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Health informatics . Controlled health vocabularies - Vocabulary structure and high-level indicators

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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.

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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 other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

- an ISO Technical Specification (ISO/TS) represents an agreement between the members of a technical committee and is accepted for publication if it is approved by 2/3 of the members of the committee casting a vote.

An ISO/TS is reviewed every three years with a view to deciding whether it can be transformed into an International Standard.

Attention is drawn to the possibility that some of the elements of this **Technical Specification/part of ISO/TS 17117** may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 17117 was prepared by Technical Committee ISO/TC 215, "Health informatics".based on a working draft submitted by ASTM entitled " Standard Specification of Quality Indicators for Controlled Health Vocabularies".

Introduction

In 1839 William Farr stated in his First Annual Report of the Registrar-General of Births, Deaths, and Marriages in England, "The nomenclature is of as much importance in this department of inquiry, as weights and measures in the physical sciences, and should be settled without delay." Since that time this theme has been heard resounding from an increasingly large group of scientists (see Appendix A). Today, the need for controlled vocabularies to support health record systems has been widely recognized (E-1238, E-1239, E-1384, E-1633, ENV 12017). Controlled vocabularies provide systems with the means to aggregate data. This aggregation of data can be done at multiple levels of granularity and therefore can enhance the clinical retrieval of a problem oriented record, data pertaining to a classification for billing purposes, or outcomes data for a given population. Maintenance of large-scale vocabularies has become a burdensome problem as the size of term sets has escalated (IS 15188). Without a well-structured backbone, large-scale vocabularies cannot scale to provide the level of interoperability required by today's complex electronic health record applications.

The solution rests with standards.i Over the past ten or more years, Medical Informatics researchers have been studying controlled vocabulary issues directly. They have examined the structure and content of existing vocabularies to determine why they seem unsuitable for particular needs, and they have proposed solutions. In some cases, proposed solutions have been carried forward into practice and new experience has been gained.ii As we prepare to enter the twenty-first century, it seems appropriate to pause to reflect on this experience, and publish a standard set of goals for the development of comparable, reusable, multipurpose, and maintainable controlled health vocabularies (IS 12200, IS 12620).

This Technical Specification is the first deliverable from the ISO/TC 215 working group "Concept Representation" that is also working on an International Standard entitled "Health informatics - Vocabulary for terminological systems" that shall be the basis for future standards in this area. This ISO/TS 17117 on Quality indicators of controlled health vocabularies is based on previous work in ASTM that naturally could not be harmonised with now started ISO work on "Health informatics - Vocabulary for terminological systems". The present work is therefore published as a Technical Specification at this time with the intent to revise it to be compatible with the planned basic vocabulary standard and converted to a full international standard after a maximum period of three years.

Health informatics . Controlled health vocabularies - Vocabulary structure and high-level indicators

1 Scope

This international standard is intended to document the principal ideas, which are necessary and sufficient to assign value to a controlled health vocabulary. The standard will serve as a guide for governments, funding agencies, terminology developers, terminology integration organizations, and the purchasers and users of controlled health terminology systems toward improved terminological development and recognition of value in a controlled health vocabulary. It is applicable to all areas of healthcare about which information is kept or utilized. Appropriately terminologies should be evaluated within the context of their stated scope and purpose. It is intended to complement and utilize those notions already identified by other national and international standards bodies. This standard explicitly refers only to terminologies that are either primarily designed to be used for clinical concept representation or the aspect of a terminology designed to be used for clinical concept representation.

This international standard will also provide vocabulary developers and authors with the quality guidelines needed to construct useful, maintainable controlled health vocabularies. These tenets do not attempt to specify all of the richness, which can be incorporated into a health terminology. However this standard does specify the minimal requirements, which if not adhered to will assure that the vocabulary will have limited generalizability and will be very difficult if not impossible to maintain. Terminologies, which do not currently meet these criteria, can be in compliance with this standard by putting in place mechanisms to move toward these goals. This standard will provide terminology developers with a sturdy starting point for the development of controlled health vocabularies. This foundation serves as the basis from which vocabulary developers will build robust large-scale reliable and maintainable terminologies.

2 Normative references

The following normative documents contain provisions, which through reference in this text, constitute provisions of this [ISO/TS 17117](#). For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this [ISO/TS 17117](#) are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 704 Principles and Methods of Terminology

ISO/DIS 860 International Harmonization of Concepts and Terms

ISO 1087-1 Terminology - Vocabulary - Part 1: Theory and Application

ISO 1087-2 Terminology - Vocabulary - Part 2: Computer Applications

ISO 11179-3 Terminology – Data Registries

ISO 12200 Terminology - Computer Applications - Machine Readable Terminology Interchange Format

ISO 12620 Terminology - Computer Applications - Data Categories

ISO 15188 Project Management for Terminology Standardization

ISO 2382-4 Information Technology - Vocabulary - Part 4: Organization of Data

TR 9789 Guidelines for the Organization and Representation of Data elements for Data Interchange – Coding Methods and Principles

ASTM Standards:

E-1238 Specification for Transferring Clinical Observations Between Independent Computer Systems

E-1239 Guide for Description of Reservation/Registration-Admitting, Discharge and Transfer for Automated Patient Care Information Systems

E-1284 Guide for Nosologic Standards and for Construction of Biomedical Nomenclatures

E-1384 Guide for Structure and Content of the Computer-based Patient Record.

