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Designing and Evaluating Healthcare ICT Innovation: A Cognitive Engineering View

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Abstract. Many healthcare ICT innovations fail in practice because of a failure to take into account user needs. User needs should be identified broadly, encompassing different levels of organization of the healthcare system and different stakeholder concerns. Full-scale simulators are starting to be used to help in the design and evaluation of novel biomedical devices and displays. Although promising, simulators have significant technical and operational limitations for this purpose and they do not address important aspects of the sociotechnical systems context in which healthcare ICT will be embedded. This argument is illustrated with a case study in which advanced auditory displays for patient monitoring were successfully evaluated in a full-scale patient simulator, but many further questions remain prior to successful translation to practice.

Keywords. Medical devices, medical equipment design, healthcare informatics, cognitive engineering, simulation and training, user studies.

1. Introduction

The need for timely, effective information in healthcare has motivated much healthcare ICT innovation but the reality often falls short of expectations and needs. In this paper I introduce some of the conceptual tools that cognitive engineers use to discuss the impact of healthcare ICT. Then I discuss the potential for full-scale simulators to support formative and summative evaluations of healthcare ICT design innovation, focusing especially on advanced auditory display technologies for intraoperative monitoring.

Finally, I conclude that although simulators can be particularly effective for providing objective empirical evidence for display effectiveness, addressing the more local sociotechnical factors at play, it is still difficult to address the full range of factors that will affect translation to practice. Further conceptual tools are needed.

2. Mismatch of healthcare ICT to use

There are many accounts of failed healthcare ICT systems, the failure often caused by mismatch between technology capabilities and the needs and constraints of healthcare workers.[1, 2] According to one estimate, as many as 75% of healthcare ICT

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implementations are considered failures.[1] Reflecting this, the Gartner Group's "hype cycle" in Figure 1 shows that inflated expectations about healthcare ICT innovation ("peak of inflated expectations") often lead to disillusionment ("trough of disillusionment") as healthcare ICT starts to be rolled out into practice.[3]

The cost to healthcare organisations and to society more generally of such failures can run to millions of dollars.[2] More probing longitudinal assessments can reveal an even worse picture because people's evaluations of healthcare ICT can change over time. In one case, an initial assessment of time gains achieved with a new electronic health record system (EHR) was overturned some months later when users realized that there were areas of use that led to significant time losses as well.[4]

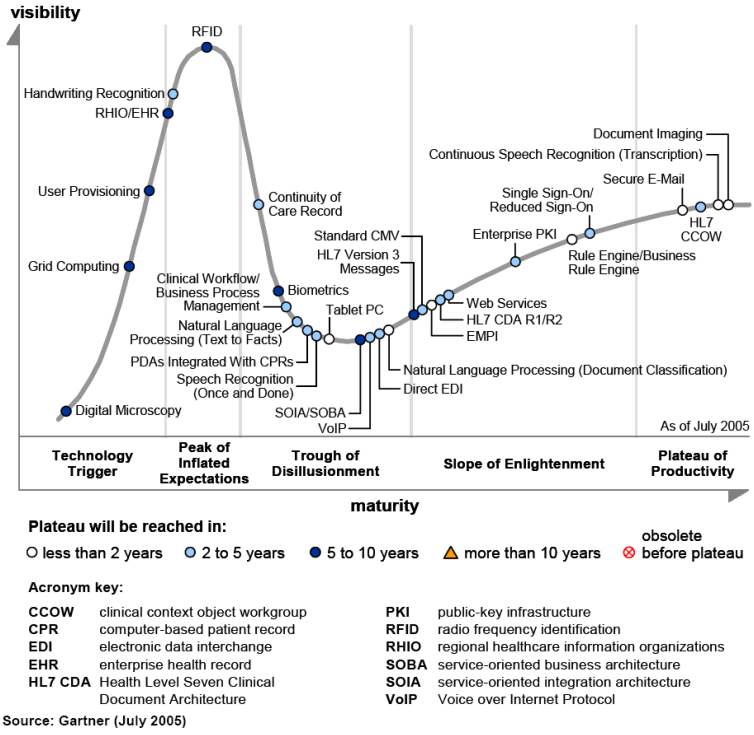

Figure 1. Gartner Group "hype cycle" of healthcare enabling technology. A similar hype cycle exists for healthcare applications. © Gartner Group, 2006.

