Safety Informatics: Meeting the patient safety challenges of health information technologies

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# Introduction

Healthcare is becoming increasingly digital and connected (Wickramasinghe and Bodendorf, 2020). 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 adaptations like video consultation, which has accelerated community learning (Wherton *et al.*, 2020). Other technologies like electronic health records, decision-support tools and handheld medical devices have been developed and used for many years with reported benefits for patient care but also with concerns for patient safety (Sittig *et al.*, 2018). It is currently unclear what the implications are for patient safety as existing health information technologies become ubiquitous with increasing pace and interact with new and emerging technologies (Benbya *et al.*, 2020). The need for an improved understanding and praxis of patient safety within the field of health informatics? is even more urgent given the accelerated development and adoption during the COVID-19 pandemic.

The Patient Safety Translational Research Centres were set up by the UK National Institute for Health Research to translate patient-safety knowledge into practice. In April 2020, a national, expert collaboration led by the Centres from both Yorkshire and Humber, and Greater Manchester was set up to appraise the academic evidence for patient safety in health information systems. Our collaborative intends to host a series of workshops that deliver publications to engage those directly involved in the delivery and study of healthcare, and to provide recommendations to address theoretical and practical gaps in the literature on/understanding of? safety informatics. Our aim is to define the field of Safety Informatics and establish a platform of safety informatics theory for future research and development.

In Section 1 of this paper, we outline the Safety Informatics domain at the intersection of safety science and health informatics and highlight the urgent need for theory development and research. Section 2 summarises the workshop process. In Section 3, we present the synthesis of challenges and patient safety implications of emerging health information technologies. Finally, in Section 4 we propose a theory-informed framework for future work in safety informatics.

# Section 1: Patient Safety and Safety Informatics

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*” (Vincent, 2010). It is sometimes conceptualised as a balance between risks of harm, resource use, and improving patient health (Cook and Rasmussen, 2005). Healthcare is a safety-critical industry (Sujan *et al.*, 2016) that must approach safety by concurrently avoiding, managing and embracing risk, depending on which of its range of services it is providing (Vincent and Amalberti, 2016); This sets healthcare apart from other safety-critical industries, which predominantly focus on only one of these approaches.

While the patient safety perspective on health information technology (HIT) is not novel (e.g. Gómez-González et al., 2020; Kostkova, 2015), the types of patient safety challenges and our capacity to address them are constantly in flux. For example, there continues to be rapid progress in the development and uptake of devices compatible with the Internet of Things: “*a network of devices all embedded with electronics, software, sensors, and connectivity to enable them to connect, interconnect, and exchange data*” (Wickramasinghe and Bodendorf, 2020). These networked devices, such as smart continuous glucose monitors (Facchinetti, 2016) and Parkinson’s disease monitoring watches (Bot *et al.*, 2016), pose novel risks (Paxton and Branca, 2020). This is because when HITs interact, they form a health information system (HIS) (Onik, Fielt and Gable, 2017). The success or failure of HISs is due to emergent rather than planned change resulting from local improvisation (Heeks, 2006). Such a conception of HISs as complex adaptive systems (Johnson, 2019) is contrary to a normative idea of planned actions and outcomes, instead acknowledging the bounded understanding and control that actors actually have. It is for this reason that standards and regulations for medical devices now recognise the need for a systems perspective and consider system configurations and processes for device integration (e.g. IEC, 2006, 2009, 2011; see Chadwick et al., 2012 for discussion). Yaqoob et al. (2019) provide a lengthy report on the security and regulatory vulnerabilities associated with networked medical devices, while Benson and Grieve (2016) provide a thorough discussion of the principles of health interoperability.

