DRAFT INTERNATIONAL STANDARD

ISO/DIS 29585

ISO/TC **215**	Secretariat: **ANSI**
Voting begins on: **2022-09-21**	Voting terminates on: **2022-12-14**

Health informatics – Framework for healthcare and related data reporting

ICS: 35.240.80

This document is circulated as received from the committee secretariat.

Reference number
ISO/DIS 29585:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

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.

This second edition cancels and replaces the first edition (ISO/TS 29585:2010), which has been technically revised.

The main changes are as follows:

— inclusion of ISO/TR 22221:2006 Health informatics - Good principles and practices for a clinical data warehouse

— Consideration of the impact of developments such as the availability of big-data and federation of services

— Following comments in the CD ballot, each requirement has an identified actor responsible for its delivery and each requirement is intended to be clear and unambiguous

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.

0 Introduction

0.1 Background

The scope of this document is the effective delivery of healthcare information to service a wide range of decision-making and research questions.

A considerable amount of data is collected during the provision of care and treatment, some of it specific to the patient being treated, and some of it not. The primary purpose of this information is to support and improve individual patient care and much of it is held under professional and legal obligations of confidentiality. However, this information, often in conjunction with other records, is of value for many other purposes to support healthcare for groups of patients or for populations.

Healthcare data reporting provides many benefits. The health and well-being of the population are improved by activities such as disease surveillance, screening, needs assessment and preventative activities such as identifying the relationship between infected water and cholera resulting in better sewers. Research has led to major benefits in health practice such as the cure of duodenal ulcers, prevention of spina bifida, effective treatment of breast cancer and the carrying out of hip replacements. Research has also reduced risks through a greater understanding of HIV prevention, the relationship between smoking and lung cancer and the ill effects of the use of aspirin for children. The regulation of new medicines and other treatments relies on evidence of safety and efficacy from clinical trials.

Providing appropriate conditions are met, these data can legitimately be used to support these other purposes. In practice, such healthcare data reporting covers a wide spectrum including:

— Protecting the health of the public through surveillance and immediate response to infectious disease and other environmental threats to health, monitoring adverse effects of therapeutic interventions and informing and evaluating screening;

— Providing better information to the general public about healthy lifestyles;

— Improving the quality and safety of care or reducing the impact of new risks to population;

— Improving the management of the health system, for example by supporting the more efficient commissioning of services and value-based care

— Improving the quality of clinical care within an institution, for example through the audit of clinical practice;

— Identifying patients who interact with multiple parts of the health system in order to monitor equity of access and provision;

— ensuring consistent care for people who interact with multiple parts of the system, and

— monitoring equity of access and provision

— Ensuring that health policy is evidence-based through carrying out empirical research.

0.2 Healthcare Data Reporting

The scope of this document has not changed, in that the purposes remain largely the same. However, where the term CDW implied a specific, bounded, repository of data, with specific functions, recent developments have greatly increased the ways of addressing potential applications. For instance:

— The era of “big data“ offering new sources and modes of data, with a massive increase in data capture and use, including structured, unstructured, text, images, near real-time, combination of data sources e.g. personal device data, also social determinant of health data to inform population health and a wide range of presentation and visualisation tools

— The establishment of federated services that can link data sources which previously could not be combined and, hence, supporting distributed queries. These federated approaches can support:

moving from hierarchical views of data to multi-layered and multi-dimensional approaches, the separation of data sources and data consumers, distributed queries and moving from data warehouses / data marts to data lakes and data labs.

— The potential for analysing data on a much wider scale, particularly for areas such as rare diseases where federated big data enables studies requiring this population size

— The push for transparency of data has further reinforced the opportunities and responsibilities of sharing the value of such analysis with a wider public

In view of these developments, this document provides a framework for healthcare and data reporting, addressing both the opportunities and the responsibilities of the handling of the data. Figure 1 summarises the stages, products and actors through the lifecycle. The following clauses describe these activities with principles, processes, standards and activities.

