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Effective Usability Engineering in Healthcare: A Vision of Usable and Safer Healthcare IT

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Abstract

Persistent problems with healthcare IT that is unusable and unsafe have been reported worldwide. In this paper we present our vision for deploying usability engineering in healthcare in a more substantive way in order to improve the current situation. The argument will be made that stronger and more substantial efforts need to be made to bring multiple usability engineering methods to bear on points in both system design and deployment (and not just as a one-time effort restricted to software product development). In addition, improved processes for ensuring the usability of commercial vendor-based systems being implemented in healthcare organizations need to be addressed. A discussion will also be provided on challenges and barriers that will need to be overcome to ensure that the heatlhcare IT that is released is both usable and safe.

Keywords:

User-Computer Interface**;** Patient Safety**;** Health Information Systems

Introduction

Usability of healthcare IT has continued to be a worldwide issue, with continued reports of systems that are unusable, negatively affect healthcare workflow, and might even introduce a new class of error – technology-induced error [1-3]. There are a wide range of problems being reported that are related to human-computer interaction, including poor usability; the inability to customize systems to local needs, terminologies and workflows; and problems integrating information from multiple systems [4-7]. In response, there has been an attempt to create more effective processes for developing healthcare IT systems, including the introduction of certification processes in an attempt to encourage and mandate user-centered design and more usable systems.

In the United States, the Office of the National Coordinator (ONC) has developed guidelines for certifying the usability of vendor-based healthcare IT, including electronic health records. These have included vendors showing evidence of having applied user-centered design processes and usability testing in the design process [8]. In Europe, similar processes are also beginning to be mandated with CE marking [9]. However, Ratwani and colleagues have shown that the application of user-centered design processes by electronic health record (EHR) vendors is quite variable, even when adhering to the new regulations [10]. Results of their work also indicated that 63% of 41 vendors studied used fewer than 15 participants in usabilty testing and only 9% used at least 15 participants with clinical backgrounds. Currently, ONC-authorized certification organizations certify EHR products, with the vendor being required to provide a written statement about the process they used, along with results of usability tests. However, Ratwani and colleagues also found that there is a lack of adherence to certification requirements and standards (even among EHR products that were certified as meeting these requirements) [10]. Despite the importance of such certification as a first step, the current approaches are also limited in that they focus only on the system design/development process, and they do not extend to the implementation processes involved in system deployment of vendor systems in real world settings (such as hospitals and hospital systems). In such settings, customizing and modifying systems such as EHRs approaches the complexity of software product development. However, similar regulation covering practices for applying usability testing in the implementation of commercial vendor-based systems in real hospitals and clinical settings has been absent.

In this vision paper we argue for the need to distinguish between usability engineering needs in the: (a) one-time design process of systems (where certification efforts have been aimed so far), and (b) continual and long-term need for usability engineering in the implementation, customization and re-implementation of healthcare IT products. In addition, the argument will be made that a multi-level approach, borrowed from work in human-computer interaction in healthcare, is needed for ensuring healthcare IT usabilty and safety.

Need for Improved Usability Engineering in Healthcare IT Product Development

A variety of approaches have been developed and used for testing the usability of systems and assessing their impact on patient safety. However, as noted above, currently there are continued reports of a lack of system usability [5-7]. One of the issues is that the currrent certification requirements are limited and do not take into account the need for a variety of different approaches to applying usability engineering methods in the context of the multiple levels of complexity in healthcare. Along these lines, the context of use is critical to consider when conducting usability analyses. The testing of systems outside of the context of their application can lead to issues when the systems are actually used, and so an argument has been made for improved usability engineering processes. However, with a centralized product certification approach system usability and safety is assessed outside of the context of the healthcare organization where is it will ultimately be used. This is problematic when systems are later released into varied contexts within a region, across a country, and particularly when systems developed and certified in one country are imported into another country, where the healthcare system and workflow may be very different from the country in which the system was developed. Greater emphasis on testing systems in a variety of local contexts is also needed before releasing new healthcare IT products.

Need for Usability Engineering in Healthcare IT System Implementation and Customization

As noted above, usability certification processes are beginning to address the issue of a lack of usability of IT products. However, it should be noted that the centralized certification of vendor-based systems, such as EHRs, by regulatory bodies does not guarantee that such systems (post development) will either be usable or free from technology-induced error when later implemented in hospitals and healthcare settings. Along these lines, in this paper we also argue for the development of best practices for usability processes not only in system design and development, but also in the implementation of vendor-based EHR products in healthcare settings. This will be needed in order to ensure the entire process of implementation includes appropriate consideration for usability and safety. In our vision, which is based on advances in human-computer interaction, this would include a multi-level approach to testing and customizing commercial systems being implemented in healthcare settings.

