TECHNICAL REPORT

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Health informatics — Guidelines for terminology development organizations

Informatique de santé — Lignes directrices pour établir une normalisation de la terminologie internationale des soins de santé

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 12309 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

Introduction

Healthcare terminological systems (terminologies) are developed to support accurate representation, communication and analysis of information about the healthcare of individuals and populations. The development and maintenance of healthcare terminologies require a robust and sustainable infrastructure and processes so that safe and consistent representation and interpretation of data and information can be supported over time.

Those wishing to use a specific terminological system (terminology), adopt it as a national or International Standard or incorporate it into other International Standards, need assurance that the required infrastructure, policies and processes are in place. This Technical Report gives a non-exhaustive list of principles and high-level processes that should be exhibited by a terminology development organization (hereafter referred to as *organization* in order to distinguish it from other kinds of organization) if it is to provide this assurance and support international healthcare terminology standardization.

Terminology standardization in general differs from other standardization in that it should address the language and cultural differences inherent in terminology itself. Standardization related to healthcare terminologies differs significantly from many other International Standards activities because of the technical nature of the content and the rapid versioning that is required. Specifically, terminologies often require a highly responsive *organization* that can accommodate the complex harmonization of nuanced “concepts”, while maintaining longitudinal consistency and utility. Furthermore, terminologies often form the foundation of many dependent systems, applications and operations, and thus should achieve a reliability and rigour coupled with availability and dissemination that are not always required of other standards. A “safety-critical” example is the use of terminologies in healthcare decision support systems such as drug interaction warnings for prescribing support.

Health informatics — Guidelines for terminology development organizations

1 Scope

1.1 Main purpose

This Technical Report specifies principles and processes that should be exhibited by developers of healthcare terminologies in support of international healthcare terminology standardization. The primary target group for this Technical Report is those establishing or reviewing *organizations*, and those evaluating the services or products maintained by such *organizations*, in the context of international healthcare terminology standardization. It complements standards such as ISO 17115 [1] and ISO 17117 [2] (which address the content of terminologies) by specifying good governance requirements for the lifecycle of those terminologies.

1.2 Topics considered outside the scope

Detailed specifications of appropriate governance structures and how *organization*s should undertake good governance are outside the scope of this Technical Report, which is limited to high-level principles and processes. Standards and guidance for the development, identification, maintenance and evaluation of healthcare terminological systems are provided elsewhere and are therefore outside the scope of this Technical Report.

2 Conformance

There is considerable literature on standards conformance assessment of organizations in general, for example related to ISO 9000 standards [3] for management systems. However, there is little experience specific to the domain of health informatics. One exception is the HITSP Standards Harmonization Committee, which uses a four-point scoring system against performance criteria relevant to its “preferred standards developer organization and process”. See reference [4]. Those evaluating healthcare terminology standards development organizations could consider using such a scoring system to demonstrate conformance to the subclauses in Clause 4 of this Technical Report.

3 Terms and definitions

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

3.1
standard
document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

[ISO/IEC Guide 2:2004, definition 3.2]

NOTE In the health informatics context the term “standard” can also refer to specifications, implementation guides, code sets, terminologies, integration profiles and other artefacts. See reference [4].

3.2
International Standard
standard that is adopted by an international standardizing/standards organization and made available to the public

[ISO/IEC Guide 2:2004, definition 3.2.1.1]

NOTE An International Standard is one that has been drafted in accordance with the rules given in the ISO/IEC Directives, Part 2 and published by ISO. An artefact adopted as an international standard by an international organization might not be an International Standard.

3.3
healthcare terminological system
healthcare terminology
set of designations within the domain of healthcare, with, where appropriate, any associated rules, relationships and definitions

3.4
standardization of healthcare terminology
official adoption of a healthcare terminology by an authoritative body, for a specific purpose

EXAMPLE The official adoption of the International Classification of Functioning (ICF) as a data entry standard by the health department of a country.

3.5
standards development organization
body that is recognised at national, regional or international level, that has as a principal function, by virtue of its statutes, the preparation, maintenance and publication of standards that are made generally available

4 Healthcare terminology standardization: organizations and process

4.1 Principles

ISO members are committed to voluntary standards development: “a transparent, consensus-based process relying on the contributions of concerned stakeholders”. Members are required to “ensure fair and responsive application of the principles:

— due process

— transparency

— openness

— impartiality”, see reference [6].

These principles are extended in the context of healthcare terminology standardization to meet the specific requirements of the domain, including: responsiveness, balance of interests, willingness to collaborate, sustainability, clear accountability boundaries, utility and safety.

4.2 Application in healthcare terminology standards development organizations

4.2.1 Governance and due process

The *organization* should have a governance structure that focuses on responsible stewardship of the standard(s) and responsiveness to all stakeholders within its defined scope. The structure should be capable of supporting unbiased decisions that take account of the inputs of all stakeholders.

It should support open and effective editorial processes, balancing the requirements of existing users of the standard with responsiveness to developments in technology and healthcare. The overriding principle for editorial decision-making and for evaluation of healthcare terminologies should be patient safety.

Governance and all activities of the *organization* should include a broad representation from all concerned stakeholders, for example: clinicians and providers or their representative organizations; vendors that develop, market, install and support health IT products or their representative organization; healthcare purchasers or employers or their representative organization; healthcare payers or health insurance companies or their representative organization; healthcare consumers or their representative organization; clinical and health services researchers or their representative organization.

The *organization* should consider the benefits of conformance to ISO 9000 standards [3] for its management systems.

