Patient-safety challenges posed by new and emerging health information technologies

# Introduction

The purposes of this section are to introduce 1) the collaboration series, its intentions, the need for theoretical and practical foundations, and our initial positions on the matter, 2) the potential benefits of technology in healthcare (Wickramasinghe & Bodendorf, 2020), and 3) the potential for unintended and ignored adverse consequences.

## \*Patient safety

\*Introduce patient safety to set the context, i.e. how is H.I.T. affecting it?

## \*Workshop series motivation

The section might read something like the following, modelled on the series of publications associated with Michie et al., (2017):

A national, expert, consensus-building collaboration was begun in April 2020 to provide a robust academic appraisal of the evidence base and subject-matter expertise relating to novel patient-safety challenges of new and emerging health information technologies. The collaboration was the first in a series 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 series was a set of publications that begin to define the field of safety informatics and serves as a platform for future research and development.

## \*History of informatics

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.

\*Need segue from ‘History of…’ to ‘Safety informatics’\*

## Safety informatics

\*What is safety informatics and why do we need it?\*

\*Add OJ graphic about Safety Informatics, i.e. intersection of patient safety and digital technology (perhaps we should use the three-circle graphic that the DI devised during strategy discussion, i.e. intersection of safety science, health service delivery, and information technology)\*

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

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).

# Background

The purpose of this section is to provide an informal review of the literature to see what it tells us about the challenges posed by health information technology (e.g. Gómez-González et al., 2020; Kostkova, 2015). The purpose of the subsections are to briefly discuss some contextual challenges that continue to exist prior to the widespread use of the new and emerging technologies described above. The set of challenges described below will be chosen based on their potential to interact with the novel challenges.

\*Ciarán McInerney (UoL) to lead on this section and its subsections\*

## \*Interoperability

The purpose of this subsection is to explain the problem of interoperability as it relates to health information technologies. We will argue that interoperability is the responsibility of policymakers, technology leaders and industry implementers, as suggested by (Benson & Grieve, 2016).

\*Ciarán McInerney (UoL) to lead on this subsection\*

## \*No testing before implementation

The purpose of this subsection is to highlight the lack of testing that precedes implementation of health information technologies and the consequences of such oversight. We will link our presentation with the large contribution of health information technologies by commercial providers, about whose testing we are unaware due to the opacity of IP.

\*Ciarán McInerney (UoL) to lead on this subsection\*

## \*Digital inequality

The purpose of this subsection is to highlight that new and increasingly-complex health information technologies are not likely to be equally affordable nor available for all (Banerjee, 2019; Lupton, 2017; McAuley, 2014; Robinson et al., 2015).

\*Ciarán McInerney (UoL) to lead on this subsection\*

## \*Transient relevance of statistical models

The purpose of this subsection is to highlight the problem that static, pre-learned models are out of data very quickly – immediately so, if historic data are already unrepresentative of the current state of affairs (Hickey, Grant, Caiado, et al., 2013; Hickey, Grant, Murphy, et al., 2013; Jenkins et al., 2018)

\*Ciarán McInerney (UoL) to lead on this subsection with David Jenkins (UoM)\*

## \*Aging population

The purpose of this subsection is to present the contextual challenge of an aging population and how it relates to the challenges presented so far. We will present examples of technological solutions proposed to address aging populations (Daly Lynn et al., 2019; Neves & Vetere, 2019) and critically discuss motivations and consequences (Pilotto et al., 2018).

\*Ciarán McInerney (UoL) to lead on this subsection\*

# Method

The purpose of this section is to describe the process by which this publication was produced and how it fits within the structure of a larger collaboration series.

An initial set of new and emerging health information technologies were collated by the main author following a scoping review of the academic, commercial and grey literature relating to health information technology. 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*>. The aforementioned new and emerging technologies provided the substrate for breakout discussions with the collaborators about the patient-safety challenges that might arise from use of these technologies, alone and in conjunction with other existing, new and emerging technologies. The suggested challenges were then sorted into classes of challenges for succinct presentation in this publication.

# What might be the new and emerging health information technologies?

The purpose of this section is to briefly and generally describe characteristics of new and emerging health information technologies.

## \*What is meant by “new” and “emerging”?

\*Introduce our framework for defining what “new” and “emerging” means. We might choose to use Levitt’s diamond and the following framework: Existing = Many people have used it; Emerging = Many people haven’t used it; New = no one has used this.