E-1633 Specification for Coded Values Used in the Computer-based Patient Record

E-1712 Specification for representing Clinical Laboratory Test and Analyte Names

CEN Standards:

ENV 12017 Medical Informatics - Vocabulary

ENV 12264 Medical informatics - Categorical structure of syntax of concepts - Model for representation of semantics

3 Terms and definitions

For the purposes of this ISO/TS 17117, the following terms and definitions apply:

3.1 terminology

set of terms representing a system of concepts within a specified domain.

NOTE This implies a published purpose and scope from which one can determine the degree to which this representation adequately covers the domain specified.

3.2

Controlled Health Vocabulary: A terminology intended for clinical use. This implies enough content and structure to provide a representation capable of encoding comparable data, at a granularity consistent with that generated by the practice within the domain being represented, within the purpose and scope of the terminology.

3.3

Classification: A terminology, which aggregates data at a pre-prescribed level of abstraction for a particular domain. This fixing of the level of abstraction that can be expressed using the classification system is often fixed to enhance consistency when being the classification is to be applied across a diverse user group, such as is the case with some of the current billing classification schemes.

3.4

Ontology: An organization of concepts for which one can make a rational argument. Colloquially, this term is used to describe a hierarchy constructed for a specific purpose. For example a hierarchy of Qualifiers would be a Qualifier Ontology.

3.5

Qualifier: A string which when added to a term changes the meaning of the term in a Temporal or Administrative sense. For example: "History of" or "Recurrent".

3.6

Modifier: A string which when added to a term changes the meaning of the term in a Clinical sense. For example: Clinical stage or severity of illness.

3.7

Canonical Term: A preferred atomic or pre-coordinated term for a particular medical concept.

3.8

Term: A word or words corresponding to one or more concepts.

6. General

6.1. Basics

Basic characteristics of a terminology influence its utility and appropriateness in clinical applications.

6.2. Concept Orientation

6.3. The basic unit of a terminology must be a concept, which is the embodiment of some specific meaning and not a code or a character string. Identifiers of a Concept must correspond to one and only one meaning and in a well-ordered vocabulary only one concept may have that same meaning (DIS 860). However, multiple terms (linguistic representations) may have the same meaning if they are explicit representations of the same concept. This implies non-redundancy, non-ambiguity, non-vagueness and internal consistency.

6.3.1. Non-redundancy - Terminologies must be internally normalized. There must not be more than one concept identifier in the terminology with the same meaning (IS 704, E-1284). This does not exclude synonymy, rather it requires that this be explicitly represented.

6.3.2. Non-Ambiguity – No Concept identifier should have more than one meaning. However an entry term (some authors have referred to this as an “interface terminology”) can point to more than one Concept (e.g. MI as a Myocardial Infarction and Mitral Insufficiency).

6.3.3. Non-Vagueness – Concept names must be context free (some authors have referred to this as “context laden”). For example “diabetes mellitus” should not have the child concept “well controlled”, instead the child concept’s name should be “diabetes mellitus, well controlled.”

6.3.4. Internal Consistency – Relationships between concepts should be uniform across parallel domains within the terminology. For example, if heart valve structures are specified anatomically the diagnosis related to each structure should also be specified using the same relationships. (note Schultz reference)

6.4. Purpose and Scope - Any controlled vocabulary must have its purpose and scope clearly stated in operational terms so that its fitness for particular purposes can be assessed and evaluated (IS 15188). Where appropriate, it may be useful to illustrate the scope by examples or ‘use cases’ as in database models and other specification tools. Criteria such as coverage and comprehensiveness can only be judged relative to the intended use and scope – e.g. *a vocabulary might be comprehensive and detailed enough for general practice with respect to cardiovascular signs, symptoms, and disorders, but inadequate to a specialist cardiology or cardiothoracic surgery unit.* Conversely, a vocabulary sufficiently detailed to cope with cardiology and cardiothoracic surgery might be totally impractical in general practice

- 6.4.1. Coverageⁱⁱⁱ - Each segment of the health care process must have explicit in-depth coverage, and not rely on broad leaf node categories that lump specific clinical concepts together. *For example, it is often important to distinguish specific diagnosis from categories presently labeled Not Elsewhere Classified (NEC), or to differentiate disease severity such as indolent prostate cancer from widely metastatic disease.* The extent to which the depth of coverage is incomplete must be explicitly specified for each domain (scope), and purpose as indicated in section 1.2.
- 6.4.2. Comprehensiveness^{iv} - The extent to which the degree of comprehensiveness is incomplete must be explicitly specified for each domain (scope), and purpose as indicated in section 1.2. Within the scope and purpose all aspects of the health care process must be addressed for all related disciplines, such as physical findings, risk factors, or functional status -- across the breadth of medicine, surgery, nursing and dentistry. This criterion applies because decision support, risk adjustment, outcomes research, and useful guidelines require more than diagnoses and procedures. *Examples include existing Agency for Healthcare Research and Quality guidelines, and the Health Care Finance Administration (HCFA) mortality model.*
- 6.5. Mapping^v - Government and payers mandate the form and classification schema for much clinical data exchange. Thus, comprehensive and detailed representations of patient data within computer-based patient records should be able to be mapped to those classifications, such as ICD-9. This need for multiple granularities is needed for clinical healthcare as well (ISO TR 9789). For example an endocrinologist may specify more detail about a patient's Diabetes Mellitus than a generalist working in an Urgent Care setting, even though both specialties may be caring for the same patient. The degree to which the terminology is mappable to other classifications must be explicitly stated.

