StandardGuide for
Quality Indicators for Health Classifications[1]

1. Scope

1.1 This international standard is intended to document principal ideas which are necessary and sufficient to assign value to a classification. The standard will serve as a guide for governments, funding agencies, terminology developers, terminology integration organizations, and the purchasers and users of classification systems toward improved terminological development and recognition of value in a classification. It is applicable to all areas of health about which information is kept or utilized. Appropriately, classifications 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 classifications. This international standard will also provide classification developers and authors with the quality guidelines needed to construct useful, maintainable classifications. These tenets do not attempt to specify all of the richness which can be incorporated into a classification. However, this standard does specify the minimal requirements, which if not adhered to will assure that the classification will have limited generalizability and will be very difficult if not impossible to maintain. We have used the word "Shall" to indicate mandatory requirements and the word "Should" to indicate those requirements which we feel are desirable but may not be widely achievable in current implementations. Classifications, 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 classification developers with a sturdy starting point for the development of useful classifications. This foundation serves as the basis from which classification developers will build robust concept systems.

2. Referenced Documents

2.1 *Normative References*—The following normative documents contain provisions, which through reference in this text, constitute provisions of this Guide E2522. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on Guide E2522 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.

2.2 *ASTM Standards:*[2]

E1238 Specification for Transferring Clinical Observations Between Independent Computer Systems (Withdrawn 2002)[3]

E1239 Practice for Description of Reservation/Registration-Admission, Discharge, Transfer (R-ADT) Systems for Electronic Health Record (EHR) Systems

E1284 Guide for Construction of a Clinical Nomenclature for Support of Electronic Health Records (Withdrawn 2007)[3]

E1384 Practice for Content and Structure of the Electronic Health Record (EHR)

E1633 Specification for Coded Values Used in the Electronic Health Record

2.3 *ISO Standards:*[4]

ISO 704 Principles and Methods of Terminology

ISO/DIS 860 International Harmonization of Concepts and Terms

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

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TR 9789 Guidelines for the Organization and Representation of Data Elements for Data Interchange—Coding Methods and Principles

2.4 *CEN Standards:*[5]
ENV 12017 Medical Informatics—Vocabulary

3. Terminology

3.1 *For the purposes of this guide, the following terms and definitions apply:*

3.1.1 *canonical term*—a preferred atomic or pre-coordinated term for a particular medical concept.

3.1.2 *classification*—collection of terms grouped by a common characteristic. Usually not intended to represent the full content of a knowledge domain. Classifications are an aggregation of a nomenclature. A classification is a terminology which aggregates data at a 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 the classification is to be applied across a diverse user group, such as is the case with some of the current billing classification schemes. Examples are ICD9-CM and CPT.

3.1.3 *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.

3.1.4 *index term*—a pointer to a concept in a classification. This can be a synonym, abbreviation, acronym or some mnemonic which can be used to indicate the correct code to use from the classification. Such use is important for mapping from the way clinicians tend to speak to the classification. These have been referred to as Entry terms by some authors.

3.1.5 *modifier*—a string which, when added to a term, changes the meaning of the term in the Clinical sense (for example, clinical stage or severity of illness).

3.1.6 *nomenclature*—the canonical set of terms comprising a given controlled vocabulary; their structure, relationships and, if existing, systematic and formal definitions; and the code, meaning formal rules and general principles, guiding how the controlled vocabulary may be changed.

3.1.7 *ontology*—an organization of concepts by relationships 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.

3.1.8 *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").

3.1.9 *term*—a word or words corresponding to one or more concepts.

3.1.10 *terminology*—set of terms representing a system of concepts within a specified domain.

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

4. General

4.1 *Basics*—Basic characteristics of a terminology influence its utility and appropriateness in clinical applications.

4.2 *Concept Orientation*—The basic unit of a terminology shall be a concept, which is the embodiment of some specific meaning and not a code or character string. Identifiers of a Concept shall 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.

4.2.1 *Non-Redundancy*—Terminologies shall be internally normalized. There shall not be more than one concept identifier in the terminology with the same meaning (ISO 704, Guide E1284). This does not exclude synonymy; rather, it requires that this be explicitly represented.

4.2.2 *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 (for example, MI as Myocardial Infarction and Mitral Insufficiency).

4.2.3 *Non-Vagueness*—Concept names shall 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."

4.2.4 *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.

4.3 *Purpose and Scope*—Any classification shall have its purpose and scope clearly stated in operational terms so that its fitness for particular purposes can be assessed and evaluated (ISO 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. For example, a classification might be comprehensive and detailed enough for aggregation of billing codes from a hospital admission (for example, DRGs), but inadequate for specifying the indication for a surgical procedure.

