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A Method of Justifying Confidence in the Safety of Digital Health Interventions

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Abstract. Digital health interventions (DHIs) enable improvements in health strategy and address health system challenges. The World Health Organization provides a formal classification for DHIs. However, safety claims, about such interventions, vary in quality and are often vague as to how they are communicated between technical, clinical experts and stakeholders. By combining the classifications with a method of safety analysis and justification, we postulate confidence in the safety of digital technology. Confidence is resulting from the application of the framework to the DHI, using defined health system challenges. The framework and derived safety justifications can be applied to any DHI. It can serve as guideline for health strategy, regulatory and standards based compliance.

Keywords. Digital health, safety, justification, health system, confidence, hazard analysis

1. Introduction

The lack of the adoption of the fundamental concepts of clinical risk management and safety methods, within health informatics, demonstrates safety's limited influence in the development of digital health technologies. It has been shown that the foundations of safety engineering concepts and methods can improve quality and safety [1]. The impact of digital health interventions (DHIs) on the safety of patients, and potential harm exercised by the unsafe actions of clinical users, is not documented openly. Evidence suggests a lack of rigor within the industry, where strategies for innovation to improve clinical outcomes and advance health using new technologies, overlook the principles of patient safety [2,3]. As these strategies often, see rigor as a barrier not an enabler to innovation. In contrast to the digital healthcare industry, traditional safety critical engineering industries have the capability of in-depth analysis and assessment, while they have been established over decades. Additionally, these, more open, safety cultures bring together concepts of quality, benefits and safety objectives into a more rigorous, systematic environment and innovation ready.

The World Health Organization (WHO) classification of DHIs [4], and their relationship to Health System Challenges (HSC),provides us with an opportunity to establish or affirm safety claims by the application of safety analysis methods. The HSC is a health service problem (e.g. lack of access to information or data, poor patient experience) and DHI is the class of technology intervention that aims to address the problem. This can offer insight and affirm confidence that the DHIs are safe and fit for

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purpose, by applying safety methods. The WHO classification promotes an accessible and bridging language between technical and clinical experts, aimed at simplifying dialogue and aiding digital health implementation. The classification represents discrete functionality of DHI, in order to achieve health sector objectives and meet the health system challenge (HSC), aimed at commissioners of digital services. We can apply these same classifications and challenges to identify hazards and construct a safety claim and justification. The objective of this paper is to implement the framework for the synthesis of safety justification for digitally enabled healthcare services. The ultimate aim is to apply the framework to a DHI and generate an assurance case, thereby provide a justification of safety and elicit confidence that the DHI is fit for purpose, not just to meet the health system challenge. This, in turn, will bridge the understanding of the health delivery organization and manufacturer clinical risk management processes, by way of guidance for each DHI classification. This will guide and influence the right behaviors of innovation within the boundary of good practice and safety methods.

2. Method

The aim is to identify hazards and construct a safety claim and justification. A safety claim follows an approach to safety justification that is commonly used in safety engineering industry. It is also used in traditional medical device safety assurance claims and, through graphical notation, provides a more efficient way of demonstrating safety between differing experts (technical and clinical). The method is explained below in Figure 1, and can be completed retrospectively or, ideally, in line with the requirements and definition phase of the planned DHI.