- 6.6. Systematic Definitions**Error! Bookmark not defined.** In order for users of the terminology to be certain that the meaning that they assign to concepts is identical to the meaning which the authors of the vocabulary have assigned these definitions will need to be explicit and available to the users. Further as relationships are built into vocabularies multiple authors will need these definitions to ensure consistency in authorship. *For example, the concept "Hypertension" might be defined as a consistently elevated Blood Pressure and not (BP > 140 / 85).*
- 6.7. Formal Definitions– A compositional system should contain formal definitions for non-atomic concepts and formal rules for inferring subsumption from the definitions (E-1712).
- 6.8. Explicitness of Relations - The logical definition of subsumption should be defined. The formal behavior of all links/relations/attributes should be explicitly defined. If a looser meaning such as 'broader than/narrower than' is used, it should be explicitly stated. *For example, the primary hierarchical relation should be subsumption as exemplified by logical implication: 'B is a kind of A' means 'All Bs are As'.*
- 6.9. Reference Terminologies – The set of canonical concepts, their structure, relationships and if present their systematic and formal definitions. These features define the core of the controlled health terminology.
- 6.10. Atomic Reference Terminologies – A Reference Terminology consisting of only Atomic Concepts and their systematic definitions. In this type of reference terminology, no two or more concepts can be combined to create a composite expression as the same meaning as any other single concept contained in the Atomic Reference Terminology.
- 6.11. Colloquial Terminologies – The set of terms, which consist of commonly used entry points, which map to one or more canonical terms within the vocabulary. These have been called "entry terms" or "interface terminologies" by different authors.

7. **Structure of the Terminology Model** - Terminology structures determine the ease with which practical and useful interfaces, for term navigation, entry, or retrieval can be supported (IS 704, IS 1087-1, EN 12264).

For Compositional Terminologies:

7.1. Compositionality Composite concepts are created from Atomic concepts (*Note: The term "Concept" in this document is used to refer to the Representation of a Concept rather than the thought itself.; also see definition below*) must be able to be combined to create composite concepts^{vi}. A concept is a notion represented by language, which identifies one idea. *For example "colon cancer" comprises "Malignant, Neoplasm" and "Large Bowel" as atomic components. In a compositional system, concept representations can be divided into atomic and composite concept representations.* Composite concept representations can be further divided into 'named pre-coordinated concept representations' and 'post coordinated representation expressions'. Within a composite concept, it may be possible to separate the constituents into three categories: the 'kernel concept', 'qualifier (also called "status") concept', and 'modifier concepts'.

7.1.1. Atomic Concept A representation of a concept that is not composed of other simpler concept representations within a particular terminology. In many cases 'atomic concepts' will correspond to what philosophers call 'natural kinds'. Such an entity cannot be meaningfully decomposed. Concepts should be separable into their constituent components, to the extent practical. These should form the root basis of all concepts. *Example: In the UMLS Metathesaurus, Colon is a synonym for Large Bowel and Cancer is a synonym for Neoplasm, Malignant. Whereas Colon Cancer is non-atomic as it can be broken down into "Large Bowel" and "Neoplasm, malignant". Each of these two more atomic terms has a separate and unique Concept Unique Identifier (CUI), as does the pre-coordinated term "Colon Cancer."*

7.1.2. Composite Concept – A concept composed as an expression made up of atomic concepts linked by semantic relations (such as roles, attributes or links).

7.1.2.1. Pre-coordinated Concept Such an entity can be broken into parts without loss of meaning (can be meaningfully decomposed), when the atomic concepts are examined in aggregate. These are representations, which are considered single concepts within the host vocabulary. Ideally, these concepts should have their equivalent composite concepts explicitly defined within the vocabulary (that is the vocabulary should be Normalized for Content). *Example: Colon Cancer is non-atomic, however it has a single CUI, which means to the Metathesaurus that it represents a “single” concept. It has the same status in the vocabulary as the site “Large Bowel” and the diagnosis “Neoplasm, malignant.”*

7.1.2.2. Post-coordinated Concepts A composite concept, which is not pre-coordinated and therefore must be represented as an expression of multiple concepts using the representation language. This is the attempt of a system to construct a set of concepts from within a controlled vocabulary to more completely represent a user’s query. *Example: The concept “Bacterial Effusion, Left Knee” is not a unique term within the SNOMED-RT terminology. It represents a clinical concept that some patient has an infected Left Knee joint. As it cannot be represented by a single concept identifier, to fully capture the intended meaning a system would need to build a representation from multiple concept identifiers or lose information to free text.*

7.1.3. Types of Atomic and Pre-coordinated Concepts We can classify unique concept representations within a vocabulary into at least three distinct types, Kernel Concepts, Modifiers, and Qualifiers (which contain Status concepts). This separation allows user interfaces to provide more readable and therefore more useful presentations of composite concepts.

7.1.3.1. Kernel Concept - This is an Atomic or Pre-coordinated Concept, which represents one of the one or more main concepts within a pre-coordinated or post-coordinated composition.

7.1.3.2. Terms which refine the meaning of a Kernel Concept - Constituents of a composite concept which refine the meaning of a Kernel concept, e.g. 'stage 1a' in 'having colon cancer *stage 1a*', or 'brittle, poorly controlled', in '*Brittle, poorly controlled* diabetes mellitus'. In general, these concepts are expressed as a link plus a value ('attribute-value pair'). Terminologies must support a logical structure that can support temporal duration and trend. Attributes must be themselves elements of a terminology, and fit into a practical model that extends a terminology. *For example, cancers may be further defined by their stage and histology, have been symptomatic for a specifiable time, and may progress over a given interval.* Attributes are required to capture important data features for structured data entry and pertinent to secondary data uses such as aggregation and retrieval. Kernel concepts can be refined in many ways including a clinical sense, a temporal sense, and by status terms (e.g. "*Recurrent*").