There is a need for rigorous study of the relationship between HISs and patient safety, i.e. a Safety Informatics. Challenges posed by an increasingly-complex HIS include: innovations that are unlikely to be equally affordable and available for all (McAuley, 2014; Robinson *et al.*, 2015; Lupton, 2017; Banerjee, 2019); the transient relevance of algorithms and models (Jenkins *et al.*, 2018); a continued lack of sufficient testing, despite early calls (Leveson, 1986); implications associated with multiple HISs interacting and societal challenges like an aging population (Pilotto, Boi and Petermans, 2018); and legal and political jurisdiction (Wismar *et al.*, 2011). Each of these challenges are associated with known and unknown implications for patient safety, which need to be addressed for responsible provision of healthcare.

## Safety Informatics

The International Medical Informatics Association (IMIA) working group on ‘Health Informatics for Patient Safety’ consider their role as “[promoting] *patient safety of health information systems and their associated medical devices. The focus…is on…how healthcare information systems can improve patient safety, as well as identifying and rectifying safety issues*” (IMIA WG7, 2018). This scope is exemplified in Singh and Sittig's (2016) Health Information Technology Safety Measurement Framework. The framework defines three safety domains embedded in a socio-technical work system: safe HIT, safe use of HIT, and using HIT to improve safety. Safety Informatics addresses problems in all of these domains using principles from information science, i.e. the representation, storage, supply, search for and retrieval of relevant information (Stock and Stock, 2013).

# Section 2: Method

A workshop of 14 collaborators was convened who represent those who develop and evaluate HIT. Collaborators discussed the patient safety implications of the challenges posed by a set of new and emerging HITs that were collated from a scoping review of the academic, commercial and grey literature relating to HISs. In subsequent meetings, the group collated and synthesised contributions to 1) describe characteristics of new and emerging HITs, 2) describe the challenges posed by evolving HISs, 3) describe the patient safety implications of these challenges, and 4) recommend approaches to address the patient safety implications.

We define emerging technology as innovation, novel application of an existing technology, or novel uptake or use of an existing technology by an organisation or user. Table x1x shows some of the example HITs considered. The technologies are characterised by personalisation, decentralisation, a systems orientation, and a move toward a user-led/patient-centred experience.

# Section 3: Workshop synthesis

## Challenges posed by new and emerging HIT

We propose there are six challenges posed by the kinds of HIT that are emerging, each with different implications for patient safety. Firstly, much of the innovation is not physical, instead leveraging existing hardware in novel ways. This manifests as software, systems architecture and communication protocols. It is challenging to conceptualise threats to patient safety from these non-physical influences because it requires more-abstract consideration of interactions and effects, with the consequence that the patient safety implications may not be adequately considered.

Secondly, it is increasingly easier to collect data but it is not clear how they can be sensibly integrated and interpreted (Ranjan *et al.*, 2018). Thirdly, 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.

Fourthly, although HITs are being developed to leverage HISs, safety considerations are often focused on the HIT in isolation. This reductionist approach leads to a myopic view of the HIT’s effects that does not consider the emergent consequences of the HIT’s involvement within a HIS. Fifthly, and related to the challenge of reductionism, is solutionism, which 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”* (Morozov, 2013). Examples include diet apps that inappropriately simplify body composition as merely a function of calorie consumption (Maturo, 2014) and many medical treatments (Gardner and Warren, 2019).

Sixthly, the increased complexity and distal connectedness of HISs challenges notions of trust that have long been a part of patient care (Thorne and Robinson, 1988; Song and Zahedi, 2007). Trust in healthcare is partly a function of inter-personal behaviours (Calnan and Rowe, 2006) and the gatekeeping and competing incentives of actors in a HIS threaten this trust (Mechanic and Schlesinger, 1996; Alaszewski, 2003). Finally, there is the question of how these challenges will interact with the existing challenges alluded to in Section 1.

## Patient-safety implications of HIT challenges

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# Section 4: Addressing challenges to patient safety

In this section, we recommend theoretically-informed frameworks to address the patient safety implications raised in Section 3.

