**Title**

Patient Safety Informatics: Meeting the challenges of emerging digital health

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# Abstract

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# Introduction

The fourth industrial revolution is based on cyber-physical systems and the connectivity of devices. ‘Healthcare 4.0’ describes the adaptation of healthcare to this new paradigm by facilitating, for example, physiological monitoring, assisted living, and telemedicine.1 Healthcare is already becoming increasingly digital and connected with moves toward fog computing and the Internet of Things.2 Additionally, at the time of writing, the COVID-19 pandemic is occurring and accelerating the conception, design, development and use of digital health technology. Healthcare providers have quickly responded with rapid wide-spread adoption of existing technology like video consultation.3 Other technologies like electronic health records, decision-support tools and handheld medical devices have been widely adopted with reported benefits for patient care along with concerns for patient safety.4 It is currently unclear what the consequences are for patient’s safety as existing digital health technologies become ubiquitous with increasing pace and interact in unforeseen ways.5 There is thus a need for an improved understanding and praxis of patient safety in relation to information technology.

Partially motivated by these concerns, the Patient Safety Translational Research Centres were set up by the UK National Institute for Health Research to translate patient-safety knowledge into practice. Beginning in 2020, a series of workshops led by the Centres from both Yorkshire and Humber and Greater Manchester was set up specifically to explore the interaction between emerging digital health technologies and patient safety. The aim of the workshops was to develop the field of Patient Safety Informatics and establish a platform of Patient Safety Informatics theory for future research and development. The first workshop in the series was convened to identify the patient-safety challenges associated with emerging digital health technologies. The 14 participants in the inaugural workshop represented a diverse range of expertise in the development and evaluation of digital health technologies, including clinicians, commercial developers of digital health technologies, software engineers, medical statisticians, and researchers in applied health, health services, safety science, human factors, health informatics, and clinical decision making.

In this viewpoint paper, we present a definition of Patient Safety Informatics that was informed by workshop and existing literature, to discuss the challenges identified in the workshop, and to present recommendations to address the patient-safety concerns posed them.

# The need for Patient Safety Informatics

## Patient safety and its relationship with digital health

Although no consensual definition exists, patient safety can be considered to be the “*avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare*”.6 It is sometimes conceptualised as a balance between risks of harm, resource use, and improving patient health.7 Healthcare is also a safety-critical industry8 that must approach safety by concurrently avoiding, managing and embracing risk.9 This sets healthcare apart from other safety-critical industries – like aviation and offshore oil production – that predominantly focus on only one of these approaches.9

While the patient-safety perspective on digital health technology is not novel10,11, the types of patient-safety challenges and our capacity to address them are constantly in flux. Policy, standards and regulations specific to digital health technology are being drafted worldwide12 to keep pace with evolving healthcare, including the US Food and Drug Administration,13 and the UK’s National Health Service and the National Institute for Health and Care Excellence.14,15 Digital health information technologies are becoming increasingly networked in line with the fourth industrial revolution16, posing novel safety issues as technologies interact.17 This is because when health information technologies interact, they form a health information system,18 or what some have referred to as information infrastructures19, the success or failure of which is partly due to emergent rather than planned change resulting from local improvisation.20 These health information systems are the inevitable structure of how digital health is evolving1,2, and will require a systemic perspective from developers, users and patient-safety researchers to mitigate emergent challenges to patient safety.21

Markus22 provides a framework to map the ways that digital health could evolve. Markus22 implies a 2x2 model describing the risks associated with both novel and existing technologies and their application (table 1). *Technochange* refers to the highest-risk of combining *novel* applications of *new* technologies. This high-risk path for digital health is driven by the relationship between vendors who want to be first to market and buyers who want to be seen to innovate. These incentives can encourage high risks for associated large rewards. It is important to note that health information systems are complex adaptive systems23 embedded within healthcare – itself a complex adaptive system. Whether technology is introduced via familiar or novel applications, it is likely to have unforeseeable consequences.

