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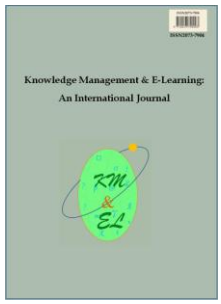

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Patient safety and quality of care: How may clinical simulation contribute?

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Abstract: The usability of health information technology (IT) is increasingly recognized as critically important to the development of systems that ensure patient safety and quality of care. The substantial complexity of organizations, work practice and physical environments within the healthcare sector influences the development and application of health IT. When health IT is introduced in local clinical work practices, potential patient safety hazards and insufficient support of work practices need to be examined. Qualitative methods, such as clinical simulation, may be used to evaluate new technology in correlation with the clinical context and to study the interaction between users, technology and work practice. Compared with the "classic" methods, such as heuristic inspection and usability testing, clinical simulation takes the clinical context into account. Clinical simulation can be useful in many processes in the human-centred design cycle. In the requirement specification, clinical simulation can be useful to analyze user requirements and work practice as well to evaluate requirements. In the design of health IT, clinical simulation can be used to evaluate clinical information systems and serve as common ground to help to achieve a shared understanding between various communities of practice. In a public procurement process, a clinical simulation-based assessment can help give insight into different solutions and how they support work practice. Before organizational implementation, clinical simulation is a very suitable means, by which to assess an application in connection with work practice.

Keywords: Clinical simulation; eHealth; Patient safety; Quality of care; Human factors

Biographical notes: Sanne Jensen has a PhD in how clinical simulation may be used in development of clinical information systems. Since 2007 she has been managing the ITX-lab in Copenhagen, where clinical simulation is used for development and evaluation of information systems for the hospitals in the Capital Region of Denmark. Sanne has co-authored several papers examining the effects of health information systems upon Patient Safety and the effect new technology has on work practice.

1. Introduction

Patient safety in relation with health IT is a paradox (Coiera, Aarts, & Kulikowski, 2012). Even though health IT can improve patient safety and quality of care (Bates et al., 2001), application of new technologies in healthcare can also increase patient safety hazards

(Koppel, Wetterneck, Telles, & Karsh, 2008). Errors persist in clinical practice even after new health IT has been introduced (Rodriguez-Gonzalez et al., 2012) because manual processes co-exist with the automated, and the interfaces between the two are seldom perfect. Electronic siloing, the isolating effect of the electronic health record (EHR) on clinical workflow that drives caregivers to work in silos, is an unintended consequence of the EHR which also affects patient safety (Stoller, 2013), and hybrid paper based and electronic systems complicates the clinical work processes. Studies show that unintended incidents in relation to new technology are related to the use of technology (Harrison, Koppel, & Bar-Lev, 2007; Koppel, Wetterneck, Telles, & Karsh, 2008) and up to 70% of patient safety incidents are estimated to be related to or due to inadequacies associated with poor human factor designs (Rall, Gaba, Howard, & Dieckmann, 2010). Methods for design of eHealth focusing on patient safety and quality of care are one of many initiatives trying to prevent adverse events (Beuscart-Zephir & Nohr, 2009; Koppel & Kreda, 2010) as well as implementation of guidelines and standards (Magrabi, Li, Dunn, & Coiera, 2011; Magrabi, Ong, Runciman, & Coiera, 2012; Magrabi et al., 2013).

Patient safety and quality of care does not entirely rely on technology but is highly influenced by the interaction with users in a local context (Coiera, 2003), and sociotechnical issues and human factors are related to many unintended consequences and patient safety hazards (Harrison, Koppel, & Bar-Lev, 2007; Beuscart-Zephir & Nohr, 2009; Beuscart et al., 2009). The substantial complexity of organizations, work practices and physical environments within healthcare influences the implementation and use of technology (Berg, 2006). All possible interactions between system components are not predictable at design, and in large complex systems, safety problems tend to merge from unexpected interactions between system components (Magrabi et al., 2013). Possible patient safety hazards as well as quality of care need to be investigated proactively when health IT is integrated with local clinical work practice including other technology and organizational structure.

Qualitative methods, including clinical simulation, can be used to proactively evaluate new technology in correlation with the clinical context throughout the software development life cycle in health informatics (Borycki, Househ, Kushniruk, & Kuziemsky, 2011; Kushniruk & Patel, 2004) and to study the interaction between users and technology as well as the potential effects on clinical workflow and organizational issues (Borycki & Kushniruk, 2005; Borycki, Kushniruk, Kuwata, & Kannry, 2006). Clinical simulation can hereby enable identification and evaluation of patient safety hazards as well as quality of care before implementation at a hospital (Jensen, Lyng, & Pnøhr, 2012).

