



Health Terminologies and Vocabularies

Environmental Scan

**Conducted for the National Committee on Vital and Health Statistics
Subcommittee on Standards**

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www.ncvhs.hhs.gov

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Introduction

Purpose and Scope

The purpose of this report is to provide a contemporary look at the health terminology and vocabulary landscape to advise the Secretary of the Department of Health and Human Services regarding:

1. The changing environment and implications for timing and approach to health terminology and vocabulary standards adoption,
2. Needs, opportunities, and problems with governance, coordination, maintenance, dissemination and adoption of health terminology and vocabulary standards.

This report does not make specific recommendations for improvement, but rather brings to light areas that would benefit from further discussion and consideration for potential future recommendations. Transaction standards are outside the scope of this environmental scan. However, health and terminology standards are coupled with transaction standards when they are used to define data elements for such transactions.

Definitions

For the purposes of this report the following definitions from the National Committee on Vital and Health Statistics (NCVHS) report on patient medical record information (PMRI)¹ apply:

Terminology – a collective term used to describe the continuum of code set, classification, and nomenclature [or vocabulary].

Code – a representation assigned to a term so that it may more readily be processed. In general, most terminologies incorporate a coding system for computer processing. A simple listing of codes and the terms with which they are associated is a code set.

Classification – arranges or organizes like or related terms for easy retrieval. For example, a classification system might organize terms by major categories, alphabetically, chronologically, or numerically.

Nomenclature or Vocabulary – a set of specialized terms that facilitates precise communication by minimizing or eliminating ambiguity.

“Controlled vocabulary” – indicates only the set of individual terms in the vocabulary.

¹ National Committee on Vital and Health Statistics. Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information [Internet]. Washington DC: National Committee on Vital and Health Statistics; 2000. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf>

“Structured vocabulary” or “reference terminology” – relates terms to one another (with a set of relationships) and qualifies them (with a set of attributes) to promote precise and accurate interpretation. These relationships and attributes may be represented in some type of an information model.

Additional definitions integral to the current environmental scan:

Adoption – formally establishing a terminology or vocabulary standard through the regulatory process, into effect, practice, or use as a named standard.

Implementation – incorporation of terminology and vocabulary standards into operational systems by the industry.

Governance – concerned with how governmental systems work, how political and administrative decisions are made, and the impact of both formal and informal institutions in how things get done.

Named Standard – terminology and vocabulary standards that are specifically identified in federal regulations requiring their implementation by the parties set forth in the regulation for purposes or circumstances denoted in the regulation. Named standards listed in this environmental scan were designated in regulations under HIPAA (Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996) or Promoting Interoperability (PI; formerly the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, commonly known as Meaningful Use).

Operational Problems – defined as possible adverse outcomes from the changing environment and implications in the timing and approach for health terminology and vocabulary standards adoption; and, the needs, opportunities, and issues with the development, dissemination, maintenance, and adoption of health terminology and vocabulary standards.

Ownership – Having rights to control the development, distribution and use of a terminology or vocabulary; having sole or shared ownership of the system's intellectual property.

Terms – a word, concept or notation that has a precise meaning in some uses or is peculiar to a science, art, profession, or subject. For purposes of this environmental scan, terms are not limited to words as combinations of letters and numbers may constitute scientific names.

Background

The need for standardized terminology in health care has long been recognized both at a national and international level. The International Statistical Classification of Diseases (ICD) was first adopted for use by the International Statistical Institute in 1893 to record causes of death.² After World War II, in 1948, the World Health Organization assumed responsibility for ICD and the classification was expanded to include morbidity.³ That same year, as the 6th Decennial Revision of the International Lists of Diseases and Causes of Death was approved by all nations, the idea was put forward to establish national committees to help address "...statistical problems in the fields of health and vital statistics for study by national technicians as a preliminary step in the international development of standards and methods."⁴ The National Committee on Vital and Health Statistics (NCVHS) was created in 1949 to fulfill this purpose in the U.S.

Over the past 30 years, numerous organizations, including the Institute of Medicine (IOM; now the National Academies of Sciences, Engineering, and Medicine), have evaluated the healthcare industry and reported on the imperative of adopting standardized terminologies and vocabularies for improving health care delivery and quality. In 1997, the IOM revised and updated its 1991 recommendations concerning the computer-based patient record, observing that vocabulary standards were necessary to ensure the integrity of clinical data in electronic health records (EHRs) -- its retrieval, interpretation, and exchange -- and that progress in improving health care would not be easily achieved without improvement in the scope, use, and automation of the patient record.⁵

Use of standardized terminology for reporting and reimbursement in clinical settings in the U.S. has evolved since the early days of Medicare and Medicaid (enacted 1965). The programs' use of national standardized forms for billing and claims and the related codes took longer to develop than expected. For example, the American Medical Association (AMA) first published the Current Procedural Terminology (CPT) codes for physician services in 1966 but use of CPT was not integrated into the broader Healthcare Common Procedural Coding System (HCPCS) until 1978.⁶ HCPCS was established to provide a standardized coding system for the description of covered services and items. Payment reform in the 1980s to address rising hospital costs (Social Security Amendments of 1983⁷) established Diagnosis Related Groups (DRG), a new prospective payment system to serve as the basis of Medicare's hospital reimbursement system. DRG is a statistical classification system, based on ICD morbidity and

² World Health Organization. Classifications [Internet]. Geneva, Switzerland: World Health Organization; [updated 2018 Feb 23; cited 2018 May]. Available from: <http://www.who.int/classifications/icd/en/>.

³ World Health Organization. Classifications [Internet]. Geneva, Switzerland: World Health Organization; [updated 2018 Feb 23; cited 2018 May]. Available from: <http://www.who.int/classifications/icd/en/>.

⁴ Kanaan SB. The National Committee on Vital and Health Statistics 1949-99: A History. Hyattsville (MD): Centers for Disease Control and Prevention: National Center for Health Statistics (U.S.); 2001 Sep. 33 p.

⁵ Institute of Medicine. The Computer-Based Patient Record: An Essential Technology for Health Care. Washington, DC: The National Academies Press; 1991.

⁶ New CMS Coding Changes Will Help Beneficiaries: Improvements Will Speed Use of Technology: CMS MEDICARE NEWS [Internet]. Washington DC: Centers for Medicare and Medicaid Services; 2004, October 6 [cited June 2018]. Available from: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/downloads/HCPCSReform.pdf>.

⁷ Social Security Amendments of 1983. H.R. 1900/P.L.98-21 (April 20, 1983).

procedure codes, that pays a flat amount based on the average cost of care for hospital services. Concerns were raised about this new system given the dependence of DRGs on ICD-9-CM which was clinically imprecise.⁸ In 1996, with health care costs continuing to rise and growing concerns about quality and access, the Presidential Advisory Commission on Consumer Protection and Quality in the Health Care Industry was established. In its final report, *Quality First: Better Healthcare for All Americans*, the Commission highlighted the then-recent passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and the NCVHS role in overseeing its implementation. The Commission recommended that national standards for the structure, content, definition, and coding of health information be established to support improvements in information systems. The Commission called on the U.S. Federal Government to consult with public and private stakeholders to assess what additional standards may be necessary to support such improvements:

“Whenever possible, this effort should encourage the widespread adoption of existing standards and build on the work of existing public and private entities rather than creating additional layers of oversight. The need also exists to consider standards as they are developing in the international marketplace to facilitate the global exchange of medical and health care information and to drive the development of international standards.”