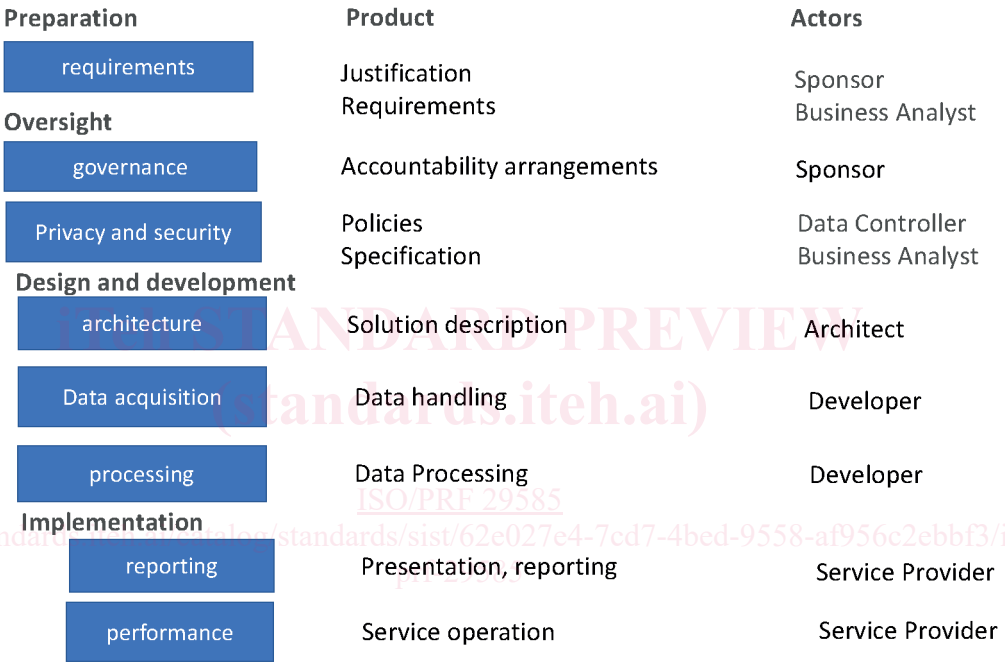

Figure 1 — Lifecycle for healthcare data reporting services

Clauses 5-12 specify requirements, each of which is allocated to one actor. Requirements are individually referenced by actor (e.g. SPnnn for sponsor, DCnnn for data controller, ANnnn for business analyst, ARnnn for architect, DVnnn for developer and PRnnn for service provider).

Health informatics – Framework for healthcare and related data reporting

1 Scope

The scope of this document is the reporting of data to support improved public health, more effective health care and better health outcomes.

This document provides guidance for those wishing to develop or deploy a healthcare data reporting service, addressing data capture, processing, aggregation and data modelling and architecture and technology approaches.

The role of a healthcare data reporting service is to enable data analyses in support of effective policies and decision making, to improve quality of care, to improve health services organizations and to influence learning and research. This document has relevance both to developing and more established health systems. It enables meaningful comparison of programs and outcomes.

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
actor
person, organization, or system that has one or more roles that initiates or interacts with activities

[SOURCE: TOGAF 9.2, 3.2, modified]

3.2
analyst
member of the technical community who is skilled and trained to define problems and to analyze, develop, and express algorithms

EXAMPLE systems engineer, business analyst

3.3
architect
person, team, or organization responsible for the process of defining a collection of hardware and software components and their interfaces to establish the framework for the development of a computer system

[SOURCE: ISO/IEC/IEEE 24765:2017, modified by combining definitions of architect (3.209) and architectural design (3.211)]

3.4
business analyst
person who bridges the gap of understanding between business and technology to accurately define software requirements and carefully control scope

3.5
clinical data warehouse
CDW
grouping of data accessible by a single data management system, possibly of diverse sources, pertaining to a health system or sub-system and enabling secondary data analysis for questions relevant to understanding the functioning of that health system, and hence supporting proper maintenance and improvement of that health system, e.g., public health services

Note 1 to entry: A CDW tends not to be used in real time. However, depending on the rapidity of transfer of data to the data warehouse, and data integrity, near real-time applications are not excluded.

3.6
dashboard
user interface based on predetermined reports, indicators and data fields, upon which the end user can apply filters and graphical display methods to answer predetermined business questions and which is suited to regular use with minimal training

3.7
data controller
organization that determines what information will be processed and why,

Note 1 to entry: The data processor is the one that does the actual processing. Controllers are responsible for creating privacy notices, implementing mechanisms to ensure that individuals can exercise their data subject rights and adopting measures to ensure the data processing meets the GDPR's principle of privacy by design and by default.

3.8

data custodian

role within the processing entity (IT department) that handles the data daily

3.9
data processor
entity that works under the direction of the owner/controller, such as an IT department

Note 1 to entry: Data processors are responsible for meeting the instructions set by the controller, therefore mitigating the risk that data is processed excessively or without a lawful basis, providing whatever information is necessary to help the controller complete a DSAR (data subject access request) and informing data subjects in advance if personal data is being transferred between jurisdictions.

3.10
data dictionary
database used for data that refer to the use and structure of other data, i.e. a database for the storage of metadata

3.11
data element
variable, clinical elements are considered synonyms in a clinical information model unit of data that is considered, in context, to be indivisible

[SOURCE: ISO/IEC 14957:2010, 3.1, modified — "variable, clinical elements are considered synonyms in a clinical information model" added.]

3.12
data mart
subject area of interest within or standalone from the data warehouse dimension

EXAMPLE An inpatient data mart.

Note 1 to entry: Data marts can also exist as a standalone database tuned for query and analysis, independent of a data warehouse.

