Technical Specification

ISO/TS 5615

First edition
2025-07

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

Reference number
ISO/TS 5615:2025(en)

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Published in Switzerland

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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 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).

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics,* in collaboration with HL7 and 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]