## 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.

OJ – pace, procurement, lack of stakeholder engagement, bleeding edge\*

# What are the challenges associated with the new and emerging health information technologies?

The purpose of this section is to describe the output of the discussions within the collaborative regarding the novel challenges posed by the new and emerging technologies listed above. We will then discuss the patient-safety implications of these challenges.

\*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*?

\*

\*I suggest a thematic map of challenges that connect them in a network graphic\*

## Patient-safety implications

The purpose of this section is to present the patient-safety implications of the classes of patient-safety challenges outlined in the previous section.

# Addressing patient-safety challenges

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

\*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).

## Design standards / charter

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. learning from Business Intelligence and sociotechnical theories (Moghimi et al., 2020), Clinical Decision Support Consortia (Wright et al., 2011), and preceding scale-up with a scoping review of international, national, and relevant local guidelines (Furlong et al., 2019).

## 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.

## Dynamic and causal modelling

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

The purpose of this section is to summarise progress made to tackle the problem of transient relevance of statistical models, making special reference to dynamic and causal modelling solutions (Hickey, Grant, Caiado, et al., 2013; Huang et al., 2016; Sperrin et al., 2019, 2018; Su et al., 2018).

## Machine Learning for data quality

The purpose of this subsection is to discuss the potential for machine-learning methods to help ensure data quality, with special reference to work by Sako et al. (2020).

## Human Factors

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

The purpose of this section will be to describe the benefits of a Human-Factors approach to innovation of health information technologies.

# Discussion

The purpose of this section is to collate additional arguments raised by the collaborative that have not already been addressed in the previous sections. For example, we might choose to discuss how events like the COVID-19 pandemic might drive some technologies ahead and the consequences of such unexpected occurrences, e.g. atypical growth in remote monitoring, remote testing, remote imaging, robotic care, and personal preventive medicine.

# Conclusion

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*”.

# 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=

Daly Lynn, J., Rondón-Sulbarán, J., Quinn, E., Ryan, A., McCormack, B., & Martin, S. (2019). A systematic review of electronic assistive technology within supporting living environments for people with dementia. *Dementia*, *18*(7–8), 2371–2435. https://doi.org/10.1177/1471301217733649

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

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

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

Health Level Seven International. (2020). *HL7 International*. Retrieved from https://www.hl7.org/

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

Houta, S., Ameler, T., & Surges, R. (2019). Use of HL7 FHIR to structure data in epilepsy self-management applications. *2019 International Conference on Wireless and Mobile Computing, Networking and Communications (WiMob)*, 111–115.

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

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

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

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

Michie, S., Yardley, L., West, R., & Greaves, F. (2017). Developing and Evaluating Digital Interventions to Promote Behavior Change in Health and Health Care: Recommendations Resulting From an International Workshop Corresponding Author : *Journal of Medical Internet Research*, *19*. https://doi.org/10.2196/jmir.7126

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

Neves, B. B., & Vetere, F. (Eds.). (2019). *Aging and Digital Technology: Designing and evaluating emerging technologies for older adults*. https://doi.org/10.1007/978-981-13-3693-5

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

Roehrs, A. (2019). *OmniPHR: A blockchain based interoperable architecture for personal health records* (Universidade do Vale do Rio dos Sinos). Retrieved from http://www.repositorio.jesuita.org.br/bitstream/handle/UNISINOS/8867/Alex Roehrs\_.pdf?sequence=1&isAllowed=y

Roehrs, A., Andr, C., Righi, R., Jos, S., & Wichman, M. H. (2019). Toward a Model for Personal Health Record Interoperability. *IEEE Journal of Biomedical and Health Informatics*, *23*(2), 867–873.

Roehrs, A., André, C., & Righi, R. (2017). OmniPHR : A distributed architecture model to integrate personal health records. *Journal of Biomedical Informatics*, *71*, 70–81. https://doi.org/10.1016/j.jbi.2017.05.012

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

Saripalle, R., Runyan, C., & Russell, M. (2019). Using HL7 FHIR to achieve interoperability in patient health record. *Journal of Biomedical Informatics*, *94*(103188). https://doi.org/10.1016/j.jbi.2019.103188

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

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

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