Whether digital health evolves along Markus’s high, moderate or low risk paths, many challenges posed by increasingly-complex digital health are similar24: innovations are unlikely to be equally affordable and available for all25–28; algorithms and models are of transient relevance29; there has been a continued lack of sufficient testing, despite early calls30; societal challenges like an aging population31; and legal and political jurisdiction.32 Each of these challenges are associated with known and unknown consequences for patient safety, which need to be addressed for responsible provision of healthcare. Hence, there is a need for rigorous study of the relationship between emerging digital health and patient safety, i.e. a Patient Safety Informatics.

## Toward a definition of Patient Safety Informatics

We propose Patient Safety Informatics to be the study of patient-safety-related information in healthcare systems. This definition is based on a synthesis of the aforementioned literature of patient safety, existing literature on safety informatics, and our clinical, professional and academic experience (Figure 1).

Informatics is the interdisciplinary study of information and its environment33. Crucially, information flow is recognised as a key component of system safety and as a reflection of safety culture.34 This understanding has led to the relatively new concept of Safety Informatics, defined as the scientific discipline studying safety information and its mechanisms, to address the lack of safety information in safety management.35 For Wang and colleagues who proposed this definition, safety information refers to safety-related data that shows systems’ safety state and its changes.36,37 Thus, our proposed definition of Patient Safety Informatics incorporates concern for the state and dynamics of patient-safety information.

Despite theoretical and practical progress in safety informatics, it has yet to be applied substantially to healthcare and patient safety. Bakken, Cimino and Hripcask38 explored how informatics can promote patient safety and provided recommendations like integrating informatics into healthcare curricula and the evaluation of digital health from health-economic, clinical and administrative perspectives. While welcomed, these recommendations, and the challenges they purport to address, concern digital health technologies in isolation and their function in promoting patient safety, only. To address emerging digital health, Patient Safety Informatics must also consider the safety of health information systems and their safe use.39

The consideration of healthcare information systems is central to our proposed definition of Patient Safety Informatics. The International Medical Informatics Association working group on ‘Health Informatics for Patient Safety’ consider their role as “[promoting] *patient safety of health information systems and their associated medical devices* [and focusing on] *how healthcare information systems can improve patient safety, as well as identifying and rectifying safety issues*”.40 Patient Safety Informatics may therefore be considered to address both the questions of: 1) whether newly developed or adopted digital health technologies are inherently safe, and 2) how technologies can be designed and applied specifically to improve patient safety. This scope is exemplified in Singh and Sittig’s Health Information Technology Safety Measurement Framework, which defines three safety domains embedded in a socio-technical work system: safe health information technology, safe use of health information technology, and using health information technology to improve safety.39

# Challenges posed by emerging digital health

During the workshop, we highlighted six challenges that emerging digital health pose, each with consequences for patient safety. Table 2 summarises the challenges and our theoretical and practical recommendations to address the safety concerns.

## Challenge 1: Conceptualising digital threats

*It is challenging to conceptualise threats to patient safety from digital influences*.

Much of the innovation in digital health technologies is not physical, instead manifesting as software, systems architecture and communication protocols, which lack the tangibility so foundational to trust in digital and robotic systems.41 This can lead to inadequate consideration of threats to patient safety. The challenges posed by the intangible nature of many of the factors that might interact to contribute to a failure in health care delivery are not specific to the digital component. Considerable work has been undertaken to develop “systems” approaches to understand adverse events, for example. Introducing digital technologies with the associated interconnections can increase system complexity, reducing transparency in cause and effect and the potential traceability of failures in the system. Structured safety cases might be a useful tool to help map the relationship between abstract influences and consequences. Safety cases are structured arguments supported by evidence that are used to justify why a system or a service is acceptably safe within a particular context.42 In safety-critical industries like petrochemical processing and nuclear power, safety cases are an established means by which confidence in the safety of the system is communicated to, and scrutinised by, the diverse stakeholders, including users, regulators and policy makers. In the UK National Health Service, compliance with the clinical safety standards DCB0129 and DCB0160 requires a safety case for digital health technologies. The process involves an exposition of risk to encourage proactive safety management.8 The preparation of safety cases guides reflexivity that can be insightful when combined with a systems approach to conceptualising risk and safety.43,44 Thus, patient safety might be facilitated by the use of dynamic45, multi-view46 safety cases for digital health technology47,48 and for healthcare services.49

