Technical Specification

ISO/TS 5384

Health informatics — Categorial structure and data elements for the identification and exchange of immunization data

Informatique de santé — Structure catégorielle et éléments de données pour l'identification et l'échange des données d'immunisation

First edition
2024-09

Reference number
ISO/TS 5384:2024(en)

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 ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
3.1 General terms 2
3.2 Terms related to subject of care data elements 3
3.3 Terms related to immunization event data elements 3
3.4 Terms related to the location, organization and provider data elements 5
3.5 Terms related to the immunization forecast data elements 6
4 Use cases **7**
5 Definition of the immunization data elements **7**
5.1 General 7
5.2 Data elements 8
5.2.1 Subject of care data elements 8
5.2.2 Immunization event data elements 8
5.2.3 Location, organization and provider data elements 16
5.2.4 Immunization forecast data elements 17
6 Data elements by use case **18**
Bibliography **22**

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).

ISO draws attention to the possibility that the implementation of this document may involve the 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.

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 125, *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.

Introduction

Public health stakeholders working with immunization information do not have a structured view of their data that is aligned with technical stakeholders who are very familiar with Health Level Seven (HL7) and other message standards. This document can enable effective and efficient interaction between public health and technical stakeholders in the planning of digital health solutions with immunization data by enabling a common understanding of the data elements required and how they can be used.

The data represented in interoperability standards such as HL7 Fast Healthcare Interoperability Resources (FHIR) does not cover all frequently encountered immunization management use cases. This includes the data elements required for an immunization registry and the level of data element definition detail to enable consistent understanding and application. There is a business need for alignment across various other existing standards such as International Patient Summary and Identification of Medicinal Products (IDMP). There is also a need to align with emerging standards regarding the document and sharing of sex and gender and the considerable amount of effort across all standards development organizations and the World Health Organization in developing data standards to address the COVID-19 pandemic challenges.

The purpose of this document is to address the challenges with sharing health care information with incompatible data structures and improve interactions and understanding of the data between technical and business stakeholders. By defining a set of data elements to be used within an immunization registry and other systems, recording and sharing immunization data with specific use cases implementation effort will be enhanced.

This document can be used to harmonize the data used in interoperability standards such as Integrating the Health Care Enterprise (IHE), HL7 FHIR and Clinical Knowledge Management Structures and other related initiatives (such as the WHO COVID-19 vaccine certificate) by providing detailed descriptions of the data elements and considerations for how to apply the data elements within digital health solutions including consumer apps.

This document can also aid low and middle-income countries in the development of an immunization registry by providing the core structures and data needed to record and monitor a population.

This document is particularly suitable for business and technical resources planning immunization digital health solutions and immunization registries.

This document can be helpful to a broad range of stakeholders such as:

— public health immunization and communicable disease stakeholders;

— government including public health agencies responsible for public health, emergency preparedness and response, and infectious disease control and prevention;

— software developers;

— vendors providing electronic medical record, pharmacy, immunization registry systems, knowledge base vendors and consumer app providers;

— educators and educational organizations to educate the health informatics and healthcare communities on the requirements for immunization terminology implementation;

— clinicians working with immunization data.

Health informatics — Categorial structure and data elements for the identification and exchange of immunization data

1 Scope

This document specifies an immunization categorial structure and data elements for use as the basis for an immunization registry and in digital health solutions that require interaction with the immunization registry and other systems in the management of immunization information. The data set includes data element descriptions, requirements, considerations for implementation and conformance with the following use cases:

— populate an immunization registry;

— record and/or share a current immunization event;

— record and/or share a historic immunization event;

— create and/or share an immunization history;

— create an immunization reminder;

— create anonymized immunization reports;

— schedule a new immunization event.

This document has adopted data element names from relevant ISO standards and leverages and elaborates on the immunization data element descriptions and constraints provided in HL7 specifications. The structure of the data element definition provides:

— business rules and requirements (e.g. rationale for including the data element and how the data element supports the use case);

— the meaning of absent data and how it can be addressed;

— how to represent the data if more information is required to clarify data type use and will include value set considerations.

The use case and related data elements out of scope for this document include adverse event following an immunization.

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 General terms

3.1.1
data element
basic unit of identifiable and definable data

[SOURCE: ISO 2146:2010, 3.4]

3.1.2
immunization registry
confidential, population-based, information system that records and manages all immunization doses administered by participating providers to persons residing within a given geopolitical area

3.1.3
active immunizing agent
complex biologic product designed to induce a protective immune response effectively and safely

3.1.4
passive immunizing agent
preparation containing pre-formed antibodies derived from humans or animals or produced by recombinant DNA technology

Note 1 to entry: Administration of passive immunizing agents can prevent certain infections or reduce the severity of illness caused by the infectious agent.

3.1.5
cold chain break
breach or failure in following a set of rules and procedures that ensure the proper storage and distribution of an immunizing agent

3.1.6
combined vaccine
vaccine that is designed to protect against two or more diseases or against one disease caused by different strains or serotypes of the same organism

Note 1 to entry: Combined vaccines contain two or more antigens that are either combined by the *manufacturer* (3.3.10) or mixed immediately before administration[7].

3.1.7
vaccine certificate
receipt provided by a health care authority that identifies the immunization information to enable proof of vaccination

3.1.8
immunization protocol
policy and/or schedule developed by government jurisdiction or their expert immunization advisory committees, based on jurisdiction-specific needs, other immunization recommendations, program resource availability and constraints, and identified priorities

3.1.9
immunization forecast
ability to provide recommendation for a client's future immunizations by considering certain information about the client and the application of a jurisdiction's *immunization protocol* (3.1.8)

3.1.10
pharmaceutical product
qualitative and quantitative composition of a *medicinal product* (3.1.11) in the dose form approved for administration in line with the regulated product information

Note 1 to entry: In many instances, the pharmaceutical product is equal to the manufactured product. However, there are instances where the manufactured item shall undergo a transformation before being administered to the patient (as the pharmaceutical product) and the two are not equal.

