USE OF CLINICAL SIMULATION IN DEVELOPMENT OF CLINICAL INFORMATION SYSTEMS

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PREFACE

This thesis is submitted to obtain the PhD degree at the department of Planning and Development at Aalborg University. The work described in the thesis was carried out between October 2011 and October 2014.

Having worked in health informatics for more than ten years, I have experienced the gap between clinical information systems and the work practice they are intended to support. My background of 20 years of nursing and further education as B.Sc. Computer Science and M.Sc. in Health Informatics has helped me to gain insight into both fields. Many attempts have been and still are made to involve users, extend the dialog and improve understanding between developers and users, but user involvement and dialog may be conducted in various ways with very different outcomes.

In 2007 I managed the establishment of the IT Experimentarium (ITX) in the Capital Region of Denmark. Since then I have managed clinical simulation in the region. Performing clinical simulation has given us an opportunity to focus on both clinical context and users and, through simulation, clinical scenarios may come alive without causing any harm. Simulation gives the users a voice and improves communication between developers, end-users, and the IT-department. Furthermore, replicating specific scenarios gives us an opportunity to form a mutual understanding as it creates common ground for dialog and discussion.

Three years of research have not only enhanced my knowledge of clinical simulation and the potential uses of simulations, but also broadened my understanding of science, methodology and socio-technology and enlarged my network of fellow health "informaticians". My view of user involvement, system development, and use of clinical simulation is far from what it was three years ago.

It has been a long journey but I have enjoyed every minute.

Sanne Jensen
October 2014

ABSTRACT

The usability of health information technology (IT) is increasingly recognized as critically important to the development of systems that are both safe to use and acceptable to end-users. 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.

This thesis sets out to examine how clinical simulation may be used in the various phases of the development life cycle of clinical information systems (CIS). The overall aim of my research is to investigate what might be gained from using clinical simulation in the development of CIS. Within this context, I will look into use of clinical simulation during the following phases; 1) requirement specification, 2) design, 3) procurement, and 4) organizational implementation and discuss opportunities and challenges involved in using clinical simulation.

To achieve this aim, an interpretive approach was employed. My research is interdisciplinary, integrating sociological and technological disciplines and is problem-driven using project-based teamwork. The research strategy is organized in three phases; 1) literature review, 2) five case studies, and 3) assessment of the opportunities and challenges involved in using clinical simulation. The case studies cover user requirement analysis and specification, design evaluation, a procurement process and application assessment in work. The methodological approach to my research is structured in an action learning cycle. In my research I apply field studies, contextual inquiry, interviews, workshops and clinical simulation. Data analysis is conducted by either instant data analysis or using a grounded theory-inspired inductive approach.

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 CIS 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 CIS 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.

The primary benefits of using clinical simulation are:

- involvement of users and clinical context
- controlled environments for experiments and formative evaluations of user satisfaction, usefulness and patient safety
- environments for addressing and visualizing cross-sectorial and cross-functional topics
- organizational learning space and common ground for gaining shared understanding.

The main concerns and challenges of using clinical simulation are:

- clinical simulation does not reflect the social-technical issues over time
- clinical simulation does not cover all possible work practice situations and issues
- to a great extent, the purpose and choice of scenarios determines the outcome.

The findings highlighted how clinical simulation can contribute to development of safe and useful CIS.

DANSK RESUME

Anvendeligheden af sundheds-it er i stigende grad anerkendt som værende yderst vigtig for udviklingen af systemer, for at sikre at systemerne er sikre at bruge og anvendelige for slutbrugerne. Den betydelige kompleksitet i både organisationer, arbejdspraksis og fysiske miljøer inden for sundhedssektoren påvirker udvikling og anvendelse af sundheds-it. Når sundheds-it er indført i lokal klinisk arbejdspraksis, bør potentielle patientsikkerhedsmæssige risici og utilstrækkelig støtte af arbejdspraksis afdækkes. Kvalitative metoder, såsom klinisk simulation, kan anvendes til at vurdere ny teknologi i sammenhæng med den kliniske kontekst, og til at studere samspillet mellem brugere, teknologi og arbejdspraksis. I modsætning til "klassiske" evalueringsmetoder, såsom heuristisk evaluering og usability test, tager klinisk simulation den kliniske kontekst med i betragtning.

Denne afhandling undersøger, hvordan klinisk simulation kan anvendes i forskellige livscyklusfaser i udviklingen af kliniske it-systemer. Det overordnede mål med min forskning er at undersøge, hvad der kan opnås ved at bruge klinisk simulation i udviklingen af kliniske it-systemer. Jeg vil undersøge brugen af klinisk simulation i de følgende faser; 1) kravspecificering, 2) design, 3) udbud, og 4) organisatorisk implementering samt diskutere muligheder og udfordringer ved anvendelse af klinisk simulation.

For at nå dette mål har jeg anvendt en fortolknings-orienteret tilgang, interpretivisme. Min forskning er tværfaglig og integrerer sociologiske og teknologiske discipliner. Den er problemorienteret og anvender projektbaseret teamwork. Min forskningsstrategi er inddelt i tre faser; 1) litteraturgennemgang, 2) fem case studier, og 3) vurdering af de muligheder og udfordringer, der er ved at anvende klinisk simulation. Casestudierne dækker brugeres analyse og specifikation af brugerkrav, formativ evaluering af design, offentligt udbud og vurdering af it-systemer i arbejdspraksis. Den metodiske tilgang til min forskning er struktureret i et aktion-læringsforløb. I min forskning anvender jeg feltstudier, interviews, workshops og klinisk simulation. Dataanalyse udføres ved brug af Instant Data Analysis og en tilgang inspireret af Grounded Theory.

Klinisk simulation kan være nyttig i mange processer i den menneskelig-centrerede design cyklus. I kravspecifikationen kan klinisk simulation være nyttigt til at analysere brugerkrav og arbejdspraksis samt til at evaluere brugerkrav. I design af sundheds-it kan klinisk simulation anvendes til at evaluere kliniske it-systemer, tjene som et fælles fundament og hermed bidrage til at opnå en fælles forståelse mellem forskellige praksisfællesskaber. I et udbud kan en simulationsbaseret vurdering hjælpe med at give indsigt i forskellige it-løsninger og hvordan de støtter arbejdspraksis. Før organisatorisk implementering er klinisk simulation velegnet til evaluering af it-understøttelsen af arbejdspraksis, patientsikkerheden og brugervenlighed i kliniske it-systemer.

De primære fordele ved at bruge klinisk simulation er:

- inddragelse af brugere og klinisk sammenhæng
- kontrolleret rum til eksperimenter og formative evalueringer af brugertilfredshed, nytteværdi og patientsikkerhed
- mulighed for afklaring og visualisering af tværsektorielle og tværgående dele af klinisk arbejdspraksis
- fælles udgangspunkt til opnåelse af fælles forståelse og organisatorisk læringsrum

De vigtigste problemer og udfordringer ved at bruge klinisk simulation er:

- klinisk simulation afspejler ikke de sociale-tekniske aspekter over tid
- alle situationer dækkes ikke af klinisk simulation
- formål og valg af scenarier bestemmer i stort omfang udfaldet af simulationerne.

Resultaterne af min forskning viser, hvornår og hvordan klinisk simulation kan bidrage til udviklingen af sikre og brugbare kliniske it-systemer.

ACKNOWLEDGEMENTS

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Thanks to my colleagues at the ITX-lab, from whom I have benefited greatly during the case studies. Thank you for sharing your thoughts and experience. Special thanks to Stine Loft Rasmussen for many fruitful discussions and dialogs. I am grateful to all the participating clinicians as well as team members in the five project teams in the five case studies, who all willingly participated in simulations, observations and interviews.

I would also like to thank my co-authors for their kind cooperation in the publication process. Thanks also to Andre Kushniruk for making my three-month stay at the School of Health Informatics, University of Victoria (UVIC), BC, in spring 2013 both possible and productive.

Last but not least, thanks to Jan, my friends and my loving daughters, Signe and Rikke, for supporting me over the past three years.

TABLE OF CONTENTS

ABBREVIATIONS

ANT: Actor Network Theory

BO: Boundary Object

CIMT: Centre for IT, Medico and Telecommunications

CIS: Clinical Information Systems

COP: Community of Practice

COPD: Chronicle Obstructive Pulmonary Disease

CPG: Clinical Practice Guidelines

DM2: Diabetes Mellitus 2

EHR: Electronic Healthcare Record

GP: General Practitioner

IDA: Instant data analysis

ISO: International Organization for Standardization

IT: information technology

ITX: IT Experimentarium

RQ: Research Question

PCM: Planning and Coordination Module

PD: Participatory design

PPP: Public Procurement Process

STS: Science, Technology and Society

WoO: Wizard of Oz (for an explanation see page 32)

OUTPUTS ARISING FROM THE RESEARCH

Publications marked with "*" are part of my thesis. Unmarked publications are part of my research. All publications are peer-reviewed.

A. *Jensen S, Lyng KM, Nøhr C. The role of simulation in clinical information systems development. Stud Health Technol Inform 2012;180:373-7.

B. Rasmussen SL, Lyng KM, Jensen S. Achieving IT-supported standardized nursing documentation through participatory design. Stud Health Technol Inform 2012;180:1055-9. Best paper selection

C. *Jensen S, Vingtoft S, Nohr C. Benefits of a clinical planning and coordination module: a simulation study. Stud Health Technol Inform 2013;183:220-4.

D. *Jensen S, Nohr C, Rasmussen SL. Fidelity in clinical simulation: how low can you go? Stud Health Technol Inform 2013;194:147-53.

E. Rasmussen SL, Jensen S, Lyng KM. Clinical simulation as a boundary object in design of health IT-systems. Stud Health Technol Inform 2013;194:173-8. Jensen S, Rasmussen SL, Lyng KM. Use of clinical simulation for assessment in EHR-procurement: design of method. Stud Health Technol Inform 2013;192:576-80.

G. *Kushniruk A, Nohr C, Jensen S, Borycki EM. From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies. Yearb Med Inform 2013;8(1):78-85.

H. *Jensen, S., Rasmussen, S. L., and Lyng, K. M., "Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms," Stud.Health Technol.Inform, Vol. 205, 2014, pp. 925-929.

I. *Jensen, S., Kushniruk, A. Boundary objects in clinical simulation and design of eHealth, Health Informatics Journal 2014

Articles under submission

J. * Jensen, S., Nøhr, C., Kushniruk, A. 2014. Clinical Simulation: A method for Development of Clinical Information Systems

K. * Jensen, S., Hermansen, B., Nøhr, C., 2014 Identification and prevention of Patient safety hazards

1 INTRODUCTION

This thesis deals with clinical simulation in relation to health IT in hospital settings. My research sets out to examine what might be gained from using clinical simulation in the development and evaluation of clinical information. I use the term *Development* in a broad sense. It includes all phases of the development life cycle of information systems, i.e. analysis, design and implementation until the system is operational. The term *Design* is used to describe the design phase, the term *Implementation* is used to describe the organizational implementation of an information system, and the term *Requirements* is used to describe user requirements unless otherwise stated.

Before summarizing my contributions, I wish to outline the structure of and background for the thesis.

1.1 SECTION OVERVIEW AND STRUCTURE OF THESIS

The thesis is structured in four parts; 1) Introduction, 2) Research Design, 3) Empirical Work and 4) Discussion, Conclusion and Perspective (See Figure 1). Part 1 is an introduction to my research, i.e. why it is of interest, my aims and my chosen approach and a literature review. Part 2 looks into the research design, i.e. theoretical approach, methods and description of case studies. Part 3 contains all my empirical work, including highlights from my publications structured in relation to my research questions. Part 4 is discussion, conclusions and perspectives in regards of my research.

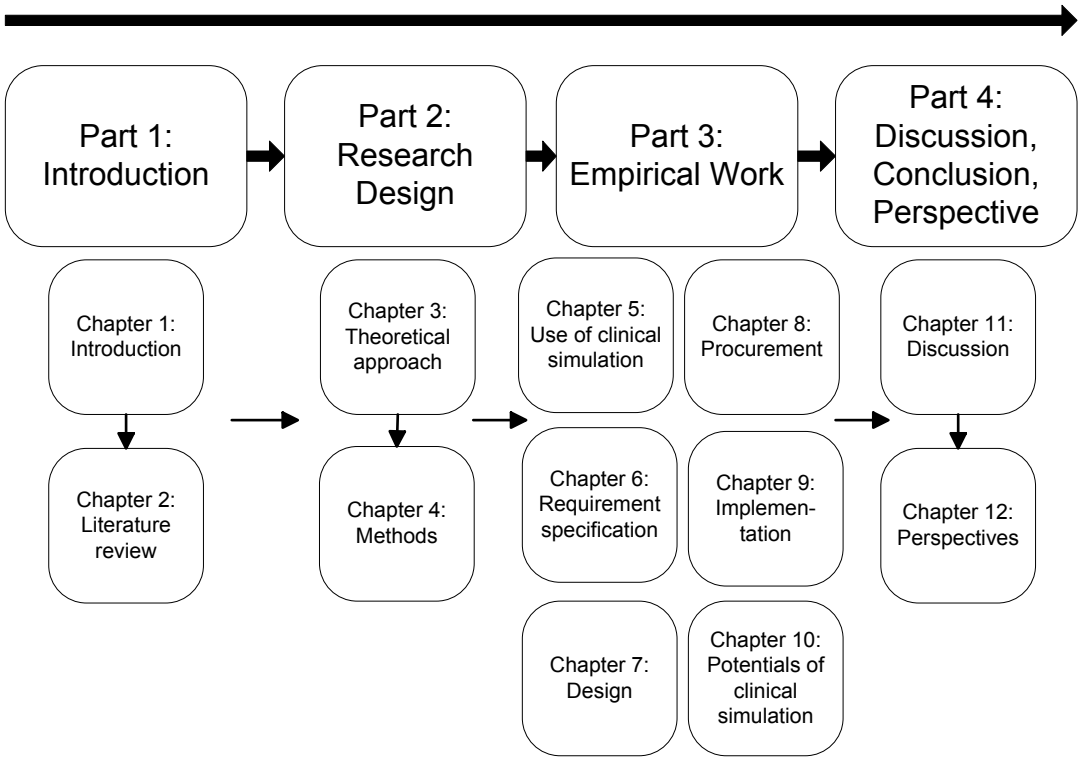


FIGURE 1 STRUCTURE OF THESIS

1.2 BACKGROUND – RESEARCH PROBLEM

Present-day health care meets increasing demands for efficiency in the form of high productivity and lower costs. Inadequate work flows may result in low efficiency and poor patient safety. Standardization of work and implementation of information technology (IT) are two methods used to optimize work flow and patient safety. However, patient safety in relation to health IT presents a paradox (1). Even though health IT may improve patient safety and quality (2), the application of new technology in healthcare may also increase patient safety hazards (3). Errors persist to occur in clinical practice even after new health IT has been introduced partly because manual processes co-exist with automated processes and the interfaces between the two seldom are perfect (4). Furthermore, new errors occur due to poor design of the information system (5; 6) and insufficient support of work flow (3). Studies show that adverse events in relation to new technology are more often related to the use of technology rather than to the technology itself (3; 6) and up to 70% of patient safety incidents are estimated to be related to or due to human factors (7).

Methods for design of eHealth focusing on patient safety are some of many initiatives trying to prevent adverse events (8; 9). Guidelines and standards (10-13) have been implemented that can address patient safety hazards in design of health IT. However, regulation and certification do not address safe use within the context of clinical work practice as this must be addressed locally in the organizations (14). Patient safety does not entirely rely on technology but is highly influenced by its interaction with users in a specific context (15). Socio-technical issues and human factors also exert an influence on unintended consequences and patient safety hazards (6; 8; 16).

The substantial complexity of organizations, work practices and physical environments within the healthcare sector impacts the development and application as well as the implementation and use of information systems (17; 18). Healthcare environments are profoundly collaborative and rely on coordination between various health professionals (19) and are characterized by delegated decision-making, multiple viewpoints and inconsistent and evolving knowledge bases (20). Multiple groups with potentially divergent values and objectives work together and face many contingencies which cannot be fully anticipated (21; 22). With staff-related variable, the difficulties complicate and challenges the wisdom of standardization in health care work (20).

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 (5). 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 (13). 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 (20).

When health IT is introduced in local clinical work practices, including existing and evolving technologies and organizational structures, possible patient safety hazards and insufficient support of work practices must be examined Evaluation of patient safety and new work flows in relation to use of technology in a clinical context is therefore highly relevant. However, most methods, such as field studies (3) and incident monitoring (13; 23), are retrospective and may therefore only be of limited use in the design and development of information systems.

Qualitative methods, including clinical simulation, have been used to proactively evaluate new technology in correlation with the clinical context throughout the software development life cycle in health informatics (24; 25), and to study the interaction between users and technology as well as the potential effects on clinical workflow and organizational issues (26; 27).

Compared with other methods, e.g. heuristic inspection and low fidelity usability evaluation, clinical simulation may have an advantage because, while other methods tend to focus merely on one or two aspects without the clinical context, clinical simulation takes the clinical context into account. Heuristic inspection focuses on the user interface and low fidelity usability testing focuses on technology and on the specific tasks of individual users. These methods may however complement clinical simulation by making a rigorous evaluation of the user interface and thus uncovering usability challenges in the graphical user interface. They do not, however, include the full clinical context and the interdisciplinary aspects of everyday clinical work.

Evaluation of clinical information systems (CIS) 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 (28). Clinical simulation studies have proven feasible for conducting safe evaluations of technology before it is introduced into routine clinical practice (29). Clinical simulation has also been used to evaluate the potential impact (30), cognitive processes and usability (25), and work practice (27). 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 (31).

One of the challenges in designing information systems is identifying user requirements. Lucy Suchman cites David Well in an article about making work visible: "*How people work is one of the best kept secrets in America*" (32). She describes how work may be invisible for others and how work may be interpreted differently. According to Suchman, work descriptions do not reveal all aspects of work processes and work practices. The more enhanced the work is done, the more difficult it is to see. Knowledge arises as much from interaction as from evidence. "*You can't write all 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*".

Needs and requirements differ throughout an organization and development is an important issue in off-the-shelf CIS products (20). 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 (33).

Since 2007 clinical simulation has been used in the Capital Region of Denmark to evaluate CIS. Since 2011, it has been mandatory ahead of the implementation of CIS at the regional hospitals. As elsewhere (5; 34-36), for many years the region had found implementations challenging, due to e.g. lack of sufficient ability to support and cooperate with the clinical work processes and user interfaces that were not user-friendly. The unintended results were many, e.g. work-

arounds, misuse of information systems, adverse events and disillusioned user, and the need to assess usability and effectiveness of CIS in a clinical context emerged. For this reason, the IT Experimentarium (ITX) was established (37). The purpose of ITX was to evaluate CIS using clinical simulation. The aim was to assess new technology in clinical practice and analyse existing and new work practices.

The resources invested in preparing and performing simulation studies are often exhaustive, depending on the required degree of fidelity, and it is essential that the resources invested in creating a realistic setting match the purposes of the evaluation and the simulation set-up (30; 38). However, the resources saved by using clinical simulation for analysis and evaluation purposes are difficult to quantity as it is difficult to put a price on the value of patients' lives.

One of medicine's moral dilemmas is that of putting today's patients at risk in order to train tomorrow's practitioners. Medical simulation has been used in connection with clinical skills training and the social-team-oriented and cognitive-individual-oriented aspects of clinical work practice for more than four decades, thereby reducing the need for unskilled practicing on patients and the risk of safety hazards (39-47). Similarly, clinical simulation is expected to become a beneficial method by which to evaluate CIS, as simulations can take place in a controlled environment where there is no risk of injuring real patients (48; 49).

Research concerning simulation in the training of healthcare professionals is comprehensive (39; 41-43; 46; 47). On the other hand, there has been no thorough research of clinical simulation in relation to design and evaluation of CIS. This thesis addresses how clinical simulation may be used in different stages of the life cycle of CIS to improve the use and outcome of the systems.

1.3 RESEARCH AIMS & OBJECTIVES

The aim of this PhD study is to develop, apply and evaluate methods for using clinical simulation at the different phases in the life cycle of information systems. My approach is to review the literature and several case studies covering various phases in the development life cycle. In the case studies, I investigated the benefits and limitations of clinical simulation and focused on how and for what purposes clinical simulation can be used. The case studies covered various phases in the CIS development life cycle.

The overall aim of my research is to investigate what might be gained from using clinical simulation in the development of clinical information systems. The PhD study investigates the significance of using clinical simulation in the development and evaluation of CIS and discusses the opportunities and potential benefits, challenges and limitations of using clinical simulation. The research questions (RQ) are described in the next section along with a short description of the topic, objectives and methodology used to investigate each question, and the papers related to each of the research questions.

1.3.1 RESEARCH QUESTIONS, OBJECTIVES AND METHODOLOGY

The primary research question this thesis sets out to examine was:

RQ 0: What might be gained from using clinical simulation during various phases in the development of clinical information systems?

Within the context of the primary RQ, the research had the following secondary RQs:

- ***RQ1 - How can clinical simulation be used in the development and evaluation of clinical information systems?***

  Topic: A description of how clinical simulation can be conducted, and the pros and cons highlighting steps towards successful simulation.

  Objective: To describe a method for planning, preparing and conducting clinical simulation, taking into account the opportunities, benefits, challenges and limitations of the method.

  Methodology: Developed out of the experiences from 25 studies performed in the period 2007 till 2014, in which clinical simulation was used to support the design, evaluation and optimization of CIS before implementation in real practice. A scientific simulation study of a prototype of a planning and coordination module was used as a recurring example. Some of the unintended consequences and benefits discovered during the evaluations were discussed. Finally, key issues in the form of steps required in order to make a successful simulation were highlighted.

  Publication: "J: *Clinical simulation: A method for Development of Clinical Information Systems*, Jensen, S., Nøhr, C., Kushniruk, A., 2014".

- ***RQ2 - What are the potentials of using clinical simulation in specification of user requirements for clinical information systems?***

  Topic: How can clinical simulation support understanding and specifying the context of use, and user and organizational requirements?

  Objectives: One paper presented a clinical simulation study, the purpose of which was to analyze user requirements for an Electronic Health Record (EHR) platform in close collaboration with end-users and their simulated daily work practice. Another paper demonstrated a formative evaluation of a cross-sectorial planning and coordination module in relation to requirement specification.

  Methodology: Two different approaches were chosen. In the first simulation study, cardboard boxes and post-it labels were used as low-fidelity mock-ups to analyze user requirements. The need for fidelity was subsequently matched up to four different fidelity dimensions. In the second study, a high-fidelity prototype was evaluated. The prototype design was based on requirements analyzed and specified by end-users, health informaticians, etc.

  Publications:

  "D: *Fidelity in clinical simulation: how low can you go*?, Jensen S, Nøhr C, Rasmussen SL,. 2013",

  "C: *Benefits of a clinical planning and coordination module: a simulation study*, Jensen S, Vingtoft S, Nøhr C., 2013".

- ***RQ3 - What are the potentials of using clinical simulation in design of clinical information systems?***

  Topic: How can clinical simulation improve the design of CIS and how can clinical simulation be used to acquire a shared understanding and common ground for discussions between the stakeholders (e.g. end-users, risk managers, quality managers and clinical management) representing dispense goals for and views on applicability and implementation of new technology?

  Objectives: The paper focused on use of clinical simulation as part of the participatory design approach and discusses the use of clinical simulation as a boundary object to translate, transfer and transform knowledge between various communities of practice (COP) in healthcare organizations.

  Methodology: A scientific case study was used to investigate how clinical simulation can act as a boundary object in a participatory design process and support stakeholders in a large healthcare organization to achieve a mutual understanding of the different domains each stakeholder represents. The application used in the study was clinical documentation templates for initial nursing assessment.

  Publication: "I: *Boundary objects in clinical simulation and design of eHealth*, Jensen, S., Kushniruk, A., 2014".

- ***RQ4 - What are the potentials of using clinical simulation in assessment of clinical information systems as part of a procurement process?***

  Topic: The cognitive aspects influencing clinical work practice in relation to any particular system are difficult to assess using quantitative methods. How may clinical simulation be used in connection with procurement?

  Objective: To develop, use and evaluate a method by which to assess qualitative aspects of user satisfaction, usefulness and patient safety. The method should cover demands from various end-users, medical specialties, and cultures, and meet demands for transparency in connection with public tender procurement in accordance with EU regulations.

  Methodology: A method for using clinical simulation to assess qualitative aspects, such as human factors and usability of three different EHR-platforms, was developed, used and evaluated in connection with the process to procure a large EHR platform. The method actively involved clinicians in the public procurement process. The method was evaluated by describing three aspects of the human factor issues that the method was designed to cover; 1) user satisfaction, 2) usefulness and 3) patient safety.

  Publication: "H: *Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms*, Jensen, S., Rasmussen, S. L., and Lyng, K. M., 2014".

- ***RQ5 - What are the potentials of using clinical simulation to acquire knowledge of implementation?***

  Topic: How can clinical simulation support the acquisition of knowledge regarding aspects of implementation, such as patient safety hazards and work practice?

Objective: To assess the potential of applying clinical simulation as a proactive method to identify and evaluate potential patient safety hazards and support of work practice prior to implementation.

Methodology: A case study investigated how a standardized information system "OPUS Inbox" supported clinical practice, and identified potential patient safety hazards and how work practice was supported prior to implementation.

Publication: "K: *Identification and prevention of Patient safety hazards*, Jensen, S., Hermansen, B., Nøhr, C., 2014".

1.4 RESEARCH APPROACH

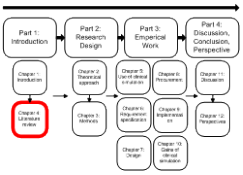
The PhD study encompassed a literature study and five case studies covering various phases of the life cycle of a CIS. For a full description of the five case studies, see section 3.2.1. The usefulness of and challenges involved in using clinical simulation in the design and evaluation of CIS was investigated in these studies. The research approach was interdisciplinary, integrating sociological and technological disciplines. The approach was also problem-driven using project-based teamwork. The study was essentially a "hybrid imagination" combining human and sociological sciences with more technical competences from IT development (50).

The degree to which I was involved in my studies was a professional challenge. On the one hand, I had to achieve and sustain academic distance. On the other hand, I offered advice on issues and had to avoid getting involved. My role as a researcher was participatory. I participated in the research as a facilitator giving advice and, at the same time, I was the manager, maintaining an overview. I observed and sought to achieve a valid, plausible and reflexive understanding of the meanings ascribed by the participants during the case studies.

My research drew on elements from various scientific approaches and combined them throughout the study without applying a predetermined theory chosen for abstract and theoretical reasons alone. I approached the subject matter cautiously and decided, along the way, which theories would best serve my purpose. My approach was explorative and embraced an iterative process. Contrary to a waterfall design process (51), my approach harmonized well with the iterative life cycle approach in user-centred design (52). The first part of my thesis focused on acquiring broad knowledge of the current research status and position worldwide regarding the use of simulation with real users in designing and evaluating CIS. The second part focused on applying this knowledge in practice in five case studies. The overall scientific approach was participatory research.

The practice of science was creative, using experimental methods of discovery, instrumental rationality and a search for workable tools and instruments. The study was empirical with emphasis on observation and data collection. Through the study I have searched for insight and for theories that can be practically applied. The project was mixed method research with a preference for quantitative methods, where I combined phenomenological approaches (observations) with hermeneutic elements in an attempt to understand the users through interviews with them.

This section has outlined the background for my research. I have presented my research aims and objectives as well as my research approach and my own relevant publications. The next section will give an overview of the experience of using clinical simulation.



2 LITERATURE REVIEW

This section is based on the two publications 1) A: The role of simulation in clinical information systems development (53), and 2) G: From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies. (48). The first paper is a literature review and the second is an exploration of human factor approaches to understanding the use of health information technology by extending usability approaches to include analysis of impact of clinical context through the use of clinical simulation.

The strategy of the literature review was to conduct a systematic review and making an exhaustive summary of current literature relevant to my research question. There are several standards and guidelines for conducting a systematic review. This review, as presented in Figure 2, selected the most relevant components following the PRISMA 2009 flow diagram (54).

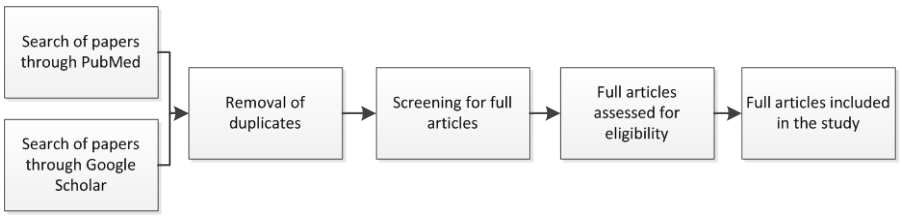


FIGURE 2 LITERATURE REVIEW

The first step was to identify potential literature. 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 after 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.

A total of 1,161 papers was found. Duplicates and papers for which a full paper was not accessible were excluded. Most of the remaining literature concerned medical simulation used in the training of healthcare professionals. Medical simulation for training has been used in the last four decades as opposed to clinical simulation used for evaluation of CIS, which has only been used for just over a decade. The proportion of papers concerning simulation in relation to development and evaluation of CIS was therefore quite small. Based on the extent to which end-users were involved in the simulations and on how they presented new knowledge about simulation in relation to the design, development and application of CIS, a total of 29 papers concerning simulation were seen to be highly relevant for this review.

Simulation may be conducted with (48) or without end-users (55), or as a hybrid, where simulation with end-users is combined with computer-based simulations (56). Simulations with real users focus on the "*human-in the-loop*" (25) as opposed to computer-based simulations focusing on the "*computer-in-the-box*" (55). This literature review was focusing on clinical simulation where real users are enacting realistic clinical work scenarios.

The literature review disclosed that simulation has been used at various stages of the life cycle 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 CIS (57; 58). In contrast to field studies, simulation studies allow for the possibility of examining a variety of complex and extreme usage scenarios during a short but highly intense test phase (59). Simulation methods have been used in biomedical informatics to study various aspects of human computer interaction in a number of research domains, including human factors, usability, doctor-patient interaction involving technology, health professional information requirements, health professional decision-making, new device testing and studies of medical errors (25; 27; 55; 59).

In the early phases of the CIS life cycle, simulation has been used to analyze user requirements using prototypes or storyboards in preliminary tests (25). Simulation has also been used to obtain and assess knowledge of user work practice (27). In the design phase, simulation has been used as a method by which to involve users and provide iterative feedback for the design of prototypes or real systems (25). The benefit of simulation studies is that they can be designed to study practical experience in the design process of new technology without introducing ethical issues or putting patients at risk. The aim of simulation studies in the design phase is to create design proposals for a new technology and may combine elements of laboratory testing and field study (29).

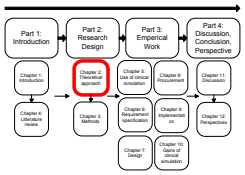
In the implementation phase, specific aspects of implementation has been visualized through simulation, e.g. user interaction in work practice, the need for training, and the impact of decision support (60). Unintended consequences of new systems, such as changes in work processes and patient outcomes may be detected and can provide organizational decision- makers, if necessary, with an opportunity to correct actions (27).

For simulations to work efficiently, it is important to define the purpose and identify an adequate level of simulation fidelity. Simulations can be adjusted to address specific issues by making participants to focus on fixed aspects. With an adequate degree of realism, evaluators can address how various elements may affect the simulated work practice and use of CIS (61).

The literature revealed that clinical simulation may be well suited for assessing work practice and human factors and should play a substantial role in the design, development and implementation of CIS. Simulation studies may be a very relevant method for evaluating CIS throughout the life cycle and provide essential feedback for continuous progress in each phase. Simulation studies may be useful for defining user requirements and analyzing work practices from the initial phases of CIS. Simulation can subsequently be used in the design and development of CIS as well as in implementation planning. By using simulations, healthcare organizations may effectively identify issues that could potentially arise from the introduction of new technology prior to their introduction in real-world settings.

The literature review did not reveal any studies containing a thorough methodological description of how clinical simulation is conducted or how fidelity influences the outcome of a simulation study. The review revealed no case studies on how clinical simulation may be used in relation to procurement. The reviewed literature indicated that correctly performed simulation studies can be an efficient method by which to prevent late system failures and may improve patient safety significantly. Further research is required to prove this.

This section has provided an overview of existing literature and experiences of using clinical simulation. The review indicated that clinical simulation is an extensive practice and suggests areas for further research. The next section describes the theoretical approach I adopted in order to achieve my research aims.



3 THEORETICAL APPROACH

This thesis investigated how and for what purposes clinical simulation can be used in the development of CIS. Little is known about these issues and the health informatics literature on simulation tends to focus on clinical simulation applied to summative evaluation. There is a need for a more sophisticated approach to evaluate the potential for using clinical simulation not only in formative and summative evaluation of CIS, but also in analyzing and investigating the effects of CIS in the clinical context and work practice.

My theoretical approach has been explorative. I sought to acquire an understanding rather than to explain. Quantitative methods seek proof and explanations focusing on summary characterizations and statistical explanations, while qualitative methods attempt to comprehend, by offering complex descriptions to explain webs of meaning (62). Kvale describes two different scientific approaches symbolized by a miner and a traveler (63). The miner represents a positivistic approach, while the traveler's is an interpretive or constructive approach. The miner believes that knowledge is buried in the ground; he only has to dig for it. The traveler sees the world as a social construction, which can only be understood in a dialog with those who live in it. As my research approach is explorative and cognitive, I perceive myself as the traveler, primarily taking an interpretive approach. According to Walshman (64), interpretive methods of research assume that our knowledge of reality is a social construction with human actors, (in the present context, researchers). There is no objective reality, which can be discovered and replicated by others.

3.1 RESEARCH PHILOSOPHY

Before initiating any research, the researcher must consider his or her fundamental philosophy regarding the nature of reality, knowledge and human behavior as these philosophies influence ontology, epistemology and the choice of methods appropriate for the research (65). In my research, a subjective ontology utilizing an interpretative epistemology was embraced. According to an interpretive view, reality is socially constructed and never objectively and unproblematically knowable. As a researcher, the identity and values of the interpretive approach are inevitably implicated in the research process (66). An interpretive researcher seeks a valid, plausible and reflexive understanding of the meanings ascribed by the actors. The aim of interpretive research according to a interpretivistic philosophy is to understand and reconstruct (65). Methodological choices are primarily hermeneutic, dialectic and phenomenological.

As my research sought to investigate how clinical simulation can be used to acquire knowledge about the correlation between technology, organization and human beings, it was important to focus on the attitudes, insights and experiences of the individuals involved. I conducted my research within a subjective interpretative paradigm which did not impose constraints on my data collection methods and analysis techniques. Interpretive methodology includes qualitative, naturalistic and pluralistic methods, where the data is analyzed for meanings and perspectives. Pluralistic methods are multiple methods preferred to give a rich picture of reality.

My research may be seen as a type of "hybrid imagination". A hybrid imagination can be defined as "the combination of scientific-technical problem-solving with an understanding of the problems that need to be solved" (50) p4. It blends scientific knowledge with technical skills and reflects the cultural implications of science and technology in general and the scientist's or engineer's own contribution. A hybrid imagination is often manifested collectively, involving collaboration between two or more people. The context of knowledge creation is transformed from disciplinary, through multidisciplinary and interdisciplinary to trans-disciplinary. Current research tends to be trans-disciplinary(50). My research tends also to be trans-disciplinary, as it looks into the fields of technology, health care and social science.

3.1.1 THE ONTOLOGY

Ontology is the theory or study of existence and refers to the perceived nature of the world around us. Ontology examines whether the empirical world is objective, independent of humans or subjective, having existence through the action of humans and recreating it (67). Ontology is prior to and subsequently governs epistemological and methodological assumptions (68).

A subjective ontological view can be described as a view which emphasizes the subjective behavior or reasoning that determines how people construct their own reality within the constraints of society's agency (67). This view implies that the researcher assumes that the social world is created and reinforced by humans through their actions and interactions. An interpretive research scientist assumes that there are multiple realities, socially constructed through symbolic interactionism, framing and sense-making (66). In other words there is no single truth but multiple truths, the world is changeable and viewed through a social psychological perspective and reality depends on time, place and context.

In order to get a profound insight into the potential of using clinical simulation, I embraced a research philosophy that uses a subjective ontological approach (67). On the basis of the research questions propounded in this study, I employed interpretive epistemology to engage with the participants in the case studies in order to gain deep insight into how and for what purposes clinical simulation may be used.

Given that the research seeks to examine how clinical simulation may be used to acquire knowledge about the relationship between clinicians, organization and technology, it was relevant to focus on the influence of technology on users (healthcare professionals) and on the organization, and, equally, to focus on the influence exerted by users and the organization on technology through e.g. the creative use of technology, new requirements and further development.

According to the socio-technical approach, work practice is conceptualized as "networks of people, tools, organizational routines and documents" (20) (p. 87). The social perspective views social aspects (information system, equipment and tools) as interdependent entities which require equal consideration when understanding work environments (21). The social and technical aspects must be considered, independently and interdependently, as optimization of the one may have a negative impact on the other. There is a need for dual focus and joint optimization (69). The socio-technical systems model views organizations as transformation agencies, which transform inputs into outputs (70). Socio-technical systems grasp three major elements in this transformation process: a technological subsystem, a personnel subsystem and a work system design covering the organization's structure and processes. These three elements interact with each other and with the external environment.

From the perspectives of symbolic interactionism focus on the actions of the actors, interaction between the actors, and the relation and integration with objects, are especially relevant. How do actors perceive, adapt and react in relation to other actors? These issues are very important to the design and evaluation of IT systems and we focus on them during clinical simulations and observations. Issues related to visible and invisible knowledge and behaviors, with which Strauss and Star have worked, are essential aspects of the development and evaluation of information systems (71; 72).

Symbolic interactionism considers meanings to be *social products*, i.e. creations that are formed and transformed in and through the defining activities of actors as they interact (73). When actors deal with the world of their objects and act in relation to it, creation and refinement of meanings might result. To understand the actions of people, it may be best to understand the worlds of their objects. Meaning thus created may be provisionally externalized through symbolic representations and concrete artifacts. Sometimes the same objects may appear in different worlds, which leads to a flexible interpretation and thereby a possible coordination between the actors of the different worlds. These objects are called boundary objects.

Star and Griesemer (74) define boundary objects as "*flexible epistemic artefacts that inhabit several intersecting social worlds and satisfy the information requirements of them". "They have different meanings in different social worlds but their structure is common enough to more than one world to make them recognizable, a means of translation*" (p393). Objects become boundary objects when they are used at the interface of different communities of practice. A community of practice has a shared understanding of what the community does, of how it does it, and of how it relates to other communities and their practices, and will develop the same world view or mental model (75). Boundary objects may be physical objects as well as symbolic objects. They are a kind of socio-technical hybrid spanning across boundaries of different worlds enabling and constraining knowledge sharing across boundaries (76) carrying information and context that may be used in translating, transferring and transforming knowledge between communities of practice (77). Boundary objects may be a sort of arrangement that allows different groups to work together without consensus, something people act against, towards, and with (78). Boundary objects may be repositories (e.g. a library or a database), ideal types (e.g. a diagram or a roadmap), coincident boundaries (e.g. the boundaries of a state) and standardized forms (e.g. classifications) (74). Technology may be considered a boundary object that can induce transformational learning in practices related to integrated design (79).

Boundary objects may be used to achieve a shared understanding of collaborative processes in the development of future collaborative processes and products (80) and as a framework for modeling and categorizing organizational interfaces (81). Boundary objects are frequently seen in eHealth, e.g. in clinical documentation and classification (82; 83). They involve the participation of actors from both sides of the boundary with professionals, who serve as mediators, and they exist at the border of two somewhat different social worlds, but there are distinct lines of accountability to each of them.

3.1.2 THE EPISTEMOLOGY

The term "epistemology" refers to beliefs and assumptions about the way in which knowledge is acquired and constructed (84). These beliefs relate to how one might understand the world and communicate this to others (85). Humans establish knowledge through negotiations, common beliefs, experience and tradition. According to an interpretive view, knowledge is subjective, context-dependent, value-laden and emerges from researcher-participant interaction (66).