7.2. Normalization of Content – Normalization is the process of supporting and mapping alternative words and shorthand terms for composite concepts. All pre-coordinated concepts must be mapped to or logically recognizable by all possible equivalent post-coordinated concepts. There should be mechanisms for identifying this synonymy for user created ("New") post-coordinated concepts as well (i.e. when there is no pre-coordinated concept for this notion in the vocabulary). This functionality is critical to define explicitly equivalent meaning, and to accommodate personal, regional, and discipline specific preferences. Additionally, the incorporation of non-English terms as synonyms can achieve a simple form of multilingual support.

7.3. Normalization of Semantics – In compositional systems, there exists the possibility of representing the same concept with multiple potential sets of atoms which may be linked by different semantic links. In this case the vocabulary needs to be able to recognize this redundancy / synonymy (depending on your perspective). The extent to which normalization can be performed formally by the system should be clearly indicated. *For example the concept represented by the term "Laparoscopic Cholecystectomy" might be represented in the following two dissections:*

7.3.1. *"Surgical Procedure: Excision"{Has Site Gallbladder}, {Has Method Endoscopic} and*

7.3.2. *"Surgical Procedure: Excision"{Has Site Gallbladder}, {Using Device Endoscope}.*

7.4. Multiple Hierarchies^{vii} - Concepts should be accessible through all reasonable hierarchical paths (i.e. they must allow multiple semantic parents), e.g. stomach cancer can be viewed as a neoplasm or as a gastrointestinal disease. A balance between number of parents (as siblings) and number of children in a hierarchy should be maintained. This feature assumes obvious advantages for natural navigation of terms (for retrieval and analysis), as a concept of interest can be found by following intuitive paths (i.e. users should not have to guess where a particular concept was instantiated).

- 7.5. Consistency of View^{viii} - A concept in multiple hierarchies must be the same concept in each case. Our example of stomach cancer must not have changes in nuance or structure when arrived at via the cancer hierarchy as opposed to GI diseases. Inconsistent views could have catastrophic consequences for retrieval and decision support, by inadvertently introducing variations in meaning which may be unrecognized and therefore be misleading to users of the system.
- 7.6. Explicit Uncertainty - Notions of “probable”, “suspected”, “history of” or differential possibilities (i.e. a Differential Diagnosis list) must be supported. The impact of certain versus very uncertain information has obvious impact on decision support and other secondary data uses. Similarly, in the case of incomplete syndromes clinicians should be able to record the partial criteria consistent with the patient’s presentation. This criterion is listed separately as many current terminological systems fail to address this adequately.
- 7.7. Representational Form – The representational form of the identifiers within the terminology should be meaningless. Computer coding of concept identifiers must *not* place arbitrary restrictions on the terminology, such as numbers of digits, attributes, or composite elements. To do so subverts meaning and content of a terminology to the limitations of format, which in turn often results in the assignment of concepts to the wrong location because it might no longer “fit” where it belongs in an hierarchy. These reorganizations confuse people and machines alike, as intelligent navigation agents are led astray for arbitrary reasons. The long, sequential, alphanumeric tags used as concept identifiers in the UMLS project of the National Library of Medicine exemplify well this principle.

8. **Maintenance** - Technical choices can impact the capacity of a terminology to evolve, change, and remain usable over time.
- 8.1. **Context Free Identifiers**^{ix} - Unique codes attached to concepts must not be tied to hierarchical position or other contexts; their format must not carry meaning. Because health knowledge is being constantly updated, how we categorize health concepts is likely to change (*e.g. Peptic Ulcer Disease is now understood as an infectious disease, but this was not always so.*) For this reason, the "code" assigned to a concept must not be inextricably bound to a hierarchy position in the terminology, so that we need not change the code as we update our understanding of, in this case, the disease. Changing the code may make historical patient data confusing or erroneous. This notion is the same as Non-Semantic Identifiers.
- 8.2. **Persistence of Identifiers** - Codes must not be re-used when a concept is obsolete or superseded. Consistency of patient description over time is not possible when concepts change codes; the problem is worse when codes can change meaning. This practice not only disrupts historical analyses of aggregate data, but can be dangerous to the management of individual patients whose data might be subsequently misinterpreted. This encompasses the notion of Concept Permanence.
- 8.3. **Version Control**^x - Updates and modifications must be referable to consistent version identifiers. Usage in patient records should carry this version information. This is true because the interpretation of coded patient data is a function of terminologies that exist at a point in time^{xi} (*e.g. AIDS patients were coded inconsistently before the introduction of the term AIDS*). Terminology representations should specify the state of the terminology system at the time a term is used; version information most easily accomplishes this, and may be hidden from ordinary review (IS 15188, IS 12620, IS 1087-2, IS 11179-3, IS 2382/4).
- 8.3.1. **Editorial Information** - New and revised terms, concepts, and synonyms must have their date of entry or effect in the system, along with pointers to their source and / or authority. Previous ways of representing a new entry should be recorded for historical retrieval purposes.
- 8.3.2. **Obsolete Marking** - Superseded entries should be so marked, together with their preferred successor. Because data may still exist in historical patient records using obsolete terms, their future interpretation and aggregation are dependent upon that term being carried and cross-referenced to subsequent terms (*e.g. HTLV III to HIV*).
- 8.4. **Recognize Redundancy** – Authors of these large-scale vocabularies will need mechanisms to identify redundancy when it occurs. This is essential for the safe evolution of any such vocabulary. This implies Normalization of Concepts and Semantics, but specifically addresses the need for vocabulary systems to provide the tools and resources necessary to accomplish this task.

