TECHNICAL SPECIFICATION

ISO/TS 21564

First edition 2019-06

Health Informatics — Terminology resource map quality measures (MapQual)





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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 215, *Health Informatics*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

0.1 General

Healthcare organizations and software vendors are increasingly using maps to convert data from one code system to another code system. In the past, data in health information systems was largely used for organizations' administrative planning and decision making. Data captured in Electronic Health Records (EHR) systems for patient care has a significant impact on patient safety. The use of this data as the source of data for other purposes and for information exchange in clinical care through the use of information technology is an emerging problem. Where that data is translated through maps from one code system to another, the safety and quality issues associated with data use can be significant. The increasing use of maps is costly.

The objective of this work is to support the definition of quality requirements for map sets to

- a) establish standard quality conformance requirements for a map for a purpose,
- b) assess the quality of a map for a purpose,
- c) guide decision makers in map project requirements and processes, and
- d) establish pathways to improvement.

Maps are widely used but the quality of these maps cannot be accurately and consistently assessed and compared against their intended use. It is not currently possible for decision makers to assess whether a map will be worth the cost of building and whether the scope and map processes will deliver a map which is able to meet the intended business case.

This document is based upon ISO/TR 12300[1]. Some terminological resources are so different in their content and purpose that they will never map closely to a resource designed and structured differently. Therefore, the decision maker might need to consider whether to map at all or to move to a new terminological resource.

Quality measures consider a wide range of requirements and processes relevant to the creation and maintenance of data maps and their use (including manual and tool-based mapping), as well as for the map sets delivered as a result of using that process.

0.2 Stakeholders and audience

This document is focused on the needs of

- a) implementers and software vendors developing and implementing maps sets,
- b) health information and data managers developing and using maps sets,
- c) data users such as researchers, government, decision makers, and
- d) developers of map sets including all in mapping teams including terminologists, coders, clinical users, epidemiologists and statisticians, project managers.

Additionally, the target audience for this document might include

- procurement officers who establish requirements of map product capacity and quality, or
- decision makers to determine and assess resources needed in projects and services associated with map produce, maintenance or use.

0.3 Challenges of mapping

Healthcare organizations and software vendors are increasingly using maps to convert data from one terminological resource to another terminological resource. In the past, data in health information systems was largely used for organizations' administrative planning and decision making.

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Today, maps are being used for a much broader range of use cases and the challenges of their use include the following:

- a) Map purpose a map built for one purpose might or might not suit use for other purposes. It is important to establish the purpose and use of a map at the beginning of a project to ensure the best result when building a map from a source code to a target code. When the purpose changes, the resultant map content is likely to need to be different.
- b) Map accuracy there are three broad aspects to accuracy. The first is whether the map development and maintained. The second is how closely the results of applying the map deliver an outcome consistent in meaning to that of original source data. The third is the ability of the outcome of the map to be used for the purpose intended.
- c) Map effectiveness Information retrieval is a critical functionality of maps.

The actual consequence of assigned map links imposed between terms of different code schemes impacts the effectiveness of information retrieval searches. Map purpose and accuracy might both impact the potential safety and appropriateness of the use of that map in healthcare. If the original meaning is changed through use of a map, this might impact clinical safety. There is also the consideration of whether the map is applied consistently to defined data elements in the health record. The data element in which the original source data is recorded might add meaning to the code allocated (e.g. family history of condition versus clinical diagnosis of the individual).

Another significant issue is the cost of creation and maintenance of a map and the ongoing risk and difficulties of maintaining currency of the map.

More information on this topic is available in ISO/TR 12300.

If map quality is neglected, maps will continue to be classified in non-standard ways, increasing barriers to establishing the purpose, accuracy, effectiveness of the quality of terminological maps. The longer the international community is without a publication in this area, the more expensive the problem will be to resolve due to the persistence of legacy metadata and the cost of modifying existing mapping processes to fit an agreed specification; therefore, a TS solution is highly desirable.

Health Informatics — Terminology resource map quality measures (MapQual)

1 Scope

This document provides quality requirements for producing a quality map between terminological systems.

This document establishes measures which can be used to assess the quality and utility of a map between terminological resources in order to determine the types and levels of measure required for common use cases in healthcare.

NOTE Examples of such cases include conformity assessment.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

3.1

auto-matching

computational mapping task, undertaken using an algorithm based upon the relationship between concepts (3.5)

3.2

categorial structure

reduced system of concepts to describe the organization of the semantic categories in a particular system of concepts

Note 1 to entry: A categorial structure for body structure representation could include the categories for body system (e.g. skin, digestive) and anatomical location (upper body, abdomen).

3.3

classification

exhaustive set of mutually exclusive categories to aggregate data at a pre-prescribed level of specialization for a specific purpose

3.4

code system

organized, managed collection of codes each of which has associated designations, meanings and in some cases relationships, properties or rules

Note 1 to entry: Code systems are often described as collections of uniquely identifiable concepts such as ICD-10, SNOMED CT and LOINC. Code systems are often established and maintained by authoritative sources such as standards development organisations.

3.5

concept

unit of knowledge created by a unique combination of characteristics

Note 1 to entry: Concepts are not necessarily bound to particular languages. They are, however, influenced by the social or cultural background, often leading to different categorizations.

3.6

context

related conditions and situations that provide a useful understanding and meaning of a subject

3.7

currency of the map

map currency

difference between the date of release of the target and source terminological resources and the map set (3.16)

3.8

determinant

influencing element or factor

3.9

equivalence

semantic equivalence

condition of being equal or the same in value, worth or function

Note 1 to entry: In terminological systems, two concepts are (semantically) equivalent if their domain of meaning overlaps and their semantic definitions are interpreted as identical. In the context of terminological resources equivalence and semantic equivalence are often considered as synonyms.