My study was explorative and the data was rich and contextual. The data had to be analyzed for meanings and perspectives, although the aim was not to strive for absolute objectivity and testability. Values, such as credibility, conformability and transferability, were embraced instead (63; 65). Brannen (86) suggests that the choice of methods and how they are used is likely to be informed by the research questions. According to Pope (87), qualitative research deals with speech and words, and answers questions such as "what is?" and "how does?". Qualitative research is "*concerned with the meanings people attach to their experiences of the social world and how they make sense of that world*" (87) p4. Qualitative research attempts to interpret social phenomena, such as interactions and behaviors, in terms of the meanings people bring to them and seeks to answer fundamental and searching questions about social phenomena. According to Gadamar (88), pre-understanding will always set the conditions for understanding. Pre-understanding includes everything we know or think we know. Pre-understanding is always present and often unnoticed. On the other hand, Gadamer states that, without some kind of pre-understanding, it is difficult to ask questions. In hermeneutic philosophy, generality is not viable because it is not possible to preclude the context (89). Generality becomes rather a matter of transferability of the interpretations to other situations, and receptiveness, sensitiveness and uprightness are embraced. Quality in knowledge is assessed and accepted inside the field of science rather than focusing on validity as would be the case when using a more positivistic approach. Kvale (63) introduces analytical generality as a considered assessment of the degree to which the results of one study may be instructive as to what might happen in the next study based on an analysis of similarities and differences.

I embraced an interpretive research approach as a way of obtaining knowledge about what may be gained from using clinical simulation and how. An interpretive approach is based on an ontology in which reality is subjective, a social product constructed and interpreted by humans as social actors according to their beliefs (90). In interpretative research the researcher does not construct a social setting before entering it, but allows constructs to emerge while the researcher is in the field, acquiring knowledge and trying to understand a phenomenon. The use of interpretive epistemology makes it possible to understand phenomena by accessing the meanings given to them (67). Using an open-ended, qualitative, subjective approach in my research, it was possible to obtain profound knowledge and an understanding of what might be gained from using clinical simulation, and what the possible challenges, limitations and potential disadvantages might be.

The research philosophy I adopted enabled me to consider the participants' subjective experience in the case studies and to embrace openness, with a subjective ontological position and an interpretive epistemology.

3.2 RESEARCH STRATEGY

The research strategy employed to collect information was organized in three main parts and relied upon the use of:

1) Literature review: Gathering of national and international experiences through literature study following a PRISMA approach (54)
2) Case studies: Five case studies were conducted using clinical simulation for development and evaluation of clinical information system during various phases in the life cycle of CIS, i.e. analysis and specification of user requirements, design, procurement and implementation
3) Assessment of the potential of and challenges in using clinical simulation during the life cycle of a clinical information system from the very early stages until implementation

I chose a qualitative research design as the most suitable design for the exploratory nature of this study. In qualitative research, theoretical orientation enables the researcher to adopt a flexible approach to the observed reality and offers concepts to explain the phenomena. The researcher is able to move beyond basic description to in-depth description, interpretation and explanation (91). I chose multiple qualitative methods in order to create a rich picture. Subsequently data was analyzed for meanings and perspectives. I do not intend my study to verify a hypothesis but aimed to describe, analyze and interpret how and for what clinical simulation may be used during the various phases of the life cycle of CIS. I chose therefore a case-based approach where cases with different characteristics and from different phases in the life cycle of CIS were applied.

3.2.1 CASE STUDIES

Context-dependent experience and knowledge are at the very heart of expert activity and lie at the core of any case study as a research method for learning (92). Case studies are especially appropriate to use in producing concrete, context-independent knowledge. Case studies produce rich insights and are very suitable for exploring "how" and "why" questions (93) which validates an interpretive approach. The advantages of case study research strategies include facilitating the study of a phenomenon in a natural context, and of a large number of issues and different aspects related to the phenomena.

According to Flyvbjerg (92) "*One can often generalize on the basis of a single case, and the case study may be central to scientific development via generalization as supplement or alternative to other methods. But formal generalization is overvalued as a source of scientific development, whereas 'the force of example' is underestimated*". The aim of my research was not to generalize. It was instead to obtain knowledge in order to investigate how clinical simulation may be used and what might be gained from using clinical simulation. Even though, generalizability can be increased by the strategic selection of cases. The greatest possible amount of information about a given problem or phenomenon may not be achieved through a representative case or a random sample (92). Flyvbjerg argues that atypical or extreme cases often reveal more information because they activate more actors and more basic mechanisms.

From an understanding-oriented and acting-oriented perspective, it is often more important to clarify the deeper causes behind a given problem and its consequences than to describe symptoms and frequency. Extreme cases are suitable for emphasizing a point in a particularly dramatic way. Meanwhile, critical cases have strategic importance in relation to general issues, e.g. the requirement analysis, where cardboard boxes represented computers and a person using post-it labels acted as the information system, or in the procurement study which had to meet the demands for uniformity and transparency in a public procurement process. Paradigmatic cases are suitable for developing metaphors or establishing a school for a domain. The studies concerning design and implementation were both typical cases with frequently used purposes. The strategies are not necessarily mutually exclusive. A case might be extreme, critical and paradigmatic at the same time because it provides several perspectives and conclusions on the case depending on whether it is viewed and interpreted as one or the other type of case. Contrary to a random selection of cases, an information-oriented selection maximizes the utility of information from single cases and small samples, where the selection is based on the expectations of their information content.

3.2.2 DESIGNING HUMAN TECHNOLOGIES

My research has focused on the development and evaluation of clinical hospital information systems. Health informatics researchers and professionals, amongst others, have argued that, of all work domains, healthcare is the most challenging, given the variety, range and complexity of situations and settings in which healthcare information systems are deployed (94). Healthcare is generally a complex area, and hospital organizations and work practice are particularly complicated as there are many different healthcare groups and many interactions and correlations (34) involved, and many acute situations are encountered during daily work practice in hospital settings (95). This complexity affects the technology that is developed and implemented at hospitals (5) and confronts the methodology used for developing and evaluating healthcare information systems. Failure to comprehend the nature and range of end-users has been highlighted as a key issue in many systems' failing to become accepted by healthcare professionals (96). Furthermore, an understanding of the context in which the systems will be used must take into account not only tasks and settings (97), but also the range, competences and cognitive capacities of an increasing variety of potential end-users (98). The risk of endangering patient security calls for careful evaluation before implementing new technology in real life settings (99). These evaluations may be conducted in realistic (high fidelity) environments, i.e. close to real life (30). In this section, I will describe the most significant aspects used in designing human technologies.

Usability may be defined as in ISO 9241: "The extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use"(100), although other definitions exist (101; 102). According to ISO 9241, *effectiveness* is defined as "accuracy and completeness with which users achieve specified goals", *efficiency* is defined as "resources expended in relation to the accuracy and completeness with which users achieve goals", *satisfaction* is defined as "freedom from discomfort, and positive attitudes towards the use of the product", and *context* is defined as "'users, tasks, equipment (hardware, software and materials), and the physical and social environment in which a product is used". In this thesis the ISO definition are used as a basis for describing usability.

There remain, however, some unanswered questions as to who the users are. Damoran (103) describes two levels of users, 1) end-users who interact directly with the information system to perform their work, and 2) users who utilize printouts or manage end-users. Conventional usability testing profiles and targets prescribe groups of users (104), whereas the healthcare sector poses challenges due to the larger potential numbers and classes of users, e.g. nurses, physicians and pharmacists (96). Each class of users may contain subclasses, such as emerging physicians, attending physicians and surgeons (105). Demographic differences, such as e.g. gender, age and computer literacy, have to be considered as well (106). In addition, the complexity of environments and tasks carried out by various types of users makes it a difficult to profile and target prescribed groups of users in healthcare (107). Furthermore, the ISO standard does not take several users and their professional interaction into account, and nor does it take parts of or a whole organization into account. Healthcare environments are profoundly collaborative and rely heavily on coordination between different healthcare professionals (19).

Hertzum points out that many views may be put on usability even though the definition is fixed (108). Hertzum divides usability into six images:

- *Universal usability*: usability in a system for everybody to use
- *Situational usability*: usability is equivalent to the quality-in-use of a system in a specified situation with its users, tasks, and wider context of use

- *Perceived usability:* usability concerns the user's subjective experience of a system based on her or his interaction with it
- *Hedonic usability:* usability is about joy of use rather than ease of use, task accomplishment, and freedom of discomfort
- *Organizational usability:* usability implies groups of people collaborating in an organizational setting
- *Cultural usability:* usability takes on different meaning depending on the users different background

Universal usability may relate to log-on, change of passwords etc. but most parts of CIS are not meant to be universal. Situational usability takes the context and collaboration between several users into account, which is highly relevant in healthcare. Perceived usability is more user-centered than usage-centered and strong focus on perceived usability may fail to recognize organizational and other contextual factors. Hedonic usability is mostly relevant in relation to consumer products and games. Organizational usability is highly relevant in complex organizational settings such as healthcare. Three elements are consistently important in health IT: common ground between collaborators (109; 110), awareness of the evolving state of collaborate work between healthcare professionals (111; 112), and coordination of healthcare activities (113; 114). Cultural usability is relevant in relation to e.g. the differences in educational, professional and speciality backgrounds among healthcare professionals (95).

<u>*Human factors*</u>

According to the International Ergonomics Association, human factors or ergonomics can be defined as "[] *the scientific discipline concerned with the understanding of interactions among humans and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance*" (115). The system represents the physical, cognitive and organizational artifacts that people interact with and can be a technology, software or medical device; a person, team or organization; a procedure, policy or guideline; or a physical environment. Ergonomics focuses on the design of systems to fit the requirements, capacities and limitations of users (116). The discipline of human factors can contribute to safe design of healthcare systems by considering the various requirements, capacities and limitations of users (117), and the quality and safety of care is influenced by various characteristics of the system(118). The discipline of human factors and ergonomics covers three main domains: 1) physical ergonomics concerned with physical activities, 2) cognitive ergonomics concerned with cognitive processes, and 3) organizational ergonomics (or macro ergonomics) concerned with socio-technical system design (116). Hendricks describes five "human-system interface technologies" of the human factor and ergonomics disciplines (119-122): 1) human-machine interface technology, i.e. hardware ergonomics, 2) human-environment interface technology, i.e. environmental ergonomics, 3) human-software interface technology, i.e. cognitive ergonomics, 4) human-job interface technology, i.e. work design ergonomics, 5) human-organization interface technology, i.e. macro ergonomics.

<u>*User-centered design*</u> focuses on incorporating the user's perspective into the development process in order to attain a usable IT system(123). The key principles of user-centered design are 1) active involvement of users and clear understanding of user and task requirements, 2) an appropriate allocation of function between user and system, 3) iteration of design solutions, and 4) multi-disciplinary design teams. The ISO standard 9241-210:2010 Ergonomics of human-system interaction Part 210: Human-centred design for interactive systems (52) describes five essential processes which should be undertaken in order to incorporate usability requirements into the software development process. Figure 3 shows the human-centred design cycle according to the

ISO standard. As shown in Figure 3, the process is iterative with the cycle being repeated until the particular usability objectives have been obtained.

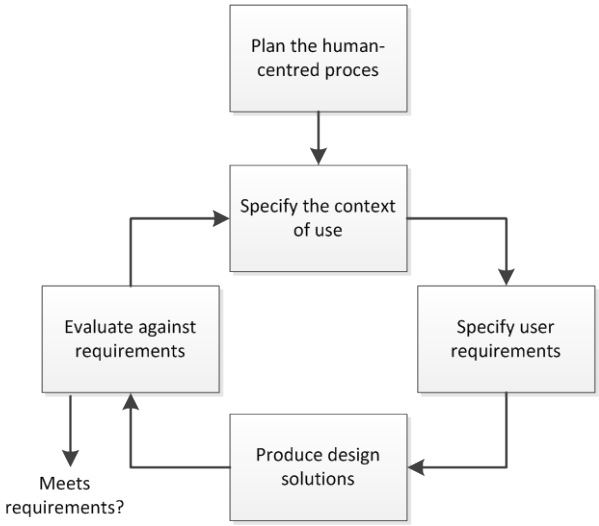


FIGURE 3 THE HUMAN-CENTRED DESIGN CYCLE

Studies show (103; 124) that effective involvement of users may lead to 1) improved quality of the system arising from more accurate user requirements, 2) avoidance of costly system features that user do not want or cannot use, 3) improved levels of acceptance of the system, 4) greater understanding of the system by the user resulting in more effective use, and 5) increased participation in decision-making in the organization. Forms of involvement can vary from informative to consultative ending in participation(103). According to Arnstein's "ladder of citizen participation" (125), users may be involved at different levels, ranging from manipulation and therapy through information and consulting to partnership, delegated power and citizen control. User-centered design is placed in the latter. Many strategies may be taken to obtain a user-centered approach. Participatory design is one of them (103).

Participatory design (PD) focuses on the involvement of stakeholders, overcoming organizational barriers and roles, and thereby establishing ownership of design solution within an organization (126). Three issues dominate the discourse about PD: 1) the philosophy and politics behind the design concept, 2) the tools and techniques supplied by the approach and 3) the ability of the approach to provide a realm for understanding the socio-technical context and business strategic aims where the design solution are to be applied (127). A core principle of PD is to allow stakeholders to participate actively in design activities, giving them the power to influence design solutions by participating on equal terms (128). PD includes a conglomerate of tools and techniques e.g. observational studies, questionnaires, diagrams, pictures, photos, interviews, workshops, role-playing and simulated environments, mock-ups and prototyping (126), as well as full-scale clinical simulation (129).

Human computer interactions, which is mostly relevant for the design and evaluation of information systems (130). Computers and software operate invisibly, often leaving the user with very little information about the state of the system (131). The user interface gives the user an opportunity to interact with the computer and to receive feedback about the status of the system. Poor user interface design greatly increases the likelihood of errors (132), while good interface design makes software easier to learn, improves performance speed, increases user satis-

faction and reduces errors (133). Types of user interfaces in healthcare may be interfaces of devices or graphical user interfaces in CIS (134).

User requirement specification

"*Understanding user requirements is an integral part of information systems design and is critical to the success of interactive system*" (135) p133. The benefits may include increased productivity, enhanced quality of work, reduction in support and training costs, and improved user satisfaction. Analysis of user requirements is not a simple process, due to e.g. complex organizational situations with many stakeholders (135) and users not knowing in advance what they want from future systems (136). As described earlier in relation to the user-centred design cycle, specification of user requirements is essential as indeed is specification of context of use in order to create the full picture of how new technology must fit into the working and living patterns of the users to allow them use the new technology efficiently and effectively (137). Various methods may be used for capturing context of use along with user requirements, e.g. contextual inquiry (138), ethnography (139), and scenarios (140; 141).

Triangulation strategies are beneficial in the specification of user requirement and may increase the reliability of user requirement investigations (142). Identification of user requirements should not be considered a linear process. Maguire (135) describes a general process for user requirements with iterative identification and evaluation activities as seen in Figure 4. To ensure a successful outcome, user needs should not only be elicited by techniques, such as interviews and surveys, but should also be reflected back to users via simulation in order to prototype the user requirements.

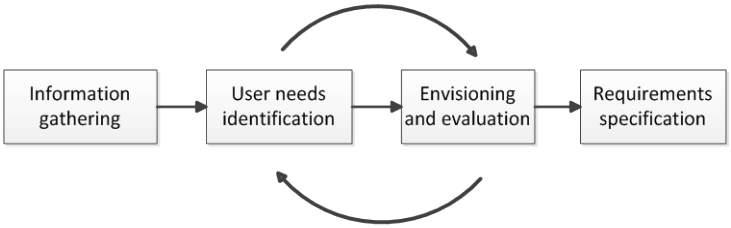
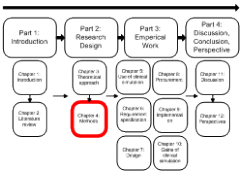


FIGURE 4 GENERAL PROCESS FOR USER REQUIREMENTS ANALYSIS BY MAGUIRE

Bødker et al (33) also emphasize the principles of user involvement and organizational roots. Information gathering may be made by analyzing stakeholders, context of use and tasks. User requirement identifications may be achieved by means of focus groups, interviews, personas, scenarios and use cases, as well as future workshops. Envisioning and evaluation may be done by card sorting, affinity diagrams, storyboards and prototyping. Requirements may be specified by use of task mapping, prioritization and criteria setting.

This section has described my theoretical approach, which is explorative. I attempt to understand rather than to explain. I have therefore embraced an interpretive approach, perceiving myself as a traveler seeing the world as a social construction, and trying to understand it through dialog with the people who live in it. This section has also provided an overview of different approaches to designing human technologies that are relevant to my research. The next section will present the methods and case studies that have been part of my research.



4 METHODS

This section outlines the methodological approach and includes a short introduction to clinical simulation and fidelity. It then presents an overview of characteristics of the five case studies and a description of each case study.

The methodological approach to my research was structured in an action-learning cycle. As shown in Figure 5, actions and reflections in the action-learning cycle are broken down into phases of planning, acting, observing and reflecting (143). In the constructive part of the cycle, planning and actions are made while observation and reflection take place in the reconstructive part of the cycle. Each phase is validated by the previous phase and looks ahead to the next. The cycle may start at any stage and does not stop after one circuit has been completed, but rather begins a new.

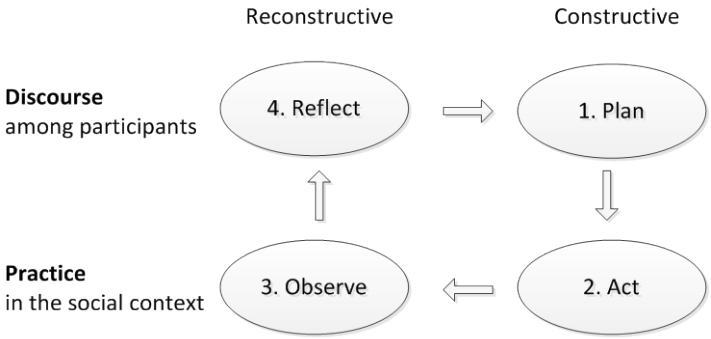


FIGURE 5 ACTION-LEARNING CYCLE

My research has been a mixed research study using both quantitative and qualitative methods with the main emphasis on qualitative methods. My intention is to understand rather than to explain (62). An initial literature review was conducted. The basis for the further experiments and case studies was clinical simulation. The empirical data was collected during the case studies using the methods described below. The different methods are highlighted in italics.

Clinical simulations involve real end-users as they simulate the use of technology in realistic environments performing realistic tasks (48). A simulation or a simulator may be defined as: a process or a device "that attempts to re-create characteristics of the real world" (144). As shown in Figure 6, clinical simulation can be used in different activities at various phases of the development life cycle of CIS from analysis of work practice and user requirements till application assessment in work practice and assessment of training programs.

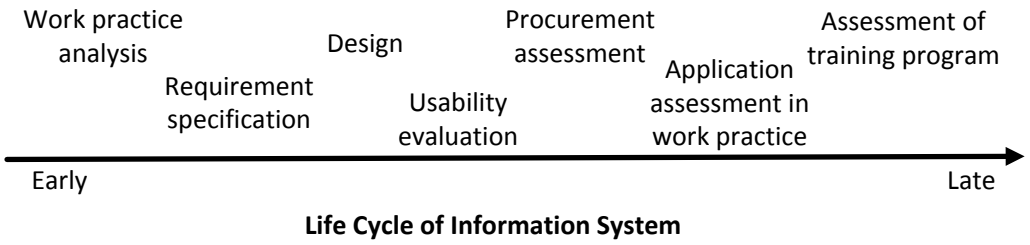


FIGURE 6 ACTIVITIES IN LIFE CYCLE OF AN INFORMATION SYSTEM USING CLINICAL SIMULATION

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*"(144) and is an index of how well the simulated environment resembles the characteristics of the real world. According to Beaubien and Baker (144), acceptance of fidelity in medical training comprises several dimensions. Dahl and colleagues (61) 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. Figure 7 shows the simulation acceptance model by Dahl et al 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.

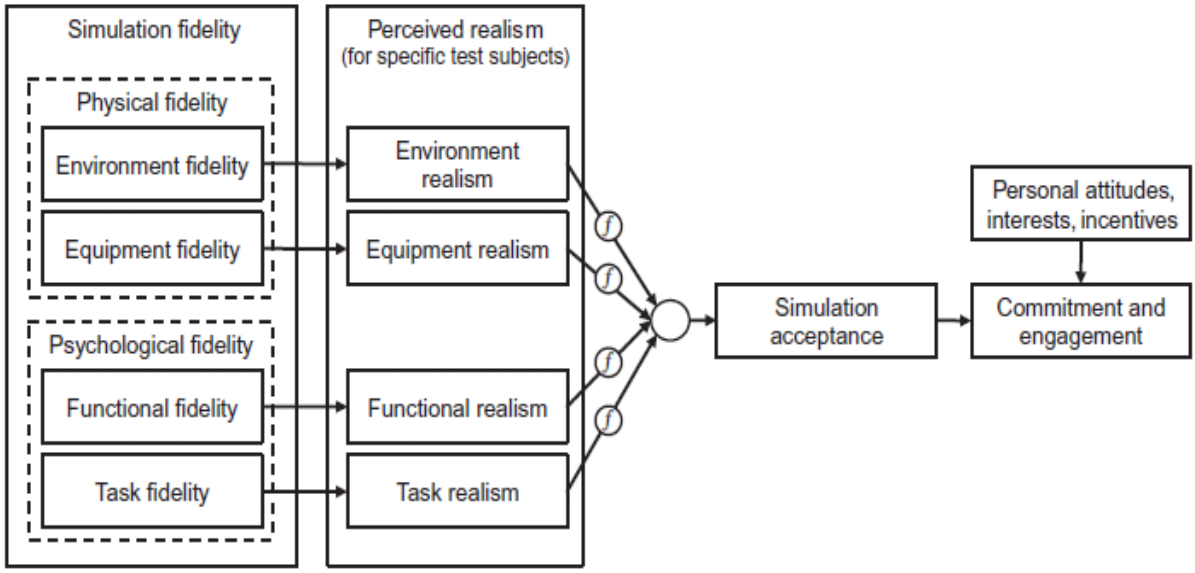


FIGURE 7 SIMULATION ACCEPTANCE MODEL BY DAHL

In my research I have used the following fidelity dimensions based primarily on Dahl et al:

- 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).

Clinical simulations are performed 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 (145). 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 Figure 8. 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.

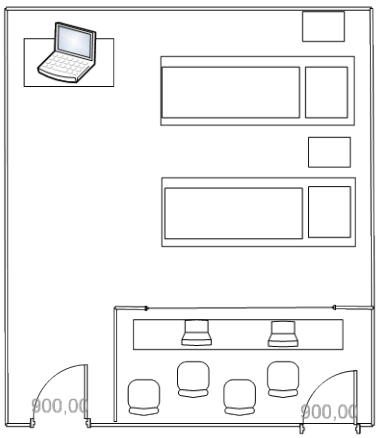


FIGURE 8 OVERVIEW OF THE PHYSICAL SIMULATION SET-UP

If possible, the clinician is asked to "*think aloud*" so that the observers can acquire a deeper understanding of the human task-behavior (146; 147). Sometimes a so-called "*obser-view"* is performed in order to gain a deeper understanding of specific issues (148). 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 (149).

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 (31). The interview and observers' notes are subsequently analyzed, e.g. using *Instant Data Analysis* (IDA) (150). 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.

Prior to and alongside the five case studies, *structured and unstructured field studies* on various departments and hospitals in the region were conducted using *contextual inquiry* (138) and *observations* (151). *Observations* were made during the five case studies. Additional data collection was conducted through *questionnaires* after each simulation regarding use of clinical simulation as a method for development and evaluation of CIS and *semi-structured interviews* of participating clinicians, patient safety experts and health informatics experts in connection to the case studies (63). *Data analysis* was performed using an inductive approach inspired by *Grounded theory* (152).

An overview of the empirical data and the related publications are outlined in Table 2. The empirical data was basically notes from observations, interviews and evaluations reports. The methods were chosen depending on the nature of the problems I wished to solve.

TABLE 2 OVERVIEW OF EMPIRICAL DATA

Topic	**Design**	**Empirical data**
Literature study	Search by use of MeSH Terms	Articles
Field studies	Unstructured observations	Notes
Case study Requirement analysis	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Requirement evaluation	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Design	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Procurement	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews
Case study Implementation	Simulation plan and script Interview guide Observations	Notes Evaluation report Interviews

4.1 DESCRIPTION OF CASE STUDIES

Five case studies were conducted. The case studies are described in this section.

As seen in Table 3, the five cases are named according to the related activities and phases in the development life cycle. The relevant activities from Figure 6 (page 28) will be highlighted prior to the description of each of the case studies.

TABLE 3 OVERVIEW OF CASE STUDIES

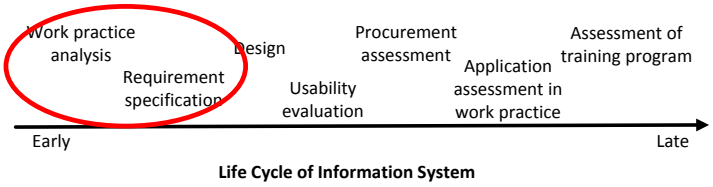
Name	**Phase in development cycle**	**Activity**
Requirement analysis	Requirement	Analysis of user requirements
Requirement evaluation	Requirement	Formative evaluation of user requirements
Design	Design	Formative evaluation of templates for nursing documentation
Procurement	Procurement	Assessment in procurement process
Implementation	Implementation	Application assessment in work practice

The five case studies encompassed different characteristics depending on how the simulation set-up was designed, i.e. fidelity applied, and when the simulation was conducted, i.e. phases in life cycle of CIS. The characteristics of the five case studies are illustrated in Table 4. The degree of fidelity applied is categorized at five levels; very low, low, medium, high and very high.

TABLE 4 CHARACTERISTICS OF THE FIVE CASE STUDIES.

Characteristics	**Requirement analysis**	**Requirement evaluation**	**Design**	**Procurement**	**Implementation**
Simulation design					
Number of clinicians	15	18	12	18	6
Number of scenarios	8	10	4	12	11
Number of simulations	18	18	12	90	11
Duration	3 days	3 days	3 days	10 days	1 day
Degree of fidelity applied					
Environment fidelity	Medium	High	Very high	High	Very high
Task fidelity	High	Very high	Very high	Very high	Very high
Equipment fidelity	Very low	Medium	Very high	Very high	Very high
Functional fidelity	Very low	Low	Very high	High	Very high

4.1.1 ANALYSIS OF REQUIREMENTS



The "*requirement analysis*" study encompassed analysis of user requirements in a large procurement of an EHR platform in Region Zealand and the Capital Region of Denmark. The new EHR platform is intended to 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 inhabitants. The study did not include an information system but was performed using a combination of low-fidelity prototypes (135; 153) and a Wizard of Oz (WoO) approach (154; 155). WoO offers interactive experience without having a real computer system and may produce adequate and sufficient input to support and extend requirement specifications (156). The method can be used to clarify user requirements without restricting users' innovativeness by asking them to work on an information system 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.

The purpose of the simulation study was to analyze user requirements concerning an EHR platform and at the same time to validate the user requirements previously specified in the project. The user requirement specifications were based on previous user requirements analysis for large EHR platforms, literature studies and workshops with healthcare professionals, quality managers, risk manager and clinical managers. The user requirements were described in use cases covering different parts of clinical and administrative work processes, and the aim of the clinical simulation study was to involve end-users and their work processes in more realistic settings in order to validate their user requirements and use cases – and, if possible, to identify new requirements.

15 physicians and nurses participated. The scenarios were not described in detail before the simulation. Patient data was not described in advance and no test data had been prepared. The scenarios were described in generic terms with no detailed information about patients and no specific context. The scenarios used in the simulation were created by clinicians nominated by hospital managers. The study scored 18 scenarios according to frequency of use and clinical relevance and the 8 scenarios with the highest scores were selected then for the validation of user requirements and use cases. The validation simulation was conducted over three days and consisted of 18 simulation runs with physicians and nurses. The participating end-users did not cover all groups of healthcare professionals. The users were selected to meet the specified scenarios covering a range of seniority and specialties.

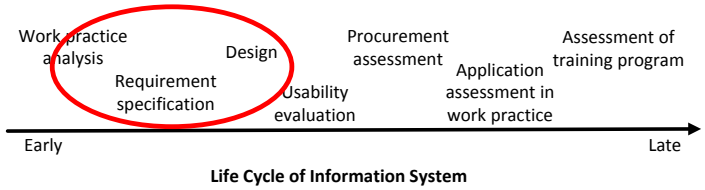
The key scenarios for the nurses were 1) dispensation and administration of drugs, 2) initial nursing assessment, 3) documentation of care, planning and status, and 4) nursing handover and distribution of tasks and responsibility. The key scenarios for the physicians were 1) ward round, 2) medical assistance, 3) admission and 4) discharge of patients. The clinicians were introduced to the aim and procedure for the simulation and asked to think of a specific patient case from one of the scenarios and then to present the scenario and the patient. The case had to be a patient they had recently treated or nursed to ensure that the details were fresh in their minds.

During the simulation, the clinician was facilitated by one of the team members who conducted an obser-view(148) at the same time. Another team member acting as WoO simulating the feedback from the information system in the shape of post-it labels (see Figure 9, left). These labels were placed on the cardboard box. A third team member acted as the patient. Figure 9 (right) shows the simulation set-up from a scenario where two nurses hand over tasks and responsibilities. The facilitator is on the left in the picture.

Figure 9 Left: cardboard boxes with post-it labels. Right: the simulation set-up (160)

From an adjoining observation room, the clinical instructor communicated with the facilitator, the team member acting as WoO and the patient during the simulations, and facilitated the clinical details of the scenario. Two observers in the observation room recorded the clinicians' need for information and documentation as well as the work processes. The clinicians not active in the simulation observed from the observation room, reflecting on their own needs and requirements in similar clinical situations. In the debriefing interview, all the clinicians were asked about further needs and requirements, and the observations made during the simulation were discussed. The clinicians were asked how well they thought the simulation reflected real work situations. At the end of the day, the notes from the simulations and de-briefing interviews were analyzed using Instant Data Analysis (150). The results were then compared with the use cases and user requirements previously identified in the EHR platform project.

4.1.2 REQUIREMENT EVALUATION



The requirement evaluation case study aimed to demonstrate the potential benefits of a Planning and Coordination Module (PCM). The PCM-project had analyzed and specified the requirements for such a system and had built and tested a PCM prototype. End-users, clinical managers, quality managers, data architects and health informaticians performed the analysis and the specification. The purpose of PCM was to support coordination across sectors regarding the status and planning for patients with Chronicle Obstructive Pulmonary Decease (COPD) and type 2 diabetes (DM2), according to the clinical practice guidelines (CPG), and handling derived activities and services. The objective of the simulation study was to assess the potential benefits of

compliance of guidelines, quality of care, work practice, communication of a PCM for healthcare professionals involved in planning and coordination of treatment programs for patients with COPD and DM2. The study primarily focused on the efficiency of the PCM, and secondarily on satisfaction. Efficacy and effectiveness were not assessed.

The evaluation was conducted as a full-scale simulation study. The evaluation encompassed a series of 18 simulation "runs"s involving six general practitioners (GPs), six community nurses, six hospital physicians and two "patients". The simulation "runs" were bundled into six simulations. Healthcare professionals from each of the three end-user groups participated in each simulation. Ten scenarios were composed; five with a COPD patient with COPD and five with a DM2 patient. The scenarios covered 1) planning of therapy and further diagnosis for a patient recently diagnosed by the GP, 2) visitation by the community nurse, 3) rehabilitation by the community nurse, 4) treatment of a patient at an outpatient clinic due to exacerbation of the chronic condition, and 5) assignment of responsibility from the hospital physicians to the GP. The scenarios reflected different points of impact focusing on core functionalities and assignments from one healthcare professional to another. Interface issues, such as colors, buttons and minor functionalities, were not part of the evaluation as the prototype only resembled a PCM. There were no real integrations to other systems. The scenarios were designed to assess nine hypotheses related to the potential benefits of a PCM.

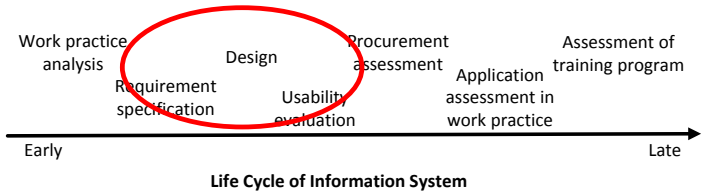
Before the simulation, the clinicians were introduced to the concept and the functionalities of the PCM. They were able to work hands-on with the information system for 30 minutes to get acquainted with it. During the simulation, the same general tasks were performed as the clinicians had trained prior to the simulations. In cooperation with the "patient" and on the basis of the patient's laboratory results and plans, the healthcare professionals were asked to revise and modify plans for the patient. The prototype had simulated integrations to other information systems in order to replicate intended integrations to legacy information systems. A simulation facilitator was seated next to the simulating healthcare professional during the simulation to assist in the event of issues related to the use of the system.

Figure 10 shows the simulation set-up. In addition to asking the clinician to think aloud, the simulation facilitator asked more exhaustive questions. By asking questions about the system, the "patient" encouraged the healthcare professional to describe the system and the functionalities in a close to real setting. Health informatics experts experienced in clinical simulations enacted the patient role. In the observation room, an instructor and several observers followed the simulation through a one-way mirror. The instructor was in radio contact with both the "patient" and the simulation facilitator during the simulation. The instructor was therefore able to direct the simulation to ensure that the objectives were covered. Observations experienced during the simulation were used in the subsequent debriefing interview. During each simulation, healthcare professionals from all three sectors were present, but only one was active in the simulation. The others observed from the observation room.

FIGURE 10 SIMULATION SET-UP

Data for the evaluation was acquired by questionnaire and debriefing interviews with healthcare professionals and observers. The questionnaire had nine questions concerning the hypothesis, two about quality, four about overview, two about the division of responsibilities, four about work practice and efficiency, and three questions about the simulation and realism of the scenarios. The interview guide started with open-ended questions concerning positive and negative features of the system, followed by specific questions to clarify and elaborate on issues from the questionnaires and other issues that came to mind. At the end of each day, the data from the interviews was analyzed using Instant Data Analysis (IDA). As supplement to IDA, the observations from the simulations, interview notes and IDA notes were analyzed using Nvivo (157).

4.1.3 DESIGN



The design case study concerned the design of electronic documentation templates and overview reports for nurses' initial patient assessment using clinical simulation. The objective of the simulation 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 a PD approach and clinical simulation, in which the various stakeholders in the design process were to be consistently involved. The overriding aim of the redesign 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, we sought to ensure that "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 Figure 11. 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.

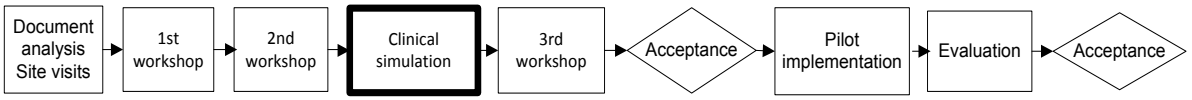
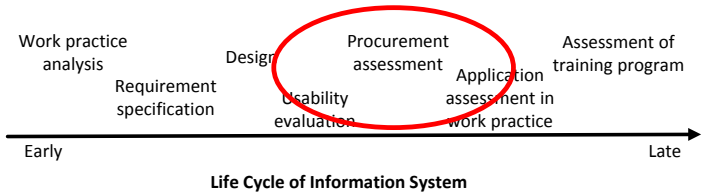


FIGURE 11 THE RE-DESIGN PROCESS INCLUDING CLINICAL SIMULATION (161)

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. Delegates from other communities of practice 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. The observers had also attended the workshops, and each delegate contributed in line with his or her background and place in the organization. Each had a well-defined role and responsibilities (81). The purpose of the clinical simulation and subsequent discussion was not to achieve unanimous consensus but to provide input for others to make the final decision. 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. Further details are presented in publications B: *Achieving IT-supported standardized nursing documentation through participatory design* and I: *Boundary objects in clinical simulation and design of eHealth*.

4.1.4 PROCUREMENT



This procurement case study was also part of the large procurement of the EHR platform (158) and thoroughly described in "H: *Evaluation of a Clinical Simulation-based Assessment Method for EHR platforms*" and section 4.1.4. In contrast to the case study regarding user requirement analysis, this study related to the actual procurement, where, following negotiations, three vendors were selected for the final selection process. The purpose of the case study was to assess user satisfaction, usefulness and patient safety in three different solutions. The new EHR platform contains broad functionality to support clinical and administrative core processes. The platform is to be used by approximately 40,000 healthcare professionals. The two purchaser regions stipulated a strategic requirement for user involvement in the procurement process. The purchasing regions requested that the assessment of the systems on offer should cover usability and human factor issues as well as system impact on a variety of working contexts. The procurement was the largest of its kind in Denmark and the new EHR platform is to be implemented at approximately 14 hospitals serving half of the Danish population.

The applied assessment methods had to cover the demands of various end-users, specialties, and cultures, and also meet the transparency demands of procurement in a public tender in accordance with EU regulations. The procurement focused on increased effectivity in quality of care. This was expressed by demands for qualitative and quantitative improvements in three areas: 1) continuity of care and patient safety, 2) streamlining of clinical processes and workflow, and 3) patient and employee satisfaction. Furthermore, cross-functional work processes and overlap of responsibility were topics of great concern. Three vendors were chosen for more thorough assessment, including a detailed assessment of the EHR platforms they offered.

A major challenge when applying clinical simulation as an assessment method in a procurement process is to convert the qualitative aspects of the process into quantitative output. The qualitative human factor aspects in the assessment were to be revealed. To do this, a new method was developed for assessment in the procurement process. The assessment method was developed on the basis of literature studies, ISO standards concerning usability requirements and seven years of experience of using clinical simulations for development and design of CIS (30; 145; 149; 159). The method was designed to uncover qualitative human factor aspects in the assessment and to include typical use scenarios and real end-users. Finally, the method had to take into account the perspectives of various stakeholders, including risk managers, quality managers and clinical managers. The basis of our assessment metrics was based on ISO standard 9241, Part 11 concerning usability in ergonomic requirements (100).

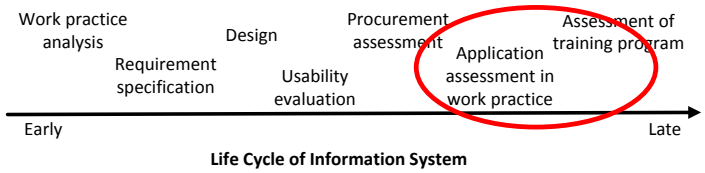
The assessment covered 12 clinical scenarios and 18 health professionals from various specialties and professions. Three EHR platforms were assessed during a period of 10 working days. The clinicians had a full day of training in each of the three platforms followed by two days of clinical simulation. Having completed one simulation scenario, the clinicians assessed how the tested platform supported the task. The assessment was scheduled for three consecutive periods of three-day, during which the clinicians would scrutinize all three EHR platforms. The clinicians

who were not part of a specific simulation followed the simulation from the observation room (see Figure 12).

FIGURE 12 SIMULATION SEEN FROM OBSERVATION ROOM

The evaluation of the assessment method was to respond to the following questions: 1) how eligible is the method?, 2) what are the advantages/disadvantages compared with other assessment methods?, and 3) does the evaluation of the method reveal issues that must be improved? The evaluation of the method was qualitative and included observations and semi-structured interviews of key actors and participating clinicians. Observations were conducted during all 10 assessment days. On the final day, all the clinicians were interviewed. Subsequently 15 interviews were conducted with project and legal managers, health informaticians, vendors, patient safety experts, and observers during the clinical simulations. The qualitative approach allowed us to conduct the evaluation without interfering with the assessment process, and concurrently obtain thorough insight into user experiences and the perceived benefits and challenges of the method. All interviews were transcribed and analyzed using a qualitative approach of content data analysis.