Decisions should include due process so that all views are considered and a dispute resolution process exists. An identifiable, realistic, impartial and readily available appeals process should exist, with appeals addressed promptly and fairly.

Decisions should respond to regulatory and market needs, as well as scientific and technological developments and should be reached through consensus among those affected. Total costs of implementation by users of the standard should also be considered in decision-making, for example the cost of implementing a change to the distribution format.

Developers of terminologies that are intended as International Standards need to consider the conceptual and language differences within and among countries; processes for consultation and negotiation are required for conceptual/cultural harmonization to support translation.

4.2.2 Openness and transparency

Essential information regarding governance, activities and decisions of the *organization* should be accessible to all stakeholders in a timely manner.

Participation in editorial policy processes should be open to all affected interests and there should be no undue financial barriers to participation. This participation should include but is not limited to:

— input from content experts relevant to scope and purpose of the terminology;

— appropriate review by “customers” to reconcile well-recognised tensions between logical rigour and clinical utility without compromising either;

— vendors to vet implementation feasibility;

— authoritative review by native speakers and users of translations and language variants (including dialects and languages) with quality control to ensure consistent concept representation across human language variants.

Formal published procedures should govern the approach to development and approval of the standard. There should be published mechanisms for wide dissemination of materials for consultation, testing and review.

4.2.3 Impartiality and balance

No one interest, individual or organization should unduly dominate the development process or be favoured over another. Participants from all affected interests should be sought with the aim of achieving balance in the consensus process.

4.2.4 Sustainability and responsiveness

The financial viability and long-term sustainability of the *organization* need to be assured. It should demonstrate adequate funding sources to maintain the standard. Although legitimate costs can be recovered, no individual or organization should profit from contribution to the development or ongoing support of the terminology.

There should be no reliance on proprietary systems in the development, maintenance and distribution process if the viability and responsiveness of these cannot also be assured.

An easily accessed, open and flexible mechanism should be in place to respond to stakeholder requirements in a timely manner, for example to identify and incorporate new content or increase the frequency of updates. This mechanism should include version control and issue change notices as well as guidance for users on managing changes in their systems.

The *organization* should demonstrate that the terminology has been maintained with backward compatibility when appropriate.

4.2.5 Intellectual property and licensing

“Standardization is intended to put ideas into the public domain, whereas protection of IPR makes them private property.” See reference [7]. In exceptional cases there may be good reasons for including patented items, a process that needs to be managed according to ISO/IEC Directives. CEN/BOSS provides useful guidance on applying the ISO/IEC Directives on copyright and intellectual property. See reference [7].

The copyright of the international terminology should be vested in the *organization* and all contributors provide material on this basis. Copyright of the terminology should protect the quality and integrity of the terminology whilst allowing local flexibility to support local requirements.

Licensing structures should be the minimum required to protect core integrity of the terminology, essential associated products and services and ensure equitable distribution across user constituencies. Licensing should be an open process based on transparent metrics.

The *organization* should make clear to stakeholders and users of the standard where the boundaries of accountability rest in relation to the licence, including guidance on the interpretation of blanket content disclaimers if these exist.

4.2.6 Collaboration and interoperability

Developers should recognise that terminology content needs to fit within a framework of other standards and manage the implications for mutual update and harmonization, including with overarching or reference information models.

The *organization* should be willing to collaborate with international standards organizations and other healthcare terminology standards developers so that interdependencies are addressed and interoperability achieved maintained.

Patient safety and quality of healthcare are supported by regulatory and professional codes, rules and guidance. Healthcare terminology development *organization*s should collaborate with relevant regulatory and healthcare organizations towards interoperability between terminology standards and regulatory/professional standards.

In the healthcare domain where multiple terminologies are required, it is desirable that terminology standards developers authoritatively conduct and publish “mapping” across related content both internally (within terminology relationship assertions such as description logic) and externally (traditional mapping).

4.3 Evaluation

Access to the content of a terminology for evaluation and enhancement purposes should be unrestricted within the provisions given in 4.2.6. Consideration could be given to methods of sharing best practices to demonstrate outcomes of evaluations for all developers. Consideration should also be given to establishment of a registry of terminologies so that potential users can find out what is in use and where it is being used.

The terminology should adhere to International Standards for construction and function, have good internal and external mechanisms of quality assurance, and balance the need for stability of structure with regular timely updates.

The *organization* should demonstrate conformity of its products to relevant international terminology standards and contribute to development and periodic review of such standards to inform their development from the user perspective. Where a standard does not exist, a terminology developer should make use of the best available research evidence and in-use experience.

There should be one or more specific functional purposes and implementation contexts declared for the terminology so that it can be evaluated against those purposes and in those contexts. Evaluation criteria for healthcare terminologies are specified in ISO 17117 [2] but examples are provided here to indicate the scope of such evaluations. To support international standardization, healthcare terminologies should be:

— safe and fit for purpose;

— relevant, including supporting multiple languages;

— technically viable;

— healthcare provider- and delivery setting-independent;

— health information system-, vendor- and application-independent;

— interoperable with international health information standards;

— affordable, with reasonable licensing and maintenance fees;

— sustainable, with processes and resources for distribution, maintenance and timely responsiveness to stakeholder inputs;

— feasible and affordable to implement;

— available.

Increasingly, there is a need for terminologies to be human-language-independent.

Technical features of healthcare terminologies should be tested in appropriate implementations. A combination of methods is recommended for evaluation of content of healthcare terminologies. See references [8] and [9].