3.10

individual map

index from one term to another, sometimes using rules that allow translation from one representation to another indicating degree of equivalence

Note 1 to entry: Entry in a map which indicates how to translate from an individual source concept to a target concept. The term map is often used to indicate a table of individual map entries. It is for this reason that the individual and map tables are being differentiated. A map is often computable. A map is the outcome of the mapping process. The use of this term is often used in ways which are confusing. It is essential to always make it clear whether one is referring to an individual map, or a map table (or set). In SNOMED CT, each individual map is represented as a row or group of rows in a map reference set. It links a single map source concept code (e.g. SNOMED CT Concept ID) to one or more codes in a map target (e.g. ICD Code).

3.11

priority map content

individual maps (3.10) in a map set (3.16) which are most important for a use case

Note 1 to entry: Importance might reflect the frequency of use or impact of the specific concepts being mapped. For example: a propriety map content set might be established to represent the most common diagnoses in hospitals for morbidity reporting and this could be the priority map content for a map from SNOMED CT to ICD based classification.

3.12

map

conversion

transformation

cross-map

device which provides an index from one term (3.19) to another, sometimes using rules that allow translation from one representation to another indicating degree of equivalence (3.9)

Note 1 to entry: The index is used to convert concepts in one code system or representation into concepts in an alternative code system or representation.

3.13

map quality determinant

attribute of a map (3.12), map development process, or map metadata that is considered a reliable measure of the suitability of the map to a use case

3.14

map quality measure

quantitative measure of the characteristics and attributes of a map (3.12)

3.15

map source

source mapping

terminology (3.21), coding scheme or classification (3.3) used as the starting point for map production

3.16

map set

map table

group of individual maps (3.10) used to convert a range of entries from source to target code system (3.4)

3.17

mapping

process of defining, building or using a relationship between *concepts* (3.5) in one coding system to concepts in another coding system in accordance with a documented rationale, for a given purpose

Note 1 to entry: Quality mapping will produce a usable map table, be a reproducible and understandable process. It is the relation with the best semantic correspondence between an element in one set and an element in another set.

3.18

semantic domain

semantic space

area of meaning covered by a terminological resource (3.20)

Note 1 to entry: This is used to evaluate the lexical or formal overlap between such resources. In value set specification this might also be called a value set domain.

Note 2 to entry: Terminology resources can include value sets, code systems, and subsets.

EXAMPLE One code system might have the domain of anatomy while another might have the domain of disease. Though these are related concepts, the semantic domain of each code system is different.

3.19

term

linguistic representation of a *concept* (3.5)

Note 1 to entry: A term can contain symbols and have variants, e.g. different forms of spelling terms are members of a terminology; a defined or limited vocabulary of terms or concepts, for example, ICD, SNOMED CT, LOINC.

3.20

terminological resource

controlled set of terms in healthcare

Note 1 to entry: These terms are usually designed and controlled for use with computers for specific healthcare purpose, such as data entry, aggregation, retrieval and analysis.

3.21

terminology

structured, human and machine-readable representation of concepts (3.5)

Note 1 to entry: This includes the relationship of the terminology to the specifications for organizing, communicating and interpreting such a set of concepts. The use of the term terminology in healthcare implies a terminology that is designed for use in computer systems. The word 'vocabulary' or 'health' or 'medical language' is used to indicate the broader idea of linguistic representation without the specification of computability.

4 Determinants of map quality

4.1 General

This document defines a set of quality determinants which cover the development and maintenance of map content, and the precision of the map between source and target content. The precision represents accuracy but also maintainability and usability.

Each determinant shall be measured separately in order to allow evaluation of purpose for use case, and in that sense, stand alone. The specific measures are listed for each determinant under "Measure". The lower the number allocated to the measure, the higher the quality of the map. These measures are intended to be used to assess the quality of a map. The required level of conformance for each determinant differs according to the use case for which the map is intended. Clause 5 covers map quality measurement and requirement specification for specific use cases, explaining how to apply the determinant measures of map quality.

4.2 Terminological resource capacity

4.2.1 General

To assess the quality of a map, it is necessary to understand the capacity and intent of the source code system and target code system, and the relationship between how each of these code systems represent concepts.

4.2.2 Determinant 1: Common categorial structure

Evaluate whether the target and the source terminological resource share the same categorial structure.

This determinant seeks to specify whether the structure of each system is common.

EXAMPLE

If one terminological resource has a structure which includes

- clinical findings,
- substances, and
- events

And the other has a structure of

body systems

The terminological resources do not share a common categorial structure.

The degree of commonality affects the ability to produce a meaningful map. If there is no categorial structure, or such a structure is not applied to the terminological resources, the ability to map between terminological resources is less likely to deliver a high-quality product. The impact upon quality might differ depending on the intended use case.

Categorial structure represents the structure within a semantic domain. Maps may be developed across an entire categorial structure or a part of that structure, depending upon the semantic domain intended for use in the map.

Measure:

- 0 source and target terminological resources share the same categorial structure.
- 4 source and target do not share the same categorial structure.

4.2.3 Determinant 2: Shared semantic domain

The ability to map one terminological resource to another assumes that each terminological resource shares a common scope of meaning, i.e. that the code system for apples applies to apples and the second code system for fruit also includes apples, if each code system does not share some concepts, it is not possible to produce a meaningful map between these code systems. It is necessary to assess whether the semantic domains are the same, overlapping, inclusive or without overlap. To evaluate the likely utility of a map, it is necessary to consider the amount of overlap.

The same semantic domain is where both terminological resources describe the same content, though they may describe it in different ways, with different categorial structures.

EXAMPLE

- a) The categorial structure is different to the thing (the object the intangible concept of an apple the apple itself) being described by the code (a code which represents an apple).
- b) The semantic domain is different one is describing the thing and its uses while the second describes the suitable uses the intended meanings differ. This provides an overlap of semantic domain which might or might not impact the quality of the map or the usability of the map.

Terminological resource 1 describes apples as eating or cooking apples, this might include additional attributes such as apple colour, origin, cultivar, etc.

Terminological resource 2 describes apples by colour and suitable uses.

Each terminological resource describes apples though the categorial structures are different. In the example of apples, each concept has the attributes of colour and use, which are areas of overlap, between these terminological resources but do not share other key attributes such as origin, cultivar.

