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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

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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 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.

3.4.1
country of immunization
country in which the subject of care has been immunized

3.4.2
health care provider full name
given and *family name* (3.2.1) of the health care provider who is medically responsible for the decision to administer an immunization product

3.4.3
health care provider identifier
jurisdictional identifier of the health care provider who is medically responsible for the decision to administer an immunization product

3.4.4
organization name
name of the organization or health authority responsible for the immunization event

3.4.5
organization identifier
jurisdictional identifier associated with the organization or health authority responsible for the immunization event

3.4.6
immunization administration location name
location within the organization where the immunization event occurred

3.5 Terms related to the immunization forecast data elements

Note 1 to entry This subclause includes the data elements required for forecasting a future immunization event that are elaborated in further detail in 5.2.4.

3.5.1
immunization forecast status
immunization status of the subject of care towards immunity against an *immunization target disease* (3.3.2)

3.5.2
immunization forecast description
description of the protocol as determined by the organization responsible for immunization administration

3.5.3
immunization forecast supporting information
subject of care information that supports requirements related to a forecasted immunization event

3.5.4
immunization forecast generated date
date the subject of care's *immunization forecast status* (3.5.1) was generated

3.5.5
immunization forecast date type
type of date classification pertinent to the administration of the forecasted immunization event

3.5.6
immunization forecast date
date provided in the subject of care's immunization forecast whose meaning relates to the *immunization forecast date type* (3.5.5)

4 Use cases

Although immunization use cases (see Table 1) should be based on using data from an immunization registry, this is not always possible in all countries and settings. Therefore, the use cases are applicable regardless of the source of data.

Table 1 — Immunization use cases

Use case name	Use case definition and considerations for use
Populate an immunization registry	The data required within an immunization registry to enable the control and elimination of vaccine preventable diseases by ensuring the provision of information and knowledge necessary to stakeholders using the registry to achieve the best possible immunization coverage for subjects of care.
Record and/or share a current immunization event	The data required by a health care provider who has just immunized a subject of care to record and/or share the immunization event. The health care provider has complete information about the product (has vial in hand) and its administration to the subject of care who received the product. This immunization record may be shared with an immunization registry or other system. This use case includes the scenario where a vaccine was not given.
Record and/or share a historic immunization event	The data required by a subject of care, subject of care proxy or health care provider who is required to record and/or share a subject of care's immunization event that occurred in the past. The information may or may not include all information pertaining the product or its administration to the subject of care.
Create and/or share an immunization history	The data required by a health care provider or subject of care with the intent to view and/or review a subject of care's immunization history. The immunization history can pertain to one vaccine preventable disease or cover all immunization events over time that pertain to a subject of care. Ideally, summary level information is sourced from an immunization registry. This use case aligns with the data requirements for a vaccine certificate.
Create an immunization reminder	The data required by a health care provider or subject of care that identifies the subject of care's next scheduled vaccination or dose. This may be generated by an immunization registry or other system.
Create anonymized immunization reports	The data required by an authorized agency or entity to create a report that demonstrates an anonymized population level immunization status or summary, e.g. a status of COVID-19 immunization, at a certain location or country. This summary level information may be produced using data from an immunization registry or other systems involved in public health.
Schedule a new immunization event	The data required by a health care provider who is required to schedule a subject of care's immunization event to take place in the future.

5 Definition of the immunization data elements

5.1 General

Clause 5 provides:

a) data element groups with a general overview of the purpose of the data element grouping;

b) data element structure that includes:

   1) the data element name (as provided in Clause 3);

   2) a formal definition (as provided in Clause 3);

   3) business requirements and notes that include dependencies to other data as applicable, synonyms etc.;

   4) the meaning of missing data;

   5) the data element format such as String, Coded, Date and Boolean;

6) example values.

5.2 Data elements

5.2.1 Subject of care data elements

Table 2 identifies the data elements required to assist in identification of the person who is the subject of care. All data elements except for "gender identity" are aligned with Clauses 6 and 7 within ISO/TS 22220:2011.

