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The Role of Simulation in Clinical Information Systems Development

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Abstract. This paper describes the role of simulation involving end-users in Health Informatics. Simulation has long been established as a widely accepted method in clinical skills training. During the last decade simulation has also gained a place in the development and evaluation of clinical information systems. Simulation is especially well suited for the evaluation of human factors and organizational aspects in relation to application of information systems. In full-scale simulation tests it is possible to evaluate socio-technical interaction. A near to real life experience can be achieved by creating high fidelity environments. The paper discusses how simulation may be used during the lifecycle of clinical information systems, and the requirements on simulation fidelity in various situations. We recommend that simulation should get a more prominent role in the design and evaluation of clinical information systems.

Keywords. Simulation, Clinical Information System, Human Factor, Usability

Introduction

The substantial complexity of organizations, work practices and physical environments within healthcare influences the development and application of IT in the healthcare sector. Human factors (HF) play a significant role in patient safety. Up to 70% of patient safety incidents are estimated to be related or due to HF [1]. It is very complicated to evaluate HF by use of quantitative testing methods [2] as these methods have difficulty including cognitive processes and the impact IT systems may have on clinical work practices.

Simulation[2] has for many years been used for clinical skills training as well as for social-team-oriented and cognitive-individual-oriented aspects of clinical work practice [4-12]. During the last decade simulations have gained a growing place in the design and evaluation of clinical information systems [13]. Simulation tests can be a beneficial method for evaluation of clinical information systems (CIS), as the tests can take place in a controlled environment, where there is no risk of injuring real patients [14-15]. Simulation based evaluation can take place in all phases of the CIS life cycle [16], and may be used for a number of different purposes. The literature describes how simula-

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[2] A simulation or a simulator may be defined as a process or a device "that attempts to re-create characteristics of the real world" [3, p 52]. This may be real work actions or processes. Simulation with end-users should cover the sociological aspect in the socio-technical interaction.

tion can be used for testing IT-systems in new contexts, for example performance optimization, safety engineering, modeling of natural or human systems, examining effects of alternative conditions and courses of actions and when real systems are not accessible [13, 17-25]. Simulations can be carried out with real or simulated users.

This paper focuses on simulations performed by real users enacting realistic clinical work scenarios and the potential role of simulations to support the design, development and optimization of CIS before launching in real practice. The paper provides a review of the research literature on simulation in relation to the CIS lifecycle. The aim of the paper is to increase knowledge about simulation as a tool for examination of CIS support for clinical work practice.

1. Methods

The PubMed database was searched using the following MeSH Terms: Computer Simulation(s) OR Humans OR User-Computer Interface(s) OR Medical/clinical Informatics AND date before 1990 AND language: English. The search was extended for all fields with: simulation OR fidelity AND clinical information system. Google scholar was searched with additional terms: Fidelity, full-scale simulation, clinical information systems, usability testing and evaluation. Only papers in English and written after 1990 were included. The relevance of each publication was examined by reading of the abstract. The search was carried out in December 2011.

2. Results

A total of 1161 papers were found[3]. Duplicates and papers where a full paper was not accessible were excluded. 29 papers were found to be highly relevant for this review on the basis of the extent of end-user involvement in the simulations, and presentation of new knowledge about simulation in relation to design, development and application of CIS. In the following an overview of the findings in the literature is presented according to how they relate to the lifecycle of CIS.

The literature review disclosed that simulation can be used in various stages of the lifecycle of CIS; from the specification of requirements to the actual implementation and maintenance of the system. Simulation has been used to evaluate a wide range of CISs, ranging from Computerized Prescription Order Entry (CPOE) systems and Clinical Decision Support System (CDS), throughout communication and information systems to Biometrics [26-27]. In contrast to field studies simulation studies allow for the possibility of examining different, complex and extreme usage scenarios during a short but highly intense testing phase [28]. A superior aim in simulation studies of CIS is to ensure patient safety even in extreme application situations in a realistic set up

Simulation studies include several steps: defining the purpose of the study, selecting representative users and tasks, designing scenarios and clinical set up, and decisions on methods for data collection, analyzing and reporting. Simulation methods have been used in biomedical informatics to study various aspects of human computer interaction in a number of research domains including HF, usability, doctor patient interac-

[3] A full list of references can be provided from the first author

tions involving technology, health professional information needs, health professional decision-making, new device testing and studies of medical errors [2, 20, 22, 28].

