Safety Informatics: Meeting the patient safety challenges posed by emerging health information technologies

*Likely word count for Viewpoint or Perspective article = 2,000 words*

# Introduction

[Words < 300] The purposes of this section are to introduce the collaboration series, its motivations, its intentions, the need for theoretical and practical foundations, and the structure of the article.

Healthcare is becoming increasingly digital and connected (Wickramasinghe & Bodendorf, 2020). 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.

In April 2020, we set up a national, expert, consensus-building collaboration to appraise the academic evidence for patient safety in health information systems. The collaborative intended 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 safety of informatics. The collaboration was led by the National Institute for Health Research Patient Safety Translational Research Centres from both Yorkshire and Humber, and Greater Manchester, UK; the proposal for the workshop is available at <*link to GitHub source*>. The primary planned deliverable from the collaboration was a set of publications that begin to define the field of Safety Informatics and serve as a platform for future research and development.

In Section 1 of this paper, we define the Safety Informatics domain and highlight the need for research in this intersection of safety science and health informatics. Section 2 briefly presents the workshop process that produced this publication. In Section 3, we synthesise the output of the first workshop, which addressed the challenges and patient-safety implications of emerging health information technologies. Finally, Section 4 finishes with recommendations for theoretically-informed frameworks to address these patient-safety implications.

# Section 1: Patient safety and Safety Informatics

[Words < 700] The purposes of this section are to 1) introduce patient safety and its relationship with health information technology, 2) define Safety Informatics and argue the case for it.

\*Introduce patient safety to set the context

\*Discuss the relationship between patient safety and health information technology

\*\*Must distinguish between health information technology and health information systems.

While the patient-safety perspective on health information technology 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 & 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 & Branca, 2020). This is because when health information technologies interact, they form a health information system, which has the potential to improve patient care but also to threaten patient safety in unintended and emergent ways (Heeks, 2006). 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.

Other challenges posed by an increasingly-complex health information system include: innovations that are not likely to be equally affordable nor available for all (Banerjee, 2019; Lupton, 2017; McAuley, 2014; Robinson et al., 2015); the transient relevance of algorithms and models (Hickey, Grant, Caiado, et al., 2013; Hickey, Grant, Murphy, et al., 2013; Jenkins et al., 2018); a continued lack of sufficient testing, despite early calls (Leveson, 1986); and societal challenges like an aging population (Pilotto et al., 2018), and legal and political jurisdiction (Wismar et al., 2011). Each of these challenges has some unknown implications for patient safety, which is why there is a need for rigorous study of the relationship between health information systems and patient safety: a safety informatics.

\*What is Safety Informatics and why do we need it?\*

\*\*Suggestion: Niels Peek (UoM) to lead on this section\*

\*(The history of informatics might be important if pursuing a Safety journal rather than Informatics journal)

Karl Steinbuch is said to have coined the term *informatik* in 1957 (Steinbuch, 1957) and it now functions as the German term for ‘computer science’ (Widrow et al., 2005). The anglicised term *informatics* has come to refer to interdisciplinary study of information and its environment*;* how it is represented, stored, searched and supplied (Gammack et al., 2011; Stock & Stock, 2013). Many subfields of informatics have been demarcated with medical informatics being one of the first (Kuhn et al., 2008). Biomedical (Shortliffe & Cimino, 2013), nursing (McCormick & Saba, 2015), clinical and clinical-research (Degoulet & Fieschi, 2012; Richesson & Andrews, 2019), public-health (Magnusson & Fu Jr., 2013), and bioinformatics (Baxevanis & Ouellette, 2020) are but a few of the further subfields recognised by the International Medical Informatics Association (IMIA, 2020), where they use principles from information science to address particular needs.

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 H.I.T., safe use of H.I.T., and using H.I.T. to improve safety. Safety Informatics uses principles from information science to address problems in these domains, which is the study of the representation, storage, supply, search for and retrieval of relevant information (Stock & Stock, 2013).

# Section 2: Method

[Words < 150] The purpose of this section is to describe the process by which this publication was produced.

A workshop of <*final count of collaborators*> collaborators was convened who represent those who develop, evaluate and use health information technologies and their data for both research and practical purposes. Collaborators included <*list of roles represented by collaborators*>. A set of new and emerging health information technologies were collated from a scoping review of the academic, commercial and grey literature relating to health information systems, and collaborators discussed the patient-safety implications of the challenges posed by them. In subsequent meetings, the group collated and synthesised collaborators’ contributions to 1) describe characteristics of new and emerging health information technologies, 2) describe the challenges posed by the evolving health information system, 3) describe the patient-safety implications of the challenges posed, and 4) recommend approaches to address the patient-safety implications.