8.5. Language Independence – It would be desirable for terminologies to support multi-lingual presentations. As healthcare confronts the global economy and multiethnic practice environments, routine terminology maintenance must incorporate multilingual support. While substantially lacking the power and utility of machine translation linguistics, this simplistic addition will enhance understanding and use globally. Have there been translations? What is the expected cost of translation?

8.6. Responsiveness - The frequency of updates, or sub-versions, should be sufficiently short to accommodate new codes and repairs quickly, ideally on the order of weeks.

9. **Evaluation** – As we seek to understand quality in the controlled vocabularies that we create or use, we need standard criteria for the evaluation of these systems. All evaluations must reflect and specifically identify the purpose and scope of the vocabulary being evaluated.^{xii}

9.1. Purpose and Scope Important dimensions along which scope should be defined include:

9.1.1. Clinical area of use, disease area of patients and expected profession of users – within what parts of healthcare is it intended to be used and by whom?

9.1.2. Primary use – *Examples Include: reporting for remuneration, management planning, epidemiological research, indexing for bibliographic, Web-based retrieval, recording of clinical details for direct patient care, use for decision support, linking of record to decision support, etc.*

9.1.3. Persistence and extent of use – some vocabularies are intended, at least initially, primarily for a specific study or a specific site. If intended to be persistent, means of updating or change management, etc?

9.1.4. Degree of automatic inferencing intended – whether it is intended that classification be automatic; whether it is intended that validation on input be possible and within what limits? Whether post-coordinated expressions are to be accepted and if so what can be inferred about them and what restrictions must be placed on them?

9.1.5. Transformations (mappings) to other vocabularies – what transformations / mappings are supported for what intended purpose – *e.g. transformation for purposes of bibliographic retrieval may require less precision than transformation for clinical usage?* What is the sensitivity and specificity of the mappings?

9.1.6. User/Developer extensibility – is it intended that the vocabulary be extended by users or application developers? If so, within what limits? If not, what mechanisms are available for meeting new needs as they arise?

9.1.7. Are Natural language input or output supported? For analysis or input? To what level of accuracy?

9.1.8. What other functions are intended – *e.g. linkage to specific decision support systems, linkage to post-marketing surveillance, etc.*

9.1.9. Current status – to what extent is the system intended to be ‘finished’ or work in progress? If different components of the terminology are at different stages of completion how is this indicated?

9.2. Measures of Quality - Terminological Tools

9.2.1. Interconnectivity (Mapping)

9.2.1.1. To what extent is the vocabulary mappable to other coding systems or reference terminologies?

9.2.1.2. To what extent can the vocabulary accommodate local terminological enhancements?

9.2.1.3. Can the vocabulary server respond to queries sent over a network (LAN, WAN)?

9.2.2. Precision and Recall

9.2.2.1. What are the vocabulary's precision and recall for mapping Diagnoses, Procedures, Manifestations, Anatomy, Organisms, etc., against an established and nationally recognized standard query test set, using a standard well-principled method? This should be evaluated only within the intended scope and purpose of the vocabulary system.

9.2.2.2. Is a standard search engine used in the mapping process?

9.2.3. Usability

9.2.3.1. Has the usability of the vocabulary been verified?

9.2.3.2. How have interface considerations been separated from vocabulary evaluation?

9.2.3.3. Support for user interfaces. Has an effective user interface been built? Has the vocabulary been shown to have an effective user interface for its intended use? If not, what are the questions or issues outstanding? Evidence for speed of entry, accuracy, comprehensiveness in practice etc. with different approaches? If not, is there a proof of concept?

9.2.3.4. Support for computer interfaces and system implementers. Is there a demonstrated proof of concept implementation in software? Can it be shown to be usable for the primary purpose indicated? Have there been failed implementations?

9.2.4. Feasibility

If it is intended for use in an Electronic Patient Record (EPR), what are the options for information storage? Has feasibility been demonstrated?

- 9.3. Measures of Quality Study Design: The Generalizability (Applicability) of any Study Design Reported (Evaluating Reported Evaluations) should be able to be evaluated.
- 9.3.1. What is the vocabulary's Healthcare/Clinical Relevance?
 - 9.3.2. What was the Gold Standard used in the evaluation?
 - 9.3.3. If published population rates are used for comparison, was the study population comparable to the population from which the rates were derived?
 - 9.3.4. Were the Specific Aims Clear?
 - 9.3.5. Was the study appropriately blinded?
 - 9.3.6. Was the Test Set Selection Randomized or shown in some sense to be a representative sample of the end user population?
 - 9.3.7. Test Location
 - 9.3.7.1. Was it different from the developer's location?
 - 9.3.7.2. How was the test site suited to the study design? (Tools, Resources, etc.)
 - 9.3.7.3. Was the Principle Investigator associated with:
 - 9.3.7.3.1. University
 - 9.3.7.3.2. Academic Medical Center
 - 9.3.7.3.3. Corporation
 - 9.3.7.3.4. Hospital
 - 9.3.7.3.5. Government Agency
 - 9.3.7.3.6. HMO
 - 9.3.7.3.7. Private Practice
 - 9.3.7.3.8. Academic Organization
 - 9.3.7.4. Was the Principle Investigator:
 - 9.3.7.4.1. Independent of the Vocabulary being evaluated?
 - 9.3.7.4.2. Does the principle investigator have a track record of publication in this field of study?
 - 9.3.7.4.3. Have there been any conflicts of interest in performing this research?
 - 9.3.8. Was the project completed in a reasonable period of time?
 - 9.3.9. Sample Size
 - 9.3.9.1. Was the sample size of sufficient size to show the anticipated effect, should one exist?
 - 9.3.9.2. Who reviewed the Statistical Methods?