The Commission cautioned that “differing interests and requirements of various actors in the system, both public and private, have made the development of standards a difficult process... A related problem is that existing coding schemes are not sufficiently rich to provide the level of clinical precision needed for quality measurement,” citing a study that found that “the major clinical classifications in use today incompletely cover the clinical content of patient records; thus analytical conclusions that depend on these systems may be suspect.”⁹ With the exception of measures for mortality and readmissions, performance measurement and quality improvement largely required clinical data abstracted from medical charts.

Another recommendation of the Commission resulted in the establishment of the National Quality Forum (NQF) in 1999. Established to bring consistency and consensus to the definition of health quality measures in use by both the public and private sectors, the NQF uses a formal measure endorsement and maintenance process. Since 2012, NQF has been increasingly involved in the consideration of ‘eMeasures’. eMeasures, intended for use in conjunction with electronic health records, use standard clinical vocabularies, such as SNOMED CT, LOINC, and RxNorm, as well as ICD-10-CM.¹⁰

⁸ Case-mix Measurement and Assessing Quality of Hospital Care [Internet]. Health Care Finan Rev. 1987(Suppl) [cited 2018 Mar]. pp 39-48. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4195096/>.

⁹ President’s Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Final Report [Internet]. Rockville, MD: Agency for Healthcare Research and Quality; [1998 Mar 12; cited 2018 Aug]. Available from: <https://archive.ahrq.gov/hcqual>.

¹⁰ National Quality Forum. What we do [Internet]. Washington DC: National Quality Forum; [updated 2018; cited 2018 Aug]. Available from: http://www.qualityforum.org/what_we_do.aspx.

Health Insurance Portability and Accountability Act (HIPAA)

The 1996 Health Insurance Portability and Accountability Act (HIPAA) established a process for identifying and establishing national code set standards that includes and goes beyond those used for recording morbidity and mortality. Part of the reason for including standards in the HIPAA legislation was to provide a mechanism for effectively moving from ICD-9-CM to ICD-10-CM/PCS. Prior to passage of the HIPAA legislation there was no mechanism or process in place within the U.S. for methodically evaluating the move that impacted all aspects of the health care community.

Under HIPAA, the Secretary of the Department of Health and Human Services (HHS) was authorized to facilitate administrative simplification through the adoption of standards for transactions, data elements for such transactions, and to enable the electronic exchange of health information. While HIPAA authorized the Secretary to adopt standards for transactions, it also recognized the potential need for standards for other aspects of the health care sector, and a mechanism for choosing the best standard for a purpose. The responsibility for these last two items was placed with NCVHS. Specifically, NCVHS was directed to “study the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information”¹¹ and provide a report to the Secretary of HHS by the year 2000 with recommendations and legislative proposals for standards for electronic exchange.

Unified Medical Language System (UMLS)

The UMLS, developed by NLM in the 1990s, started as an effort to overcome two (at the time) significant barriers to effective retrieval of machine-readable information: 1 - the variety of ways the same concepts are expressed in different sources and by different people, and 2 - the distribution of useful information among many disparate databases and systems. Today the UMLS consists of three knowledge sources, the Metathesaurus (including 150+ terminologies and vocabularies, concepts, relationships, and attributes), semantic network (including semantic types (categories) and semantic relationships), and lexical resources (including the SPECIALIST lexicon and lexical tools). The primary UMLS resource, the Metathesaurus, clusters synonymous terms from different terminologies by meaning into a single concept under a concept unique identifier (CUI). A default preferred term is assigned for each CUI, however users can select a different preferred term to better suit their use case. The semantic network includes broad subject categories (e.g., clinical drug, virus) and links between categories (e.g., ISA, causes, treats) to make up the semantic relationships. These semantic types and relationships form the structure of the semantic network which can be used to broadly categorize the biomedical domain.

Another critical aspect of the UMLS project has been the development of the UMLS Terminology Services (UTS), a one stop shop for terminology distribution and dissemination. The terminologies available from the UTS are all covered by the UMLS Metathesaurus License, allowing users to obtain basic access to these terminologies for free. Some of the resources included in the UMLS

¹¹ Health Insurance Portability and Accountability Act (HIPAA) of 1996 [Internet], Pub. L. 104-191, 110 Stat 1936 (Aug 21, 1996) [cited 2018 Aug]. Available from: <https://www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf>

Metathesaurus have regular update schedules, whereas others have irregular update schedules. While the Metathesaurus provides a new versioned release two times a year, only those resources that provided revisions are updated in the new version of the Metathesaurus. Additionally, the UTS allows users to obtain SNOMED CT (the Affiliate License is incorporated as Appendix 2 in the UMLS Metathesaurus License) and RxNorm in their native form. The NLM also uses the UTS to ensure copyright compliance on a variety of additional terminology tools and resources (e.g. Value Set Authority Center (VSAC) and AccessGUDID).

Terminology and Vocabulary Milestones

In the early 1990's NCVHS was hearing "calls for greater leadership on the part of the Federal Government in developing data standards, especially regarding terminology and its use."¹² To address this issue, coupled with the knowledge that healthcare legislation was being proposed, NCVHS began holding hearings to clarify the basic needs of the healthcare community regarding data collection and analysis. Subsequent recommendations to the Secretary of HHS were provided, initially to inform and guide the discussion and then to address implementation of the legislation.¹³ NCVHS began meeting its new responsibilities under HIPAA in 1998 by publishing initial guiding principles for the selection of standards to be adopted by the Secretary.¹⁴

In 2000, the Committee published its first report on patient medical record information (PMRI) including an overall framework, refined guiding principles for selecting PMRI standards and an initial set of recommendations. Another set of recommendations followed in 2003.^{15 16 17 18} NCVHS established a

¹² Jones JM. The National Committee on Vital and Health Statistics, 1993 [Internet]. Hyattsville (MD): Centers for Disease Control and Prevention: National Center for Health Statistics; 1994 May. [cited 2018 Aug]. 95 p. Available from: <https://www.cdc.gov/nchs/data/ncvhs/nchvs93.pdf>.

¹³ U.S. Department of Health and Human Services. National Committee on Vital and Health Statistics (NCVHS). 50th Anniversary Symposium Report [Internet]. Hyattsville (MD): Centers for Disease Control and Prevention: National Center for Health Statistics; 2000, June [cited 2018 Aug]. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/ncvhs50th.pdf>.

¹⁴ National Committee on Vital and Health Statistics. First Annual Report to the Congress on the Implementation of HIPAA, NCVHS Website for Recommendations, Report, & Presentations [Internet]. 1998 Feb 3 [cited 2018 Aug]. Available from: <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/yr1-rpt-508.pdf>.

¹⁵ National Committee on Vital and Health Statistics. Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information as Required by the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act of 1996 [Internet]. Washington (DC): National Committee on Vital and Health Statistics (U.S.); 2000 Jul [cited 2018 Aug]. 65 p. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf>.

¹⁶ National Committee on Vital and Health Statistics. Letter to the Secretary: Recommendations for the First Set of PMRI Standards [Internet]. Washington (DC): National Committee on Vital and Health Statistics (U.S.); 2002 Feb [cited 2018 Aug]. Available from: <https://ncvhs.hhs.gov/rrp/february-27-2002-letter-to-the-secretary-recommendations-for-the-first-set-of-pmri-standards/? sf s=PMRI& sft rp categories=recommendation-letter-to-the-secretary>.