4.1.5 IMPLEMENTATION



The implementation case study primarily encompassed work practice and the usefulness of a facility for doctors to sign for laboratory results with the objective of assessing the work practice, usefulness, user satisfaction and patient safety of the new application. For a long time, the Capital Region of Denmark has sought to obtain an IT- supported work flow for physicians receiving and signing laboratory test results in order to improve patient safety. In the existing workflow this was done on paper; i.e. prints were made from digital systems in order to document that test results had been reviewed by a doctor. The laboratory tests were handled by various information systems. Some test results were on paper and others were electronic. The

background for the local work flows was based on interpretations of a national guideline for handling laboratory test results. The national guideline was developed as part of a quality assurance initiative to increase patient safety. As a rule, the physicians sign to confirm that they have seen a laboratory test result. The physician also signs to confirm that he or she has handled the test results in the patient's record. The essential challenges about the paper based workflow were 1) lack of overview about whether a result has arrived, 2) uncertainty about whether a test result has been seen by a physician, 3) lack of documentation about which physician has seen a test result. The objective of purchasing the IT-system was to increase quality in work practice and minimize the risk to patient safety by implementing a new standard information system, "OPUS inbox", which collects laboratory test results and supports electronically documentation of acknowledging the results.

The study was expected to be moderate and manageable because the information system was a standard off-the-shelf product and the intended work flow was supposed to be narrow and well-defined. The information system was to be implemented at two pilot departments. Both departments included patient wards and outpatient clinics. Prior to implementation, the existing work practice was analyzed and future generic work flows defined. The functionality of the information system and collaborative future work practice were evaluated by means of clinical simulation.

The aim of the implementation case study was to assess the potentials of clinical simulation as a proactive method by which to identify and evaluate potential patient safety hazards prior to implementation. The aim of the simulation evaluation was to examine how the "OPUS inbox" system supported clinical practice and to identify potential patient safety hazards prior to its implementation.

Initial field studies were carried out at the two pilot departments covering both patient wards and outpatient clinics in order to gain insight into existing work practice concerning receipt, handover and acknowledgement of laboratory test results. Two workshops were then held with physicians, nurses and medical secretaries from the pilot departments, health informaticians and experts from the regional quality unit. At the first workshop, future work practice and the information system were analyzed and required changes were identified. At the second workshop, future work practice was determined, focusing on improved efficiency, quality, continuity and communication. Existing routines were contested and organizational changes were initiated ahead of implementation in order to create acceptance and a readiness to change among future end-users.

In order to evaluate patient safety, usefulness and usability clinical simulation was conducted after the workshops. The purpose of the clinical simulation was to evaluate patient safety issues and future work practice using the new information system before its implementation. Six healthcare professionals from the two pilot departments (two physicians, three nurses and one medical secretary) were selected to participate in the simulations. The observers were clinical managers from the pilot sites, implementation experts and health informatics experts. Figure 13 shows the simulation room seen from the observation room through a one way mirror. To the left are the observers in the observation room. To the right is an outpatient clinic set-up where a physician is preparing for a meeting with a patient.

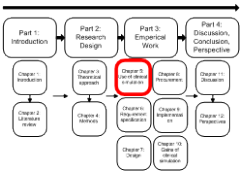
FIGURE 13 LEFT: OBSERVATION ROOM WITH OBSERVERS. RIGHT: SIMULATION ROOM SEEN FROM OBSERVATION ROOM (162)

A total of 11 scenarios were performed during the evaluation; six scenarios from patient wards and five scenarios from outpatient clinics. All scenarios were related to signing and handling laboratory test results. Some of these were frequently performed work flows; e.g. ward rounds and visits to the outpatient clinic, while others were critical work flows; e.g. urgent test results and sorting test results and handover of responsibility. The simulation set-up was very realistic. The computers used were identical with those used at the hospitals and the system was fully developed and operational. The scenarios were composed in participation with clinicians from the pilot sites and based on realistic patient cases. The simulation room was designed as either a ward bedroom or clinical office. The role of patient was enacted by a healthcare professional.

Clinical simulation as a method was evaluated by means of interviews with the project manager, a manager from one of the pilot hospitals and an expert from the patient safety unit. The pilot implementation was evaluated at a workshop with clinicians, clinical managers, and representation from the patient safety unit and the quality unit, and used to decide whether the information system should be implemented at the remaining hospitals.

After a 4-week pilot implementation at the first pilot site, the implementation was evaluated. In the end the system was stopped and the project was terminated.

This chapter has presented my methodological approach and given an overview of the characteristics of the five case studies as well as a description of each. The findings of the five case studies will be presented in the following sections, starting with key issues and concerns in the engineering of clinical simulation, which will be presented in the following section.



5 RESEARCH FINDINGS – USE OF CLINICAL SIMULATION

In this section, I discuss the research question "*How can clinical simulation be used in the development and evaluation of clinical information systems?".* The aim of this section is to describe a methodological approach for planning, preparing and conducting clinical simulation highlighting the most important key issues and concerns in the shape of 10 steps towards a successful simulation. These 10 steps are highlighted throughout the section. Reference is made to the publication "J: *Clinical Simulation –A Method for Development of Clinical Information Systems*". The publication is inspired by more than 25 clinical simulations performed in the ITX-lab since 2007, and is based on the five case studies included in my research. The case study "Requirement evaluation" (described in section 4.1.2, page 33) is used as a recurrent example in the publication.

Clinical simulation may be part of various activities in the human-centred design cycle; *plan the human-centred process*, *specify the context of use*, *specify user requirements* and *evaluate against requirement*. These activities are highlighted above.

Purpose:

The first step is to define the purpose of the clinical simulation. The purpose of clinical simulation may vary throughout the different stages of the development life cycle (53). In the early stages, the purposes may be to analyze work practices and user requirements (149; 160). In the design phase the purpose is often to create a shared understanding of new technology and work practice as well as to evaluate the design and user interface (145; 161). Before an information system is implemented, the purpose may be to learn more about various aspects of implementation, such as the need for training and the influence of the new technology on existing or new work practices, including patient safety (31; 162). As indicated in Figure 14, engineering of clinical simulation includes iteration and agile phases. The purpose influences the planning and preparation of the study and establishes the scope of its actual performance. It is therefore important that the purpose is focused, defined in close cooperation with key stakeholders, and accepted by the owners of the project (31).

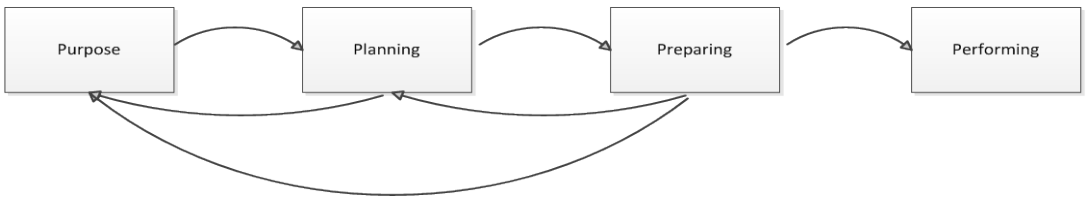


FIGURE 14 ITERATIVE PHASES IN ENGINEERING CLINICAL SIMULATION

During the planning and preparation phases, new knowledge may be acquired, which may lead to redefinition of the purpose.

Step 1:
The purpose of the clinical simulation must be focused and rooted in the organization

Planning

The planning phase starts by defining the scope, which includes scenarios, number of simulation "runs" and the number and profiles of participating clinicians. Each scenario reflects typical tasks in a small fraction of clinical work practice. Together the scenarios should more or less cover the parts of work practice affected by the new technology; reflecting the purpose (149).

> **Step 2:**
> Choice of scenarios is crucial and must reflect the purpose of the clinical simulation

The profiles of the participating clinicians and observers must reflect both the purpose and the scenarios. If the technology covers broad functionality used in many different specialties and by many different groups of healthcare professionals, the number of scenarios and simulations must be higher than if the technology was used by e.g. physicians in a very specialized field for a very specific purpose. Choice of profiles may also have to reflect experience in healthcare as well as in the use of technology; again depending on the purpose of the simulation (31).

> **Step 3:**
> Choice and profile of clinicians must reflect the purpose of the clinical simulation

Preparing:

Having dealt with the overall frame, the simulations have to be prepared. Preparation includes writing scenarios and designing the clinical and technical set-up. Complex scenarios and patient cases are resource demanding tasks and the need for complexity must therefore be carefully considered, and must reflect the purpose and frame of the simulation (31).

> **Step 4:**
> Complexity in scenarios and patient records must be carefully considered

Planning and preparing clinical simulation may be time-consuming, but careful preparation of the clinical and technical set-up entails effective time spend by the clinicians (162).

> **Step 5:**
> Planning and preparing clinical simulation is resource demanding in order to make it effective for clinicians

As mentioned earlier, the simulation process attempts to re-create characteristics of the real world (144). The need for fidelity in the recreation of the real world depends on the purpose of the simulation. Dahl et al presents four characteristics of fidelity in clinical simulation (61). These characteristics are described in section 6 *Research findings* - requirement specification. The need for fidelity varies depending on the purpose of the simulation and the stage reached in the life cycle of the information system. The fidelity dimensions include equipment fidelity, environment fidelity, task fidelity and functional fidelity (61). Equipment and functional fidelity correspond to the maturity of the technology, while environmental and task fidelity correspond to the clinical context. If the purpose is to assess technology, equipment fidelity and functionality fidelity needs to be high. Where simulations focus on work practice, the need for equipment fidelity and functionality fidelity will be lower (160). If the purpose is to assess patient safety issues ahead of implementation at a hospital, all fidelity characteristics need to be high (162). In

clinical simulation, characteristics concerning clinical context should not be low. A high degree of task fidelity is pivotal to clinical simulation and environmental characteristic such as the patients, colleagues and physical environments are important in order to stimulate the cognitive acceptance of the simulation (31).

Step 6:
The degree of fidelity must reflect the purpose of the clinical simulation and the maturity of the technology

Rehearsals are well worth the effort. Pilot testing the simulation before bringing in the participants for real simulation runs is valuable because unrealistic scenarios, interruptions and delays influence how participants accept the simulation (31). Rehearsals may be conducted on scenarios, the clinical set-up, technical set-up and data collection.

Step 7:
Rehearsals and pilot studies are important and well worth the effort

Performing:

In order to create a high degree of clinical fidelity, the participating clinicians must be familiar with real work practice. Quality nurses, clinical managers etc. are appropriate to use as observers but cannot replace end-users in the simulation (30; 161). During the simulation it is beneficial to observe the simulation through a one-way mirror or by using video recordings. Thereby it is possible to let specialists and key stakeholders focus on other issues, such as the need for user interface training, organizational and technical challenges and patient safety issues (149).

Step 8:
Real clinicians (end-users) should be used as participants

Data collection and analysis:

Data collection may be performed by means of questionnaires and interviews (31). The validity of using questionnaires depends on the number of participants, but they may serve the purpose of encouraging the participants to reflect on specific issues (31). The composition of questions in questionnaires and interviews should reflect the purpose of the simulation. Observations and reflections made during the simulation may be used as input during the interview. The simulation may also be video recorded. These recordings may also be used during the debriefing interview or analyzed afterwards. In the case studies, data from interviews and observations were analyzed using a cost-saving analysis method *Instant data analysis* (IDA)(150).

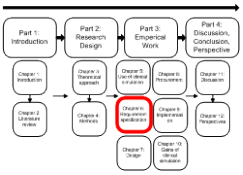
Step 9:
Cost-saving analysis methods, such as IDA, are very useful and can be applied to analyze the resultant data

Finally a report is composed on the basis of the findings of the simulation study. The report includes results and recommendations. It must be clarified in advance to whom the results are to be presented and how the results and recommendations should be implemented. Furthermore, the participants' and observers' respective mandates must be clear (161).

Step 10:
The clinicians' and observers' respective mandates must be clear. It must also be clear how the results will be used, reported and implemented

As scenarios often only cover fractions of the clinical work practice, clinical simulation cannot substitute pilot implementations. In a pilot implementation, an information system is implemented in a small and controlled environment for a shorter or longer period. Time-based elements are not well-matched with clinical simulation. Getting acquainted to new technology may take time and clinical simulation does not reflect the social-technical impact over time.

This section presented a methodological approach to engineering and conducting clinical simulation. 10 steps to a successful simulation have been highlighted. The next section will discuss how clinical simulation can be used in activities related to user requirement specification.



6 RESEARCH FINDINGS - REQUIREMENT SPECIFICATION

In this section I discuss the research question "*What are the potentials of using clinical simulation in specification of user requirements for clinical information systems*?". The discussion is based on two case studies. The first study investigated the analysis of user requirements (see section 4.1.1 Analysis of requirements) and the second case study (see section 4.1.2 Requirement evaluation) investigated formative evaluation of previously specified user requirements. Human-centred activities in the first case study are highlighted in red above, and activities in the second case study are highlighted in blue. The simulation set-up in the two case studies differed widely where equipment and functional fidelity were concerned. The two different approaches are discussed in the following. The publications related to the research question are: 1) D: *Fidelity in clinical simulation – how low can you go*? (160), and 2) C: *Benefits of a Clinical Planning and Coordination Module* (149).

Preparing clinical simulation can be quite resource exhaustive and the degree of fidelity should therefore correspond closely to the purpose of simulation (31). High fidelity prototypes may not be accessible for analyzing user requirements in the very early stages of the life cycle (135). In the first case study (see section 4.1.1), the goals were to validate previously identified user requirements and use cases and, if possible, identify new requirements and use of work (160), and, thirdly, to explore the lower limit of degree of fidelity required to perform an effective clinical simulation study.

There was no fully functioning information system in the study. We used a simple mock-up in the form of cardboard boxes with post-it labels for input and output from the 'system' (153). We used a WoO approach to simulate the functionality of the information system. WoO offers interactive experience without having a real computer system and may produce adequate and sufficient input to support and expand requirement specifications (154; 155). The scenarios were not described in detail before the simulation. No patient data were known in advance and no test data had been prepared. The scenarios were described in generic terms without detailed information about the patient or the specific context. Just before the simulation began, the clinicians were asked to think of a specific patient case and describe the scenario and patient. The actor playing the role of the patient acted according to the clinician's description of the patient.

The simulation provided an opportunity to focus on context-sensitive needs. It examined clinical work practice and user requirements for information and documentation across various use cases and work processes, in a range of frequently used scenarios(160). Due to the rather high fidelity tasks and environment, the simulation stimulated the clinician's experience of working practice despite low functional and equipment fidelity. The realism of daily work practice and the interactive experience with the prototype supported the creativity of the clinicians. The clinicians found the interaction with the patient vital in order to make the scenario come alive. However, the patient was required to act in accordance with the scenario described by the clinician ahead of the simulation. In a few scenarios, the instructor attempted to change the behavior of the patient by issuing new directions through the intercom, which confused the simulating clinician.

As result of the simulation, previously specified user requirements were validated and new user requirements were identified. Some requirements were not clarified sufficiently during the simulation study but were clarified later in discussions with the vendors during the dialog phase. The realism of the simulation and the simulation with other healthcare professionals and patients supported the identification of new cross-disciplinary requirements.

The simulation study also resulted in useful knowledge concerning daily work practice. This information was not new but had not arisen in the previous workshops. Clinicians have vast amounts of implicit knowledge of the activities and processes which may go unmentioned in typical experimental settings. However, if health information systems are to be designed on an informed basis, it is imperative that this knowledge is made explicit. Different methods should be used to elicit this implicit knowledge. Lucy Suchman describes how work processes may be invisible to others and how working processes are perceived differently by different people. The better a work practice is performed, the less visible it is, which makes it difficult to describe (32).

TABLE 5 DEGREE OF FIDELITY USED IN REQUIREMENT ANALYSIS SIMULATION (160)

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

Table 5 shows the fidelity dimensions and the degree of fidelity in each dimension in the requirement analysis study. 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 as they were taken from real life, but the actual simulation of the scenario was not as realistic. During the simulation, the clinicians were asked about the need 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, the clinicians became confused and fidelity plummeted. This issue was a severe limitation in the simulations. We were stuck with the scenario. On the other hand, it was realistic. The debriefing interview compensated for this limitation. During the debriefing, it was possible to ask more specific questions about other types of scenarios and situations.

The realistic scenarios and the dialog with the patient were important elements in maintaining task fidelity. Senior clinicians often generate higher task fidelity. However, if we allow clinicians to describe a real life scenario, less experienced clinicians are able to maintain high task fidelity. This limits the number of clinicians that can take part in the same simulation as, if they are to do simulations together, they must have experienced the same situation. Part of the task fidelity was low because the test data was not specified in advance. 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 information system.

The degree of functional fidelity in the prototype was low as we were using post-it labels as input and out from the IT-system. Low fidelity prototypes present no richness of interactivity and are of no use in evaluating interactive features. The use of cardboard boxes represented low functional fidelity but helped to simulate interaction with the computer. In the same way, the post-it notes helped to preserve a certain degree of functional fidelity. These types of clinical simulation may be regarded as more suitable for analyzing less detailed user requirements. When examining very large health information systems, low functional fidelity is more suitable for analyzing user requirements broadly than at a very detailed level. The equipment fidelity concerning devices in the system was low. However, this helped the clinicians as they were not hindered by familiarity with the devices they usually use or by devices chosen for the project.

The observing clinicians are can dissociate themselves from the simulation and reflect on how things would be in other situations. These reflections may be discussed in the debriefing along with other observations and questions that may arise during the simulation. The results of the clinical simulation were validation of previously known user requirements, and a means by which to connect these requirements with realistic work practice and thereby identify context sensitivity requirements.

In the second case study (see section 4.1.2) concerning requirement specifications, the purpose was to evaluate already identified requirements (149). The purpose of the study was to assess benefits and challenges of a planning and coordination module. To realize the intended benefits of a PCM, the usability of the system is pivotal (163), and should be reflected back to users (135). Compared to the requirement analysis simulation study, this study was conducted with a higher degree of fidelity. The CIS was a relatively mature prototype of a planning and coordination module built on the basis on an operational information system with a user interface designed to realize the user requirement already specified. The main focus of the evaluation focused more on the concept of the module and potential inherent in such a module and less on the user interface, because the user interface was designed only as an example of how such a system could look. The focus was more on functionalities and usefulness than on ease of use. Integrations with other systems were faked. The system was basically designed to establish and maintain a cross-organizational overview and virtualized management of all health services in individual patient cases among all relevant healthcare actors. The system was meant to be used across sectors by general practitioners, community nurses and hospital doctors.

Most of the clinicians found it difficult to understand the concept of the information system in spite of having been introduced to it prior to the simulation. The concept was innovative and forced the clinicians to view planning and coordination in a new way. The simulation itself and the observation of other clinicians using the information system helped the clinicians to understand the concept. Overall the system was assessed as very useful. The results of the evaluation showed that the PCM would increase clinical value, e.g. by presenting the recommended activities in the continuity program and displaying an overview of the plans and activities during the course of a disease. The participating clinicians concluded that quality of care would improve. The clinicians found that the PCM would be beneficial for the patients, although no real patients were included in the evaluation. Had real patients participated, the outcome of the simulations would have been better..

New future users were identified and new potential ways of using the system were revealed. The system was found to be a powerful learning tool for the new users in spe. Several new issues of concerns were brought up concerning sharing responsibilities and terminology.

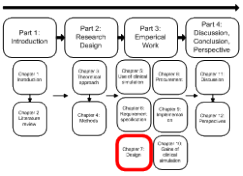
As in the case study concerning analysis of requirements, the degree of task and environmental fidelity was high. In the requirement specification study, the degree of functional and equipment fidelity was also high. The PCM was a fully functional prototype. The user interface was not complete but the users were nonetheless able to use all the functionalities. All integrations were faked and the users experienced using the PCM as if it was integrated to adjoining IT-systems. Table 6 shows the degree of fidelity used in the requirement evaluation study.

TABLE 6 DEGREES OF FIDELITY USED IN REQUIREMENT EVALUATION STUDY

	Low fidelity	**High fidelity**
Environmental fidelity		Realistic environments supported the perceived realism
Task fidelity		Realistic patient cases allowed participants to align scenarios with personal work practice and own patient cases Realistic test data implemented in prototype
Equipment fidelity		Fully functional prototype
Functional fidelity	Simulated integrations	Fully functional prototype

As stated by Maguire (135), users should participate in user need identification, and envisioning and evaluation. These activities and specification of the context of use are also part of the human-centred design model (52). The requirement analysis study was an analysis of work context and user requirements whereas the requirement evaluation study was a formative evaluation of previously specified user requirements. The two case studies revealed that clinical simulation made it possible to involve clinicians and the clinical context actively without endangering patient safety. Both studies might have been improved by also involving patients. Clinical simulation cannot stand alone but should be regarded as one part of a triangulation strategy (142) for specifying user context and user requirements.

In this section the use of clinical simulation in activities pertaining to requirement specification has been discussed. Findings from a case study concerning analysis of user requirements have been presented here as well as findings from a case study concerning formative evaluation of user requirements. Differences in the degree of fidelity in the two case studies have been discussed. The degree of fidelity should reflect the purpose of the simulations as fidelity has a strong impact on the results. The next section discusses how clinical simulation can be used in connection with design activities in the development of clinical information systems.



7 RESEARCH FINDINGS – DESIGN

In this section I discuss the research question "*What are the potentials of using clinical simulation in design of clinical information systems?".* Publication I: "*Boundary objects in clinical simulation and the design of eHealth"* is related to this research question*.* The publication examines how clinical simulation can be used as part of participatory design when designing CIS and discusses how clinical simulation can be used to communicate and transfer knowledge between different groups of people in order to get a shared understanding and common ground for discussions and negotiations. Clinical simulation was used to understand the context of use, specify user and organizational requirements, and evaluate design (highlighted in red in the upper right-hand corner of this page). The publication is related to the Design case study, which is described in detail in section 4.1.3.

The design case study (145; 161) dealt with re-design of documentation templates and overview reports for nurses regarding nurses' initial patient assessment. The design process (presented in Figure 11 at page 36) included document analysis, site visits and workshops, and clinical simulation was used to involve end-users actively (145). Clinical simulation was used as a boundary object serving as a media and common ground through which to communicate and negotiate in order to gain a shared understanding and reach agreement on the future design of the templates (164).

To evaluate this approach I observed and took notes from the workshop and simulation session and subsequently interviewed representative qualitative nurses, who had taken part in the clinical simulation and the design process. I also investigated reviewed the literature on boundary objects and participatory design.

The results concerning the design of the templates were (161):

- Requirements for structured data should be kept to a minimum to ease nurses' documentation processes. Many structured fields were removed and a few were added.
- Better overview of patients' record. The original overview was optimized and an additional version of the overview was designed.
- Template content requirements were aligned for the most part. The parties agreed to evaluate some minor elements during the pilot implementation. The present content focused on the most generic areas and elements of the initial nursing assessment, e.g. details concerning hearing aid were reduced.

The results of using boundary objects and the specific design method were:

- All communities of practice were involved and showed great interest in participating.
- Ownership was obtained by including all communities of practice in the process, leading to broad acceptance of the system in the organization.
- The gap between the quality nurses' theoretical approach and the ward nurses' practical approach was effectively bridged.

- Using clinical simulation as a boundary object helped to visualize the use of the templates and obtain a shared mental model.
- The de-briefing interviews and discussions, and workshops helped to align expectations and provided input for final decisions regarding template design and content.

Clinical simulations may be used as boundary objects. Clinical simulations as boundary objects are constructed at the intersection of the communities of practice of design and use of CIS. They reveal the divergences between the different communities. Relations are reshaped, alliances shifted and the balance of power realigned during the clinical simulation (164). Clinical simulation makes it possible to actively participate in design activities. Choosing a PD approach empowered the participants to influence the design solutions on equal terms, which ensured that they took ownership of the subsequent implementation of the information system.

The simulation gave important input regarding resolution of some of the practical challenges facing the daily work with documentation templates. The simulation became a boundary object because it was used at the interface of different communities of practice. By observing end-users using the templates, the discussion between the different communities of practice served as common ground, supported a shared understanding, and changed the focus 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. Bowker and Star argue that "*the more at home you are in a community of practice, the more you forget the strange and contingent nature of its categories seen from outside*" (82) p294. Clinical simulation was a pragmatic approach to boundary objects and visualized the consequences and the impact of implementing an information system. Clinical simulation transformed knowledge about a process and created new knowledge. Things were depicted differently by different communities of practice and in different contexts (82). However, as in the example of Iansiti's work on the role of prototypes (165), clinical simulation enhanced the process of transforming knowledge.

Clinical simulation is conventionally used to evaluate technology but can also be used as a learning space, in which to acquire knowledge of other parts of the organization. . Clinical simulation provided the different communities of practice 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*". Some communities of practice 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 (79).

Prentice argues (164) that "*surgical learning occurs at the interface of bodies and instruments, through simultaneous sculpting of the surgical site and training of the surgeons body*", a process she calls "*mutual articulation*". In the same way, clinical simulation provides an opportunity to investigate the impact of work practice before it impacts the daily work in a hospital. Another way of expressing the use of boundary objects is stated by Bowker and Star (82): "*the medium of an information is not just wires and plugs, bits and bytes, but also conventions of representation, information both formal and empirical. A system becomes a system in design and use, not the one without the other*". 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.

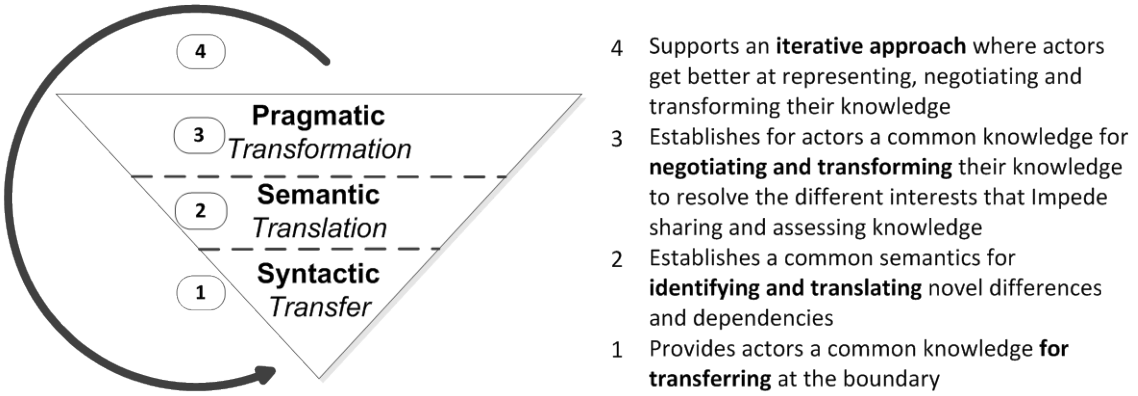
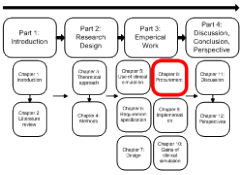
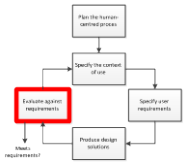


FIGURE 15 CARLILE'S INTEGRATIVE FRAMEWORK FOR MANAGING KNOWLEDGE ACROSS BOUNDARIES AND THE FOUR CHARACTERISICS OF A "PRAGMATIC" BOUNDARY CAPABILITY

Carlile describes following the three approaches to knowledge boundaries in product development: syntactic, semantic and pragmatic (77; 143) as seen in Figure 15. Clinical simulation was used as boundary object transferring and translating knowledge between different communities of practice. Clinical simulation helped in transferring knowledge from one community of practice to another and helped different parts of an organization in 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 the communities of practice an opportunity to voice their point of view and to affect the final result.

This section has discussed how clinical simulation may be used in design activities regarding the development of clinical information systems. Clinical simulation can be used in a PD approach providing common ground for dialog and discussions, and supporting the acquisition of a shared understanding between different communities of practice. The next section will discuss how clinical simulation can be used in activities in a procurement process.





8 RESEARCH FINDINGS – PROCUREMENT

In this section I will discuss the research question "*What are the potentials of using clinical simulation in assessment of clinical information systems as part of a procurement process?*" The publication related to this research question is: "H: *Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms*". The publication is related to the case study regarding assessment of an EHR platform (158), which is described in detail in section 4.1.4 Procurement.

Human-centered design methods, in which the entire development process is focused on user-centered activities in order to create safe and useful applications, are well described (52; 166; 167). However, when it comes to assessing human-computer interaction and work process support in relation to procurement of electronic health record (EHR) systems, the methods are inadequately described. Even though new technology is intended to reduce errors, it is well known that CIS may introduce new types of errors; i.e. adverse events due to increased strain on cognitive processes and unintended use (3; 168; 169). Maguire and Bewan describe how scenarios, personas and prototyping may be used in analyzing user demands, and how prototyping may be used in evaluating information systems (135). Qualitative methods, including clinical simulation, may also be used to capture the cognitive aspects influencing clinical work practice in relation to any particular system (25).

Qualitative aspects, such as the interaction between technology and end-users and other human factors, are generally difficult to assess. Public procurement processes (PPPs) involve compliance with strict rules and an assessment must be quantitative in order to equally and precisely compare the information systems on offer. A PPP is typically a structured assessment of the vendors' textual descriptions of the solutions they offer and their written replies to the requirement specifications. Assessment of textual descriptions is, however, inadequate as it fails to fully assess human factor issues (38). In the procurement case study (described in section 4.1.4), clinical simulation was used to assess CIS from three different vendors. While the literature describing how clinical simulation can be used to evaluate a single information system is comprehensive, there are few publications describing how simulation can be used to systematically assess and compare several information systems and their support of clinical work processes in a PPP.

The aim of the simulation set-up was primarily to assess the three EHR platforms in the final phase of the procurement process and secondarily to actively involve clinicians in the PPP.

To gain insight into the potential for using clinical simulation for assessment in a procurement process, we developed a method based on existing knowledge and previous experience with clinical simulation. As the EHR platform was to be used in two different regions with 20 hospitals and approximately 40,000 users, the assessment methods applied had to address the requirements of various end-users, specialties and cultures. The methods also had to meet the transparency demands of procurement in a public tender process in accordance with EU regulations. Focus in the procurement was on increased efficiency in quality of care. This was expressed as demands for qualitative and quantitative improvements in three areas: 1) continuity of care and patient safety, 2) streamlining of clinical processes and workflow, and 3) patient and employee satisfaction. Cross-functional work processes and overlap of responsibility were top-

ics of great concern. In a public tender process, the results of the assessment of the various platform solutions should be quantitative in order to facilitate accurate and uniform comparisons between the offerings of competing vendors. As stated by Maguire (135), CIS should be evaluated by users. In the procurement case study, this was achieved by using clinical simulation. A major challenge when applying clinical simulation as an assessment method in the procurement process was to convert the qualitative aspects of the process into quantitative output.

To accomplish this, a new method was developed for assessment in the procurement process. The method was intended to reveal the qualitative human factor aspects of the assessment and include typical use-scenarios and real end-users. Furthermore, it had to take into account the perspectives of various stakeholders, including e.g. risk managers, quality managers and clinical managers. Our assessment metrics were based on ISO standard 9241, part 11 concerning usability in ergonomic requirements (100). The method we developed combines clinical simulation with quantitative measurement methods. The method is described more thoroughly in the publication "F: *Use of Clinical Simulation for Assessment in EHR-Procurement: Design of Method*". We used a participatory approach as the project participants and organizational stakeholders were actively involved in developing the method.

The assessment method and metrics were inspired by the usability framework in the ISO standard: "*ISO 9241 Ergonomic requirements for office work with visual display terminals (VDTs) - Part 11: Guidance on usability*" (100). Davis (170) developed measurement scales for assessing perceived usefulness and perceived ease of use. These scales were used as inspiration in the development of questionnaires. Abran et al proposed a consolidated and normative model for evaluating software usability (171). Their measurement proposals were also an inspiration in the development of usability measures. DeLone and McLean was yet another source of inspiration (172). In their "Information Systems Success Model" (see Figure 16), DeLone and McLean describe the conditions for a successful information system.

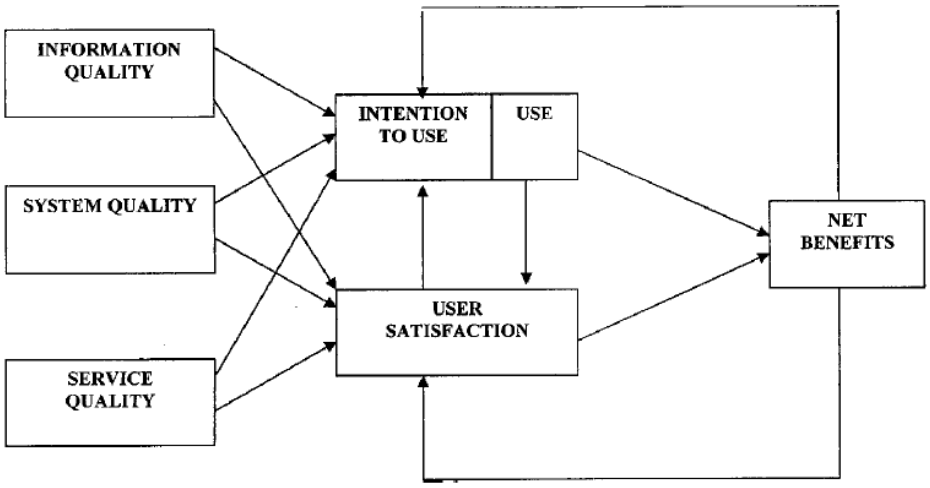


FIGURE 16 INFORMATION SYSTEM SUCCESS MODEL BY DELONE & MCLEAN

The model indicates the association between several quality measures, - Information Quality, System Quality, Service Quality - and the success dimensions - Intention to Use, Use and User satisfaction - and their relation to Net Benefits. In our work, we were inspired by the dimensions and relations in the model which define and qualify objectives and outputs from the simulations. Clinical simulation techniques provided the substantial basis to our method (27).

The metrics of assessment were based on the criteria and purpose of the assessment. ISO standard 9241 – part 11 (100) recommends making an evaluation to encompass at least one of each of the three usability measures included in the standard. These measures are interpreted by Davis as perceived usefulness and perceived ease of use (170), and by DeLone and McLean as intention to use/use and user satisfaction (172). These two dimensions constituted the basis for our assessment measures.

During the clinical simulations, two measurements were monitored; 1) fulfilment of tasks and 2) difficulties in using the information systems (ease of use). As described in ISO 9241 – part 11 (100), the relative importance of components of usability depends on the context of use and the purpose. There is therefore no general rule for how measures should be chosen or combined. The choice of measures and level of detail of each measure depends on the objectives, and the relative importance of each measure to the goals had therefore to be considered. Patient safety is not, however, a direct component of the ISO standard.

When it is not possible to obtain objective measures, subjective measures (based on the user's perception) may provide an indication of effectiveness and efficiency. Observations made during the clinical simulation were therefore supplemented by questionnaires. The questionnaires were primarily based on the work done by Davis (170). To assess patient safety issues, the evaluation criteria were partly based on adverse events and experiences of the use of CIS in the regions. The criteria were mapped to the areas of the assessment.

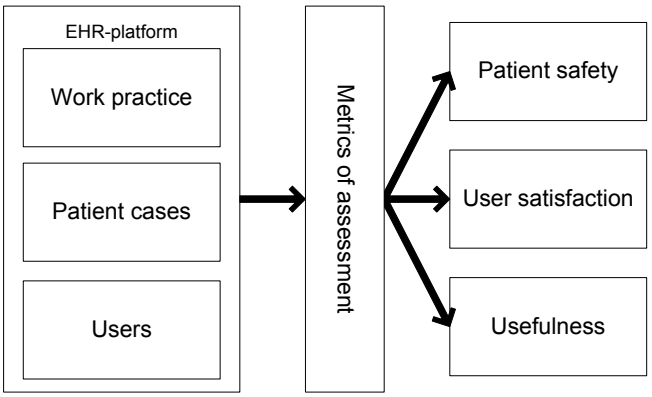


FIGURE 17 MODEL FOR ASSESSMENT OF USE IN PROCUREMENT

Figure 17 shows a model for the assessment serving as the specification of the assessment set-up. To the left is the object that is to be assessed, i.e. the EHR platform, in the middle the means by which the results are to be collected, i.e. the metrics of assessment, and to the right is what will be assessed ,i.e. patient safety, user satisfaction and usefulness. These dimensions from DeLone & McLean, *intention to use/ use* and *ease of use*, may be interpreted in the ISO 9241 standard (100) as *effectiveness* and *satisfaction*. In our model, the terms *usefulness* and *user satisfaction* are used. As patient safety is a vital dimension in healthcare it is brought in to our model. It was not possible to assess efficiency as resources expended in relation to effectiveness would require a high degree of proficiency among the participating clinicians.

Working with assessment on such a large scale made it clear that prioritization is a key factor. In order to comply with the complexity of the scope of the assessment as well as with the deadlines in a procurement process, it was imperative to remain focused. The assessment had to be conducted over a very short period of time and the results had to be collected, analyzed and pre-

sented without delay. The assessment also had to cover a variety of stakeholders with varying tasks and diverse aspects of clinical use of the EHR platform. There is a risk that the assessment process will not provide a complete picture of the system in use. We have not been able to develop a method for assessing the long-term effects, i.e. what happens when the clinicians have become accustomed to the system. When clinicians are accustomed to the system, other features may be prioritized.

Not all groups of healthcare professionals were involved in the clinical simulation. To compensate for their absence, other groups of professionals, such as therapists and midwives, might have been included as observers in the simulation setup along with other stakeholders, such as risk managers, quality managers and clinical managers. As described in the requirement evaluation case study (149), observing clinicians are able to reflect on their own use while observing colleagues doing simulations. Observations of how and for which purposes other healthcare professionals use an information system are a valuable supplement to performing the simulations yourself. Such observations may also be alternative courses of action , when it is not possible for all clinicians to participate personally in the simulations (149). In the procurement study the observer clinicians had the opportunity to dissociate themselves from the simulation and reflect on the usefulness of the system. The use of multi-disciplinary teams enabled the participants to assess the system's capacity to support multi-disciplinary documentation and work processes.

Tasks, work practice and users are core elements in the context of use. We were aware that the scenarios did not cover all possible aspects of work practice but, by mapping these three dimensions in the scenarios, we ensured that different contexts were represented in them. The choice of scenarios did, however, reflect the business strategies. In one case, the need for test data was too time-consuming to be used for clinical simulation.

In a public procurement process, suppliers must be treated uniformly. It was essential that the clinical simulations were performed uniformly, contrary to what is common practice in explorative studies for design purposes. The scenarios had to be minutely described and the roles of the users and patients had to be followed to the letter.

The procurement process implied the following challenges to the assessment: 1) the results had to be comparable; 2) the assessment of the different EHR platforms had to be homogenous; 3) the process had to be transparent; 4) time to conduct and report on the assessment was very limited; 5) the assessment data had to be easily collectable and quickly made available for analysis. The size of the actual project from which this case study evolved was responsible for three further challenges: 1) all aspects of the EHR platform had to be covered, 2) all clinical specialities had to be dealt with, and 3) all possible types of users had to be considered and preferably included in the assessment.

The challenge was to cover key aspects of the EHR system without compromising more complex and peripheral aspects. Selection and prioritization were key elements at the risk of omitting essential parameters. On the other hand, this was necessary in order to make an assessment that could, on the one hand, embrace the full variety and complexity of system use and user satisfaction within an EHR platform covering several hospitals and ten thousands of users and, on the other hand, could meet the stringent demands of a public procurement process. Clinical simulation was just one sub-method applied in the assessment process, and it had to be supplemented by other assessment activities. The clinical simulation assessment method was, however, an important opportunity to assess the usefulness and ease of use of the systems and also a chance

for users to voice an opinion. They will after all be using the system selected on a daily basis in the years to come.