9.3.10. Personnel

9.3.10.1. What was the average level of training of the study personnel?

9.3.10.2. Reviewers

9.3.10.2.1. What was the inter-reviewer variability?

9.3.10.2.2. What was the type of reviewer (Physician, Nurse, other clinician, Coder, knowledge engineer) used in the study?

9.3.10.2.3. Were the reviewers blinded to the other reviewer's judgments (i.e. reviewer independence)?

Appendix A

History of Classification

The present coding practices rely on data methods and principles for terminology maintenance that have changed little since the adoption of the statistical bills of mortality in the mid-17th century.^{xiii} The most widely accepted standard for representing patient conditions, ICD9-CM^{xiv}, is an intellectual descendent of this tradition. ICD9-CM relies overwhelmingly on a tabular data structure with limited concept hierarchies and no explicit mechanism for synonymy, value restrictions, inheritance or semantic and non-semantic linkages. The maintenance environment for this healthcare classification is a word processor and its distribution is nearly exclusively paper-based.

The first edition of *Physicians' Current Procedural Terminology* (CPT) terminology appeared in 1966. In the United States, CPT is the coding system used by Medicare and virtually all third-party payers, including workers compensation and Medicaid. As part of the Medicare Part B physician payment schedule, CPT codes are associated with the Resource Based Relative Value Scale (RBRVS) and used to determine payment for services. The CPT code set is Level I of the Health Care Financing Administration Common Procedure Coding System (HCPCS). The CPT code set, currently in its fourth edition contains numeric modifiers, notes, guidelines and an index designed to provide explanatory information and facilitate the correct usage of the coding system. The American Medical Association (AMA) is currently working to develop the next generation of CPT (i.e., CPT-5).

Significant cognitive advances in disease and procedure representation took place in 1928 at the New York Academy of Medicine, resulting in industry-wide support for what became the Standard Nomenclature of Diseases and Operations. The profound technical innovation was the adoption of a multiaxial classification scheme.^{ivvii} Now a pathologic process (e.g. Inflammation) could be combined with an anatomic site (e.g. Oropharynx Component: Tonsil) to form a diagnosis (e.g. Tonsillitis). The expressive power afforded by the compositional nature of a multiaxial terminological coding system tremendously increased the scope of tractable terminology and additionally the level of granularity that diagnosis could be encoded about our patients.^{xv,vii}

The College of American Pathology (CAP) carried the torch further by creating the Systematized Nomenclature of Pathology (SNOP), and subsequently the Systemized Nomenclature of Medicine (SNOMED). In these systems, the number, scope, and size of the compositional structures has increased to the point where an astronomical number of terms can be synthesized from SNOMED atoms. One well-recognized limitation of this expressive power is the lack of syntactic grammar, compositional rules, and normalization of both the concepts and the semantics. Normalization is the process by which the system knows that two compositional constructs with the same meaning are indeed the same (e.g. that the term "Colon Cancer" is equivalent to the composition of "Malignant Neoplasm" and the site "Large Bowel"). These are issues addressed by CAP in their efforts to make SNOMED a robust reference terminology for healthcare.^{vii,xv}

Other initiatives of importance are the Clinical Terms v3 (Read Codes), which are maintained and disseminated by the National Health Service in the United Kingdom and the Galen effort, which expresses a very detailed formalism for term description. The Read Codes are a large corpus of terms, which is now in its third revision that is hierarchically designed and is slated for use throughout Great Britain. A development of interesting note is the newly signed agreement of CAP and the NHS to merge the content of SNOMED-RT and Clinical Terms Version 3 into a derivative work (Announced 4/99), which will be named SNOMED Clinical Terms.

Annex A

(Normative)

Implementation Guide

- 1 **General** - Basic characteristics of a terminology influence its utility and appropriateness in clinical applications.
 - 1.1 **Concept Orientation** ⁱⁱⁱ – Is the terminology concept oriented? To how many meanings can one identifier correspond? This must be the case.
 - 1.1.1 **Non-redundancy** – Can concepts be redundantly instantiated within the terminology? This must not be the case.
 - 1.1.2 **Non-Ambiguity** – Can concepts be ambiguous? This must not be the case.
 - 1.1.3 **Non-Vagueness** – Are concept definitions independent of their context? This must be the case.
 - 1.1.4 **Internal Consistency** – Are the relationships used in the terminology applied consistently? This must be the case.
 - 1.2 **Purpose and Scope** – What is the purpose of the terminology? What is the scope of the terminology? Please state these in operational terms (what functions is the terminology intended to serve?).
 - 1.2.1 **Coverage**^{xvi} – What is the intended coverage of the terminology?
 - 1.2.2 **Comprehensiveness**^{xvii} – What is the degree of comprehensiveness (expressed in percent completion) of the terminology within the intended area of coverage? What studies can be referenced to support this assertion (Use the criteria under section #4 for assess the validity and generalizability of the study referenced)?
 - 1.3 **Mapping**^{xviii} – Is the terminology mappable to classifications or other terminologies? If so, which ones? If it is partially mappable to some classifications or other terminologies, to what extent is this true (expressed in percent completion)? Use the criteria under section #4 for assess the validity and generalizability of the study referenced?