3.1.11
medicinal product
pharmaceutical product (3.1.10) or combination of pharmaceutical products that can be administered to human beings (or animals) for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions

[SOURCE: ISO 11615:2017, 3.1.50 modified — notes were removed.]

3.2 Terms related to subject of care data elements

Note 1 to entry This subclause includes the subject of care data elements elaborated in further detail in 5.2.1.

3.2.1
family name
part of a name a person usually has in common with some other members of their family, as distinguished from their preferred and given names

[SOURCE: ISO/TS 22220:2011, 6.2.2]

3.2.2
preferred name
name by which the subject chooses to be identified

[SOURCE: ISO/TS 22220:2011, 6.3]

3.2.3
subject of care identifier
number or code assigned to a person by an organization, establishment, agency or domain in order to uniquely identify that person as a subject of health care within the jurisdiction of that health care organization, establishment, agency or domain

[SOURCE: ISO/TS 22220:2011, 5.2]

3.2.4
birth date
date, as exact as possible, when the subject of care is known or estimated to have been born

3.2.5
gender identity
individual's personal sense of being a man, woman, boy, girl, nonbinary, or something else

Note 1 to entry: Gender identity represents an individual's identity, ascertained by asking them what that identity is.

3.3 Terms related to immunization event data elements

Note 1 to entry This subclause includes the immunization event data elements elaborated in further detail in 5.2.2.

3.3.1
immunization administration status
information on the status of the immunization event

3.3.2
immunization target disease
disease caused by bacteria or virus that immunization provides protection against

3.3.3
common name
official non-proprietary or generic name recommended by the World Health Organisation (WHO), or, if one does not exist, a non-proprietary name recommended by the region within which the name is used

[SOURCE: ISO 11615:2017, 3.1.15 modified — note was removed.]

3.3.4
medicinal product name
name of a medicinal product as authorised by a medicines regulatory agency

[SOURCE: ISO 11615:2017, 3.1.54, modified — note was removed.]

3.3.5
medicinal product identifier
unique identifier allocated to a *medicinal product* (3.1.11) supplementary to any existing authorisation number as ascribed by a medicines regulatory agency in a region

[SOURCE: ISO 11615:2017, 3.1.53, modified — notes were removed.]

3.3.6
medicinal product package identifier
unique identifier allocated to a packaged *medicinal product* (3.1.11) supplementary to any existing authorisation number as ascribed by a medicines regulatory agency in a region

[SOURCE: ISO 11615:2017]

3.3.7
medicinal product batch identifier
unique identifier (BAID2), allocated to a specific batch of a *medicinal product* (3.1.11), which appears on the immediate packaging, where this is not the outer packaging

[SOURCE: ISO 11615:2017, 3.1.5.2, modified — "2" was removed from end of term, note was removed.]

3.3.8
medicinal product batch expiration date
date until which the *manufacturer* (3.3.10) guarantees the full potency and safety of a particular batch or lot of *medicinal product* (3.1.11)

3.3.9
marketing authorization holder
organization that holds the authorization for marketing a *medicinal product* (3.1.11) in a region

[SOURCE: ISO 11615:2017, 3.1.41]

3.3.10
manufacturer
organization that holds the authorization for the manufacturing process

[SOURCE: ISO 11615:2017, 3.1.38, modified — note was removed.]

3.3.11
antigen grouper name
substance or group of substances that are recognized by the immune system and induce an immune response to a specific disease

3.3.12
antigen grouper identifier
coded representation of a substance or group of substances that are recognized by the immune system and induce an immune response to a specific disease

3.3.13
dose quantity
volume of the dose of a *medicinal product* (3.1.11) given to a subject of care

3.3.14
dose quantity unit of measure
unit of measure in which the *dose quantity* (3.3.13) is expressed

3.3.15
dose number
number of the dose received within a specific immunization series

3.3.16
series number of doses
recommended number of doses in a series that are required for immunity

3.3.17
immunization administration date
date the *medicinal product* (3.1.11) was administered to the subject of care

3.3.18
immunization estimated date flag
flag to indicate that the *immunization administration date* (3.3.17) was estimated

3.3.19
immunization reporting source
source of information regarding the reported immunization event

3.3.20
route of administration
path by which the *pharmaceutical product* (3.1.10) is taken into or makes contact with the body

[SOURCE: ISO 11615:2017, 3.1.76]

3.3.21
immunization anatomical site
body location to or through which a *medicinal product* (3.1.11) was administered

3.3.22
adverse reaction following immunization flag
flag to indicate that an adverse reaction was reported following administration of a *medicinal product* (3.1.11)

3.3.23
adverse reaction date
date the *adverse reaction following immunization* (3.3.22) occurred

3.3.24
adverse reaction manifestation
specific type of *adverse reaction following immunization* (3.3.22) that occurred

3.3.25
immunization notes
additional information relevant to the immunization record

3.3.26
reason for immunization
reason an immunization event was scheduled, planned, or given

3.3.27
reason for immunization not given
reason a planned or scheduled immunization event was not carried through

3.4 Terms related to the location, organization and provider data elements

Note 1 to entry This subclause includes the immunization event location, organization and provider data elements elaborated in further detail in 5.2.3.