Regarding the eligibility of clinical simulation as a method to uniformly assess human factor issues in PPPs, we found that the method was indeed useful and made it possible to assess qualitative aspects that were otherwise difficult to specify and assess (53). Careful attention was, however, essential in order to develop textual requirements that could provide a solid foundation for the assessment criteria. Clinical simulation proved to be an adequate method for assessing user satisfaction as it gave the users firsthand experience of the EHR platforms in a close to real life setting, focusing on the interaction between technology, users and work practice. Although it was difficult for the clinicians to become proficient at using the EHR platforms within the short assessment period, they were able to state reasons for good and bad user experiences with each of the three EHR platforms. The lack of proficiency might be compensated for by training the simulation facilitator more extensively in the use of the EHR platforms and providing comprehensive guidance on platform functionality during the simulations. Compared with other methods, such as heuristic inspection and low fidelity usability evaluation, clinical simulation takes the clinical context into account. Other methods tend to focus on only one or two topics without their clinical context. Heuristic inspection focuses only on the user interface and low fidelity usability testing focuses on technology and specific tasks for single users. These methods may, however, complement clinical simulation in creating a rigorous assessment of the user interface.

Regarding usefulness, the clinicians found that the clinical simulation facilitated an understanding of the extent to which the EHR platforms were able to support daily clinical work practices. At first there was some reluctance to working in interdisciplinary groups but this proved to be essential to facilitating a richer understanding of the functionality of the EHR platforms in collaborative work situations. This would not have been possible in a low fidelity usability test, in which a single user solved a single task.

Patient safety issues proved to be especially difficult to assess due to the fact that many patient safety challenges lie in the details and are triggered by adverse events and disturbances. In one of the three solutions, it was possible to document a note but it was very difficult to determine whether anything had been documented as it only appeared as an underline or mouse-over. During the simulation, it became very obvious that the clinicians failed to notice this, which meant that they might have overlooked important information. In another case, it turned out that information about allergy was not always automatically transferred to all other allergy fields. Potential patient safety hazards like these did not become evident before the information systems were actually used in clinical simulations. It can therefore be difficult, if not almost impossible, to pinpoint such issues beforehand. They are necessarily encountered along the way. Clinical simulation is, however, an appropriate method by which to assess patient safety issues as it provides a comprehensive view of the information system taking into account the correlation between IT, work practice and adverse events. We recommend, however, that in order to gain in depth views on patient safety issues this should be conducted in close collaboration with patient safety experts.

Creating an assessment process that was both transparent and uniform and which ensured not only that the scenarios were realistic and relevant for the customer but also that the vendors were involved in decisions related to scenarios, test data and configurations, was a difficult balance to strike. The assessment was not blinded. When users are involved, there is a risk of mutu-

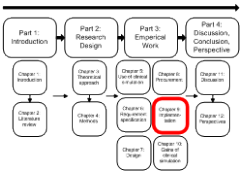
al influence. This may be dealt with in the design of the simulation set-up. However, we found that the benefits of involving users across specialties and professions outweighed the difficulties.

Clinical simulation made it possible to assess qualitative aspects that were otherwise difficult to measure, like patient safety and human factors (53). In a requirement specification, the purchaser describes something that already exists. In return he receives a textual description, which he is required to evaluate by giving points based on a standard evaluation method. . The use of clinical simulation in the early phases of the procurement process may improve assessment of the systems on offer and make it possible to expose and assess qualitative aspects, such as human factor aspects, patient safety and support of work practice (149; 168). Patient safety issues are difficult both to describe in sufficient detail and to assess without involving clinical context and work practice either in real life or in a simulated set-up. In PPPs, a real-life assessment is seldom possible, although clinical simulation is a very suitable substitute. To set up a clinical simulation-based assessment in a PPP was a huge task. However, bearing in mind the immense impact of the procured platform on the healthcare organization, we believe that a clinical simulation should always be undertaken. The value of making such an investment on a thoroughly enlightened base cannot be overestimated. The assessment may further be applied as a basis on which to discuss future challenges and opportunities during platform implementation(173).

A clinical simulation-based assessment of a PPP was beneficial for gaining insight into user satisfaction, usefulness and patient safety. Conventional methods focus on the relation between users and user interfaces without involving the clinical context. Clinical simulation illuminates the relation between users, technology and work practice and hereby provides deep insight into the system in question. It remains difficult, however, to assess clinical decision support systems using clinical simulation as clinicians make fewer errors during simulation than they do in real life (30).

The evaluation process we applied made it possible to systematically assess each of the platforms and their differences. Clinical simulation was eligible in a PPP of CIS as a supplement to other assessment activities. We can recommend the use of clinical simulation as a method by which to assess user satisfaction, usefulness and patient safety. It provides an excellent basis for user involvement and also gives the users an opportunity to express an opinion. We recommend, however, that clinical simulation is supplemented by low fidelity usability evaluation and heuristic evaluation in order to assess minor variances in ease of use.

This section has discussed the use of clinical simulation in assessing activities in a procurement process. Clinical simulation is suitable for use in a CIS procurement process as a supplement to other activities. Clinical simulation is recommended as a method by which to assess user satisfaction, usefulness and patient safety. It provides an excellent basis for user involvement and also gives the users an opportunity to express an opinion. The next section discusses the use of clinical simulation in application assessment in work practice.



9 RESEARCH FINDINGS – IMPLEMENTATION

In this section I will discuss the research question "*What are the potentials of using clinical simulation to acquire knowledge of implementation?".* Publication K:*"Identification and prevention of patient safety hazards"* is related to this research question and describes how clinical simulation can be used for both evaluation of CIS and the acquisition of knowledge prior to implementation of these systems. The publication is related to the Implementation case study, which is described in detail in section 4.1.5. As the title indicates, the publication focuses on patient safety issues but also presents how clinical simulation can be used to evaluate information systems and work practices as well as the relationships between them.

One of the purposes of using clinical simulation in relation to implementation was to investigate the support of clinical practice of an information system. The need for a high degree of fidelity on all four fidelity dimensions (see section 4 *Methods* page 27) increases in line with the need for realism throughout the simulation (61). If the purpose is to evaluate training materials and the need for information in connection with an implementation, the same applies to training of clinicians prior to the simulation. If the purpose is to evaluate, then all aspects must be as realistic as possible. In the implementation case study, the goal was to determine whether the information system should be implemented at the hospitals. The need for fidelity was therefore high.

The aim of the implementation case study was to investigate how a standard information system, "OPUS Inbox" supports clinical practice, and to identify potential patient safety hazards prior to its implementation. In addition to implementation aspects such as training and information, the purpose was also to evaluate future work practice, the relation between technology and existing work processes, and the extent to which clinical simulation may be applied as a proactive method to identify and evaluate potential patient safety hazards prior to implementation (162). Clinical simulation as a method was evaluated by means of interviews with the project manager, a manager from one of the pilot hospitals, and an expert from the patient safety unit. An analysis of work practice conducted prior to the clinical simulation revealed that there were significant differences between the hospitals, between the patient wards, and the outpatient clinics - and indeed also between the individual healthcare professionals. Furthermore, the design of future work practice presented a number of challenges and it was not possible to design a generic work flow to cover both patient ward and outpatient clinic. This was to some extent due to differences between local work flows but also due to the fact that the information system functionality did not provide adequately support for work practice.

The clinical simulation identified many uncertainties concerning work flow, handling of responsibility, and other organizational and technical challenges. The process also showed that the choice of observers is very important. Each expert focuses on his or her own field. For this reason, observers must be chosen carefully and bearing in mind the purpose of the evaluation. During the simulation there were no observers with patient safety expertise. The simulation results were presented to patient safety experts, who identified many patient safety issues. Several organizational and technological issues, which were regarded as inconveniences by others, were detected as patient safety risks by the patient safety experts. High fidelity functionalities, such as

integration to other information systems, revealed patient safety issues; e.g. notes related to a test result were not shown in relation to the test result in OPUS Inbox. The physician could only find the notes in the lab system. Apart from many negative findings, there were also positive findings, including improved overview of laboratory test results and no paper test results were left lying around, at the risk of disappearing.

The evaluation was formative and primarily used as a learning process. Formative evaluation studies can facilitate system adoption and utilization (174) and aim to improve a system during its development or implementation, while summative evaluation focuses on evaluation of a system that is already up and running (175). Formative evaluation may identify potential problems, such as patient safety issues, during the development phase and thus provide opportunities to improve a system as it develops. In the simulation study, the results of the formative evaluation regarding patient safety issues and work practice for handling laboratory test results was presented and discussed at meetings with the various stakeholders, i.e. the patient safety unit, the quality unit and the implementation departments. Precautions were taken in relation to patient safety matters and work practice. Many of these precautions were subsequently implemented, regardless of the implementation of information system.

It is very often unclear whether errors occur due to the technology itself or due to human error on the part of the individual healthcare professional. Incidents usually occur in the interaction between humans, technology and work practice. The correlation between human, technology and organization is visualized during clinical simulation, which therefore clarifies all three aspects. More conventional usability evaluations tend to visualize the interaction between the user and the technology but do not include work practice context (27; 38; 48). By including all three aspects (humans, technology and organization), patient safety challenges were revealed as well as organizational and technical challenges. New work practice in itself may also lead to unintended incidents. This was also revealed during the clinical simulation.

Clinical simulation makes it possible to expose and focus on patient safety matters. The use of patient safety experts as observers makes it possible to identify the risks and challenges. In the implementation study, patient safety experts were not used as observers. The simulation evaluation report was subsequently shown to the patient safety experts. Having patient safety experts observe the simulation would have improved the outcome considerably. These experts have great experience of what can go wrong and are able to focus on these matters during the simulation. They obseve the interaction between the user and the interface of the technology but just as much the interaction with the technology in the clinical context. Inclusion of clinical context is one of the most powerful elements in clinical simulation. By allowing clinicians to use new technology in the way it is supposed to be used, patient safety issues become visible. Clinical simulation enables visualization of technology in connection with clinical context without endangering patients (53).

To expose cognitive and socio-technical issues, fidelity needed to be high. The overall simulation fidelity configuration affects how the realism of the simulation experience is perceived (61). Cognitive aspects of work practice relate to the clinical context and therefore depend on the degree of environment and task realism (160). Socio-technical aspects and patient safety matters lie in the intersection between user, organization and technology (176). Fidelity configuration must be high on all four dimensions.

Traditional information systems are often designed around an idealized model of the tasks and workflow, and failures in information systems are often blamed on human social and cultural

"barriers" to technology adoption (15). The implementation case study revealed differences between such an idealized model of the task that needed to be accomplished and the way in which clinicians were actually working. Some of the differences were due to local interpretations of the regional guidelines and one of the conclusions reached was that the regional quality unit should develop a regional standard for signing off test results. Another issue lay in the fact that the information system was a standard system which did not provide adequate opportunities to configure the system to match the local setting. If work practice differs from department to department, local configuration is a requirement. A regional standard was introduced to resolve this issue.

Clinical simulation did not reveal all the challenges that were due to the information system. The challenges about handling pre-ambulatory test results and unusual test results were not exposed during the clinical simulation. Clinical simulations are no better than the scenarios and patient cases they cover. In the implementation case study, the scenarios during the simulations did not include unusual results or the pre-ambulatory test results. Clinical simulation involves an inherent risk of giving an idealized picture compared to real life. When planning and designing the evaluation, it is important to take such matters into account. Another aspect was the purpose of the evaluation and the relation between existing and future work practice. What is to be evaluated - future or existing work practice? And do the end-users comprehend and approve of the new work practice? Furthermore, if the existing work practice in a department does not follow the existing guidelines, this may influence the evaluation of the interaction between future work practice, end-users and technology as well as subsequent implementation.

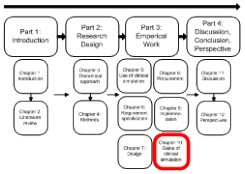
To what extent is it possible to allow technology to be the entry point for improving quality? Should such projects be regarded as technology projects or organizational development projects? The balance is delicate and should be carefully defined in each project. The "'OPUS Inbox"' project failed to achieve that balance, partly due to the technological limitations. For the project to succeed, the technology would have had to have supported future work practice more effectively, and made it easier for the clinicians to comply with it. Subsequent observations showed that nearly 300 test results were not acknowledged. The project evaluation recommended that a regional guideline should be developed and implemented before implementing new technology.

Similarly, muddled work flows became clear during the simulation and observers focusing on work flows agreed that a further work flow analysis was needed. This resulted in revision of the future work practice. The sheer range of differences in existing work practices at hospitals, departments, wards and clinics meant that it was not possible to design generic future work flows. As a result, the regional quality unit was asked to design a regional guideline for handling laboratory test results. Many of the issues found during the simulation were addressed before the pilot implementation, and those that were not solved were observed again during the pilot implementation. However, not all challenges were revealed during the clinical simulation. Issues such as the handling of pre-ambulatory test results and unusual test results were not identified. In short, clinical simulation cannot replace a pilot implementation, but should rather be regarded as a valuable supplement.

Patient safety issues are difficult to assess due to the fact that many patient safety challenges lie in the details and are triggered by adverse events and disturbances (176). The results of the case study showed that clinical simulation took the clinical context into account, while other methods,. e.g. heuristic inspection focus on the user interface. Low fidelity usability testing focuses on technology and specific tasks for single users. It can therefore be difficult, or almost impossible, to pinpoint patient safety hazards using these methods. Clinical simulation provided a compre-

hensive view on the information system taking into account the correlation between IT, work practice and adverse events, and is therefore a more appropriate method for assessing patient safety issues. Clinical simulation is costly and time-consuming (30) and the purpose of simulation studies should be planned carefully.

This section discussed clinical simulation for application assessment in work practice. In the case study clinical simulation revealed organizational and technical challenges as well as patient safety issues. The next section discusses potential benefits and limitations inherent to the use of clinical simulation.



10 RESEARCH FINDINGS –GAINS FROM USING CLINICAL SIMULATION

In this section, I will discuss the overarching research question RQ0 *" What might be gained from using clinical simulation during various phases in the development of clinical information systems?"* and examine the opportunities and potential benefits as well as the challenges and limitations of using clinical simulation. This will be done with reference to all five case studies and the related publications. Table 7 (below) describes the potential purposes, benefits, limitations and the types of results that have come out of the five case studies.

TABLE 7 POTENTIAL AND CHALLENGES OF CLINICAL SIMULATION IN VARIOUS PHASES

Topic	**Requirement specification**	**Design**	**Procurement**	**Implementation**
References	(149; 160)	(145; 161; 173)	(31; 177)	(162)
Purposes	Analysis and evaluation of: • work practice • user requirements • cross-disciplinary requirem. • handovers • cross-organizational systems • efficiency, satisfaction and feasibility	Formative evaluation of new technology Investigation of impact of new technology and work practice	Assessment of • of tenders • qualitative aspects; patient safety, human factors, user satisfaction User involvement	Evaluation of: • design • support of work practice • technology in work practice and • training program • existing & future work practice Formative evaluation Summative evaluation
Types of results	Requirements: • context-sensitive • user requirements • cross-disciplinary Work practice information Unintended benefits Organizational challenges and concerns Potential new users and ways of using technology	Visualization of • interaction with IT system • effect on work practice • similarities and differences between specialties and parts of an organization Knowledge of: • beliefs and practices of others • new practical challenges Formative evaluation of design and support of work Translation of pros & cons of technology & work practice	Subjective evaluation of user satisfaction Insight in EHR platform support of patient encounters Stated reasons for good and bad user experience Assessment of qualitative aspects; patient safety and human factors Cross-disciplinary assessments	Effect on work practice Organizational challenges Technical challenges Input for design of technology Input for redesign of work practice End-users understanding of system model Patient safety issues Intended and unintended potential benefits

Topic	Requirement specification	Design	Procurement	Implementation
Challenges and limitations	No richness of interaction in low fidelity prototypes Not all possible applications of technology may be covered	Costly and time-consuming Is not a substitute for pilot implementation Does not cover • long periods of time • all parts of an organization • all parts of work practice • all possible events and patient cases	Difficult to assess • minor variations of use • objective user satisfaction Difficult balance to ensure • transparent and uniform assessment process • realistic and relevant scenarios Assessment not blinded Lack of complexity • in patient cases • number of patients Less stressful environments Short introductions entail • many interruptions • difficult to achieve proficiency Difficult to assess aspects other than end-user aspects	Purpose must be clear regarding assessment of existing or future work flow Challenging to allow assessment of IT system based on use of new work flow Does closely resemble the use of technology → no substitute for pilot implementation Clinicians make fewer errors during simulation than in real life
Achievements	Involvement of clinical context Involvement of user Safe experimental setting in a realistic clinical context Appreciation of new concepts Visualization of interaction between different groups of healthcare professionals Understanding of other healthcare processes Knowledge of • difficulties in understanding new concepts • cross-organizational work processes • organizational issues, challenges and potential benefits that need to be addressed Setting for discussion and exploration of cross-organizational work flow in new technology	Alignment of expectations, mutual acceptance and understanding Ownership, involvement and inclusion of users Creation of new knowledge of e.g. use of new technology Learning space, where knowledge of other parts of an organization or other organizations is acquired Opportunity to observe and discuss own practices as well as others' practices An approach to tackle tensions between divergent viewpoints Shared understanding and common ground for discussion and negotiation Visualization of perception gap Transformation of knowledge and attitudes	User involvement Assessment across specialties and healthcare professions Clarification of differences in clinical requirements Assessment and reflection on different CIS First-hand experience for end-users in a close to real life setting, focusing on the interaction between technology, users and work practice Deep insight into CIS and how the systems support work practice Deep insight into needs and concerns related to organizational implementation Comprehensive view, correlation between IT, work practice and adverse events	Visualization of • possible work-around • potential patient hazards without endangering the patient Safe space for analysis and experimenting with future work practice and use of technology

The main challenges and concerns in using clinical simulation were:

- the purpose must be rooted in the organization as the purpose impacts the choice of scenarios, users and observers and the need for fidelity (178)
- choice of
  - scenarios determines what part of work practice is evaluated (178)
  - users determine the requirements and needs, against which the information systems will be evaluated (31)
  - observers determine the focus of the evaluation (162)
  - fidelity reflects the performance of the simulation (160)
- lesser complexity in work practice and short time frame
- clinical simulation does not reflect
  - the social-technical impact over time (31)
  - effectiveness (31; 149)

The main achievements of using clinical simulation were:

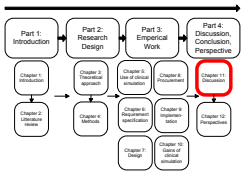
- user involvement (31) and involvement of clinical context (162)
- controlled environments for experiments and formative evaluation (149)
- evaluation environments for addressing cross-sectorial and cross-functional topics (149)
- common ground to gain shared understanding (161) and organizational learning space (161)
- strengthens dialog with vendors (31)
- visualization of unintended benefits and challenges (149)
- rich understanding of functionality by working in interdisciplinary teams (31)

As described in my findings and in Table 7, clinical simulation may be used in different activities in the user-centred design cycle (52) (described on page 25) and for various purposes during all phases of the development life cycle of information systems. The purposes and different aspects that were evaluated varied throughout the five case studies. Table 8 presents different evaluation aspects and shows that clinical simulation may be used to assess various aspects. The different assessment aspects and the need for fidelity when conducting clinical simulation will be discussed in the next section.

TABLE 8 EVALUATION ASPECTS IN THE CASE STUDIES

Evaluation aspects	Requirement analysis	Requirement evaluation	Design	Procurement	Implementation
Human factors	x	x	x	x	x
Patient safety		x	x	x	x
Usability		x	x	x	x
Work practice	x	x	x	x	x
HCI			x	x	x
Common ground	x	x	x	x	x
Requirem.	x	x	x	x	x

This section discussed the opportunities and benefits as well as the challenges and limitations of using clinical simulation. The section presented a structured overview of potential purposes, challenges and limitations, and achievements in various phases of the development cycle together with different types of results. The next section discusses the overall findings of my research.



11 DISCUSSION

By embracing technology, users and the clinical context (e.g. work practice and patient cases), it was possible to analyze (160) and evaluate (31; 149) new technology in close to real situations without endangering patient lives (162). Methods such as low fidelity usability evaluation (102; 179) and functional testing (green oval in Figure 18) explore the human-machine interface (121). The human-software interface (122) discussed by Hendricks focuses on single end-users' interaction with the technology without taking the medical context into account as it omits e.g. acting patients, interruptions, colleagues and the physical environment. The low fidelity relates to environmental fidelity, whereas equipment and functional fidelity may be high. Task fidelity may be high but only focuses on tasks involving a single user. Inadvertent challenges and benefits in relation to organization and work practice as well as patient safety issues may not be revealed when conducting traditional low fidelity usability studies.

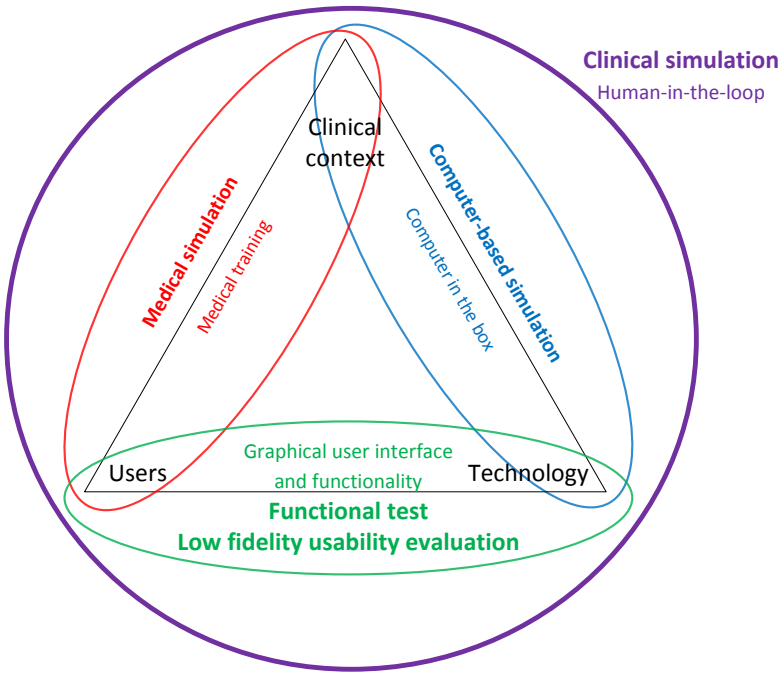


FIGURE 18 FOCUSING ASPECTS IN CLINICAL SIMULATION

Medical simulation (red oval in Figure 18) used for purposes of training healthcare professionals (40) focuses on the clinical context and the clinicians (users), but does not focus on technology itself because medical simulation is used for training medical skills, social-oriented work and cognitive-individual-oriented aspects of clinical work practice. Computer-based simulation (blue circle in Figure 18) focuses on the "*computer-in-box*" simulation and extends from clinical context to technology, where the clinical context is simulated without involving real users. Clinical simulations (purple circle in Figure 18) combined clinical context, users and technology, revealing the relationship between the three areas and focuses on sociological aspects in the socio-technical interaction; "*human-in-the-loop*".

By embracing all three aspects, with the limitation of e.g. lesser complexity in work practice and short time frame, the "*human-in-the-loop*" approach converges with the human factor aspects' understanding of interaction between humans and other elements of a system, such as e.g. technology, procedures, persons and physical environments (116). As presented in Table 9, investigation of the remaining interfaces described by Hendricks (70; 120), i.e. human-environment interface, human-job interface and human-organization interface technology, required high environmental and high task fidelity.

TABLE 9 NEED FOR FIDELITY IN EVALUATION OF HUMAN FACTORS

Human factor interfaces technology vs fidelity dimensions	**Environmental fidelity**	**Task fidelity**	**Equipment fidelity**	**Functional fidelity**
Human-machine interfaces technology	Low	Very low	Very high	High
Human-environment interfaces technology	Very high	High	Low	Very low
Human-software interfaces technology	Very low	Low	High	Very high
Human-job interfaces technology	High	Very high	Low	Medium
Human-organization interfaces technology	Very high	Very high	Very low	Low

Types of results differ according to the degree of the different components of fidelity. The choice of fidelity should therefore reflect the purpose of the clinical simulation. In Table 10 the different degrees of the fidelity dimension from the two case studies concerning requirement specification are presented together with the different types of outcomes from the studies. In the requirement evaluation study, the degree of equipment and functional fidelity was high, and this resulted in more advanced knowledge of the use of technology and the organizational benefits and challenges due to the visualization of technology applied. Both studies revealed latent user requirements related to context-sensitive and cross-disciplinary needs. In the requirement evaluation study, however, the results were richer as they revealed several examples of organizational potential, e.g. using the PCM for communication and coaching across sectors. Meanwhile the requirement analysis study revealed requirements for the information system, e.g. the need for different modes in a CIS to reflect the work flow.

TABLE 10 DIFFERENCES IN FIDELITY DIMENSIONS AND TYPES OF RESULTS IN REQUIREMENT CASE STUDIES

Fidelity dimensions	**Requirement analysis**	**Requirement evaluation**
Environmental fidelity	High: realistic environments and 'acting patients'	High: realistic environments and 'acting patients'
Task fidelity	High: Real scenarios	High: scenarios based on realistic patient cases
Equipment fidelity	Low: cardboard box mock-up	High: electronic prototype
Functional fidelity	Low: post-it labels and WoO approach	High: fully functional prototype with faked integrations
Facilitating method	Obser-view	Think-aloud

Fidelity dimensions	Requirement analysis	Requirement evaluation
Type of results	User requirement Knowledge of work practice	User requirement Knowledge of work practice Evaluation of usability Potential new users and use of technology Unintended benefits Organizational challenges

There are a variety of answers to the question, "how low can fidelity go?" depending on the purpose of the clinical simulation and the different fidelity dimensions. In the case study concerning requirement evaluation, the purpose was to evaluate the usefulness of a PCM looking into more organizational aspects, and therefore there was a need to visualize the use of the application in an organizational setting.

In the case study of the analysis of requirements, the fidelity of the task content had to be rather high, although there was no need for high fidelity in the execution of the tasks. High fidelity environments are required to help increase clinicians' perception of realism. As one of the clinicians in the requirement analysis case study said: "*it is the patient who makes the scenario come alive*". The purpose of the simulation study was to acquire knowledge of user requirement in a specific area of clinical work practice, whereas the actual interaction with a computer or an information system was less important. The need for equipment and functional fidelity was therefore rather low. The low degree of technical fidelity meant that no limitations were imposed in the guise of well-known functionalities and technology. This was actually beneficial in this case. 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 higher. When specifying user requirements, clinical simulation cannot stand alone but should be used as an add-on to other methods, such as field studies and workshops (142).

As described by Beaubein (144) and Dahl (61), the four dimensions of fidelity may be seen as two types of fidelity; 1) psychological fidelity and 2) physical fidelity. Another view could be to group the four dimensions in two fields, i.e. a) clinical fidelity and b) technical fidelity. Environments and tasks reflect the clinical set-up in a simulation, whereas equipment and functionality reflect the technical set-up. The two different views are presented in Figure 19.

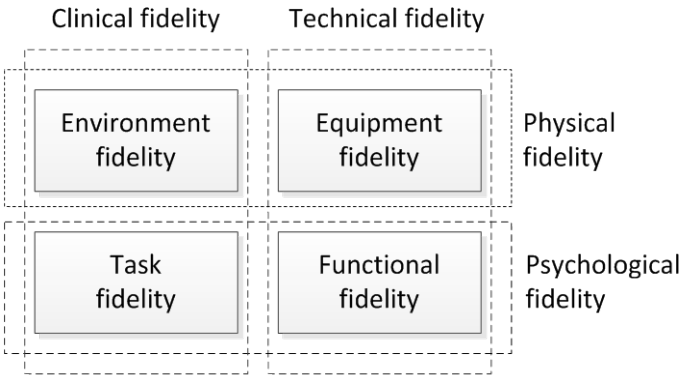


FIGURE 19 VIEWS ON SIMULATION DIMENSIONS

In Table 11, environmental and task fidelity are merged into "clinical fidelity", whereas functional and equipment fidelity are merged into "technical fidelity". The figure presents the different need for fidelity for various activities and purposes. The two lower areas with low clinical fidelity are not relevant in relation to clinical simulation, as clinical simulation relates to real users performing realistic tasks in realistic environment. As mentioned earlier activities in the two lower areas should be used as supplement to clinical simulation as they focus on other areas.

TABLE 11 DEGREE OF FIDELITY IN VARIOUS ACTIVITIES

		Technical fidelity	
		Low	**High**
Clinical fidelity	**High**	Experiments Analysis Formative evaluation • *Design*	Formative evaluation • *Design* Summative evaluation • *Procurement assessments* *Application assessment in work practice*
	Low	Heuristic evaluation Mock up test	Functional test Technical test Usability evaluation

In Dahl's four fidelity dimensions, by there is no direct reference to the degree of fidelity concerning the actual performance of the simulation. The requirement analysis case study indicated 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. Although task and functional fidelity are high in both cases, acceptance of the simulation may vary between a simulation where the facilitator has conducted "obser-views" during the simulation and a simulation where there were no interruptions. It can be argued that the two cognitive fidelity dimensions cannot be high when "obser-views" are conducted during the simulation, but a fifth dimension could be added to fully describe simulation fidelity.

11.1 CONCLUDING NOTE

The complexity of organization and work practices in healthcare creates challenges regarding the choice and application of methods used in developing and implementing CIS (34). 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. These issues in eHealth influence the cost and resources invested in the acquisition and implementation of new technology at the hospitals as well as their subsequent adoption, and may cause a lack of acceptance and understanding among end-users. 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. Clinical simulation is a useful method by which to analyze these issues. It serves as a reflective means by which to improve solutions to the problem (161). Organizational differences can be overcome and shared understanding is made possible by achieving a mutual clinical agreement on the basis of shared mental models and mutual discussions.

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 (145; 161). If users are not adequately involved in these processes, the new technology developed may endanger patient safety and result in inadvertent events and increased mortality (162). Acceptance of new technology may be earned by giving the different communities of practice 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 (30; 149). The case studies reveal that clinical simulation can be useful in different activities in the human-centred design cycle.

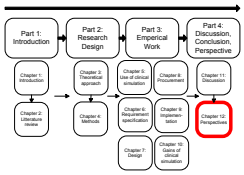
Unintended benefits may not be revealed prior to implementation and their full potential may not be achieved (149). Clinical simulation offers an opportunity to create a space in which healthcare professionals working in different locations or healthcare sectors can meet and exchange knowledge about work practices and requirement needs (31; 160). This approach proved effective in identifying important unintended benefits and challenges (149), and acquiring knowledge of how new technology may impact work practices (161) and patient safety issues (162).

The resources invested in preparing and performing simulation studies are quite exhaustive, although the cost depends on the desired degree of fidelity. It is therefore essential to adjust the cost of creating a realistic setting to the aims of the evaluation and simulation (27; 59). On the other hand, cost savings are difficult to quantify as benefits, such as saved lives, are difficult to measure. However, many of the results of the simulation studies in the five case studies would not otherwise have been revealed.

Much has been learned during my research. New knowledge has been acquired about the use of clinical simulation in a procurement process and about clinical simulation as a boundary object in the development of CIS. This thesis offers a thorough description of a methodological approach for planning, preparing and conducting clinical simulation and of the use of clinical simulation in various phases of the development life cycle of CIS.

My short reply to the question: *What might be gained from using clinical simulation during various phases in the development of clinical information systems*? is that clinical simulation can involve users and the clinical context in human-centred activities throughout the various phases in the development cycle and contribute to the development of safe and useful CIS.

This section has discussed the overall findings in my research. Related areas may need to be investigated further. These areas are introduced in the next section.



12 PERSPECTIVES

Simulation conducted in the same way as clinical simulation, where end-users use new technology in realistic set-up whilst doing realistic tasks, may beneficially be used in other high risk areas in the same way as clinical simulation is used in healthcare. Potential areas could be pharmacy, fire departments and aviation. Other spheres within healthcare than those described in this thesis could make use of simulation. My research has focused on CIS in a hospital setting but areas, such as primary nursing and general practitioners could benefit from the principles and techniques of clinical simulation. As such, clinical simulation might be used as a gatekeeper function throughout health IT.

As healthcare technology moves into patients' homes, simulation could also be used in private settings. As patient-oriented functionalities are part of the new EHR platform in the Capital Region of Denmark and Region Zealand, these and similar issues will have my attention. A set-up with a one-way mirror and cameras mounted in the ceiling is not appropriate in a private home. Mobile cameras and intercom must be used as part of the technical set-up during the simulation. This mobile technical set-up has been used in a simulation study at one of the regional hospitals. The results were promising although there remain some technical challenges regarding band width. The study showed that using a mobile set-up in a hospital department made it easier to focus on an entire patient flow between different hospital units as it was easier and more flexible for the clinicians to attend the simulation than it would have been if they should have been removed from their local settings. The simulation and subsequent debriefing interview were vivid for the participants and the user involvement was more apparent to the rest of the staff.

Other fields, such as biomedical engineering, could use clinical simulation to analyze and evaluate biomedical equipment. Biomedical equipment is covered by the CE marking regulation (180) where e.g. evaluation of usability is concerned. IT solutions are extensively applied to the use of biomedical equipment why areas in health IT are also being included, and simulation-based evaluations might be also be valuable in relation to the procurement and purchase of medical technology and in aligning the different types of equipment scattered around the hospitals.

Clinical simulation in examination of adverse advent might also be useful, as it is possible to stage adverse event scenarios with a view to creating more controlled and safer environments.

The areas mentioned above are all recommended as areas for further research.

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13 APPENDICES - OVERVIEW OF PAPERS

Appendix 1: Jensen S, Lyng KM, Nøhr C. The role of simulation in clinical information systems development. Stud Health Technol Inform 2012;180:373-7.

Appendix 2: Jensen S, Vingtoft S, Nohr C. Benefits of a clinical planning and coordination module: a simulation study. Stud Health Technol Inform 2013;183:220-4.

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Appendix 4: Kushniruk A, Nohr C, Jensen S, Borycki EM. From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies. Yearb Med Inform 2013;8(1):78-85.

Appendix 5: Jensen, S., Rasmussen, S. L., and Lyng, K. M., "Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms," Stud.Health Technol.Inform, Vol. 205, 2014, pp. 925-929.

Appendix 6: Jensen, S., Kushniruk, A. Boundary objects in clinical simulation and design of eHealth, Health Informatics Journal 2014 - in press

Appendix 7: Jensen, S., Nøhr, C., Kushniruk, A. 2014. Clinical Simulation: A method for Development of Clinical Information Systems - not published

Appendix 7: Jensen, S., Hermansen, B., Nøhr, C., 2014 Identification and prevention of Patient safety hazards - not published

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].

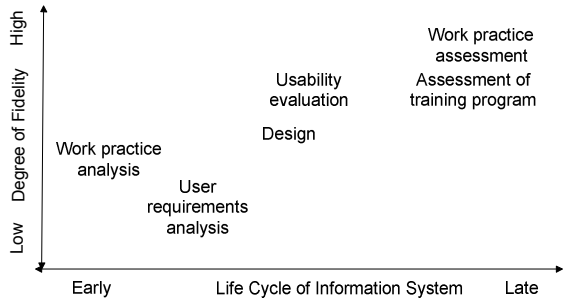

Figure 1. Use of simulation during life cycle of CIS

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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Benefits of a Clinical Planning and Coordination Module: A Simulation Study

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Abstract. Digital Clinical Practice Guidelines are commonly used in Danish health care. Planning and decision support are particularly important to patients with chronic diseases, who often are in contact with General Practitioners, Community Nurses and hospitals. In the Capital Region of Denmark the potential benefits of a planning and coordination module has been assessed in a full-scale simulation test including 18 health care professionals. The results showed that health care professionals can benefit from such a module. Furthermore unexpected new possible benefits concerning communication and quality management emerged during the test and potential new groups of users were identified.

Keywords. Clinical simulation, eHealth, clinical practice guidelines, usefulness

Introduction

Clinical practice guidelines (CPG) have been used more frequently during the last years [1]. Continuity of care programs containing CPG aimed at planning and decision support for healthcare professionals are therefore being developed [2]. The Capital Region of Denmark is exploring the potential benefits of an information system supporting the planning and coordination of chronic patient across sectors [3]. Patients with Chronic Obstructive Pulmonary Disease (COPD) and Diabetes Mellitus Type 2 (DM2) are selected to establish a proof of concept project. Currently there are no information system supporting the coordination and planning across community nursing, general practitioners and hospitals in Denmark. The consequence is limited planning and reduced coordination across the three sectors followed by decreased quality and compliance of CPG. International experiences indicate that IT-systems can enhance compliance as well as quality of care [4;5].

The Capital Region in Denmark has launched a project: "Chronic 5" that aims to demonstrate the potential benefits of a Planning and Coordination Module (PCM). The project analyzes and specifies requirements for such a system and builds and tests a PCM prototype. Clinician end-users, clinical managers, quality managers, IT-architects and health informaticians performed the analysis and the specification.

The PCM is basically designed to establish and maintain a cross organizational overview and virtualized management of all health services in individual patient cases among all relevant health actors – including the patient. All health services in an individualized patient plan are mapped to relevant CPGs

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The purpose of PCM is to support the coordination across sectors, concerning the status and planning for patients with COPD and DM2 according to the CPG, and handling of derived activities and services. This digital support will be groundbreaking in Denmark, and will offer new opportunities for coherence and continuity in the care activities. Moreover it will possibly ensure a higher compliance to the existing continuity programs and CPG.

To realize the intended benefits of a PCM usability of the system is pivotal [6]. Usability may be defined as "extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" [7]. When using simulation it is possible to assess the effect of an information system in different contexts as well as evaluating efficiency, satisfaction and effectiveness [8]. The objective of the simulation study was to assess the potential benefits of a PCM for health care professionals involved in planning and coordination of patients with COPD and DM2, primarily focusing on the efficiency of the PCM, and secondary on satisfaction. Efficacy and effectiveness has not been assessed.

This paper presents the test of the PCM-prototype and the results from the test, and discusses the potential benefits and concerns of a PCM. Furthermore the use of simulation as a method for testing potential use of clinical information systems is discussed.

1. Method

The test was conducted as a controlled full-scale simulation study. The concept of simulation has been used for training medical skills during the last 40 years [9] and has during the last decade been used to assess health information systems [10]. A simulation study makes it possible to assess the use of a prototype in a realistic environment [11], and is well suited for assessing potential impact [12] as well as cognitive processes and usability [13].

The test encompassed 18 simulation runs including six general practitioners (GP), six community nurses, six hospital physicians and two simulation patients. The simulation runs were bundled into six tests. In each test healthcare professionals from each of the three end-user groups were participating. 10 scenarios were composed; five about a patient with COPD and five about a patient with DM2. The scenarios covered planning of therapy and further diagnosing concerning a recently diagnosed patient at the GP, visitation at the community nurse, rehabilitation at the community nurse, treatment of a patient at an outpatient clinic due to exacerbation of the condition, and assignment of responsibility from the hospital physicians to the GP. The scenarios resembled different points of impact focusing on core functionalities and the assignments from one healthcare professional to another. Interface issues such as colors, buttons and minor functionalities were not part of the assessment. The scenarios were composed to assess nine hypotheses i.e. the first nine questions in Figure 1.

Before the simulation took place the testers were introduced to the concept and the functionalities of the PCM and they could get hands-on in order to get acquainted with the information system. During the test the same general tasks were performed. In cooperation with the "patient" and on the basis of the existing findings and plans, the healthcare professionals were asked to revise and modify the plans for the patient. The prototype had simulated integrations to other information system in order to replicate the intended integrations to legacy information systems. A test-coordinator was sitting

next to the tester during the test to assist the tester in case of problems using the system. The tester was asked to "think-aloud" [14] during the test, and the test-coordinator did obser-view [15] asking more exhaustive questions if necessary. By asking questions about the system, the "patient" was able to force the tester to describe the system and the functionalities in a close to natural setting. Health informatics experts experienced in simulation test conducted the role of the patient. In the control room a test instructor and several observers followed the test through a one-way mirror. The instructor was in radio contact with both the "patient" and the test-coordinator during the test. Hereby the instructor was able to direct the test to ensure the objectives. The observers monitored the test and their observations were used in the subsequent debriefing-interview. During each test testers from the three sectors were present, but only one was testing, while the others observed from the control room.

