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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

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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).

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*.

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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.

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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.

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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.

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