¹⁷ National Committee on Vital and Health Statistics. Letter to the Secretary: Recommendations for the Second Set of PMRI Standards [Internet]. Washington (DC): National Committee on Vital and Health Statistics (U.S.); 2003 Nov [cited 2018 Aug]. 8 p. Available from: <https://ncvhs.hhs.gov/wp-content/uploads/2014/05/031105lt3.pdf>.

precedent of building on previous work of the IOM and others. This approach of building on previous work would be adopted by subsequent authoritative groups working in this area.

The 2000 report led to two important initial actions:

- **SNOMED License** – the National Library of Medicine (NLM) negotiating for a U.S. wide license for use of SNOMED (achieved in 2003). SNOMED had previously been identified as the best fit for a general clinical terminology (once combined with READ codes) however it was considered too expensive for wide adoption. The negotiated license agreement ensured free usage of SNOMED CT within the U.S. to users who sign up for a free UMLS Metathesaurus License.
- **Consolidated Health Informatics (CHI)** – one of 24 electronic government initiatives begun in the early 2000's to support the President's Management Agenda (active 2001 – 2007). CHI was a "collaborative effort to adopt Federal government-wide health information interoperability standards to be implemented by Federal agencies in order to enable the Federal government to exchange electronic health information."¹⁹ The initiative was built on the premise that, because the Federal government represented more than 50% of healthcare spending within the U.S., if the Federal government could identify and begin using standard terminologies and vocabularies, it would offer a strong incentive for voluntary compliance by the remainder of the healthcare industry. The portfolio of 20 adopted standards in 26 domains was intended to be "used by all Federal agencies in implementing new, and to the extent possible, in modifying existing health information technology systems, as well as related business processes." NCVHS provided advice and a venue for public comment on the CHI recommendations, prior to being finalized.

Subsequent milestones:

2002 – NLM began producing RxNorm, a non-proprietary vocabulary that represents drugs at the level of granularity needed to support clinical practice. The initial model for RxNorm built upon work from Health Level Seven International (HL7) and benefited from joint work by NLM, the Food and Drug Administration, and the Department of Veterans Affairs.

2002 and 2003 – NCVHS letters to the HHS Secretary recommended adoption of PMRI standards. The letter also includes the recommendation to make NLM the central

¹⁸ National Committee on Vital and Health Statistics. Letter to the Secretary: ICD-10 Recommendations [Internet]. Washington (DC): National Committee on Vital and Health Statistics (U.S.); 2003 Nov [cited 2018 Aug]. Available from: https://ncvhs.hhs.gov/rrp/november-5-2003-letter-to-the-secretary-icd-10-recommendations-attachment-ii/?sf_action=get_data&sf_data=results&sf_s=ICD-10+&sf_rp_categories=recommendation-letter-to-the-secretary.

¹⁹ Office of the Secretary, HHS (US). Consolidated Health Informatics (CHI) Initiative; Health Care and Vocabulary Standards for Use in Federal Health Information Technology Systems [Internet]. Final rules. Fed Regist. 2005 Dec 23 [cited 2018 Jun];70:76287-76288. Available from: <https://www.federalregister.gov/documents/2005/12/23/05-24289/consolidated-health-informatics-chi-initiative-health-care-and-vocabulary-standards-for-use-in>

coordinating body for clinical terminology standards within HHS (so designated in 2004) and that rulemaking for the move to ICD-10-CM/PCS commence.

- 2004** – President Bush, first in his State of the Union Address, and in subsequent statements, called for widespread adoption of electronic health records within 10 years, doubling funding to \$100 million for demonstration projects on healthcare information technology, and creating a new sub-Cabinet position of National Health Information Technology Coordinator, reporting to the HHS Secretary. The National Coordinator began investigating the mechanisms available to the federal government for naming standards for health information technology.
- 2005** – The National Coordinator established the Healthcare Information Technology Standards Panel (HITSP; active 2005 – 2010). HITSP was a joint public and private organization. Built upon the work of CHI by again focusing on domains and using the CHI recommendations as a starting point. HITSP produced U.S. Interoperability Specifications that were required for use in federal Health Information Technology (HIT) systems and recommended for use in the private sector.
- 2007** – The International Health Terminology Standards Development Organisation (IHTSDO) was established to purchase the intellectual property rights to SNOMED CT (and all antecedent versions) from the College of American Pathologists (CAP). NLM joined the IHTSDO as the U.S. Member on behalf of HHS to ensure continued free access to SNOMED CT within the U.S. Creation of the IHTSDO highlighted the need to view healthcare and terminology standards as a global, rather than national issue.
- 2009** – The Health Information Technology for Economic and Clinical Health Act (HITECH), part of the American Recovery and Revitalization Act (ARRA), established the Office of the National Coordinator for Health Information Technology (ONC) in law and created two new federal advisory committees, the Health Information Technology Policy Committee and the Health Information Technology Standards Committee, to advise the National Coordinator and the Secretary of HHS on matters related to standardization, certification, adoption and implementation of EHR systems; and established programs to encourage the meaningful use of EHRs by health professionals and hospitals that serve the Medicare and Medicaid populations. The advisory committees used the output of both CHI and HITSP as a starting point for formulating their recommendations for standard terminologies.
- 2013** – Clinical Data Architecture (CDA) was introduced into Meaningful Use Stage 2 to support care coordination and patient engagement use cases. CDA defines the structure of building blocks used to contain a multitude of healthcare data elements that can be captured, stored, accessed, displayed and transmitted electronically for use and reuse in many formats.
- 2015** – ICD-10-CM and ICD-10-PCS became effective as the HIPAA named standard replacing ICD-9-CM Volumes 1, 2, and 3. The procedure coding system (PCS) was a new

classification system developed for the Centers for Medicare and Medicaid Services and not based on an international ICD standard as had been the case with earlier versions of procedure classification.

- 2015** – Under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) the Medicare EHR Incentive Program as it applies to physicians, commonly referred to as Meaningful Use, was transitioned to become one of the four components of the new Merit-Based Incentive Payment System (MIPS) for physicians. MIPS harmonizes existing CMS quality programs (including meaningful use), the Physician Quality Reporting System, and Value-Based Payment Modifiers. MIPS consolidates multiple, quality programs into a single program to improve quality care.²⁰
- 2016** – The 21st Century Cures Act merged the two advisory committees established under HITECH into one called the Health Information Technology Advisory Committee (HITAC). HITAC is charged with making recommendations to the National Coordinator for Health Information Technology on policies, standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information.²¹
- 2018** – As required by the Cures Act, ONC developed (and HITAC approved) a draft Trusted Exchange Framework; public comments received are still under review at the time of this publication. The final Trusted Exchange Framework and Common Agreement will set common principles, terms, and conditions that facilitate trust between disparate health information networks. The draft specifies use of the US Core Data for Interoperability (USCDI), a core data set that will provide semantic standards for data to be exchanged so it can be accurately captured, accessed, exchanged, understood, and used. The core data set will be expanded and modified according to an annual update cycle.
- 2018** – CMS announces “Promoting Interoperability”, an overhaul of the Medicare and Medicaid EHR Incentive Programs (commonly known as Meaningful Use) to focus on interoperability, improve flexibility, relieve burden and place emphasis on a reduced set of measures that require the electronic exchange of health information between providers and patients.

