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Fidelity in clinical simulation: how low can you go?

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Abstract. Clinical simulation may be used to identify user needs for context sensitive functionalities in e-Health. The objective with this paper is to describe how user requirements and use cases in a large EHR-platform procurement may be validated by clinical simulation using a very low-fidelity prototype without any existing test data. Instead of using test scenarios and use cases, the healthcare professionals who are participating in the clinical simulation are generating both scenario and patient data themselves. We found that this approach allows for an imaginative discussion, not restricted by known functionalities and limitations, of the ideal EHR-platform. Subsequently, we discuss benefits and challenges of using an extremely low fidelity environment and discuss the degree of fidelity necessary for conducting clinical simulation.

Keywords. Clinical simulation, fidelity, user requirements, healthcare informatics

Introduction

Qualitative methods such as clinical simulation may be used in evaluation of new technology in order to capture the cognitive aspects influencing clinical work practice in relation to any particular system [1]. Clinical simulation provides the opportunity to create a high degree of realism and still maintain the possibility of experimental control during the trial. However, the resources spent conducting clinical simulation may be quite exhaustive, depending on the degree of fidelity [2]. The degree of fidelity is an index of how well the simulated environment resembles the characteristics of the real world [3] and should therefore correspond closely to the purpose of the evaluation. Clinical simulation may be used for various purposes and in all stages of the lifecycle of clinical information systems [4].

In the very early stages of the lifecycle, high fidelity prototypes may not be accessible for analyzing user requirements. Instead, scenarios, personas, and low fidelity prototyping may be used in analyzing user needs. Low fidelity prototypes may be used in evaluation of information systems [5]. Furthermore, involvement of end-users is imperative and critical in specification of user needs [6]. For this purpose methods such as participatory design [7], Wizard of Oz (WoO) [8] and clinical simulation [9] may be used. Simulation has been used for training clinicians for more than 40 years [10]. Dahl and colleagues compared fidelity dimensions in training with

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fidelity dimensions in simulation-based usability assessment of mobile technology for hospitals [11] and identified a set of fidelity dimensions. These authors also explained how the configuration of these fidelity dimensions reflects various degrees of realism. We will compare the findings from this case study with the Dahl and colleagues' findings.

In 2012 and 2013, a large procurement process of a new Electronic Health Record-platform (EHR-platform) for health care in two large administrative regions in Denmark is taking place. The new EHR-platform will provide basic functionalities to support clinical and administrative core processes and will be used by approximately 40,000 healthcare professionals, at 12 hospitals, serving half the Danish population of 5.6 million. The analysis of user requirements has been based on previous user requirements analysis for large EHR-platforms and through workshops with healthcare professionals, quality managers, risk manager and clinical mangers. Detailed use cases have specified the requirements and experience has taught us the importance of an extensive involvement of end-users [12]. The aim of the simulation was to validate the users' requirements regarding clinical functionality of the EHR-platform. The objective of this paper is to determine and discuss the lower limit of fidelity to perform a clinical simulation study.

1. Method

The user requirements were defined at workshops organized specifically for the EHR-platform procurement and supplementary based on experiences from the two regions and literature studies. The user requirements were described in use cases covering different parts of clinical and administrative work processes. The simulation study was intended to validate the user requirements and use cases by involving end-users and emphasizing work processes in a more realistic setting. We did not use any full functioning health information system; instead we used low-fidelity prototypes or dummies, in the form of cardboard boxes [5; 13]. The prototypes came in different shapes and forms (as seen in Fig. 1) representing different types of hardware, mobile phones, tablets and other kinds of computers.

In order to deal with this imaginative IT-system in the simulation a WoO approach was used. WoO offers interactive experience without having a real computer system and may produce adequate and sufficient input to support and extend the requirements specification [8, 14]. WoO in controlled experiments with end-users explores key tasks, in specified contexts. This method can be used to clarify user requirements without restricting users' innovativeness by asking them work on information systems they already know. A team member acted as "The Wizard of Oz" and simulated the response from the system in form of hand written post-it labels (as seen in Figure 1).

The scenarios were not described in detail before the simulation. Data about the patients were thereby not known beforehand, and no test data had been prepared. Instead, the scenarios were described in generic terms without detailed information of patients and specified context. Clinicians pointed out by hospital managers generated the scenarios. 18 scenarios were scored according to frequency of use and clinical relevance. Subsequently, the eight highest scoring scenarios were selected for the validation of user requirements and use cases. The key scenarios for the nurses were 1) dispensation and administration of drugs, 2) initial nursing assessment, 3)

documentation of care, planning and status, and 4) nursing handover and distribution of tasks and responsibility. The key scenarios for the physicians were 1) ward round, 2) medical assistance, 3) admission and 4) discharge of patients.