- 1.4 Systematic Definitions**Error! Bookmark not defined.** Are the meanings of each specific concept within the terminology made available for the users? These should be provided.
- 1.5 Formal Definitions– Does your terminology support formal definitions? If so, to what extent (expressed in percent completion) is it fully defined? What studies can be referenced to support this assertion (Use the criteria under section #4 for assess the validity and generalizability of the study referenced)? It is essential that reference terminologies support formal definitions.
- 1.6 Explicitness of Relations – Does your terminology support formal subsumption? To what extent are the hierarchies automatically generated by the description logic (expressed as a percentage of all the concepts contained in the terminology)? This is a desirable characteristic.
- 1.7 Reference Terminologies – Is the terminology intended to be used as a reference terminology?
- 1.8 Atomic Reference Terminologies – Is there an explicit mechanism for identifying the atomic portion of the reference terminology? Is it intended that pre-coordinated terms can be used within compositional expressions? This should be a goal of all reference terminologies.
- 1.9 Colloquial Terminologies – Specifically, what is the association between the colloquial terms and the reference terminology? How are these two terminologies maintained so as not to create ambiguous or redundant instantiation of data? This is necessary for all reference terminologies intended to be used clinically.

- 2 **Structure of the Terminology Model** - Terminology structures determine the ease with which practical and useful interfaces, for term navigation, entry, or retrieval can be supported (IS 704, IS 1087-1, EN 12264).

For Compositional Terminologies:

- 2.1 **Compositionality** Does your terminology support the creation of compositional expressions? How is a compositional expression created? If this is governed by rules please elaborate them. If so, can you identify equivalence between arbitrary compositional expressions? If so, by what method?
- 2.1.1 **Atomic Concept** Do you make explicit which of your concepts are atomic?
- 2.1.2 **Composite Concept** – A concept composed as an expression made up of atomic concepts linked by semantic relations (such as roles, attributes or links).
- 2.1.2.1 **Pre-coordinated Concept** Does your terminology make explicit which concepts are pre-coordinated? This must be true for all compositional terminologies.
- 2.1.2.2 **Post-coordinated Concepts** Does your terminology support the creation of post-coordinated expressions?
- 2.1.3 **Types of Atomic and Pre-coordinated Concepts** We can classify unique concept representations within a vocabulary into at least three distinct types, Kernel Concepts, Modifiers, and Qualifiers (which contain Status concepts). This separation allows user interfaces to provide more readable and therefore more useful presentations of composite concepts.
- 2.1.3.1 **Kernel Concept** – Does your terminology identify separately kernel concepts? This should be identified by compositional terminologies.
- 2.1.3.2 **Terms which refine the meaning of a Kernel Concept** – Does your terminology identify modifiers and qualifiers within the terminology? If so, how are they used? This should be identified by compositional terminologies.

- 2.2 Normalization of Content – Is the content of the terminology normalized? What studies can be referenced to support this assertion (Use the criteria under section #4 for assess the validity and generalizability of the study referenced)? This must be accomplished for all compositional terminologies.
- 2.3 Normalization of Semantics – Are the semantics of the terminology normalized? What studies can be referenced to support this assertion (Use the criteria under section #4 for assess the validity and generalizability of the study referenced)? For compositional expressions, is it possible to represent the same concept with different semantics? This must be accomplished for all compositional terminologies.
- 2.4 Multiple Hierarchies^{xix} – Are multiple hierarchies supported? Are they present within the current version of the terminology?
- 2.5 Consistency of View^{xx} – Is a consistency of views into the terminology maintained? This must be the case for terminologies that support multiple hierarchies.
- 2.6 Explicit Uncertainty – Does your terminology support the input of explicit uncertainty and incomplete syndromes? This should be a feature of compositional terminologies.
- 2.7 Representational Form – Does the representational form of the concept identifier place restrictions on the terminology? If so, what are the restrictions? This must not be the case.

- 3 **Maintenance** - Technical choices can impact the capacity of a terminology to evolve, change, and remain usable over time.
- 3.1 Context Free Identifiers^{xxi} – Does the terminology support context free identifiers? This must be the case.
- 3.2 Persistence of Identifiers – Are codes ever reused for different concepts? If so, when can this occur? This must be the case.
- 3.3 Version Control^{xxii} – Are your codes tied explicitly to the version of the terminology? This must be the case.
- 3.3.1 Editorial Information - When the terminology is revised, do you record the date of the update and the source or authority of the information leading to the update? This must be the case.
- 3.3.2 Obsolete Marking – Have you included obsolete marking in your entries? This must be the case.
- 3.4 Recognize Redundancy – Does your terminology recognize redundancy? If so, how is this accomplished? This must be the case.
- 3.5 Language Independence – Is your terminology presently multilingual? If not, does it have the capacity to become multilingual? If so, please explain. This should be the case.
- 3.6 Responsiveness – What is the frequency of updates to the terminology? Is it less than or equal to 12 weeks? This should be the case.