When new technology is integrated in healthcare work practices, the implementation is difficult as it may not be possible to anticipate all actions and behaviors in a large socio-technical system (Ash, Berg, & Coiera, 2004). All possible interactions between the socio-technical system components are not predictable in the design phase and, in large complex systems, safety problems tend to emerge from unexpected interactions between the different components of a socio-technical system (Magrabi et al., 2013). Descriptions of work practices may be useful, but they are incomplete, summarized and rigid descriptions of modeled work practices, whereas specific work practices only unfold in their execution, in constant interaction with the context in which they are located (Berg, 1999).

Needs and requirements differ throughout an organization and development is an important issue in off-the-shelf CIS products (Berg, 1999). Such products require extensive tailoring and configuration to match local requirements and context. Many different views need to be taken into account in the development and retailoring, and a

shared understanding between the different stakeholders is imperative. Furthermore, communication between end-users and developers is often challenging and dialog and discussions with a view to finding common ground is often needed to bridge the gap between the parties (Bødker, Kensing, & Simonsen, 2004). Clinical simulation offers a means by which to achieve a mutual clinical agreement on the design of a new information system (Jensen & Kushniruk, 2014). Clinical simulations involve real end-users as they simulate the use of technology in realistic environments performing realistic tasks (Kushniruk, Nohr, Jensen, & Borycki, 2013). Clinical simulation is a valuable method for development and evaluation of clinical information systems as it takes place in a controlled environment where there is no risk of injuring real patients (Jensen, Lyng, & Pnøhr, 2012; Kushniruk, Borycki, Kuwata, & Kannry, 2006).

To deal with the challenge, this study has designed and implemented a dual mapping learning environment, to help learners to visualize their problem solving and knowledge construction processes, and more importantly, to support the transformation between the two. Medical education is selected as the domain of this study, where problem-based learning is regarded as crucial to learning and expertise development in this field. Although problem-based learning is increasingly used in medical education, there is a concern about its weakness in general study design in relation to its impact on learners' knowledge base. This study aims to address the challenge by investigating how learning through problem solving can be supported by the design of a technology-enhanced learning environment that makes complex cognitive processes visible for problem solving and knowledge construction. The design is focused on a dual mapping learning environment that involves concept mapping and argument mapping tools to represent learners' problem solving process and the underlying domain knowledge in visual formats, in addition to other functions to support the problem solving and learning process. To evaluate the proposed design, the dual mapping learning environment has been implemented, used and evaluated by learners from two medical schools in China.

2. Clinical simulation

A simulation or a simulator may be defined as: a process or a device "*that attempts to re-create characteristics of the real world*" (Beaubien & Baker, 2004).

Simulation has for more than 40 years been used for training healthcare professionals in clinical skills. In medical training simulation has proven superior to more traditional medical education methods (Grenvik & Schaefer, 2004; Stefan, Belforti, Langlois, & Rothberg, 2011; Struys, De Smet, & Mortier, 2008). Computer controlled mannequins are typically used in medical training (Wright et al., 2006). These high fidelity patient-simulators are well suited for teaching and evaluating core clinical competences and training advanced management of complicated or rare incidents, reflecting both the social-team-oriented and cognitive-individual-oriented aspects of human factors. Non-technical skills such as communication, teamwork and leadership may also be trained by use of simulation (Borycki, Kushniruk, Anderson, & Anderson, 2010; Lippert, Dieckmann, & Oestergaard, 2009; Müller & Rannenberg, 1999; Ostergaard, Dieckmann, & Lippert, 2011; Vozenilek, Huff, Reznek, & Gordon, 2004).

The realism and acceptance of the simulation depend on the degree of fidelity in the simulation set-up. The degree of fidelity may be defined as: "*The degree to which the simulation replicates reality*" (Beaubien & Baker, 2004) and is an index of how well the simulated environment resembles the characteristics of the real world. According to Beaubien and Baker (Beaubien & Baker, 2004), acceptance of fidelity in medical training

comprises several dimensions. Dahl and colleagues (Dahl, Alsos, & Svanæs, 2010) have compared fidelity in training with fidelity dimensions in the simulation-based usability assessment of mobile technology for hospitals. Their study identifies a set of fidelity dimensions and explains how the configuration of these fidelity dimensions reflects various degrees of realism. Fig. 1 shows the simulation acceptance model by Dahl and colleagues with four fidelity dimensions: environment, equipment, functionality and tasks. These fidelity dimensions affect the perceived realism and thereby acceptance of the simulation made by the involved clinicians.

