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MEDINFO 2021: One World, One Health – Global Partnership for Digital Innovation

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Preface from the Scientific Program Committee Co-Chairs

Why “one world, one health”?

The Constitution of the World Health Organization defines health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The Constitution also asserts that health for all peoples is “dependent on the fullest co-operation of individuals and States” – hence our “one world” theme.

But human health is part of a bigger picture. The “one health” concept recognizes the interconnected global ecosystem of our planet. Three examples highlight this key principle. Firstly, recent events have reminded us of the threats of zoonotic diseases, where pathogens pass from animal to human populations. Secondly, human interaction with microbes. This can be seen both in a positive way such as the vital symbiosis of the human microbiome, and in a negative way with risks like antimicrobial resistance due to overuse of antibiotic drugs. Thirdly, and perhaps most obviously, the continuing devastation of the environment by human stupidity and greed threatens the health of the one fragile world we share.

The pandemic has dramatically emphasised the power of healthy and unhealthy information. Healthcare and public health services have depended upon both timely and accurate data and continually updated knowledge to organize and deliver treatment, prevention and policy advice. Unparalleled global scientific cooperation has demonstrated what can be done when information and methods are rapidly shared and scrutinized. Unfortunately, social media has shown how unhealthy misinformation can be spread and amplified. This has reinforced existing prejudices, conspiracy theories and political biases to sustain and justify spurious beliefs and selfish behaviour like pandemic denial, vaccine rejection and mask refusal.

The worldwide community of the International Medical Informatics Association continues to work as a global partnership for healthy information and digital innovation. The 18th World Congress of Medical and Health Informatics, MedInfo 2021, was held as a virtual event from 2–4 October, with pre-recorded presentations for all accepted submissions and six live online sessions for the invited panels, keynotes and awards.

The MedInfo 2021 Scientific Programme Committee (SPC) called for submissions under five themes:

1. Information and Knowledge Management
2. Quality, Safety and Outcomes
3. Health Data Science
4. Human, Organizational and Social Aspects
5. Global health informatics

We received 352 submissions from 41 countries across all IMIA regions. Peer review was organized by the SPC co-chairs and eight track chairs and co-chairs, involving over 100 reviewers. Finally, 147 full papers, 60 student papers and 79 posters were accepted and are included in these proceedings.

The live online sessions of MedInfo 2021 included six invited panels and awards for best paper, best student paper and the François Grémy Award of Excellence.

The SPC would like to thank the track chairs and co-chairs, the reviewers, the editorial assistants and the Chair and CEO of IMIA for their invaluable contribution to the success of this first virtual MedInfo conference, prepared and held during a time of unprecedented global disruption.

Philip Scott and Paula Otero, MedInfo 2021 SPC co-chairs

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ISO/IEC-Standards on Quality and Safety of Telehealth Services and Mobile Medical Apps

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Abstract

This paper investigates consistency of ISO/IEC-standards on quality and safety of telehealth services and mobile medical apps.

Since mobile medical apps are 'software as a medical device', requirements for these apps are in software standards, in particular health software standards, as well as in medical device standards.

These requirements were analyzed within an analysis model that has three domains: quality and safety management, core healthcare processes and resources. Telehealth services are healthcare processes and mobile medical apps are resources.

There is good alignment of the standards that pertain to quality and safety management, the healthcare processes and medical devices. However, there is a lack of alignment, consistency and transparency of the ISO/IEC-standards on quality and safety of telehealth services and mobile medical apps.

An international effort to address these issues is recommended.

Keywords:
Telehealth, standard, medical device

Introduction

The importance of telehealth services and mobile medical apps has become very clear in the Covid-19 pandemic. Telehealth enables healthcare workers and patients to communicate at a distance.

For the quality and safety of telehealth services and mobile medical apps, there is a wide variety of international and national standards, both from standardization organizations and regulatory bodies. This paper focuses on use-related requirements. Information management, security and financial management are outside the scope of this paper.

This paper focuses on ISO/IEC-standards, but we are aware of other international and national documents of high quality that addresses same issues. For instance: International Medical Device Forum of Regulators (IMDFR), regional regulations (European Union: Medical Device Regulation) and national regulations in Australia, USA (FDA). It is desirable that expertise and knowledge are combined in a future collaborative effort.

