol Inform 222, IOS Press, Amsterdam, 2016.

[6] See also: R. Marcilly et al., From usability engineering to evidence-based usability in health IT, in: ibid.

towards commercial and IT applications [28]). According to Pilemalam and Timpka, participatory design "has traditionally presumed a certain degree of homogeneity as regards the information system target group". To address this issue they propose a hybrid approach for large scale health projects which may involve elements of both user-centered design (e.g. usability testing studies with a larger number of users) alongside traditional participatory design processes with smaller groups of users. In the literature other issues have appeared including the following: (a) the perception by some developers that there may not be enough time in the system development life cycle to involve users as extensively as they would like, (b) obtaining access to representative users (particularly in healthcare) may be difficult, (c) there is the potential to have too many "user voices" leading to difficulty in obtaining consensus, and (d) users may need to be educated about aspects of design in order to work more collaboratively with the design team [6].

The issue of how and when to consider differing "voices" within design and evaluation needs to be considered in the context of the systems development life cycle of health information systems. There are currently a number of open challenges and issues regarding increased user input into design processes. These include the following: (a) how to define and recruit users for participatory design and related approaches; (b) when and how users can most effectively be brought into design and evaluation processes throughout the system development life cycle; (c) the representativeness of the user and user groups involved, (d) what evaluative methods can best be applied when designing and developing systems using the participatory approach; and (e) how to translate user input into improved systems. Kensing and Blomberg also echo some of these issues and concerns and have identified three main areas of challenges: (a) the politics of design in terms of the degree of ability of users to influence and shape the design of systems they will end up using, (b) the nature of user participation, and (c) the selection of the right tools and techniques for effective user participation [29].

9. Discussion and Conclusion

Lack of user satisfaction with healthcare information systems has been a serious issue in the area of health informatics. Indeed, consistent with the general literature on system design and adoption, lack of user input into design has been shown to be one of the most significant factors associated with failure of systems to be adopted by end users [25]. Evidence relevant to designing more effective systems involving greater user input has shown that approaches such as user-centered and participatory design can improve the effectiveness and adoption of a wide range of information systems [6].

In this contribution we have explored a number of different approaches to increasing user input into system design for the improved design and evaluation of healthcare information systems. Although the approaches vary, the common and clear thread is the need for increased user involvement in design. A number of challenges and issues exist for effectively increasing user input into design. In particular further work is needed to determine what aspects of design are best enhanced through increased user involvement as well as what methods are most appropriate for facilitating increased user involvement through the different phases of the system development life cycle.

The challenges of incorporating effective evaluation into participatory design are varied, including issues of how to incorporate user needs, and how to incorporate evaluation of designs using both low and high fidelity prototypes in mobile, home or naturalistic environments. Innovative approaches such as use of design games and other methods involving collection of user artifacts, photographs and video clips have also been employed in a number of projects in healthcare in Denmark, Canada and internationally and are promising. The projects described in this contribution are examples of projects where end user input was significant for obtaining a successful outcome. Future work should include an emphasis on understanding both the benefits and challenges of increasing user involvement so that users can be most effectively incorporated in the design of healthcare software.

Recommended further readings

1. J. Simonsen, T. Robertson, *Routledge International Handbook of Participatory Design*, Routledge, New York, 2013.
2. L. Botin, P. Bertelsen, C. Nøhr (Eds.), *Techno-Anthropology in Health Informatics. Methodologies for Improving Human-Technology Relations*, Studies in Health Technology and Informatics, Vol. 215, IOS Press, Amsterdam, The Netherlands, 2015.
3. A.M. Kanstrup, P. Bertelsen, *User Innovation Management, a handbook*, Aalborg University Press, Aalborg, Denmark, 2011.

Food for thought

1. What are the key points in a system's conception and completion that user participation is important?
2. What methods do you think are most effective for involving users in design?
3. How can knowledge about the importance of increased user input be translated into practices in the healthcare software industry?
4. What group(s) of strategically important users are likely to be overlooked in involving users in design participation?

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