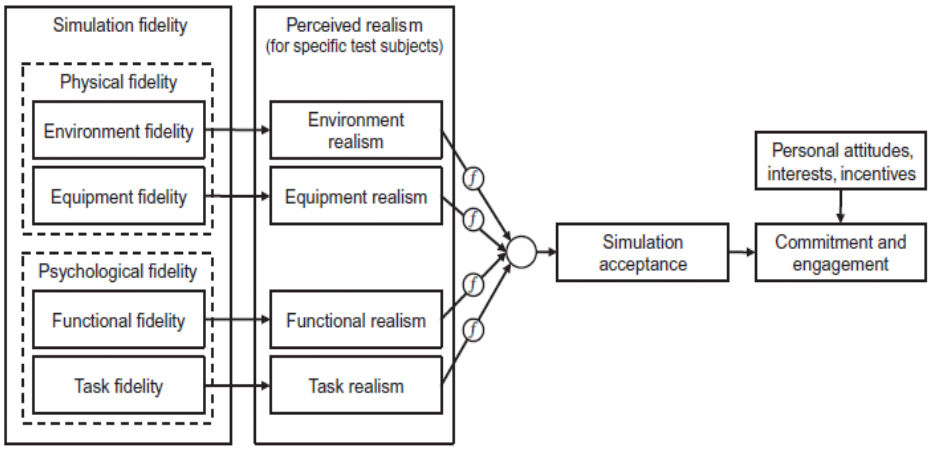

Fig. 1. Simulation acceptance model by Dahl

The four fidelity dimensions may be described as:

- Environmental fidelity: the extent to which physical elements, such as rooms, beds and patient are realistically represented in the simulation
- Task fidelity: the degree to which the clinical task involved in the simulation for a given domain (e.g. administration of drugs and ward rounds) is replicated in the simulation
- Equipment fidelity: the extent to which elements, such as mock-ups and electronic devices, are replicated for participants in the simulation to work with
- Functional fidelity: the degree to which the technology reacts like "the real thing" (e.g. system functionalities and interactive devices).

The need of fidelity varies depending on the purpose of the clinical simulation (Jensen, Kushniruk, & Nøhr, 2015).

3. How to conduct clinical simulation

Clinical simulation is conducted in three phases; 1) introduction, 2) simulation, 3) evaluation. Prior to the simulation, the participants are introduced to the information system and to the simulation. During the simulation, a simulation facilitator is located in the simulation room. The facilitator facilitates the simulation and supports the participating clinician. An instructor located in the observation room instructs the patient and the simulation facilitator. The simulation is observed by health informatics experts

and sometimes by key stakeholders, such as colleagues from hospitals, clinical managers, quality managers and vendors (Rasmussen, Lyng, & Jensen, 2012). The observers are located in the observation room. The various roles are described in Table 1.

Table 1
Description of roles in clinical simulation

Roles	**Description**
Instructor	Overall responsible for the simulation. Instructs simulation facilitator and patient(s) during simulation by use of intercom equipment and facilitates debriefing. Is located in observation room.
Simulation facilitator	Briefs clinicians prior to simulation and provides support during simulation. Receives instructions from and assists instructor during simulation, and conducts "obser-view" during simulation if necessary. Is located in simulation room.
Observer	Observes and makes notes during simulation; e.g. use of technology, usability, support of work practice, patient safety. Is located in observation room.
Patient	Acts as patient during simulation and receives instructions from instructor. Is located in simulation room.
Clinician	Simulates scenario. Thinks aloud during simulation. Participates as interviewee in interview

An overview of the simulation room and observation room is presented in **Error! Reference source not found.**. The observation room with laptops and chairs is located in the right-hand corner. In the simulation, there are two beds and bedside tables placed together with a laptop computer. A one-way mirror separates the two rooms.

