

Health technology, quality and safety in a learning health system

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Abstract

Health technology quality and safety is an important issue for health informatics (i.e. digital health) professionals. Health technologies have been used to (1) collect data that can be analyzed to improve the quality and safety of healthcare activities and (2) re-engineer and/or automate error-prone processes. Health technologies are also able to introduce new types of errors (i.e. technology-induced errors) and have been implicated in propagating errors across digital health ecosystems. To develop a learning health system, health technologies need to be considered in terms of how they can improve the quality and safety of health activities traditionally carried out by humans (patients and health professionals) and also how the technology's quality and safety can be improved. This article outlines how this can be done by integrating evidence from health informatics research into practice using a learning health systems approach.

Introduction

Health technology safety has emerged as an important international issue in the field of health informatics.¹⁻⁵ Research has shown that health technologies (i.e. health information technologies, medical devices, and technology systems of care) have the capacity to improve patient outcomes, healthcare processes, and patient safety.^{2,3} Health technologies have also been involved in patient safety incidents.⁴⁻¹⁰ Patient safety incidents involving technology have been documented in acute care,^{6,8-10} clinic,¹⁰ home care,¹¹ and community settings.¹¹ Human factors researchers from the discipline of health informatics have developed strategies that can be used to design, test, and evaluate health technologies and technology systems of care for their safety.^{9,10} To create a learning health system, using health technology safety theories,^{9,12} methods,^{10,11} maturity models,¹ and monitoring systems,¹³ these activities need to be formally included as part of organizational quality and safety activities. Such integration is needed to address the gap between modern approaches to digital health safety and current organizational practices.^{1,2,5} A focus on technology and its role in (and contributions to) safety is an essential aspect of learning health systems.^{1,4,5,12,13} Learning health systems can be defined as systems of healthcare “in which progress in science, informatics, and care culture align to generate new knowledge as an ongoing, natural by-product of the care experience, and seamlessly re-fine and deliver best practices for continuous improvement in health and healthcare.”¹³ Learning health systems employ modern, evidence-based, quality mechanisms to create safe systems of digital care.^{1-3,13}

In this article, we will discuss the importance of health technology safety in a learning health system. It is important to integrate quality and safety mechanisms into organizational technology departments that support healthcare activities. To do this, we employ the overview method of conducting literature reviews as described in Grant and colleagues typology of reviews.¹⁴

Health technology: From improving safety to becoming a safety issue

Health technologies have the ability to improve as well as diminish safety. In 2000, the Institute of Medicine (US) Committee on healthcare quality identified that 98,000 people die in hospitals each year from medical errors.³ The number of deaths due to medical errors was more than the number of yearly deaths from Acquired Immunodeficiency Syndrome (AIDS), breast cancer, and motor vehicle accidents. Yet, these three causes of death received more attention than medical errors. The IOM report *To Err Is Human* established that “the problem is not bad people in healthcare - it is that good people are working in bad systems that need to be made safer.”³ The report identified a need to design and implement safe systems of care. One of the report's recommendations suggested that technologies such as electronic health records, clinician order entry, pharmacy information systems, and decision support systems replace error-prone paper processes in health settings to reduce medical errors.³ Over a period of several years, we saw the introduction of varying technologies designed for patient, health professional, administrative and policy use implemented in order to reduce medical errors.³ These recommendations were significant as they influenced the healthcare sector globally and led to a revolutionary modernization of healthcare systems. We saw a paper-based system of care move towards one that is highly supported by many technologies (i.e. a digital health ecosystem).^{3,5,12}

In 2005, the publication of research identifying how health technologies, when introduced to hospital settings, could

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inadvertently lead to new types of errors (i.e. technology-induced errors) emerged.^{6,10} Researchers identified that as we introduce new technologies, we now need to recognize the following:

- (1) technology is part of a digital health ecosystem¹⁵;
- (2) technology leads to the creation of new healthcare processes that can introduce new types of errors (i.e. technology-induced errors) (see [Table 1](#)); and
- (3) technology-induced errors can propagate throughout a digital health ecosystem (i.e. they become part of an error's trajectory).^{16,17}

In 2011, in response to a growing number of documented cases of technology-induced errors in the media and research literature, the IOM struck another committee focused on patient safety and health information technology. The committee published a report on *Health IT and Patient Safety: Building Safer Systems for Better Care*.⁴ The report had identified that health technologies could introduce new types of errors as well as reduce them, but when designed, implemented, and used inappropriately, health technologies can “add complexity to an already complex delivery of healthcare. Poorly designed Information Technology (IT) can introduce risks that may lead to unsafe conditions, serious injury, or even death.”⁴ The report further identified that poor human-computer interactions (affecting the usability, usefulness, and healthcare workflows) may result in diagnostic error, the wrong tests taking place, and the wrong treatment being applied to treat a health condition. The IOM identified that “safe implementation of health IT is a complex, dynamic process that requires a shared responsibility between vendors and healthcare organizations.”⁴ Today, healthcare has become even more complex with a growing number of new technologies aimed at healthcare consumers and health organizations coming to market.¹⁵ In addition to this, health technologies (software, hardware, and medical devices) are increasingly becoming integrated across the healthcare system providing data and information that needs to be understood by health professionals and citizens so that effective health decisions are made (via devices such as

phones and wearable sensors).¹⁵⁻²⁰ Today's healthcare system is highly dependent on technology for its effectiveness, efficiency, and safety. Health technologies are now an integral part of our digital health ecosystem.²¹