The validation simulation was conducted during three days and consisted of 18 performances with 9 physicians and 9 nurses. Physicians and nurses did not cover all healthcare professional end-users. Instead, end users were selected to meet the needs of the specified scenarios covering different seniority and specialties. The clinicians were introduced to the aim of the simulation and asked to think of a specific patient case from one of the scenarios and afterwards present the scenario and the patient. The case should be a patient they had treated or nursed one of the recently days in order to have the details fresh in memory. During the simulation the clinician was facilitated by one of the team members who at the same time did obser-view [15]. Another team member acted as the WoO and simulated the feedback from the IT-system by placing post-it labels on the cardboard box (as seen left in Fig. 1). A third team member acted as the patient. Fig. 1 shows the simulation set-up from a scenario where two nurses are handing over tasks and responsibilities.

Figure 1: Left: cardboard boxes with post-it labels. To the right the simulation set-up

A clinical instructor communicated with the facilitator, the patient and the WoO from an adjoining control room during the simulations to guide the clinical details in the scenario. Two observers in the control room recorded the clinicians' needs for information and documentation as well as the work processes. The clinicians who were not performing in the simulation at the time also observed from the control room and reflected on their own needs and requirements in similar clinical situations. In a debriefing interview, all of the clinicians were asked about further needs and requirements and the observations from the simulation were discussed with the clinicians. The clinicians were also asked how well they were able to relate the simulation with real work situations. At the end of the day the notes from the simulations and debriefing interview were analyzed using Instant Data Analysis [16]. Afterwards, the results were compared with the use cases and user requirements already identified in the project.

2. Results

The clinical validation simulation provided an opportunity to focus on context sensitive needs, by looking at clinical work practice and user needs for information and documentation across various use cases and work processes, in a range of frequently used scenarios. Due to the rather high fidelity tasks and environment, the simulation stimulated the clinicians' experience of working practice, despite low functional and equipment fidelity. This study both validated several previously established user requirements as well as identified several new topics that needed further clarification. During the debriefing interview, clinicians were asked to reflect on the simulation they just had been part of. One of the physicians described how the simulation had made her come up with the idea of having various modes of the IT-system. The realism of daily work practice and the interactive experience with the prototype supported her creativity and she believed she would not have thought of this requirement during a workshop. Another participant mentioned that the possibility to interact with a patient had been vital in order to make the scenario come to life. However, it required that the patient acted according to the scenario that had been described by the clinician previous to the simulation. In a few scenarios, the clinical instructor, located in the control room, tried to change the behavior of the patient by issuing new directions through the intercom which confused the clinician in the simulation. The realism of work practice in the simulation led to new information concerning work processes across the individual use cases and user requirements.

New user requirements were discovered such as the need to group the patient in various ways according to the context. For example, ambulatory nurses needed to group particular outpatients to whom they should administer drugs whereas hospital ward nurses needed to group patients depending on whether they were on day shift or night shift. Other user requirements were identified but not clarified during the simulation study but were clarified later in discussions with the vendors during the dialog phase. Specifically, it was not clear how the clinicians would know whether information was missing from the patient record. In some contexts, clinicians needed to be able to see historical patient data at the time they were documenting new data. In the hospitalization scenario, the physician needed a space to document temporarily prescriptions as well as prescription for the nurses. In the discharge scenario, the physician needed to be able to see what medication prescriptions the patient had previously requested.

The realism of the scenarios and the simulation of interactions with other healthcare professionals and patients supported the identification of new cross-disciplinary needs. For example, a special area in the patient record was needed, where all healthcare professionals had access for patients who did not want life-sustaining treatment. This information should be shared among the healthcare professionals at the hospital and also with general practitioners, so hospitalization can be avoided. The nurses documented degree of pain only in the nursing documentation, which is not read by the physicians. This was not part of the use cases covering pain documentation. Joint log on was also identified as a user requirement. The use cases described in the project were very detailed and did not cover broad work processes (e.g., discharge of patient) in the same way as the simulation study. During the simulation, one of the physicians requested that the information system should be able to get into a kind of discharge mode in order to support the clinicians working processes when discharging patient. For example, this could mean gathering information for discharge letters and

providing functionality for indicating medication status. During the debriefing interview it became clear that a discharge state was just one example of context sensitive states the information system should be able to support. This need for a context sensitive health information system was not revealed during the previous workshops.