Data for the evaluation was acquired by questionnaire and debriefing-interviews with testers and observers. The questionnaire had nine questions concerning the hypothesis, two about quality, four about overview, two about the division of responsibilities, four about work practice and efficiency, and three questions about the simulation and the realism in the scenarios. The interview guide started with open-ended questions concerning positive and negative features of the system, followed by specific questions to clarify and elaborate on issues from the questionnaires and other issues that came to their mind. At the end of each day the data from the interviews were analyzed using Instant Data Analysis (IDA) [16]. As supplement to IDA the observations from the simulations, the notes from the interviews and the IDA notes were analyzed using Nvivo (QSR International).

2. Results

The results from the questionnaire are shown in Figure 1. The horizontal scale depicts the median of the respondents answer on a five point likert agree/disagree scale to the 24 questions on the vertical axis. The hypotheses tested in the first nine questions were verified. Among the remaining questions only one obtained a lower score than 3 i.e. the question concerning whether the PCM would release more time to be spend with the patients. From the interviews, however, the general opinion was that the PCM would reduce the time spend on the planning and coordination, but it remain unresolved, whether the time would be spend with the patients. This result was the only one with discrepancy between interview and questionnaire.

The core concept of the PCM was assessed as being very useful and creating many benefits. New ideas were brought up during the interviews – eg. the PCM could be a coaching tool for senior doctors and an instrument for communication among colleagues or between other groups of healthcare professionals. Primary care nurses were not part of the original scope, but were spotted as new potential users by a GP who saw the PCM as a very valuable tool for them. Also quality management was perceived to be enhanced, and the content of referrals and discharge letters could possibly be reduced, since information concerning the patient would be known by all parts.

Most of the healthcare professionals had difficulties understanding the concept of a PCM in the beginning. The concept was innovative and forced them to see planning and coordination in a new way. The simulation and observation of the others using the system helped them to understand the concept. Several issues of concern were also brought up. 1) The healthcare professionals found that the PCM module gave a good

overview of the patients, but at the same time they wanted the possibility of looking into more details about the patient. They recommended to specify this in the requirements. 2) The test showed that the terminology used in the three sectors, differed on several central terms such as "referred to" and "deselected". 3) Sharing of responsibility as all will have the same access to data, but should it be possible for a physician at

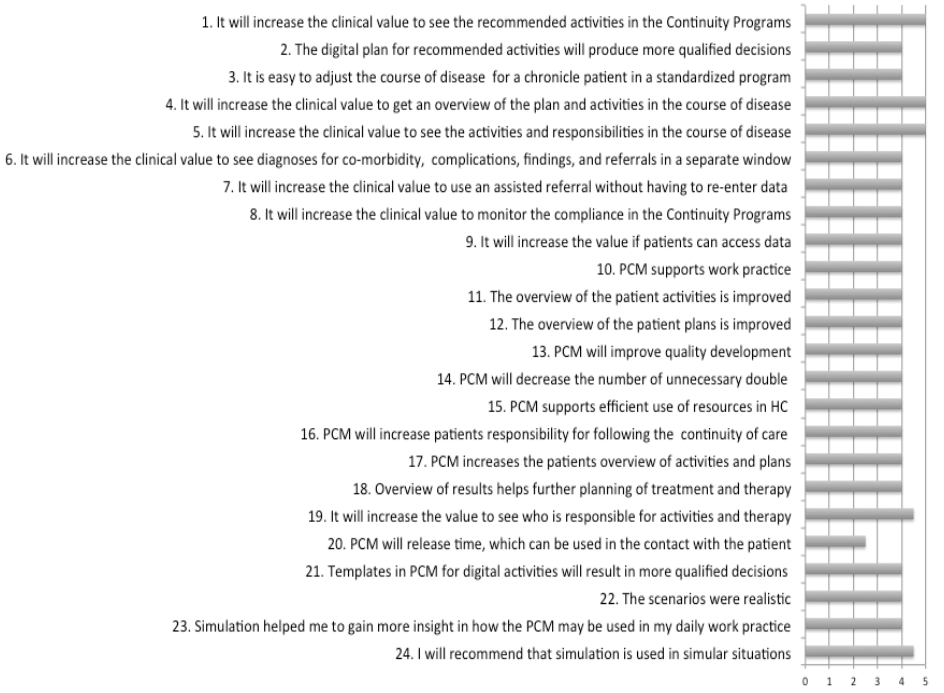

Figure 1. Potential benefits: Result from Questionnaires (n=14)

the hospital to overrule a prescription from the PG - or vice versa? 4) Several users stressed that realization of integrations were of vital significance.

3. Discussion

The healthcare professionals found potential clinical benefits in using the PCM, which would improve quality and patient safety. Furthermore new future users were discovered and new potential ways of using the PCM were revealed. Only simulated patients were used during the test, but several potential benefits for the patients were detected. A supplementing simulation with genuine patients would therefore be recommended to test the sustainability of these observations. The healthcare professionals were quite satisfied with the realism in the simulation, and it helped them to gain insight in the possibilities of PCM.

The scenarios did not cover all possible applications of the PCM but were composed to enable assessment of the nine hypotheses. A simulation test does not fully resemble the use of an information system in the clinic, but offers a high degree of

realism, depending on the degree of fidelity. A simulation test should therefore not be a substitution for a pilot implementation, but regarded as a complementary test without risk of injuring real patients.

Several issues that were brought up e.g. terminology and responsibility had not been visible before the simulation test, but are very relevant and needed to be addressed prior to implementation. Furthermore it was discovered how the simulation was a powerful learning tool for the new users in spe.

The results from this simulation study conclude that GPs, community nurses and the hospital physicians and patients will benefit from a PCM. The benefits include improvements in communication, planning and coordination, work practice, and quality management. Several organizational issues have to be addressed including use of terminology and delegation of responsibilities before an information system as PCM can be implemented. Furthermore the results show that full-scale simulation studies are a useful method for testing the feasibility of information systems.

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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 limited 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 fidelity dimensions in simulation-based usability assessment of mobile technology for

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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 Fig. 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 specialities. 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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From Usability Testing to Clinical Simulations: Bringing Context into the Design and Evaluation of Usable and Safe Health Information Technologies

Contribution of the IMIA Human Factors Engineering for Healthcare Informatics Working Group

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Summary

Objectives: The objective of this paper is to explore human factors approaches to understanding the use of health information technology (HIT) by extending usability engineering approaches to include analysis of the impact of clinical context through use of clinical simulations.

Methods: Methods discussed are considered on a continuum from traditional laboratory-based usability testing to clinical simulations. Clinical simulations can be conducted in a simulation laboratory and they can also be conducted in real-world settings. The clinical simulation approach attempts to bring the dimension of clinical context into stronger focus. This involves testing of systems with representative users doing representative tasks, in representative settings/environments.

Results: Application of methods where realistic clinical scenarios are used to drive the study of users interacting with systems under realistic conditions and settings can lead to identification of problems and issues with systems that may not be detected using traditional usability engineering methods. In conducting such studies, careful consideration is needed in creating ecologically valid test scenarios. The evidence obtained from such evaluation can be used to improve both the usability and safety of HIT. In addition, recent work has shown that clinical simulations, in particular those conducted in-situ, can lead to considerable benefits when compared to the costs of running such studies.

Conclusion: In order to bring context of use into the testing of HIT, clinical simulation, involving observing representative users carrying out tasks in representative settings, holds considerable promise.

Keywords

Ussability, clinical simulation, patient safety, technology-induced error, health information systems

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Introduction

The usability of health information technology (HIT) has been increasingly recognized as being of critical importance in the design and deployment of systems that are both effective and acceptable to end users. Despite the considerable potential range of healthcare applications such as electronic health records, clinical decision support systems and consumer e-Health applications, there continues to be many reports of HIT that are unusable, that do not fit the workflow of users and that do not end up being adopted. In addition, in recent years, the relation between poor usability and unsafe systems has begun to be better understood [1,2], with growing evidence that highly unusable systems may not only be bothersome in terms of end user dissatisfaction, but that poor usability may underlie and lead to safety incidents and potential patient death [3-5]. Furthermore, recent studies have indicated that the extent of such problems may have been under-reported and may be more prevalent than previously thought [3-5]. All this is despite the increased consideration, discussion and publication of work and research aimed at improving the usability and safety of HIT, particularly over the past two decades [1, 3, 4, 6-9].

Although many vendors of HIT now operate commercial usability laboratories where healthcare software systems products are designed and tested, reports of serious usability and safety issues continue to be reported globally [3-5,10]. The question therefore arises as to why, despite this increased understanding and attention given to usability, reports of unusable and potentially unsafe systems are still appearing [3-5]? In this paper we will examine the need for considering the impact of context of system use on the ultimate usability and safety of HIT. Indeed, health informatics researchers and professionals have argued that of all work domains, healthcare is the most challenging given the variety, range and complexity of situations and settings where HIT is used and deployed [11]. Furthermore, a lack of understanding of the nature and range of end users of HIT has been highlighted as being a key issue in the failure of many systems to be adopted by health professionals and consumers [12]. Along these lines, understanding the context in which systems will be used must take into account not only tasks and settings but also the range, capabilities and cognitive capacities of an ever growing variety of potential end users [13-17].

In recent years, methodologies have begun to emerge where the design and evaluation of complex HIT has focused on an improved understanding of how such systems will work and be used in a range of complex and challenging settings. These settings typically vary considerably from those where healthcare software products are initially developed and tested (i.e. vendor usability laboratories and beta test sites at a few selected healthcare organizations) [1, 15, 18]. As will be discussed in this paper, this movement represents an extension of "traditional" laboratory usability engineering approaches to methods

that incorporate evidence about system use under "near-live" or "live" conditions (in a range of settings and healthcare contexts) prior to widespread system deployment. It will also be shown how such methods are becoming increasingly used by organizations to obtain evidence about fit of commercial systems to their organizations in an effort to procure systems that more closely match organizational requirements, end user needs, and local healthcare practices [e.g. 19-22].

From Usability Testing to Clinical Simulations and Rapid In-Situ System Testing: Bringing Context to the Fore

Since the early 1990's a considerable number of published works have appeared describing the application of usability engineering methods to improving HIT. This has included description of the application of "classic" methods such as usability testing and usability inspection methods for improving the design and usability of a wide range of HIT [7, 8, 15]. Usability testing, as it has been defined in these works, typically refers to the observation of representative users of a system (or user interface) interacting with that system while carrying out representative tasks [15]. For example, in a range of studies of users of electronic health records (EHRs), this has involved observing and video recording health professionals (e.g. doctors and nurses) as they interact with EHRs in carrying out data entry, retrieval and decision making tasks [1,13,14]. The results of such study have been reported to have improved the design and adoption of many healthcare information systems [19, 20]. Complementary methods of usability inspection, including heuristic evaluation and cognitive walkthrough, have also been reported as being increasingly used in evaluating and testing a variety of health information systems [23, 24]. Unlike usability testing (which involves observing end users of a system), usability inspection methods have been noted for being particularly cost effective in that they are conducted by an analyst and do not involve testing of human users of a system [23, 24]. Indeed, in initial work in applying usability engineering to HIT, it has been assumed by many that methods involving observation of users were more labour intensive and costly than usability inspection. The assumption that conducting usability testing (typically involving video analysis and coding) is expensive has been challenged recently as described below when considering evidence from cost-benefit analyses of rapid usability testing methods in healthcare [27, 28].

Low-cost Rapid Usability Testing: Adding Context by Bringing Testing to the Setting of Use

In order to make usability testing more relevant by bringing testing of systems to contexts closer to real system use (than might be achieved in fixed usability laboratories) a range of approaches have appeared. These approaches typically involve free or very low cost screen recording software that can be installed on one or more computers in the actual environment where a system will be deployed [25]. This has typically involved having participants from the organization where the system will be deployed (e.g. health professionals) interact with the system under study in its naturalistic context and interfaced with other technologies it will be deployed with [e.g. 1, 25]. Scripts are typically created for "driving" the usability testing, whereby participants may be instructed to carry out specific tasks using the system under study, while their interactions are recorded (i.e. screens and physical interactions with the HIT, as well verbalizations) [1,15,25]. Participants might be instructed to "think-aloud" while carrying out tasks, as has become standard practice in many usability laboratories, but here the studies are conducted in the real environment of deployment, thereby decreasing costs associated with fixed laboratories while increasing ecological validity [13,15,25,26]. The interpretation and analysis of resultant data from such studies can vary in complexity but it has been found that even surface level analysis of resultant video can lead to identification of serious usability problems [1, 15]. Results from studies involving commercial systems already in deployment may lead to recommendations that feedback to: (a) the implementation team, who may be able to customize the system to mitigate identified usability problems whenever possible, (b) the team that trains new users, if problems found are best dealt with through training, (c) the vendor of the product, especially when problems found must be fixed as they are of an important or safety critical nature [27]. The economic benefits of conducting this type of analysis has recently been demonstrated by Baylis and colleagues [27] who found that a modest investment of under $5,000 could lead to benefits (in terms of finding and fixing usability problems prior to widespread system release) in the order of five to ten times the cost of conducting the study [25,27]. Furthermore, when the potential consequences of usability errors that could lead to adverse patient events are taken into account, the benefits from such study increase considerably [27]. In another recent study examining the impact of this approach to usability testing in improving usability and refining the workflow of a tele-health decision support system in Canada, researchers found that usability analysis of users interacting with the system led to highly significant reductions in time per tele-triage calls [28]. Such studies, conducted in live settings (i.e. "in-situ" usability testing) have therefore been shown to be highly cost effective, much as usability inspection methods (which do not involve recruiting end users) have previously been shown to be cost-effective and therefore labelled as "discount" usability methods by Nielsen and others [25, 26].

The location of such testing can be in a range of settings. These locations can vary to the extent that the environment of the testing matches the environment in which the system being tested will actually be deployed (see Figure 1). For example, many facilities where HIT systems are tested could be considered "Laboratory" environments, including conventional usability testing laboratories at centralized conformance testing sites. Clinical simulations are located in the middle part of Figure 1, which we define in this paper as an extension of usability testing (which involves observing "representative users" doing "representative

tasks"). Clinical simulations include a third dimension, namely "representative settings" [1, 17, 19, 20, 28]. Clinical simulations may be conducted in a laboratory setting (as will be described in the next section of this paper [16, 17]) or in the actual real settings in which HIT will be deployed, which will be described in a subsequent section of this paper). From the far right side of Figure 1, we can see that recording of users interacting with a system under study can also take place in the "live" environment where the system has been deployed, which we have labelled as "naturalistic" studies in Figure 1. In some studies [e.g. 29, 30] this may simply involve continuing to record user interactions from clinical simulations being conducted "in-situ" (i.e. in the real setting of system use), but doing so after the system has actually gone "live" and is being used for real patient care.

As illustrated in Figure 1, in moving from pure laboratory-based studies (depicted on the left hand side of the figure) to testing of systems that brings into consideration context to a greater degree, the possibilities range from conducting realistic testing using laboratory-based clinical simulations to clinical simulations conducted in real settings where systems will ultimately be deployed. Recent work in advancing clinical simulation methods in healthcare will be discussed in the remainder of this paper, beginning with an example of an advanced simulation laboratory in Denmark followed by discussion of work in conducting in-situ clinical simulations. In both types of testing the role and importance of context of system use is critical and is a focus of understanding the impact of system deployment.

Addressing Clinical Context in a Simulation Laboratory: Experiences from the ITX-lab in Copenhagen

In the Capital Region of Denmark clinical simulation has been used since 2007 to evaluate clinical information systems prior to implementation in hospitals in the region. In 2007 the IT Experimentarium (ITX) was established with the purpose of strengthening the quality and optimizing the use of clinical information systems by using clinical simulation. The clinical simulations take place at the Danish Institute for Medical Simulation (DIMS) at one of the major university hospitals in Copenhagen (i.e. the Herlev Hospital). The top floor of the hospital is equipped with 13 simulation rooms consisting of the following: ordinary bed rooms, intensive care units, operating room, and a medication room (most of them with a control room separated with a one way mirror). Each simulation room is equipped with computer-controlled mannequins representing patients of all ages from babies to adults, remote controlled ceiling mounted video cameras, loud speakers, microphones and intercoms linked to the control room. The facilities are mainly used for clinical training, but the laboratory facilities (in conjunction with the use of clinical simulations) have also been employed in the development and evaluation of clinical information systems. Figure 2 shows the simulation room as it is seen from the control room through the one-way-mirror. Here, a simulation is being undertaken where there are two patients in a simulated hospital room. Figure 3 is a more complex example of a simulation. In Figure 3 an operation is being simulated. Included in the simulation is the equipment typical of an operation as well as the HIT. During the simulation the people in the control room are able to communicate with actors playing patients. The computer screens used by the physicians and nurses are mirrored in the control room.

The clinical simulations have appeared to be cost-effective, and since 2011 it has become mandatory to conduct clinical simulation tests before new systems that affect clinical work practices are implemented. During the last 5 years more than 20 simulation studies have been performed in the ITX-lab to improve HIS development activities and assist in the evaluation of clinical information systems [31, 32]. The simulation studies have been used to design computerized clinical decision support and standardized nursing documentation as well as to evaluate the impact of innovative technology.

In the ITX-lab clinical simulation studies are performed in representative realistic environments with real end-users (see Figures 2 and 3). Before the actual simulations take place, the scenarios are created, and the design of the evaluation study is developed. Depending on the maturity of the information system being tested, test data and technical environments must be prepared and implemented. The resources spent on preparing simulation studies can be quite exhaustive and depend on the requested degree of fidelity (i.e. the degree of fidelity must therefore be carefully chosen). The actual simulation with end-users, however, is not so time consuming. By preparing the clinical and technical set-up carefully, the time spent by physicians and nurses is often not more than a couple of hours (depending on the scenario and evaluation set-up).

The simulations are performed in three phases. When the clinicians arrive, they are introduced to the information system and to the simulation. They normally get some hands-on experience with the system before the simulation starts. Each simulation is observed by health informatics experts and sometimes by key stakeholders, such as colleagues from hospitals, clinical managers, quality managers and vendors. 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. After

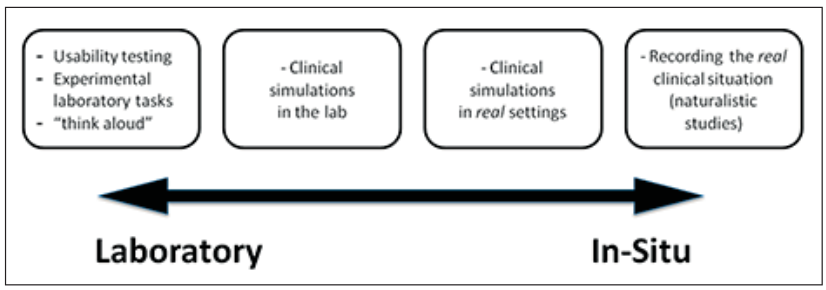

Fig. 1 The context of system testing - a continuum from laboratory to naturalistic settings.

Fig. 2 Simulation room seen from the control room.

Fig. 3 Complex simulation of an operating room environment.

the simulations are completed, an evaluation is performed. Participants are asked to complete questionnaires and participate in a de-briefing interview. Observations made by the observers during the simulations are used as background for the interviews. The interview and notes from the observers are analyzed by use of Instant Data Analysis (IDA) [33]. 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 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.

In the Capital Region of Denmark clinical simulations are used in all phases of the software development life cycle of clinical information systems, starting with analysis of user requirements through to the development, evaluation, and implementation phase of a HIT. Clinical simulation has been used to analyze user requirements with use of different degrees of clinical simulation fidelity; both in connection with well described scenarios and mature prototypes with realistic test data and in a more experimental way with use of a "wizard-of-oz" approach, where clinicians themselves describe the scenarios from a typical patient case they have recently experienced [34-36]. In the design phase, clinical simulations have been used to obtain consensus among differing stakeholders; e.g. end-users and the quality unit. Clinical simulations make it possible for different stakeholders to observe new technology in use. The interviews and discussions that follow clinical simulations provide an opportunity for obtaining and understanding work practices and user needs. Clinical simulations may therefore help to reveal divergences of opinion among differing stakeholders and may make it possible to discuss and gain a common understanding of other stakeholders' views.

Clinical simulations have also been used as part of a participatory design approach making stakeholders actively involved in the design activities and thereby allowing stakeholders to influence HIT design solutions. In this case the clinical simulations were preceded by several design workshops with all stakeholders, where prototypes were built. The clinical simulations were performed by clinicians, who had not taken part in the workshops and therefore it was possible for evaluators to assess the effect of the prototype upon clinical work practices. Before an actual implementation takes place, clinical simulation makes it possible to assess health professional training and information needs. Such knowledge concerning work practices and patient safety issues may be gained, and used as important inputs before or during a pilot implementation of a HIS.

A wide range of results have emerged from the simulation work conducted in the ITX-lab. In one paper by Jensen and colleagues [35] new potential users and new potential ways of using HIT were discovered. The study also revealed unintended benefits regarding new technology as a powerful learning tool and revealed unintended organizational issues concerning terminology and staff responsibility. The study also demonstrated clinical simulations could provide input into HIT design and configuration. In another study [31] using a participatory design approach clinical simulation contributed to the inclusion of stakeholders from all levels of the organization and offered a visualization of future work processes in relation to the new technology. Clinical simulations assisted the participants to gain a shared mental model which helped to reach some kind of consensus in the design

discussions. In a large European project concerning contextualized computerized decision support [36] clinical simulation led to important insights into the potential harmful effects of deployment of information technologies. In this study the effect of a prototype was assessed in the simulation-lab as the prototype was too immature to be implemented at a hospital. Clinical simulation was used in different phases of the project and also led to creation of design principles encapsulating central themes of different kinds of clinical decision support [34].

In addition, the ITX-lab will be used this summer as part of a major procurement process in the Capital Region of Denmark and Region Zealand. This work will include comparison of vendor EHR products and will involve evaluation of three tenders. During the clinical simulation 12 clinical key scenarios such as ward rounds, administration of drugs, admission to and discharge from the hospital will be simulated in realistic clinical settings. The assessment of the EHR vendor products will involve 18 healthcare actors who are physicians and nurses from different specialties. The assessment is expected to run in three parallel tracks over a period of 10 days. The results of the simulation testing of the three products will be used in the decision making process for system selection.

Addressing Clinical Context in In-Situ Testing

In addition to testing of systems within simulation laboratories as described in the previous section, there is also a growing need to evaluate systems within the live contexts in which they will ultimately be deployed, with much of the interest in this direction coming from the desire to ensure system safety [9]. A variety of studies have been conducted in real settings such as hospital rooms, operating rooms and clinical settings. In many cases this has involved setting up clinical simulations (including full computer screen recording and video recording of participants) within hospitals, clinics and even home settings [16, 19, 29]. For example, in one study of the use of a new medication administration system in a hospital in Japan, a typical hospital room was secured for the study. The study was undertaken over several days. Technologies that were to be interfaced with the new system, such as a bar code scanner, were also included in the study to increase its realism. A set of scenarios were created to drive the simulations. Participants in the study (i.e. nurses and physicians) were asked to carry out the tasks defined by the scenarios and were video recorded as they interacted with a "dummy" patient (i.e. a mannequin) and the computer system to carry out medication administration tasks [9]. From this work, it was found that key aspects of the system needed to be customized prior to releasing the system widely in the hospital it was to be deployed in. For example, from the simulation testing, the system was found to be generally safe except when a patient emergency occurred that required the health professional to "break out of" the rigid sequence of steps imposed by the system when time did not allow for the workflow imposed by the system. Based on these results, an emergency override capability was added to the system, to be used only during emergency situations where a health professional would not have enough time to complete the prescribed work sequence of the computer system. It should be noted that this type of evaluation tested the system under the conditions typical of the institution where it was to be deployed, including working with all interfacing technologies. In addition, as it was conducted off hours in a hospital room it did not require use of an expensive laboratory setting, but rather included the context of the real setting at a low cost. Also, the realism of the setting allowed for system evaluation that included analysis of how the system interacted with situational factors (e.g. room size, frequency of emergency situations, bar code scanning technology etc.).

Increasing Ecological Validity: from Clinical Simulations to Naturalistic System Testing

An important aspect of clinical simulation is ecological validity. "Ecological validity refers to an acknowledgment of the fact that human action is situated and highly contingent on contextual factors/variables." Therefore, "to obtain 'valid' results, humans should be studied in the richness of their natural environment" [37]. When an environment is ecologically valid, the research setting matches the real-world setting. This "real-world" match ensures that the problem under study can be fully described and understood [38]. Clinical simulations provide an opportunity for this. Therefore, ecological validity is an important part of clinical simulations. For a clinical simulation to be ecologically valid, attention needs to be paid to setting (i.e. environment), task, users, and scenario representativeness (see Figure 4).

Such realism is critical as it ensures the results of the study are generalizable to the real-world. The more realistic the clinical simulation, the more generalizable and use-

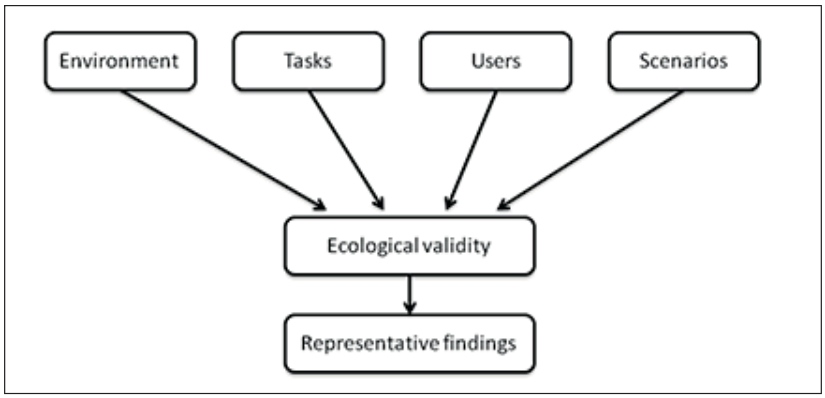

Fig. 4 Aspects of a clinical simulation that ensure it is ecologically valid.

ful its results will be to real-world, systems designers, developers and implementers [13, 17, 38]. For example, in designing a clinical simulation there is a need to address the setting or environment, where the study will take place [39]. Whether one is conducting a clinical simulation in a traditional laboratory setting (i.e. a room set aside for clinical simulations) or in-situ (i.e. in a hospital room or clinic room that is not being used at the moment), an emphasis should be placed on ecological validity. In a laboratory setting this involves identifying the medical equipment (e.g. intravenous pumps, hospital beds, bedside tables, blood pressure monitoring cuffs etc.) that are the same or similar to the ones that will be used in the clinical setting where the software will be implemented. In addition to this, the hardware that is used in that setting will also need to be used in the clinical simulation. This may include desktop or laptop computers, tablet devices or mobile/Smart phones that are currently being used or will be used in that setting (should there be a need for testing). In addition to this, existing software (currently being used) and the new or newly customized software that will be introduced to the setting will need to be included in the clinical simulation. Here, there is an emphasis on replicating the existing setting as well as knowing what hardware and software will be introduced to the setting to determine its effects on health professional work. Following this, there is a need to identify what tasks will be undertaken using the newly introduced hardware and/or software. Tasks should include those that users will be expected to perform using the new technology. A range of tasks should be selected: from the routine to the complex, from the typical to the atypical and from the non-urgent to urgent (see Table 1 for examples).

To illustrate, we use the example of a physician order entry system that will be tested using a clinical simulation approach. Here, users (i.e. physicians) are asked to undertake a range of physician order entry tasks using the new system. In addition to this, scenarios need to be developed to fully simulate the conditions under which the software will be used. Scenarios should be realistic and representative of the types of situations that would be encountered in the clinical setting.

Table 1 Examples of tasks using computerized physician order entry.

Task Type	Example
Routine to complex:	Routine: Entering a single oral medication order. Complex: Entering 5 oral medication orders, an order for an intravenous medication and an order for a subcutaneous injection.
Typical to atypical:	Typical: Entering an order for a blood pressure medication. Atypical: Entering orders for a chemotherapy regime for a rare cancer.
Urgent to non-urgent:	Non-urgent: Entering an order for a Tylenol to be taken as needed. Urgent: Entering an order for a stat medication.

Therefore, much like tasks, scenarios must also range from the routine to the complex, from the typical to the atypical and from the urgent to the non-urgent (see Table 1 for examples). A range of scenarios need to be tested. Scenarios can be developed with the planned users of the new technologies and technology-implementers. This work can be done in the context of focus groups. Lastly, there is a need to ask representative users to participate in clinical simulations. Users should represent all health professionals who will be using the technology and should include novices, intermediates and experts (in an area of disciplinary practice – e.g. physician, nurse; in the domain of practice – e.g. medicine, surgery, neurology; in working with technology that will be used – e.g. new mobile device, new physician order entry system) [13]. For example, novice through to expert physicians should be asked to participate in the clinical simulations as well as novice through to expert hardware and software users to fully understand the implications of introducing new software and/or hardware in a clinical setting. In summary, ecological validity is an important aspect of designing clinical simulations. Attention to the ecological validity of a simulation ensures that the results can provide significant insights when a new technology (i.e. hardware/software) is used.

Recent work reported by Li and colleagues [29] illustrates some of the types of results that can be collected from using realistic clinical cases and simulations. In their study, the objective was to optimize clinical decision support embedded within a commercial EHR system, taking context of use into account. Their study involved three phases: (1) a standard usability test of the user interface driven by a script that led users through its functions for two clinical cases, (2) a clinical simulation where participants interacted with a digital patient (i.e. recording of patients with different respiratory problems), (3) naturalistic recording of physicians interacting with the system just prior to widespread system release. It was found that the three layers of testing led to different results which were all used to optimize the decision support tool for use within the EHR. For example from the initial usability testing it was found that physicians did not recognize the terminology used in the user interface (i.e. labels for buttons) and as a result did not access the decision support. Based on that and related findings the interface was optimized and the second phase of testing began – i.e. the clinical simulation. During the clinical simulations it became clear that the decision support was not being triggered (i.e. invoked) at the points in clinician workflow that the designers have expected. As a result of this finding, the integration of the decision support tool in the EHR was modified to lead to more appropriate invocation. Finally, during the final phase of naturalistic testing (in the "near live" environment) it was found that certain features of the user interface and its integration with clinician workflow needed further optimization. After undergoing these layers of testing the decision support tool was widely released, with a high level of uptake by end users and a high rate of acceptance of recommendations made by the system [29].

Comparing Approaches: Trade-offs in Selecting Methods

A wide range of approaches to evaluation of HIT have emerged based on methods from the human factors literature [40]. As described in this paper, a number of the approaches, including usability testing methods, have been used and adapted for evaluation of HIT [15]. In addition, we have seen the emergence of new types of testing, for example, clinical simulations, which borrow from the underlying human factors literature but also specialize the methods and techniques further for application in the complex domain of healthcare. Given the range of approaches possible, consideration of trade-offs in selecting methods for evaluating HIT is an important issue [41]. In this paper we have described conducting usability testing and clinical simulations in both laboratory and naturalistic settings. Obviously the availability of facilities such as fixed usability or simulation laboratories is one major consideration, and when such facilities are available they can form an important hub or centre for carrying out usability engineering methods with HIT [34,35,36]. Such work can entail testing systems throughout the system development life cycle, from prototype to completed system. In addition, a new area of testing HIT emerged during the procurement and selection process of systems such as EHRs. However, it has also been shown that low-cost portable approaches can also be employed to carry out studies that range from laboratory-based through to naturalistic evaluations [15, 25, 29]. Furthermore, when systems need to be tested in the actual environment they will be used (to ensure both usability and safety) low-cost portable methods have the advantage of being able to be conducted in the real (or close to real) setting of system use (along with all interfacing technologies). In the future we hope to see more integration of varied testing methods, including conformance testing of HIT at central laboratories in conjunction with localized testing in real settings and contexts of use. It is argued that only with such a combined approach will the usability and safety of HIT improved.

Towards Increased Considerationof Context: The Context Sensitive Health Informatics Pre-Medinfo 2013 Conference

As outlined above, human factors / ergonomics adopts a system-based approach to understanding and explaining the interactions between humans and other elements of a health care system. Humans approach tasks and systems with perspective, experience, knowledge, skills and preferences. The Human Factors approach is distinctly design driven and aims to optimize performance, safety and users' sense of well-being associated with their use of a system through the application of user-centred systems design and evaluation. On a health care system level, the socio-technical perspective maintains that the health information system integrates the human, social, organizational and technological dimensions and in so doing contributes to an essential body of knowledge of existing healthcare systems and contributes to their continuous evolution.

The design, implementation, and evaluation of safe, effective, efficient and easy to adopt HIT, therefore requires proper consideration of human and organizational factors. Health care organizations, health policy makers and regulatory bodies globally are starting to acknowledge this essential role of human and organisational factors and progressively incorporate them into regulations and safety initiatives. The two perspectives (Socio-technical and HF/E) are highly complementary to each other in terms of their methods, concepts, models and recommendations. Both contribute to a common body of knowledge and evidence allowing a better understanding of the reasons for success or failure in the Health Informatics and HIT domains, and more importantly opening the way for more efficient and safer practices in design, implementation, usage and evaluation of HIT.

The pre-Medinfo conference "**Context Sensitive Health Informatics**" merges and continues two conference series: *ITHC -Information Technology in Health Care: Socio-Technical approaches* previously held in 2001 (Rotterdam, Netherlands), 2004 (Portland, USA), 2007 (Sidney, Australia) and 2010 (Aalborg, Denmark) and *HFE-HI: Human Factors / Ergonomics for Health Informatics* previously held in 2006 (Lille, France), 2007 (Aarhus, Denmark), 2008 (Amsterdam, Netherlands), 2009 (Sonoma, USA) and 2011 (Trondheim, Norway). The conference will be held on August 17-18, 2013 in Herlev Hospital in Copenhagen. For more information see the conference web-site: *www.cshi2013.org*

Conclusions

The usability of HIT has been increasingly recognized as being of critical importance in the design and deployment of systems that are both effective and acceptable to end users. In this paper we have discussed several approaches to collecting evidence about the impact of HIT deployments. It was noted that there appears to be a trend in the human factors in healthcare literature towards increasing the ecological validity of system testing by bringing consideration of context into greater focus. Different approaches have been described in terms of a continuum that runs from laboratory-based usability testing to clinical simulations and testing of systems in their naturalistic environments. While conventional laboratory-based usability testing is an important component of ensuring that systems are usable and safe, it has been argued that they may be insufficient to ensure usability and safety once systems are released in real healthcare settings. Therefore, complementary methods are needed, along with the need for development and dissemination of new low-cost approaches that can be applied widely within healthcare organizations and settings to provide healthcare organizations, systems developers and customizers with evidence about how HIT will impact healthcare processes and patient safety in differing contexts of use.

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Evaluation of a Clinical Simulation-based Assessment Method for EHR-platforms

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Abstract. In a procurement process assessment of issues like human factors and interaction between technology and end-users can be challenging. In a large public procurement of an Electronic health record-platform (EHR-platform) in Denmark a clinical simulation-based method for assessing and comparing human factor issues was developed and evaluated. This paper describes the evaluation of the method, its advantages and disadvantages. Our findings showed that clinical simulation is beneficial for assessing user satisfaction, usefulness and patient safety, all though it is resource demanding. The method made it possible to assess qualitative topics during the procurement and it provides an excellent ground for user involvement.

Keywords. Clinical simulation, eHealth, Human Factor, Procurement, Assessment

Introduction

Qualitative aspects such as human factors and interaction between technology and end-users are generally challenging to assess. In a public procurement process (PPP) one further have to follow strict rules, where the assessment must be quantitative in order to equally and precisely compare the offered information systems. Typically, assessment in a PPP is done by structured assessment of the vendors' textual descriptions of the offered solutions and their written replies to the requirement specification. Assessments of textual descriptions however, are insufficient in order to fully assess human factor issues [1]. Clinical simulation is a well-known qualitative method for evaluating clinical information systems; the method is useful to illuminate the interaction between technology and human factors [2-6]. While the literature is comprehensive regarding descriptions of how clinical simulation can be used in evaluation of a single information system, literature is limited on how simulation can be used to systematically assess and compare several information systems and their support of clinical work processes in a PPP.

In connection with a large PPP of an EHR-platform in two large regions in Denmark, covering 40.000 clinicians, 20 hospitals serving 2.5 mill citizens, we have developed and evaluated a clinical simulation-based method for assessing and comparing human factor issues [7]. The method was developed to support assessment of qualitative aspects such as user experience, usability and patient safety. While the method

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draws upon existing and well documented practices of evaluation of human factor issues [4,8-10] it was necessary to make some adjustments to these practices because of the rigid nature of a PPP. The PPP implies several challenges to the use of a qualitative assessment approach: 1) assessment results must be comparable, 2) assessment of the different EHR-platforms must be done uniformly, 3) the process has to be transparent, 4) the results have to be easily collected and rapidly analyzed. The size of the actual PPP further adds a couple of challenges 1) all aspects of the EHR-platform should be covered, 2) all clinical specialties and professional needs should be dealt with, 3) all possible types of users should be considered and preferably included in the assessment.

The assessment method was developed based on our previous experience with simulations [4, 9-12] and applied in practice in the PPP process. The aim of the simulation set-up was primarily to assess the three EHR-platforms in case and secondarily to actively involve clinicians in the PPP. The aim of this paper is to describe the evaluation of the method, its advantages and disadvantages. The evaluation of the method is described according to the three aspects of human factor issues that the method was designed to cover; 1) user satisfaction, 2) usefulness and 3) patient safety.

1. Methods

The purpose of the evaluation of the assessment method was to answer the following questions: 1) what is the eligibility of the method, 2) what are the advantages/disadvantages compared with other assessment methods, and 3) reveal possible issues to be improved. The assessment covered 12 clinical scenarios and 18 health professionals from various specialties and professions. Three EHR-platforms were assessed during a period of 10 working days. The clinicians had a full day of training in each of the three platforms followed by two days of clinical simulation [7], after accomplishment of a simulation scenario the clinicians assessed how the tested platform supported the task. The testing was scheduled in three subsequent three-day periods, where the clinicians would scrutinize all the platforms.

The evaluation of the assessment method was qualitative, including observations and semi-structured interviews of key actors and participating clinicians. Observations were conducted during 10 days of assessment, and on the last day all clinicians were interviewed in three groups. Subsequently 15 interviews were conducted with project and legal managers, health informatics, vendors, patient safety experts, and observers during the clinical simulations. The qualitative approach enabled us to conduct the evaluation without interfering with the assessment process, and concurrently obtain a thorough insight in user experiences and perceived benefits and challenges of the method. All interviews were transcribed, and analyzed using a qualitative approach of content data analysis.

2. Results

There was a high level of concordance among the interviewees in the study. The results from the interviews supported the findings from the observations in the study. Generally, the use of ‘patients’ in the simulations supported fidelity of the scenarios and facilitated a smooth flow in the simulations. The clinicians however expressed that the patient cases lacked complexity; there were fewer patients than in every-day work, the

working environment was less stressful than normal. Furthermore, they found it difficult to learn a complete new EHR-platform in the short time given. The evaluation results in table 1 below reflect the three themes the method was designed to address.

Table 1 Results from evaluation of assessment method.