Where the attributes are represented differently in each code system but share a semantic domain, it can be possible to map these concepts. <u>Table 1</u> shows a shared semantic domain which would result in a quality map. <u>Table 2</u> indicates how shared semantic domain is to be measured.

System ASystem BMeaning1MMale2FFemale3IIndeterminate9UUnknown or not provided

Table 1 — Example of shared semantic domain

Table 2 — Measures of semantic domain

Measure	Description	Example
0: Exact match on semantic domain	The source terminological resource includes the same semantic domain as the target terminological resource.	
1: Fully inclusive overlap of semantic domain	The source terminological resource covers all of the target terminological resource and also other concepts (or vice versa).	A classification of fruit includes apples. A classification of apples is completely included in the classification of fruit.
2: Non-inclusive overlap of semantic domain	The source terminological resource covers some of the target terminological resource, and either code system may have additional content beyond the scope of the other.	A classification of red edible items, does include some apples, but not green apples, it also includes items which are not fruit such as red onions.
3: No overlap	Where the concepts described by one terminological resource are not covered by the second terminological resource, a map will be difficult.	
	It might be possible to map concepts at a very high level of abstraction or by establishing some guidance and rules to be applied when making mapping decisions but the outcome will not retain the meaning of the source when represented in the target.	

Where there is an overlap, it is necessary to assess how much the areas which do not overlap will be relevant to the map required. If the map only requires the mapping of red apples, the lack of complete overlap between the two different terminological resources would not impact the quality of the result.

In each of these cases, it is necessary to determine the impact of this compatibility or lack of compatibility on the outcome of the map for the purpose it is being developed or used.

4.2.4 Determinant 3: Language and translation

A source terminological resource can be available in a specific language (such as English). The target terminological resource can also be available in that language (English). If one terminological resource is available in the language required and the other is not, a translation of language shall be undertaken. It is appropriate to consider the cost of that translation and its maintenance and the potential impact upon accurate representation of meaning.

If translations have been published by the terminology resource owner, they are more likely to be accurate than those developed in smaller projects. The governance of the translations process might be relevant to the assessment of the language quality requirement for the use case. Details of translations and guidance on their use can be found in ISO 17100.

It is difficult to judge the semantic equivalence in linguistic translation (semantic equivalence). Use the measures for semantic equivalence that are used in 4.3.

Different standards environments use the term translation and in some, such as HL7 FHIR, it means to map. A common use case for translation is where a value set is published in English and is translated and mapped for use in another language. Similarly, if a terminological resource source is in French and there is a desire to use that code system in English, the terminological resource source shall first be translated into English. This way, the map is between concepts in the same language.

The translation process firstly requires the translation of the target and or source into the required language, thereby producing a version of the concepts to be mapped in the required language. Only after this has been done and verified should the map be created.

Measure:

- 0 no translation required, source, target and map are all in the same language.
- 1 translation is required from target to source.

4.3 Equivalence of individual maps

4.3.1 General

A map between two different terminological resources will involve a certain amount of compromise. Identification of equivalence criteria is therefore crucial to establishing a level of acceptability and safety for use of that map.

4.3.2 Determinant 4: Equivalence identification/Publication

This determinant indicates whether equivalence assessments are published in the map and available to all users. Each individual map [i.e. each source concept to target concept(s)] shall have equivalence identified and published. This information is then available when the map is used to provide assistance in determining the validity of specific individual mapped values. If the meaning is not retained, the equivalence can be used to assess the level of difference between the original source and the resultant representation after applying the map. If equivalence is not published with the map set, then it is not possible to assess the quality of the map for a specific purpose nor to alert the user of the map where the meaning of a concept might have changed when converted to the target concept representation.

Measure:

- 0 equivalence measure is identified and published in the map. This measure may be a more complex, ontologically based measure than the one identified in Determinant 5: Equivalence assessment.
- 1 equivalence measure is available but is not in the published map.
- 2 equivalence measures are available but are less specific than those identified in <u>4.3.3</u>.
- 4 no equivalence measures are provided or available.

4.3.3 Determinant 5: Equivalence assessment

There are two types of equivalence assessment. For a given use case one of two equivalence methods should be selected to assess the quality and utility of the map for a specific purpose.

Either use

- a) the median equivalence for the map set, or
- b) median equivalence for priority map content.

Equivalence measures are based upon ISO/TR 12300 and are represented in a numeric measure (rather than a code). This measure can then be arithmetically calculated.

Measure:

- 0 equivalent meaning, where the highest quality equivalence is represented by the lowest number, 0 is the 'best score'.
- 1 source is wholly included in target.

- 2 source is partially included in target.
- 3 source is mapped, however there were many options of possible target and overlaps. The map produced is a best comparison rather than an actual correspondence. Such a map requires significant manual input to create and maintain and should be used with care.
- 4 no map possible (it is considered that no map is a safer and cheaper option than option 4). For instance, if it is determined that a map set being established produces many individual maps with equivalence of no map possible the creation of the map set should be reconsidered. The resultant map set is not likely to be safe for clinical use and it would involve fewer resources and expenses not to attempt a map at all than to produce one of this type.

Map set equivalence — average equivalence [sum equivalence measure for each individual map (row) (from the full or priority set) divided by the number of individual maps]. <u>Table 3</u> shows an example of how the overall equivalence of a map set is represented.

Individual map row	Equivalence
A	0
В	0
С	1
D	1
Е	2

Table 3 — Example of equivalence measures average calculation

The use of an average is not likely to provide a meaningful evaluation of this determinant, however median or mode might provide a context which is can be useful in specific use cases.

Where a map is created for a large number of concepts, a subset of the whole map might be considered of priority if it is used extensively for the most common conditions. In some situations, it is more relevant to assess the average equivalence for the priority component(s) of the map — rather than to consider the median equivalence of the whole map — as this impacts the majority of cases.

EXAMPLE Diagnosis map from SNOMED CT to ICD (variant).