3. Discussion

The clinical simulation resulted in useful knowledge concerning the daily work practice. This information was not novel but had not arisen during the previous workshops. Clinicians have a vast amount of implicit knowledge of activities and processes that may go unmentioned / undetected in typical experimental settings. However, it is imperative for this knowledge to be made explicit to inform the design of health information systems and therefore different methods should be used to elicit this implicit knowledge. Lucy Suchman describes how work processes may be invisible for others and how working processes are perceived differently. The better work practice is performed, the less visible it is, which makes it challenging to describe [17].

Table 1 shows the fidelity dimensions and the level of fidelity in each dimension. Scenarios are part of the task fidelity, and in this case the task fidelity may be split into two parts: the scenarios were very realistic, taken from real life, but the actual simulation of the scenario was not as realistic. During the simulation, the clinicians were asked about the needs for information and documentation. When using scenarios described by the clinicians, it is important to follow the scenario. If the "patient" tried to change the scenario, clinicians were confused and the fidelity weakened. This issue was the most limiting to the simulations. You are stuck with the scenario, but on the other hand the scenario is realistic. The debriefing interview can compensate for this limitation. During the debriefing it is possible to ask more specific questions concerning other types of scenarios and situations.

The realistic scenarios and the dialogue with the patient was an important element in maintaining the task fidelity. As one of the physicians pointed out, it is the patient who creates the situation and the scenario. Senior clinicians often generate higher task fidelity but by letting the clinicians describe a real life scenario, less experienced clinicians can maintain high task fidelity. At the same time, this limits the amount of clinicians present in the simulation since they must have experienced the same situation. In contrast, task fidelity was lowered because the test data was not known beforehand.

Table 1. Fidelity dimensions and levels of fidelity used in the clinical simulation

	Low fidelity	**High fidelity**
Task fidelity	Obser-view during simulation No test data on forehand	No limitation of designed cases allowed participants to align scenarios with personal work practice and own patient cases
Environmental fidelity		Realistic environments supported the perceived realism
Functional fidelity	No limitation of known functionality supported imagining the functionality of the ideal EHR-platform	
Equipment fidelity	No limitation of known technology allowed for unrestricted ideas about the ideal EHR-platform	

The environment fidelity was high due to the realistic clinical environments in the simulation lab. This helped the clinicians to think about physical aspects of their work in relation to a new IT-system. For example, one of the physicians used the wall to show how she normally hung post-it labels with prescriptions in similar situations.

The functional fidelity was low. Low fidelity prototypes have no richness of interactivity and are of no use in evaluation of interactive features. The use of cardboard boxes challenged the functional fidelity, but helped simulate the interaction with the computer. In the same way, the post-it notes helped preserve a certain form of functional fidelity. These types of clinical simulation may be regarded as more suitable for analyzing less detailed user requirements. Low functional fidelity is more suitable for analyzing user requirements broadly instead of at a very detailed level, when looking at very large health information systems. The equipment fidelity concerning devices of the system was low, but this helped the clinicians because familiar devices or devices chosen for the project did not limit them.

The observing clinicians are very important when conducting low fidelity simulation because they are able to dissociate themselves from the simulation and at the same time reflect on how it would be in other situations. These reflections may be discussed in the debriefing along with other observations and questions that may have come up during the simulation. An example is that one of the physicians kept asking for alerts, but because of the low fidelity, no alerts appeared and the effect of these alerts were not seen. Instead this was discussed with the clinicians in the debriefing interview.

The context sensitive needs when discharging a patient is but one example of a valuable outcome even low fidelity clinical simulation can bring. In the end, the results of the clinical simulation were both a validation of already known user requirements, and a method of connecting these requirements with near-real work practice and thereby identifying needs for context-sensitivity. The case study indicates that task fidelity might be categorized into two parts: one part related to the content of scenarios and tasks, and another part related to the execution of scenarios and tasks.

The answer to how low fidelity can go differs depending on the purpose of the clinical simulation. In this case the fidelity of the content of the tasks (scenarios and "patients") needed to be rather high, but the fidelity of the execution of the tasks did not need to be high. High fidelity environments are needed in order to support the perceived realism by the clinicians. In this study the purpose of the simulation study was to gain knowledge of user requirement in specific area of the clinical work practice, whereas the actual interaction with a computer or an information system less important. The need for equipment and functional fidelity was therefore rather low. However, if the purpose of the clinical simulation had been to evaluate the usability of a specific device or information system, the need for equipment and functionality fidelity would have been high.

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