Health technology as a part of a learning health system: Improving quality and safety

Health technologies are a fundamental building block of a learning health system. Learning health systems use organizational data and experiences to incorporate research evidence into organizational structures and knowledge into practice. As a result, patients receive higher quality, safer, and efficient healthcare, and healthcare organizations can become better places for individuals to work.¹³

Health technologies: Capturing data to improve healthcare

Health technologies are key to a future-focused, efficient, effective, high quality, and safe learning health system. Most health leaders and policy-makers view health technologies as a tool for capturing data that can then be analyzed and used to predict changes in healthcare utilization (e.g. emergency room visits) and support organizational decision-making (such as strategic planning for a healthcare region).^{21,22} Data allow us to understand healthcare utilization and improve resourcing of health services and can even help health leaders make incremental improvements in the quality and safety of healthcare. Collected and analyzed data can help us to understand when a process is in control and when a process needs examination, to determine the source of the variation and/or errors.^{21,22} Data captured by technology allow us to learn from the data and improve the quality and safety of healthcare.^{21,23}

Health technologies: Re-engineering healthcare to improve quality and safety

Health technologies are also a form of quality improvement and allow organizations to improve the quality and safety of services while reducing opportunities for medical errors to

Table 1. Non-exhaustive examples of technology-induced errors.

Technology-induced error	Example
Incomplete patient information	Wrong medication may be given ^{6,8-10}
System difficulty reading bar codes during medication administration	Wrong amount of medication is dispensed ^{6,8-10}
Default auto-populates a field	Wrong medication dose may be given ^{6,10}
Poor display	Wrong medication, strength or dose may be given ⁸⁻¹⁰
Conflicting or duplicative display	Duplicated treatment ^{8,9}
Difficult to enter values in the system (i.e. using stylus, typing using keyboard)	Wrong medication dose may be given ^{10,11}
Difficult to locate information	Decisions are made in the absence of information may lead to errors in health-related decision-making ¹¹

occur.²⁴ Health informatics researchers have demonstrated that the right health technology, when designed and implemented using evidence-based approaches from the health informatics literature, can significantly improve the quality and safety of a process or healthcare activities associated with its use.^{12,21,22} Health technologies are used to re-engineer processes,²⁴ automate error-prone activities to enhance safety,²⁵⁻²⁷ and eliminate some types of medical errors.^{3,27} For example, computerized order entry systems can prevent the loss of information associated with illegible prescriptions or the loss of a prescription while it is moved from one location to another (e.g. a nursing unit to a pharmacy in a hospital), thereby improving the safety of healthcare overall.^{3,27} Such radical quality and safety improvements have led to significant safety advances in a learning health system.

Health technologies: Learning from technology-induced errors

In order for the safety of our digitized healthcare system to improve, there is a need to understand how software, hardware, and devices are designed, developed, implemented, interfaced, and maintained to ensure safety.^{16,28,29} Individual technologies and the way these technologies are integrated into a digital health ecosystem may introduce new technology-induced errors.²⁸⁻³² Technology-induced errors may arise from the very human activities that are involved in moving software from an initial idea or design activity (e.g. co-design with patients, participative design with health professional groups) to a fully functional technology.²⁸ Technology-induced errors can arise from/during the design, development, programming, implementation, and maintenance of technologies used to support health and healthcare activities. Methods that test or evaluate technology safety can be integrated into and used to prevent technology-induced errors.²⁸ Lastly, quality and safety (e.g. health informatics—quality improvement and risk management professionals) need to understand how errors propagate across a digital ecosystem of care, when technologies are integrated and interfaced across settings (e.g. from hospital to home).^{31,32} Such learning is critical to a learning health system that takes place within digital health structures. If we learn from technology-induced errors, we can prevent them or build in human review and technological redundancies that prevent errors from influencing health-related decision-making or from propagating across a system of care.

Health technologies: Methods for improving health technology safety lessons learned to date

Over the past two decades, there has been considerable health informatics research in the area of quality and safety. Canadian and international health informatics researchers have led the way in the development of methods and approaches for improving the quality and safety of individual technologies

and technologies integrated into digital ecosystems and infrastructures. There has been considerable research in many areas of digital health aimed at developing new methods specific to quality and safety focused on health technology and digital ecosystems (see [Table 2](#)).