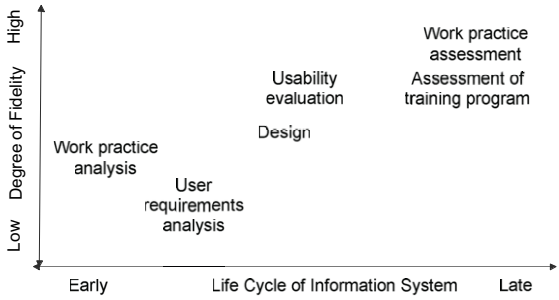

Figure 1. Use of simulation during life cycle of CIS

Figure 1 shows the use of simulation through a system life cycle in relation to the degree of fidelity. Patient safety issues may be explored in all phases of the lifecycle by observing and analyzing errors and work flows in simulated situations close to real life in a high fidelity environment [23]. Fidelity is defined as the degree to which the simulation replicates reality [3]. The need for fidelity is closely related to the purpose of the simulation. In the early phases of the CIS life cycle, the degree of fidelity may not need to be high whereas in a simulation with the purpose of studying implementation aspects the fidelity should be high.

In the early phases of the CIS lifecycle simulation may be used to analyze user requirements using prototypes or storyboards in preliminary tests [2]. Hereby it is possible to assess how the system may support existing or future work processes. Simulation may also be used for obtaining and assessing knowledge of user work practice [22]. This involves observation of clinicians applying existing information technology under simulated conditions to assess what kind of information and documentation is needed and how and when it is used. The use of simulation in this phase is experimental and do therefore not require the same degree of fidelity as in the later CIS lifecycle phases.

In the design phase simulation is well suited as a method for user involvement. Simulation studies may provide iterative feedback to the design of prototypes or real systems [2]. The benefit of simulation studies are that they can be designed to obtain practical experiences in the design process of new technology without introducing ethical issues or putting patients at risk. Thus it can be possible to test prototypical software in realistic scenarios. In this way it is possible to obtain design suggestions closely related to reality. Simulation studies in this phase are more explorative rather than representative in respect of possible design scenarios, and may help shorten the development process. The results achieved reflect the maturity of the prototype. Immature prototypes may pull an evaluation to focus on single screen issues, whereas mature prototypes establish a more realistic set up and offers a more realistic experience as they may include an entire workflow.

Simulations can be performed in laboratories as well as in situ in a ward, an operating theater or an outpatient clinic [26]. Simulation studies in the design phase aims to obtain design proposals for a new technology and may combine elements of laboratory test and field study [29].

In the implementation phase particular aspects of the implementation can be visualized by simulation e.g. user interaction in work practice, the need for training, and the

impact of decision support [24]. In these kinds of simulation studies the users are provided with the same amount and type of training as planned for the implementation. After the training the users use the system in a realistic though simulated set-up, which makes it possible to assess user interaction and possible effects on work practice. Unintended consequences of new systems such as changes in work processes and patient outcome may hereby be detected and can provide organizational decision makers with the possibility of correcting actions if required [22].

3. Discussion

Simulation with end-users is well suited for assessing the significant role of HF in patient safety [1]. HF are influential in all phases of the lifecycle of CIS. Applying simulation for evaluations allow for a high degree of experimental control while concurrently maintaining a high degree of realism [16, 29, 30].

The resources spend on preparing and performing simulation studies can be quite exhaustive, depending on the requested degree of fidelity. It is our experience, from numerous simulations in our simulation laboratory [15, 24, 30, 31], that it is essential to adjust the efforts spend on creating a realistic setting to the aims of the evaluation and the simulation set-up [22, 28]. As reflected in Figure 1 the need for a high degree of fidelity grows during the lifecycle of CIS.

For simulations to work effectively and efficiently it is important to define the purpose and hereafter identify the adequate level of simulation fidelity. Simulations can be adjusted to address specific issues by forcing participants to focus on fixed aspects. By providing a sufficient degree of realism, evaluators can address how various elements may affect the simulated work practice and the use of CIS [32].

In the early phases of the CIS lifecycle the fidelity of the simulation does not need to be as high as in the implementation phase where the more complex implementation aspects are to be assessed. When assessing implementation aspects the demand for realism is high in order to make the users accept the simulated trials and act as if they were using the system for real [32]. Full scale simulations including realistic environments and a realistic clinical set-up and tasks are therefore important.

4. Conclusion

Simulation is well suited for assessing work practice and HF and should play a substantial role in the design, development and implementation of CIS. Simulation studies are a highly relevant method for evaluating CIS in the entire lifecycle providing essential feed-back for continuous progress in each phase. Simulation studies can be useful from the first start of new CIS for defining user requirements and analyzing work practices. Simulation can subsequently be used in the design and development of CIS as well as for implementation planning. By using simulations health care organizations can in an effective and efficient way identify potential issues arising from introduction of new technology prior to the introduction in real-world settings. The degree of fidelity in the simulation study though has to correlate to the purpose of the study and the need for realism. The reviewed literature indicates that properly performed simulation studies can be an efficient method for preventing late system failures and may improve patient safety significantly. Further research has to be carried out to prove this.

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