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Technical Specification

ISO/DTS 5615

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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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health 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.

Introduction

The COVID-19 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 of pandemic-related risks typically associated with face-to-face visits.

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

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

— 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 can be considered when developing remote care / Mobile Health solutions?

— What safety, effectiveness & security (SES) standards 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 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 pandemic in Remote Connected Care and Mobile Health (RCC-MH). The impact of the COVID-19 pandemic 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 Normative references

There are no normative references in this document.

3 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/obp

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

3.1
effective
successful in producing a desired or intended result

3.2
effectiveness
ability to produce the intended result

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, 3.2]

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 [36]]

3.8
manufacturer
natural or legal person with responsibility for the design and/or manufacture of a *medical device* (3.9) with the intention of making the medical device available for use, under their name, whether or not such a medical device is designed and/or manufactured by that person themselves or on their behalf by another person(s)

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

3.9
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: ISO/IEC Guide 63:2019, 3.7]

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

EXAMPLE Monitoring via general hospital and personal use monitoring devices, anaesthesiology monitoring devices, cardiovascular monitoring devices, etc.

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

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.

3.12
safety
freedom from unacceptable risk

[SOURCE: ISO/IEC Guide 51:2014, 3.14]

3.13
security
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/TS 82304-2:2021, 3.1.22]

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.

Note 2 to entry: Adapted from World Health Organization[1)].

1) https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1

3.15
telehealth
use of telecommunication techniques for the purposes of providing telemedicine, medical educations and health education over distance

[SOURCE: ISO/TR 16056-2:2004, 3.75]

3.16
telehealth service
healthcare activity supported at a distance by information and communication technology service(s)

Note 1 to entry: It is possible that the subject of care is not directly involved in a telehealth service, e.g. in the case of tele-dermatology where one physician consults another physician who is at a distant location.

Note 2 to entry: Healthcare activities may include healthcare provider activities such as diagnosis, treatment, review or advice, and self-care activities as prescribed or recommended by a health professional, preventive (educational) advice and management of healthcare processes.

Note 3 to entry: Healthcare activities may include both synchronous (real-time) and asynchronous (delayed) interactions between actors. For example, a radiology examination can be transmitted and subsequently reported by a radiologist over a communications network. A discussion on the diagnostic findings can occur real time over a telephone or video conferencing connection between a patient and health professionals.

[SOURCE: ISO 13131:2021, 3.5.2]

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

AAMI	Association for the Advancement of Medical Instrumentation
AUDA	African Union Development Agency
ANVISA	Agência Nacional de Vigilância Sanitária (Brazil)
CCU	critical care unit
CDC	Centers for Disease Control (US)
CDSCO	Central Drugs Standard Control Organization (India)
DICOM	Digital Image Communication in Medicine
EHR	electronic health record
EMR	electronic medical record
ER	emergency room
EU	European Union
EUA	emergency use authorization
FCC	Federal Communications Commission (US)
FDA	Food and Drug Association (US)
FW	firmware
GP	general practitioner
HCP	health care provider

HHS	Health and Human Services
HL7	Health Level 7
ICU	intensive care unit
IEEE	Institute of Electrical and Electronic Engineers
IoT	Internet of Things
LTAC	long-term acute care
MDIRA	Medical Device Interoperability Reference Architecture
MFDS	Ministry of Food and Drug Safety (South Korea)
NIST	National Institute of Standards and Technology (US)
ONC	Office of the National Coordinator (US)
PCP	primary care physician
PHD	personal health devices
PMDA	Pharmaceutical and Medical Device Agency (Japan)
PoCD	point-of-care devices
PPE	personal protective equipment
RCC-MH	Remote Connected Care – Mobile Health
SDC	Service oriented Device Communication
SDO	standards development organization
SFDA	Saudi Food and Drug Association
SNF	skilled nursing facility
SW	software
TGA	Therapeutic Goods Administration (Australia)
UDI	unique device identifier
US	United States
VCT	virtual clinical trial

5 RCC-MH care locations and evolution

5.1 What is RCC-MH?

RCC-MH (Remote Connected Care – Mobile Health) belongs to the broader context of telehealth services that allow health care providers (HCPs) and patients to connect using technology to deliver health care remotely. Modalities include:

— synchronous, including real-time phone or live audio-video interaction, typically with a patient using a smartphone, tablet, or computer;

— asynchronous, including “store and forward” technology where messages, images, or data are collected at one point in time and interpreted or responded to later;

— remote patient monitoring, which allows direct transmission of a patient’s clinical measurements (such as vital signs and point-of-care lab results) remotely (real time, intermittent, continuous, etc.);

— patient monitoring at a bedside in ICU (alerts, risk index, reports), which allows for healthcare staff to provide care (as much as possible) while socially distancing themselves from the potentially infectious patient, thus cutting down on infection risk and PPE consumption.