While ISO/IEC-standards are widely accepted as authoritative, a thorough analysis in 2013 (ISO/TR 17791:2013) concluded that the ISO/IEC standards for enabling safety and health software lack a strong patient-safety focus and do not fully align with one another.

The objective of this paper is to investigate whether this conclusion is still valid 8 years after that publication. This paper investigates the consistency of the main ISO/IEC-standards on quality and safety of telehealth services and mobile medical apps.

Medical apps are also referred to as 'Software as a medical device'. Accordingly, requirements for mobile medical apps are related to the fact that they are software, but also medical devices. So, the research questions are:

1. which conceptual framework, that covers medical devices and software, is appropriate to review the significance of ISO/IEC standards on quality and safety of mobile medical apps
2. which ISO/IEC standards on medical devices are relevant to mobile medical apps
3. which ISO/IEC standards on software are relevant to mobile medical apps
4. do the publicly available ISO/IEC-standards, that are relevant to telehealth services, constitute a consistent and transparent set of standards that is easy to use for the participants in telehealth services.

Methods

For the first research question a conceptual framework was constructed by adapting the domain model of ISO 13940:2015 to the area of quality and safety management. Within this framework, a key-system of concepts was identified, based on an analysis of relevant ISO/IEC-standards.

The second and third research question were investigated by literature search in ISO/IEC-standards. In the literature there is consensus on which standards are central, such as the generic standards for quality management systems (ISO 9001) and risk management (ISO 31000). Also, in the domains of healthcare processes, medical devices and health software, the ISO/IEC-standards are clear about which standards are central.

The fourth research question was investigated in two steps. Firstly, key-concepts and interrelationships between standards were identified by using the ISO-standard on concepts of quality of care (ISO 13940) and analyzing the standards. Secondly, the selected ISO/IEC-standards were positioned in the 3 domains of the conceptual model and interrelationships were evaluated. Based on the functional relationships, in the second step the strength of interrelationships between standards was assessed. Indications for a strong relation was reference to

another standard as a normative reference, as well as strong similarity in the structure of the standard.

Results

Concerning the three first-mentioned research questions, we adapted the conceptual framework that is provided by ISO 13940, the ISO-standard on concepts to support continuity in healthcare, leading to 3 domains (Figure 1):

1. quality and safety management
2. clinical processes; a clinical process is a set of interrelated or interacting healthcare activities, which are performed for a subject of care with one or more health issues.
3. resources.

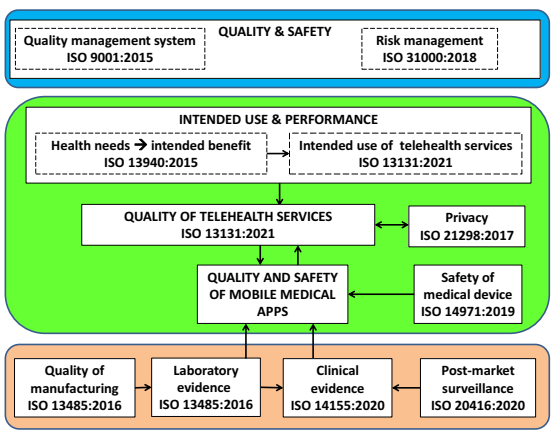

Figure 1 Conceptual model of quality and safety of telehealth services and medical apps

The upper domain (quality and safety) contains the two generic quality and management systems (ISO 9001 and ISO 31000) that are basic to all quality and safety standards.

In the healthcare domain, intended use and performance are primary. In this system, the term 'use' relates to the process of using the device while the term 'performance' means the result of using the device (definitions according to ISO 9001:2015).