This map is considered safe for use to support clinical coding, reporting and financial claims and the most common conditions are those which will most impact the results obtained. The map users and developers could agree that a number of common conditions (e.g. 10 000 of a potential 30,000) need to be accurate and represent high equivalence while the additional conditions are less important and would not significantly impact the utility of the map for the use case defined.

4.3.4 Determinant 6: Map set outliers

This determinant is used to indicate how much of the map set evaluated for equivalence is within a predetermined acceptable range of equivalence. This way, it is possible to assess whether the majority of the map has the level of equivalence required and only a small number of outliers are outside this limit, or whether there are many outliers outside that limit.

The percentage applies to whichever (full or priority) map set group the equivalence has been calculated.

EXAMPLE 1 The way to calculate an outlier value for <u>Table 3</u>, is to identify the measure level at which the entry is considered an outlier (in this case 2 or over). There is one entry out of 5 entries with an equivalence of that level. The map shown in <u>Table 3</u> has an outlier value of 20 % (1/5).

The acceptability of outliers or higher levels of inequality is dependent upon the use case.

EXAMPLE 2 For data used for service planning, 5 % of individual map entries which have equivalence of 2 or higher (i.e. equivalence which is not an exact match or aggregated match) is acceptable for the use case.

Measure:

- 0 no outliers.
- 1 <x percentage to be determined according to the use case.
- $2 \longrightarrow x$ and < y.
- $3 \longrightarrow y$ and $\langle z$.
- 4 z or greater.

4.4 Building a map set

4.4.1 Map development process

The quality and utility of a map is affected by the processes used to build and maintain the map. These quality determinants will impact quality according to the intended use of the map. Where a map is used for one-time conversion of data from a legacy system to a new system, the documentation of the map process and decisions might have a different focus and impact as there is a low requirement to be able to replicate the building process to maintain the map. The one-time map documentation is still of value to ensure consistent methodology throughout the map development.

4.4.2 Determinant 7: Clear documentation of the purpose of the map

A map is developed for a purpose which may or may not be associated with a clinical information model as well as the terminological resource used. The clear specification of the use case is essential to determine how to map from source to target, and also to know how and where the application of such a map is appropriate.

The criteria which should be included in assessing the requirements for this use case and map conformance include the following:

- a) use case has a single purpose which is precisely described;
- b) reason for using the map and its intended use;
- c) benefits expected from using the mapped data;
- d) stakeholders including implementers (such as vendors), and users of the mapped content.

Each of these criteria might impact the utility and quality of the map for a use case. It is necessary that the evaluation of the map consider the importance of each criterion based upon the business case of the map.

Measure:

- 0 the documentation includes all the 4 specified components.
- 1 the documentation includes only 3 of the specified components.
- 2 the documentation includes only 2 of the specified components.
- 3 the documentation includes only 1 of the specified components.
- 4 the document does not include any of the specified components.

4.4.3 Determinant 8: Currency of the map

Evaluation should include consideration of the importance and impact of the currency of the map. If the map represents existing target and source terminological resources consistent with those used in the current source and target information systems, the accuracy of the map application should be as high as possible given the equivalence measures of the map. If any of the existing and current target and source

terminological resources are not both using the current versions, then there might be difficulties in achieving the equivalence required.

Measure:

- 0 map reflects current source and target systems used in systems where the map will be applied.
- 1 3 map reflects current source and target systems within a defined time frame of the release of those systems (assessor to determine the impact of this difference and assign value to weight this risk appropriately).
- 4 map does not reflect current source and target systems.

4.4.4 Determinant 9: Business arrangements

The business arrangement under which a map is developed might impact its quality or maintenance. If the map is developed by the owner/s of the terminological resources with open harmonisation efforts, the likely quality might be higher than that done by a single commercial arrangement.

It is necessary to assess whether this determinant might impact the quality of the map for the specific use case involved.

No measure is provided here. It is up to the user of the map to determine their requirement in this area with the lower number the lower the potential risk.

EXAMPLE If it is essential that the owner of the source or target code system develop and maintain the map, this determinant might be measured to have a weight of 0 to reflect that this is the only acceptable map quality for this determinant.

4.4.5 Determinant 10: Methodology documentation

The methodology for development of the map shall be specified clearly and documented. There are many methods which can be applied, and each should be described to a level where that method could be reliably repeated to maintain the map. This determinant reflects the quality of methodology specification, not the actual methodology which is assessed by other determinants. Documentation should clearly indicate the versioning and update processes to be used to maintain the map. This documentation is important if the map is to apply to historical data or to data which changes into the future, but if the map is applied once to convert data to the source terminological system and the 'old' data is no longer maintained this may not impact the quality of the map for this use case.

Documentation should include details of

- a) the purpose of the map (including intended use),
- b) the map development process:
 - 1) skills and team;
 - 2) tools used and how these tools were used;
 - 3) method of map initial development;
 - 4) validation;
 - 5) consensus management process;
 - 6) record of decisions made with rationale supporting that decision.
- c) the currency for source and target, including update requirements for maintenance,
- d) the business agreements associated with contract/s for creation and maintenance of the map content,

- e) publication process and content, and
- f) the map evaluation report a report produced by an independent party which can be used to assess the safe and appropriate use of this map. Such a report should include
 - 1) scoring requirement for purpose,
 - 2) score achieved for the specified version of the map,
 - 3) risk assessment of the specified version of the map, and
 - 4) recommended actions to reduce risk when used or next modified. For instance, medicines with a narrow therapeutic index that have a high risk of causing harm if the map includes non-exact matches, should have extra assurance steps associated with the mapping methodology and or implementation.

Measure:

- 0 full documentation of the methodology is provided including process for development, validation, tooling, consensus management and map set maintenance.
- 1-3 the user may determine their requirements between the two extremes dependent upon their use case and the potential risk. For example, if the map is a one-off use map, just to convert data from a legacy system to a new system, the map documentation should be available but the need to maintain the map will not be an issue and may impact the requirement for quality documentation.
- 4 no documentation available regarding the methodology for development and maintenance of the map.

4.4.6 Validation

4.4.6.1 General

Validation is the process of explicit confirmation and/or approval of the precision of the "Equivalence assessment".