²⁰ The Office of the National Coordinator for Health Information Technology. Meaningful Use [Internet]. Washington (DC): The Office of the National Coordinator for Health Information Technology; [updated 2017 Sep 05; cited 2018 May]. Available from: <http://www.healthit.gov/topic/federal-incentive-programs/meaningful-use/>.

²¹ The Office of the National Coordinator for Health Information Technology. Health Information Technology Advisory Committee (HITAC) [Internet]. Washington (DC): The Office of the National Coordinator for Health Information Technology; [updated 2018 Apr 05; cited 2018 May]. Available from: <http://www.healthit.gov/hitac/committees/health-information-technology-advisory-committee-hitac/>.

Key Organizations

The standard terminologies and vocabularies used in the U.S. are not created by one entity but a group of organizations both federal and non-federal, national, and international. To fully understand the environment of health terminologies and vocabularies one needs to understand the role of these key organizations.

It is important to remember that standards are never complete but must be maintained over time as knowledge of medicine and healthcare evolve. As such, these organizations generally have an ongoing role until and unless their activities are assumed by another organization.

Federal Agencies - Responsible for national regulations, selecting appropriate standards, removing barriers to use, enabling distribution, direct development and/or funding support to ensure their availability.

U.S. Department of Defense (DoD) – One the largest healthcare providers within the federal government, the DoD actively works with HHS and VA to facilitate interoperability.

U.S. Department of Health and Human Services (HHS):

U.S. Centers for Disease Control and Prevention (CDC):

National Center for Health Statistics (NCHS) – NCHS is responsible for the creation and maintenance of ICD-10-CM and the ICD-10-CM Official Guidelines for Coding and Reporting. NCHS is also one of the ICD-10-CM/PCS Cooperating Parties involved in the publication of Coding Clinic for ICD-10-CM and ICD-10-PCS (formerly Coding Clinic for ICD-9-CM) developed with unanimous agreement of the Cooperating Parties. NCHS also serves as the Collaborating Center for North America that assists World Health Organization and users with the development, dissemination, implementation and update of WHO-FIC classifications.

Public Health Information Network (PHIN) – Provides tools and resources to facilitate electronic exchange of health data and information between public health agencies. Includes access to the PHIN Vocabulary Access and Distribution System (PHIN VADS).

U.S. Centers for Medicare & Medicaid Services (CMS) – CMS is responsible for the development, maintenance, and distribution of ICD-10-PCS and the ICD-10-PCS Official Guidelines for Coding and Reporting, CMS is also one of the ICD-10-CM/PCS Cooperating Parties involved in the publication of Coding Clinic for ICD-10-CM and ICD-10-PCS (formerly Coding Clinic for ICD-9-CM) developed with unanimous agreement of the Cooperating Parties. CMS also produces Healthcare Common Procedure Coding System (HCPCS) Level II codes and coordinates with AMA on HCPCS Level 1 codes.

U.S. Food and Drug Administration (FDA) – Produces drug inserts, the National Drug Code (NDC), the unique ingredient identifier (UNII) for use in the Substance Registration System, and the unique device identifier (UDI). FDA also provided content expertise in development and maintenance of medical product representation in HL7 Structured Product Labeling (SPL), and provided technical advice on the initial development of the Global Medical Device Nomenclature (GMDN) and supports the use of both GMDN and SNOMED CT for medical device categorization. The FDA supports Medical Dictionary for Regulatory Activities (MedDRA) as a medical terminology developed by ICH to facilitate sharing of regulatory information internationally for medical products used by humans.

U.S. National Library of Medicine (NLM) – Designated central coordinating center for clinical terminology standards within HHS, ensures core terminologies are available (SNOMED, LOINC, RxNorm), as well as 150+ additional terminologies via the Unified Medical Language System (UMLS) Metathesaurus. NLM developed, maintains, and licenses several tools and resources for health information technology and health data standards including the UMLS, RxNorm, SNOMED CT (both International and US Editions), Value Set Authority Center (VSAC), and Medical Subject Headings (MeSH).

Office of the National Coordinator for Health Information Technology (ONC) – Principal federal entity charged with coordination of nationwide efforts to support the adoption of health information technology and the promotion of nationwide health information exchange to improve healthcare through EHR certification and promulgation of other regulations.

U.S. Social Security Administration (SSA) – Administers the social insurance program consisting of retirement, disability, and survivors' benefits.

U.S. Department of Veterans Affairs (VA) – One the largest healthcare providers within the federal government, the VA actively works with HHS and the Department of Defense to facilitate interoperability. Produces the Medication Reference Terminology (MED-RT) and its predecessor the National Drug File - Reference Terminology (NDF-RT).

Non-Federal Agencies – standards development organizations (SDOs) and others with a significant stake in standard terminologies. These represent both U.S. and International organizations.

American Dental Association (ADA) – Developed and maintains Code on Dental Procedures and Nomenclature (CDT) and the Systematized Nomenclature of Dentistry (SNODENT), an official subset of SNOMED CT.

American Hospital Association (AHA) – Maintains the *Coding Clinic* for ICD-10-CM/PCS, an official resource created through a formal cooperative agreement between the AHA,

AHIMA, CDC/ NCHS, and CMS. This agreement established these organizations as “Cooperating Parties” that must unanimously approve *Coding Clinic* content and the *ICD-10-CM/PCS Official Guidelines for Coding and Reporting*.

American Health Information Management Association (AHIMA) – One of the ICD Cooperating Parties responsible for approving *ICD-10-CM/PCS Official Guidelines for Coding and Reporting* and AHA’s *Coding Clinic* for ICD-10-CM/PCS.

American Medical Association (AMA) – Developed, maintains, and licences Current Procedural Terminology (CPT).

American Medical Informatics Association (AMIA) – AMIA is a non-profit organization formed by the merger of the American Association for Medical Systems and Informatics, American College of Medical Informatics, and Symposium on Computer Applications in Medical Care. AMIA provides support for informatics education, science, and practice.

College of American Pathologists (CAP) – Original developer of SNOMED CT and all previous versions prior to purchase of the intellectual property rights in 2007 by SNOMED International. Produces eCC (electronic Cancer Checklists).

National Academies of Sciences, Engineering, and Medicine (NASEM) - Includes the former Institute of Medicine (IOM). NASEM provides independent, objective, evidence-based advice on matters of medicine, health, biomedical sciences, and health policy.

Regenstrief Institute – Developed, maintains, and licences LOINC (Logical Observation Identifiers Names and Codes) and UCUM (Unified Code for Units of Measure).

SNOMED International (Trading name of the International Health Terminology Standards Development Organisation (IHTSDO)) – Owns, maintains, and licences SNOMED CT.

World Health Organization (WHO) – Develops, maintains and licenses the family of international classifications including the International Classification of Diseases (ICD), International Classification of Functioning, Disability and Health (ICF), the International Classification of Health Interventions (ICHI) and other classifications.

Selection of Standards for Adoption

With the enactment of HIPAA, the U.S. government role in the collection, exchange, and protection of health data according to nationally established standards was explicitly recognized.