Table 2 — Subject of care data elements

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Family name	The 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. (ISO/TS 22220:2011)	Synonym: last name This field shall not be blank or missing.	String	Brown
Preferred name	Indicates the name by which the subject chooses to be identified. (ISO/TS 22220:2011)	Some people do not have a family name and a given name; they have only one name by which they are known. If the subject of care has only one name, that name should be recorded in the family name field and the given name field should be blank (or missing).	String	Mary
Subject of care identifier	A 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. (ISO/TS 22220:2011)	Synonym: patient identifier Some identifiers are assigned by government agencies or other regulatory bodies to subjects of care for special purposes (billing or claiming benefits). Therefore, such identifiers should not generally be used for purposes other than these special purposes. The individual requirements of legislation in individual countries or public health authorities can be applied. This field shall not be blank or missing. A temporary identifier can be used if a formal jurisdictional identifier is not available.	String	12345
Birth date	The date, as exact as possible, when the subject of care is known or estimated to have been born.	Values should include the year of birth at a minimum (which can be estimated). This field shall not be blank or missing.	Date	19531110
Gender identity	An individual's personal sense of being a man, woman, boy, girl, nonbinary, or something else. This datum represents an individual's identity, ascertained by asking them what that identity is. (Definition is sourced from the HL7 Gender Harmony Project)	This field shall not be blank or missing. This data element follows the recommendations as outlined by the HL7 Gender Harmony project[6].	Coded	Female

5.2.2 Immunization event data elements

Table 3 identifies the key aspects of an immunization event.

IDMP standards typically focus on the manufactured product as opposed to the administrable product (which is mainly required for clinical care). When a data element was used from ISO 11615:2017, the specific name and definition have been provided from Clause 3 of that document.

Table 3 — Immunization event data elements

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Immunization administration status	Information on the status of the immunization event.	Not to be confused with the subject of care's immunization status. This is required for an interoperability message. Not required at user interface.	Coded	completed
Immunization target disease	Disease(s) caused by bacteria or virus that immunization provides protection against.	Multiple values for an immunization event can be necessary if the common name or medicinal product name includes a combined vaccine. Because the immunization target disease can be derived from medicinal product name, this field may be blank.	Coded	Shingles
Common name	The official non-proprietary or generic name recommended by the World Health Organization (WHO), or, if one does not exist, a non-proprietary name recommended by the region within which the name is used. (ISO 11615:2017)	Synonym: immunizing agent Generic representation of the formulation administered that includes one or more specific antigen(s) aimed at developing an immune response in an individual to provide protection from an immunization target disease(s). The values to support this data element include both active immunizing agents or vaccines (e.g. Hepatitis A +B vaccine), and passive immunizing agents, (e.g. Rabies Immunoglobulin). The values may be high-level (COVID-19 vaccine) or more detailed (COVID-19 mRNA vaccine). This data element should be specified when the brand name is not known (such as a recording of an immunization event that took place in the past). Because the common name can be derived from medicinal product name, this data element field may be blank.	Coded	Hepatitis A +B Vaccine

Table 3 *(continued)*

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Medicinal product name	The name as authorized by a medicines regulatory agency. (ISO 11615:2017)	Synonym: medicinal immunizing product trade name The values to support this data element include both active immunizing agents or vaccines (e.g. Hepatitis A +B vaccine) and passive immunizing agents, (e.g. Rabies Immunoglobulin). The values may include only the brand name of the product or a complete description of the product that may include the immunizing agent, dose form and brand name (or other attributes to distinguish the product). Because the values to support this data element can be derived from the medicinal product identifier and/or the medicinal package identifier, this field may be missing or blank.	Coded	TWINRIX JUNIOR [(Hepatitis A virus HM175 strain inactivated 360 unit) and (Hepatitis B virus subtype adw recombinant surface antigen 10 mcg (µg)) per 0,5 mL suspension for injection vial] GLAXOSMITHKLINE INC.
Medicinal product identifier	The unique identifier allocated to a medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory agency in a region. (ISO 11615:2017)	Synonyms: medicinal immunizing product identifier, trade name identifier An identifier that is a representation of a brand specific immunizing agent authorized for use in a jurisdiction. The identifier (including the generation and maintenance of it) shall be unique within the reference terminology system that is used and follow good terminology practices such as “The identifier shall never be re-used over time to identify other products”. It can be a global or national identifier. See Table 6 for information regarding missing data.	Coded	6881000087104