A consistent requirement for validation of a map product is vital to assure semantic interoperability and the accuracy of data capture and representation.

Currently, map products are produced by

- a) experts using tacit individual knowledge,
- b) consensus using Delphi or IRR: InterRater Reliability techniques, or as
- c) a combined approach using properties of each method.

In addition, time-constraints are frequently imposed on the validation process due to the volume of data element concepts in the medical terminologies, such as SNOMED CT, which involves over 300 000 concepts. Each validation process becomes time consuming. The decision-making determinants indicate techniques for use at a semantic level to support the explicit confirmation of a mapping product's accuracy, data representation and implied quality, portability, and reuse.

4.4.6.2 Determinant 11: Percentage of map validated

Progressive development impact upon validation assessment — Where a map may have different validation quality in different areas of individual content — e.g. percentage of commonly used concepts well defined, In this case less common concepts may not be mapped at all or have lower validation applied.

Measure:

0 — amount of validation is equal to the use case requirements percentage.

- 1 amount of validation is within $10\,\%$ of the use case requirement percentage.
- 2 amount of validation is within 20 % of the use case requirement percentage.
- 3 amount of validation is within 50 % of the use case requirement percentage.
- 4 amount of validation is not within 50 % the use case requirement percentage.

4.4.6.3 Determinant 12: Method of validation

- a) Single validation where there is one person who creates and validates the content of each individual map. The single validation process may be undertaken by a team. This method could be used for mapping between small terminological resources of similar content e.g. Male = 1 or M, Female = 2 or F. This methodology might not provide a suitable validation result for more complex or extensive terminological resources.
- b) Single Independent validation where one person creates the map and another person validates the map.
- Double blind validation where two people create and validate the content of each individual map without knowing the result obtained by the other person. The results are compared and if they are equivalent, the content, is considered validated, if not the content shall go through a consensus process. This process requires two teams of people who each create individual maps, i.e. the process is dependent upon comparison of duplicated work.
- d) Automated validation single and other forms of validation can be automated, but if the tooling used is the same as the tools used to create the map this may not provide a suitable validation method.

Measure:

- 0 double blind validation.
- 1 single independent validation.
- 2 single validation.
- 4 automated or no validation.

4.4.7 Determinant 13: Decision making — Consensus building process

Where source concepts are mapped to targets using rules or agreed decisions, these need to be included in the map documentation in a manner which is consistent and applied throughout the map set.

Delphi is 1950's consensus building technique, originally developed to forecast the impact of technology by the Rand Corporation on warfare. The Delphi method involves convening a group of experts who anonymously render opinions on subject matter and subsequently receive feedback in the form of a statistical representation of the 'group response', after which the process repeats itself. The goal is to reduce the range of responses and arrive at 'expert consensus'. The Delphi method has been widely adopted and has an objective to obtain the most reliable consensus of opinion of a group of experts. Details of the Delphi approach are available at: http://www.rand.org/topics/delphi-method.html.

Inter-Rater Reliability (IRR): IRR is a numeric score of the consensus among reviewers ('raters'). There are a number of statistics used to determine the IRR including Cohen's kappa and Cronbach's alpha as a measure of internal homogeneity, i.e. how closely related a set of items are as a group. For example, items contained (group) in an equivalence assessment.

If there is disagreement, the process for determining what and how that disagreement is managed shall be documented including the following:

- a) documentation of rationale behind decisions;
- b) how consistent application of the rationale is ensured.

This documentation shall be available to all those involved in map creation and maintenance.

Where tooling is used to support the map creation and maintenance processes this documentation should be applied within that tooling.

Final decision making shall occur in the absence of undue pressure or singular influence.

EXAMPLE The process for map management documents decisions made about mapping of conditions which are not an exact match, including the rationale for the decision. The intention of this documentation is to support future use of mapped data and to support consistent ongoing map maintenance.

Measure:

- 0 a recognized methodology for conflict resolution is applied, and the rationale behind all decisions is clearly documented, and consistently applied (generically throughout the map), and no undue pressure or singular influence is prevalent.
- 1 the rationale behind all decisions is clearly documented, and consistently applied (generically throughout the map), and no undue pressure or singular influence is prevalent.
- 2 the rationale behind all decisions is clearly documented, and consistently applied (generically throughout the map).
- 4 no rationale, methodology for conflict resolution is documented and there may be pressure or singular influence prevalent in results.

4.4.8 Determinant 14: Tools used to develop or maintain the map

Software tools can be used to assist the mapping of concepts from one terminological resource to another. Such tools include terminology development and maintenance tools. These tools can provide candidate matches by comparison between individual concepts in the target and source terminological resources. This will often require the data being mapped to be 'cleaned', e.g. made singular, prior to running through the tools.

These tools do not remove the need for human review.

Tools include

- a) natural language processing,
- b) ontology management tools,
- c) terminology service tools, and
- d) auto-matching processes, and
- e) terminology management tools.

Where tools have been used to generate map content the name and version of that software tool should be clearly identified in the map.

Measure:

- 0 tools were used, name and version of software tool identified in map, data pre-prepared before the tool was used and manual review was incorporated into the process.
- 1 tools were used, data pre-prepared before the tool was used and manual review was incorporated into the process.
- 2 tools were used, data pre-prepared before the tool was used no manual review.
- 4 tools were used but no pre-preparation or manual review was incorporated.

NOTE If tools have not been used, this determinant cannot be applied in the scoring evaluation.

4.4.9 Determinant 15: Workforce

The development and application of maps requires considerable specialized skill. The following skill requirements should be assessed to determine their importance to any mapping project. The skills are presented based upon the role an individual might be playing in the map development process. ISO/TR 12300:2014, 5.4, indicates that skilled mapping personnel are required to ensure the quality and integrity of map development and mapping rules. Subclause 4.4.9 specifies how this may be assessed.

Broadly there are five role groups involved in map development or application.