In the healthcare and resources domain, Figure 1 shows:

- the intended use and performance that the manufacturer defines in the design phase; based upon determined health needs, the manufacturer claims benefits of the device (ISO 13940:2015). For telehealth services, the wide variety of use cases is presented in ISO 13131:2021.
- privacy protection; a contributing factor for privacy protection can be a system of role-based access control; such a system requires the definition and implementation of roles to describe mandates; the framework for establishing roles is provided by ISO 21298:2017
- safety of the medical device (ISO 14971:2019)
- laboratory evidence that is obtained by testing (verification) in the laboratory setting; a prerequisite to the laboratory evidence is that the quality of manufacturing the device must be ensured by appropriate documentation (ISO 13485:2016)
- clinical evidence that results from the pre-market clinical investigation to validate the usability and performance of the device (ISO 14155:2020)
- post-market surveillance (ISO 20416:2020).

The quality of telehealth services depends on the quality and safety of employed apps, such as mobile medical apps.

To answer the 4th research question, Figure 2 shows the interrelationships between the standards.

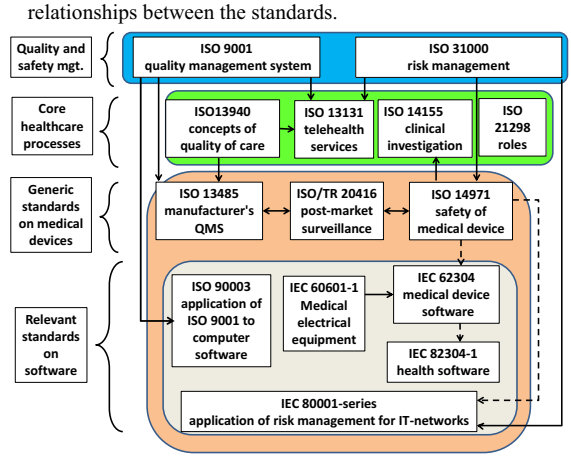

Figure 2 Interrelationships between the standards

Explanation of Figure 2

The solid lines/arrows represent a strong relation while the dashed lines/arrows represent a weaker relation.

The inter-relationship of ISO/TR 20416 with ISO 13485 and ISO 14971 standards is explained in ISO/TR 20416:2020, as follows. The double arrows mean that ISO 13485 sets requirements for ISO/TR 20416 and that inversely, ISO/TR 20416 provides the deliverables for ISO 13485. The same relations exist between ISO/TR 20416 and ISO 1971.

The alignment and consistency of standards is illustrated by the quality characteristics. Quality characteristics describe properties that correspond to basic and ethical values. Examples of basic and ethical values are good health, safety and inclusiveness. Also, effectiveness of a medical device (in the sense of benefiting the health state of a patient) is a value.

According to ISO 13940, the upper domain (quality and risk management) contains basic and ethical values.

For good governance, requirements should be the (direct or indirect) expression of basic and ethical values.

In ISO 13131:2021 (quality planning for telehealth services) basic and ethical values are fundamental to the applied quality characteristics (such as patient safety). ISO 13131 translates these quality characteristics into quality objectives (e.g. improved care recipient safety) and quality procedures(e.g. identify care recipients at an increased risk of harm). A quality procedure includes who should be responsible for implement-

ing, monitoring and reviewing the quality plan. In scheme: basic and ethical values → quality characteristics → quality objectives → quality procedures. This scheme has been systematically applied in ISO 13131:2021 for the various domains in the High Level Structure (ISO 9001:2015), leading to a consistent and transparent set of requirements for telehealth services.

The standards that relate to the software, are further described in Figure 3.

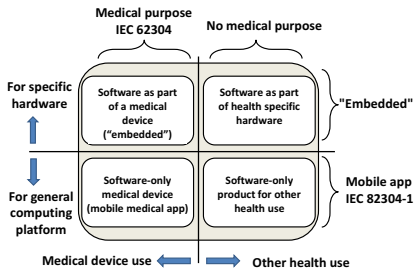

Figure 3 Health software application domains and IEC 62304 and IEC 82304

Figure 3 (adopted from IEC 82304) shows that software with a medical purpose is in the application domain of IEC 62304. Mobile health software is governed by IEC 82304-1. Mobile medical apps fall in the application domains of both standards. Accordingly, for mobile medical apps the requirements are provided by both IEC 62304 and IEC 82304-1.

These health software standards provide requirements with regard to product safety and quality of the manufacturing process.