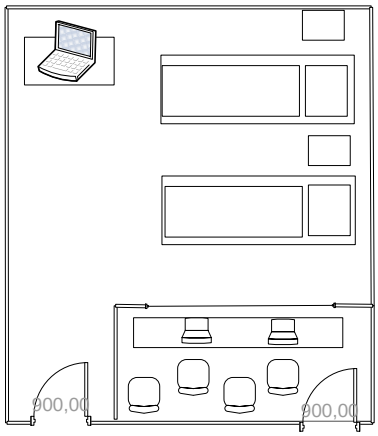

Fig. 2. Overview of the physical simulation set-up

If possible, the clinician is asked to "*think aloud*" so that the observers can acquire a deeper understanding of the human task-behavior (Jaspers, Steen, Bos, & Geenen, 2004; Van Someren, Barnard, & Sandberg, 1994). Sometimes a so-called

"*obser-view*" is performed in order to gain a deeper understanding of specific issues (Kragelund, 2013). Depending on the purpose of the clinical simulation, the clinicians are sometimes also able to observe their colleagues, when not participating in the simulation themselves (Jensen, Vingtoft, & Nohr, 2013).

After the simulation, the information system is evaluated. Participants are asked to complete questionnaires and participate in a de-briefing interview. Further to interview guides, observations made by the observers during the simulations are used as background for the interviews (Jensen, Rasmussen, & Lyng, 2014a). The interview and observers' notes are subsequently analyzed, e.g. using Instant Data Analysis (IDA) (Kjeldskov, Skov, & Stage, 2004). IDA is a cost-saving analysis technique which allows usability evaluations to be conducted, analyzed and documented in less than a day. In a case study conducted at Aalborg University, it was discovered that IDA reduced the time required to do a video data analysis by 90%. IDA also identified 85% of the critical usability problems in the evaluated system. Results from each of the five case studies were gathered in evaluation reports.

4. A case study

In a case study clinical simulation was used in the design of electronic documentation templates and overview reports for nurses' initial patient assessment (Rasmussen, Lyng, & Jensen, 2012). The objective of the study was to evaluate 1) the content of the templates, 2) user satisfaction with the templates, 3) usefulness of the templates, and 4) the need for training in connection with implementation. Several specific parts of the templates and work practice were also addressed. The simulation was also used as an observation site and boundary object for discussions between different communities of practice.

The first version of the electronic documentation templates had previously been rejected by end-users and hospital management due to disagreement about the documentation procedure between the various stakeholders in the organization. Problems regarding acceptable time consumption as well as the need for rigorous design of the templates (i.e. clinical content, number of highly structured fields and overview of patient data, and differences in work practices) were key issues in the rejection. It was decided to address the organizational disagreements by redesigning the templates using clinical simulation as part of a participatory design approach, in which the various stakeholders in the design process were to be consistently involved. The overriding aim of the re-design process was to create a new set of structured templates that concurrently supported the daily clinical work practices of the nurses and adjusted the documentation in accordance to the regional guidelines and accreditation requirements. In order to achieve this it was necessary first to establish consensus on the template design among the clinical nurses, quality units and nursing managers at all 12 hospitals in the region. Furthermore, the templates had to be applicable for use by nurses at all types of bed wards. Essentially, the aim was to ensure 'one size fits all'. Specifically, the re-design had to respond to all the major criticisms disclosed in the first pilot implementation. It was argued that the templates should:

- Handle highly structured data entry in an efficient way
- Support daily nursing work practices.

Multiple stakeholders with many different views and positions were involved. The activities in the re-design process are illustrated in Fig. 3 (Rasmussen, Lyng, &

Jensen, 2012). Nurses with specialized knowledge of documentation and accreditation requirements from all the regional hospitals participated in the workshops. At the first workshop, a prototype designed on the basis of the evaluation of the first version was presented to the participants. The nursing processes were then discussed and compared to the features of the prototype.

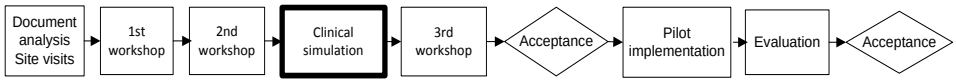

Fig. 3. The re-design process including clinical simulation

A new version of the templates based on the comments was presented and discussed at a second workshop. The prototype was subsequently further adjusted based on the comments from the workshop. After the second workshop, clinical simulation was conducted. During the clinical simulations, the stakeholders were able to observe the new technology in use. The interviews and discussions that followed gave us an opportunity to obtain and understand work practices and user requirements, and helped to reveal divergences of opinions between the stakeholders. The clinical simulation offered a shared mental model and supported discussion and an understanding of other stakeholders' views.

