Human factors based risk analysis - a way to inform systems design, user satisfaction and organizational success in healthcare innovation?

Betina RANGSTRUP and Helle Boelsmand BAK

Department of Applied Psychology, FORCE Technology, Copenhagen, Denmark

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1. Introduction

Telemed.nu is a project funded by the Danish National Board for Research and Innovation and is intended to promote development of telemedicine in Danish healthcare. At the Department for Applied Psychology at FORCE Technology, we have been included in the project to develop and promote the use of Human Factors centered methods and strategies. As part of this, we have applied a demonstration of a Human Factors based Risk Analysis to a national telemedicine project in the treatment of ulcers. Traditionally, the Human Factors based Risk Analysis is applied when human error can contribute significantly to a hazard in a socio-technical system. In health care, the risk analysis is applied by the manufacturer as part of the development process of a medical device, or it can be applied by a health care institution to evaluate and perform risk reduction for a selected workflow.

2. Methods

Due to time constraints and limited access to stakeholders, we decided to address only the risks associated with the direct use of the specific technology applied in the telemedicine project: The database and communication system 'Pleje.net'. This was further necessitated with the realization that workflows and organizational structures at the different hospitals and municipalities were too disparate for a structured risk analysis to be applicable. Our work thus resembled the risk analysis applied by manufacturers of medical devices even though the technology 'Pleje.net' could not be labeled as a medical device under the current European directive. Furthermore, we limited our user scope to that of the medical professionals and defined risks as only the risks associated with causing harm to patients.

We gathered data about the telemedicine context through desk research and stakeholder interviews. Through observations and contextual inquiries at three hospitals and one municipality working with Pleje.net, we were able to perform a task analysis and define four general user scenarios around the interaction with the technology. Lastly, we invited the system manufacturer and three super-users to a half day workshop. During the workshop, the user scenarios were validated and corrected, and a qualitative risk analysis was performed on selected processes by applying the Failure Mode Cause and Effects Analysis (FMCEA) method. The insights generated throughout the workshop were finally discussed and evaluated with the participants.

3.   Results

The demonstration of applying the Human Factors based Risk Analysis to 'Pleje.net' led to several findings for further exploration and innovation. Firstly, applying the risk analysis only to the direct use of the technology revealed a limited result as to addressing the overall structure of risks in the telemedicine project. Secondly, the FMCEA method proved limited as a tool for understanding and discussing the nature of risks in 'Pleje.net': Often the conclusion from the users was that several failure modes "would never happen", and that this was related to several tangible and intangible buffers in the system setup, or that several unfortunate circumstances would have to be involved if a failure mode was to have effect. Thirdly, it was problematic that no defined responsibilities or acceptance criteria were established, and this is perhaps one of the real challenges of health care innovation projects, such as the national telemedicine project for treating ulcers. Fourthly, it was discussed whether the risk analysis could be broadened to include not only risk of harm to patients, but also risks associated with economy and trust in the system, e.g. through data security breaches or compromising user experiences.

When applying a socio-technical framework, it can be said that health care innovation projects often involve fundamental changes in all parts the socio-technical system. Hence it becomes evident that it is necessary to consider risks through system thinking. Exemplified by the national telemedicine project for treating ulcers, these projects are of a complex nature with a vast array of stakeholders, information flows, power structures, processes and feedback mechanisms. Applying methods such as a Human Factors based Risk Analysis is a challenging task, and important questions must be addressed before the method can be fully applied: Who are we performing the risk analysis for? What kind of hazards are we talking about? Who has the responsibility for mitigating risks, and how can we consider risks for disparate processes and workflows? Furthermore, the risks to be considered in health care innovation projects should not be strictly limited to those that harm patients, but should be equally considered towards economic factors and issues of trust. In this way, the risk analysis could be applied as a tool to inform the overall design of resilient systems, user satisfaction and organizational success. We hope to further explore and demonstrate these possibilities through the Telemed.nu project, which is continuing throughout 2014 and 2015.