User satisfaction
• Subjective evaluation of user satisfaction is easily done by clinical simulation followed by questionnaires, but objective assessment of user satisfaction is difficult, due to the close correlation to work practice and clinical tasks. • It was difficult to assess minor variances in ease of use. • Clinical simulation supports user involvement, but it is difficult to assess other aspects than the end-user aspect in the assessment. • Use of all the tested EHR-platforms during the testing period made it possible to reflect on and assess each of the platforms and their differences. • There were a lot of interruptions during the simulations, which affected the fidelity and realism and made it difficult to observe the usability on the spot. • The standardized assessment questionnaires supported the clinicians in assessing each single system and their diversity.
Usefulness
• Clinical simulation was an efficient way to exhaustively examine the vendors' textual descriptions of the platforms. • The assessment method made it possible to gain deep insight in the EHR-platforms and how they provided support of work practice and needs and consideration concerning organizational implementation • Clinicians perceived clinical simulation as a good way to be involved in the PPP • Assessment across specialties and healthcare professions were made possible and differences in clinical requirements became obvious. • Structured training provided insight in other parts of the EHR-platforms, than users would have obtained if they were to explore the platforms on their own. • Scenarios covered most standard procedures and daily work practices and made it possible to gain insight in how the EHR-platforms supported patient encounters. • Functional fidelity was high even though the EHR-platforms had not been configured according to the local work practices and the clinicians were fully capable of distinguishing between clinical tasks and system functionality.
Patient safety
• Assessment of patient safety issues lies in the detail and is difficult to define in general requirements that most often are truisms of little significance. • Explicated patient safety requirements and a mention of patient safety assessment issues in the procurement material would legalize patient safety questions in questionnaires and use of patient safety experts as observers during clinical simulation. • Clinical simulation may reveal safety aspect not evident from textual descriptions. • The method could have benefitted by using patient safety experts as observers.
General
• Assessment criteria should be defined early in the PPP and clear requirements regarding human factors and patient safety should be part of the requirement specification. • Vendors found they were treated equally and fair, but would have preferred to use their own test data as implementation of scenario test data was resource exhausting.

3. Discussion

Regarding the eligibility of clinical simulation as a method to uniformly assess human factor issues in PPP's, we found that the method is indeed useful and makes it possible to assess qualitative aspects that are otherwise difficult to specify and assess [3]. Careful attention is however essential in order to develop textual requirements that can provide a solid foundation for the assessment criteria.

Clinical simulation is a sufficient method for assessing user satisfaction as it gives the users firsthand experience with the EHR-platforms in a close to real-life setting focusing on the interaction between technology, users and work practice. Although it was hard for the clinicians to obtain proficiency with the EHR-platforms within the short assessment period, they were able to state the reasons for good and bad user experiences in each of the three EHR-platforms. Training the simulation facilitator more extensively in the EHR-platforms, to enable comprehensive guidance on platform functionality during the simulations, might compensate for the lack of proficiency. Compared to other methods like heuristic inspection and low fidelity usability evaluation, clinical simulation has an advantage in taking into account the clinical context where other methods tend to focus at just one or two topics without the clinical context. Heuristic inspection focus only on the user interface and low fidelity usability test focuses on technology, and specific task for single users. These methods may however complement the clinical simulation in making a rigorous assessment of the user interface.

Regarding usefulness the clinicians found that the clinical simulation facilitated an understanding of how well the assessed EHR-platforms could support daily clinical work practices. At first there was some reluctance to work in interdisciplinary groups but this proved to be essential in facilitating a richer understanding of the functionality of the EHR-platforms in collaborative work situations. This would not have been possible in a low fidelity usability test where a single user solves a single task.

Patient safety issues proved to be especially hard to assess due to the fact that many patient safety challenges lies in the details and are triggered by unintended incidents and disturbances. It can therefore be hard, or nearly impossible, to pinpoint these challenges beforehand, instead they need to be explored along the way. Clinical simulation is however an appropriate method 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 unintended incidents. It is our recommendation though that in order to gain in depth views on patient safety issues this should be done in close collaboration with patient safety experts.

It is a difficult balance to make the assessment process transparent and uniform and to ensure that the scenarios are realistic and relevant for the customer and at the same time let the vendors into the decision on scenarios, test data and configurations. The assessment was not blinded, and by involving users there is a risk of mutual influence. This may be dealt with in the design of the simulation set-up. We however found that the benefits of involving users across specialties and professions were superior to these challenges.

Clinical simulation makes it possible to assess qualitative aspects that are otherwise difficult to measure, like patient safety and human factors [3]. In the requirement specification one try to specify something that is superior to what you already have, in return you get a textual description from the vendor that you try to assess by marks. Use of clinical simulation in the early phases of the procurement process may improve assessment of the offerings and make it possible to expose and assess qualitative as-

pects such as human factor, patient safety and support of work practice [4;5]. Patient safety issues are difficult to describe in sufficient detail and assess without involving clinical context and work practice either in real life or in a simulated set-up. In PPPs assessment in real life is seldom possible, whereas clinical simulation is a very suitable substitute. To set up a clinical simulation-based assessment in a PPP is a huge task, but in on our experience it should be done hence the impact of the procured platform on the healthcare organization is immense, so the value of making the procurement on a thoroughly enlightened base cannot be overestimated. The assessment may further be applied as a basis to discuss future challenges and possibilities in the implementation of the platform [12].

We can conclude that clinical simulation based assessment in a PPP is beneficial for gaining insight in user satisfaction, usefulness and patient safety. Traditional methods focus on the relation between users and user interfaces without involving the clinical context, whereas clinical simulation illuminates the relation between users, technology and work practice and hereby provides deep insight in the offered system. The applied assessment process made it possible to systematically assess each of the platforms and their differences. Clinical simulation is eligible in PPP of clinical information systems as supplement to other assessment activities. Clinical simulation is a recommendable method for assessing user satisfaction, usefulness and patient safety and provides an excellent ground for user involvement and giving voice to the users. We recommend clinical simulation to be supplemented with low fidelity usability evaluation and heuristic evaluation for assessment of minor variances in ease of use.

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Boundary objects in clinical simulation and design of eHealth

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Abstract
Development and implementation of eHealth is challenging due to the complexity of clinical work practices and organizations. Standardizing work processes and documentation procedures is one way of coping with these challenges, and acceptance of these initiatives and acceptance of the clinical information system are vital for success. Clinical simulation may be used as "boundary objects" and help transferring of knowledge between groups of stakeholders and help to better understand needs and requirements in other parts of the organization. This article presents a case study about design of electronic documentation templates for nurses' initial patient assessment, where clinical simulation was used as a boundary object and thereby achieved mutual clinical agreement on the content. Results showed that meetings prior to and in between workshops allowed all communities of practice an opportunity to voice their point of view and affect the final result. Implications of considering clinical simulations as boundary objects are discussed.

Keywords
collaborative work practices and information technology, eHealth, information technology design and development methodologies, information technology healthcare evaluation, organizational change and information technology

Introduction

Clinical simulation refers to simulation performed by real users enacting realistic clinical work scenarios in close to real-life environments. Clinical simulation can be a valuable method for the evaluation of clinical information systems as the testing can take place in a controlled environment where there is no risk of injuring real patients (1; 2). Simulation-based evaluation may take place in all stages of the life cycle of an information technology (IT) system (3; 4) and may be used for a number of different purposes. Clinical simulation methods have been used in health informatics to study various aspects of human–computer interaction in a number of research domains including human factors, usability evaluation, doctor–patient interactions involving technology, health professional information needs, health professional decision-making, new device testing and studies of medical Errors (5-8). In contrast to field studies, clinical simulation studies allow for the possibility of examining different, complex and extreme usage scenarios during a short but highly intense testing phase (8).

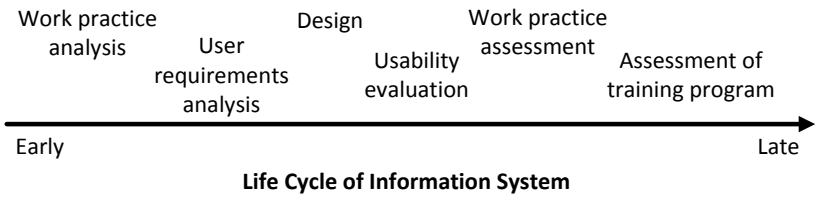


Figure 1 Activities using clinical simulation in life cycle of information system

As seen in Figure 1, clinical simulation may be used for various purposes in the different phases in the life cycle of a clinical information system. In the early phases, clinical simulation may be used to analyze user requirements (7), assess how the system supports existing or future work processes (6), and obtain the knowledge of user work practice (6). In the design phase, clinical simulation may be used for encouraging user involvement and providing iterative feedback to the design of prototypes or real systems (7), and it may combine elements of laboratory testing and field study (9). In the implementation phase, particular aspects of the implementation can be visualized using clinical simulation, for example, user interaction in work practice, the need for training and the impact of decision support (10). Unintended consequences of new systems such as changes in work processes and patient outcomes can be detected and provide organizational decision-makers with the option of early cor-

recting actions if required (6). By providing a sufficient degree of realism, various elements affecting work practice and the use of new technology may be evaluated (11) and can help support healthcare organizations to identify potential issues arising from the introduction of new technology before it is implemented in real-world settings.

Applying simulation in information system evaluation allows for a high degree of experimental control while concurrently maintaining a high degree of realism, particularly in high fidelity testing (3; 9; 12). In such testing, clinicians are invited to use the information system in a realistic but controlled environment, resembling the clinical setting with respect to surroundings, patient cases, interaction with other staff members, information systems and so on. Hence, the context feels real, but shields consequences of system use and testing from patients. The simulation thereby provides a psychological safe space for the participant in which to try out new systems. By providing a sufficient degree of realism, evaluators can address how various elements may affect the simulated work practice and the use of the clinical information system (11; 13). During the clinical simulation, it is possible to observe the clinicians' interaction with the information system and to assess to what extent the information system influences work practices and the organization. Work practices that cannot be verbalized are not uncommon (14), and clinical simulation increases the visibility of such "invisible" work. Use of clinical simulation as a common ground for discussion of design and organizational issues does, however, not come by itself. A certain focus needs to be placed on using clinical simulation as a media for dialog and communication across different organizational groups and healthcare professions, with specific attention on the design of the simulation and evaluation set-up. Furthermore, the mandate of each of the participants needs to be clear.

The aim of this article is to describe how clinical simulation may be used as a boundary object to transfer and translate knowledge between different communities of practice. In the presentation, we will draw on related theoretical perspectives.

Boundary objects

Symbolic Interactionism considers meanings to be "social products," creations that are formed and transformed in and through the defining activities of actors, as they interact (15). When actors deal with the world of their objects and act in relation to it, this might result in creation and refinement of meanings. To understand the actions of people, it may be best to understand the worlds of their objects. Meaning thus created may be provisionally externalized through symbolic representations and concrete artifacts. Sometimes the same objects may appear in different worlds, which leads to a flexible interpretation and thereby a possible coordination between the actors of the different worlds. These objects are called Boundary objects. The next section expands on this topic.
Star and Griesemer (16) define boundary objects as "flexible epistemic artefacts that inhabit several intersecting social worlds and satisfy the information requirements of them." "They have different meanings in different social worlds but their structure is common enough to more than one world to make them recognizable, a means of translation" (p. 393). Boundary objects may be repositories (e.g. a library or a database), ideal types (e.g. a diagram or a roadmap), coincident boundaries (e.g. the boundaries of a state) and standardized forms (e.g. classifications). Objects become boundary objects when they are used at the interface of different communities of practice. A community of practice has a shared understanding of what the community does, of how it does it and of how it relates to other communities and their practices. A community of practice will develop the same world view or mental model (17). Boundary objects may be physical objects as well as symbolic objects. They are a kind of socio-technical hybrid spanning across boundaries of different worlds enabling and constraining knowledge sharing across boundaries (18) carrying information and context that may be used in translating, transferring and transforming knowledge between communities of practice (19). Boundary objects may be a sort of arrangement that allows different groups to work together without consensus, something people act against, toward and with (20). Technology may be considered a boundary object that can induce transformational learning in practices related to integrated design (21).

Carlile (19; 22) describes the following three approaches to knowledge boundaries in product development: syntactic, semantic and pragmatic. The *syntactic* approach to boundaries is based on the existence of a shared and sufficient syntax at a given border and ensures accurate communication between sender and receiver across a boundary to solve challenging communication or information processing problems (23; 24). The *semantic* approach recognizes that even though a common syntax or language is present, interpretations are often different, which makes communication and collaboration difficult. In product development, differences in meaning or language across functions are challenging (25) and make communication difficult because individuals use different meanings in their functional setting. Integrating devices should be seen as processes or methods for translating and learning about the differences and dependencies at a boundary. The *pragmatic* approach highlights the

importance of understanding the consequences that exist among things that are different and depend on each other. Here transforming knowledge refers to a process of altering current knowledge creating new knowledge and validating it. This may be done by letting users interact with prototypes (26). Integrating devices, in this case, suggests that knowledge has to be transformed and in order to create new knowledge old knowledge has to be changed.

Boundary objects may be used to evaluate structures within an organization (27) and can include computer-assisted design, sketches and drawings in design engineering (28) and as a strategic tool (29). Boundary objects are used for gaining a shared understanding of collaboration processes in the development of future collaborative processes, products, services and business models (30) and as a framework for modeling and categorizing organizational interfaces (31). Boundary objects can be seen as appearing in many places in eHealth, for example, in clinical documentation and classification (23; 32). To the extent that boundary objects provide stability, they do so through the consent of actors on all sides of the boundary (33). They involve the participation of actors from both sides of the boundary and professionals, who serve as mediators, and they exist at the border of the two somewhat different social worlds, but they have distinct lines of accountability to each of them.

Clinical simulation contains many objects and representations which themselves may be considered as boundary objects, and at a high conceptual level, an entire clinical simulation can be considered to be a boundary object itself. Apart from describing related theoretical perspectives to boundary objects, this article presents a case study where we describe how clinical simulations can be viewed as boundary objects to improve communication and shared mental models (i.e. "common ground" (34)), and what this approach can gain from the development of eHealth applications will be outlined and discussed.

Related theoretical perspectives

Shared mental models

Theoretical perspectives on shared mental models may elucidate how boundary objects support the process of achieving mutual agreement. The concept of mental models varies from field to field. A mental model of an IT system may consist of knowledge of the system or knowledge about the different tasks that may be performed in relation to the system (35) and may allow people to explain and predict the behavior of an IT system. Mental models help people to understand the world because they provide them with the possibility of constructing a working model in their minds and enable them to understand phenomena, to decide what actions to take and to control system mechanism (36). Scientists in cognitive science and cognitive psychology suggest that mental models are important to the more general understanding of how humans interact and cope with the world (37). Shared mental models for teams can be defined as "knowledge structures held by members of a team that enables them to perform accurate explanations for the task, and, in turn, to coordinate their actions and adapt their behavior to demands of the task and other team members" (p. 228) (31). In this article, we define mental models as described by Rouse and Morris (37) as a "mechanism whereby humans generate descriptions of system purposes and form, explanations of system functioning and observed system states, and predictions of future system states" (p. 360).

Mental models support interaction with the environment (35) and enable people to structure information in meaningful patterns (36; 37) containing several classes of information: concepts, features and their relationships (38). Mental models allow knowledge about situations, objects and environments to be classified and afterward reorganized based on their features (39). The purpose of mental models is that they support people in the description, explanation and the prediction of system behavior (37) and allow skilled decision-makers to forecast the outcome of a decision before it is taken (40). Mental models can also be used as means to evaluate a user's knowledge of the performance of a complex system supporting the analysis of effective and ineffective performance (41; 42). Shared mental models are valuable for improving system design and may be used to explain human cognitive functioning and human–computer interaction. They may also be used as common models of a problem or a situation (43), providing a context where communication can be interpreted and thereby giving a basis for predicting behavior and needs of other members (44). Shared mental models support decision making (40) and hence lead to an improvement in communication and coordination (45). Shared mental models do not imply identical mental models (31). Instead shared mental models are compatible mental models that lead to common expectations.

The degree of efficiency of collaborative teamwork depends on how well the team exchanges knowledge for continual learning and how well the team members develop shared mental models. Their individual mental mod-

els are bounded within their specialized practices and their work. Visualization enhances development of shared mental models (46) and is effective for improving shared mental models between negotiators and supports a pro-social climate. Visualization also supports communication and offers participants the ability to develop a sense of "what is seen" (47) which may be transformed into evidence. Thereby visual evidence may be perceived as being powerful. Communication in connection with visual evidence supports socialization. Problem solving in groups requires communication and collaboration, and communication breakdowns are often experienced due to differences in cultures, norms, symbols or representations. Supporting communication and the process of reflection within a shared context enhances the creation of shared understanding and may lead to new insight and new ideas (48). Technology may be used as a media for creating such environments providing opportunities and resources for design activities embedded in social debates and discussions actively involving all stakeholders.

Common ground

A similar idea to shared mental model that has been applied into healthcare is common ground. Common ground refers to the knowledge shared between two persons or agents communicating with each other (49) and thereby relates to the process of transferring and translating knowledge. The agents or persons involved in the conversation have to share knowledge about language and about the subject under discussion. In healthcare, discussions about a medical problem with a clinical colleague lead to very different conversations than discussions with patients. Messages may be concise and mutual knowledge may be assumed between colleagues. On the other hand, explaining an issue to a non-expert requires that the main message is sent along with background knowledge, which is needed to make the message understandable (34). Sharing of common ground may be seen as a key reason for similar agents to find it easy to communicate with each other.

Case study of clinical simulation as a boundary object

The case study described in this article concerns the design of electronic documentation templates and overview reports for nurses' initial patient assessment using clinical simulation (50). The case study took place in the Capital region of Denmark where a set of electronic documentation templates had previously been rejected by end-users and hospital management due to disagreement about the documentation procedure among the various stakeholders across the organization. Problems regarding acceptable time consumption due to technical difficulties as well as the need for rigorous design of the templates (i.e. clinical content, amount of structured fields and overview of patient data and differences in work practices) were key issues in the rejection of the templates. It was decided to address the organizational disagreements by redesigning the templates using a participatory design (PD) approach and clinical simulation through which the various stakeholders in the design process were to be thoroughly involved. PD focuses on involvement of stakeholders, overcoming organizational barriers and establishing ownership of the design solution within an organization (51). Three issues dominate the discourse about PD: (1) the philosophy and politics behind the design concept, (2) the tools and techniques supplied by the approach and (3) the ability of the approach to provide a realm for understanding the socio-technical context and business strategic aims where the design solution are to be applied (52). A core principle of PD is that stakeholders actively participate in design activities, where they have the power to influence the design solutions, and that they participate on equal terms (52; 53).

PD is not a predefined method, but an approach that includes a conglomerate of tools and techniques to be applied. These tools and techniques serve as ways to establish a shared realm of understanding based on the knowledge of how work is carried out, and how it can be carried out in the future, and may be used as boundary objects. Among these tools are observational studies, questionnaires, diagrams, pictures, photos, interviews, workshops, role-playing and simulated environments, mockups and prototyping[51] as well as clinical simulation.[50]

Methodological approach

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 that adjusted the documentation in accordance with the regional guidelines and accreditation requirements. In order to achieve this, it was necessary to gain consensus about the template design among the clinical nurses, quality units and nursing managers across the 12 hospitals in the region. Furthermore, the templates should be applicable for use by nurses in all types of bed wards. In essence, "one size had to fit all." Specifically, the re-design had to respond to all the major critiques that were disclosed from the first pilot implementation. As a result, it was argued that the templates should

- Handle highly structured data entry in an efficient manner. The previous highly structured data entry templates had led to increase in time to complete tasks (i.e. nurses had complained about the time taken to complete documentation using the templates).
- Support daily nursing work practices. During the first pilot implementation, focus had been mainly on fulfilling documentation standards and accreditation requirements.

Besides these specific demands for change within the templates, a main lesson from the first pilot implementation was that there are many stakeholders involved in nursing documentation. Not only do registered nurses in the wards have an interest in the design of documentation templates so do quality coordinators, regional planners and hospital managers.

Stakeholders (54) may also be called communities of practice (55) or social worlds (56). A community of practice is defined by Wenger et al. (55) as "groups of people who share a concern or a passion for something they do and who interact regularly to learn how to do it better." It is the combination of three elements—domain, community and practice—that constitute a community of practice. The knowledge of its members is communicated by unique vocabulary, artifacts and patterns of practice. In healthcare, both "domains" and "practice" are significant in relation to different specialities and different parts of the organization. Different communities in different hospitals may also differ in their cultural behavior, and clinical simulation can be used to evaluate how new technology supports daily work practice in different healthcare contexts. In the following, we will use the expression "community of practice" when talking about the different parts of both healthcare and technology organizations. The terms "community" and "practice" aptly describe the essential elements which differentiate the different groups involved in the design of the templates. Patient care processes are supported by teams or communities of health professionals, for example, nurses and physicians. Each newcomer to a health profession learns the language of care as part of the process of membership. This varies from community to community. A community may be a department or a speciality. Furthermore, a community may be a quality unit or a patient safety unit. In the case study, the different communities included different departments and hospitals, the quality unit in the region, clinical documentation experts, clinical management and the IT department, which was responsible for the design and the development of templates as well as the pilot implementation.

By choosing a PD approach for the re-design process, all communities of practice were actively involved in the design activities and had the power to influence the design solutions (52). Additionally, clinical simulation was used as a boundary object to translate and visualize the impact of the information system in work practice and thereby gain a shared mental model. By using clinical simulation, knowledge was transferred and transformed between the different communities of practice to support gaining a shared understanding. The aim was to overcome the organizational barriers that were experienced during the first pilot implementation of structured documentation templates. The first pilot implementation had led to considerable disagreement about the documentation procedures among the various communities of practice across the organization. The clinical simulation allowed the different groups to work together to arrive at consensus based on the simulation rather than preconceived notions.

The use of boundary objects is especially important when the communities are geographically separated, as in this case. The ability to work together is correlated to how well the geographically distributed communities share information and knowledge at the interfaces (27). This was also the case here. The quality control department is located outside the hospitals and the hospitals themselves are also geographically separated. Clinical simulation as a boundary object was used to represent, learn about and transform the knowledge to determine the consequences that exists at a boundary. It may explain how knowledge is localized, embedded and invested in practice, as described by Carlile (19; 22).

A core principle in PD is that communities of practice are actively participating in design activities, where they have the power to influence the design solutions (53; 57). The different communities of practice were invited to and took part in some of the central steps in the design process during the clinical simulation. In the end, the participants consisted of two regional quality experts, two hospital quality experts, one hospital director, four nursing managers from different hospital departments, six documentation nurses and two health informatics experts, who were experts in the design and configuration of documentation templates. All hospitals showed great interest in participating, and some of the hospitals actually asked to have more than one participant. It was, however, decided that each hospital had just one participant.

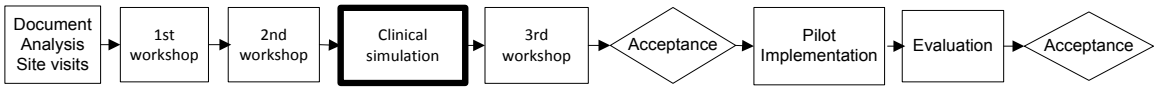


Figure 1 The re-design process including clinical simulation

The activities in the re-design process are illustrated in Figure 2. Before the first workshop, all relevant documents were analyzed and meetings were held with one regional quality expert, one nursing manager and one documentation nurse in order to develop a shared understanding of the internal disagreements and potential ways of addressing them, and site visits were conducted at various hospitals to gain knowledge about work practice. On the basis of document analysis and site visits, a prototype of the templates was developed. The templates were presented and used to initiate the development and discussions about user requirements and the need of clinical content at the first workshop. All communities of practice, that is, clinical nurses, quality managers and nursing managers from all the regional hospitals, attended the workshops as well as health informatics experts and technical experts. The nursing processes were compared to the features of the prototype. Modifications in content and user interface design were agreed on at the workshop, and after the workshop, the templates were modified according to the agreed changes. Issues, which the participants could not agree on, were noted and were to be dealt with at a later time, that is, at the next workshop, during the clinical simulation or after the pilot implementation. Follow-up meetings to the first workshop, where more detailed matters were settled, were held with a few representative nurses and quality experts before the second workshop. These details were discussed at the second workshop where a new version of the templates based on the comments was presented and discussed. Again not all issues were agreed on. Some issues were to be addressed in the clinical simulation, and some issues were to be addressed in the pilot implementation. Issues to be examined in the clinical simulation concerned the amount of structured data and the terms used to guide and label the structured spaces as well as support of work practice. Furthermore, the quality experts were asked to clarify some disagreements concerning how the regional standard was interpreted. Some of the clinical nurses wanted a space in the documentation to record how the patient felt, whereas other nurses wanted the patient's opinion to be part of the rest of the documentation. These disagreements were not actually positioned to specific hospitals or specific specialities, but were merely rooted in different graduate educational backgrounds. After the second workshop, the templates were further adjusted based on the outcome of the workshop. As such the meetings made it possible to take the discussions at the workshops to a higher level supporting a fast PD process.

The next step was to let a group of end-users simulate the use of the templates in a clinical simulation. In the first attempt to create the documentation templates, clinical simulation had also been used, but at that time, the purpose of the simulation had been to let the end-users evaluate the templates, and the outcome had afterward been discussed at a workshop with the different communities of practice. The end-users in the first attempt came from eight pilot departments located at eight different hospitals. In the second attempt, the pilot site was an entire hospital in the region instead of having pilot departments scattered all over the various regional hospitals. The idea was to prove that the templates were usable in an entire hospital and thereby usable in the rest of the hospitals in the region. In the second attempt, the participating end-users involved in the clinical simulation came from all departments at the pilot hospital. The purpose of the clinical simulation was broadened to focus not only on end-users but also to use the clinical simulation actively as an observation site and boundary object for discussions among the different communities of practice.

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 h. In some scenarios, one nurse made a full initial nursing assessment, whereas in other scenarios, half of the assessment was already documented and the nurse had to finish the documentation. Thereby, 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. Delegates from other communities of practice observed the simulation from an adjoining control 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 from the interview. The observers had also attended the workshops, and each delegate contributed depending on their background and organizational relation and each had well-defined roles and responsibilities (31). The purpose of the clinical simulation and the discussion that followed the simulation was not to gain unanimous consensus but, just as importantly, to provide input for others to make the final decision. The participants were in no way homogeneous either with respect to expertise, roles and responsibilities.

Results from the observations, interviews and discussions were gathered and presented at a third workshop. At the workshop, the final modifications to content and user interface design were agreed on. Issues that were not solved at the third workshop were noted and were to be examined during the pilot implementation. The prototype was modified and accepted by the regional patient record committee. Following that the system was evaluated during a 3-month pilot implementation at an entire hospital in the region. The pilot implementation was evaluated through field observations, clinical simulation in situ, audit of 50 patient records, questionnaires and focus group interview and technical monitoring. The evaluation served as basis for decisions on further implementation of the templates in all hospitals in the region.

Results

Use of clinical simulation as a boundary object resulted in an increased focus on the practical challenges when working with the templates on a daily basis, such as how to have a genuine conversation with a patient and concurrently document the conversation using a computer. The key differences between the first version and the second version of the templates were the following:

- Requirements for structured data were reduced to a minimum to ease the nurses' documentation processes. Many structured fields were removed, and a few were added.
- The overview of the patients' record was improved. The original overview was optimized and an additional version of the overview was designed
- Requirements concerning the content of the templates were aligned for most parts, and it was decided that minor elements would be evaluated during the pilot implementation. The modified content focused on the most generic areas and elements of the initial nursing assessment, e.g. details concerning hearing aids were reduced.

Table 1 Results from the question: Do you assess that the templates have increased the documentation quality? (n=140)

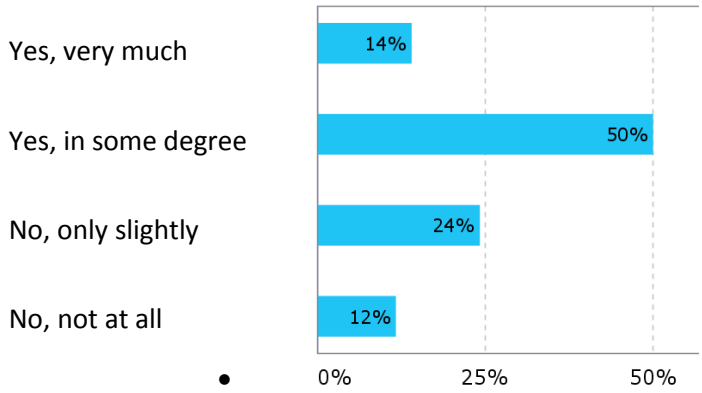
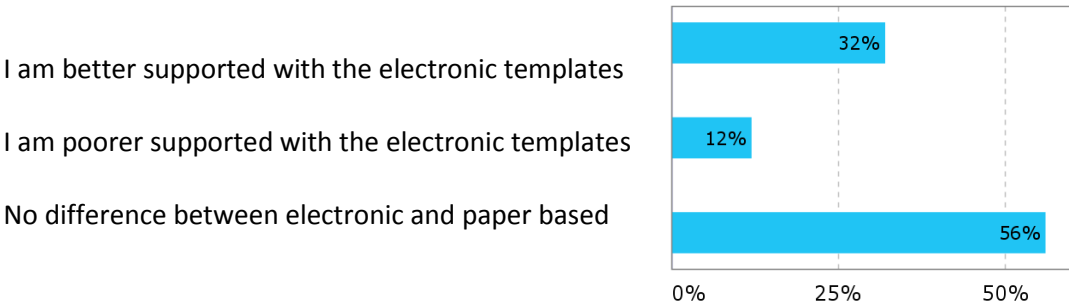


Table 2 results from the question: How do you assess the support and guidance from the electronic templates (n=140)



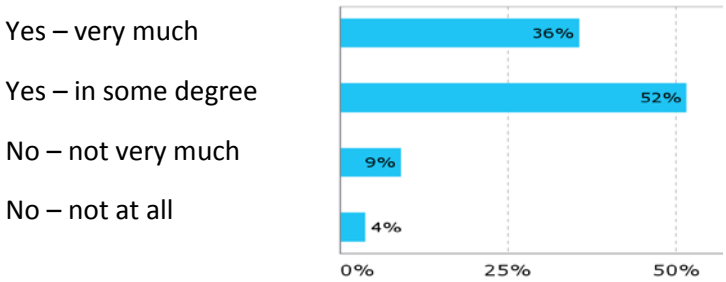
The evaluation of the implementation of templates at the pilot hospitals resulted in the following:

- *Higher quality of nursing documentation*. As shown in Table 1, 14 percent of the nurses perceived that the quality had increased considerably, 50 percent felt the quality had increased in some degree, 24 percent did not perceive any difference and 12 percent felt that the quality had decreased. The audit of 50 patient records showed increased documentation of the patients' habitual and actual condition in up to 25 percent of the electronic templates, as compared to paper-based nursing documentation. In the paper-based records, it was difficult to distinguish the patient's own assessment from the assessment made by the nurses.
- *Higher support and guidance*. As shown in Table 2, 31 percent of the nurses assessed that the templates supported their work very much, 12 percent assessed that the support had decreased and 56 percent did not experience any difference.

- Measurements of time spent in doing initial assessments showed an almost equal amount of time was used for documentation using paper-based documentation and electronic documentation. An observational study found that 10.07 min (mean time for 30 initial assessments) was spent in doing initial nursing assessments using the paper-based documentation, while 11.45 min (mean time for 14 initial assessments) was spent when using electronic documentation. Furthermore, six laboratory tests were conducted where the time spent on documentation of an initial assessment test case was measured. These tests indicated that 8.29 min was the mean time spent on paper-based documentation, while 9.18 min was the mean time spent on electronic documentation.

- In total, 87 percent of nurses would to some degree recommend the use of the templates. As shown in Table 3, 88 percent of the nurses would in some degree or very strongly recommend the implementation of the templates in other hospitals in the region.

Table 3 Results from the question: Would you recommend an implementation of the templates to other hospitals in the region? (n=140)



The evaluation resulted in the recommendation to continue the implementation, and the templates have now been implemented at all hospitals in the region. The representatives from each separate hospital who participated in the design process of the templates were each responsible for the implementation in the departments at their own hospital. These users did not have any problems in not being able to participate in the clinical simulation and the pilot implementation as long as users (nurses) from another hospital had already evaluated the templates. The implementation has resulted in changes in the documentation process at some departments in ways that depended on their existing processes. At one hospital, the templates were implemented as paper templates before the implementation of the electronic templates, and therefore, the documentation process was changed before the implementation of the electronic templates. At another hospital, a disagreement emerged concerning whether the templates should contain a separate field for the documentation of the patient's own view of their illness or whether this should be encompassed in the other fields. This disagreement has not been overcome yet; however, the templates are being used as planned. Overall, the implementation of the templates has been one of the most successful implementations in the region.

New documentation templates for psychiatric departments have also been developed, and the development of documentation templates for pediatric departments has also taken place.

The results of using boundary objects and the specific design method include the following:

- All communities of practice were involved and showed great interest in participating.
- Ownership was obtained by including all communities of practice in the process, leading to a wide adoption of the system in the organization.
- The gap between quality nurses' theoretical approach and the ward nurses' practical approach was overcome.
- Using clinical simulation as a boundary object helped to visualize the use of the templates and to obtain a shared mental model.
- Debriefing interviews and discussions and workshops helped to align expectations about the templates and gave input to final decisions about design and content of the templates.

Clinical simulations may be used as boundary objects. Clinical simulation as boundary objects are constructed at the intersection of the communities of practice of design and the use of clinical information systems. They reveal the divergences between the different communities, and during the process, they reshape the relations and shift alliances and the overall balance of power (58). Clinical simulation makes it possible to actively participate in design activities. Choosing a PD approach empowers the participants to influence the design solutions on equal terms, which ensures ownership in the subsequent implementation of the information system.

Clinical simulation also consists of many features and aspects which themselves may be been seen as boundary objects. We can also "open the box" and consider the objects (i.e. artifacts and activities) that make up clinical simulation that can be shared. As can be seen in Figure 3, these include simulation artifacts (i.e. scenarios and prototypes), activities (i.e. observation, interview and questionnaire) and evaluation artifacts (i.e. notes, screen recording, video recording and audio recording).

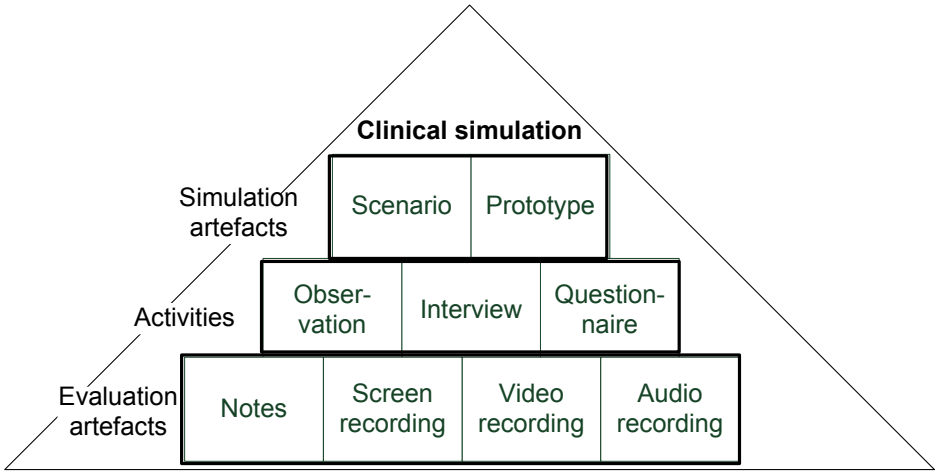


Figure 2 Artifacts and activities in clinical simulation

Simulation artifacts

Simulation artifacts are used during clinical simulation in order to simulate the use of technology for clinical work practice in clinical contexts.

Scenarios are used as basis for simulations. Scenarios are narrative descriptions of work practices, a kind of story about people and their activities (59) reflecting typical tasks in a smaller or larger fraction of work practice. Scenarios may be described as "springboards," artifacts serving as boundary objects, where scenarios represent the essential and typical aspects of a situation (60). A scenario can be regarded as an ideal type of boundary object (16), carrying information and context that can be used in translating, transferring and transforming knowledge between communities of practice (22). In the case study, scenarios were used to outline the context of clinical work practices that are being looked into as well as the content of the work practice.

Prototypes and mockups allow for commentary early in the design phase and offer a way to involve and consult communities of practice (61). In the case study, the prototype enhanced the communication between users and developers (62), but they can also be used to describe the work done by technicians (63). In relation to clinical simulation, prototypes are useful for participants and observers during the simulation and for the debriefing interview and discussion.

Activities

A range of activities are performed during the simulation and afterward as part of the evaluation. Evaluation activities involve both users and observers. The process of *observation* as a group became a group shared experience and a kind of boundary object. *Questionnaires* were not used in the case study, but they can be used as a supplement to interviews in evaluation studies. A questionnaire survey is a standardized method that may be used for common communication across dispersed work groups (16) and may hereby also be regarded as a boundary object. *Interviews* may in the same way be regarded as boundary objects. The results from the interviews were discussed in other situations and locations, and the different interviews took place in different places and time.

Evaluation artifacts

Evaluation artifacts are used for manual and electronic data collection during the simulation, during the evaluation and discussion with users and observers and afterward as part of the analysis and evaluation and at follow up workshops with different communities of practice. *Notes* and transcriptions from observation of users were shared and used for common discussion across the dispersed work groups in different situations and locations, and created shared mental models and shared understanding. *Recordings* from *screens* and *videos* as well as *audio recordings* may be used as tools for communication, discussion and transferal of knowledge across distance and time and offer the possibility of gaining shared understanding as the people watching and listening to these recordings may use this to gain a shared mental model. In the case study, recordings of the simulation were

not used. Instead, the results from the simulation and debriefing discussions were presented at the third workshop.

Clinical simulation and the various objects and representations were used as boundary objects to improve communication and shared mental models (i.e. "common ground" (34)). The participants subsequently reported that the clinical simulations had supported them in gaining a shared mental model, and the result was, as described by Rouse and Morris (37), that shared mental models can help in delineating the requirements of a new system (e.g. eHealth system) as well as providing shared understanding of how the system operates and was used effectively during the design process. None of the participants had experienced any problems related to the use of resources as their participation was highly prioritized in all parts of the organization.

Discussion

The simulation provided an important input about how to solve some of the practical challenges facing the daily work with the documentation templates and itself became a boundary object as it was used at the interface of different communities of practice. By observing end-users using the templates, the discussion among the different communities of practice served as common ground, supported a shared understanding and changed the focus to the usage of the templates from a less informed approach according to the stakeholders' own specific area and practice. Bowker and Star (23) argue that "the more at home you are in a community of practice, the more you forget the strange and contingent nature of its categories seen from outside" (p. 294). Clinical simulation is a pragmatic approach to considering boundary objects and visualizes the consequences and the impact of implementing an information system. Clinical simulation transforms the knowledge about a process and creates new knowledge. Things are depicted differently by different communities of practice and in different contexts (23) however, as in the example provided by Iansiti's (26) work on the role of prototypes, clinical simulation enhanced the process of transforming knowledge. In the first design round, the debriefing interview was not used to the same degree as a media for dialog and discussion. In the second round, clinical simulation as a boundary object provided the different communities of practice with the opportunity to observe and discuss the impact of the re-designed template and offered a way to manage the tension between divergent viewpoints, which was of great assistance in this case study, especially, concerning different views on content and structure of documentation. As some of the participants subsequently expressed, "We no longer discussed based on our own ideological attitude. Instead we gained a shared mental model to discuss from." Some communities of practice found that the highly structured nature of the templates limited the flexibility of 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 debriefing interviews and workshops and as part of the design process (21).

Prentice argues (64) that "surgical learning occurs at the interface of bodies and instruments, through simultaneous sculpting of the surgical site and training of the surgeons' body," a process she calls "mutual articulation." In the same way, clinical simulation provided the opportunity to investigate the impact of work practice before it affects the daily work in a hospital. Another way of expressing the use of boundary objects is stated by Bowker and Star: (23) "the medium of an information is not just wires and plugs, bits and bytes, but also conventions of representation, information both formal and empirical. A system becomes a system in design and use, not the one without the other." Clinical simulation provides the opportunity to observe the system in both design and use.

