TECHNICAL REPORT

ISO/TR 12310

First edition
2015-05-15

Health informatics — Principles and guidelines for the measurement of conformance in the implementation of terminological systems

Informatique de santé — Principes et lignes directrices pour le mesurage de la conformité dans la mise en oeuvre des systèmes terminologiques

Reference number
ISO/TR 12310:2015(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 215, *Health informatics*.

Introduction

This work item is a Technical Report that will identify and discuss principles and guidelines for the measurement of conformance in the implementation of terminological systems, in particular, as applied to Electronic Health Record (EHR) systems.

This item will leverage the current work under way in Canada and will be developed in liaison with International Health Terminology Standards Development Organization (IHTSDO) and the Vocabulary Committee of HL7 in the spirit of harmonization across organizations with similar interests. Additional terminology organizations, active projects and existing expertise will be sought out for input into this work item.

Conformance is a key step in helping stakeholders determine if implementations of terminology systems have been done in a correct and consistent manner, particularly as implemented in EHRs. Loose declarations regarding terminological systems that cannot be tested with meaningful results do very little to support the end goal of the interoperable EHR. Therefore, the principles and guidelines for establishing and measuring conformance will focus on identifying the degrees of conformance of terminological systems with or without use in messaging standards.

This Technical Report is intended to define what is meant by conformance with respect to terminology systems, particularly as applied to EHR systems, and it is expected to facilitate the formulation of policies and governance practices locally or nationally. This Technical Report is timely as the emerging IHTSDO and progressive implementation of the EHR will lead to the increasing awareness of conformance with respect to terminologies and consistent implementations that allow interoperability by all end-users.

The focus of this Technical Report is to define best practices and a framework for establishing and measuring conformance. The scope of this Technical Report will include the identification of definitions and best practice considerations for what constitutes conformance to terminology systems and the principles for which conformance can be demonstrated.

Health informatics — Principles and guidelines for the measurement of conformance in the implementation of terminological systems

1 Scope

The purpose of this Technical Report is to define a framework of good practices for terminology system maintenance and the principles for which conformance can be demonstrated. The primary focus is the application of terminology system to Electronic Health Record (EHR) systems, although the principles and guidelines can be applied broadly in health informatics

The scope of this Technical Report will include, at a minimum, the following considerations for keeping terminology systems and associated reference material clinically and/or technically relevant and valid:

— governance models and practices;

— high level processes;

— requirements for managing the change.

The scope of this Technical Report will not include a definition of the detailed processes for performing terminology maintenance.

This Technical Report aims to define the framework of good practices for EHRs and systems regarding terminology maintenance within these systems. This Technical Report relates directly to the ability of these records to be safe and legally accurate records of healthcare in the environment of changing technologies related to the use of clinical terminologies to represent meaning within these systems.

2 Objective

This Technical Report identifies considerations for the expression and evaluation of conformance for solutions that make use of terminology. The specific focus of this Technical Report is terminology used in healthcare solutions. However, the principles should apply to solutions implementing terminology across the health industry. “Solutions” is interpreted broadly and includes both software and hardware technical implementations, as well as other specifications that are based on or claim to adhere to all or part of the specification against which conformance is being assessed. Implementation in this Technical Report does not consider procedural or governance requirements.

By using the definitions and recommendations found here-in, standards bodies, implementers, and other parties can better achieve their objectives in the development and use of specifications that make use of terminologies and can better express their terminology capabilities.

This Technical Report is intended to be independent of any particular terminology or terminological approach, though some portions of the guidance provided will only apply to certain types of terminologies.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE Because “terminology” is such a broad term, conformance actually needs to be stated in terms of the various terminology components that are referenced in a specification. These components will also be defined.

3.1
conformance
adherence of a system or specification to the expectations set by another specification

Note 1 to entry: The general definition for conformance has changed over time and been refined for specific standards. In 1991, ISO/IEC 10641 defined conformance testing as "test to evaluate the adherence or non-adherence of a candidate implementation to a standard." ISO/IEC/TR 13233 defined conformance and conformity as "fulfillment by a product, process or service of all relevant specified conformance requirements." In recent years, the term conformity has gained international use and has generally replaced the term conformance in International Standards.