## Challenge 2: Trusting opaque and complex systems

*Digitisation and complexification of healthcare technology increase the risk of mis- and disinformation, competing incentives and ‘safety theatre’.*

Trust is integral to patient care and is, partly, a function of inter-personal behaviours between patients, healthcare professionals, and digital health technology developers.50–52 Unlike intermediary technologies that facilitate inter-personal interactions (e.g. telephone appointments and online booking systems), other technologies like risk assessment algorithms53 or web-based treatment-options apps54 complicate the person-to-person relationship synonymous with quality care. This complication introduces alternative sources of information, the origin and quality of which might not be known by patient nor healthcare professional. Patients’ safety can be threatened by the misinformation and disinformation provided by these sources.55

Furthermore, patients’ perceptions of competing incentives jeopardise their trust that healthcare professionals have the best knowledge and will apply it in the patient’s interest.56,57 Similar to how doctors’ relationships with the pharmaceutical industry can jeopardise this trust,58 doctors’ relationships with digital health developers might jeopardise it as they are incentivised to make use of the latest digital health technologies.

Finally, with public wariness of technology like artificial intelligence,59 developers of digital health are incentivised to promote their products persuasively with, for example, focus on short- rather than long-term benefits.41 This can result in ‘safety/security theatre’, which describes deliberate safety-related activities intended to provoke feelings of improved safety regardless of whether they actually influence safety.60 Patients’ safety is threatened directly by the misdirection of attention and indirectly from allocation of limited resources to support the distraction. This risk is in addition to the illusion of patient safety assumed from ignorance or lack of engagement with what patients perceive as inaccessibly complex technology and systems.61,62

We suggest that a socio-technical perspective will help all stakeholders in healthcare to acknowledge the systemic nature of digital health systems. Such a perspective can support an awareness and transparency as a foundation of trust63, in line with the Transparency for Trust initiative.64 Socio-technical models like the Systems Engineering Initiative for Patient Safety65–67 relate the components of healthcare systems, which also map to the determinants of trusting relationships with technology (cf. figure 2 in 59).

Practically, developers and vendors of emerging digital health technologies could consider supplier declarations of conformity to industry standards, and ‘FactSheets’ co-developed with user communities.68 Such approaches contribute to proactive, community-led regulation of digital health to facilitate transparency and understanding.

## Challenge 3: Integrating and interpreting data sources

*Inadequate integration of data sources can lead to misuse, abuse, and non-use of data*.

Advances in monitoring technologies means that a greater variety of data can be collected with greater ease and speed. Increasing the availability of data increases opportunity to support the provision of high quality and safe healthcare but only if the data are coherent and interpretable to healthcare decision makers and practitioners. Appropriate integration is needed to avoid misuse, abuse and non-use of data, which has been implicated in patient deaths.69,70

To mitigate these hazards, safe development and use of middleware – software that interfaces systems and applications – will be essential to provide an intermediary between heterogeneous healthcare data.71 Proposed solutions include standards for exchanging electronic health records (see 72,73 for application in epilepsy data), distributed architectures to integrate electronic health records74–76, and 3rd-party infrastructure for linkage and querying of electronic health records, e.g. the CSIRO Health Data Integration tool.77

Other contributing solutions include dynamic modelling of the data29, which can provide a solution to the transient relevance of predictive models. Safety might also be facilitated by an improved understanding of the latent processes generating healthcare data. Methods that respect these latent processes are available to health informaticians.78 Finally, progress in artificial intelligence (particularly anomaly detection) might help to mitigate unsafe decisions made from data errors.79,80 For example, Sako et al81 provides a conceptual framework for automated assessment of data quality and information integrity. These methods are examples of how developments in digital health can be used to improve patient safety as well as help with its safe use.