Not all communities of practice were able to participate either by using the information system themselves or by observing the use of the system. Therefore, the results were presented and discussed at a third workshop. At the workshop, issues addressed for the clinical simulation and new issues that had been identified during the simulation and the debriefing interview with the end-users were discussed. Not all issues were agreed on but had to be addressed at the pilot implementation. As mentioned, the pilot implementation was conducted at an entire hospital, and as a consequence, the benefits of using electronic templates became more obvious. In the first attempt, the initial nursing assessment had to be printed when the patient was moved from a department using electronic templates to a department using paper-based templates. Initial assessment documentation that had started out digitally but not yet finished was documented using paper-based template at the next department.

The major difference between the initial design project and the re-designed project was that the re-designed project used clinical simulation and a PD approach, involving a number of communities of practice, not only proponents of the highly structured nursing documentation. The simulation, the debriefing interview and the subsequent workshop made it possible to achieve the mutual clinical agreement on the actual content of the templates and thereby design. Furthermore, the meetings prior to and in between the workshops allowed all the

community of practice an opportunity to voice their point of view and to affect the final result. The templates were regarded as "one size fits all" templates for adults with somatic illnesses. Although the psychiatric departments and the pediatric departments were not able to use the templates, new documentation templates for these departments have now been developed using the same design process as in the case study with the original templates as a basis for the design.

Implications of clinical simulation as boundary object for eHealth

The complexity of both organizational and work practices in healthcare creates challenges regarding the choice and application of methods used for the development and implementation of clinical information systems (65). As in the case study, the complexity of health organizations and the varied types of healthcare actors complicate the specification of user requirements and the design and implementation of clinical information systems. These issues in eHealth influence the cost and resources needed in acquiring and implementing new technology at hospitals as well as adoption afterward and may be due to lack of acceptance and lack of understanding among end-users. As described in the case study, clinical simulation may be useful in gaining shared mental models and shared understanding of user requirements, work practice and organizational requirements. The study of boundary objects provides a significant way to analyze these issues and can serve as a reflective approach to improve solutions to the problem. This case study shows that the adoption and acceptance of new technology may be greatly improved by involving end-users as well as other parts of the organization in both the design of new technology and the design of future work processes. If users are not adequately involved in these processes, the new technology developed may end up endangering patient safety and result in unintended events and increased mortality.

Considering clinical simulations as boundary objects in the design phase of the development of clinical information systems offers a means to transfer knowledge from one part of the organization to another and thereby creates shared understanding of complex work practices and requirements. In the case study, organizational differences were overcome, and shared understanding was made possible in achieving a mutual clinical agreement on the basis of shared mental models and joint discussions. Acceptance of new technology may be gained by giving voice to the different communities of practice and thereby supporting the acceptance and use of new technology.

Other case studies (13; 66) show the possibilities in having different healthcare actors participate in clinical simulation and subsequent debriefing discussion. Clinical simulation as a boundary object offers an opportunity to create a space where healthcare professional working in different locations or healthcare sectors can meet and exchange knowledge about work practices and requirement needs. This approach proved effective in identifying important unintended benefits or challenges (13), gaining knowledge about the effect that new technology may have on work practices (66), or patient safety issues (67).

Conclusion

We conclude that clinical simulations (and their components) can be considered and used as boundary objects for transferring and translating knowledge among different communities of practice. In the case study described in this article, clinical simulation helped in transferring knowledge from one community of practice to another and helped different parts of an organization in gaining shared understanding about needs and requirements. Clinical simulation offered a means to achieve a mutual clinical agreement on the design of a new information system. Furthermore, subsequent discussion allowed all the communities of practice an opportunity to voice their point of view and to affect the final result. We recommend that the use of clinical simulation as a boundary object should be expanded and propose further research in this area. This might involve further identifying, characterizing and optimizing components of clinical simulation that serve to promote shared understanding. Comparisons among different types of boundary objects, including their forms and formats, could be conducted in order to identify optimal ways of providing shared understandings among different stakeholders in the design, deployment and testing of health information systems. We are currently undertaking such work and find the approach to considering clinical simulations in the context of boundary objects as promising.

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Clinical simulation: A Method for Development and Evaluation of Clinical Information Systems

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Abstract

Use of clinical simulation in the design and evaluation of eHealth systems and applications has increased during the last decade. This paper describes a methodological approach for using clinical simulations in the design and evaluation of clinical information systems. The method is based on experiences from more than 20 clinical simulation studies conducted at the ITX-lab in the Capital Region of Denmark during the last 5 years. A ten step approach to conducting simulations is presented in this paper. To illustrate the approach, a clinical simulation study concerning implementation of Digital Clinical Practice Guidelines in a prototype planning and coordination module is presented. In the case study potential benefits were assessed in a full-scale simulation test including 18 health care professionals. The results showed that health care professionals can benefit from such a module. Unintended consequences concerning terminology and changes in the division of responsibility amongst healthcare professionals were also identified, and questions were raised concerning future workflow across sector borders. Furthermore unexpected new possible benefits concerning improved communication, content of information in discharge letters and quality management emerged during the testing. In addition new potential groups of users were identified. The case study is used to demonstrate the potential of using the clinical simulation approach described in the paper.

Keywords

Clinical simulation, eHealth, evaluation, human factors, clinical information systems, clinical practice guidelines

Introduction

eHealth is extremely complicated due to the substantial complexity of organizations, work practices and physical environments in healthcare. These matters greatly influence the development and application of IT in the healthcare sector. Additionally, poor eHealth puts patient safety at risk. Up to 70% of patient safety incidents are estimated to be related or due to human factors (1). Human factors are very difficult to evaluate by use of quantitative testing methods (2) as quantitative methods are limited in describing and characterizing underlying cognitive processes. The study of human factors is also called ergonomics and may be described as the "scientific discipline concerned with the understanding of interactions among human and other elements of a system, and the profession that applies theory, principles, data and methods to design in order to optimize human well-being and overall system performance" (3)[p2]. The impact that information systems may have on clinical work practices is also difficult to assess by use of quantitative methods, necessitating application of qualitative approaches. Clinical simulation has gained acceptance during the last decade as a powerful qualitative method for evaluating clinical information systems and their impact on human factors and work flow (4;5).

A simulation or a simulator may be defined as a device "that attempts to re-create characteristics of the real world" (6)[p52]. This may be real work actions or processes. Simulation has been used for training clinical skills for more than 40 years (7-10). Also social-team-oriented and cognitive-individual-oriented aspects of clinical work practice may be

trained by use of simulation (11-13). During the last decade simulation has gained a growing place in the design and evaluation of clinical information systems (4). Simulation testing can be a beneficial method for evaluation of clinical information systems, as the tests can take place in controlled environments, without the risk of injuring real patients (14). Simulation based evaluation may take place in all phases of the life cycle of a clinical information system (15), and may be used for a number of different purposes (5).

Simulation can also be used for testing IT-systems in new contexts. This may involve consideration of performance optimization, safety engineering, modeling of natural or human systems, examining effects of alternative conditions and courses of actions when real systems are not accessible (4;16-18).

Simulation may be conducted with (17) or with-out end-users, or as a hybrid, where simulations with end-users are combined with computer-based simulations (4). This paper focuses on simulation with real users enacting realistic clinical work scenarios; subsequently called clinical simulation. Clinical simulation should cover the sociological aspects in the socio-technical interaction, and these kinds of tests are focused at the "*human-in-the-loop*" as opposed to computer-based simulations focused on the "*computer-in-the-box*" simulations (16).

In the Capital Region of Denmark clinical simulation has been applied since 2007 for evaluation of clinical information systems before they are implemented at the hospitals in the region. The clinical simulations take place at the IT Experimentarium (ITX) (17;19), which is located at the Danish Institute for Medical Simulation (DIMS) (20) at one of the major university hospitals in Copenhagen. The ITX-lab was established in 2007 with the purpose of improving the quality and optimization of clinical information systems. The results have been promising, and since 2011 it has been mandatory to conduct clinical simulation evaluations before new systems that affect clinical work practice are implemented. In the last 5 years there have been more than 20 clinical simulation studies conducted in the ITX-lab to improve the development of activities and assist in the evaluation of clinical information systems (17). The simulation studies vary from design of computerized clinical support (21;22) and standardized nursing documentation (23) to evaluation of the impact of innovative technology (24;25). This has included evaluation of various kinds of clinical information systems ranging from Computerized Prescription Order Entry (CPOE) for medications (26) and clinical documentation templates (27) to the evaluation of entire Electronic Health Records (EHR) (28).

Usability may be defined as the "extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use" (29)[p3]. When using simulations it is possible to assess the effect of an information system in different contexts as well as evaluating efficiency, satisfaction and effectiveness (30). Efficiency may be defined as "resources expended in relation to the accuracy and completeness with which users achieve goals" (29)[p3], effectiveness may be defined as "accuracy and completeness with which users achieve specified goals" (29)[p3], and satisfaction may be defined as "freedom from discomfort and positive attitudes towards the use of the product" (29)[p3].

The aim of this paper is to describe a methodological approach for planning, preparing and conducting clinical simulations. The method is a generalization gleaned from our experiences from more than 20 studies where clinical simulation has been used to support the design, evaluation and optimization of clinical information systems before launching them in real practice. In this paper one simulation study of a prototype for a planning and coordination module will be used as a running example (25). In addition, some of the unintended consequences and benefits discovered during the evaluations will be discussed. In the end key issues and a methodological approach, in form of 10 steps to conduct a successful simulation will be highlighted.

Materials and Methods

Case study

In this section of the paper a case study involving clinical practice guidelines will be presented and the case study will be used to illustrate our approach to clinical simulations. Clinical practice guidelines have been used more frequently in recent years (31). Continuity of care programs, containing clinical practice guidelines aimed at planning and decision support for healthcare professionals, have been a focus of some of recent work (32). The Capital Region of Denmark is exploring the potential benefits of an information system for supporting the planning and coordination of chronic patient across sectors (33). Patients with Chronic Obstructive Pulmonary Disease (COPD) and Diabetes Mellitus Type 2 (DM2) were selected to establish a proof of concept project. At that time there were no information systems supporting coordination and planning across community nursing, general practitioners and hospitals in Denmark. The consequence was limited planning and reduced coordination across the three sectors followed by decreased quality and compliance with clinical practice guidelines. International experiences indicated that information systems can enhance compliance as well as quality of care so such systems began to be considered (34;35).

The project called "Chronic 5" was launched and aimed to demonstrate the potential benefits of a Planning and Coordination Module (PCM) (36). The project analyzed and specified the requirements for such a system involving clinician end-users, clinical managers, quality managers, IT-architects and health informatics experts. In the end a PCM prototype was built on the basis of the gathered requirements.

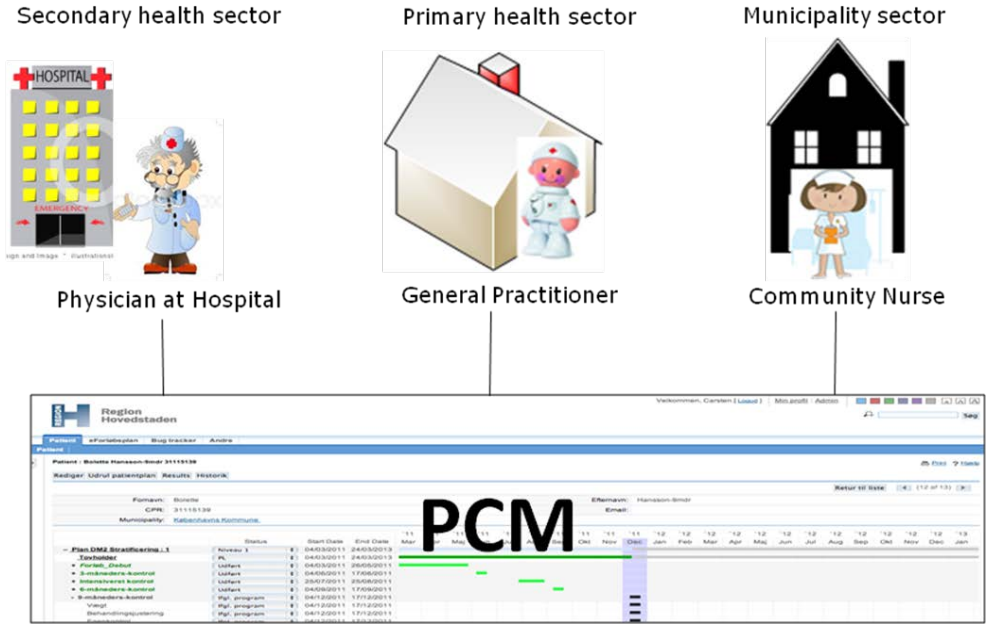


Figure 1: the PCM and users from different sectors

The purpose of the PCM was to support the coordination across sectors, concerning status and planning for patients with COPD and DM2 according to clinical practice guidelines, and handling of derived activities and services. Figure 1 shows the connection between user groups and the PCM. The digital support was anticipated to be groundbreaking in Denmark, and was hoped to offer new opportunities for coherence and continuity in care activities. Moreover it was expected that the system would be able to ensure a higher compliance with the existing continuity programs and clinical practice guidelines.

To realize the intended benefits of a PCM the usability of the system was essential (37). The objective of the simulation study was to assess the potential benefits of a PCM for health care professionals involved in planning and coordination of patients with COPD and DM2, primarily focusing on effectiveness and usefulness of the PCM and user satisfaction. Prototypes may be evaluated in relation to accuracy and completeness with which users achieve specified goals, but evaluations of the resources spent in relation to this is difficult with prototypes and immature systems, and efficiency cannot be assessed. The clinical simulation approach is well suited for assessing user satisfaction in realistic contexts of use.

Nine hypotheses have been proposed in the project discussed in this paper as a case study:

1. The PCM will increase clinical utility by allowing users to easily see recommended activities in the Continuity Programs

2. The digital plan for recommended activities will lead to improved decisions

3. It will be easy for users to adjust the course of disease for a chronic patient in a standardized program

4. The PCM will increase clinical utility by allowing users to get an overview of the plan and activities in the course of disease for a patient

5. The PCM will increase clinical utility by allowing users to see the activities and responsibilities in the course of disease

6. The PCM will increase clinical utility by allowing users to see relevant diagnoses for co-morbidity and complications, relevant findings and referrals in a separate window

7. The PCM will increase clinical utility by allowing users to use an assisted referral without having to re-enter data

8. The PCM will increase clinical utility by allowing users to monitor compliance in the Continuity Programs

9. The PCM will increase the utility if patients can easily access data

The nine hypotheses were to be verified or falsified in order to demonstrate the usefulness of the system.

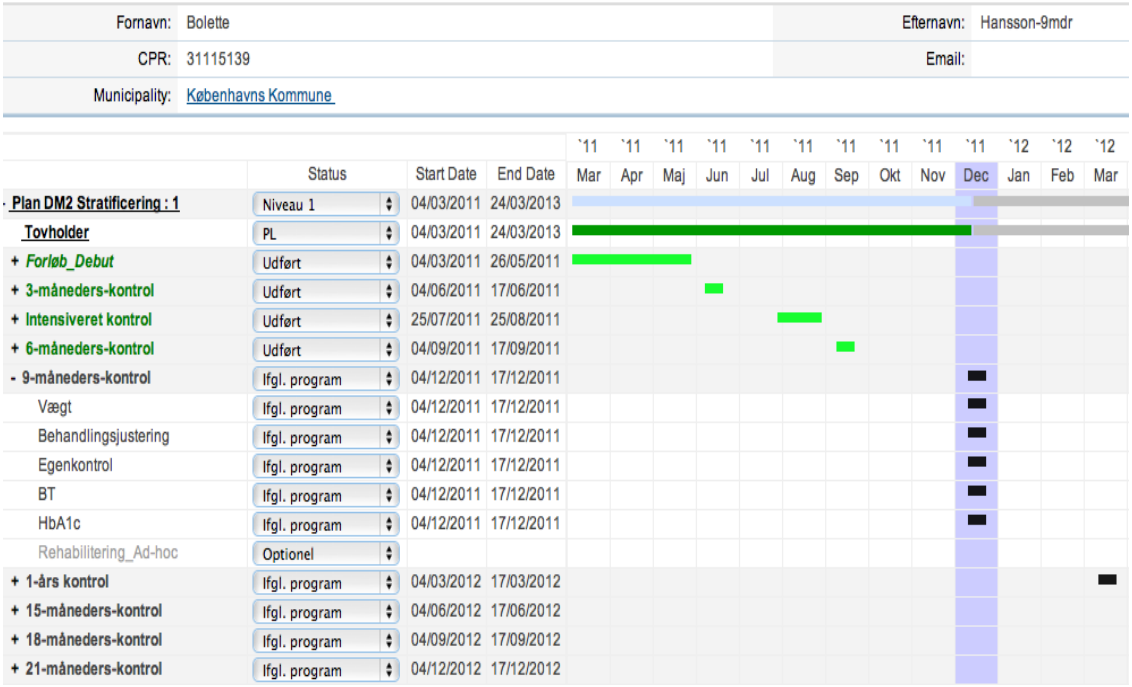


Figure 2: user interface of a 9 month plan for DM2 patients

Figure 2 shows an example of the user interface of the system. The column furthest to the left consists of activities and check-ups in relation to the continuity of care programs (i.e. measurement of blood pressure or weight and 1 year check-up), the second column from the left shows status for the activities (i.e. planned or done) and the third and fourth column from the left shows starts and end dates for activities and check-ups. The columns to the right show what activities have taken place at a certain date. Every line is an activity or a check-up according to the clinical practice guidelines in the continuity program for a certain area of disease.

Method

A clinical simulation study makes it possible to evaluate the use of a prototype in realistic environments (38) and is well suited for evaluating potential impact (26) as well as cognitive processes and usability (2). The overall approach we propose and describe in this paper involves the following four steps: Purpose, Planning, Preparing and Performing (see Figure 3). In this section we will describe the overall methodological approach and illustrate each stage of the approach in the context of the case study described in the previous section.

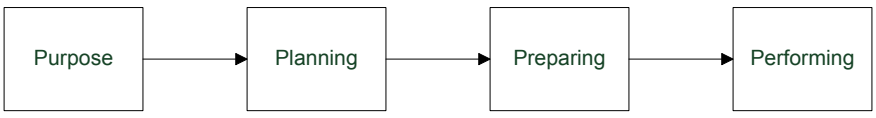


Figure 3: Steps in engineering clinical simulation

Purpose

In the initial phases the purpose of clinical simulation may include analysis of work practice and user requirements, followed by design and evaluation of new technologies. Later on the purpose may include implementation aspects such as assessing training programs and the influence of new technology on existing or new work practices.

In the design phase clinical simulations may be used as a boundary object to gain consensus among different stakeholders; e.g. helping to develop common understanding between end-users and the quality unit (27). Clinical simulation makes it possible for different stakeholders to observe new technology in use and the de-briefing interview and discussions that are part of simulations provide an opportunity for obtaining an understanding of work practices and user needs. Clinical simulations thereby assist in revealing divergences between different stakeholders and make it possible to gain an understanding of other stakeholders' views. This may be as part of a participatory design approach making stakeholders actively involved in the design activities and influence the design solutions (23). The clinical simulations may also be preceded by several design workshops with all stakeholders, where prototypes are built.

Clinical simulation also makes it possible to assess the needs for training and information before an actual implementation takes place. Knowledge concerning work practices and patient safety issues may be gained, and used as important inputs before or during a pilot implementation.

When conducting simulation studies it is important to define the purpose from the beginning (39). As indicated in figure 2 the purpose influences the planning and preparing of the study and establishes the scope of the actual performing of the evaluation. It is therefore important that the purpose is defined in close cooperation with the key stakeholders and accepted by the owners of the project (40).

> *No 1: The purpose of the clinical simulation must be focused and anchored in the organization*

To illustrate, the purpose of our running example, i.e. the evaluation of "Chronic 5",was to evaluate the potential benefits of a PCM for healthcare professionals involved in planning and coordination of patients with COPD and DM2, which means that it was mainly the effectiveness of the PCM, that was evaluated, with a partial focus on user satisfaction (as noted above efficiency of the system was not evaluated during this round of clinical simulation). The purpose was defined in close collaboration with the core group of the project which represented the most important stakeholders such as quality managers, clinical managers, IT-architects and end-users from all three sectors and it was subsequently accepted by the steering committee of the project. The PCM was a prototype built to demonstrate the concept of such an information system and as such the user interface was merely a presentation of what such a system could look like. The main focus of the study was therefore on evaluation of potential usefulness of the system more than on the ease of use. The steering committee had decided that the clinical simulation should encompass healthcare professionals only and not patients, thus no real patients were included in the evaluation.

Planning

After defining the purpose the next phase is planning and defining the scope for the evaluation. This includes defining which scenarios to use, deciding how many rounds of evaluations are to be conducted and determining the number and profile of the participating clinicians. The number of rounds of evaluation depends of the number of scenarios that needs to be evaluated, the amount of participating clinicians and the purpose of the evaluation.

No 2: Choice of scenarios is crucial and must reflect the purpose of clinical simulation

Each scenario reflects typical tasks in a small fraction of the clinical work practice and together the scenarios used in clinical simulation should more or less cover the parts of work practice that the new technology affects. Scenarios are narrative descriptions of work practices; a kind of "story" about people and their activities (41). Scenarios may highlight goals suggested by the appearance and behavior of the technology, and how people try to interact with and what they carry out with using the technology. Scenarios have characteristic elements such as environments and settings, and include actors. They include sequences of actions and events, things actors do and things that happens; i.e. changes in circumstances of the setting. The choice of scenarios affects the entire evaluation and must be considered carefully in order to meet the objectives of the evaluation.

The profile of the clinicians who participate in the clinical simulation must be defined. This concerns both the role of the potential users and the expectations to their participation during the evaluation (42).

If the evaluation covers broad functionality used in many different specialties and by many different groups of healthcare professionals, the number of evaluation scenarios tested must be greater than in evaluation of technology only used by physicians from a very specialized field for a very specific purpose. Depending on the purpose of the study, clinicians with several years of experience may be preferable rather than recently qualified clinicians in order for them to focus on the technology instead of focusing on their performance of the clinical skill. This may however not always be appropriate, as some studies may focus on use of technology by novice clinicians. Again the purpose of the evaluation decides the choice of profile for the clinicians.

No 3: Choice and profile of clinicians must reflect the purpose of the clinical simulation

In our running case study example, 5 scenarios were created. The scenarios covered key aspects in the coordination across sectors, and concerned status and planning for chronic patients according to the clinical practice guidelines. Since the POC was covering two patient groups; patients with COPD and patients with DM2, we ended up with 10 scenarios. The user groups were defined as hospital doctors, general practitioners and community nurses. Patients were not included in the evaluation and it was therefore decided to let team members act as patients during the simulations. It was decided to let 6 clinicians from each user group participate in the evaluation. The result was 18 simulation runs bundled into six rounds, where one from each user group was represented in each round. The profiles of the clinicians covered both management level and expected end-users.

Preparing

When the overall frame for the evaluation has been planned out the actual test has to be prepared. This includes finding potential users, writing the scenarios as well as preparing the clinical and technical set-up (22). The clinical set-up should reflect the real settings

No 4: Complexity in scenarios and patient records must be carefully considered

and the technical set-up must support the expected use of the system according to the scenarios, tasks and work practice.

The resources spent on preparing simulation studies can be rather expensive and time consuming, depending on the degree of fidelity and must therefore be carefully chosen and must correspond closely to the purpose (26;30).

The time spent with end-users in the actual simulation is however not that time consuming. By preparing the clinical and technical set-up carefully, the time spent by physician and nurse participants may be only a couple of hours for a session, depending on the evaluation set-up and the scenarios.

No 5: Planning and preparing clinical simulation is resource demanding in order to make it time effective for clinicians

Figure 4 shows the general relationship among the purpose of the evaluation, the degree of fidelity needed during the simulation and the different phases of the life cycle of clinical information systems (5).

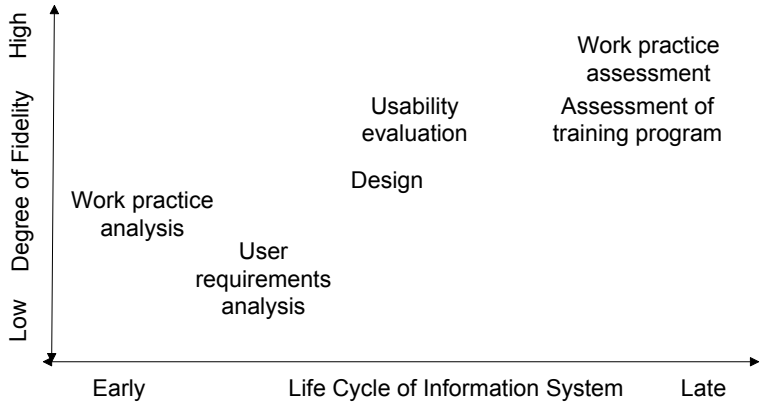


Figure 4: Clinical simulation and degree of fidelity during development life cycle

The need for fidelity varies depending on the purpose of the clinical simulations, and the phase of the life cycle of the information system. The degree of fidelity involves attempts to re-create characteristics of the real world (6) and may include equipment fidelity, environment fidelity, task fidelity and functional fidelity (30). The equipment and functional fidelity corresponds to the maturity of the system and the phase of the development life cycle, and the task and environment fidelity may be changed according to the purpose of the simulation study.

Analysis of user requirements may be conducted with the use of different degrees of fidelity; both in connection with high fidelity tasks in form as well described scenarios and high fidelity equipment and functionality in form as mature prototypes with realistic test data (26) and in a more experimental way with use of low fidelity equipment and functionality (43). A "wizard-of-Oz" approach may be used in the latter, where cardboard boxes replace equipment and a person simulates the response and functionalities from the system in form of handwritten post-it labels (43). The "Wizard of Oz" method offers interactive experience without having a real computer system and may produce adequate input to identify user requirements or explore key tasks in controlled environments (44;45).

No 6: Degree of fidelity must reflect the purpose of the clinical simulation and the maturity of the technology

Rehearsals are well worth the effort to pilot test the simulation before bringing in the test participants for real simulation runs. Rehearsals may be conducted on scenarios, clinical set-up, technical set-up, test data implemented in information systems, and data collection.

No 7: Rehearsals and pilot studies are important and well worth the effort

In our running example the fidelity of tasks and environments were relatively high. The scenarios reflected the everyday life and health of patients with COPD and DM2 and the planning and coordination done by the healthcare professionals involved in their treatment and care. The task fidelity was also high reflecting real tasks typically performed by the healthcare professionals. The simulation room was set up as an office, which could simulate an office in all three sectors. The technology and functional fidelity was not as high; it was an electronic prototype built to demonstrate the concept of a PCM with just enough functionality needed for assessing usefulness and as such the user interface was merely a presentation of what such a system could look like. Even though it was installed on a PC, there was no real integration and log in with other systems.

18 healthcare professionals participated as subjects: six general practitioners from primary care, six nurses from Community nursing, six hospital doctors and two simulation patients. The simulation runs were bundled into six tests. In each test healthcare professionals from each of the three areas participated, and the profiles of testers covered both the management level and the expected end-users. Ten scenarios were composed; five with a patient diagnosed with COPD and five with a patient diagnosed with DM2. The scenarios represented situations involving planning of therapy and further diagnosis concerning a recently diagnosed patient at the general practitioner, visitation with a community nurse, rehabilitation with the community nurse, treatment of the patient at an outpatient clinic due to exacerbation of the condition, and assignment of responsibility from the hospital doctor to the general practitioner. The scenarios did not cover all possible uses of the PCM but represented different points of impact focusing on core functionalities and the assignments from one healthcare professional to another, since these aspects were the main topics for the assessment. Issues such as user interface colors, buttons and minor functionalities were not as such part of the assessment.

The scenarios were composed in a way which made it possible to assess the nine hypotheses. The same general tasks were performed by the participants during the tests: 1) read relevant information in the system, 2) document relevant actions, 3) adjust the plan for the patient. The scenarios were tested and adjusted at a rehearsal one week before the actual test.

Performing

Before an actual simulation takes place it is important to introduce the participants to the purpose and the concept of the test e.g. that it is the system that is being tested and not the participants' performance. It is also important to introduce the system and all relevant functionalities of the system needed in the scenarios. Opportunity and time spent on hands-on tasks should reflect the purpose of the evaluation. In evaluation of the intuitiveness of a system, users might not be offered the opportunity of getting highly acquainted with the system beforehand. In some studies, more extensive training on the system might be provided before the evaluation (this will depend on the purpose of the evaluation).

After the introduction and training, the healthcare professional, who is performing the simulation, is briefed to both the environment and the scenarios. This includes the loca-

tions, the patients and possible colleagues who are part of the scenario from the beginning, and the part of the clinical work practice the scenario is covering. Depending on the purpose of the evaluation, there might be simulated disturbances incorporated in the scenario, which the healthcare professional should not know of beforehand (26). It is however important that the participant should be able to feel comfortable about the simulation in order to focus on the scenario and technology instead of the simulation (30).

A facilitator may be located in the simulation room in order to support the clinician in the use of the technology and during the simulation of the scenario. Depending on the purpose the facilitator may stay as a "fly on the wall" and remain unobtrusive or alternatively actively engage with the clinician. If a high degree of fidelity is required the facilitator should engage as little as possible, in order to make the simulation flow naturally. All interruption will interrupt the cognitive processing of the clinician and the acceptance of the simulation, and lower the perceived realism (30).

If possible the participant may be asked to "think-aloud" during the simulation in order for the observers to gain a deeper understanding of the human task-behavior (46). This method helps reveal the more cognitive aspects of the interaction between users and technology and is useful when analyzing user requirements. Depending on the purpose of the test, the "think-aloud" method can be supplemented with obser-view, where a facilitator asks more exhaustive questions about the system use and requirements (25;47). It is also possible to make the participant describe the system and the functionalities in a fairly natural setting by letting a "patient" or a "colleague" ask questions about the system and the use of it during the simulation (22). In order to create a high degree of fidelity it is important that the participating clinicians have great familiarity with real work practice. Often clinical and quality managers are offered to be the participating clinicians but they are not always familiar with the work processes in real life. Their knowledge is more focused on how work should be done instead of how work is actually done. If the participants are not familiar with work practice the simulations are conducted under false pretense and the outcome may not be valid. Clinicians with extensive experience in testing and evaluation of health IT may also think of themselves as testers instead of clinicians (40).

No 8: Real clinicians should be used as participants

If the simulation room has an adjoining control room the simulation instructor and observers may follow the simulation through a one-way mirror. The role of the instructor is to instruct the facilitator and the patient during the simulation. The test instructor has the overall responsibility for the test, and makes sure, that the purpose of the simulation is fulfilled. During the simulation the instructor is in radio contact with the facilitator and the person(s) acting as patient(s) or colleague(s). The instructor is thereby able to steer the simulation in any direction necessary to attain the objectives of the test. The observers monitor the simulation and makes notes of their observations. Semi structured observation guides may be used for observations. The observations are later used in the debriefing-interview, and in the evaluation report.

In our running case study example the participants had only short time with hands-on access to the prototype to be used in the simulation. Table 1 shows the schedule for one of the three days. Each day was partitioned into two parts with three clinicians coming in in the morning and three new clinicians coming in at noon. The first scenario was performed by the general practitioner, the next two scenarios were performed end to end by the community nurse, the fourth scenario was performed by the hospital physician and the fifth and last scenario was performed by the general practitioner.

Table 1: Daily schedule of clinical simulation

Time	Activity
8.30 – 8.35	Presentation of schedule, preparation and tasks
8.35 – 8.50	Preparation of simulation room and control room
8.50 – 8.55	Gathering up
9.00 – 9.30	Introduction to clinical simulation and IT-system
9.30 – 9.40	Hands on
9.40 – 10.00	Clinical simulation: general practitioner
10.00 – 10.20	Clinical simulation: Community nurse
10.20 – 10.40	Clinical simulation: Hospital doctor
10.40 – 11.00	Clinical simulation: general practitioner
11.00 – 12.00	De-briefing interview
12.00 – 12.30	Lunch
12.30 – 13.00	Introduction to Clinical simulation and IT-system
13.00 – 13.10	Hands on
13.10 - 13.30	Clinical simulation: general practitioner
13.30 – 13.50	Clinical simulation: Community nurse
13.50 – 14.10	Clinical simulation: Hospital doctor
13.10 – 14.30	Clinical simulation: general practitioner
14.30 – 15.30	De-briefing interview
15.30 – 16.30	Instant data analysis and recapitulation of test

During the clinical simulation the participants performed the tasks associated with the scenarios. As part of the scenarios a patient was seeking the health care professionals. The role of the patient was played by a health informatics expert with special knowledge concerning clinical simulation. In all scenarios the healthcare professionals were asked to revise and modify the plans for the patient. This was done in cooperation with the patient and on the basis of the existing findings and plans. The prototype included simulated integration with other hospital information systems in order to replicate the intended integration with legacy information systems.

Figure 5: Simulation set up: from left “patient”, clinician and facilitator

As shown in figure 5 a facilitator sat next to the participating clinician during the scenario, facilitating the simulation and helping the clinician in case problems arose using the system. This was due to the rather immature prototype, the short usage of the system, and furthermore the purpose of the test was to assess efficiency and to a lesser degree satisfaction (since the prototype was meant as a demonstration of the concept). Ease of use was therefore not the main focus of this simulation, although it has been the focus of

other studies we have conducted. During the simulation the participant was asked to "think-aloud.

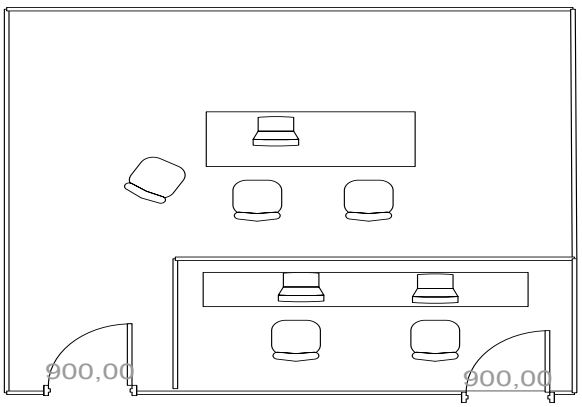


Figure 6: overview of the simulation set-up

The simulation room had adjoining control rooms as shown at figure 6. In the control room the simulation instructor was located together with two observers. The observers were representatives from the different stakeholder groups. Furthermore the two clinicians, who were not doing simulation at the time, were able to follow the simulation from the control room. This helped them to understand the use of the system and the potential use across the three sectors.

Data collection and analysis

Clinical simulation evaluation may be carried out by use of qualitative and quantitative methods (48). After each set of simulation scenarios are completed the participating clinicians are asked to fill out a questionnaire and a debriefing-interview is held with the clinicians and the observers. The questionnaires must reflect the purpose and may contain questions concerning efficiency and satisfaction, as well as questions concerning the simulations and the realism of the scenarios.

The interview guide may be composed of open-ended questions starting with a couple of overall questions concerning positive and negative features of the system (49). Afterwards more specific questions can be asked in order to let the healthcare professionals clarify and elaborate on both the questions from the questionnaires and other subjects that came into their mind. The composition of questions should reflect the purpose of the test. The interviews may be held individually or in focus groups. At the end of each day the data from the interviews may be analyzed using the Instant Data Analysis method (IDA) (50). IDA is a cost-saving analysis technique which allows usability evaluations to be conducted, analyzed and documented in just one day. In a case study from Aalborg University, Denmark it was discovered that in only 10% of the time required to do video data analysis, IDA identified 85% of the critical usability problems in the evaluated system. IDA is conducted right after the evaluation has taken place and observers and facilitators from the usability evaluation participate in it. On basis of observations and notes from the simulations and debriefing interviews, usability problems are identified, described and categorized. The IDA facilitator subsequently types up the findings.

1. *No 9: Cost saving analysis methods like IDA are very useable and can be practically applied to analyze the resultant data*

In some simulation studies it may be necessary to do the analysis in a more traditional manner such as using video data analysis or Grounded Theory. However, these methods are very resource intensive, and choice of data collection and analysis should recommendable reflect the purpose of the evaluation. Observations from simulations, results from IDA and notes from observations and interviews may be analyzed using analyzing tools such as e.g. Nvivo (51).

The results from the evaluation are gathered in a report describing the duration of the clinical simulation and evaluation. On forehand it must be clarified for whom the results should be presented and the results and recommendations are to be used and implemented. It must also be clear what the mandate of the clinicians and observers are.

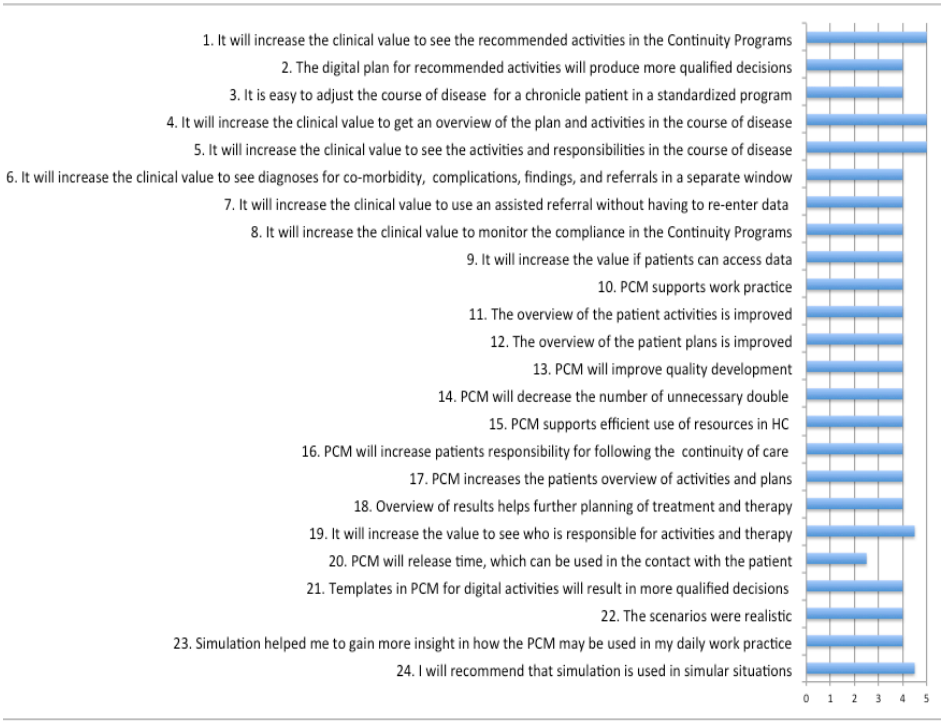
No 10: It should be made clear what the mandate of the clinicians and the observers is and how the results will be used, reported and implemented

In our running example the questionnaire was composed of nine questions concerning the hypothesis, two questions concerning quality management, four questions concerning overview of the plan for the patient, two questions concerning the division of responsibilities, four questions concerning work practice and efficiency, and three questions about the simulation and the realism in the scenarios. The questionnaire answers were given using a five point Likert agree/disagree scale. The interviews were held in focus groups at the end of each day with semi-structured questions concerning possibilities & challenges of the concept, quality, coordination & planning, overview, functionalities & tasks, acceptance, responsibility and work practice. In our running example the purpose was to assess the potential benefits of a PCM for healthcare professionals involved in planning and coordination of patients with COPD and DM2, and the prototype was only a representation of what such a system may look like. The focus was therefore not on the more specific usability problems, hence IDA was considered a sufficient method of analysis.

Results of the Case Study

The case study described in this paper involved giving the participants of the simulation a questionnaire as well as conducting a semi-structured interview with them after the Performing stage was completed. The results from the questionnaire given participants are shown in figure 7.