Note 2 to entry: In 1996 ISO/IEC Guide 2 defined the following three major terms used in this field:

— conformity - fulfillment of a product, process, or service of specified requirements;

— conformity assessment - any activity concerned with determining directly or indirectly that relevant requirements are fulfilled;

— conformity testing - conformity evaluation by means of testing.

3.2
code system
managed collection of *concept representations* (3.4) intended for use in persisting or sharing of information

3.3
concept
single mental representation of some real or abstract thing

Note 1 to entry: Concepts should be unique within a *code system* (3.2).

3.4
concept representation
mechanism by which the system can express a *concept* (3.3)

Note 1 to entry: Different representations can serve different purposes. Most *code systems* (3.2) support multiple representations for each *concept* (3.3), sometimes even multiple representations of a given type. In some cases, distinct representations of a *concept* (3.3) may have their own identifier assigned within the *code system* (3.2) for maintenance and internal reference purposes. The types of representations are *code* (3.4.1), *concept id* (3.4.2), and *concept designation* (3.4.3).

3.4.1
code
concept representation (3.4) intended for use when representing a *concept* (3.3) in a computable manner

EXAMPLE Passing into a decision support tool or for use in data exchange.

3.4.2
concept id
concept representation (3.4) that is unique within the *code system* (3.2) and that is used internally by the *code system* (3.2) when referencing *concepts* (3.3)

3.4.3
concept designation
human consumable representation of the *concept* (3.3)

Note 1 to entry: A concept designation may or may not be a string of characters (could be multimedia); generally subject to language variants.

3.4.3.1
concept name
concept designation (3.4.3) that is the unique designation of the *concept* (3.3) in the *code system* (3.2) and intended for human understanding

Note 1 to entry: This is usually text but might also be graphical for some *code systems* (3.2). For example, images of different facial expressions for a *code systems* (3.2) representing pain scales.

3.5
code system partition
result of dividing a code identifier namespace into constituent components in order to delegate responsibility among organizations

Note 1 to entry: Some *code systems* (3.2) divide their "code" identifier namespace and delegate responsibility for different sets of *codes* (3.4.1) to different organizations.

Note 2 to entry: Examples include SNOMED-CT and LOINC. Each delegated organization is then responsible for the development, maintenance, and publication of the content for its delegated namespace of *codes* (3.4.1). This delegation allows organizations to introduce needed *codes* (3.4.1) more quickly than would be possible with a centralized approval mechanism. A code system partition is the set of *codes* (3.4.1) maintained by a single organization in such a delegated scheme.

3.6
code system supplement
informative extension to a *code system* (3.2) involving non definitional information to support implementation

Note 1 to entry: When introducing the use of a *code system* (3.2), the representations, properties, and relationships of the *concepts* (3.3) within that *code system* (3.2) do not always meet the needs of the potential users of that *code system* (3.2). For example, they may require translations of display names or definitions to other languages or using terminology more familiar to their community. They may need additional properties indicating allowed use of the *concepts* (3.3), for example, "Which lab tests are orderable?" These users may choose to "supplement" the *code system* (3.2) with additional information so that it meets their requirements. Because no *codes* (3.4.1) or *concepts* (3.3) are added, interoperability based on the underlying *code system* (3.2) is still maintained. This set of independently published supplemental information for an existing *code system* (3.2) is known as a code system supplement.

3.7
local code system
code system (3.2) used only within the organization that maintains the *code system* (3.2) or in direct communication with that *code system* (3.2)

Note 1 to entry: These *code systems* (3.2) are useful for achieving consistency within an organization but do not achieve interoperability across organizations. Because they are maintained directly by the organization using the *codes* (3.4.1), their maintenance processes are normally very responsive in the addition of new *codes* (3.4.1); however, they are frequently not as robust in the following of good vocabulary processes such as avoiding *code* (3.4.1) re-use, avoiding overlap, etc.