# Section 3: Workshop synthesis

[Words < 300] The purposes of this section are to 1) briefly and generally describe characteristics of new and emerging health information technologies, 2) describe the output of the discussions within the collaborative regarding the novel challenges posed by the new and emerging technologies listed above, and 3) present the patient-safety implications of the classes of patient-safety challenges outlined in the previous section.

## Characteristics of new and emerging H.I.T.

\*What is meant by “new” and “emerging”? We might choose to use Leavitt’s diamond.

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.

\*Characteristics of new and emerging technologies. The table of 16 technologies can provide the substrate for the development of characteristics of new and emerging H.I.T., which will provide context for discussion of possible challenges.

## Challenges posed by new and emerging H.I.T.

\*Outputs from the short, initial workshop:

* It is difficult to conceptualise safety issues for digital technology in comparison to physical technology.
* Solutionism: The idea that every solution has a technical fix (as opposed to cultural, social, political, emotional, etc.)
  + Do we have any non-CompSci contacts who study social/relational dynamics?
  + Connect with Centre for Decision Research for insight into how people approach problems in healthcare.
  + Connect with Rebecca Lawton about the psychology of Patient Safety, given who she is and given she is module leader on a module called “Psychology of Patient Safety”.
* As it becomes easier to collect more data, how do we correctly incorporate and interpret it?
* How will novel challenges interact with existing challenges?
  + Digital inequality: will the characteristics of new and emerging technologies contribute to a new class of digital inequality?
* Regulations are still reactive rather proactive, so the gap between what is done and its regulation will accelerate as innovation accelerates.
  + Connected issue about necessity for gatekeepers for ubiquitous H.I.T.
* Technologies still being viewed in isolation rather than as a system. This applies to both technological innovation but also safety reviews of technologies.
* Trust: Who are we entrusting with *more* of our data *faster* and *more often*?

## Patient-safety implications of H.I.T. challenges

\*

# Section 4: Addressing challenges to patient-safety

[Words < 400] The purpose of this section is to present techniques, theories, approaches and frameworks that can help to address the patient-safety challenges identified by the collaborative.

## Safety cases

\*Suggestion: Ibrahim Habli (UoY) to lead on this section\*

The purpose of this subsection is to present the concept of a safety case (Denney et al., 2015; Despotou et al., 2012; Flood & Habli, 2011; Habli et al., 2019; Sujan et al., 2016, 2013, 2015).

## Standards

The purpose of this subsection is to present efforts to develop design standards for health information technology (Kux & Majeed, 2017; Macrae, 2019; Masum et al., 2013), e.g. IEC 80001 standard (IEC, 2011), learning from Business Intelligence and sociotechnical theories (Moghimi et al., 2020), Clinical Decision Support Consortia (Wright et al., 2011), preceding scale-up with a scoping review of international, national, and relevant local guidelines (Furlong et al., 2019), Hippocratic Oath for Connected Medical Devices ; and using frameworks that sufficiently consider socio-technical systems and lifecycles of technology (Greenhalgh et al., 2017).

## Interoperability solutions

The purpose of this subsection is to present efforts made to improve the interoperability of health information technologies and health information technology systems.

\*With no specific expertise within the group and no particular citation, this could be the first subsection to be removed if space is constrained.

## Dynamic and causal modelling

\*Suggestion: David Jenkins (UoM) to lead on this section\*

\*Possible citations: (Hickey, Grant, Caiado, et al., 2013; Huang et al., 2016; Sperrin et al., 2019, 2018; Su et al., 2018).

## Machine Learning for data quality

\*Potential subsection discussing the use of machine-learning methods to help ensure data quality, with special reference to work by Sako et al. (2020).

## Human Factors

\*Suggestion: Jon Benn (UoL) to lead on this section\*

# 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 collaboration in the series “*The implications of contemporary safety theory (Safety-I and Safety-II) for digital innovation in healthcare*”.

\*Space permitting, we might make the publication relevant to the COVID-19 pandemic by discussing patient-safety concerns arising from sudden atypical growth in remote monitoring, remote testing, remote imaging, robotic care, and personal preventive medicine.