- a) Map decision maker/Sponsor. The person or group of people who are responsible for the decision to map and the identification of the purpose and quality requirements of the map.
- b) Map project leader. The person leading the mapping project, this individual might be a manager and is not always both a mapping specialist and a manager. This person is responsible for establishing map methodology, developing the mapping team (project leader, specialist and governance team) to obtain the highest quality map for the purpose of the project.
- c) Map specialist. These individuals have skills in both the source and target terminological resources as well as the process of mapping and are responsible for building and maintaining the map.
- d) Map implementer. The individual responsible for taking the published or completed map and implementing the map in computer systems to obtain the intended data conversion.
- e) Map governance team member. This includes members of advisory groups, those providing clinical, linguistic or other forms of guidance to resolve conflict where the alternative map results could be different.

When considering the skills needed, it is important to understand that a description of the topic of knowledge is insufficient. There are two common methods used to determine the level of skill being defined in a skill or competency statement. The Skills Framework for the Information Age (SFIA Foundation, 2016) is widely used in IT as an internationally recognized skill level representation. SFIA is based upon Bloom's taxonomy. This document uses the SFIA levels.

- Level 1: Follow
- Level 2: Assist
- Level 3: Apply
- Level 4: Enable
- Level 5: Ensure, advise
- Level 6: Initiate, influence
- Level 7: Set strategy, inspire, mobilize

In this document, general skills such as project management, are not included, but there are some personal skills which have been included as these are useful to include in the development team. Table 4 refers to skills and level of skills appropriate to mapping projects and roles.

Table 4 — Skill matrix

Skill/Role	Map decision maker/ Sponsor	Map project leader	Map spe- cialist	Map imple- menter	Map govern- ance team member
General skills					
Works independently		Apply	Apply	Apply	Assist
Works in a team		Apply	Apply	Apply	Apply

Table 4 (continued)

Skill/Role	Map decision maker/ Sponsor	Map project leader	Map spe- cialist	Map imple- menter	Map govern- ance team member
Good communicator		Apply	Apply	Assist	Apply
Availability and ability to meet timelines		Apply	Apply	Apply	Apply
Seek and assess advise provided on mapping skills, tools, process and quality	Set strategy	Enable	Ensure	Ensure	Apply
Mapping process skills					
Create individual maps using a standardized, scientifically validated and consistently applied mapping methodology		Initiate	Enable	Apply	Assist
Appropriately used mapping tools		Ensure	Apply	Apply	Assist
Practice within a standardized operational framework to develop process reliability		Ensure	Ensure	Apply	Apply
Provide support to map implementers		Apply	Apply		Apply
Develop simple, complex and rule- based map content		Enable	Apply		Assist
Implement simple, complex or rule- based map content		Enable		Apply	
Target/Source skills	Follow	Follow	Advice	Advice	Assist
Obtain accurate coded values to represent a concept in the target terminological resource, applying all relevant rules		Assist	Ensure	Assist	Assist
Obtain accurate coded values to represent a concept in the source terminological resource, applying all relevant rules		Assist	Ensure	Assist	Assist

The quality of a map is dependent upon the capability of those who build and implement the map. A method of confirmation of those skills shall be established in order to support that evaluation.

Measures:

- 0 the map has been developed with skills consistent with those specified in this document, including detailed, current skills of the source and target terminological resources.
- 1 the map has been developed with at least 3 of the roles being completely conformant to the skills specified in this document, including detailed, current skills of the source and target terminological resources.
- 2 the map has been developed with at least 2 of the roles being completely conformant to the skills specified in this document, including detailed, current skills of the source and target terminological resources.
- 3 the map has been developed with a team with skills that are current in the source and target terminological resources.
- 4 no skill requirements were specified or assessed.

4.5 Map governance and maintenance

4.5.1 Determinant 16: Governance

The decision to map, and the ongoing governance of the map processes and content shall be established.

The implementation of IT governance during the MapQual process should facilitate alignment between IT and business strategy.

MapQual governance is essential to ensure strong coordination among process initiatives and eliminate misalignment between organizational strategy and process endeavours^[9]. The MapQual focus on governance is to harmonize process, process designs and strategies to achieve alignment of the product to the desired outcome and use case^[10].

- 0 The governance process is documented and available to all map users.
- 3 The governance process is documented but is not available to all map users.
- 4 The governance process is not documented.

NOE This determinant does not have a measure value of 1 or 2 as there is no situation where a position between that measured as 0 and 3 is of value.

4.5.2 Determinant 17: Map maintenance

The quality of a map is not only dependent upon the initial product, but on the ability to maintain that map for ongoing use. Where a map is intended for purposes that are not one-off conversion the effort required to maintain that map shall be considered.

Key issues to be considered include the following:

- Frequency of update of target and source terminological resources if each terminological resource is updated frequently and implemented in systems, the map set should be updated to reflect changes in either system. It is important to recognize that an update to target and code source systems can impact the map utility and accuracy. It is up to the map author to identify their update process and cycle.
- The version of the source and target terminological resources shall be identified in the map and the version of the map should also be identified clearly in the data produced by that map.

It is possible that a new map may not be released in conjunction with a new version of a terminological resource (source or target). Where these are not synchronized, the implementation of the terminological resources and of the map might not be as accurate as expected.

Measure:

- 0 Map metadata includes the version information of source/target and the map set and the update cycle applied to each version. The map owner provides a service level agreement which clearly determines the commitment to map maintenance.
- 1 Map metadata includes the version information of source/target and the map set and the update cycle applied to each version. A service level agreement is provided by the map owner but there is no commitment to map maintenance.
- 2 Map metadata is provided but there is no version information or update cycle information included. A service level agreement is provided.
- 3 A service level agreement is provided.
- 4 Map metadata is not provided and there is no service level agreement.

5 Using map quality determinants

5.1 Required determinants

In order to evaluate the quality of a map, it is necessary to consider which determinants are essential for the specific use case.

