

ICD-10 to MedDRA Mapping Conventions

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1. Introduction

There is a need to establish interoperability between the different medical terminologies that are employed in different arenas of public health. The Medical Dictionary for Regulatory Activities (MedDRA) which is owned by ICH and maintained and distributed by the MedDRA Maintenance and Support Services Organization (MSSO) and the Japanese Maintenance Organization (JMO), is an international standardised terminology used to facilitate the sharing of regulatory information on medical products in both pre- and post-authorisation phases. The International Statistical Classification of Diseases and Related Health Problems (ICD), is a global standard classification for reporting diseases and health conditions that is developed and maintained by the World Health Organization (WHO). It is used worldwide in systems such as patient registries, insurance claims systems, mortality and morbidity statistics, and patient health records. Since its first adoption in 1990, ICD-10 is used by more than 150 countries around the world and has been translated into more than 40 languages. A number of clinical modifications and adaptations evolved over time but there is a core version of ICD-10 that is common to the individual modifications.

Organisations have attempted over the years to create their own mappings between MedDRA and ICD but these are not standardised, are of uncertain quality, and have no maintenance process. In many cases, organisations will resort instead to resource-intensive and costly manual re-coding in an attempt to convert data between terminologies. A standardised mapping that is developed and maintained by ICH and WHO in collaboration would provide a high quality, more automated solution to terminology interoperability with a sustainable maintenance process for the future.

2. Use Cases

Mappings between ICD-10 and MedDRA could facilitate reporting in MedDRA of suspected adverse drug reactions recorded as clinical events in ICD in registries, implementation of a common data quality system in registries using different terminologies (automated data entry control, checks for data consistency, routine statistical screening), data exchange, common data analysis on a large number of patients and interpretation of results from different registries.

Given the very large number of registries established in Europe and the United States by hospitals, specialists, patients' associations or public health authorities, the mapping of medical terms, diagnoses and adverse events across different registries using standard terminologies such as ICD and/or MedDRA would be beneficial to many stakeholders. It would be of particular value in safety evaluations of medicines for rare diseases with small populations where multiple registries internationally may contribute data.

Mapping between MedDRA and ICD-10 also has the potential to expand availability of outcomes data for implantable medical devices, for which there is often a disproportionately large body of device performance data relative to patient safety and outcome data.

Beyond patient registries, there are other sources of ICD-coded data that can be converted to MedDRA for the purposes of analyzing adverse events and outcomes including insurance claims databases, mortality and morbidity statistics, clinical trials, and observational studies.

ICD-10 coded data in patient health records could also be converted to MedDRA for the purpose of

identifying eligible patients for clinical trials.

In addition, mappings from ICD-10 to MedDRA would support the use of Real World Data and Real World Evidence in regulatory decision making ([FDA. 21st Century Cures Act of 2016](#)).

3. Development of the Map (Methodology)

The initial draft map was developed using the 2019 international core version of ICD-10 and MedDRA Version 23.1.

Chapters I – XIX of ICD-10 contain concepts for organ specific diseases, signs and symptoms, injury and poisonings that are similar to the content of MedDRA. A mapping to select the closest conceptual matching Lowest Level Term (LLT) for each ICD-10 term has been performed. Most of the terms in Chapters XX (External causes of morbidity and mortality) and XXI (Factors influencing health status and contact with health services) have not been mapped as these concepts are largely out of the scope of MedDRA and also are mostly not relevant for the pharmacovigilance use cases for the map.

Chapter XXII, Codes for special purposes, which also includes COVID-19 related terms, has been mapped to MedDRA where applicable.

Names for Chapters (for example, Chapter II Neoplasms) and Blocks (for example, C00-C97 Malignant Neoplasms) have not been mapped. Individual 3-digit and 4-digit ICD-10 codes in each chapter have been mapped to MedDRA LLTs.

An autoencoding tool was used to identify direct (exact) matches of ICD-10 terms to MedDRA LLTs. The remaining terms which the tool identified as a “partial” or as a “no match” were mapped manually. The ICD-10 notes which contain synonyms, inclusions, and exclusions were used to understand the ICD-10 concept and to inform the most appropriate choice of LLT. Terms were mapped through a dual, independent, blinded mapping process. Map records were then reviewed by two blinded individuals performing Quality Assurance (QA) checks. The results of the QA step were reviewed and any discrepancies in mappings were discussed in consensus with the entire mapping team. Final resolution was agreed upon, and the map pairs were recorded.