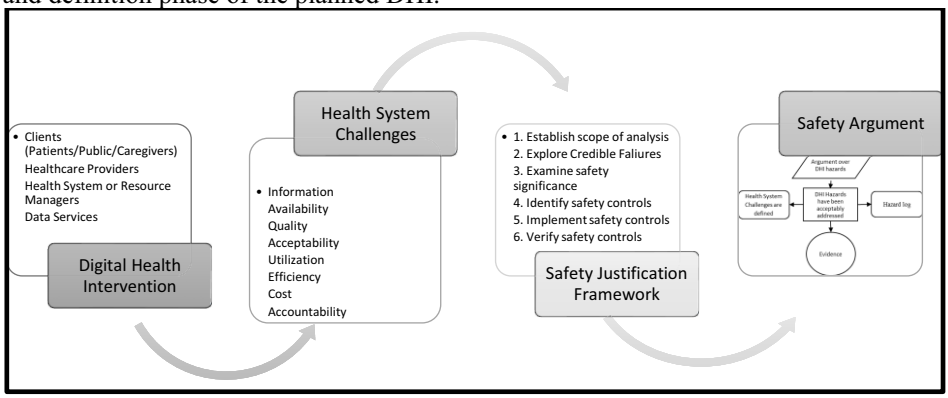

Figure 1 Method & sequence of DHI analysis

Select the DHI is a straightforward exercise, as the interventions are well defined and utilize established taxonomies, from mobile and more traditional digital health solutions. **Assess credible failures** is completed by examination of the use of the DHI and the deviation from that use. The inclusion of health system challenges provides synergy between intended operational use and the challenge faced in the health system. It is purposeful for examining the relationship between HSC, Hazard, Effect and Contribution, which is important when safety claims are made. **Examine safety significance & Identify safety controls** is where the clinical risk management methods are used – hazard analysis. An examination of DHI hazards is completed using likelihood and consequence to derive a severity level. Safety controls are identified to enable mitigation

of hazards, and this is where HSC form an important link into the framework. **Implementation and verification,** the final stage, evidences controls implemented and aligned to hazards and shape the final safety justification.

3. Results

We have applied the framework to a DHI, a self-management mobile app & web based portal for children / young people with Type 1 diabetes. The hazard assessment shows at least two health system challenges forming part of the causes to safety hazards. The framework has been applied to the DHI category of Client, Targeted Client Communication and Transmit Targeted Health Information to Client(s) Based on Health Status of Demographics. A Hazard Identification (HAZID) was undertaken to identify hazards that could cause harm to a "User" Patient. The assessment includes health system challenges in bold type as contributory causes (table 1).

Table 1 Hazard Analysis of an example Digital Health Intervention (mobile app for Diabetes Type 1)

HazID	Hazard	Clinical Safety Impact	Cause	Control
1	Mobile App and/or linked clinical website unavailable	Inability to support clinical services, stress or anxiety to service users, delayed action of treatment plans.	Unsupported mobile device configuration, Key information is not available, security issue, technical / configuration error. Lack of out of hours or system outage messages. **Poor Patient Experience. Lack of access to information or data.**	Care planning and intervention includes outage continuity plans. Alternative services information available through other sources. Technical assurance coverage includes mobile variants, webpage content and OS.
2	Clinical information presented is incorrect and/or misinterpreted	Reliance on information leads to inappropriate action of treatment plan or advice to manage condition.	**Lack of quality/reliable data Insufficient utilization of data and information.** UX issues with information presented. Out of date clinical guidelines. Lack of or inappropriate referrals.	Clinical care plans and workflows are controlled by policy and governance. Technical assurance includes UX & accessibility. Content change processes and training is implemented regularly.
3	Users rely on digital health intervention solely for care and advice and exclude care giver/clinical support	Service users/patients, care givers and health care practitioners lose confidence in the DHI. Reduced benefit of using the DHI. Patient condition may be uncontrolled and adversely impacted.	**Lack of alignment with local norms. Poor adherence to guidelines. Inadequate supportive supervision.** Lack of understanding of the service by users. Low technical awareness within the cohort.	Demo version of the DHI is available for training. Human factors / codesign workshop as part of the content and workflow management.

				Performance, outcomes and benefits indicators.
4	Inappropriate / incorrect implementation of DHI into health system Poor and/or declining quality of clinical information or data	Potential delay in the ongoing care of a patient, transfer or communication of critical information to support the treatment of the patient.	User(s) adopt the application informally and evolve its use into "informal" clinical care pathways. **Insufficient health worker competence. Low health worker motivation. Poor adherence to guidelines. Inadequate workflow management. Poor planning and coordination.**	High risk patients prioritized by local health workers. Use of recommended governance, planning and clinical engagement agreements. Use of feedback mechanisms to monitor performance and accountability.

4. Discussion and Conclusions

The exponential growth, diversity of DHIs and associated regulatory position are the biggest challenges to the industry. Policy makers, manufacturers, health organizations and digital technology users (healthcare professionals and patients) have different understandings and objectives of DHIs. The benefit for the communication between stakeholders, for safety claims aligned with the classifications of DHIs. The presented framework and associated justifications contribute to application guidance and best practice. The DHI classification scheme has been used to generate guidance on effectiveness for DHIs [5]. The results of this work indicate that the domains of security, safety and effectiveness can be correlated. The use of taxonomies, synonyms and ontologies, with established graphical notation methods, allow us to automate, predefine and guide through case studies. Further work is needed, in order to demonstrate this method and build the guidance across the DHI classification scheme. The implementation and verification of DHIs, justified this way, will provide a direct correlation to the health system challenge.

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