Table 3 *(continued)*

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Medicinal product package identifier	Unique identifier allocated to a packaged medicinal product supplementary to any existing authorization number as ascribed by a medicines regulatory agency in a region. (ISO 11615:2017)	Synonym: medicinal immunizing product package identifier The identifier (including the generation and maintenance of it) shall be unique within the reference terminology system that is used and follow good terminology practices such as "The identifier shall never be re-used over time to identify other products". It can be a global (e.g. global trade identification number GTIN) or a national identifier. The identifiers may refer to different package levels such as primary packaging or secondary packaging. The identifier of the lowest packaging level should be captured for all the use cases within this document. See Table 6 for information regarding missing data.	String	620641015623
Medicinal product batch identifier	Unique identifier (BAID2), allocated to a specific batch of a medicinal product, which appears on the immediate packaging, where this is not the outer packaging. (ISO 11615:2017)	Synonym: lot number The medicinal product identifier, along with the medicinal product batch identifier and expiration date, uniquely identifies an immunizing product. It is possible that the medicinal product batch identifier is not unique. See Table 6 for information regarding missing data.	String	UI412AA
Expiration date	The date until which the manufacturer guarantees the full potency and safety of a particular batch/lot of medicinal product. (ISO 11615:2017)	Synonym: expiry date The medicinal product, along with the medicinal product batch identifier and expiration date, uniquely identifies an immunizing product. This data element is a key variable in vaccine recalls because each batch number may have more than one expiration date. Expiration date may be changed (reduced) due to a cold chain break. See Table 6 for information regarding missing data.	Date	20201226

Table 3 *(continued)*

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Marketing authorization holder	The organization that holds the authorization for marketing a medicinal product in a region. (ISO 11615:2017)	Synonym: market authorization holder (MAH) The MAH may the same as the manufacturer. This information is used within the region and present on the label of authorized products. For example, one of the Covid-19 vaccines has been manufactured in a partnership between Pfizer and BioNTech and the MAH is BioNTech in Canada and Pfizer Australia Pty Ltd in Australia. In other countries the MAH is Pfizer-BioNTech. See Table 6 for information regarding missing data.	String	Sanofi Pasteur Inc.
Manufacturer	The organization that holds the authorization for the manufacturing process. (ISO 11615:2017)	The MAH may the same as the manufacturer. See Table 6 for information regarding missing data.	String	Sanofi Pasteur Inc.
Antigen grouper name	A substance or group of substances that are recognized by the immune system and induce an immune response to a specific disease.	Used to provide accurate information in the calculation of a subject of care's immunization forecast schedule, as an allergen or to assess a subject of care's immunization status (e.g. up to date or overdue) and vaccine coverage reports. Values may include detailed ingredients (such as Live attenuated Human Alpha-herpesvirus 3 Oka Strain Antigen) or grouper level ingredients (such as Human Alphaherpesvirus 1 Antigen). There may be more than one antigen within a medicinal product if the vaccine is a combined vaccine product. Since this can be derived from medicinal product or common name this field may be blank. See Table 6 for information regarding missing data.	Coded	Hepatitis A
Antigen grouper identifier	A 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.	See Table 6 for information regarding missing data.	Coded	334455

