TECHNICAL SPECIFICATION

ISO/TS 17117-2

First edition
2022-03

Health informatics — Terminological resources —

Part 2: Implementation Capability (TIC)

Reference number
ISO/TS 17117-2:2022(E)

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Published in Switzerland

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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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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.

Introduction

0.1 Objective

The aim of the ISO 17117 series is to enable health care organizations, vendors (including cloud services and conventional software products), governments and other decision makers to

— understand requirements for implementation of terminology in healthcare systems, and

— describe organization capability needed when using terminological resources.

This document defines the capability of implemented terminological resources based on the information lifecycle. Terminology implementation is assessed by review of each of the following 5 terminological implementation component parts:

— Data design;

— Data capture;

— Data storage;

— Data retrieval;

— Data exchange (interoperability) and re-use.

And reviewed according to the implementation processes and capabilities as defined across 5 areas:

— Terminological resource functionality;

— Tool functionality;

— Workforce capability;

— Governance;

— Conformity to standards.

0.2 Stakeholders and audience

The users of this document include

— health care organizations – to assess product capabilities and plan future directions and purchases;

— vendors (including cloud services and conventional software products) to

  — support implementation of terminological resources in their products,

  — enable semantic interoperability across different systems, and

  — assess product requirements influencing future directions for software development.

— government and other decision makers to identify areas of terminology practice that require improvement or should be included in purchasing or tender arrangements,

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

— terminological resource developers to assist in defining the services needed to best support their resources.

Health informatics — Terminological resources —

Part 2: Implementation Capability (TIC)

1 Scope

This document defines the components (benchmarks) of capability of terminological resources implementation in healthcare software products, including electronic health record systems. It is intended that these benchmarks form the basis of a maturity model. The document will support analysis of requirements to meet use cases in the implementation of terminological resources in healthcare.

This document does not specify requirements for any specific terminological resource. It is intended to provide a basis from which requirements for terminological resources capabilities can be specified in the future. The tooling being used can impact the level of maturity reached but is not covered in detail in this document. Terminological resources include code systems of all types, terminologies, classifications, value sets, and value domains.

The impact of tooling (computer–assisted coding, speech recognition, template development) on the capability of the terminological resources is not covered in detail in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO/TS 22287, *Health informatics — Workforce roles and capabilities for terminology and terminology services in healthcare (term workforce)*

ISO/TS 21564, *Health Informatics — Terminology resource map quality measures (MapQual)*

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
term
word or words corresponding to one or more concepts

Note 1 to entry: Value domains can be enumerated (e.g. Total centimetres NNN) or non-enumerated (e.g. Sex code N).

3.2
code system
organized, managed collection of codes, each of which has associated designations, meanings and in some cases relationships, properties or rules

3.3
classification
exhaustive set of mutually exclusive categories to aggregate data at a pre-prescribed level of specialization for a specific purpose

3.4
terminology implementation
process of taking a terminological system and applying it for concept representation to achieve efficient and accurate concept representation

3.5
map
device that provides an index from one term to another, sometimes using rules that allow translation from one representation top another indicating the degree of equivalence

3.6
terminology
structure, human and machine-readable representation of concepts

3.7
workforce capability
ability of those working on terminology implementation in an organization to perform their job properly

Note 1 to entry: Properly implies that the job is done in a manner which supports safe representation of concepts in the health record and health data supply chain, as well as efficient practice.

3.8
terminological resource
controlled set of terms in healthcare

4 The terminology implementation capability pillars

Terminology implementation capabilities are viewed across different functional areas to support identification of measures associated with terminology implementation maturity. These functional areas include

— data requirements for terminology implementation in healthcare software including the use of terminology in health records and health data,

— functional requirements of terminology implementation including its use in health records, clinical information systems, clinical guidelines or decision support systems, and

— tooling as a delivery mechanism for terminology representation or collection or the management of such implementations.

The capabilities of terminological resources implemented in healthcare information systems are defined considering the information lifecycle (data specification (design), capture, management, storage, and use). Specific components of the capability assessment will include

— choice of terminology resource to represent semantic concepts appropriately,

— user interface issues,

— meaning maintenance in health record content, and

— terminology resources implementation functionality (often provided by tooling).

This document will provide the following benefits to the health community:

— Define the capability of terminological resource implementation which deliver required safe outcomes for use in healthcare;

— Support healthcare software vendors and organizations to

  — compare terminological resource capabilities and organizational requirements for those resources, and

  — plan improvements, i.e., align requirements and capabilities, as needed.