The clinical simulations were performed in realistic environments and with realistic scenarios from actual patient cases. All scenarios were based on patients assessed at the hospital within the first 24 hours. In some scenarios, a nurse made a full initial nursing assessment, whereas in others half of the assessment was previously documented and the nurse was asked to complete the documentation. This meant that the scenarios covered hand-over situations. Eight nurses simulated the scenarios. An actor played the role of the patient in order to make the simulation realistic. The various stakeholders from the previous workshops observed the simulation from an adjoining observation room. Debriefing interviews were held with the nurses after the simulations. The observers also participated in the interview and were able to ask questions during the interview. After each interview, the observers discussed their observations and the outcome of the interview. Before the final decision was made, a third workshop was held, in which the results of the clinical simulation and the subsequent negotiation were discussed.

The simulations gave important input regarding resolution of some of the practical challenges facing the daily work with documentation templates. The simulations became boundary objects as they was used at the interface of different stakeholders (Jensen & Kushniruk, 2014). By observing end-users using the templates, the simulations served as common ground in the discussion between the different stakeholders, and supported a shared understanding. By that mean focus changed to practical usage of the templates instead of a more theoretical approach to template content, which depended on the individual stakeholder's area and practice. Hereby clinical simulation became a pragmatic approach to boundary objects and visualized the consequences and the impact of implementing an information system.

In the case study clinical simulation was used as a learning space, in which to knowledge acquire of other parts of the organization. Clinical simulation provided the different stakeholders with an opportunity to observe and discuss the impact of the re-designed template and offered a means by which to manage the tension between divergent viewpoints, which was of great assistance in the design case study, especially where different views on content and structure of documentation were concerned. As one

of the participants later said: "*We no longer discussed based on our own ideological attitude. Instead we gained a shared mental model to discuss from*" (Jensen & Kushniruk, 2014). Some stakeholders found that the highly structured nature of the templates limited flexibility in the conversation with the patient and made the documentation unnecessarily complicated. Thus clinical simulation was used as a boundary object to facilitate meetings, such as de-briefing interviews, workshops and as part of the design process (Forgues, Koskela, & Lejeune, 2009). Clinical simulation provided an opportunity to observe the system in terms of both design and use. The simulation offered a method or approach by which to tackle the tension between divergent viewpoints and helped different parts of the organization to gain a shared understanding of needs and requirements. Clinical simulation offered a means by which to achieve a mutual clinical agreement on the design of a new information system. Furthermore, subsequent discussion allowed all stakeholders an opportunity to voice their point of view and to affect the final result.

5. Use of clinical simulation – When and why

Simulation in relation to development and evaluation of clinical information systems can be used in different activities at various phases of the development life cycle of clinical information systems from analysis of work practice and user requirements till application assessment in work practice and assessment of training programs as shown in Fig 4 (Jensen & Kushniruk, 2014).

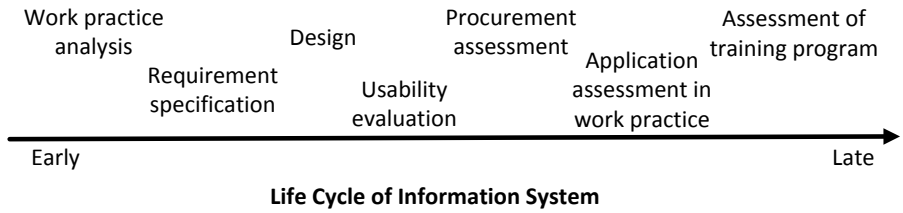

Fig. 4. Activities in life cycle of an information system using clinical simulation

In the early phases of the lifecycle simulation may be used to analyze and specify user requirements using prototypes (Jensen, Nohr, & Rasmussen, 2013; Kushniruk & Patel, 2004). Hereby it is possible to assess how the system may support existing or future work processes. Simulation may also be used to analyze work practice (Borycki, Kushniruk, Kuwata, & Kannry, 2006). 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 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 (Jensen & Kushniruk, 2014; Kushniruk & Patel, 2004)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 evaluate 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 (Ammenwerth, Buchauer, Bludau, & Haux, 2000). 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 (Burkle, Ammenwerth, Prokosch, & Dudeck, 2001).

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 (Ammenwerth et al., 2011; Jensen, Kushniruk, & Nøhr, 2015). 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 (Borycki, Kushniruk, Kuwata, & Kannry, 2006).

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 (Kushniruk, Borycki, Kuwata, & Kannry, 2006).