3.8
terminology binding
assertion of what *codes* (3.4.1) are to be used at a particular place within a specification, including an indication of *conformance* (3.1) expectations

4 Purposes for conformance

For the evaluation of conformance to serve a useful purpose, there has to be some sort of benefit. There are a variety of benefits to seeking conformance with a specification that includes a terminology component. This Clause summarizes some of the most frequent objectives.

4.1 Interoperability

One of the most frequent objectives for the enforcement of terminology specifications is to aid interoperability between systems that use those specifications. Two systems that use different codes for the same concept or that do not understand the same set of codes are unlikely to interoperate safely.

4.2 Data analysis

Knowledge bases, decision support engines, clinical studies, and other forms of analysis usually require coded information to be captured in a consistent way. Verifying the conformance of a system or specification can help to confirm that the data collected using that system will be able to be analysed.

4.3 Consistency of user experience

When users in a particular community will be making use of multiple systems, there are significant benefits to learning curve and user acceptance if those systems capture data in a consistent way. This includes the terminologies used to capture data.

4.4 Application functionality

The terminology capabilities of a system or specification are one measure of the sophistication of that system or specification. A system that is capable of capturing detailed post-coordinated coded information is significantly more sophisticated than a system that is only capable of capturing free-text information. As a result, conformance with a terminology specification can be used as a quality measure independent of any particular expectation of use of the data.

4.5 Acceptance filter

Sometimes, an expectation of conformance may be used as a bar for acceptance in some sort of program. This might be for a regulatory purpose, as part of a procurement process, or for other reasons. The expectations might be driven by one or more of the preceding rationales, but it can also just act as a "filter" to reduce the number of qualifying systems.

5 Conformance process

Once a determination has been made that conformance to a terminology specification will be useful, the following are four steps to the conformance process.

a) Ensure the specification that conformance is being evaluated against (base specification) clearly documents terminology expectations.

b) Document the capabilities of the system or specification being evaluated for conformance in terms of the base specification.

c) Evaluate the documented capabilities against the expectations set by the base specification.

d) If dealing with a system, test the system to verify that the documented capabilities reflect the actual capabilities.

These steps are discussed in detail in the following subclauses.

5.1 Documenting expectations

Documenting expectations is the most critical step in any terminology conformance exercise. If the base specification is unclear about requirements, then any evaluation of conformance will be uncertain and the desired objectives of achieving conformance will not be met. This subclause will discuss areas a terminology specification should cover in order to be clear and complete.

5.1.1 Optionality

Many specifications allow a degree of flexibility in exactly how terminology (and other aspects of the specification) needs to be implemented in order to be conformant. This may be due to variations in the environments in which the specification is being implemented, recognition of reasonable diversity of implementer capability requirements or needs, or other reasons. It is therefore essential that terminology specifications clearly differentiate which options are required and which are not. Recommended terms and definitions are listed below.

5.1.1.1 Optional

Optional requirements are those that may be supported but need not be supported by conformant systems. The expectation is that any conformant system that does support the requirement will support the requirement in the manner specified, i.e. the mechanism of implementation is not optional, but the choice of whether to implement or not is optional. Terminology specifications identifying a requirement as optional will often use the term “MAY”.

5.1.1.2 Recommended

A “recommended” requirement is an optional requirement where the author of the terminology specification wishes to assert a best practice. While systems that do not implement a recommended requirement would technically be conformant, they might still be considered somewhat deficient or “non-optimal”. Terminology specifications identifying a requirement as recommended will often use the term “SHOULD”.

5.1.1.3 Required

A “required” portion of a terminology specification shall be implemented by all implementations that wish to be conformant with the base terminology specification. Failure to implement a required component automatically renders the solution non-conformant. Terminology specifications identifying a component as required may use the term “MUST” or “SHALL”.