For example, these can be rules or conventions associated with the use of the source or target terminological resource, attributes that imply specific meaning, or documented principles that have been applied to maps in certain circumstances. Determinants should be unambiguous. Some determinants, (e.g., tooling if automated tools are not being used) might not be relevant. Other determinants might not be important for specific situations, such as when a map is used to convert data once when changing from one version of a terminological resource to another. This document identifies the determinates for such quality assessment and suggests potential quality requirements for a limited range of use cases (Clause 6). These suggestions are informative only.

5.2 Level of quality

This document has a simple framework of measures used to evaluate and determine the quality of the map for each quality determinant. This standard method is used as it is reliable, viable, efficient, encourages best practice, and highlights key areas impacting the quality and utility of a map for a given purpose.

Each determinant shall be rated. Zero is the highest quality and 4 is the lowest.

Each quality determinant should be allocated a required value based upon the use case to which the map is to be applied (quality required). The map is then reviewed and each determinant is scored (quality actual). A comparison of requirement vs actual can then be made.

It is important to note that the required and actual scores will differ according to the use case to which the map is to be applied. A map which is considered low quality for one purpose might meet requirements for another purpose. Few maps can be considered of high quality for all purposes.

5.2.1 Step 1: Establish map quality requirement

For each required determinant, establish the level of quality required based upon the specific use case.

- 0 = perfect, complete, totally meets specified criteria (all criteria are met whether essential or not).
- 1 = meets all essential criteria (specify any criteria which are not essential). It is necessary to consider the use case to establish which criteria for each determinant are essential.
- 2 = meets most essential criteria, but not all.
- 3 = meets few essential criteria.
- 4 = does not meet essential criteria.

Annex A provides an informative guideline on the quality levels appropriate for some sample healthcare use cases.

5.2.2 Step 2: Assess map against requirement

Assess the map against each determinant to gain the actual scores.

5.2.3 Step 3: Calculate the score and actions required

When complete, add up the score for each key area and assess whether the map will suite the intended purpose or not and what action might be required. <u>Table 5</u> provides an example of the measure levels which could be considered appropriate to clinical use.

Table 5 — Example of measure evaluation in a clinical user case

Area	Determinant	Required measure level	Actual
Terminological resource	1: Common categorial structure	0	0
	2: Shared semantic domain	0	0
	3: Language and translation	N/A	N/A
Equivalence	4: Equivalence identification/Publication	1	4
	5: Equivalence assessment (full or priority content)	1	1
	6: Map set outliers	2	2
Building a Map Set	7: Clear documentation of the purpose of the map	1	2
	8: Currency of the map	0	1
	9: Business arrangements	2	0
	10: Methodology documentation	1	1
	11: Validation — percentage of map validated percentage required — 100	0	2
	12: Method of validation	0	1
	13: Decision making	1	4
Tools	14: Tools used to build and maintain map set	1	1
Skills	15: Workforce	0	2
Governance	16: Map governance process documented and available	0	1
	17: Map metadata versions and maintenance	1	1
Total		10	22

6 Use cases

6.1 General

Clause 6 provides a template for quality requirement determination and defines the scope measures which shall be achieved to be considered compliant with this document.

6.2 Determining requirements for a purpose

6.2.1 General

The use case or purpose for which a map is to be used will influence measuring the quality of a map required for that purpose and how this can then be used to assess a given map product or process. These processes and measures are used to

- evaluate level of conformance to quality map standards,
- establish vendor conformance requirements,
- establish ongoing improvement pathways, and
- provide quality and safety benchmarks to industry.

6.3 Direct patient care use case

6.3.1 General

A map is needed to convert data collected in the electronic health record at the general practice. Data in the record represents the substance(s) to which the patient is recorded to have an allergy. The national allergy alert system uses an international terminology to represent clinical conditions. The doctor's desktop system uses a local terminological resource for diagnosis. This terminological resource is developed and maintained by the software vendor. The map source is the local system codes for diagnosis and the target is the international terminology.

Subclause 6.3 defines the range of quality measure results to which a map shall conform if it is to safe and efficient for use in the specific use case. Today, there are numerous and diverse quality improvement initiatives underway at all levels of the health care system — federal, state, regional, local, and within health care organizations — that are putting quality measures to use. Quality improvement initiatives within and across health care organizations are core to these efforts. The initiatives require clinical terminologies in all clinical areas to identify opportunities for improvement, enable providers to assess and track how their patients are doing in terms of key aspects of care and potential complications in order to identify areas for improvement.

6.3.2 Direct patient care level of conformance required and rationale

For direct patient care, it is essential that the meaning of the information recorded is retained and can be analyzed over time. Where data is mapped, this meaning may be subtly or significantly modified. There are clinical safety issues associated with such maps. Table 6 indicates an example of the map requirement minimum standards suited to thee in direct patient care. These are examples which need to be considered when evaluating a map set.

Table 6 — Example of measure requirements for clinical use

Area	Determinant	Measure shall be this value or lower	Rationale
Terminological resource	1: Common categorial structure	0	To retain meaning, it is necessary that each terminological resource have the same structure.
	2: Shared semantic domain	1	To retain meaning, it is necessary that each terminological resource shall at least have a fully inclusive overlap.
	3: Language and translation		No recommendation is made regarding language and translation. This should be evaluated according to the environment in which the map is to be used.
Equivalence	4: Equivalence identification/ Publication	0	The publication of equivalence measures is required to support display of non-exact matches to clinicians who may use the information to support decision making.
	5: Equivalence assessment (full or priority content)	0	Full equivalence is needed if the meaning is not being changed.
	6: Map set outliers	0	No outliers.
Building a map set	7: Clear documentation of the purpose of the map	1	3 components are required, i.e. the business case for the map or expected benefits are not required.