The methods and tools that have been developed have a focus on (1) individual users of technologies interacting with a user interface, (2) individual users interacting with several health technologies in a digital ecosystem of care, and (3) multiple users interacting (with each other) and health technologies within a digital ecosystem of care and digital infrastructure (see [Figure 1](#)).³³ The approach has been used to proactively solve potential safety issues during procurements,^{29,33-36} prior to technology implementation,^{34,35} and after technology deployment has taken place.^{34,35} The methods allow for an elimination and substitution of technologies that are identified as having safety issues,²⁹ the development of a hierarchy of controls³⁷ (i.e. through the re-configuration of software and devices to improve safety),³⁸⁻⁴⁰ and the administrative identification of how safety can be improved with policies, procedures, and training (to equip users with knowledge about safe practices).^{16,41}

Quality and safety in a digital healthcare ecosystem

Many of today's healthcare organizations have quality and safety programs or departments. Few have developed quality and safety departments that include technology quality, safety, and risk management.⁵⁶ Even fewer have dedicated health informatics professionals that have specific competencies focused on quality and safety across the spectrum of approaches as described in [Table 2](#). To date, most quality and safety programs view technology as a method of collecting data to improve human enacted processes.⁵⁷ Today's learning health system requires an understanding of digital health ecosystems that includes understanding how technologies have and can be used to re-engineer healthcare to remove error-prone processes²⁴⁻²⁷ and how these technologies can contribute to or introduce new types of errors.²⁸ Trained professionals (e.g. health informatics professionals) are needed, who have competencies in the health, information, and management sciences⁵⁷ with expertise in human factors and safety.⁵⁸

As an industry, we need to extend our conceptualization of quality and safety to create programs and departments that recognize the role of technology in (1) collecting data to improve healthcare quality and safety activities, (2) re-engineering and/or automating error-prone processes to improve their safety using technology, and (3) improving the quality and safety of the health technologies, digital ecosystems, and digital infrastructures that arise from the above mentioned activities.

Today's healthcare organization needs to learn that digital health changes are part of the healthcare system. Health informatics (digital health) professionals develop, design, procure, implement, and maintain health technologies.⁵⁷ Digital ecosystems of care, infrastructures, and architectures

Table 2. Examples of methods and tools focused on technology, digital ecosystem, and digital infrastructure safety.

Examples	References
Methods to assessing and evaluating safety during health technology procurements (i.e. evidence-based heuristics, usability testing, clinical simulations, computer based simulations)	29,33-36,39,40,42,43
Models and frameworks for understanding technology-induced errors	30,34
Design checklists for software user interface safety	38-40
Design guidelines that improve software user interface safety	38-40
Approaches that test and evaluate the safety of user interfaces and their connection to usability and workflow	10,11,44,45
Methods for safety testing user interfaces, workflows and digital integrations for quality and safety before, during and after systems implementation (i.e. heuristics, usability testing, clinical simulation, computer based simulation)	10,11,29,33-36,39,40,42-45
Software configuration checklists for safety	38-40
Dashboards for viewing quality and safety issues	46
Incident reporting	8,9
Taxonomies specific to technology-induced errors (data and text analytics)	7-9,47
Manual and automated approaches to analyzing incident reports and detecting errors	7-9,48-50
Incident investigation to improve systems	51
Employee digital safety surveys	52
Downtime and technology failure management	53,54
Learning from reports and recalls	55