Note 2 to entry: Data marts are typically suitable to adhere to localised requirements such as GDPR in Europe, via clear specification of purpose for analysis, permissions of data subjects, and data minimalization procedures

3.13
data warehouse dimension
subject-oriented, often hierarchical business relevant grouping of data

3.14
developer
individual or organization that performs development activities (including requirements analysis, design, testing through acceptance) during the system or software life-cycle process

[SOURCE: ISO/IEC 25000:2014, 4.6]

3.15
drill down
exploration of multidimensional data which makes it possible to move down from one level of detail to a more detailed level depending on the granularity of data

EXAMPLE Number of patients by departments and/or by services.

3.16
episode of care
identifiable grouping of healthcare-related activities characterized by the entity relationship between the subject of care and a healthcare provider, such grouping determined by the healthcare provider

3.17
health indicator
single summary measure, most often expressed in quantitative terms, that represents a key dimension of health status, the healthcare system, or related factors

Note 1 to entry: A health indicator is informative and also sensitive to variations over time and across jurisdictions.

[SOURCE: ISO/TS 21667:2010, 2.2]

3.18
healthcare data reporting service
managed service to provide reporting of data to support improved public health, more effective health care and better health outcomes

3.19
metadata
information stored in the data dictionary which describes the content of a document

3.20
master data management
enablement of a program that provides for an organization's data definitions, source locations, ownership and maintenance rules

3.21
organization
unique framework of authority within which a person or persons act, or are designated to act towards some purpose

[SOURCE: ISO/IEC 6523-1:1998, 3.1]

3.22
performance indicator
measure that supports evaluation of an aspect of performance and its change over time

3.23
person
human being regarded as an individual

3.24
role
usual or expected function of an actor or the part somebody or something plays in an action or event

Note 1 to entry: It is also defined as a part an individual plays in an organization and the contribution they make through the application of their skills, knowledge, experience, and abilities.

Note 2 to entry: An Actor may have several roles.

[SOURCE: TOGAF 9.2, 3.31]

3.25
service provider
organization or part of an organization that manages and delivers a service or services to the customer

Note 1 to entry: A customer can be internal or external to the service provider's organization.

3.26
sponsor
person or group who provides resources and support for the project, program, or portfolio and is accountable for enabling success

[SOURCE: ISO/IEC TR 24587:2021, 3.15]

3.27
star schema
dimensional modelling concept that refers to a collection of fact and dimension tables

4 Abbreviations

DICOM[SM]	Digital Imaging and Communications in Medicine
AES	Advanced Encryption Standard
API	Application Programming Interface
CDW	Clinical Data Warehouse
CIM	Clinical Information Model
DDS	Dimensional Data Store
DPO	Data Protection Officer
EHR	Electronic Health Record
ELT	Extract, Load, Transform
ETL	Extract, Transform, Load
GDPR	General Data Protection Regulation
HL7	Health Level 7
ICD©	International Classification of Diseases
LOINC©	Logical Observation Identifiers, Names and Codes
MBUN	Meaningless But Unique Number
NLP	Natural Language Processing

OCR	Optical Character Recognition
NCPDP	National Council for Prescription Drug Programs
PIA	Privacy Impact Assessment [020 – amended]
RBAC	Role-based Access Control
RxNorm	*RxNorm* provides normalized names for clinical drugs
SLA	Service Level Agreement
SNOMED CT©	Systematized Nomenclature of Medicine — Clinical Terms
TEFCA	Trusted Exchange Framework and Common Agreement
TRE	Trusted Research Environment
XCDR	(IHE) Cross-Community Reliable Interchange

5 Preparing: Requirements and Planning

5.1 Overview

Clause 5 describes steps to be taken when planning the development of healthcare data reporting service or the extension of existing services. Potential benefits and uses are described in informative Annex A.

The primary actors responsible for the provisions in this clause are the sponsor and the business analyst responsible for specifying requirements.

Healthcare data reporting services typically become more valued than originally anticipated and grow in size, complexity and rate of access.

SP001 The sponsor should ensure healthcare data reporting service be viewed as an on-going development and not as a fixed project with an endpoint.

SP002 The sponsor should provide an "extensibility" plan can include import and export to other systems and communications with other systems, which retain the integrity of the data.

5.2 Prioritisation of requirements

There are many factors relevant to the prioritisation of requirements.

SP003 A sponsor wishing to develop, extend or make use of the healthcare data reporting service should justify the purposes of use prior to commencing implementation.

SP004 The sponsor shall have a clear value proposition for the foreseen applications.

SP005 The sponsor should, when developing new services, include engagement with initial information providers, users, service providers and other relevant systems with which the healthcare data reporting service is expected to exchange information/services.

SP006 The sponsor shall ensure that proposals are designed to achieve a clear outcome for users or the system. It is imperative to understand how outputs will result in better provision and/or outcomes for people and the health and care system.

SP007 The sponsor shall ensure the intended purpose(s) is legal and defensible.

SP008 The sponsor should ensure budgets balance costs and performance needs.

SP009 The sponsor can enter into contractual requirements for the healthcare data reporting service with current information systems and service suppliers.