# References

Banerjee, A. (2019). Digital health interventions and inequalities: The case for a new paradigm. *BMJ Evidence-Based Medicine*, *2*, 2–5. https://doi.org/10.1136/bmjebm-2019-111282

Baxevanis, A. D., & Ouellette, B. F. F. (Eds.). (2020). *Bioinformatics: A Practical Guide to the Analysis of Genes and Proteins* (2nd ed.). https://doi.org/10.1007/s10439-006-9105-9

Benson, T., & Grieve, G. (2016). *Principles of Health Interoperability: SNOMED CT, HL7 and FHIR* (3rd ed.). Retrieved from https://s3.amazonaws.com/academia.edu.documents/62118976/Principles\_of\_Health\_Interoperability\_-\_SNOMED\_CT\_\_HL7\_\_and\_FHIR20200217-30649-712nov.pdf?response-content-disposition=inline%3B filename%3DPrinciples\_of\_Health\_Interoperability.pdf&X-Amz-Algorithm=

Bot, B. M., Suver, C., Neto, E. C., Kellen, M., Klein, A., Bare, C., … Trister, A. D. (2016). The mPower study, Parkinson disease mobile data collected using ResearchKit. *Scientific Data*, *3*, 1–9. https://doi.org/10.1038/sdata.2016.11

Chadwick, L., Fallon, E. F., Van Der Putten, W. J., & Kirrane, F. (2012). Functional safety of health information technology. *Health Informatics Journal*, *18*(1), 36–49. https://doi.org/10.1177/1460458211432587

Degoulet, P., & Fieschi, M. (2012). *Introduction to clinical informatics*. New York: Springer.

Denney, E., Pai, G., & Habli, I. (2015). Dynamic Safety Cases for Through-Life Safety Assurance. *Proceedings - International Conference on Software Engineering*, *2*(2), 587–590. https://doi.org/10.1109/ICSE.2015.199

Despotou, G., White, S., Kelly, T., & Ryan, M. (2012). Introducing safety cases for health IT. *2012 4th International Workshop on Software Engineering in Health Care, SEHC 2012 - Proceedings*, 44–50. https://doi.org/10.1109/SEHC.2012.6227010

Facchinetti, A. (2016). Continuous glucose monitoring sensors: Past, present and future algorithmic challenges. *Sensors (Switzerland)*, *16*(12), 1–12. https://doi.org/10.3390/s16122093

Flood, M., & Habli, I. (2011). Multi-view safety cases. *IET Conference Publications*, *2011*(578 CP), 1–6. https://doi.org/10.1049/cp.2011.0260

Furlong, E., Darley, A., Fox, P., & et al. (2019). Adaptation and Implementation of a Mobile Phone–Based Remote Symptom Monitoring System for People With Cancer in Europe. *JMIR Cancer*, *5*(1), e10813. https://doi.org/10.2196/10813

Gammack, J., Hobbs, V., & Pigott, D. (2011). *The Book of Informatics*. Cengage Learning.

Gómez-González, E., Gomez, E., Márquez-Rivas, J., Guerrero-Claro, M., Fernández-Lizaranzu, I., Relimpio-López, M. I., … Capitán-Morales, L. (2020). Artificial intelligence in medicine and healthcare: a review and classification of current and near-future applications and their ethical and social Impact. *ArXiv*. Retrieved from http://arxiv.org/abs/2001.09778

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A’Court, C., … Shaw, S. (2017). Beyond adoption: A new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. *Journal of Medical Internet Research*, *19*(11). https://doi.org/10.2196/jmir.8775

Habli, I., Jia, Y., White, S., Gabriel, G., Lawton, T., Sujan, M., & Tomsett, C. (2019). Development and piloting of a software tool to facilitate proactive hazard and risk analysis of Health Information Technology. *Health Informatics Journal*, *5*. https://doi.org/10.1177/1460458219852789

Heeks, R. (2006). Health information systems: Failure, success and improvisation. *International Journal of Medical Informatics*, *75*(2), 125–137. https://doi.org/10.1016/j.ijmedinf.2005.07.024

Hickey, G. L., Grant, S. W., Caiado, C., Kendall, S., Dunning, J., Poullis, M., … Bridgewater, B. (2013). Dynamic prediction modeling approaches for cardiac surgery. *Circulation: Cardiovascular Quality and Outcomes*, *6*(6), 649–658. https://doi.org/10.1161/CIRCOUTCOMES.111.000012

Hickey, G. L., Grant, S. W., Murphy, G. J., Bhabra, M., Pagano, D., McAllister, K., … Bridgewater, B. (2013). Dynamic trends in cardiac surgery: Why the logistic euroscore is no longer suitable for contemporary cardiac surgery and implications for future risk models. *European Journal of Cardio-Thoracic Surgery*, *43*(6), 1146–1152. https://doi.org/10.1093/ejcts/ezs584

Huang, X., Yan, F., Ning, J., Feng, Z., Choi, S., & Cortes, J. (2016). A two-stage approach for dynamic prediction of time-to-event distributions. *Statistics in Medicine*, *35*(13), 2167–2182. https://doi.org/10.1002/sim.6860.A

IEC. (2006). *International Electrotechnical Commission 62304:2006. Medical device software–Software life-cycle processes*. Geneva: International Electrotechnical Commission.