In the early 1990’s, following advice from industry experts, HHS began laying out the steps needed to achieve health data standards to enable interoperability of health care systems within the U.S. These steps have been reiterated and reaffirmed over the years by reports from the IOM, NCVHS, and other

experts.^{22 23 24 25} The NCVHS recommendations and Guiding Principles from the 2000 PMRI report²⁶ as well as subsequent NCVHS recommendations are reflected in the HHS approach. It is important to note that it was always the intent of HHS and NCVHS to introduce an iterative process wherein decisions are made using the best available information at the time, subject to review and revision as lessons were learned through practical experience. The HHS steps are:

- **Establish a mechanism for designating U.S. standards**

Healthcare in the U.S. is not centralized so there is no one organization with the authority to designate health data standards. To achieve interoperability there must be consistent standards across U.S. federal and state agencies as well as the private sector. The U.S. federal government is the closest candidate, but, unless authorized by Congress, the federal government can only place requirements on federal systems and make recommendations to the private sector. For standards to be effective at a national level, they would need to be chosen with input from both the public and private sector. HHS has used several mechanisms since 1996, including congressional legislation, each building upon the work of the previous mechanisms:

- **Health Insurance Portability and Accountability Act of 1996 (HIPAA)** – Under the Administrative Simplification provisions of HIPAA, the Secretary of HHS was authorized to facilitate administrative simplification through the adoption of standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically. NCVHS was charged with studying issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information. Tasking the NCVHS with this study ensured the private sector would have a voice in the process.
- **Consolidated Health Informatics Initiative (CHI)** – From 2001 - 2007 CHI evaluated standards that would be best for 26 domains of health. The selected standards were required for use in U.S. Federal government systems for the electronic exchange of clinical health information. This federal adoption offered a strong incentive to encourage use of standards in the private sector since more than 50% of healthcare

²² Commission on Systemic Interoperability. Ending the Document Game: Connecting and Transforming Your Healthcare Through Information Technology [Internet]. 1st ed. Washington (DC): U.S. Government Printing Office; 2005 [cited 2018 Aug]. 250 p. Available from: <https://endingthedocumentgame.gov/PDFs/entireReport.pdf>.

²³ Institute of Medicine. The Computer-Based Patient Record: An Essential Technology for Health Care. Washington, DC: The National Academies Press; 1991.

²⁴ Cimino JJ. Desiderata for Controlled Medical Vocabularies in the Twenty-First Century. *Methods Inf Med*. 1998 Nov; 37(4-5):394-403.

²⁵ Chute CG, Cohn SP, Campbell JR. A Framework for Comprehensive Health Terminology Systems in the United States: Development Guidelines, Criteria for Selection, and Public Policy Implications. *J Am Med Inform Assoc* [Internet]. 1998 Nov-Dec [cited 2018 Aug]; 5(6):503–510. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC61331/>.

²⁶ National Committee on Vital and Health Statistics. Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information [Internet]. Washington DC: National Committee on Vital and Health Statistics; 2000 [cited 2018 Jun]. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf>.

within the U.S. is purchased by the federal government. While the private sector did not formally participate in the process, they were aware of the initiative and often consulted for advice and expertise.

- **Healthcare Information Technology Standards Panel (HITSP)** – From 2005 – 2010 HITSP was a joint public and private organization. ONC was created with the authority to formally interact with the private sector to facilitate interoperability of healthcare systems. Under ONC’s authority CHI was transitioned to HITSP in order to formally incorporate participation of the private sector. Outcomes of HITSP were U.S. Interoperability Specifications required for use in federal HIT systems and recommended for use in the private sector.
- **Health Information Technology for Economic and Clinical Health Act (HITECH)** – Part of the American Recovery and Revitalization Act (ARRA) passed by Congress in 2009. HITECH introduced incentive programs to encourage the meaningful use of EHRs by health professionals and hospitals that serve the Medicare and Medicaid populations. By establishing two Federal Advisory Committees (Health Information Technology Policy Committee and Health Information Technology Standards Committee) Congress ensured the private sector had a continuing voice in the process.
- **Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)** – In 2015 Congress passed legislation transitioning meaningful use to become one of the four components of the new Merit-Based Incentive Payment System (MIPS).
- **21st Century Cures Act** – The two advisory committees established under HITECH were merged into one Federal Advisory Committee called the Health Information Technology Advisory Committee (HITAC) with ONC charged to evaluate the need for a core common set of data elements. This approach streamlined the process and again ensured the private sector has a continuing voice in the process.

Each activity, either through initial legislation or initial charter, began their work by recording their approach and the criteria by which they would designate standards.

- **Pick best available standard as a starting point**
Most individuals, upon realizing they need a terminology, assume they need to develop a new one to suit their use case. This assumption may be made without knowing what terminologies already exist or the high cost to develop and maintain a terminology. HHS instead encourages evaluation of existing terminologies to determine if one will suit the needs of the individual’s use case. This evaluation may show the needed codes already exist (either as is or with small modifications) or that the needed codes can be created because they would fit within the scope of the terminology. Building on existing terminologies rather than creating new ones also helps facilitate interoperability across the healthcare industry.

In 1996 NLM conducted a large-scale vocabulary test using the UMLS to demonstrate “the ability of the test vocabularies to serve as a source of controlled vocabulary for health data

systems and applications.” The test was designed to “provide the basis for realistic resource estimates for developing and maintaining a comprehensive “standard” health vocabulary that is based on existing terminologies.”²⁷ NCVHS, as well as the various groups tasked with designating U.S. standards, started their work by evaluating existing terminologies to determine their suitability. Those new to standards development may not be aware of this approach so educational materials are needed as the use of standardized terminologies expands to new domains.

- **Support development, maintenance, and low/no cost distribution of selected standards to remove barriers to use**

While the “best available standards” could be identified as a starting point, many candidate terminologies had clear barriers to use that had to be removed before they would be accepted as standards by the healthcare community. For example, SNOMED (once merged with the United Kingdom’s READ Codes) was identified as the best general purpose clinical terminology but few wanted to adopt SNOMED given the high cost to license. NLM, on behalf of HHS, worked with CAP to put in place a license for free use of SNOMED CT within the U.S. thus removing this barrier to use in 2003. NLM now serves as the US Member to SNOMED International, on behalf of HHS, to ensure continued free access to SNOMED CT within the U.S. Similarly, LOINC was considered the best available terminology for reporting laboratory information but funding for continued maintenance was not initially guaranteed so many were reluctant to adopt the standard. NLM established a contract with the Regenstrief Institute, the owners of LOINC, to ensure the ongoing maintenance and free distribution of LOINC thus removing this usage barrier.

- **Coordinate development of selected standards to minimize redundant effort**

“No single terminology has the depth and breadth to represent the broad spectrum of medical knowledge; thus, a core group of well-integrated, nonredundant clinical terminologies will be needed to serve as the backbone of clinical information and patient safety systems.”²⁸

Standards development organizations (SDO) of well-managed terminologies establish clearly defined scope and purpose of their terminology. This scope and purpose, developed and refined to meet the ever-evolving needs of their user community, allows the SDO to set the boundaries of what will or will not be included in the terminology. In many cases the scope of two terminologies will overlap but the purpose (the lens through which the user community views the world) will differ. For example, both NDC and RxNorm cover drugs. The purpose of NDC is to provide a unique identifier for branded products and the purpose of RxNorm is to provide a unique identifier of drug substance and dose form to identify all the branded products

²⁷ Humphreys BL, Hole WT, McCray AT, Fitzmaurice JM. Planned NLM/AHCPR Large-scale Vocabulary Test: Using UMLS Technology to Determine the Extent to Which Controlled Vocabularies Cover Terminology Needed for Health Care and Public Health. *J Am Med Inform Assoc* [Internet]. 1996 Jul 01 [cited 2018 Mar];3(4):281-287. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC116311/>.