5.2 Care locations: hospitals, home and community, nursing, outpatient

RCC-MH is all about connecting patients and caregivers regardless of where they are located, also recognizing that patients and caregivers can be mobile. There are many ways of grouping these locations and this is the approach adopted in this document (see Annex K):

— Home and community care: patient home, extended family, senior housing.

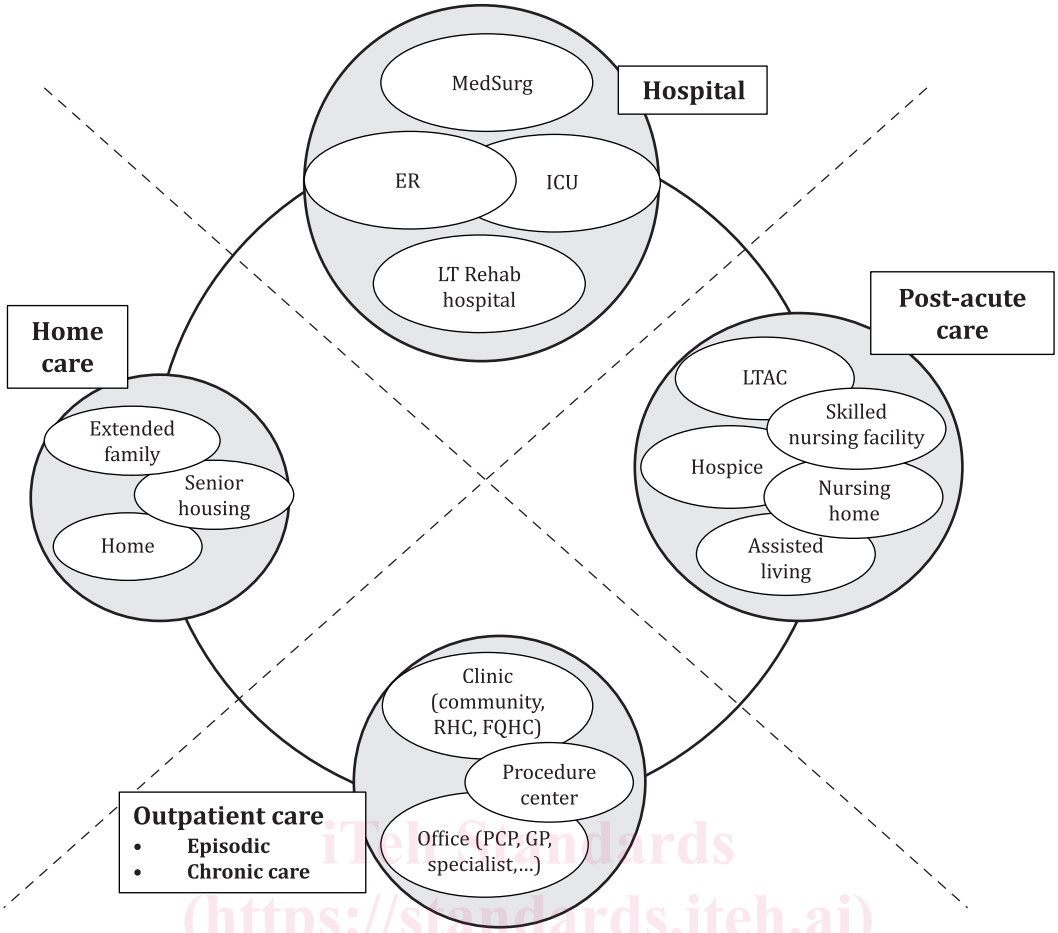
— Outpatient care: clinic, procedure centre, office [primary care physician (PCP), general practitioner (GP), specialist, etc.].

— Post-acute care: skilled nursing facility (SNF), long-term acute care (LTAC) facility[2)], hospice, nursing home, assisted living.

— Hospital: emergency room (ER), intensive care unit (ICU), medical surgery unit (MedSurg), long term rehabilitation hospital.

Figure 1 shows the main locations and pre-pandemic typical patient care locations and flows that have been considered. Most pre-pandemic care was taking place in the hospital or in post-acute care facilities, with much less care taking place in the home or in outpatient locations.

