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Health informatics~~-~~ — Accelerating safe, effective and secure remote connected care and mobile health through standards-based interoperability solutions addressing gaps revealed by pandemics

Informatique de santé — Augmentation de la sûreté, de l'efficacité et de la sécurité des soins à distance et de la santé mobile par l'intermédiaire de solutions d'interopérabilité fondées sur les normes, en remédiant aux insuffisances mises en évidence par la pandémie

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Contents

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO ~~documents~~document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

~~Attention is drawn~~ISO draws attention to the possibility that ~~some of~~ the ~~elements~~implementation of this document may ~~be~~involve the ~~subject~~use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents~~.~~. ISO shall not be held responsible for identifying any or all such patent rights. ~~Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see).~~

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html~~www.iso.org/iso/foreword.html.~~

This document was prepared by ~~the~~ Technical Committee ISO/TC 215, *Health* ~~Informatics.~~*informatics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html~~www.iso.org/members.html~~.

Introduction

The COVID-19 ~~Pandemic~~pandemic has created an enormous need to allow patients and clinicians to communicate with each other and report in a more flexible and virtual way outside of the traditional care delivery infrastructure. Numerous studies and reports from healthcare organizations have shown the dramatic increase in the use of telehealth visits and their associated benefits:

— ~~Reduction~~reduction of pandemic-related risks ~~is~~ typically associated with face-to-face visits.

— ~~Alleviation~~alleviation of care capacity pressures due to pandemic-induced patient influx.

— ~~Stemming~~stemming the tide of continually increasing healthcare costs driven by aging populations and associated growth of chronic disease.

— ~~Catering~~catering to patient preferences and enabling patients to stay in their home longer, return sooner, or manage their condition at home altogether.

Many healthcare organizations have gone beyond telehealth in an attempt to deploy remote care approaches to interact with patients in the hospital as well as track the status of patients at home or alternate care institutions. This technology is also used for clinical trial data collection, real word evidence and patient surveillance, especially under the limitations and pressure of a pandemic. This is termed as “Remote Connected Care and Mobile Health (RCC-MH)”.

This document explores the current challenges of deploying RCC-MH widely in the current environment. In addition to technical gaps, this document also identifies techno-social gaps that will need to be overcome. The question then becomes: how to educate and motivate manufacturers and ‘consumers’ (hospitals, alternate care settings, patients and their advocacy groups, etc.) so they understand the benefits of interoperability and, since RCC-MH will not be realizable without interoperability, begin to demand interoperable devices and apps that take advantage of interoperable devices?

This document answers questions such as:

— What informatics standards ~~could~~can be considered when developing remote care / Mobile Health solutions?

— What safety, effectiveness & security (SES) standards ~~could~~can be leveraged to balance solution options with risk-based public good assessments?

— How can the application of these standards be scaled in crisis situations where resources and time are highly constrained?

— How can we develop more efficient interoperability solutions to rapidly address the needs of telehealth in pandemics cases?

~~This document was initially prepared as part of the Gemini joint project between HL7 and IHE. That work was used as a baseline for this document. Content has considered standards work from IEEE 11073, ISO, IEC as well as international regulatory and legal frameworks.~~

This document is intended to inform a diverse set of stakeholders, including:

— industry – medical device vendors, point-of-care lab systems, pharma, SW and IoT vendors, apps vendors;

— government – regulatory, public health, state and local government;

— providers – primary care physicians (PCPs), general practitioners (GPs), specialists, healthcare delivery organizations (HDOs);

— SDOs (standards development organizations);

— patients (including advocacy groups);

— payors – government, private, and public insurers;

— infrastructure vendors – networking, security, cloud, mobile devices and apps.

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1 Scope

This document reviews the structural changes that have been precipitated by the COVID-19 Pandemicpandemic in Remote Connected Care and Mobile Health (RCC-MH). The impact of the COVID-19 Pandemicpandemic on care settings such as home/ and community care, acute care and outpatient care are reviewed discussing how well these healthcare environments were prepared to address the encountered connectivity challenges from a standards point of view. The current standards landscape is reviewed and gaps are identified leading to recommendations for future standards work.

2.0 Stakeholders

This document is intended to inform a diverse set of stakeholders. These include:

- Industry - medical device vendors, point-of-care lab systems, pharma, SW and IoT vendors, apps vendors,
- Government - regulatory, public health, state and local government
- Providers - primary care physicians (PCPs), general practitioners (GPs), specialists, healthcare delivery organizations (HDOs)
- SDOs (standards development organizations)
- Patients (including advocacy groups)
- Payors - government, private, and public insurers
- Infrastructure vendors – networking, security, cloud, mobile devices and apps

112 Normative references

There are no normative references in this document.