²⁸ Institute of Medicine (US) Committee on Data Standards for Patient Safety. *Patient Safety: Achieving a New Standard for Care* [Internet]. Aspden P, Corrigan JM, Wolcott J, Erickson SM, editors. Washington DC; Institute of Medicine of the National Academies, National Academies Press (US); 2004 [cited 2018 Aug]. Available from: <https://www.nap.edu/read/10863/chapter/1>.

that contain the same substance. In these cases, the links between the overlapping terminologies in the UMLS Metathesaurus provides rich definitions that are not present in either terminology. This richness can be further enhanced by using the UMLS Metathesaurus as a concept map with natural language processing (NLP) algorithms. When two named standards have the same scope *and* purpose the result is redundant concepts that are expensive to maintain and lead to confusion in the user community when it is unclear which terminology to use for a given purpose. To reduce redundant overlaps HHS specified the use associated with named standards. In growth areas (e.g. genomics) more than one SDO may expand their scope and purpose to include this new domain. Where appropriate HHS works with the SDOs to remove redundancies.

Today this is very much a work in progress. International influences on SDOs also affect decisions about national approaches. For example, the U.S. government's approach is adoption of a suite of vocabulary standards to support interoperability that includes SNOMED CT, LOINC, ICD-10 and RxNorm. In the United Kingdom, the approach is to minimize the number of vocabulary standards by pulling as much as possible into SNOMED CT.

- **Broaden participation in standards development**

Achieving interoperability requires participation of all sectors of the healthcare community. This means ensuring that all sectors have a seat at the table for evaluating and selecting named standards, as well as being active participants in the ongoing maintenance of said standards to ensure they meet all use cases. As is discussed later, progress has been made in openness and transparency of development and maintenance, but many interested and affected parties are not able to participate in meaningful ways. In its first report to Congress, NCVHS noted that "This implementation strategy was designed to assure coordination among HHS agencies, participation by other Federal departments, as well as interaction with the industry and the research and public health communities."²⁹ Today Federal agencies and the major SDOs are increasing efforts to reach out to and engage with all sectors of the community.

- **Promote use and improvement to the selected standards**

Standards, if they are to achieve their stated goal of enabling interoperability, need to be used and maintained over time. HHS utilizes several techniques to promote use of standards including early federal adoption (e.g. CHI), conformance and production testing, demonstration projects, and incentives (e.g. HITECH and MIPS). Once a standard is implemented, feedback from the user community is key to ensure the named standards are usable and meet the healthcare community's needs going forward. Today most SDOs have implemented an open and transparent maintenance process to facilitate and encourage open communication with the user community in accordance with the American National Standards Institute (ANSI) accreditation.

²⁹ National Committee on Vital and Health Statistics. First Annual Report to the Congress on the Implementation of the Administrative Simplification Provisions of the Health Insurance Portability and Accountability Act [Internet]. 1998 February 3 [cited 2018 Mar]. Available from: <https://ncvhs.hhs.gov/wp-content/uploads/2018/03/yr1-rpt-508.pdf>.

Evolving Levers for Standards Adoption

Under HIPAA, standards are adopted through regulatory processes. It is notable that PMRI standards are also being adopted through sub-regulatory levers associated with evolving use cases that rely on capturing, transmitting and using standardized health data. Examples include quality measures required for value payment,³⁰ criteria to determine eligibility for Promoting Interoperability (formally the EHR Incentive Program, commonly known as Meaningful Use),³¹ and uniform clinical data for the trusted exchange framework.³² CMS and ONC have used sub-regulatory levers to advance payer policy, the adoption of health IT, and exchange of health information at a pace that is far faster than could be achieved through regulation.

Relevant vocabularies and terminologies reflect current scientific knowledge. To be of value, vocabularies and terminologies must keep pace with developments. Realizing that lengthy regulatory processes could impede relevance, the original PMRI Guiding Principles called for “incorporating flexibility to more easily adapt to changes in the healthcare infrastructure (such as new services, organizations, and provider types) and changes in information technologies (such as new forms of data capture, knowledge representation and information presentation).” The complete list of PMRI Guiding Principles can be found in *Appendix 3: Guiding Principles for Selecting PMRI Standards*.

As discussed later, the time lag associated with the regulatory process may impede the ability of vocabularies and terminologies to support evolving uses. For example, advancing USCDI requires that underlying terminology standards be available and be widely used so codes are available for use in current versions of the exchange framework. Coordination and alignment are needed between USCDI and source terminologies and vocabularies to properly pace advancements.

Health Terminology Standards

Named Standards

This section summarizes the current U.S. named health terminology standards designated through the regulatory process under HIPAA or Promoting Interoperability (PI; formerly Medicare and Medicaid Incentive Program). This concise overview describes the core purpose for each named health terminology standard. Additional details can be found in *Appendix 1: Named Health Terminology*

³⁰ Centers for Medicare & Medicaid Services. CMS Value-Based Programs [Internet]. Baltimore, MD: U.S. Centers for Medicare & Medicaid Services; [updated 2018 June; cited 2018 July]. Available from: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/Value-Based-Programs.html>.

³¹ Centers for Medicare & Medicaid Services. Promoting Interoperability (PI) [Internet]. Baltimore, MD: U.S. Centers for Medicare & Medicaid Services; [updated 2018 May 31; cited 2018 July]. Available from: <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentivePrograms>.

³² The Office of the National Coordinator for Health Information Technology. Draft Trusted Exchange Framework [Internet]. Washington, DC: The Office of the National Coordinator for Health Information Technology; [updated 2018 Jan 5; cited 2018 Jul]. Available from: <https://www.healthit.gov/sites/default/files/draft-trusted-exchange-framework.pdf>.

Standards. The additional details include the coverage, overlaps, development and maintenance, partnerships, and dissemination of the specific standards. Beyond the named standards there are additional terminologies, vocabularies, and code systems in common use in the U.S. and around the world. Information about selected additional standards can be found in *Appendix 2: Additional Health Terminologies.*

| Named Terminology/Code Set Standard | Purpose |
|--|---|
| CDT | Documentation of dental services in patient health records, and reporting services (procedures) on claims submitted to dental benefit plans – HIPAA standard as HCPCS Level II “D” codes. |
| CPT | Billing for physician and other professional services and procedures; billing for hospital services and procedures in outpatient settings - HIPAA standard as HCPCS Level I. |
| HCPCS-Level II | Billing for products, supplies, and procedures not included in CPT. |
| ICD-10 | Mortality reporting. |
| ICD-10-CM | Morbidity in outpatient, inpatient and other care setting; Basis for Diagnosis Related Groups (DRG) and other grouper-based payment models in association with ICD-10-PCS. |
| ICD-10-PCS | Hospital reporting of inpatient procedures; Basis for DRG and other grouper-based payment models in association with ICD-10-CM. |
| LOINC | Electronic exchange of clinical and laboratory observations, measurements, and documents. |
| NDC | Product identifier for packaged prescription medications products approved by the FDA. |
| RxNorm | Communication of medication data. |
| SNOMED CT | Encode problem lists, procedures and some clinical findings (smoking status), as well as medical devices, allergies, history and family history. |
| Various standards are named in the eQMs. | Clinical Quality Measures - Requires EHR technology to be capable of capturing, exporting, importing, calculating, and electronically submitting the information necessary for clinical quality measures. |