When a suitable MedDRA LLT was not available to map, where appropriate, a change request was submitted to add a new term to an upcoming release of MedDRA. The map will continue to be updated to the latest release of MedDRA.

Because there are inherent differences in the structure and scope of the two terminologies, there are frequent instances where a direct conceptual match cannot be found between an ICD-10 term and a MedDRA term. Since ICD-10 is focused on precise recording of clinical conditions, the terms can be more detailed than their corresponding MedDRA counterparts and thus there can be a loss of information in applying a map from the detailed source terminology to the target terminology. To aid in the understanding and implementation of the maps, each term pair in the map has therefore been assigned an attribute of “Equivalent”, “Loss of Information”, or “Unmapped”. Chapters XX (External causes of morbidity and mortality) and XXI (Factors influencing health status and contact with health services) which are largely not mapped have also been assigned the attribute “Unmapped”. These attributes are described in detail in section 5.

4. General Mapping Guidance/Principles

A. Mapping to an exact conceptual match

ICD-10 terms are mapped to the closest conceptually matching current MedDRA LLT, according to the following principles:

- When an ICD-10 term is a direct or close match to a current LLT, this MedDRA term is selected
- When an ICD-10 term is a direct or close match to a non-current LLT, this term is re-mapped to the closest current MedDRA LLT. In most cases, this closest LLT is under the same PT as the non-current LLT but there are instances of the closest current LLT being located under a different PT
- ICD 4-digit codes without direct or close LLT matches are mapped to the same LLT as their corresponding broader 3-digit code, where conceptually appropriate
 - Example: K35.2 Acute appendicitis with generalized peritonitis maps to LLT *Acute appendicitis* which is the same map as the broader 3-digit code (K35 Acute appendicitis to LLT *Acute appendicitis*)

B. Following MedDRA structure

Mapping of ICD-10 terms is generally performed in accordance with MedDRA structural principles and placement conventions

- Terms representing a “congenital” or “inherited” condition, are mapped to an LLT within SOC *Congenital, familial and genetic disorders*
- Terms representing neoplasms are mapped to an LLT within SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*
- Terms representing an infection are mapped to an LLT within SOC *Infections and infestations*
- Terms representing injuries are mapped to an LLT within SOC *Injury, poisoning and procedural complications*
- Other terms are generally mapped to LLTs in the SOC that corresponds to the ICD-10 chapter (e.g., Diseases of the digestive system and SOC *Gastrointestinal disorders*) however, because of differences in classification between the two terminologies, the closest LLT match may be located in a different SOC in MedDRA
 - Example: E63.1 Imbalance of constituents of food intake in Chapter IV Endocrine, nutritional and metabolic diseases maps to LLT *Inadequate diet* in SOC *Social circumstances*

C. Mapping of combination and complex concepts

- When a specific combined LLT is not available, dual concepts are mapped to the clinically more relevant condition, a more general inclusive condition, or the broader anatomical part
 - Example: I72.3 Aneurysm and dissection of iliac artery maps to LLT *Iliac artery dissection*
 - Example: M21.5 Acquired clawhand, clubhand, clawfoot and clubfoot maps to LLT *Limb deformity* (SOC *Musculoskeletal and connective tissue disorders*)
 - Example: N45.0 Orchitis, epididymitis and epididymo-orchitis with abscess maps to LLT *Testicular abscess*

- ICD terms that encompass ‘sequelae’, ‘late effects’, ‘resulting in’ or ‘complicating’ a condition along with the underlying cause are mapped to the first diagnosis
 - Example: B21.0 HIV disease resulting in Kaposi sarcoma maps to LLT *HIV disease* as the resulting complication is represented in C46 Kaposi sarcoma which maps to LLT *Kaposi’s sarcoma*
- Terms with ‘acute’ or ‘chronic’ – are mapped to the corresponding ‘acute’ or ‘chronic’ LLT where available, and if not available, mapped to the specific condition
 - Example: J20.1 Acute bronchitis due to Haemophilus influenzae maps to LLT *Haemophilus bronchitis*