IEC. (2009). *International Electrotechnical Commission PD IEC/TR 80002:2009. Medical device software.* Geneva: International Electrotechnical Commission.

IEC. (2011). *International Electrotechnical Commission 80001:2011. Application of risk management to information technology (IT) networks incorporating medical devices*. Geneva: International Electrotechnical Commission.

IMIA. (2020). *International Medical Informatics Association*. Retrieved from https://imia-medinfo.org

IMIA WG7. (2018). *WG7 - IMIA Working Group on Health Informatics for Patient Safety*.

Jenkins, D. A., Sperrin, M., Martin, G. P., & Peek, N. (2018). Dynamic models to predict health outcomes: current status and methodological challenges. *Diagnostic and Prognostic Research*, *2*(1), 1–9. https://doi.org/10.1186/s41512-018-0045-2

Kostkova, P. (2015). Grand challenges in digital health. *Frontiers in Public Health*, *3*(134), 1–5. https://doi.org/10.3389/fpubh.2015.00134

Kuhn, K. A., Knoll, A., Mewes, H. W., Schwaiger, M., Bode, A., Broy, M., … Ziegler, S. (2008). Informatics and Medicine - From Molecules to Populations. *Methods of Information in Medicine*, *47*(4), 283–295. https://doi.org/10.3414/ME9117

Kux, B. R., & Majeed, R. W. (2017). Factors Influencing the Implementation and Distribution of Clinical Decision Support Systems (CDSS). *Studies in Health Technology and Informatics*, *243*, 127–131. https://doi.org/10.3233/978-1-61499-808-2-127

Leavitt, H. J. (1962). Applied Organizational Change in Industry: Structural, Technological and Humanistic Approaches. In J. G. March (Ed.), *Handbook of organisation* (pp. 1144–1170). Chicago, IL: Rand McNally and Company.

Leveson, N. G. (1986). Software Safety: Why, What, and How. *Computing Surveys*, *18*(2).

Lupton, D. (2017). *Digital Health: Critical and Cross-Disciplinary Perspectives* (K. Chamberlain & A. Lyons, Eds.). Retrieved from https://books.google.co.uk/books?hl=en&lr=&id=09srDwAAQBAJ&oi=fnd&pg=PT8&dq=Novel+challenges+of+new+and+emerging+digital+health+technologies&ots=5dgCyGehlJ&sig=OTsQkQj\_iHtz5W12G\_z5aSUt8F4&redir\_esc=y#v=onepage&q&f=false

Macrae, C. (2019). Governing the safety of artificial intelligence in healthcare. *BMJ Qual Saf*, *28*, 495–498. https://doi.org/10.1136/bmjqs-2019-009484

Magnusson, J. A., & Fu Jr., P. C. (Eds.). (2013). *Public health informatics and information systems* (2nd ed.). London: Springer.

Masum, H., Lackman, R., & Bartleson, K. (2013). Developing global health technology standards: what can other industries teach us? *Globalization and Health*, *9*(49).

McAuley, A. (2014). Digital health interventions: Widening access or widening inequalities? *Public Health*, *128*(12), 1118–1120. https://doi.org/10.1016/j.puhe.2014.10.008

McCormick, K., & Saba, V. (2015). *Essentials of nursing informatics* (6th ed.). Retrieved from https://lib.hpu.edu.vn/handle/123456789/32430

Moghimi, H., Wickramasinghe, N., & Adya, M. (2020). *Intelligent Risk Detection in Health Care: Integrating Social and Technical Factors to Manage Health Outcomes*. https://doi.org/10.1007/978-3-030-17347-0\_11

Paxton, N. C., & Branca, D. L. (2020). Managing the Risks of Emerging IoT Devices. In N. Wickramasinghe & F. Bodendorf (Eds.), *Delivering Superior Health and Wellness Management with IoT and Analytics* (pp. 447–467). https://doi.org/10.1007/978-3-030-17347-0\_22

Pilotto, A., Boi, R., & Petermans, J. (2018). Technology in geriatrics. *Age and Ageing*, *47*(6), 771–774. https://doi.org/10.1093/ageing/afy026

Richesson, R. L., & Andrews, J. E. (Eds.). (2019). *Clinical research informatics* (2nd ed.). Springer.