Towards a Layered Approach to Usability Engineering Throughout the SDLC

Work in usability engineering in healthcare has shown that the application of methods emerging from the field of human-computer interaction need to be considered at multiple levels. Given the complexity of healthcare, it is not enough to test systems for human-computer interaction in isolation of their real use in complex and dynamic settings. Typical usability testing (such as it is specified currently by certification bodies) consists of observing and recording a small number of end users (e.g. physicians or nurses) as they interact with the system to carry out representative tasks (e.g. entering medication orders into a computer system). This level (which we refer to as Level 1) is useful to help identify and screen off surface level usability problems (such as labelling problems, navigational issues, font size issues, etc.). However, as shown in Figure 1, in order to ensure that healthcare IT will work properly in the context of carrying out work activities involving complex cognitive and social processes, Level 1 testing is not sufficient, and additional layers of testing will be required. (See Figure 1 for the proposed levels and their associated usability engineering methods listed on the right hand side of the figure.) As an example, Level 1 usability testing might involve observing physicians interacting with an EHR in isolation to carry out tasks and might determine that specific surface level aspects of the user interface need to be improved (such as making alerts and reminders more prominent on the computer screen). Although this might satisfy current certification requirements during the product's development, prior to releasing the system in hospitals it may also be important to know if the system integrates into daily work practices. For example, in the case of an EHR it might be important to know whether or not the system can be easily used during actual clinical interactions or if it interferes with clinical reasoning. In order to more fully test systems, a second level of testing is then needed: clinical simulations, as illustrated as Level 2 in Figure 1. (The up arrow in the figure shows the typical recommended progression of testing from Level 1 up to Levels 2 and 3.)

Clinical simulations extend usability testing by examining systems under real or realistic conditions, settings and contexts of use. For example, in order to assess if an EHR system works as expected when a physician user interacts with it during a patient interview, a clinical simulation can be created whereby the user's (i.e. physician's) interactions with the system are recorded while they interact with either a real or standardized patient (i.e. someone playing the role of the patient). Such testing, although essential to ensure a system works in realistic contexts of use, is beyond the scope of current regulations or certifications. However, a variety of published studies have reported on how this type of clinical simulation can be set up with relatively low cost and high impact for improving the design, as well as customization, of EHR systems [19].

Although clinical simulations are useful in assessing the potential impact of systems on workflow and more complex cognitive activies of health professionals, they can never fully predict how a system will work under real conditions. Along these lines, additional testing in restricted live or near-live contexts of use is recommended (see Level 3 in Figure 1). Studies where this was done have indicated it was worth the effort in terms of reducing usability problems and avoiding errors [11].

What Will be Required for this Improved Application of Usability Engineering in Healthcare?

Currently, a variety of usability methods and approaches exist that have been applied in projects and published in the health informatics literature. For example, work has been conducted in carrying out a wide range of usability tests, clinical simulations, and combinations of these approaches in order to improve heatlhcare IT usability and safety [19]. This has included work in: (a) improvement of software, (b) improvement of the process of development, (c) customization of vendor products and improvement in user training, (d) new approaches to software testing, and (e) selection and procurement of safe healthcare IT [12-20]. Along these lines, Marcilly and colleagues have argued for "evidence-based usability" in health IT, as the scientific body of reported methods that have proven effective has grown considerably [21]. Some of the results and methods that have emerged from this work have begun to be incorporated into regulatory processes in a number of countries [22]; however, progress in doing this has not kept up with the increasing reports of issues related to usability and safety of healthcare IT.