D. Mapping of infection terms

- If a combination term including pathogen and site is not available the term is mapped to the broad pathogen group at the specific site, where available
 - Example: M00.1 Pneumococcal arthritis and polyarthritis maps to LLT *Arthritis bacterial*
- Where a specific anatomical site is not available, the term is mapped to the pathogen at a broad anatomical site
 - Example: A56.1 Chlamydial infection of pelviperitoneum and other genitourinary organs maps to LLT *Chlamydial pelvic inflammatory disease*

E. Mapping of unspecified terms

- If an ICD-10 term containing “unspecified” has a direct autoencoding match to an LLT, then that LLT is mapped
 - Example: G72.9 Myopathy, unspecified maps to LLT *Myopathy, unspecified*
- If an ICD-10 term containing “unspecified” does not have a direct match to an LLT, but there is a lexical or conceptual match containing “unspecified”, then that LLT is used for the map
 - Example: E32.9 Disease of thymus, unspecified maps to LLT *Unspecified disease of thymus gland*
- If there is no direct, lexical or conceptual match for ICD-10 “unspecified” terms, the base concept LLT is mapped
 - Example: H27.9 Disorder of lens, unspecified maps to LLT *Lens disorder*
- NOS terms in MedDRA are not used for the map
 - Example: G47.9 Sleep disorder, unspecified maps to LLT *Sleep disorder*, not LLT *Sleep disorder NOS*

5. Attribute Categories

A. Equivalent - direct conceptual match. Includes:

- Direct matches
- Lexical variants
- Synonyms
- Semantically equivalent
- Others, other specified, without mention, other, not elsewhere classified, and unspecified

- Others
- Other specified
- Without mention
- Other
- Not elsewhere classified
- Classified elsewhere (no specific other disease(s) mentioned)
 - Example: E35.0 Disorders of thyroid gland in diseases classified elsewhere maps to base disease, LLT *Thyroid disorder*
- Plurals can map to singular and vice versa
- American/British spelling variations. ICD-10 mostly uses British English spelling and these terms are mapped to their corresponding British English spelling counterparts in MedDRA. Where an ICD-10 term uses the American spelling, it is mapped to its American spelling counterpart in MedDRA.
- Terms describing severity concepts such as mild, moderate, and severe
 - Example: F32.0 Mild depressive episode maps to LLT *Depressive episode*
- When the manifestation is the medical definition of the condition, the mapped terms are considered Equivalent
 - Example: J92.0 Pleural plaque with presence of asbestos maps to LLT *Asbestosis*
- Terms describing components of a distinct anatomical structure
 - Example: J38 Diseases of vocal cords and larynx, not elsewhere classified maps to LLT *Laryngeal disorder*. The vocal cords are considered to be a part of the larynx.

B. Loss of information – scenarios in which there is a loss of information from the ICD-10 concept to the MedDRA concept:

- Specificity loss (For example, loss of information about organism, anatomical site, disease process, acute/chronic form of condition, etc.)
- ‘Sequelae’, ‘late effects’, ‘resulting in’ or ‘complicating’ a condition
- Condition with procedural concepts are considered loss of information if the MedDRA term only represents the base condition and not the procedural concept
 - Example: J95.5 Postprocedural subglottic stenosis maps to LLT *Subglottic stenosis*
- Condition with manifestation from other system or disease condition is considered loss of information
 - Example: J10.1 Influenza with other respiratory manifestations, seasonal influenza virus identified maps to LLT *Influenza*
 - Example: J99.1 Respiratory disorders in other diffuse connective tissue disorders maps to LLT *Respiratory disorder*

C. Unmapped. No term exists for the ICD-10 concept in MedDRA or the ICD-10 term is out of scope of the map.

This identifies relevant concepts in MedDRA that might be missing and are required to provide a more complete mapping. A change request may be submitted to add the term to MedDRA provided it meets the criteria for inclusion in the terminology. The map will then be updated with the newly added MedDRA term.

There are ICD-10 concepts in Chapters XX (External causes of morbidity and mortality), XXI (Factors influencing health status and contact with health services) and XXII (Codes for special purposes) which are considered out of scope and are marked as Unmapped. The three chapters are provided in full for completeness for users implementing the map which accounts for the entirety of ICD-10 2019 international core edition.

Exceptions in Chapter XX were made for certain concepts with high relevance to pharmacovigilance such as self-harm and self-poisoning; these ICD-10 concepts are mapped to their MedDRA counterparts.