It has been suggested that the loose coupling of many healthcare systems, where coordination and information flow is achieved through multiple means, is incompatible with the tighter coupling usually imposed by healthcare ICT[5] and so leads to a mismatch between technology and human needs. In addition, the fact that there are stakeholders at different levels of the healthcare system with different priorities and needs means that multiple constraints must be satisfied for healthcare ICT to work effectively.

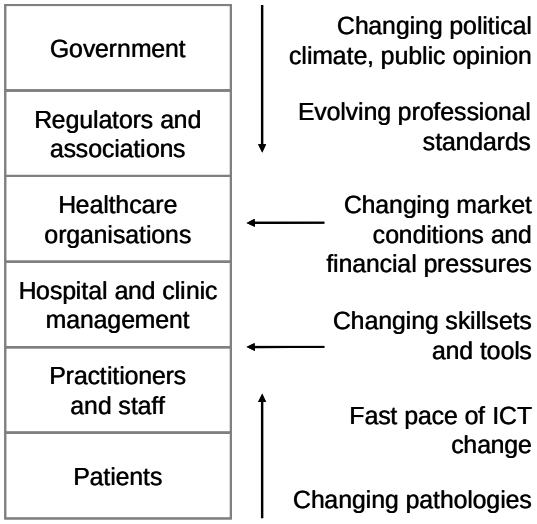

Figure 2. "Patients to politicians" model (Vicente).

3. Scoping perspectives needed

3.1. Patients to politicians model

The healthcare system is subject to multiple pressures from its various stakeholders, which have been outlined succinctly in Vicente's[6] "patients to politicans" model (see Figure 2). This model is an application to healthcare of Rasmussen's[7] analysis of risk management for complex sociotechnical systems—similar diagrams have been developed to show pressures bearing on the power industry, manufacturing and other sociotechnical systems. They are a template from which to start organizing more detailed thinking about the relationship between different stakeholders in a complex sociotechnical system., such as when analyzing incidents or working through the consequences of technology innovation.

Patients and the healthcare practitioners who treat them are at the so-called "sharp end" of the healthcare system (see lower part of Figure 2). The pathologies with which patients present are shaped by epidemiological trends—both acute and chronic—that the healthcare system must accommodate. Healthcare ICT is rapidly changing in response to those needs. We see the introduction of new technologies for sensing, imaging, diagnosing, monitoring, and for storing and retrieving data. As already noted, such technologies almost always require adjustment by patients and practitioners at the sharp end.

At the management and organization levels, healthcare providers must provide resources to meet sharp-end demand with a supply of knowledge, skills, and access to

diagnostic technologies and treatments. Increasing healthcare costs and financial pressures restrict how well demand can be resourced, leading to stresses within the system.

At the societal levels, professional associates develop standards of professional practice and manage accreditation. Regulators set standards that must be met. Patients and practitioners themselves are also members of a public whose expectations of the healthcare system have been shaped by their own experiences and by media reports of the healthcare system in crisis

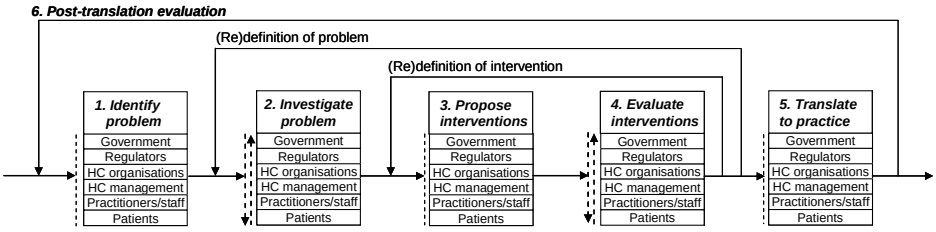

Figure 3. Problem-driven research and intervention in healthcare informatics and patient safety, using the "patients to politicians" model to maintain systems perspectives.