123 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ——ISO Online browsing platform: available at https://www.iso.org/obphttps://www.iso.org/obp

— ——IEC Electropedia: available at https://www.electropedia.org/

12.13.1

effective
successful in producing a desired or intended result

12.23.2

effectiveness
ability to produce the intended result

[SOURCE: ISO 81001-Note 1 :2021, 3.2.5]

NOTE 1 to entry: Clinical effectiveness is based on valid scientific evidence that in a significant portion of the target population the use of the device for its intended uses will provide clinically significant results.

[SOURCE: ISO 81001-1:2021, 3.2.5, modified — Note 1 to entry was added.]

3.3
harm
physical injury, or damage, or both, to the health of people or damage to property or the environment

[SOURCE: ISO/IEC Guide 51:2014, 3.1, modified — "injury or damage" was changed to "physical injury or damage, or both".]

3.4
hazard
potential source of *harm* (3.3)

[SOURCE: ISO/IEC Guide 51:2014, 3.5]

3.5
gateway
network entity (software or hardware) that interfaces between networks that use different protocols, or are of different, potentially incompatible, technology

Note 1 to entry: A gateway operates with a focus on network translation (network gateway) or service translation (service gateway).

[SOURCE: Reference [26]

3.6
interoperability
ability of two or more systems or components to exchange information and to use the information that has been exchanged

Note 1 to entry: "Open Interoperability IS achieved using open (publicly available) protocols, syntax, semantics, etc."

Note 2 to entry: "Proprietary Interoperability IS achieved using proprietary protocols, syntax, etc. AND is not Open(accessible) to All and has issues sharing data"

Note 3 to entry: "Seamless Interoperability IS achieved 'out of the box' between components that have never been tested together."

[SOURCE: Reference [27]

]]

3.7
in vitro diagnostic medical device
(IVMD)
medical device (3.9), whether used alone or in combination, intended by the *manufacturer* (3.8) for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note 1 to entry: IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status.

Note 2 to entry: In some jurisdictions, certain IVD medical devices may be covered by other regulations.

[SOURCE: Reference [36IMDRF/SaMD WG/N10Final:2013, 5.2.2]]]

12.53.8
manufacturer
natural or legal person with responsibility for designing, manufacturing, packaging, or labelling the design and/or manufacture of a *medical device* (3.9(3.9); assembling a system: or adapting a) with the intention of making the medical device (3.9) before it is placed on the market and/or put into service, regardless of available for use, under their name, whether these operations are carried outor not such a medical device is designed and/or manufactured by that person themselves or by a third party on that person'son their behalf by another person(s)

[SOURCE: ISO 14971:2000, 2.6]2019, 3.9, modified — Notes to entry were removed.]

12.63.9
medical device
any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* (3.8) to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information by means of in vitro examination of specimens derived from the human body;,

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances,

— aids for persons with disabilities,

— devices incorporating animal and/or human tissues,

— devices for.in-vitro fertilization or assisted reproduction technologies.

[SOURCE: ~~IMDRF/SaMD WG/N10Final:2013, 5.2.1 and~~ ISO/IEC Guide 63:2019, 3.7]

~~12.7~~3.10
patient monitoring
process of observing and measuring physiological parameters via *medical devices* (3.9) to guide patient care

~~Note 1 to entry: Examples include~~EXAMPLE Monitoring via general hospital and personal use monitoring devices, ~~anesthesiology~~anaesthesiology monitoring devices, cardiovascular monitoring devices, etc.

~~12.8~~3.11
remote patient monitoring
patient monitoring (3.10) from a distance over time

~~Note 1 to entry: Examples include monitoring~~EXAMPLE Monitoring a patient's health while they are at their home, while they are in a hospital from a central location, while they are in an ambulatory, etc.

~~12.9~~3.12
safety
freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 51:~~1999~~2014, 3.~~1~~14]

~~12.10~~3.13
security
~~protection of information and data so that unauthorized people or SYSTEMS cannot read or modify them and so that authorized persons or SYSTEMS are not denied access to them~~

condition that results from the establishment and maintenance of protective measures that ensure a state of inviolability from hostile acts or influences

Note 1 to entry: Hostile acts or influences can be intentional or unintentional.

[SOURCE: ISO/~~IEC 12207:1995~~TS 82304-2:2021, 3.~~25~~1.22]

~~12.11~~3.14
social determinants of health
~~(~~SDH~~)~~
non-medical factors that influence health outcomes

Note 1 to entry: Social determinants of health are the conditions in which people are born, grow, work, live, and age, and the wider set of forces and systems shaping the conditions of daily life. These forces and systems include economic policies and systems, development agendas, social norms, social policies and political systems.

4	~~ICE Data Logger Draft Standard - SW95 - WD - 3-May-2018.docx~~