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Health informatics — Personal health data generated on a daily basis

Informatique de santé — Données personnelles de santé générées sur une base journalière

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. 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 www.iso.org/patents).

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.

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

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.

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Introduction

The increasing number of smart phones, mobile applications and remote monitoring devices combined with EHRs, patient portals and PHR systems enhance the patient's engagement in healthcare services. However, patient health data, which are constantly created, recorded, gathered or inferred have not yet been actively utilized at the point of care.

Specifically, un-coded data are too subjective and informal. In order to be applicable to clinical environment, ambiguity should be minimized or eliminated, and more precise. The health-related data should accurately convey the concept they are intended to deliver. The ISO/IEEE 11073 series and IHE-PCD Rosetta work are one of candidates to accomplish this goal. For health-related data to be reliably integrated into the process of diagnostic and therapeutic decision making, they should be quality-assured, trusted in accordance to accuracy of measurements.

In terms of safety and interoperability, AAMI/UL 2800 defined safety and related specifications of Medical Device (MD) interface to be labelled or declared as Interoperable Medical Device. The standard specifies MD interface characteristics to operate in safety conditions and focus on the mitigation of risk associated with interoperability within the Integrated Clinical Environment (ICE) and Interoperable Scenario (IS). It might be complementary to ISO/IEEE 11073-20601, particularly in mobile environments for improving care delivery, optimizing workflow and reducing ambiguity.

The Personal Connected Health Alliance (PCHAlliance) released the Continual Design Guidelines (CDGs) to enable the secure, private, reliable and accurate sharing of patient generated health data with healthcare providers, built-on HL7 FHIR®[1)] (Fast Healthcare Interoperability Resources) specifications. The Continua Design Guidelines define an open, flexible framework for end-to-end interoperability and the convenient collection and exchange of clinical grade health data for improved health, wellness and disease management. They are built on existing open, international standards and specifications including ISO/IEEE deliverables, IEC deliverables, HL7 deliverables, USB and Bluetooth. The International Telecommunication Union (ITU) recognizes the Continua Design Guidelines as an international standard for personal health systems and makes them available for global adoption in the several languages. Valuable tools and resources support product certification via the Continua Design Guidelines, including: the Continua Enabling Software Library (CESL), CODE for Healthcare and test tool development, representing millions of dollars worth of software development created by Continua to enable complete end-to-end functionality. PCHAlliance members have access to Continua Certified Experts (CCE), pre-market interoperability testing, Technical Operations Leads and brand support for Continua Certified products. PCHAlliance also participates in a series of events around the world to connect members with buyers, as well as Plugfests, Summits and an online Product Showcase highlighting Continua Certified products and services[18].

Furthermore, Health-related data have in-depth relevance with IoT and related technologies because health-related data are usually created by IoT devices. In order to ensure quality and safety of Health-related data along with IoT, the Standard Development Organizations (SDOs) should collaborate with each other more effectively.

1) FHIR® is an example of a suitable product available commercially. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of this product.

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Health informatics — Personal health data generated on a daily basis

1 Scope

This document provides an environmental scan of common data elements that are captured through various modalities such as cell phones, smart phones, mobile applications and remote monitoring devices that are combined with EHRs, patient portals and PHR systems which can ultimately be applicable to a variety of healthcare service environments.

The Health-related data can be used to supplement existing clinical data, filling in gaps in information and providing a more comprehensive picture of ongoing patient healthcare.

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 terminological databases for use in standardization at the following addresses:

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

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

3.1
assessment
measurement, evaluation or judgment for a study variable pertaining to the status of a subject

3.2
biometric
use of specific attributes that reflect unique personal characteristics, such as a fingerprint, an eye blood-vessel print, or a voice print, to validate the identity of entities

3.3
clinician
health professional who delivers health services directly to a patient/client

3.4
disorder
alterations or attributes of the health status of an individual which might lead to distress, interference with daily activities, or contact with health

3.5
experience
facts, information and skills acquired through experience, reasoning or education

3.6
personal health data
personal data relevant to the health of an identified or identifiable natural person

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3.7
individual
single discrete entity

3.8
measure
collect quantifiable data about a function or process

3.9
monitor
medical device designed to acquire, display, record, and/or analyse patient data and to alert caregivers of events needing their attention

3.10
observation
measurement of a single variable or single value derived logically and/or algebraically from other measured or derived values

3.11
pain
health condition that results in some disability, pain and/or activity limitation

3.12
patient
synonym for a subject of care

3.13
symptom
untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product that does not necessarily have a causal relationship with this treatment

3.14
treatment
medical or surgical management of a patient

4 Use cases of health-related data

4.1 General

Health is more than healthcare. The County Health Rankings[20] are based on a model of community health that emphasizes the many factors that influence how long and how well we live. According to the County Health Rankings Model, health factors help communities understand what will impact their health in the future. Health factors are composed of Physical Environment (10 %), Social and Economic Factors (40 %), Health Behaviours (30 %), and Clinical care (20 %). The following are health-related data use cases that patients / customers write or report in a non-hospital setting.

4.2 Patient Reported Outcomes (PRO)

4.2.1 General

A PRO is a health outcome directly reported from patient who experienced it. It is different from an outcome reported by someone else, like physician-reported outcome, a nurse-reported outcome, and so on. PRO methods, such as questionnaires, are used in clinical trials or other clinical setting, to help better understand a treatment's efficacy or effectiveness.

Incorporating the patient perspective through patient reported outcome measures is a crucial element for clinical care, quality performance management and clinical research. PROs are any report coming directly from patients regarding their health condition and treatment, including symptoms, functional status and health-related quality of life. Some PRO measures are generic and appropriate for use in

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