3.2. Patients to politicians—and translation of research to practice

A focus on the relationship between different stakeholders can guide the design of research programs with a strong emphasis on transition to practice. Figure 3 shows the patients to politicians model embedded in such a program, outlined in its most abstract form. Problems of any kind, including problems with healthcare ICT, can first manifest themselves amongst any group of stakeholders—from wrong-side surgery for an individual patient to political unrest at delays patients experience in emergency departments—but problems are usually caused by a complex set of interdependencies involving other levels.

As Figure 3 shows, investigating a problem must move from the level at which it manifests itself to explore its potential causes and effects at other levels of the model. Similarly, interventions might be proposed at multiple levels and those interventions evaluated at multiple levels. Finally, after translation to practice, the effectiveness of an intervention must be assessed not only at levels at which the intervention occurs, but also in other places that it might affect practice.

4. Healthcare ICT innovation and full-scale simulators

4.1. Role of simulators in healthcare

Healthcare ICT innovation can only succeed if design is deeply informed by practice. There is no substitute for participant observation or, even further, for a researcher being

embedded in a community of practice as a learner engaged in "legitimate peripheral participation".[2] However, the behavioural research involved in moving innovative design into practice is considerably more complex, especially if innovation involves medical equipment that will come into contact with patients. Clinicians, manufacturers, healthcare organizations, regulators and, by implication, governments require objective empirical evidence of the effectiveness and safety of innovative design—elements at different levels of the patients to politicians model in Figure 2. Such evidence must be collected while preserving patient confidentiality and safety.

Simulation environments provide a partial solution to the problem of acquiring such evidence. Many healthcare systems in developed countries around the world have simulation facilities where healthcare practitioners can learn skills relating to clinical procedures, emergency response, crisis management, teamwork and communication. Simulation centres offer a physical environment for such learning, including part- and whole-task training devices and simulators.[8]

Importantly, simulation centres also offer immersive experiences with devices and simulators. Although there is always an artificiality and sometimes a hypervigilance associated with learning experiences in a simulation centre, participants find their experiences sufficiently compelling and health care systems are sufficiently convinced of the benefits to continue investing large sum in such centres.

4.2. Simulators and the system development life cycle

Increasingly, researchers are considering how simulators might be used to help evaluate innovative medical equipment or devices.[9, 10] Indeed, simulators can potentially be useful at all stages of the system development life cycle. Figure 4 shows the system development life cycle and indicates the potential role of simulators.

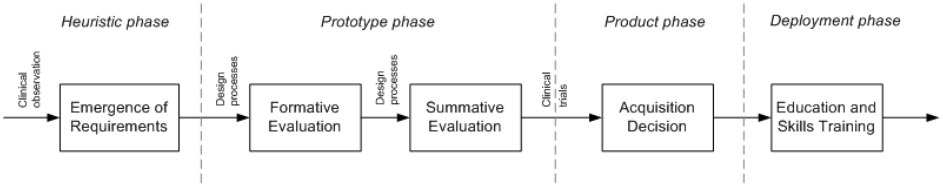

Figure 4. Phases in the use of simulators for healthcare ICT.

Currently, as shown at right of Figure 4, simulators are used almost exclusively for education and skills training in the deployment phase of the system development life cycle. Clearly, skills training is best done on the equipment that healthcare workers will encounter in the field. Still in the deployment phase, some healthcare systems are exploring the use of simulators to introduce new equipment into practice.[9]

From the above point, it is a relatively small step to contemplate using simulators prior to acquisition. For example, simulators can be used at the product phase in order to support an acquisition decision.

[2] As an example, when starting research in the healthcare domain the author trained as an emergency medical technician in the USA in 1996 and was licensed as an EMT-A in the state of Illinois.

Simulators can also be used when a device or system is in prototype form. Summative evaluation of an advanced prototype or pre-release version of a device or system is intended to provide a "summary" or final assessment of performance against a set of benchmarks or standards prior to release.[11] Formative evaluation is more often done on a relatively early prototype in order to help "form" the final design. Design processes therefore surround formative evaluation in a process familiar to practitioners of user-centred design.[12]

Finally, simulators can also provide a context for observation of and discussion about practice that may help unmet requirements and "seeds of innovation" emerge.