— Improve the safety and utility of healthcare information systems and the data in them, such as implementation of clinical decision support systems;

— Enable information sharing (semantic interoperability) between organizations;

— Support of short- and long-term analytics within the organization and more broadly to enable knowledge acquisition.

5 Design of the data (data specifications)

5.1 General

The choice of a terminological resource is the first key to quality implementation. The resource chosen shall be suited to the task and robust if it is to be used in health records and systems which share data and persist over time. The key requirements for initial design of the data from a terminology implementation perspective are provided in this clause.

5.2 Choice of terminological resource

No matter which type of terminological resource, Terminology, Classification, Code System, Value set or Value domain, is being discussed, the concept representation influences the ability of the resource to meet implementation needs and to represent the data elements accurately and appropriately.

For further information on the attributes of a terminological resources see ISO 17117-1.

The following apply to the choice of a terminological resource for any specific use case:

a) Terminological resources for clinical use

  i. shall have the ability to represent a concept at different levels of granularity,

  ii. shall have the ability to represent the precise meaning of that concept,

  iii. shall have the ability to persist meaning over time, and

  iv. shall support retrieval of concepts by multiple attributes (multi-hierarchical).

b) Terminological resources for statistical use

  i. shall have the ability to represent not otherwise specified or unspecified concepts, and

  ii. shall support data aggregation at a specified level of granularity so that concepts can be counted.

c) Scope of the terminological resource content shall be able to represent all content required for the use case

  i. when a terminological resource is chosen, it shall include all concepts that are needed for representation in the use case. In many cases, the terminological resource will have more

concepts than are needed for the use case, in which case the value domain for the specific data element shall be restricted to only those concepts required for the use case.

For example: if a data element is to record types of fractures (not the body location but the fracture type such as: spiral, comminuted, greenstick. The terminological resource chosen shall be able to represent all of these concepts.

d) Scope of the terminological resource shall be reduced to only the concepts required for the specific data element and use case.

e) The terminological resource shall clearly differentiate between different concepts to ensure clarity and accuracy of data capture.

For example

A code system representing types of fractures which includes spiral, comminuted, greenstick, open and closed as the values does not meet this need. As a fracture can be comminuted and open.

To effectively use this code system two data elements would be required, in which case the terminology would be fit for purpose.

Data Element – Fracture exposure: with values Open or Closed

Data Element – Fracture type: with values spiral, comminuted, greenstick, etc.

f) Existing, preferably international, robustly governed and maintained terminological resources should used wherever possible. Governed code systems have the following:

i. An Organization responsible for the creation and maintenance of the code system content;

ii. Regular release cycles to ensure currency and ability to represent clinical practice;

iii. A maintenance regime undertaken by those skilled in working with terminological resources (See TermWorker);

iv. A mechanism for submission of code system queries and change requests;

v. A standard published rationale for changes applied consistently throughout the code system.

g) Reflect data source code systems. Where a data element is abstracted or extracted from an existing data collection the code systems should be the same in each system. This is intended to reduce the use of expensive and often poor-quality data maps.

5.3 Relationship to the information model

This capability identifies the need for terminological resources used in systems to be able to be associated with the data element or information model within which they are used as these can influence the meaning intended when the concept is recorded.

This includes the requirements for post-coordination of concepts. Terminology cannot represent every concept effectively without an appropriate information model for the data being collected will give a more maintainable and robust data.

EXAMPLE 1

ICD-10 Activity Codes

These codes include concepts of the following:

— What a person was doing such as playing soccer;

— What industry a person was working in – Education;

— Whether they were employed in paid work or not.

The current information model used to collect morbidity data about injuries does not support these three concepts. The activity code is recorded (in some countries not all) as a code which follows the injury code group and only one code is included. Different countries and organizations make their selection based upon different criteria. This means that data is lost about the causes of injury due to the lack of an effective information model. If the data collection model included concepts for the following:

— Activity being undertaken when injured;

— Industry in which a person was occupied when injured;

— Employment status when injured.

More accurate and usable information would be available.

EXAMPLE 2

Secondary diagnosis codes. Using the morbidity data example hospitals collect data about the reason a person was admitted to hospital but also data about chronic conditions of that individual, and in some countries whether that chronic condition was actively treated during the stay. Different approaches to solve this problem, which is again the lack of an effective information model for morbidity data collection, include:

a) Collection of all chronic conditions in the episode of care, making it difficult to determine

   a. Which conditions were actually treated?

   b. Which conditions were part of the reason for admission?

   c. Which conditions complicated the admission?

   d. Which chronic conditions exist for this patient but did not impact nor were they treated during the stay?

b) Creation of an additional set of codes to represent a condition if it is treated and if it is not treated during the stay. For example: in ICD-10-AM 11th edition - I10 is used for hypertension if treated but if ongoing care for the disease is undertaken with no change or active review it is coded as a supplementary code for chronic conditions so that the condition can be analysed for public health purposesU82.3 for hypertension if it is not treated.

