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

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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).

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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.

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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.

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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/

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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.

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