6. Discussion

The complexity of organization and work practices in healthcare creates challenges regarding the choice and application of methods used in developing and implementing CIS (Berg, 2006). The complexity of health organizations and the various types of healthcare actors complicates the specification of user requirements and the design and implementation of CIS. Clinical simulation serves as a reflective means by which to improve solutions to these problems (Jensen & Kushniruk, 2014). As described in the case study clinical simulation can be a useful means by which to create shared mental models and shared understanding of user requirements, work practice and organization requirements.

Involvement of end-users and other parts of the organization greatly improves both the design and implementation of new technology and the design and implementation of future work processes (Jensen & Kushniruk, 2014; Rasmussen, Lyng, & Jensen, 2012). Acceptance of new technology may be earned by giving the different stakeholders a chance to voice an opinion and thereby support the acceptance and use of the new technology. Studies show the possibilities in having different healthcare actors to participate in clinical simulation and subsequently debriefing discussions as part of different activities in the human-centred design cycle (Ammenwerth et al., 2012).

Unintended benefits may not be revealed prior to implementation and their full potential may not be achieved. Clinical simulation offers an opportunity to create a space in which healthcare professionals working in different locations or healthcare sectors can meet and exchange knowledge about work practices and requirement needs (Jensen, Rasmussen, & Lyng, 2014a). This approach has proved effective in identifying important

unintended benefits and challenges, and acquiring knowledge of how new technology may impact work practices (Jensen & Kushniruk, 2014) and patient safety issues (Jensen, Rasmussen, & Lyng, 2014a).

Methods like heuristic inspection and low fidelity usability evaluation focus on user interface, technology and specific tasks for a single user without including the clinical context, whereas clinical simulations focus on the use of technology in a clinical context involving one or several users incorporating interdisciplinary and organizational aspects. Heuristic evaluation and low fidelity evaluation may complement the clinical simulation in making a rigorous assessment of the user interface, and may uncover some usability challenges in the graphical user interface. Evaluation based on clinical simulation allows for a high degree of experimental control while maintaining a high degree of realism of clinical context (Kushniruk, 2002). Clinical simulation studies are feasible for conducting safe evaluations of technology before it is introduced to routine (Burkle, Ammenwerth, Prokosch, & Dudeck, 2001) and makes it possible to evaluate potential impact (Ammenwerth et al., 2012) as well as cognitive processes and usability (Kushniruk & Patel, 2004) and patient safety matters (Jensen, Lyng, & Pnøhr, 2012). Patient safety issues are hard to evaluate because they are often triggered by unintended incidents and work related interruptions. These challenges are nearly impossible to pinpoint beforehand but need to be explored when a new technology, e.g., an IT-system in use. Clinical simulation is feasible for assessment of patient safety aspects as it provides a comprehensive view on the IT-system taking into account the correlation between IT, work practice and adverse events (Jensen, Rasmussen, & Lyng, 2014b).

The choice of scenarios is one of the main concerns in using clinical simulation. The result of simulation very much depends on the chosen scenario as the scenario determines what part of work practice is being evaluated. The scenario also determines the complexity of the simulation. Clinical simulations may not reveal the real complexity in daily work practice and are most often conducted with a short timeframe as high complexity and long timeframes are exceedingly resource demanding. Therefore clinical simulation does not reflect the social-technical impact over time. These limitations and concerns have to be taken into account in when planning and designing the simulation.

7. Conclusion

Evaluation of clinical information systems based on clinical simulation may allow for a high degree of experimental control and still allow maintenance of a high degree of realism with regard to the clinical context (Kushniruk, 2002). Clinical simulation studies have proven feasible for conducting safe evaluations of technology before it is introduced into routine clinical practice (Burkle, Ammenwerth, Prokosch, & Dudeck, 2001). Clinical simulation has also been used to evaluate the potential impact (Ammenwerth et al., 2012), cognitive processes and usability (Kushniruk & Patel, 2004), and work practice (Borycki, Kushniruk, Kuwata, & Kannry, 2006). Patient safety issues are difficult to evaluate due to the fact that many patient safety challenges lie in the details and are triggered by an adverse event and work-related interruptions. It is often difficult, sometimes almost impossible, to pinpoint these challenges in advance. They must instead be explored when a new technology e.g. an information system is to be applied. Notwithstanding the above, clinical simulation may be an appropriate method by which to assess patient safety aspects as it provides a comprehensive view of the information system taking into account the correlation between IT, work practice and adverse events (Jensen, Rasmussen, & Lyng, 2014a).

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