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 (Gibbings & Wickramasinghe, 2020), and 3) the potential for unintended and ignored adverse consequences.

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. 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 in Leeds, UK 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.

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. This initial set was amended following input from *final count of collaborators* collaborators that were included as representatives of those who develop, evaluate and use health information technologies and their data for both research and practical purposes. Collaborators included *fist of roles represented by collaborators*.

What might be the new and emerging health information technologies?

The purpose of this section is to describe the set of new and emerging health information technologies on which the collaboration would focus. This section ends with a brief summary of health information technologies that were considered but not selected for further review of novel challenges that they might promote.

The purpose of Table 1 is to succinctly present the list of technologies being considered in this publication before each is discussed in further depth.

Table 1 Sixteen health information technologies that a literature review suggested were new or emerging.

<see 'Table 1.docx'>

Health information technologies considered but not included

The purpose of this section is to briefly summarise the health information technologies that were considered but not selected for further review of novel challenges that they might promote.

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. This section will also be informed by commentaries in the academic literature (Gómez-González et al., 2020; Kostkova, 2015). One example, interoperability, is provided below.

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). This challenge at least relates to the Omics, IoT, and Digital Twin technologies.

Other challenges

The purpose of this subsection is 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 presented in the previous section. Some examples are provided.

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.

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).

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)

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).

How do the technologies relate?

The purpose of this section is to present the collaborative's opinions of how the aforementioned health information technologies relate across dimensions of their generating motivations, their proposed solutions, and their challenges.

Potential solutions

The purpose of this section is to present solutions to the novel challenges identified by the collaborative. Special effort will be made to connect solutions to specific challenges and technologies. Some examples are provided.

Safety cases

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. Special reference will be made to the HL7 FHIR standard created by HL7 International (Health Level Seven International, 2020), which is a standard for exchanging EHRs (Saripalle et al., 2019; see Houta et al., 2019 for application in epilepsy data), and an example of a distributed architecture to integrate EHRs (Roehrs et al., 2019, 2017), which makes use of blockchain approaches (Roehrs, 2019).

Dynamic and causal modelling

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).

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 types of new and emerging health information technologies considered, 3) succinctly summarise the types of novel challenges that the collaborative suggests are posed by the aforementioned technologies, 4) succinctly summarise the class of solutions needed, 5) suggest the next steps required to facilitate these solutions, 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

- 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
- 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
- Gibbings, R., & Wickramasinghe, N. (2020). *The Enabling Role for Technology in the Support of Care Coordination in Health Care*. 425–446. https://doi.org/10.1007/978-3-030-17347-0_21
- 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
- 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
- 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
- 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
- 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
- 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. 345–359. 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
- 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
- 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
- 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