The health software standards and product safety

For assessing product safety, the validation phase in the development of software and/or medical devices is crucial. In the validation phase the product is compared to the product and patient safety requirements. ISO 14971 contains generic safety requirements for medical devices.

However, validation is outside the scope of ISO 62304 . And ISO 82304-1 states that it does not require a formal and full risk management as, for example, per ISO 14971 (ISO 82304-1,4.1, Note 1).

Conclusion: in the health software standards (IC 62304, IEC 82304-1), the safety requirements are less strict than the safety requirements in ISO 14971.

The health software standards and the quality of the manufacturer's processes

The processes by which the manufacturer design and develop a mobile device, are governed by ISO 13485. That standard prescribes the manufacturer's quality management system. Since a medical app is, by definition, a medical device (ISO 13485), ISO 13485 also applies to these apps.

However, ISO 62304 states concerning 'quality management system' that the ability to consistently meet customer requirements and applicable regulatory requirements can also be demonstrated by the use of a quality management system that complies with a national quality management system standard or a quality management system that is required for national regulation. This phrase seems to suggest that compliance with ISO 13485 is not necessary for the manufacturer's quality management system.

Discussion

It was found that the safety requirements in the health software standards (IC 62304, IEC 82304-1) are less strict than the safety requirements in ISO 14971.

As a consequence, for mobile medical apps the safety requirements from the health software standards (ISO 62304 and ISO 82304-1) lead to less guarantees for patient safety, compared to the medical device standards. It can be anticipated that hazards, that are systematically described in ISO 14971, will be overlooked or not appropriately managed, when such a laxity of method is allowed.

It has also been found that ISO 62304 suggests that compliance with ISO 13485 is not necessary for the manufacturer's quality management system because an alternative to compliance with ISO 13485 is compliance with a national quality management system standard or the quality management system required for national regulation. So, ISO 62304 allows a manufacturer to use another standard, irrespective of whether it ensures the same level of quality and safety as ISO 13485.

In sum, the health software standards ISO 62304 and ISO 82304-1 lead to less guarantees for safety, compared to the medical device standards.

This is a concern because software has been found to be a major source of incidents in healthcare and for that reason, software had been included in the definition of medical device.

Conclusions

ISO/TR 17791:2013 concluded that the ISO/IEC-standards for enabling safety and health software lack strong patient-safety focus and do not fully align with one another. Our findings indicate that the relevant ISO/IEC-standards on health software do not fully align with the medical device standards. The medical device standards are well aligned and offer a consistent whole of standards, but they have not been systematically translated to the subset of medical apps.

The challenge is to develop a guidance, possibly in the form of one or more standards, to combine the strengths of the different groups of standards and to overcome the issues that arise from insufficient alignment.

Considering the scope and complexity of these issues, an international collaboration is recommended that could include members from international organizations (such as ISO, IEC, IMIA, IMDFR), national regulatory bodies and organizations and persons with specific expertise.

References

ISO 9001:2015 Quality management systems — Requirements

ISO Quality management principles, 2015

ISO 13940:2015 Health informatics — System of concepts to support continuity of care

ISO 21298:2017 Health informatics — Functional and structural roles

ISO/TS 13131:2014 Health informatics — Telehealth services — Quality planning guidelines

ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes

ISO 14971:2019 Medical devices — Application of risk management to medical devices

ISO/TR 20416:2020 Medical devices — Post-market surveillance for manufacturers

ISO/IEC/IEEE 90003:2018 Software engineering — Guidelines for the application of ISO 9001:2015 to computer software

ISO/IEC 38500:2008 Corporate governance of information technology

IEC 62304:2006+AMD1:2015 Medical device software - Software lifecycle processes

IEC 82304-1 Health software - Part one: General requirements for product safety

IEC 80001-series Application of risk management for IT-networks incorporating medical devices.

ISO/TR 17791:2013 Health informatics — Guidance on standards for enabling safety in health software

ISO 16142-1:2016 Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

ISO 16142-1:2016 Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards

ISO 16142-2:2017 Medical devices — Recognized essential principles of safety and performance of medical devices — Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards

ISO/IEC Guide 63:2019 Guide to the development and inclusion of aspects of safety in International Standards for medical devices

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