Novel challenges that new and emerging digital health technologies pose for patient safety

# 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 digital health 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 xlink to GitHub sourcex. 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 digital health technologies were collated by the main author following a scoping review of the academic, commercial and grey literature relating to digital health technology. This initial set was amended following input from xN\_participantsx collaborators that were included as representatives of those who develop, evaluate and use digital health technologies and their data for both research and practical purposes. Collaborators included xList of roles represented by attendeesx.

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

The purpose of this section is to describe the set of new and emerging digital health technologies on which the collaboration would focus. This section ends with a brief summary of digital health 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 digital health technologies that a literature review suggested were new or emerging.*

## Digital health technologies considered but not included

The purpose of this section is to briefly summarise the digital health 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 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 digital health 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 digital health technologies and the consequences of such oversight. We will link our presentation with the large contribution of digital health 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 digital health 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 digital health 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 digital health 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 digital health 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 digital health 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*”.