4.3. Using simulators to evaluate novel anesthesia displays

Within the Cognitive Engineering Research Group at The University of Queensland, we have been using full-scale patient simulators to evaluate the effectiveness of advanced auditory and visual displays for monitoring anesthetized patients. In terms of Figure 4, our research is best described as being at the early summative stage.

Watson and Sanderson[13, 14] have designed a way of representing in sound (as a "sonification") the values of vital signs relating to breathing—specifically, respiration rate (RR), the amount of CO2 coming out of the patient's lungs with each breath (end-tidal carbon dioxide or ETCO2) and the amount of gas being forced towards the lungs or being taken in by the lungs on each breath (tidal volume, or Vt). Watson[15] has also developed a way of representing in sound (as an "earcon") the patient's blood pressure (BP) as read from intermittent inflations of the non-invasive blood pressure cuff.

Figure 5. Formative evaluations of advanced auditory displays for monitoring anesthetized patients being carried out at The University of Queensland Usability Laboratory. View through control room window.

Formative evaluations were initially performed of the above advanced auditory display designs in a so-called "spartan" laboratory context (see Figure 5). The results gave us an opportunity to make adjustments to the designs.

After the formative evaluations the designs were ready for early summative evaluation, prior to consideration for potential adoption by medical equipment manufacturing companies. The full-scale simulation environment appeared to provide an ideal test-bed for summative evaluation, allowing us to bring together expert professionals, familiar and richly informative intra-operative tools, and familiar medical situations. In collaboration with colleagues at Royal Adelaide Hospital, and using the Adelaide simulator, we performed a summative evaluation of the respiratory sonification and the blood pressure earcons.[10] We also included a test of head-mounted displays of the same information that was in the auditory displays, for control purposes.

Our summative evaluation provided strong evidence that when anesthetists are distracted by other intraoperative tasks, as sometimes happens, the auditory displays were far more effective for alerting anesthetists to significant changes in the patients' status than were the head-mounted displays or current standard monitoring equipment.

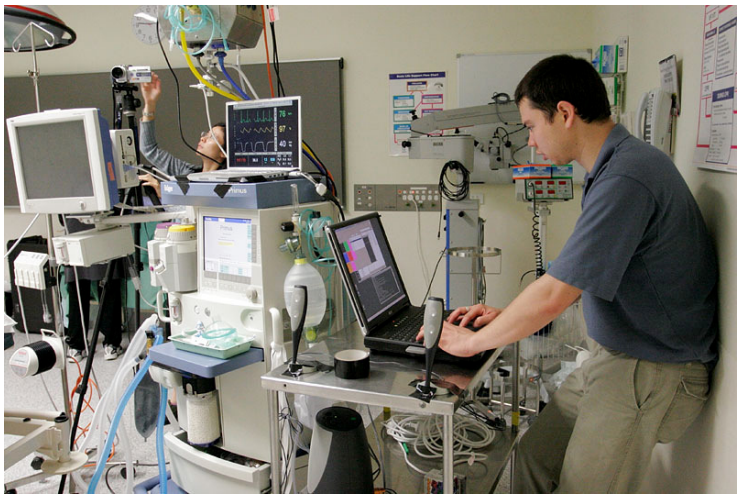

Figure 6. Simulated operating theatre at Queensland Health's Skills Development Centre being set up for research on advanced auditory and visual displays for anesthesia monitoring. Photograph by David Liu, 2006.

4.4. Challenges with simulators

Despite the fact that simulators appear to lend themselves to the prototyping phase of the system development life cycle, there are considerable technical difficulties in practice in acquiring the kind of objective empirical data that encourages the interest of investors and medical equipment manufacturers in innovative designs. Full-scale patient simulators have been designed and developed to support training rather than

controlled experimentation. When training sessions are run, there is usually a general goal to be achieved. For example, the simulated patient may experience anaphylactic shock and the trainee will try to exercise good crisis management skills in response. The manikin and displays will either be programmed to show the signs of anaphylactic shock at a certain point in the scenario, or the signs of anaphylactic shock will be initiated on the fly. Actors improvise their medical and nursing roles within the professional constraints of those roles, and will either take direction from the trainee or act otherwise, as the training situation demands.

