



# 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.

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## 1. 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]. 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, p. 2]. 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, p. 52]. This may be real work actions or processes. Clinical 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 clinical 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-based evaluation 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 without end-users, or as a hybrid, where simulations with end-users are combined

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with computer-based simulations [4]. This paper focuses on clinical simulation with real users enacting realistic clinical work scenarios in relation to development and evaluation of clinical information systems.

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]. Simulation-based evaluations lead to both technical changes in the IT system and organizational changes. The technical part of changes might be user-interface aspects as well as functional changes according to the support of clinical work flows [2,23,25]. The socio part of changes might be changes or optimization of work practice and implementation aspects such as training [26,27,39].

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, as seen in Table 1, 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, p. 3]. 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, p. 3], effectiveness may be defined as “accuracy and completeness with which users achieve specified goals” [29, p. 3], and satisfaction may be defined as “freedom from discomfort and positive attitudes towards the use of the product” [29, p. 3]. Traditional usability testing methods such as heuristic inspection and usability testing tend to focus on technology assessing the user-technology interface taking the clinical context into account, whereas clinical simulation enables inclusion of additional aspects of the complex clinical work context [17]. Heuristic inspection focuses on the user interface and low fidelity usability testing focuses on the observation of representative user interacting with the technology while carrying out representative tasks. These methods may make a rigorous evaluation of the user interface and uncover usability challenges in the graphical user interface. They do not, however, include the full clinical context and the interdisciplinary aspects of everyday clinical work. Clinical simulation also focuses on work flow and organization looking into human–job, human–environment and human–organization interface technologies as opposed to usability testing and heuristic inspections looking mostly into human–technology interface technologies.

**Table 1**  
An overview of clinical simulation studies in the ITX-lab from 2007 to 2014 with description of system types, purpose of study, system maturity and stage in system life cycle.

System type	Description	Purpose of study	System maturity	Life cycle stage
Clinical documentation templates	Vital signs	Input to design and evaluation	Mature prototype	Design
	Cardiologic nursing			Design
	Nutrition screening			Design
	Medical treatment stomach tube			Design
Tele health	Multi Disciplinary Team Conf.			Design
	Initial nursing assessment of somatic patient		Running system	Design configuration
	Initial nursing assessment of psychiatric patients			Design configuration
CPOE	Nursing plans and status of care			Design and conf.
	Out patient with COPD	Evaluation of usability	Mature prototype	Design
Patient safety	Out patient with COPD	Usability evaluation in patients own home	Immature system	Design
	Integration to national medical record	Input to design	Immature system	Design
	Drug administration	Evaluation of usability	Mature system	Test
	Integration to national EMR	Assessment of need for training	Immature system	Design
EHR	Merging of 2 different versions of CPOE	Assessment of effect on patient safety	Running system	Implementation
	Clinical decision support for medication	Input to design	Immature prototype	Design
Patient safety	Context-aware sensor and display system for improved patient safety during operation	Assessment of effect on patient safety	Mature prototype	Implementation
	Input to design and evaluation of usability			
EHR	Platform for clinicians and electronic health record	Analysis of user requirements	Post-it labels and cardboard boxes	User requirement analysis
	Assessment of 3 solutions		Mature systems	Procurement
	Planning and coordination between healthcare sectors	Assessment of usefulness and efficiency	Mature prototype	User requirement analysis
EHR	Signaling documentation of test result	Evaluation and work practice assessment	Running system	Implementation

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