5.1.1.4 Not recommended

In some cases, a terminology specification will identify what sort of content is not allowed rather than what is allowed. This can be stated with varying strengths. Non-recommended content is similar to optional content. The inclusion of the non-recommended content is not non-conformant, but may indicate that the implementation is “non-optimal”. Terminology specifications identifying a requirement as not recommended will often use the term “SHOULD NOT”.

5.1.1.5 Not permitted

This is the opposite of “required”. Rather than being non-conformant if the content is not supported, a system would be non-conformant if it does support non-permitted requirement. Terminology specifications identifying content as not permitted will often use the term “SHALL NOT”.

5.1.1.6 Conditional

Any of the above degrees of optionality may be conditional. This means that a given part of a terminology specification might be required, recommended, optional, not recommended, or not permitted based on some condition. The condition might be based on what other aspects of the terminology specification are supported, the environment in which the terminology specification are being implemented, or other factors. Care should be taken when marking components of a terminology specification as “conditional” that the condition is clearly stated and can be consistently evaluated to either true or false for a given implementation. As well, the terminology specification shall be clear as to the type of optionality that applies if the condition is true. For example, is the requirement “conditionally recommended” or “conditionally required”?

6 Terminology artefact conformance considerations

The following subclauses describe the various questions that should be answered when creating terminology specifications that reference different types of terminology artefacts. By ensuring the terminology specification provides clear answers to each of these questions, ambiguity is reduced enabling conformance to be more accurately assessed.

6.1 Code system considerations

This subclause covers the questions that should be addressed when implementing each code system referenced by a terminology specification, as well as by terminology specifications that reference code systems.

6.1.1 What is the code system being referenced?

Ensure that the code system being referred to is clearly identified. For example, "ICD" would not be a useful reference as there is multiple code systems with that label that have been published over time, does the author mean ICD9? ICD10? Even specifying ICD10 might not be sufficient as many jurisdictions have their own versions of the ICD code system that have been supplemented and organized differently. If the code system is a local code system, it is important that the responsible organization be clearly distinguished. The set of "lab order types" for one hospital (or even one department) might not be the same as they are for another, even if they are nearby or even in the same building.

In the event that a terminology specification supplements codes from some non-local code system with additional local codes, a clear distinction shall be made between the third party codes (which come from one code system) and the local codes (which come from a distinct code system). This is because updates and validations may be processed differently against the third party code system than they are against the local codes.

Reference to a unique identifier assigned by a registry of code systems can help avoid ambiguity when referring to code systems.

6.1.2 What version(s) of the code system are supported?

Code systems frequently change over time. New codes may be introduced. Older codes may be deprecated. In some code systems, codes may even be assigned to different code systems over time. Code systems that follow this practice are extremely risky to use and should be avoided, if possible. Other information within the code system may also change, such as concept designations, definitions, relationships, etc. Because of this variability in the content of code systems over time, knowing what version (or versions) of the code system are expected to be used makes a difference in the expected behaviour of a system. Clear descriptions of expected behaviour are essential to conformance, therefore identification of the version or versions of a code system that are supported is essential when defining terminology conformance.

Code system authors may define different mechanisms for identifying versions of the code system. Some code system authors may not recognize the concept of version at all. They simply change the contents of the code system as and when they need to or wish to. Even among those code systems that do assign version identifiers, the consistency with which versioning occurs may vary. For example, some code system authors may still apply changes within a version, making the maintainer-assigned version id insufficient, or at least sub-optimal for identifying exactly what set of code system content is being referred to.

Because of the non-reliability or even non-existence of code system author assigned version identifiers, a date stamp or even a timestamp may be the most effective mechanism for explicitly referring to a particular version of many code systems. If taking this approach, the terminology specification should be clear on exactly what the date means, is it the date the content is changed, the date the content is published, or the date the content is "intended for use"?

Where using a terminology maintenance organization-assigned version identifier, care should be taken to ensure consistency in the representation of the identifier with respect to the capitalization,