4.3.1 *Coverage*—Each segment of the healthcare process shall 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

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[5] Available from European Committee for Standardization (CEN), 36 rue de Stassart, B-1050, Brussels, Belgium, http://www.cenorm.be.

extent to which the depth of coverage is incomplete shall be explicitly specified for each domain (scope) and purpose as indicated in 4.3. (**1**)[6]

4.3.2 *Comprehensiveness*—The extent to which the degree of comprehensiveness is incomplete shall be explicitly specified for each domain (scope) and purpose as indicated in 4.3. Within the scope and purpose, all aspects of the healthcare process shall 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 CMS mortality model. (**2**)

4.4 *Mapping:*

4.4.1 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 or a nurse assessing the extent to which the individual is coping with their disorder, even though all may be caring for the same patient. The degree to which the terminology is mappable to other classifications shall be explicitly stated. (**3**)

4.4.2 The rules for mapping from a classification to a nomenclature are the same rules that are defined for the formation of compositional expressions from the reference terminology and therefore are by definition terminology dependent. As a well-formed classification is defined as a pre-coordination from the reference terminology, different constructs (codes in the classification) developed are built for a specific purpose. Therefore, if a classification is useful for a purpose and it is fully specified, then by definition it is coordinate with the reference terminology. Two classifications defined by the same reference terminology are coordinate and interoperable. Mapping here is accomplished at the level of the reference terminology and therefore is correct at the lowest level of computable meaning.

4.5 *Systematic Definitions*—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."

4.6 *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 B's are A's."

4.7 *Multiple Hierarchies*—Concepts should be accessible through all reasonable hierarchical paths (that is, they shall allow multiple semantic parents). For example, 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 (that is, users should not have to guess where a particular concept was instantiated). (**4**)

4.8 *Consistency of View*—A concept in multiple hierarchies shall be the same concept in each case. Our example of stomach cancer shall 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. (**5**)

4.9 *Explicit Uncertainty*—Notions of "probable," "suspected," "history of," or differential possibilities (that is, a Differential Diagnosis list) shall 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.

4.10 *Representational Form*—The representational form of the identifiers within the terminology should be meaningless. Computer coding of concept identifiers shall 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 a 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.

5. Use Cases for Bounding Classifications

5.1 *Principles:*

5.1.1 Classifications should serve a stated purpose.

5.1.2 Classifications should have an explicit scope.

5.1.3 The quality of the classification should only be evaluated within the context of its purpose and scope.

5.1.4 Classifications should be created and maintained in response to a real world need.

5.1.5 Classification should be able to be derived from aggregations of data specified in detailed health nomenclatures.

5.1.6 Classification should evolve gracefully.

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[6] The boldface numbers in parentheses refer to the list of references at the end of this standard.

5.2 *Use Cases for Classifications*—These use cases set the boundary definitions for the types of uses which are more appropriate for a controlled health terminology or a classification. The scale is from 0 to 10 with ten being most appropriate for a nomenclature and zero being most appropriate for a classification. These categories are slices across a general problem that needs to address the boundaries and overlap between these two types of knowledge representation.

Specifying categories of health problems or procedures for the purpose of determining reimbursement	3
Public Health Surveillance	6
Utilization Review	3
Managing the financial side of Medical Practice. Budget Planning, Purchasing, etc.	3
Patient Safety	8
Hospital Discharge Planning	6
Effectiveness of Care (Planned interventions)	7
Education (practitioner, patient)	6
Quality Assurance	8
Credentialing (competencies)	5
EBM	8
Decision Support	9
Information Retrieval (Querying)	7
Data Representation	9
Mandatory Reporting	3
NLP	9
Outcomes Analysis	7
Morbidity Coding	7
Mortality Coding	5
Health Indicators	5
Healthcare provider roles	1
Partition of Health Information on the web	6
Data Warehousing	7

5.3 *Questions to be Answered*—We have attempted to answer these questions within the body of the standard.

5.3.1 What domains are valid to represent in a classification?

5.3.2 What is the boundary between classifications and detailed nomenclatures?

5.3.3 What are the rules for mapping between nomenclatures and classifications?

5.3.4 How can multiple consistent views allow classifications to serve multiple purposes? For example, a classification which needs to provide administrative aggregation for public health purposes as well as reimbursement information.

5.3.5 Are there indicators of quality for mapping between and among classifications?

5.3.6 What are the quality indicators for building, organizing, distributing, and maintaining classifications?

5.3.7 What are the international concerns regarding the methodology identified in 5.3.6?

6. Maintenance

NOTE 1—Technical choices can impact the capacity of a terminology to evolve, change, and remain usable over time.

6.1 *Context Free Identifiers*—Unique codes attached to concepts shall not be tied to hierarchical position or other contexts; their format shall not carry meaning. Because health knowledge is being constantly updated, how we categorize health concepts is likely to change (for example, 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 shall 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. (**6**)

6.2 *Persistence of Identifiers*—Codes shall not be reused 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.

6.3 *Version Control*—Updates and modifications shall 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 (for example, 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 (ISO 15188, ISO 12620, ISO 1087-2, ISO 11179-3, ISO 2382-4). (**7, 8**)

6.3.1 *Editorial Information*—New and revised terms, concepts, and synonyms shall have their date of entry or effect in the system along with pointers to their source or authority, or both. Previous ways of representing a new entry should be recorded for historical retrieval purposes.

6.3.2 *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 (for example, HTLV III to HIV).

6.4 *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.

6.5 *Language Independence*—It would be desirable for classifications to support multilingual presentations. As healthcare confronts the global economy and multiethnic practice environments, routine classification maintenance shall 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?

6.6 *Responsiveness*—The frequency of updates, or subversions, should be sufficiently short to accommodate new codes and repairs quickly, ideally on the order of weeks.

6.7 *Distribution Format:*

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<Classification name = " ">
  <Code>
    <Text-Long, Language = " ">
    <Text-Short, Language = " ">
    <Entry Term, Language = " ">
    <Relation name = " " code = " ">
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