## Safety cases

Safety cases are structured arguments supported by evidence that are used to justify why a system or a service in acceptably safety within a particular context (Bishop and Bloomfield, 2000). In safety-critical industries, particularly in the UK, these 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 NHS, compliance with the clinical safety standards DCB0129 and DCB0160 requires a safety case for HITs. The process involves an exposition of risk to encourage proactive safety management (Sujan *et al.*, 2016). Patient safety might be facilitated by the use of dynamic (Denney, Pai and Habli, 2015), multi-view (Flood and Habli, 2011) safety cases for HIT (Despotou *et al.*, 2012; Habli *et al.*, 2018) and for healthcare services (Sujan *et al.*, 2015).

## Interoperability

An evolving market of HITs creates a dynamic network of information flows that might not be compatible. Safe development and use of middleware will be essential to provide an intermediary “*to abstract* [the] *heterogeneity* [of HITs] *… to achieve a seamless integration*” (Díaz, Martín and Rubio, 2016). Proposed solutions include standards for exchanging electronic health records (Saripalle et al., 2019; see Houta et al., 2019 for application in epilepsy data), distributed architectures to integrate electronic health records (Roehrs, André and Righi, 2017; Roehrs, 2019; Roehrs *et al.*, 2019), and 3rd-party infrastructure for linkage and querying of electronic health records, e.g. the CSIRO Health Data Integration tool (Hansen, Pang and Maeder, 2007).

## Dynamic and causal modelling

Dynamic-modelling methods (Su *et al.*, 2018) are methods for building prediction models that (at least) maintain predictive performance over time in response to observed changes in the underlying the phenomena of interest (Jenkins *et al.*, 2018). They provide a solution to the transient relevance of predictive models that are typically informed by a single snapshot of data, which might already be outdated depending on the pace at which the phenomenon evolves and the rate at which data can be collected. Dynamic-modelling methods have already been applied for predicting relapse of cancer (Huang *et al.*, 2016) and mortality after cardiac surgery (Hickey *et al.*, 2013). Recently, progress continues to be made developing models that respect the latent, data-generating processes underlying the phenomena of interest (Sperrin *et al.*, 2019).

## Machine Learning for data quality

As an example of the HIS’s self-regulation (Comfort, 1994), progress in artificial intelligence (particularly anomaly detection) might help to mitigate problems arising from data errors, despite the potential threats to patient safety (Challen *et al.*, 2019; Macrae, 2019). To minimise inappropriate decisions due to poor data quality, Sako et al. (2020) provides a conceptual framework for automated assessment of data quality and information integrity. Such models are guides to operationalise data quality assessment protocols (Weiskopf *et al.*, 2013, 2017), themselves informed by taxonomies of data quality dimensions (e.g. Feder, 2018; Weiskopf & Weng, 2013).

## Human Factors/Sociotechnical Approach

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# Conclusion

[Words < 150] The purposes of this section are to 1) summarise the intention of this first collaboration in the series, ~~2) succinctly summarise the characteristics of new and emerging health information technologies, 3) succinctly summarise the classes of patient-safety challenges and their safety implications, 4) succinctly summarise our suggested approaches to address the patient-safety challenges,~~ 5) suggest the next steps required to facilitate these approaches, 6) foreshadow the subsequent collaborations in the series.

The intention of this article was to begin the process of developing the theoretical and practical foundations of safety informatics, contributing to a unifying theory that is lacking in safety science (Swuste *et al.*, 2020). The workshop described herein took placed during the COVID-19 pandemic of 2020, which spurred swift development and use of HIT. Rapid adoption of HIT has brought many benefits and new ways of working but has also brought with it existing and novel threats to patient safety. While the progress toward a more integrated and digital healthcare system is welcome, we urgently need to address the associated patient-safety concerns, both theoretically and practically.

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Subsequent workshops in our series on the theoretical and practical foundations of safety informatics will address the implications of contemporary safety theory for digital innovation, sociotechnical evaluation of digital technology, and digital technology designed to improve patient safety (Johnson *et al.*, 2020).

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