5.4 Tool functionality

No specific capability requires have been determined in this area.

5.5 Design conformity to standards

The design of health data and terminological resource implementation should be consistent with the following:

— ISO 11179;

— ISO 21526 MetaReq;

— HL7 Value Set Specification.

5.6 Capability of governance processes and data management

Healthcare information is a vital resource for healthcare. That information consists of data about patients, their care, health status, plans, administrative information. Data is collected about individuals and groups for a wide variety of purposes and often using a range of terminological resources. The organization shall have a governance process in place to ensure appropriate collection, use and integrity of the data collected and the safe and accurate communication of data from the organization and between systems.

The terminology resource governance process shall have an information governance strategy, which provides vision and guiding principles for the health data ecosystem supported by the following:

— Clear scope of concept representation – terminology resource use cases.

— Evolves over time allowing for new medical concepts while maintain the meaning intended when the record was originally created.

— Management of information at rest and in motion (within and outside the organization).

— Consistent principles of concept representation across all data irrespective of format. Information governance requirements shall be applied across all data whether paper, born digital, or reproduced form other sources.

— A shared information model, data specification and concept representation approach, preferably global.

— Usable information governance standards supporting all use cases and requirements for information design, use and transformation.

— Application of the organization's information governance standards.

— Maintained and applied data governance roadmap for ongoing improvement.

— Governance participation by those with the skills required.

— A priority on patient care.

— Broad user engagement.

Operational data governance shall

— preserve data provenance with traceability to point of origin,

— preserve relationships between data and individual identity of patients and contributors to the record,

— specify organizational accountability for data quality at all points through the data supply chain,

— apply a cohesive long-term approach to data governance, and

— Evaluate and enable skill development to support data governance and quality.

Data governance shall cover the design, use and technical implementation requirements of all concept representation throughout the organization's data supply chain. This includes data governance strategy, vendor management (use of vendor neutral concept representation), data specification and code system management, quality measures and analysis. Use of global approaches with national and local extensions shall be applied where possible.

5.7 Capability of workforce to make terminology resource decisions and implementation

Those who are involved in making terminology decisions and implementation require the skills defined in ISO/TS 22287. It is important to recognize that those making decisions about the representation of concepts also need specific skills. Terminology resource decision making should be made with the following skills available to advise on the impact of decisions made:

— Understand the concept representation requirements of those who collect and use the data for direct patient care;

— Understand the data supply chain pathway relevant to each data or group of data and how this impacts collectability of the data and the implementation requirements;

— Ability to evaluate data supply chain needs vs safety and utility of data for direct patient care;

— Understand implementation options associated with data transformation for the data supply chain, such as the cost and safety issues associated with data mapping;

— Ability to evaluate the information model and its association with meaning represented through concepts and the terminological resources;

— Evaluate the scope and utility of terminological resources available and their suitability to the task required;

— Identify and plan for terminological resource implementation maintenance.

6 Data capture (user interface) in healthcare implementations

6.1 General

Terminological resources are used to capture data throughout the healthcare system. Accurate data capture is heavily dependent upon the ability of users to accurately represent the information they need quickly and efficiently. The capabilities described in this section indicate requirements for safe, quality data capture in health systems.

6.2 Capability to display code system content

6.2.1 Code selection support

Many tools are used to assist with data capture. These tools need to be designed to make data capture fast, easy and accurate.

The following criteria have been determined.

The data capture process should be designed to ensure that systems

a) shall include no more than 10 options from which to choose (in list),

b) when using embedded lists or tree lists shall have no more than 3 sublists,

c) the code (conceptID) should not be used as a retrieval mechanism (particularly where the conceptID is not structured 'meaningless identifiers',

d) shall display the preferred definition of the concept rather than synonyms or abbreviations,

e) shall not display the concept ID in the clinical user interface if that conceptID is not structured 'meaningless identifiers' (e.g. SNOMED 7771000 – left), and

a) shall use text-based filtering to reduce list sizes where it is not possible to restrict the list to 10 options or a tree to 3 levels. Where text-based filtering is used a filter should be applied to the data element to restrict the search to relevant concepts only.