Figure 7: Potential benefits: Result from Questionnaires, n=18



The vertical scale shows to what extent the healthcare professionals agreed to the statement (1 correspond to totally disagree and 5 corresponds to totally agree). The horizontal scale depicts the median of the respondents' answers on a five point Likert agree/disagree scale to the 24 questions on the vertical axis. The hypotheses evaluated in questions 1-9 were all confirmed with a score at 4 or higher. Questions 13 and 21 concerning quality management had a mean score of 4. Questions 11, 12, 17 and 18 concerning overview of the plan for the patient scored 4 on average. Questions 16 and 19 concerning the division of responsibilities scored 4 on average. Questions 10, 14 and 15 concerning work practice and efficiency scored 4 on average. Questions 22, 23 and 24 about the simulation and the realism of the scenarios scored 4 or higher. The only question that obtained a lower score than 4 (3.5) was question 20, concerning the question of whether the PCM would release up more time to be spend with the patients or not. This result was not however consistent with the interview. In the interviews the general opinion was that the PCM would reduce the time spent on the planning and coordination, but it remains unresolved whether the time would be spent with the patients. This result was the only discrepancy between the interview and questionnaire results.

During the interviews the core concept of the PCM was assessed as being very useful and as creating many benefits. New ideas were brought up during the interviews. For example ideas were presented by participants such as using the PCM as a coaching tool for senior doctors and as an instrument for communication among colleagues or between other groups of healthcare professionals.

New possible users of a PCM were also identified during the interviews. Nurses in primary care were not part of the original scope of the testing, but one general practitioner saw the PCM as a very valuable tool for the nurses in primary care. In particular, as a tool for quality assessment, this was previously done manually looking into all patient records one at a time. A PCM would be able to do the same task automatically across all patients. Quality management in general was perceived to be enhanced by almost all clinicians, and two doctors suggested that the content of referrals and discharge letters could possibly be reduced with the implementation of PCM, since much of information concerning the patient would be known by all parts.

Although the concept of the PCM was found to be innovative and made the healthcare professionals see the planning and coordination of for patients in a new way, most of the healthcare professionals had difficulties in understanding the concept of a PCM in the beginning. Its purpose had been explained in advance of the clinical simulation, but it turned out that the introduction and training was not quite sufficient. However, the simulations and observations of clinicians from the other sectors using the system helped them to understand the concept.

Several issues of concern were brought up during the simulations. Firstly, the healthcare professionals found that the PCM module gave them a good overview of the patients, but at the same time they wanted the opportunity to look into details about the patient. They recommended that this should be looked into when specifying requirements. The same applied to the use of terminology. The test showed that the terminology used in the three sectors differed for several central terms such as "referred to" and "deselected". An alignment of terminology would be a positive side effect of implementing PCM.

Another issue to be addressed was the sharing of responsibility. With PCM all healthcare professionals have the same access to all data, but should it be possible for a physician at the hospital to overrule a prescription from the general practitioner - or vice versa? As it is today, the area between primary and secondary care in Denmark is distinctly separated, but with a PCM the division is not unambiguous. This is something that has to be addressed before implementing a PCM. As mentioned there was no real integration with existing information systems. Several users stressed that the implementation of such integration would be of vital significance if the PCM should be used. The alternative would be to enter the data by hand and no participants saw this as a realistic scenario.

The healthcare professionals who participated in the simulations were asked (1) whether the simulations were realistic, (2) whether the simulation helped them gain insight in possible use of the PCM, and (3) whether they would recommend simulation study as a future method for this kind of test. The average scores were 3.6, 4.0 and 4.4 on a Likert scale between 1 and 5 in response to each of these questions respectively. Furthermore the project members subsequently expressed that the results would not have been the same using traditional low fidelity studies, even though they had had doubts about the usefulness of using clinical simulation with high fidelity.

Discussion

In this paper we have described a method for conducting clinical simulations during the life cycle of a clinical information system, and used a specific case study as a running example. In the case study the results from a questionnaire survey given after clinical participants interacted with the system confirmed the nine hypotheses. The healthcare professionals found potential clinical benefit in using the PCM, which would improve quality and patient safety. Furthermore new future users were discovered and new potential ways of using the PCM were also uncovered. Project team members expressed that opinion the results would not have been the same if the evaluation had not been conducted using high fidelity clinical simulation.

Actual patients were not part of the clinical simulation, but during the evaluation, several potential benefits for patients were mentioned by the HI experts. An additional clinical simulation with actual patients is therefore recommended in future work with the PCM.

The degree of realism reflected the purpose of the evaluation, hence the evaluation was semi-experimental with obser-view during the test as the system was a prototype and was not meant to be implemented in its present form.

As mentioned the scenarios did not cover all possible use of the PCM but were designed to enable assessment of nine hypotheses. Furthermore the simulation does not fully resemble the use of an information system in a real clinical ward, but offers a high degree

of realism and clinical context. Clinical simulations should therefore not be a substitute for evaluation conducted during a pilot implementation, but instead regarded as a complementary way of testing without the risk of injuring real patients. It should also be noted that 18 questionnaires is a very small sample, and the results cannot be generalized to all hospital settings. However, the quantitative data, with a single exception, are consistent with the qualitative data from the results obtained from the interviews and the observations. The use of triangulation strengthens the validity of the results in such studies (48).

Several unintended consequences were uncovered. These unintended consequences did not directly concern the PCM, but were organizational issues that had to be addressed before implementing a PCM. Unintended consequences such as issues concerning terminology and responsibility had not been apparent before the simulation test. However, they were most relevant and needed to be addressed before a final implementation of the PCM. Furthermore it was found that a new and innovative concept such as a PCM needs to be explained thoroughly for all users and stakeholders before it is implemented. Clinical simulation includes the clinical context by viewing clinicians, technology, and work practices together and thereby facilitates findings regarding impact on clinical activities not possible using traditional low fidelity evaluation methods.

The scenarios used in the study covered only fraction of the clinical work practice. The selection of the scenarios was based on their relevance with regards to frequency and complexity of work practice and organization. The effort spent should also reflect these considerations (26). Time elements are not well-matched with clinical simulation, with the time health professionals spend with a system during a test not reflecting the social-technical impact over time. As mentioned in the case study it took some time before the participants became acquainted with the system. Clinical simulation should therefore not be a substitute for pilot implementations where an IT-system is implemented in a small and controlled environment for a shorter or longer period. This is consistent with our experiences from other clinical simulation studies in the ITX-lab.

Regarding the general methodological approach described in this paper, key points that have become apparent from following 10 steps for clinical simulations are the following:

1. The purpose of the clinical simulation must be focused and anchored in the organization
2. Choice of scenarios is crucial and must reflect the purpose of clinical simulation
3. Choice and profile of clinicians must reflect the purpose of the clinical simulation
4. Complexity in scenarios and patient records must be carefully considered
5. Planning and preparing clinical simulation is resource demanding in order to make it time effective for clinicians
6. The degree of fidelity must reflect the purpose of the clinical simulation and the maturity of the technology
7. Rehearsals and pilot studies are important and well worth the effort
8. Real clinicians should be used as participants
9. Cost saving analysis methods like IDA are very useable and can be practically applied to analyze the resultant data
10. It should be made clear what the mandate of the clinicians and the observers is and how the results will be used, reported and implemented

Conclusions

In this paper we described a method for conducting clinical simulations highlighting 10 steps to a successful simulation. The results from the simulation case study about the PCM indicate that HC professionals from primary care, community nursing and the hospitals will benefit from an implementation of such a module. The benefits concern primarily communication issues, planning and coordination, work practice enhancements, and quality management. Several organizational issues have to be addressed, including use of terminology and delegation of responsibilities before an information system as PCM can be implemented.

Furthermore the results from this, and additional simulation studies, show that full scale simulation studies are a useful method for testing the feasibility of information systems especially when taking into account the resources spent. Not only were the hypotheses confirmed in this study but new unintended potential benefits were identified during the simulation test. Clinical simulation covers only part of the range of tests which should be conducted, and it should not be a substitute for a pilot implementation test in real settings. However it is possible to use clinical simulations to gain important knowledge concerning work practices, usability and human factors prior to widespread system release, and they can thereby contribute greatly to ensuring patient safety.

Acknowledgments

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Identification and prevention of Patient Safety Hazards

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Abstract

Background. Clinical simulation makes it possible to assess new technology in a specific clinical context before implementation in a hospital, and thereby enable identification and evaluation of patient safety hazards. **Method and material**. In a case study concerning implementation of a new IT-system that allowed physicians to sign for laboratory test result the system was evaluated by use of clinical simulation before implementation at a pilot ward. **Results**. The evaluation identified several organizational and technical challenges that had to be solved before the implementation because of important patient safety risk. Furthermore clinical simulation clarified the challenges in supporting local guidelines by a basic information system that was supposed to be used on wards and outpatient clinics in all hospital in the region. **Conclusion**. What was expected to be a small IT-project turned out to imply large organizational challenges and substantial patient safety hazards. The project has consequently been terminated and the IT-system shut down.

Keywords. Clinical simulation, patient safety, eHealth, evaluation, clinical information system, human factors

Introduction

Patient safety in relation with health IT is a paradox (1). Even though health IT can improve patient safety and quality (2), application of new technology in healthcare can also increase patient safety hazards(3). Errors persist in clinical practice even after new health IT has been introduced (4) 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 (5), and hybrid paper based and electronic systems complicates the clinical work processes. In 2013 182,000 unintended incidents were reported in Denmark (6), and 18 % were related to communication. In the US 436 critical incidents involving health IT were reported to the US Food

and Drug Administration from January 2008 to July 2010. Studies show that unintended incidents in relation to new technology are more often related to the use of technology than to the technology in itself (3;7) and up to 70% of patient safety incidents are estimated to be related to or due to human factors (8). Methods for design of eHealth focusing on patient safety are one of many initiatives trying to prevent adverse events (9;10). Implementation of guidelines and standards (11-13) are other methods that can address patient safety hazards in design of health IT, but regulation and certification do not address safe use within the context of clinical work practice as safe use (14) in a local context must be addressed locally by the local organization (15). Patient safety does not entirely rely on technology but is highly influenced by the interaction with users in a specific context (16), and sociotechnical issues and human factors are related to many unintended consequences and patient safety hazards (7;9;17). The substantial complexity of organizations, work practices and physical environments within healthcare influences the implementation and use of technology (18). When new technology is integrated in health care work practices the implementation is challenged with a large sociotechnical system in which many behaviors can never be fully predicted (19). 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 (13). Possible patient safety hazards need to be investigated when health IT is integrated with local clinical work practice including other technology and organizational structure. Proactive evaluation of patient safety in regards to use of technology in a clinical context is pivotal, however most methods such as field studies (3) and incident monitoring (13;20) are retrospective.

Qualitative methods, such as clinical simulation are qualified for proactive evaluation of new technology for clinical work practice in clinical context (21;22). Clinical simulation study effects on clinical workflow (23;24) and enables identification and evaluation of patient safety hazards before implementation at a hospital (25).

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 simulation focus on the use of technology in a clinical context involving one or several users embracing 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 (26). Clinical simulation studies are feasible for conducting safe evaluations of tech-

nology before it is introduced to routine (27) and makes it possible to evaluate potential impact (28) as well as cognitive processes and usability (22) and patient safety matters (25). 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 is 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 (29).

In the Capital Region of Denmark receiving and signing laboratory test results is paper based and it has for long been a request to develop an IT supported work flow for physicians receiving and signing laboratory test results to ensure patient safety. The laboratory tests are handled by various information systems and some results are on paper whereas others are electronic. The local work flows are based on local guidelines, which are interpretations of a national guideline for handling laboratory test results. These local interpretations may vary between the regional hospitals, departments throughout a single hospital and even between local units in a single department such as patient wards and outpatient clinics. The national guideline was developed as part of a quality insurance initiative to increase patient safety. The national guidelines prescribe that the physicians document decisions on whether a laboratory test result generates further actions concerning the patient, as well as the acknowledgement and handling of the result. The essential challenges about the paper based workflow are 1) lack of overview about whether a result has arrived, 2) uncertainty about whether a test result has been seen by a physician, 3) lack of documentation of which physician has handled a test result. There are 10 hospitals in the Capital Region of Denmark with approximately 365 outpatient clinics and the same amount of patient wards. The 365 outpatient clinics are distributed in nearly 950 local outpatient clinics.

The intention by purchasing the information system was to increase quality in work practice and decrease patient safety risk by implementation of a new standardized information system, “OPUS inbox” (in Danish OPUS “Indbakke”). OPUS Inbox collects laboratory test results from various laboratory systems and support electronically documentation for acknowledging the results. Approximately 7 % of unintended events at the Danish hospitals in 2012 were related to reaction on laboratory test results (6). The expected benefits with the new information system were 1) improved overview and attention on new laboratory test results, 2) signing and handling of new results independent of time and location, 3) no lost test result, 4) reduced time spend on archiving paper results.

The study reported here was expected to be rather straightforward and manageable because the information system was a standard of-the-shelf product and was supposed to support a narrow and well defined work flow. The information system was to be implemented at two pilot departments; a neurological medical department at and a gastroenterology surgical department. Both departments included patient wards and outpatient clinics. Prior to the implementation the existing work practice was analyzed and future generic work flows were designed. Functionality of the information system and collaborative future work practice was evaluated. A four week pilot installation were the system was going to be used in real life was planned to take place at a medical department and subsequently at a surgical department in two different hospitals in the region.

Initial field studies were carried out at the two pilot departments covering both patient wards and outpatient clinics in order to gain insight in existing work practice concerning receipt, handover and acknowledgement of laboratory test results. The field studies were conducted during two whole days with the participation of one health informaticians and one technical expert. The focus of the field studies was to gain knowledge of the existing work practice and the information process related to laboratory test results, and were conducted with an obser-view approach (30) where samples of active physicians, nurses and medical secretaries were interviewed while they were observed performing their daily work. Work practice were documented regarding 1) what information were needed and documented, 2) how, where and when this was done, and 3) who the involved actants were, i.e. health care professionals, information systems, and, documents. The observations and obser-view were supplemented with photographs.

Afterwards two workshops were held with physicians, nurses and medical secretaries from the pilot departments, health informaticians and experts from the regional quality unit (31). At the first workshop the existing work practice were analyzed and existing challenges such as unnecessary duplication of work, bottlenecks and handovers and potential changes were identified. Hereby further needs for requirements in the information system and needs for changes in existing work to secure correlations between future work practice and information system were determined. At the second workshop future work practice was decided focusing on improved efficiency, quality, continuity and communication. Furthermore existing routines were challenged and organizational changes were initiated up front to gain acceptance and readiness to change.

At the same time the information system and the integration with the various laboratory systems were tested, and training materials were produced. Hereafter clinical simulation was performed and the functionality of the information system and the collaborative future work practice was evaluated.

The aim of this study is to assess the potentials of clinical simulation as a proactive method to identify and evaluate potential patient safety hazards prior to an implementation. The aim of the study case was to investigate how the standardized information system OPUS "Inbox" supported clinical practice, and identify potential patient safety hazards prior to the implementation. In the following we discuss clinical simulation as a method for evaluation of patient safety issues. Furthermore the case study, the results from the clinical simulation, the initiatives and actions that needed to be completed before the implementation and the results from the pilot implementation will be presented.

Methods

Patient safety, usefulness and usability were evaluated by use of clinical simulation. Clinical simulation is a qualitative method, where clinicians use an IT-system in a realistic simulated set-up (32). Clinical simulation may be used for various purposes and in different phases of the development life cycle of an IT-system (25), and is well suited for identifying and evaluating patient safety issues (33). In this study the purpose of clinical simulation was to evaluate patient safety issues and future work practice when using the new IT-system before the implementation. Identification of appropriate scenarios and participating users is critical for the outcome (34;35). Depending on the purpose of the evaluation scenarios should cover key areas such as frequently used work flows (e.g. assignment of patient to the hospital), complex or dangerous work flows (e.g. medication (20)) and areas where adverse events often happens (e.g. hand overs (36)). Identification of users depends on the scenarios and should cover characteristic users and healthcare groups included in the scenarios (37;38).

Stakeholders, e.g. implementation managers, risk managers, quality experts, and end-users, and health informaticians observe the simulation through a one-way mirror. Selection of observers depends on the purpose of the simulation study (39); observers may focus on e.g. patient safety, usefulness and implementation aspects; training and work practice. The demand for realism of simulation set-up also depends on the purpose. The strength of high fidelity test such as clinical simulation is the ability to create an illusion of clinical context (40). The technical fidelity does not always need to be high; again it depends on the purpose (41). Patient safety issues often lies in the details and evaluation of patient safety issues therefore demands high fidelity on environments, technology, functionality and task (29). During the simulation the clinicians are asked to think-aloud in for the observers to gain insight in the challenges and benefits of the system (42). A debriefing interview is conducted after the simulation and at the interview the observers might be able to participate and discuss various aspects of the use of and the interaction with the system (43).

In this study six healthcare professionals from the two pilot departments (two physicians, three nurses and one medical secretary) were selected to participate in the simulations. The observers were clinical managers from the pilot sites, implementation experts and health informatics experts. Figure 1 shows the simulation room seen from the observation room through a one way mirror. To the left are the observers placed in the observation room. To the right is an outpatient clinic set-up where a physician is preparing the meeting with a patient.

Figure 1 Left: observation room with observers. Right: simulation room seen from the observation

11 scenarios were performed during the evaluation; six scenarios from patient wards and five scenarios from outpatient clinics. All scenarios were related to signing and handling laboratory test results, some of them were often performed work flows; e.g. ward round and visit in outpatient clinic, whereas others were critical work flows; e.g. urgent test results and dangerous work flows; e.g. sorting of test results and handover of responsibility. The simulation was a full scale high fidelity simulation. The degree of fidelity involves attempts to re-create characteristics of the real world (44) and includes equipment fidelity, functional fidelity, task fidelity and environmental fidelity (40). The fidelity was high on all parameters. According to equipment fidelity the simulation was conducted with the same computers as the ones at the hospitals and according to functional fidelity the system was fully developed and running. In relation to task fidelity the scenarios was composed in participation with clinicians from the pilot sites on basis of realistic patient cases. Regarding environmental fidelity the simulation room was designed as either ward room or clinical office and the role of the patient was acted by a healthcare professional. The scenarios did not include disturbances such as interruptions from other colleagues or patients, but the realistic tasks, the realistic environment and having a patient as part of the scenario ensured a cognitive acceptance of the clinical context (40).

During the simulation the observations made by the observers were noted and were used during the de-briefing interview in addition to an interview guide. After the interviews the result were analyses using Instant Data Analysis (IDA)(45). IDA is cost-saving analysis technique which allows analysis of

the results to be conducted in just one hour. IDA is conducted right after the de-briefing interview and observers and simulation facilitators participate. The results from the clinical simulations were described in an evaluation report, which amongst others was send to the patient safety unit.

Clinical simulation as a method was evaluated by interviews with the project manager, a manager from one of the pilot departments and an expert from the patient safety unit. The pilot implementation was evaluated at a work shop with clinicians, clinical managers, and representation from the patient safety unit and the quality unit and used to decide whether the information system should be implemented at the rest of the hospitals.

The Case: "OPUS Inbox"

OPUS Inbox is part of a commercial off-the-shelf product suite. OPUS Inbox is not in use in other places. Figure 2 shows the overall work flow in OPUS Inbox. All test results are received in the system and notified. The results are shown at two levels; patient identification (ID) number and department.

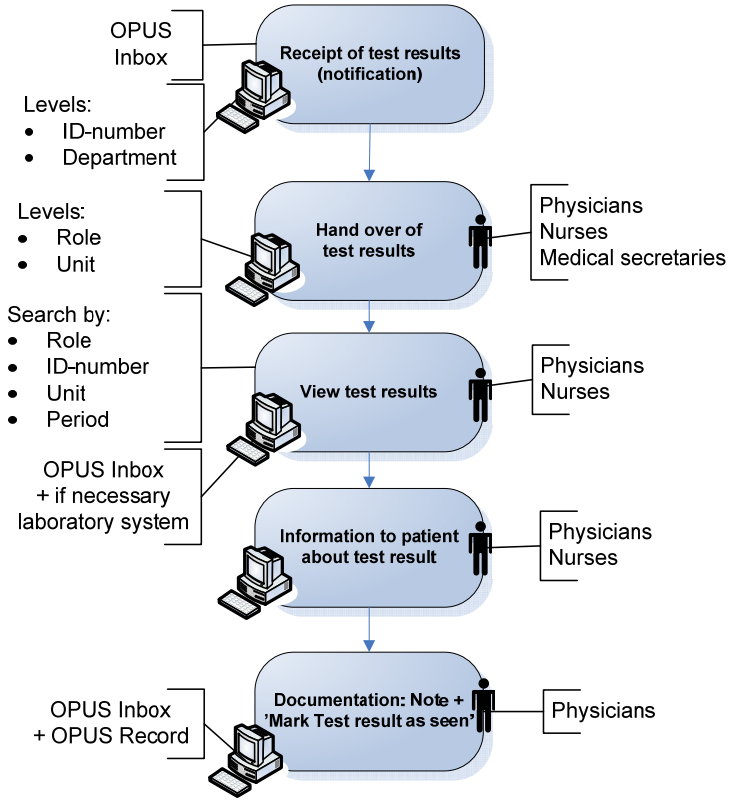

Figure 2 The work flow of OPUS Inbox from receipt of test results to documentation of the test results seen

After a test result has been received it is possible to hand over the responsibility of the results as shown in Figure 3. This can be done by physicians, nurses, and medical secretaries. It is possible to do this either by unit (e.g. department) or role (e.g. senior physician in charge).

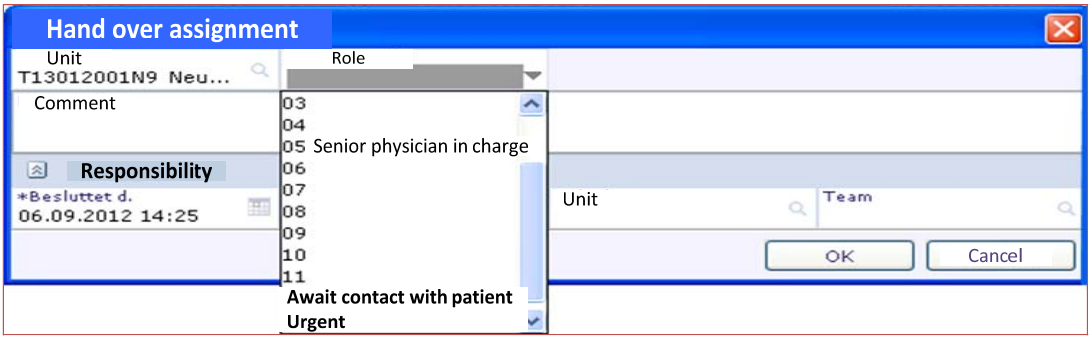

Figure 3 delegation of responsibility for handling a test result

Overview of test results are sorted in three possible ways; 1) list of test results from one single patient, 2) list of test results from all patient in one unit, 3) list of test results that are assigned a role, e.g. senior physician in charge. Figure 4 shows a list of test results from one single patient.

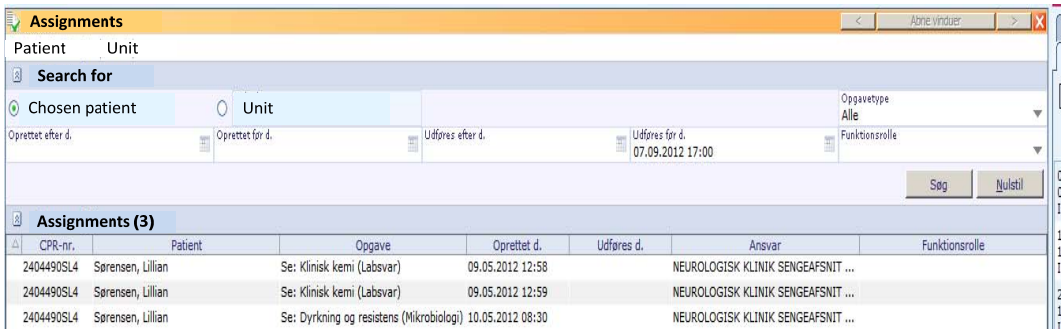

Figure 4 List of test results from one single patient. The results are shown by double-clicking the test

Figure 5 shows a list of test results from all patients in one department. It is possible to search for test results by role, patient ID number, unit or period of time. This might be the responsible physician wanting to view all test result for the past two hours or test results for a single patient during the last 24 hours.

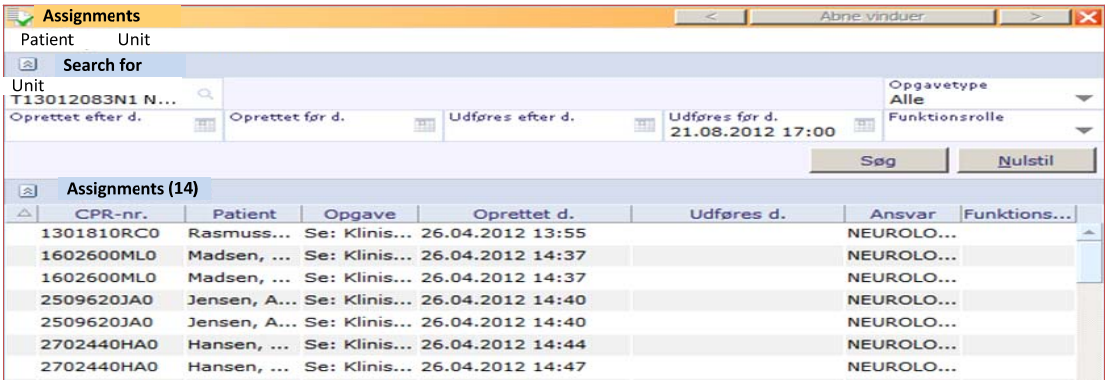

Figure 5 list of test results for patients in one department. The results are shown by double-clicking the test

Before a test result is marked as seen (signed), the physician or nurse informs the patient about the test result and the physician makes a note of it in the patient's record. Only physicians are able to sign a test result. Figure 6 show one test result with functionality to mark as seen.

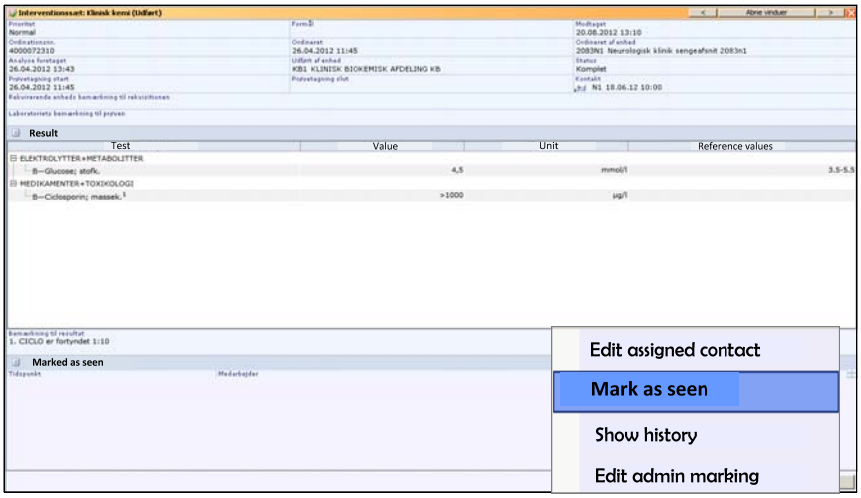

Figure 6 One single test result with functionality to mark as seen

Results concerning the information system and work processes in the case study

The analysis of work practice revealed substantial differences between the hospitals, between the patient wards and the outpatient clinics and between the individual healthcare professionals. In the outpatient clinics the time span for handling test results was much longer than in the inpatient departments. The documentation of acknowledgement for having looked at test results differed very much from the local guidelines; e.g. not all laboratory test results were signed according to the local guideline. The actual handling of the results differed a lot between the patient wards and outpatient clinics; e.g. initial handling (sorting and delegation of test results) by a nurse was only practiced at one of the hospitals and work practice it differed between the nurses. On the other department all test results were presented for a physician without initial sorting and delegation. At one of the pilot sites there were none local guidelines at all for handling of test results except for handling of histology results. Design of future work practice was quite challenging. It was not possible to design a generic work flow covering both patient ward and outpatient clinic partly due to large differences in local work flows and partly because the functionality of the information system didn't sufficiently support the work practice. Table 1 below presents the results from the clinical simulation.

Table 1: Prioritized results from clinical simulation evaluation

Issue	Risk
Direct risk – patient safety issues – prioritized	
Paper based pathology results and test results from private laboratories	Risk of overlooking test results
Comments did not stand out distinctly	Comments are not easily noticed and important information may be overlooked
Signing cannot be undone	If by mistake a test result is signed, it disappear from list of incoming test results and may be overlooked
There were no difference between a temporary test result and a final test result.	It was not possible to distinguish between the two types of results, and unsuitable actions may be taken on a temporary test result or a final result may be mistaken for a temporarily result and thereby delayed or overseen
No interaction between paper based prescription of laboratory test and electronically signing of test results	Siloing leads to unintended incidents
It had not been clarified who was responsible for sorting and distributing the test results to the responsible physicians	If delegation of responsibility is unclear there is a risk that nobody takes action of a test result
The distribution of responsibility and roles among physicians concerning handling of test results was not clear	Delegation of assignments may be performed incorrect if the different roles are unclear
Several users are able to look and react at the same result at the same time	Two users may handle the same test result in different ways and if it is done at the same time, there is no telling of which treatment is valid
Indirect risk - work flow and other issues	
Not possible to sort and filter date and time in the list of new results were identified.	New test result may be hidden among old test result
No support work flow	Pour support of work flow may stop the users using the system.
The information system was difficult to use	Poor usability may lead to wrong use of the system
Special requirements concerning confidential test results were not supported.	Confidential test results may not be treated in secret.
Need for redesign of future work flows	Suboptimal Work flow might lead to work around and unintended incidents later on
Work flow at the outpatient clinic were not transferable to other patient wards and outpatient clinics; e.g. referral of test results, sorting of normal and urgent results and the time wise aspect that in some outpatient clinics the time span between visits for patients may be long whereas it might be short in other specialties or at the departments	Local work flows may lead to unintended incidents when healthcare professionals switch between work places
Local interpretations of national guidelines for assignment of test results	Miscellaneous ways of handling test results may lead to misconception
Many test results were not signed before the pilot implementation	If all test results were not signed in the system, old test results would accumulate and new test results may be overlooked

The clinical simulation revealed several challenges in the future work flow and as a result the future work flow had to be redesigned and one more evaluation with simulation-based evaluation was per-

formed; this time in situ – at the pilot department. New functionality for sorting the list of laboratory results according to date and time for the results was developed. Additional new requirements to the information system were determined. It was decided to initiate a pilot implementation despite the fact that the information system did not fully support the work flows. Some of the organizational challenges were solved and it was agreed that the remaining challenges regarding future work practice should be subject to scrutiny during the pilot implementation. Apart from many negative findings, there were also favorable findings such as improved overview of laboratory test results and no paper test results were lying around in risk of disappearing.

The challenges not solved prior to the pilot implementation were the transferability of work practice between patient wards and outpatient clinics, confidentiality of some test results, risk of several users handling the same test result simultaneously, missing interaction between prescription of test and signing of test results, no possibility of undoing signing of test results, comments do not stand out distinctly and integration between information system and paper-based test results from private laboratories.

A review at the pilot sites two months after the information system implementation showed that nearly 300 test results that had not been signed by a physician. Higher rate in signing of test results was one of the main reasons for the project. Furthermore the information systems was expected to be in use in another region which it turned out not to be and there were no money set aside for further development. Due to these matters and the many patient safety risks and organizational challenges the project was terminated and the information system was shut down. Instead the intention was to wait for a new EHR-platform, which was supposed to be purchased during the next couple of years. The quality unit was asked to develop a regional guideline concerning signing and handling of laboratory as a substitute for the local guidelines, based on locally interpretations of the national guideline. The regional guideline was to be implemented regardless that OPUS Inbox was shut down.

Results concerning the clinical simulation method

Subsequent interviews with the project leader, a clinical manager from the first pilot department and a patient safety expert gave primarily results concerning clinical simulation as a method for evaluating clinical information systems. The results are presented in table 2.

Table 2 Results concerning clinical simulation as a method for evaluation of clinical information systems

Issue	Risk
The scenarios in the clinical simulation were realistic.	The value of clinical simulation is very much depending on task and environmental fidelity especially regarding assessment of patient safety issues. Focus is transferred from the information system to the clinical practice, if the test data and scenarios are not realistic.
Patient safety experts, health informatics experts, quality experts, decision-makers, implementation managers and end-users should observe the clinical simulation and participate in the debriefing interview and discussions.	Important issues may be overlooked without specialized experts knowledge and focus, and important aspect might be missed during discussions if relevant experts are omitted
The clinical simulation should be performed by health professionals without any knowledge about neither project nor information system on forehand	Clinicians may be biased if they have prior knowledge and may not evaluate unprejudiced
Local guidelines and work flows may not always be practiced	If the existing work practice is not followed the simulation may be misrepresenting.
Not all technical issues may be solved	If the information system cannot be changed, it is important to assess how work practice add ups.

Discussion

Consequences of the case study

The clinical simulation revealed several organizational and technical challenges, and choice of observers was very important. Each expert focus on their own field and as such the observers must be chosen carefully and in close relation to the purpose of the evaluation. During the simulation there had been no observers with patient safety expertise. Instead the results from the simulation had been presented to patient safety experts, and thereby many patient safety issues were identified. Several organizational and technological issues, that were regarded as inconveniences by others were detected as patient safety risks by patient safety experts.

In the same way unclarified work flows became clear during the simulation and observers focusing on work flows agreed to perform one more work flow analysis where the future work practice was revised. The high degree of differences in existing work practices at hospitals, departments, patient wards and outpatient clinics meant that it was not possible to design generic future work flows. As a result the central quality unit was asked to design a regional guideline for handling laboratory test results.

Many of the issues found during the simulation were handled before the pilot implementation, and those that were not solved were observed again during the pilot implementation. Not all challenges

were revealed during the clinical simulation though. Issues such as handling of pre-ambulatory test results and handling of unusual test results were not found, and clinical simulation cannot replace a pilot implementation, but should be seen as a valuable supplement.

Utility of clinical simulation

The evaluation was formative and primarily used as a learning process. Formative evaluation studies can facilitate system adoption and utilization (46) and aims at improving a system under development or during implementation, whereas summative evaluation focus on assessment of a system that is already up and running (47). Formative evaluation may identify potential problems, such as patient safety issues, already during the development phase, and provide opportunities to improve a system as it develops. In this study the results from the formative evaluation regarding patient safety issues and work practice was presented and discussed at meetings with different stakeholders; i.e. the patient safety unit, the quality unit and the implementation departments. Many precautions were taken during the pilot implementation in relation to patient safety matters and work practice, e.g. clarification and distribution of responsibility, and local interpretation of guidelines. As most of these precautions were organizational many of them were subsequently used regardless of the implementation of information system. Experience from the project will also be used prospectively when the region eventually implements technology to handle and acknowledge laboratory test result in the future.

Experts from the patient safety unit hold a tremendous amount of knowledge concerning unintended incidents when implementation and use of new technology due to the many reports they read every day. In The Capital Region of Denmark about 17,000 incidents at hospitals are reported every year and all unintended incidents are analyzed by patient safety experts (31). It is very often not possible to say whether it is the technology itself or the individual healthcare professional, that is the cause of the incident, because the incidents mostly appears in the interaction between humans, technology and work practice (48). Clinical simulation clarifies the interaction by visualizing the correlation between human, technology and organization whereas more traditional usability evaluations mostly visualize the interaction between the user and the technology without including work practice (24;49;50). By including all three aspects, humans, technology and organization, patient safety challenges and other organizational challenges are revealed. As it turned out during the simulation signing could not be undone with the risk of missing a test result. This risk had not been revealed before the simulation. Potential adverse events were revealed, e.g. unclear responsibility of assignments with a risk of nobody looking at urgent test results.

Clinical simulation exposes and focuses on patient safety matters and patient safety experts as observers may thereby identify potential risks and challenges. Several patient safety risks and challenges were identified in the study just by letting patient safety experts read the evaluation report from the clinical simulation, but having patient safety experts observing the interaction between the user and the interface of the technology and the interaction with the technology in the clinical context would have improved the outcome. Inclusion of clinical context is a very powerful element in clinical simulation. By letting clinicians use new technology the way it is supposed to be used in a realistic clinical context patient safety issues becomes visible without endangering patients (25).

The overall simulation fidelity configuration affects how the realism of the simulation experience is perceived (40), so in order to reveal cognitive and sociotechnical issues the fidelity needed to be high. Cognitive aspects in regards of work practice relate to the clinical context and thereby depend on the degree of environment and task realism (41). Sociotechnical aspects relate the interaction between user, organization and technology and thereby equipment and functional fidelity should be high. Patient safety matters lies in the interaction between user, organization and technology (29), and configuration of fidelity must be high on all four dimensions.

Traditional information systems are often designed around an idealized model of the tasks and workflow and failures in information systems are often explained by "blaming" human social and cultural "barriers" to technology adoption (16). The simulation evaluation revealed differences between such an idealized model of the task that needs to be accomplished and the actual way the clinicians are working, partly due to local interpretations of a national guideline, and the quality unit was asked to develop a regional standard on signing of test results to be used all over the region. Beside this the information system was a standard system without sufficient possibilities in the existing version to configure the system according to local setting. There was no budget for further development of the system.

Clinical simulation does not reveal all challenges. Challenges about handling of pre-ambulatory test results and handling of unusual test results were not revealed during the clinical simulation. Simulation evaluations are no better than the scenarios and patient cases they cover, and in this case the scenarios did not include unusual results and results from pre-ambulatory tests. Thus clinical simulation in some way risk to be somewhat idealized in regard to real life.

The same goes for the purpose of the evaluation and the relation between existing and future work practice. What is to be evaluated - future or existing work practice? Do end-users comprehend and

approve of the new work practice? If the existing work practice in a department does not follow the existing local guidelines this may influence the evaluation of the interaction between future work practice, end-users and technology as well as the following implementation. In this study it made the implementation more challenging as it became evident that the laboratory test results were not acknowledged according to the local guidelines during the pilot implementation. The technology may be blamed for not supporting work flows that was not carried out beforehand and thereby is an organizational issue.

To what extend is it possible to let technology be the entry point of increasing quality? And should such projects be regarded as technology projects or organization development projects? The balance is delicate and should be carefully defined in each project. In this project, the balance did not succeed, which is partly due to the limitation of technology. If the project should have succeeded the technology should have supported future work practice more sufficiently, and made it easier for the clinicians to comply with.

Patient safety issues are hard to assess (29), and as the patient safety expert expressed during the interview: "*many patient safety challenges lies in the detail and are triggered by unintended incidents and disturbances*". Clinical simulation has an advantage in taking the clinical context into account, whereas methods like heuristic inspection focus only on the user interface and low fidelity usability test focuses on technology, and specific task for single users. It can therefore be hard, or nearly impossible, to pinpoint patient safety hazards by use of these methods. Clinical simulation provides a comprehensive view on the IT-system taking into account the correlation between IT, work practice and unintended incidents and thereby a more appropriate method for assessing patient safety issues. Clinical simulation is resource demanding though (28) and the purpose of simulation studies should be carefully planned. Situation where clinical simulation are appropriate could be work practice regarding hand overs and new work flows, dangerous situations such as medication, acute situations, interruptions, and complex situations involving many actors and many patients.

Conclusion

The evaluation identified several organizational and technical challenges that had to be solved before the implementation because of a substantial risk of patient safety. Furthermore clinical simulation clarified the challenges in supporting local guidelines by a basic information system that was supposed to be used on patient wards and outpatient clinics in all hospital in the region. What was ex-

pected to be a small IT-project turned out to imply large organizational challenges and patient safety hazards. As a result the information system was shut down.

Implementation of new technology as part of implementation of new quality approaches such as standardization of work practice may lead to problems that could have been overcome if done in two steps. In this case the implementation of an information system, that did not sufficiently support work practice in combination with implementation of new workflow made it too resource demanding for the clinicians. If instead a regional guideline had been implemented before the implementation of the new information system, the information system would have made the work flow easier, and the implementation may have succeeded. As a result it has been decided to develop a regional guideline for handling of laboratory results regardless of a new information system and wait for a new EHR-platform, that is to be implemented in a couple of years.

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