Robinson, L., Cotten, S. R., Ono, H., Quan-Haase, A., Mesch, G., Chen, W., … Stern, M. J. (2015). Digital inequalities and why they matter. *Information Communication and Society*, *18*(5), 569–582. https://doi.org/10.1080/1369118X.2015.1012532

Sako, Z., Adibi, S., & Wickramasinghe, N. (2020). *Addressing Data Accuracy and Information Integrity in mHealth Solutions Using Machine Learning Algorithms*. https://doi.org/10.1007/978-3-030-17347-0\_16

Shortliffe, E. H., & Cimino, J. J. (Eds.). (2013). *Biomedical Informatics: Computer applications in healthcare and biomedicine* (4th ed.). New York: Springer.

Singh, H., & Sittig, D. F. (2016). Measuring and improving patient safety through health information technology: The health IT safety framework. *BMJ Quality and Safety*, *25*(4), 226–232. https://doi.org/10.1136/bmjqs-2015-004486

Sittig, D. F., Wright, A., Coiera, E., Magrabi, F., Ratwant, R., Bates, D. W., & Singh, H. (2018). Current challenges in health information technology–related patient safety. *Health Informatics Journal*, (2), 1–9. https://doi.org/10.1177/1460458218814893

Sperrin, M., Jenkins, D., Martin, G. P., & Peek, N. (2019). Explicit causal reasoning is needed to prevent prognostic models being victims of their own success. *Journal of the American Medical Informatics Association*, *26*(12), 1675–1676. https://doi.org/10.1093/jamia/ocz197

Sperrin, M., Martin, G. P., Pate, A., Van Staa, T., Peek, N., & Buchan, I. (2018). Using marginal structural models to adjust for treatment drop-in when developing clinical prediction models. *Statistics in Medicine*, *37*(28), 4142–4154. https://doi.org/10.1002/sim.7913

Steinbuch, K. (1957). Informatik: Automatische Informationsverarbeitung. *SEG-Nachrichten*, *4*.

Stock, W. G., & Stock, M. (2013). *Handbook of Information Science*. Berlin: De Gruyter.

Su, T. L., Jaki, T., Hickey, G. L., Buchan, I., & Sperrin, M. (2018). A review of statistical updating methods for clinical prediction models. *Statistical Methods in Medical Research*, *27*(1), 185–197. https://doi.org/10.1177/0962280215626466

Sujan, M. A., Habli, I., Kelly, T. P., Pozzi, S., & Johnson, C. W. (2016). Should healthcare providers do safety cases? Lessons from a cross-industry review of safety case practices. *Safety Science*, *84*, 181–189. https://doi.org/10.1016/j.ssci.2015.12.021

Sujan, M. A., Koornneef, F., Chozos, N., Pozzi, S., & Kelly, T. (2013). Safety cases for medical devices and health information technology: Involving health-care organisations in the assurance of safety. *Health Informatics Journal*, *19*(3), 165–182. https://doi.org/10.1177/1460458212462079

Sujan, M. A., Spurgeon, P., Cooke, M., Weale, A., Debenham, P., & Cross, S. (2015). The development of safety cases for healthcare services: Practical experiences, opportunities and challenges. *Reliability Engineering and System Safety*, *140*, 200–207. https://doi.org/10.1016/j.ress.2015.03.033

Wickramasinghe, N., & Bodendorf, F. (Eds.). (2020). *Delivering Superior Health and Wellness Management with IoT and Analytics*. https://doi.org/10.1007/978-3-030-17347-0

Widrow, B., Hartenstein, R., & Hecht-Nielsen, R. (2005). Eulogy: Karl Steinbuch 1917-2005. *IEEE Computational Intelligence Society*, *5*. Retrieved from http://helios.informatik.uni-kl.de/euology.pdf

Wismar, M., Palm, W., Figueras, J., Ernst, K., & van Ginneken, E. (2011). *Cross-border Health Care in the European Union: Mapping and analysing practices and policies*. Retrieved from https://apps.who.int/iris/bitstream/handle/10665/327961/9789289002219-eng.pdf

Wright, A., Sittig, D. F., Ash, J. S., Bates, D. W., Feblowitz, J., Fraser, G., … Middleton, B. (2011). Governance for clinical decision support: case studies and recommended practices from leading institutions. *J Am Med Inform Assoc 2011;18:187e194.*, *18*, 187–194. https://doi.org/10.1136/jamia.2009.002030

Yaqoob, T., Abbas, H., & Atiquzzaman, M. (2019). Security Vulnerabilities, Attacks, Countermeasures, and Regulations of Networked Medical Devices-A Review. *IEEE Communications Surveys and Tutorials*, *21*(4), 3723–3768. https://doi.org/10.1109/COMST.2019.2914094