Table 3 *(continued)*

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Dose quantity	The volume of the dose of a medicinal product given to a subject of care.	For products such as influenza, Hepatitis B vaccines and passive agents, the recommended volume of product to be injected may vary (based on the subject of care's age or weight) and can impact the subject of care's immunization forecast. Business rules including conditions for use can be created for the specific agents where this is applicable. Business rules should consider the use of the data element dose quantity unit of measure when this data element is being used. See Table 6 for information regarding missing data.	String	0,5
Dose quantity unit of measure	The unit of measure in which the dose quantity is expressed.	This data element is conditional and should only be populated when the data element dose quantity is being used. See Table 6 for information regarding missing data.	Coded	mL
Dose number	The number of the dose received within a specific immunization series.	This data element should be designed to work for vaccines where full immunity is not achieved with the first dose and that require additional doses over time to provide immunity. This includes the use case where it is known at the initial vaccine event that a booster is required, or it may be used to allow for booster doses after the initial vaccine event. Values can assist a clinician in identifying if the subject of care is protected at a specific point in time. If this data element is populated, the series number of doses should be populated if applicable. Business rules including conditions for use of this data element should be developed. See Table 6 for information regarding missing data.	Positive integer	1

Table 3 *(continued)*

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Series number of doses	Recommended number of doses in a series that are required for immunity.	This data element when applicable shall be used together with the dose number data element. The series is dependent on the jurisdiction's protocols. A series can provide immunity for a defined period of time or for the lifetime of a subject of care. Business rules including conditions for use of this data element should be developed. See Table 6 for information regarding missing data.	Positive integer	2
Immunization administration date	The date the medicinal product was administered to the subject of care.	This data element is used to assess whether the subject of care is protected against a particular disease. Jurisdictions may have different business rules for dealing with partial or estimated dates when complete dates are not known. See Table 6 for information regarding missing data.	Date	20201226
Immunization estimated date flag	A flag to indicate, when true (Yes), that the immunization administration date was estimated.	To be used in conjunction with the immunization administration date data element to indicate that an estimated date was recorded for an immunization event as part of the subject of care's history. See Table 6 for information regarding missing data.	Boolean	Yes
Immunization reporting source	Source of information regarding the reported immunization event.	Confidence in the accuracy of a reported immunization record is dependent on the source. This is important in reviewing the subject of care's history and the risk / benefit decision as to whether it is necessary to re-vaccinate a subject of care. Each immunization event that is reported may have a different value for this data element. This data element is not intended to be used for a complete and consolidated history. See Table 6 for information regarding missing data.	String	Health care provider documented, subject of care/or parent documented

Table 3 *(continued)*

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Route of administration	The path by which the pharmaceutical product is taken into or makes contact with the body. (ISO 11615:2017)	Synonym: immunization route of administration Assists with management reporting such as adverse event management. See Table 6 for information regarding missing data.	Coded	78421000, intramuscular route
Immunization anatomical site	The body location to or through which a medicinal product was administered.	It is important to record where the medicinal product was delivered to the body in the event of a reported local reaction to a vaccine. When multiple agents are administered to multiple sites on the body, anatomical site helps determine which vaccine could have been responsible. Business rules including conditions when this data element is used should be developed. See Table 6 for information regarding missing data.	Coded	368208006, left upper arm
Adverse reaction following immunization flag	A flag to indicate, when true (Yes), that an adverse reaction was reported following administration of a medicinal product.	Used as a signal to practitioners that an adverse reaction was reported in relation to a particular immunization event. This field can also prompt the practitioner to send an adverse event report if an adverse reaction occurs in the office shortly after immunization or is reported at a future visit. Business rules including conditions for use of this data element should be developed. This information may be missing if there is no need for it to be documented. See Table 6 for information regarding missing data.	Boolean	Yes
Adverse reaction date	The date the adverse reaction following immunization occurred.	Not to be confused with the date the reaction was reported. This data element is conditional and should only be populated when the data element adverse reaction following immunization flag has value “yes” or equivalent (indicating True). Business rules including conditions for use of this data element should be developed.	Date	20201030