Importantly, a great variety of behaviour results usually results and is improvised, based on the reactions of the trainee which are, of course, relatively unpredictable. Strict control and replication of the exact conditions leading up to the event and following the event are not needed during training, whereas they are needed when novel equipment is being evaluated against existing equipment for the purposes of generating objective empirical data.

As a result, our group needed to make considerable one-off enhancements to the simulator software environment in order to achieve the control and replicability needed.[16] Just some of the technical innovation is evident in Figure 6. This need, however, has stimulated our thinking about how simulator technology might be enhanced to better support some of the other roles that simulators might play apart from training and skills development.

4.5. From simulators back to the sociotechnical systems context

A key concern is how innovative designs might safely move from the simulator environment to clinical contexts, and so back to their full sociotechnical systems context. A summative evaluation is incomplete without such as step. As immersive as simulators might be, they do not function in the full sociotechnical systems context outlined in Figure 2. A summative evaluation in a simulator may answer some questions about how an innovative design fits into the intraperative context, for example, but the sociotechnical system being represented in the simulator is drastically attenuated compared with actual workplace practice.

By performing summative evaluation in a simulator we have addressed some of the factors that (using the terms of the Garner Group “hype cycles” in Figure 1) might cause “inflated expectations” of auditory displays for intraoperative monitoring, and have exposed the displays to some of the factors that might lead it to fall into the “trough of disillusionment” in practice, by no means have all factors been addressed.

For example, we do not know what the long-term effects of attention to auditory displays might be. We do not know whether some operating suites will allow auditory display sounds to penetrate from one operating room to another. We do not know how medical personnel moving between different operating theatres will adapt to the different sounds coming from the patients in different room. Although we have tested the displays with ambient music, as often is used in the real operating theatre, we have not assessed all situations or all relationships between the different professional groups “competing” for the auditory space (or for quiet). We do not know whether anesthetists and their staff will wish to switch between speaker-based listening and earpiece-based listening, and what the impact on other professional groups will be of such decisions. We do not know how default settings for auditory displays will be set on medical equipment and what the role of biomedical engineering departments and executive medical direction of the hospital or clinic might be in determining such settings. We do

not know how patients themselves will react to further auditory displays of their own physiological functioning (beyond the existing pulse oximetry or heart monitor beeps), if such further auditory displays are active while the patient is conscious. We do not know if insurance companies will continue to require alarms even if auditory displays might give the same information in a more compelling way.

Two responses are possible. Which response is most practical depends upon resources and safety considerations. First, translating the design innovation to a carefully-selected area in the workplace is the preferred response. The impact of the design innovation on real workplace practice can then be observed. Whether this is feasible depends upon whether a safety case has been successfully answered, whether insurance will cover the trial, and whether consent can be ethically obtained from participants and particularly from any patients affected.

Second, if a trial translation to practice is not possible then simulation might again play a role. Simulation experts are exploring how simulators can be extended to support organizational simulation—in other words, simulating the functions of large-scale organizations using simulator facilities.[17] However, such level of simulation increases the expense of an already-expensive activity and risks to be assessed or benefits to be sought must be overwhelming in order to justify the investment required.

5. Conclusion

Healthcare ICT has a poor track record of enthusiastic adoption in practice. Part of the problem is the failure to address adequately during development the context of use of healthcare ICT. User studies can be effective, but such studies are not always performed at the most appropriate points in the system development life cycle, or in a way that captures the critical aspects of the sociotechnical systems context in which novel healthcare ICT will be embedded.

Simulation technology and full-scale simulators in particular can go part of the way in addressing the above problem, especially when a device or design being developed will directly affect patient care and safety is a consideration. Simulators can be extended beyond their current use for training and skills development to use for formative evaluation of innovative design during development, and summative evaluation prior to production and release. However a full use of simulators for such purposes will require technical development of simulator technology. Moreover, simulators still do not replicate the rich sociotechnical context of healthcare work. Further development is needed for methods for performing formative and summative evaluations of novel designs so that broader aspects of the sociotechnical systems context can be considered. In this way, evaluations with certain assurances can be achieved.

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