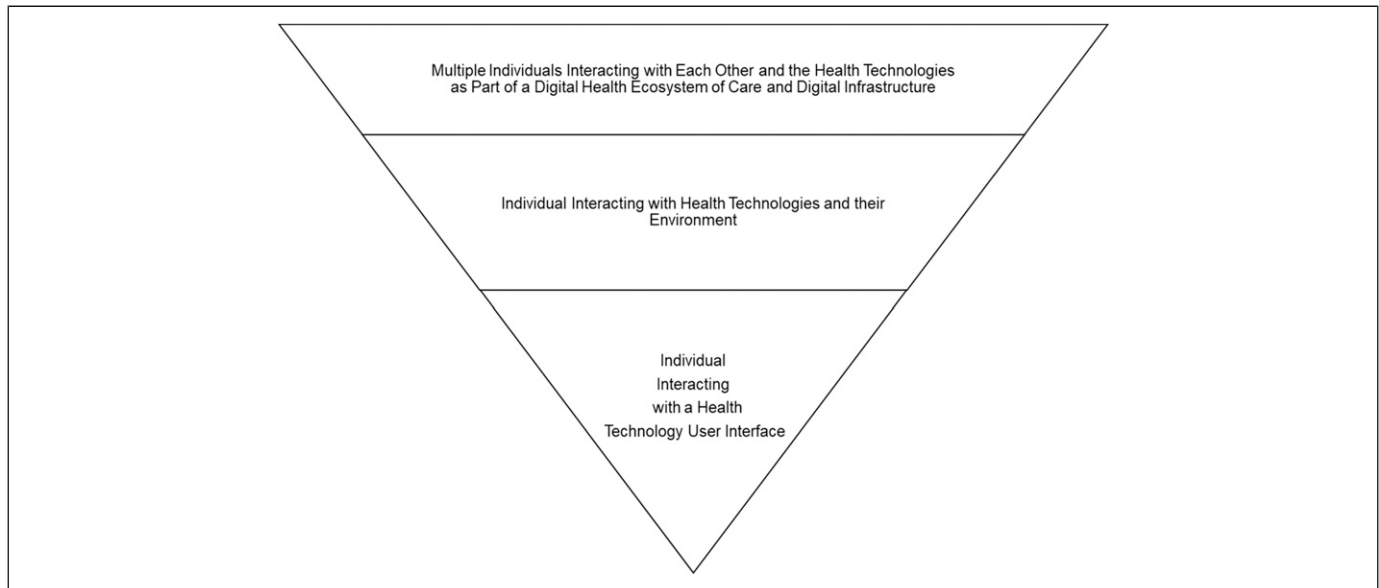


Figure 1. Framework for conducting cognitive-sociotechnical analyses.

are now the backbone of a modern healthcare system.¹² Researchers have developed an understanding of the interactions between clinical/health processes and technologies. Researchers have created taxonomies, methods, and educational approaches to improve quality, safety, and risk management in a digital health system.^{10-55,59} Training programs are available and trained health professionals (i.e. health informatics professionals) are part of our industry workforce.⁵⁷

Discussion and conclusions

In a modern digital health ecosystem, there is a need to understand how software, hardware, and medical devices that make up our digital health infrastructure are integrated so that quality and safety of healthcare remains an important focus while risks are managed. There is also a need for professionals, who understand how healthcare processes have already been re-engineered and automated to improve

quality and safety and to ensure the safe integration and interfacing of new technologies (i.e. software, hardware, and medical devices) in an already complex system of care. Such knowledge will help to manage risks. Application of evidence-based methods is an essential part of a learning health system to continue to achieve quality and safety gains and to prevent or avoid introducing new errors arising from the technology or interactions among technologies.^{10-55,59} To do this effectively, we need health professionals who understand 1) health and disease, 2) healthcare processes and health technology (design, development, and implementation), and 3) how to manage the risks associated with an increasingly complex digital ecosystem. Health informatics professionals hold such competencies and they are drawing on these competencies in an increasingly digitized healthcare system.^{57,58} This is the case internationally.^{5,35} Health leaders can collaborate with health informatics professionals. Health informatics professionals work in roles such as Vice President (Digital Health, Information Services, and Innovation), Chief Information Officer, Chief Nursing Informatics Officer, Chief Medical Informatics Officer, Director of Clinical Informatics, and Chief Technology Officer as well as other management roles in the information technology and information management departments in their healthcare organizations.⁶⁰

Collaborations between regional health authorities and vendors are also key and begin during the procurement and contracting process.³³ Once an ideal technology is procured, it is configured, tested, and implemented at the local organization.³⁸⁻⁴⁰ Clinicians are an integral part of this process.^{12,21} Here, implementers engage and support clinicians before, during, and after the implementation, so they can safely use the technologies (once implemented). Such engagement includes the use of evidence-based training approaches.⁴¹ As clinicians learn the technology, and the new care processes that arise from its use, safety improves.²⁰ Such work involves partnerships between regional health authorities, governments, vendors, and researchers to design, develop, and implement evidence-based practices so that digital health infrastructures (like bricks and mortar physical structures) are safe and can respond to our changing health environment. Lastly, feedback from regional health authorities and governments regarding technology safety to vendors (and the health technology industry) throughout this process helps to close the loop on safety and emphasizes the importance of a learning health system.^{61,62}

In recognition of this new, emergent, and evolving digital health ecosystem environment, health policy-makers and administrators need to support continued technology innovation and use of evidence-based research from the field of health informatics. Health informatics research helps us to understand how technologies, digital health ecosystems, and infrastructure can be used to make incremental (technology as a data collection tool) as well as radical (business process engineering) gains in quality and safety. In a learning health system, this includes improving the quality and safety of the technologies and ecosystems. This

is part of a learning health systems approach.⁵² Learning health systems form the basis for integrating the “science, [health] informatics, incentives, and culture.” Learning health systems “are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral byproduct of the delivery experience” to achieve incremental and radical improvements in the quality of healthcare.^{13,61,62}

Declaration of conflicting interests

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