Table 6 (continued)

Area	Determinant	Measure shall be this value or lower	Rationale
	8: Currency of the map	0	For clinical safety, the versions of the source and target used in the in- formation system shall be the same as those to which the map applies.
	9: Business arrangements	User to deter- mine	No conformance requirement established.
	10: Methodology documentation	0	Where the map is used for ongoing mapping of data, as in this use case, it is essential that the documentation support validation and ongoing map maintenance. If the use case were a one-off conversion of data from a legacy system to a new system, the documentation is still valuable but not essential for ongoing maintenance or query support.
	11: Validation — percentage of map validated	0	For clinical safety, all content of the map should have been validated. The option to validate a priority content set is reasonable but if this option is used, it shall be completely validated.
	12: Method of validation	0	Double blind validation shall be used to ensure accuracy for clinical use.
	13: Decision making	1	Clinical data requires an open process of consensus management and consistent application of rationale for the consensus decisions made without pressure being born on any group to achieve agreement.
Tools	15: Tools used and method of use	1	Only assess tools if used.
Skills	14: Skills	1	The map shall be developed and maintained by people with at least the skills defined in this document, including skills and experience in the use of the source and target terminological resources, as well as the processes of mapping.
Governance	16: Map governance process documented and available	0	The map governance process shall be documented and available to all users of the map
	17: Map maintenance	0	The map metadata shall be documented, versions maintained appropriately and update cycles specified in service agreement.

6.4 Administrative, financial or service planning use case

6.4.1 General

This use case is for a map from a terminology to a classification with a specific statistical and epidemiological use case. These conformance criteria may also be suitable for research and public health use cases. Whatever the use case, it is essential that the map quality assessor determine the requirement for conformance. The requirements identified here are considered the standard to which

maps used in these environments should at least conform. Assessors of map quality may determine that they require higher levels of conformance to meet their specific situation. In this environment, the interface terminologies vs the classification for financial purposes is considered. There may be rules applied to classification and maps used for financial purposes which are not applicable in the general or service planning use case, such as ICD-10 to DRG.

6.5 Administrative, financial or service planning level of conformance required and rationale

<u>Table 7</u> represents an example of the level of measures which might be considered acceptable for non-patient care purposes such as service planning, finance or administration.

Table 7 — Administrative, financial or service planning conformance requirement

Area	Determinant	Measure shall be this value or lower	Rationale
Terminological resource	1: Common categorial structure	2	Some lack of specificity can be accepted in the map as the result is looked at from a less detailed level than clinical care and is not likely to change the intended information significantly.
	2: Shared semantic domain	2	Depending on the actual source and target terminological resources, consideration of the required overlap in semantic domain should be considered. Level 1 is preferred but the level has been set at level 2, acknowledging that there are instances where this would suffice and still have utility.
	3: Language and translation		No recommendation is made regarding language and translation. This should be evaluated according to the environment in which the map is to be used.
Equivalence	4: Equivalence identification/ Publication	1	It is preferred that the identification shall be included in the published map but it is acceptable that it not be published provided that this information is available.
	5: Equivalence assessment (full or priority content)	3	At least level 3 equivalence shall be available in the map, but Level 1 or 2 is preferred for this use case. In case such as research or public health level 1 or 2 should be required.
	6: Map set outliers	1	Outliers shall be permitted but only to the defined percentage of the total individual maps.
Building a map set	7: Clear documentation of the purpose of the map	1	Three components are required, i.e. the business case for the map or expected benefits are not required
	8: Currency of the map	1	The currency of the map shall meet a reasonable compromise between currency, utility and maintenance.
	9: Business arrangements	User to deter- mine	No conformance requirement established.

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 Table 7 (continued)

Area	Determinant	Measure shall be this value or lower	Rationale
	10: Methodology documentation	1	Where the map is used for ongoing mapping of data, as in this use case it is essential that the documentation support validation and ongoing map maintenance. If the use case were a one-off conversion of data from a legacy system to a new system, the documentation is still valuable but not essential for ongoing maintenance or query support.
	11: Validation — percentage of map validated	1	The user should determine the percentage of validation required for their purpose.
	12: Method of validation	1	Validation should be level 0 — double blind validation where high quality is required, but level 1, which represents single validation, shall be considered conformant.
	13: Decision making	1	Clinical data requires an open process of consensus management and consistent application of rationale for the consensus decisions made without pressure being born on any group to achieve agreement.
Skills	14: Skills	1	The map shall be developed and maintained by people with at least the skills defined in this document, including skills and experience in the use of the source and target terminological resources, as well as the processes of mapping.
Governance	15: Map governance process documented and available	0	The map governance process shall be documented and available to all users of the map.
	16: Map metadata versions and maintenance	0	The map metadata shall be document, versions maintained appropriately and update cycles specified in service agreement.

6.6 Other use cases

A similar process can be used to assess the utility and safety of a map in other uses cases such as research, and public health.

Annex A

(informative)

Example of map quality evaluation

<u>Table A.1</u> provides guidelines for suggested quality determinate levels for a common use case in healthcare. This is provided for assistance but can be used as a starting point for evaluation of an individual case establish specific requirements based upon that use case.

Table A.1 — Example of measures for evaluation of a common use case

Determinate	Clinical use case	Decision making or public health
1. Common categorial structure	0	2
2. Shared semantic domain	1	2
3. Language and translation (importance will be relevant to the source/target language and use case)	These components a	re not ranked in this example.
4. Equivalence/Identification and Publication	0	1
5. Equivalence Assessment	0	3
6. Map set Outliers	0	1
7. Clear documentation of purpose	0	0
8. Currency of the map	0	1
9. Business Arrangements	0	2
10. Methodology documentation	1	1
11. Percentage of map validated	0	1
12. Method of validation	0	1
13. Decision making documentation	1	1
14. Tools (only to be scored if used)	1	1
15. Skills	1	2
16. Map governance process documented	0	0
17. Map metadata versions and maintenance governance	0	0

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Code systems referenced in the document

ICD International Statistical Classification of Diseases and Related Health Problems. http://www.who.int/classifications/icd/en/

ICPC International Classification of Primary Care (ICPC) http://www.who.int/classifications/icd/adaptations/icpc2/en/

CCC Clinical Care Classification System. http://www.springerpub.com/clinical-care-classification-ccc-system-version-2-5-2nd-edition.html

SNOMED CT Clinical Terminology owned by SNOMED International. <u>www.snomed.org</u>

LOINC Logical Observation Identifiers Names and Codes. https://loinc.org/

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