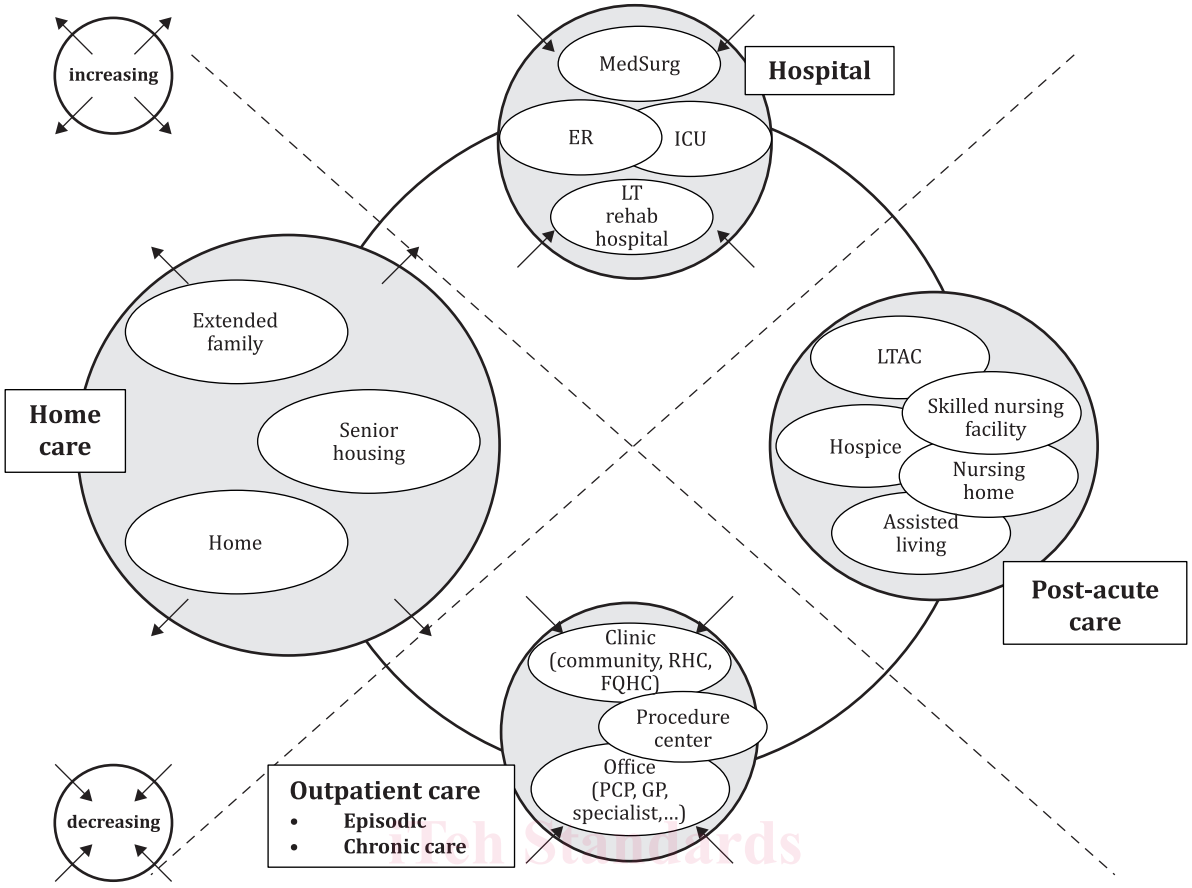
2) An LTAC is a hospital that treats patients with serious medical conditions that require ongoing complex care but no longer need intensive care or extensive diagnostic procedures



NOTE The size of circles is not to scale with the amount of care taking place in the different locations.

Figure 1 — Pre-pandemic locations of care

What healthcare systems have experienced, and rapidly accelerated as a result of the COVID-19 pandemic, is a huge shift of care locations away from traditional hospital and outpatient care areas to home and community care and post-acute care. This transition was also enabled by adjustments to the regulatory and reimbursement environments in various countries (see Annex A). There are numerous reports showing the exponential increase in virtual visits using telehealth services platforms (see Annex H for some relevant standards). Patients that would normally be monitored in the hospital, are being transitioned to home care with a similar level of monitoring, sometimes termed the “hospital at home”. Figure 2 illustrates the shifts in the flow of patients.



NOTE The size of circles is not to scale with the amount of care taking place in the different locations.

Figure 2 — Post-pandemic locations of care

While the changes were dramatic in the initial phases of the COVID-19 pandemic, only a partial return to the state that existed pre-pandemic has occurred as the disease subsided and became endemic. Patients find the convenience of telehealth visits and the benefits of being taken care of outside of an institutional setting to be very alluring. There are also economic benefits that have been recognized and will certainly be popular with reimbursement entities such as government and public or private insurers.

6 RCC-MH relevant care delivery modes and use cases

6.1 General

This clause reviews several high-level care delivery modes which illustrate the scope of RCC-MH. These range from in-hospital environments where caregivers could be just around the corner to more 'remote' situations such as a nursing home or patient home. Each of these modes provide opportunities for remote monitoring, diagnosis and care.

A longer list of care delivery locations can be found in Annex D.

6.2 Hospital care

6.2.1 Isolation room

During the COVID-19 pandemic the need to isolate patients became almost routine. However isolated patients become more complicated to manage due to the desire to limit contact as much as possible. Therefore, the