Table 1: The list of terminology and code set standards for U.S. regulations and requirements for electronic

health data exchange.^{33 34}

CDT

Current Dental Terminology (also known as the Code on Dental Procedures and Nomenclature), is owned and maintained by the American Dental Association (ADA). CDT codes are available for distribution in the U.S. and internationally and are used for electronic and paper dental claims, and in electronic and paper patient records, to enable accurate, consistent, and uniform reporting of dental treatment. As mentioned above, the code set is included in Level II of the Healthcare Common Procedure Coding System (HCPCS) as CDT. CDT is a named HIPAA standard (August 17, 2000) and any claim submitted on a HIPAA standard electronic dental claim must use dental procedure codes from the version of the CDT Code in effect on the date of service. The CDT Code is also used on paper dental claims, and the ADA's paper claim form data content reflects the HIPAA electronic standard.

CPT

Current Procedural Terminology (CPT) is developed, copyrighted, and maintained by the American Medical Association (AMA). The terminology is primarily used in the U.S. but also used in other countries. The code set is used to report services and procedures provided by physicians and health care professionals, and by hospitals in outpatient settings. CPT must be licensed. The terminology is a named HIPAA Standard as HCPCS Level I.

HCPCS

Healthcare Common Procedure Coding System (HCPCS) is used by both public and private health care plans. HCPCS is divided into two principal subsystems – Level I and Level II.

HCPCS Level I

Level I contains Current Procedural Terminology (CPT), which is maintained by the American Medical Association (AMA), and is used primarily to identify medical services and procedures provided by physicians and health care professionals, and by hospitals in outpatient settings.

HCPCS Level II

Level II is a standardized code system maintained by CMS and used primarily to identify products, supplies, and services not included in the CPT codes. Current Dental Terminology (CDT) codes are a separate category of national codes, copyrighted to the American Dental Association (ADA), and are considered HCPCS Level II codes.

³³ Certification Guidance for EHR Technology Developers Serving Health Care Providers In-eligible for Medicare and Medicaid EHR Incentive Payments [Internet]. Washington (DC): The Office of the National Coordinator for Health Information Technology (U.S.); 2013 Sep 9 [cited 2018 Jul]. Available from: https://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13_0.pdf

³⁴ Anthony ES, Lipinski ML. 2015 Edition Final Rule: Overview of the 2015 Edition Health IT Certification Criteria & ONC Health IT Certification Program Provisions [Internet]. Washington (DC): The Office of the National Coordinator for Health Information Technology; 2015 Oct 28 [cited 2018 May]. Available from: https://www.healthit.gov/sites/default/files/onc_2015_edition_final_rule_presentation_10-28-15.pdf.

HCPCS Level III

Level III are HCPCS local codes, developed by state Medicaid agencies, Medicare contractors, and private insurers for use in specific programs and jurisdictions. Regulations provided for the elimination of Level III local codes by October 2002, at which time, the Level I and Level II code sets could be used. The elimination of local codes was postponed, because of section 532(a) of BIPA (Biometric Information Privacy Act), which continued the use of local codes through December 31, 2003.

International Classification of Diseases

In 1993, ICD-10 was completed and NCVHS recommended the replacement of ICD-9-CM. From 1993 through 1998 there were many public discussions regarding ICD-10 and the development of ICD-10-CM and ICD-10-PCS. In 1999, the U.S. adopted the use of ICD-10 for mortality. In 2003, ICD-10-CM was completed and from 2003 through 2008, ICD-10-CM was available for public evaluation and comment. In 2009, a 5-year implementation plan was started and in 2015, ICD-10-CM and ICD-10-PCS were formally adopted for use in the U.S. The following describes the WHO-FIC family of ICDs, and classifications related to ICD-10, which replaced ICD-9.

ICD-10

The International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) is owned by the World Health Organization (WHO). It is used to promote international comparability in the collections, classification, processing, and presentation of mortality statistics. It is used to track epidemiological trends. The 10th Edition replaced ICD-9. The classification is a named standard for cause of death coding from death certificates; in use in U.S. since 1999 (statutory basis).

ICD-10-CM

The WHO has authorized the development of an adaptation of the ICD-10 for use in the United States for U.S. government purposes. The National Center for Health Statistics (NCHS) is the U.S. Federal agency responsible for use of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) in the United States. NCHS has developed a clinical modification of the classification for morbidity purposes (ICD-10-CM). ICD-10-CM and the ICD-10-CM Official Guidelines for Coding and Reporting is used for diagnosis coding in clinical and outpatient settings and is a HIPAA standard (replacing ICD-9-CM Volumes 1 and 2) for morbidity in outpatient, inpatient and other care settings.

ICD-10-PCS

The International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) is maintained by the Centers for Medicare and Medicaid Services (CMS). CMS is the U.S. governmental agency responsible for overseeing all changes and modifications to the ICD-10-PCS. The code system is used for hospital reporting of procedures performed in hospital inpatient health care settings. It, along with *the ICD-10-PCS Official Guidelines for Coding and Reporting*, is a named HIPAA standard (replacing ICD-9-CM Volume 3) for hospital reporting of inpatient procedures.

LOINC

Logical Observation Identifiers Names and Codes (LOINC), is owned, maintained, and licensed by Regenstrief Institute, funded primarily by the NLM. LOINC is a globally used universal standard for identifying health measurements, observations, and documents. The terminology is a named standard for Meaningful Use in the U.S. The final rule for Meaningful Use Stage 2 specifies LOINC should be used for the electronic exchange of laboratory test results, clinical observations such as vital signs, social, psychological, and behavioral data, and documents such as care/referral summaries.

NDC

National Drug Codes (NDC) are a universal product identifier for packaged prescription medication products approved for human consumption. The NDC code denotes labeler, product, and commercial package size. The product labeler/manufacturer assigns two segments of the code and FDA assigns the third segment. The FDA produces the National Drug Code Directory. The NDC code is present on all nonprescription (OTC) and prescription medication packages and inserts in the U.S. It is used for billing and reimbursement purposes and varies depending on payer. Additionally, the NDC information and listing in the NDC Directory are used in the implementation and enforcement of the Act. It is a named HIPAA standard.

RxNorm

RxNorm is a normalized naming system for generic and branded drugs; and a tool for supporting semantic interoperability between drug terminologies and pharmacy knowledge base systems. It is owned and maintained by the NLM. The terminology represents the U.S. drug market but is available internationally. RxNorm is a named standard for Meaningful Use in the U.S. The final rule for Meaningful Use Stage 2 specifies RxNorm in the communication of medication data and medication allergies.

RxNorm and NDC

As described above, RxNorm is a normalized naming system for generic and branded drugs, used to support semantic interoperability between drug terminologies and pharmacy knowledge base systems. Hospitals, pharmacies, and other organizations use computer systems to record and process drug information. Because these systems use many different sets of drug names, it can be difficult for one system to communicate with another. To address this challenge, RxNorm provides normalized names and unique identifiers for medicines and drugs. The goal of RxNorm is to allow computer systems to communicate drug-related information efficiently and unambiguously.