EXAMPLE

Diagnosis Field (restricted to clinical findings):

Text entered: Fractured Femur.

System returns: Fracture of Femur (Disorder) and it is children for the user to select from. Figure 1 shows the children of this concept as well as the concept definition itself).

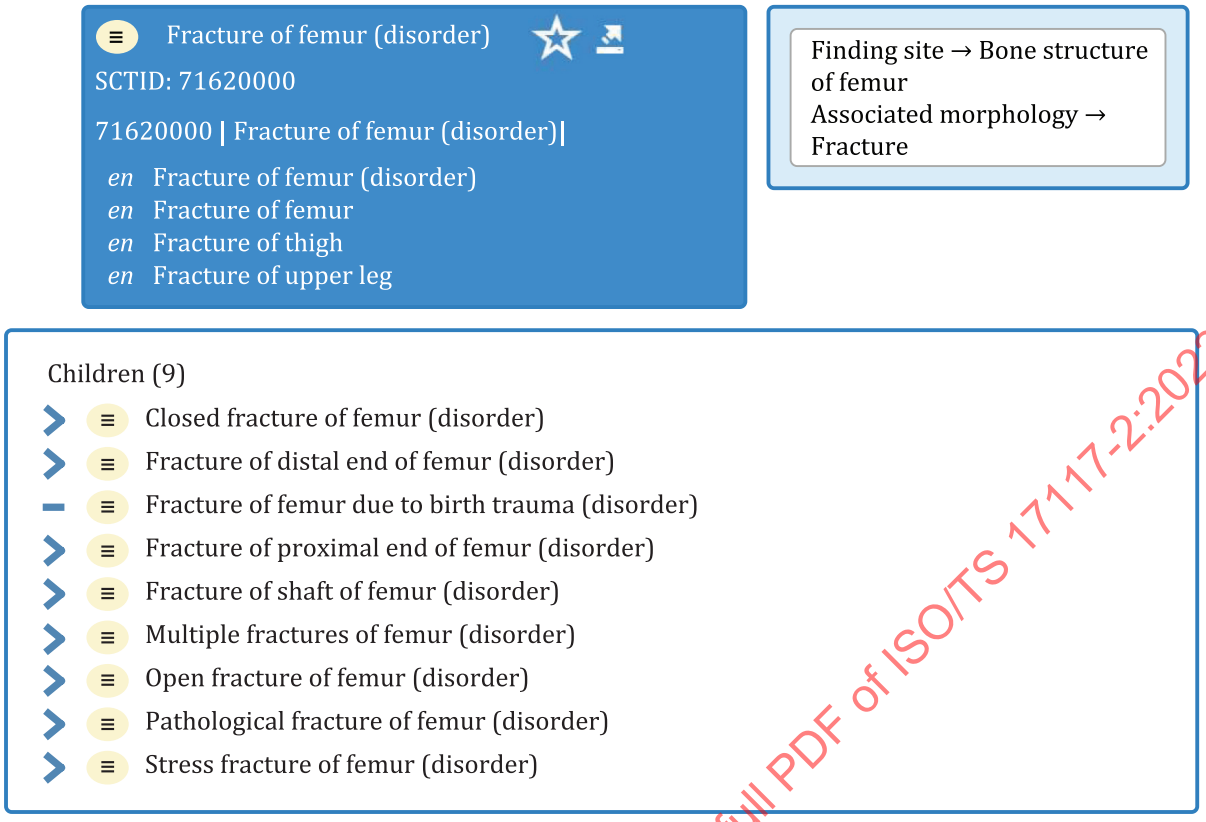

Figure 1 — SNOMED CT browser - SNOMED international edition (2021-07-31)

6.2.2 Tooling

Though the design components listed in 6.2.1 are to some degree dependent upon the tooling, the tooling implementation needs are defined more fully in later sections. The key consideration for data capture is that terminology browser software shall not be used as a user interface tool in clinical systems

6.2.3 Standards conformance

This document defines capabilities of terminologies that can be used to assess implementation needs and terminology product requirements.

6.2.4 Workforce

Capability of the workforce to define concepts for data collection and to record appropriate documentation for maintenance of clinical meaning is required see ISO/TS 22287 and ISO/TS 21564.

7 Data storage

7.1 Semantic concept permanence

The terminological resource shall be bound to the instance of data being held in the healthcare system.

The system shall store the identification information for the terminological resource and the version of that resource used when the data was created. The specific requirements are the following:

a) Identity of the issuer of terminological resource identifiers (the manager or namespace of the resource being used);