4 **Evaluation** – As we seek to understand quality in the controlled vocabularies that we create or use, we need standard criteria for the evaluation of these systems. All evaluations must reflect and specifically identify the purpose and scope of the vocabulary being evaluated.^{xxiii} These criteria stipulate the methods for evaluating studies, which make claims regarding controlled terminologies. These criteria are also useful as a guide to individuals or organizations who wish to perform valid and useful evaluations of one or more controlled health terminologies.

4.1 **Purpose and Scope** Important dimensions along which scope should be defined include:

- 4.1.1 **Clinical area** of use, disease area of patients and expected profession of users – Within what parts of healthcare is it intended to be used and by whom?
- 4.1.2 **Primary use** – What is the primary use of the terminology? *Examples Include: reporting for remuneration, management planning, epidemiological research, indexing for bibliographic, Web-based retrieval, recording of clinical details for direct patient care, use for decision support, linking of record to decision support, etc.*
- 4.1.3 **Persistence and extent of use** – Is the intent of the terminology to persist and evolve? If intended to be persistent, means of updating or change management, etc?
- 4.1.4 **Degree of automatic inferencing intended** – Is the terminology intended to support automated classification? Is it intended that validation on input be possible and within what limits? Whether post-coordinated expressions are to be accepted and if so what can be inferred about them and what restrictions must be placed on them?
- 4.1.5 **Transformations (mappings) to other vocabularies** – What transformations / mappings are supported for what intended purpose – *e.g. transformation for purposes of bibliographic retrieval may require less precision than transformation for clinical usage?* What is the sensitivity and specificity of the mappings?
- 4.1.6 **User/Developer extensibility** – Is it intended that the vocabulary be extended by users or application developers? If so, within what limits? If not, what mechanisms are available for meeting new needs as they arise?
- 4.1.7 **Are Natural language input or output supported?** For analysis or input? To what level of accuracy?
- 4.1.8 **What other functions are intended?** – *e.g. linkage to specific decision support systems, linkage to post-marketing surveillance, etc.*
- 4.1.9 **Current status** – To what extent is the system intended to be ‘finished’ or work in progress? If different components of the terminology are at different stages of completion how is this indicated?

4.2 Measures of Quality - Terminological Tools

4.2.1 Interconnectivity (Mapping)

- 4.2.1.1 To what extent is the vocabulary mappable to other coding systems or reference terminologies?
- 4.2.1.2 To what extent can the vocabulary accommodate local terminological enhancements?
- 4.2.1.3 Can the vocabulary server respond to queries sent over a network (LAN, WAN)?

4.2.2 Precision and Recall

- 4.2.2.1 What are the vocabulary's precision and recall for mapping Diagnoses, Procedures, Manifestations, Anatomy, Organisms, etc., against an established and nationally recognized standard query test set, using a standard well-principled method? This should be evaluated only within the intended scope and purpose of the vocabulary system.
- 4.2.2.2 Is a standard search engine used in the mapping process?

4.2.3 Usability

- 4.2.3.1 Has the usability of the vocabulary been verified?
- 4.2.3.2 How have interface considerations been separated from vocabulary evaluation?
- 4.2.3.3 Support for user interfaces. Has an effective user interface been built? Has the vocabulary been shown to have an effective user interface for its intended use? If not, what are the questions or issues outstanding? Evidence for speed of entry, accuracy, comprehensiveness in practice etc. with different approaches? If not, is there a proof of concept?
- 4.2.3.4 Support for computer interfaces and system implementers. Is there a demonstrated proof of concept implementation in software? Can it be shown to be usable for the primary purpose indicated? Have there been failed implementations?

4.2.4 Feasibility

- 4.2.4.1 If it is intended for use in an Electronic Patient Record (EPR), what are the options for information storage? Has feasibility been demonstrated?

4.3 Measures of Quality Study Design: The Generalizability (Applicability) of any Study Design Reported (Evaluating Reported Evaluations) should be able to be evaluated.

- 4.3.1 What is the vocabulary's Healthcare/Clinical Relevance?
- 4.3.2 What was the Gold Standard used in the evaluation?
- 4.3.3 If published population rates are used for comparison, was the study population comparable to the population from which the rates were derived?
- 4.3.4 Were the Specific Aims Clear?
- 4.3.5 Was the study appropriately blinded?
- 4.3.6 Was the Test Set Selection Randomized or shown in some sense to be a representative sample of the end user population?
- 4.3.7 Test Location

- 4.3.7.1 Was it different from the developer's location?
- 4.3.7.2 How was the test site suited to the study design? (Tools, Resources, etc.)
- 4.3.7.3 Was the Principle Investigator associated with:
 - 4.3.7.3.1 University
 - 4.3.7.3.2 Academic Medical Center
 - 4.3.7.3.3 Corporation
 - 4.3.7.3.4 Hospital
 - 4.3.7.3.5 Government Agency
 - 4.3.7.3.6 HMO
 - 4.3.7.3.7 Private Practice
 - 4.3.7.3.8 Academic Organization
- 4.3.7.4 Was the Principle Investigator:
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 - 4.3.7.4.2 Does the principle investigator have a track record of publication in this field of study?
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- 4.3.9 Sample Size
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- 4.3.10 Personnel
 - 4.3.10.1 What was the average level of training of the study personnel?
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 - 4.3.10.2.1 What was the inter-reviewer variability?
 - 4.3.10.2.2 What was the type of reviewer (Physician, Nurse, other clinician, Coder, knowledge engineer) used in the study?
 - 4.3.10.2.3** Were the reviewers blinded to the other reviewer's judgments (i.e. reviewer independence)?

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