## Challenge 4: Reactive regulations and standards

*As the pace of innovation accelerates, the current reactive (rather than proactive) regulatory- and standards-based approaches to safety will be increasingly ineffective at assuring patients’ safety* (Xplaceholder – OJ and CMc paperX).

The consequence of reactive regulations and standards is that avoidable harm might be experienced before mitigations are put in place. We recommend synchronisation of the development and evaluation of digital health technologies, similar to the Idea-Development-Exploration-Assessment-Long term study (IDEAL) framework and the US Food and Drug Administration’s Software Pre-Cert Pilot Program.13 The IDEAL framework champions gradual approval of medical devices rather than the one-shot approval of CE marking82, which would allow “*graded, responsible, but earlier patient access*”.83,84 Such frameworks simultaneously address concerns that the increased administrative burden of more-stringent regulations might delay products that are imperfect but practically useful.85

We also recommend that regulators and developers of standards adopt a systems approach to conceptualising risk43 to appropriately reflect the complex adaptive nature of healthcare.86 Practically, this would be reflected in the guidance and requirements relating to risk assessments. It is hoped that these recommendations might help to manage increased sensitivity to safety during development. This is in line with the aforementioned Software Pre-Cert Pilot Program’s focus on the “*digital health technology developer, not the product*”.

## Challenge 5: Emergent patient-safety consequences

*Focusing on technologies in isolation does not consider the patient-safety consequences that emerge when technologies interact.*

Healthcare systems are complex with a diversity of organizational forms, interdependence, and feedback effects.87 Interactions between digital health technologies can make threats to patient safety more visible, change the nature of risk, and introduce new failure modes/incident types.88 Sufficient theoretical and practical guidance is needed to navigate the novelty of emergent consequences and to understand how, through interaction, technologies and users anticipate outcomes and act to influence them.89

Healthcare systems are holarchical – nested systems-of-systems – as exemplified by the Heimdall framework of learning health systems90 and Carayon et al’s91 model of workplace safety. Systemic and holarchical conceptualisations of healthcare processes and patient-safety consequences can help to reveal factors underlying systems’ unpredictability. For example, the framework of Non-adoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability (NASSS) can help to identify uncertainties and interdependencies of technology-supported change in healthcare.92

Our theoretical recommendations are to use systems-based definitions of risk and of resilience43,93 to complement a systems approach to patient safety.94 As noted by Weicks,89 resilience is an emerging ability of a system to respond to unexpected demands such that normal operations can continue. It moves away from a deterministic paradigm of safety research that assume merely-complicated and attributable sources of hazard.

Practically, we recommend the aforementioned safety cases and gradual approval of medical devices as appropriate approaches to handle the limited capacity to predict the behaviour of complex systems. Such complexity approaches will also be useful in addressing the question of how emerging challenges will interact with the other challenges.

## Challenge 6: Solutionism

*Techno-optimism and technology push can drive ineffective and adverse digital health interventions.*

Solutionism is an ideology that inappropriately recasts “*complex social situations…as neatly defined problems with definite, computable solutions…if only the right* [technologies] *are in place”*.95 Examples include diet apps that inappropriately simplify body composition as merely a function of calorie consumption96, and downplaying the unimproved quality of life of patients treated for neurological disorders because treatment did improve measurable variables of motor control.97 Interventions might be unfit to address health and safety concerns if digital implementations are prioritised on ideological grounds. The driving techno-optimism might arise from differences of perceived risk or perceived capacity for control98, which relate to existing problems of inequality in technical education and access to digital health, respectively.99

In addition to earlier recommendations of adopting socio-technical perspective and a systems approach to conceptualising risk, solutionism can be addressed by adopting a systemic approach to patient safety. Ravitz et al.44 describe such an approach with a case study on medication infusion pumps, while the Systems Engineering Initiative for Patient Safety model provides a framework for understanding the structures, processes and outcomes in healthcare, more generally.65,66 These approaches can help to sensitise developers and users of digital health to the relationships within healthcare systems that might facilitate unintended consequences.