Table 3 *(continued)*

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Adverse reaction manifestation	Indicates the specific type of adverse reaction following immunization that occurred.	This data element is conditional and should only be used when the data element adverse event following immunization flag has a "yes" type of value. Business rules including conditions for use of this data element should be developed.	Coded	Rash
Immunization notes	Additional information relevant to the immunization record.	The notes may be related to the immunization event, agent or antigen grouper. This information may be missing if there is no need for it to be documented.	String	The patient fainted
Reason for immunization	Represents the reason an immunization event was scheduled, planned, or given.	The values used can relate to the subject condition or immunization protocol.	String	Protocol followed
Reason for immunization not given	Represents the reason a planned or scheduled immunization event was not carried through.	This data element is conditional and should only be used when the value for the immunization administration status indicates the immunization event was cancelled, not given, or not completed. This information may be missing if there is no need for it to be documented. This data element may be coded if the implementer is certain they can encode all possible reasons. Business rules including conditions for use of this data element should be developed.	String	Subject of care refused

5.2.3 Location, organization and provider data elements

Table 4 identifies the provider, organization and location data elements related to an immunization event. Although much of the content for these data elements was leveraged from ISO/TS 27527:2010, Clause 5, the data element names and definitions were insufficient for use.

Table 4 — Location, organization and provider data elements

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Country of immunization	The country in which the subject of care has been immunized.	Country may be written with code (see ISO 3166-1:2020) or with full name.	Coded	CA – Canada
Health care provider full name	The given and family name of the health care provider who is medically responsible for the decision to administer an immunization product.	Due to organizations who comply with general data protection regulation (GDPR), this information may be missing and therefore conditionally provided.	String	Mary Brown
Health care provider identifier	The jurisdictional identifier of the health care provider who is medically responsible for the decision to administer an immunization product.		String	556677
Organization name	The name of the organization or health authority responsible for the immunization event.		String	Manitoba Public Health
Organization identifier	The jurisdictional identifier associated with the organization or health authority responsible for the immunization event.		String	889900
Immunization administration location name	The location within the organization where the immunization event occurred.	The location where the immunization occurred is a further specification of the organization name.	String	RBC Winnipeg Convention Centre

5.2.4 Immunization forecast data elements

Table 5 provides the following data elements required for forecasting a future immunization event.

Table 5 — Immunization forecast data elements

Data element name	Data element definition	Business rules and notes	Format	Example(s)
Immunization forecast status	Represents the immunization status of the subject of care towards immunity against an immunization target disease.	A person's immunization forecast status changes over time and is dependent on the interval of time between immunizations, the person's age and other risk factors (such as pregnancy).	Coded	overdue
Immunization forecast description	Represents the description of the protocol as determined by the organization responsible for immunization administration.	This information assists the health care provider and subject of care in understanding the immunization forecast status.	String	Recommend 3 doses of the HPV vaccine starting at age 15 years
Immunization forecast supporting information	Represents subject of care information that supports requirements related to a forecasted immunization event.	This includes elaboration of the immunization forecast status, immunization forecast description, observations, adverse reactions, etc.	String	Blood clots with low levels of blood platelets occurred after vaccination with viral vector vaccines
Immunization forecast generated date	The date the subject of care's immunization forecast status was generated.	The date the subject of care's immunization forecast status was generated may not be the same as the immunization forecast date.	Date	202012313
Immunization forecast date type	Type of date classification pertinent to the administration of the forecasted immunization event.	This data element shall align and be used with immunization forecast date data element.	Coded	Earliest due date
Immunization forecast date	The date provided in the subject of care's immunization forecast whose meaning relates to the immunization forecast date type.	This data element shall align and be used with immunization forecast date type data element.	Date	20230303

6 Data elements by use case

Table 6 provides guidance on how to interpret the conformance requirements by use case.

Table 7 provides the conformance requirements for each data element for each use case.