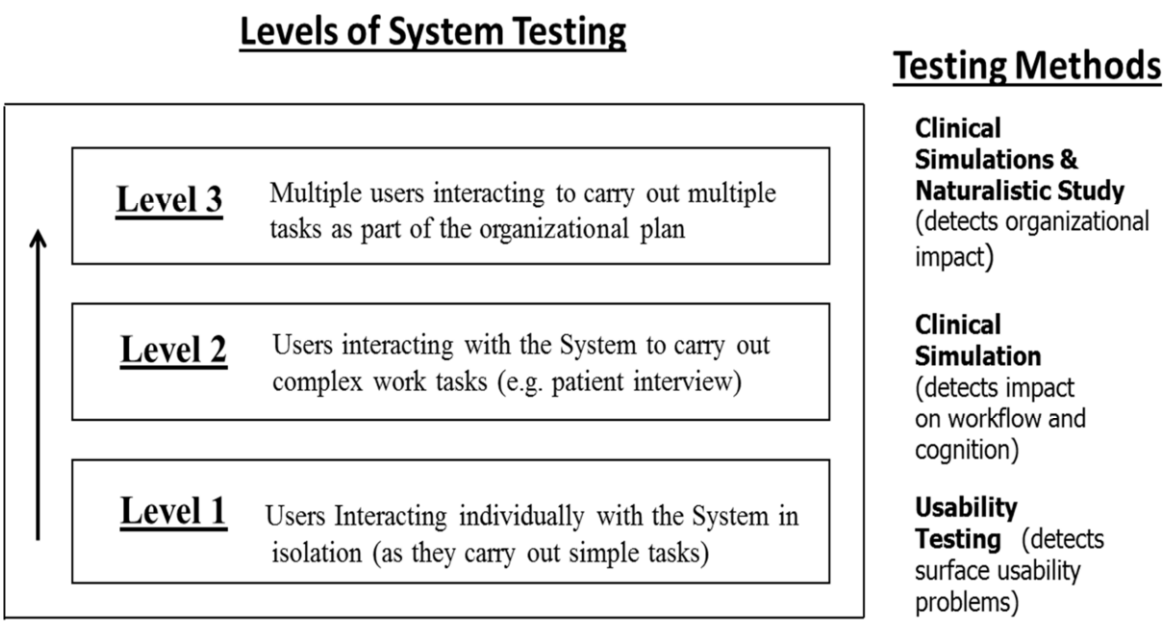

Figure 1 - A Multi-layered Approach to Usability Engineering in Healthcare

Despite the research in this area, healthcare is still plagued by unusable and potentially unsafe systems. So the question remains as to what is needed for a vision of more usable and safer systems, and how can that vision be attained?

Recommendations and Potential Directions

In order to achieve usable and safe healthcare IT, a number of recommendations and potential directions for further work and effort have emerged from the earlier discussion in this paper and are presented below.

Firstly, regarding more thorough usability evaluations, it is argued that all 3 levels in Figure 1 need to be considered when (a) developing health information technology or systems and (b) when customizing and deploying complex systems (such as EHRs) in real hospital and healthcare environments. It has been found that problems detected at Level 1 do not encompass the full range of usability issues. This will require going beyond current usability certifications and regulations to include multi-level usability evaluation. It will also require going beyond considering usability in the realm of system design and, as importantly, as part of organizational system deployment and implementation strategies. It will be essential to take into consideration the impact of local context when implementing healthcare IT.

Secondly, this vision will require certification and regulation with "teeth" that will involve more rigorous testing and lead to improved support and enforcement of basic usability principles. Along these lines, improved reporting mechanisms for the reporting of known usability and safety issues across the healthcare industry is needed globally (particularly as some systems are beginning to have a global market) [23-24]. Stronger regulatory measures will also be needed, specifying more stringent application of usability engineering approaches before certifying products.

Thirdly, a critical area that needs to be considered in making the vision of usable and safe systems a reality is the need for improved education about not only the importance of usability engineering and user-centered design, but also education about the full range of methods themselves that are included under these headings. This includes disseminating knowledge of alternative and emerging approaches at the levels of software designers, managers, clinical users and healthcare decision makers.

Fourthly, a critical issue that to some extent may prevent use of methods described in this vision paper is that of perceived cost and the amount of time it would take to use and apply methods known to lead to improved system usability and safety. Along these lines, there is growing evidence from studies on the cost-effectiveness of applying more thorough and advanced usability engineering processes [25]. These findings need to be more widely disseminated to not only heatlhcare IT professionals, but also to government and hospital decision makers, particularly when it comes to system procurement. Some progress has been made in the recent application of usabiltiy engineering leading to improved healthcare IT procurement by requiring test installs of systems and having them undergo rigourous usability evaluation before selecting software products for implementation [26].

Conclusion

A vision of healthcare IT can be conceived of where systems are seen as being highly usable; flexible within complex work activities; error-reducing, and sensitive to the contexts of different users, uses and locations. Unfortuately, reports continue to appear that seem to indicate that this ideal is not being met in many healthcare institutions [27]. To make the vision a reality will require considerably more effort along several fronts, including better dissemination of methods and

approaches that are known to work to improve healthcare IT usability, along with better sharing of this information and knowledge through improved practices and regulation. Furthermore, it should be the responsibility of healthcare organizations that buy and deploy healthcare IT to demand products that are designed to be more usable and that their IT staff be familiar with methods in usability engineering. From the vendor side, it is hoped that this could be achieved prior to extensive regulatory requirements, and improved usability and safety would become features of commercial products that provide market advantage (by distinguishing themselves in terms of improved user interaction and user experience). In summary, it has become clear that the usability of healthcare IT has become a critical issue that must be given greater consideration at multiple levels, from healthcare IT professionals to the governmental level. In this vision paper we have discussed approaches and methods we feel will be important in improving the current situation regarding usability and safety of healthcare IT.

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