# Conclusion

The intention of this article was to begin the process of developing the theoretical and practical foundations of Patient Safety Informatics, answering calls for practical progress in safety science100, for a unifying theory101, and for bridging the gap between research and practice102. We presented six challenges posed by emerging digital health, described the consequences for patient safety, and recommended theoretical and practical mitigations.

These challenges, consequences and recommendations were gathered at an expert, interdisciplinary workshop focused on exploring the theoretical and practical foundations of Patient Safety Informatics. A key implication of considering the challenges and opportunities for Patient Safety Informatics is the interdisciplinary contribution required to study digital health technologies within their embedded context. While some recommendations are specific to challenges, the underlying principles are that of prospective action and a systems perspective that relates the social, technical and regulatory facets. These ideas will be further explored in subsequent workshops in our series that will address the consequences of contemporary safety theory for digital innovation, socio-technical evaluation of digital health, and digital health interventions designed to improve patient safety.

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\*\* Tables and figures must be submitted separately\*\*

\*\* FYI, tables have to be presented in this simplified format but the Lancet editing team will improve aesthetics \*\*

|  |  |  |
| --- | --- | --- |
|  | *New technology* | *Existing technology* |
| *Novel application* | High risk | Moderate risk |
| *Familiar application* | Moderate risk | Low risk |
| ***Table 1:* Contingency table illustrating the risk categories associated with interactions of novel and existing technology and its application. Adapted from Markus**22**.** | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Challenges** | **Consequences for patient safety** | **Recommendations** | **Safe**  **HIT** | **Safe**  **use of**  **HIT** | **HIT to**  **improve**  **safety** |
| 1 | Difficult to conceptualise threats to patient | Inadequate consideration of threats | Systems approach to conceptualising riskT; Safety | x | x | - |
|  | safety from non-physical innovations. | to patient safety. | casesP; Socio-technical perspective |  |  |  |
| 2 | Unclear how to sensibly integrate and | Missed opportunities to use data; | Dynamic and causal modelling continuously | x | x | x |
|  | interpret new and voluminous data streams. | Inappropriate use of data; Biased use | surveilled for performanceP; Middleware for |  |  |  |
|  |  | of data. | interoperabilityP; Standards for linkage and |  |  |  |
|  |  |  | exchange of healthcare dataP; Automated anomaly |  |  |  |
|  |  |  | detection |  |  |  |
| 3 | Reactive regulatory- and standards-based | Avoidable harm is experienced before | Gradual approval of medical devicesP; Systems | x | - | - |
|  | approaches to safety. | mitigations are put in place. | approach to conceptualising riskT |  |  |  |
| 4 | Difficult to build and maintain trust in health | Misinformation and disinformation | Socio-technical perspectiveT; FactSheetsP | x | x | x |
|  | information systems that are obscure and | threaten patient safety. |  |  |  |  |
|  | complex. |  |  |  |  |  |
| 5 | Emergent patient-safety consequences in | Hazards cannot be completely | Systems approach to conceptualising riskT; | x | x | - |
|  | health information systems. | foreseen. | Systems approach to patient safetyT; Safety |  |  |  |
|  |  |  | casesP; Socio-technical perspectiveT; Gradual |  |  |  |
|  |  |  | approval of medical devicesP |  |  |  |
| 6 | Solutionism inappropriately simplifies | Unfit interventions and assurances | Socio-technical perspectiveT; Systems approach to | x | - | - |
|  | problems and predicaments. | might be suggested. | conceptualising riskT |  |  |  |
| Recommendations are tagged as theory development (T) and practical application (P) in line with the foundational aim of the workshop series. The rightmost columns are the domains of safety for Health Information Technology (HIT), as per Singh and Sittig’s Health Information Technology Safety Measurement Framework.39 | | | | | | | |
| ***Table 2:* Summary of recommendations to address safety concerns posed by the challenges of emerging digital health.** | | | | | | | |

|  |
| --- |
| ***Figure 1:* Our definition of Patient Safety Informatics incorporates elements of digital innovation, safety science and clinical care** |