However, the ability to share drug information across the extensive drug ecosystem (drug development, testing, distribution and regulation pipeline) is complex. In the case of NDC, it is required for use by both CMS and FDA, for two very different purposes.

SNOMED CT

SNOMED CT is a globally used clinical reference terminology for enabling detailed recording and automation of reasoning and analytical approaches to processing EHR data. The terminology standard is owned, maintained, and licensed by the International Health Terminology Standards Development Organisation (IHTSDO; trading name SNOMED International) an international, not-for-profit

organization. The NLM, on behalf of the Department of Health and Human Services, is the Member for the United States and licenses SNOMED CT for the U.S. Additionally, the NLM maintains and distributes the US Edition of SNOMED CT, a named standard for Meaningful Use in the U.S. In Stage 1 of Meaningful Use, it was required that EHR systems must encode problem list data in either SNOMED CT or ICD-9-CM. The final rule for Meaningful Use Stage 2 (and in the 2014 EHR Certification Criteria) expanded use of SNOMED CT and required EHR systems to use the US Edition of SNOMED CT for documenting problem lists, encounter diagnosis, procedures, and some clinical findings and vital signs such as smoking status.

Additional Standards

In addition to the named standards there are many additional terminologies, vocabularies, and code systems in common use in the U.S. and around the world. Information about selected additional standards can be found in *Appendix 2: Additional Health Terminologies*. The additional details include the coverage, overlaps, development and maintenance, partnerships, and dissemination.

The next section describes some of the current gaps in health terminology standards as well as the challenges, and issues being voiced around the health interoperability community.

Gaps in Content

A content gap can reflect the lack of a terminology or it can reflect the lack of adoption of a terminology as a named standard. Terminologies provide structured domain knowledge and are increasingly being used as the foundation of healthcare information systems. They have been widely used for encoding clinical data for diagnoses, problem lists, observations and billing. They are also used as knowledge-bases for natural language systems to identify structured concepts in unstructured clinical text notes. And encouragingly, the need and use of terminologies and vocabularies in healthcare continues to grow, as does recognition of the need for coverage of health-related domains beyond the direct provision of or payment for healthcare services and clinical research. As such, expanding the coverage of these resources becomes extremely important. "As our knowledge increases, so will the need to expand our terminology to specifically and unambiguously represent these new concepts. Thus, terminology development will never be "done"...."³⁵

With an understanding that an all-encompassing terminology or set of standards to encode all of health and healthcare will never be complete, it is beneficial to acknowledge the current known content gaps, regulation omissions, and health domain areas of interests, that could benefit from better representation in, or coordination with, health terminology standards. In the first part of this environmental scan we looked at the current landscape of health terminologies, vocabularies, and code systems, with a focus on the named standards. The next part of the environmental scan highlights some avenues of interest for content or regulation coordination efforts. Each of the key standards (SNOMED CT, LOINC, RxNorm, ICD) were developed with a specific use case and user community in mind. While

³⁵ Case JT. Are we really communicating? Standard terminology versus terminology standards in veterinary clinical pathology. *Vet Clin Pathol*. 2005; 34(1):5-6.

the coverage of these and other standards cover a large domain, there are still areas of health and medicine that are not included and where coordination and adoption for use should be strengthened. The following domains and areas should be taken into consideration for improved coverage or adoption of new health terminology standards.

Demographics

Demographic data - data that describe a population and particular groups within it - provide essential information for assessing individual health and community well-being. This is a vocabulary issue because various use cases include different demographic data elements. One example of this is the ONC Certification Criteria that includes a limited set of demographic data. Another example is the NCVHS Measurement Framework for Community Health and Well-Being.³⁶

Adding demographic data to facilitate the matching of patient records within and across a broad range of applications improves interoperability. In addition to meeting the needs of clinical stakeholders, this interoperability issue is also important to federal stakeholders who need the ability to connect patient data to national health data sets, particularly death sets. Two approaches to improving patient matching through standards have been discussed by the Health IT Advisory Committee. The first option builds upon existing standards from the U.S. Postal Services (USPS) for address. Use of the USPS approach to standardize the data elements has been recently tested and demonstrated significant improvement in the ability to match records. A second option is to standardize the collection of new data elements for matching. Select additions to the ONC criteria (e.g. email address) could improve interoperability.³⁷

Functioning

The International Classification of Functioning, Disability and Health (ICF) is available from WHO but there are few implementations in the U.S. The WHO defines a conceptualization where functioning is a 'dynamic interaction between a person's health and personal factors.'³⁸ The classification identifies six domains of functioning: cognition, mobility, self-care, getting along, life activities, and participation. Within the U.S., there is no current consensus on what is needed for terminologies describing functioning. The Social Security Administration has tried to implement ICF but due to the gap between contemporary ways of defining disability and how SSA operationalizes the statutory definition of disability, it was believed that ICF would need major modifications before it can be implemented by

³⁶ National Committee on Vital and Health Statistics. NCVHS Measurement Framework for Health and Well-being, V4 [Internet]. Washington DC: National Committee on Vital and Health Statistics: January 2017. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2013/12/NCVHS-Measurement-Framework-V4-Jan-12-2017-for-posting-FINAL.pdf>

³⁷ Morris G, Farnum G, Afzal S, Robinson C, Greene J, Coughlin C. Patient Identification and Matching Final Report Prepared for the Office of the National Coordinator for Health Information Technology [Internet]. 2014 Feb 7 [cited 2018 Mar]. Available from http://www.healthit.gov/sites/default/files/patient_identification_matching_final_report.pdf.

³⁸ World Health Organization. How to use the ICF: A practical manual for using the International Classification of Functioning, Disability and Health (ICF). Exposure draft for comment [Internet]. Geneva, Switzerland: World Health Organization; 2013 Oct [cited 2018 Mar]. 122p. Available from: <http://www.who.int/classifications/drafticfpracticalmanual.pdf>.

SSA.³⁹ The U.S. Department of Veterans Affairs requires content to be added and modified within SNOMED CT to support more accurate recording of functioning, disability, and health status along with direct mappings to ICF. Medicare requires reporting on functioning by outpatient therapy services (physical therapy, occupational therapy, and speech-language pathology) using G-codes defined by CMS that capture physical and not mental aspects of function.⁴⁰ In clinical practice, functioning is assessed by many provider types in many care settings. Some such assessments (tests, measures, patient-reported status) are represented in LOINC. Similarly, some functioning problems are represented in SNOMED CT. Although all three vocabularies have functioning content, they have been found to fulfill different roles.⁴¹

Gender and Sexuality

Content describing aspects of gender and sexuality are gaining traction within health and wellness fields stemming from current societal changes. The language around gender and sexuality continue to evolve rapidly as our understanding of these complex constructs become defined. Historically this area has not found consensus in the terms surrounding sexuality and gender⁴² and recent research strongly suggests there is much needed improvement in the searching and reporting in LGBT health systematic reviews - suggesting the ability to record gender and sexuality information is lacking in EHRs.⁴³ The 2015 Meaningful Use program defined a certification criteria to enable a user to record, change, and access sexual orientation data in SNOMED CT.⁴⁴ As the importance of recording health information surrounding personal identity increases, the need to update health terminologies becomes imperative.

Genetics/Genomics

Genomic targeted therapies and the rise of immunotherapy as common medical practice has revolutionized medicine. Drivers such as the Precision Medicine Initiative, a long-term research

³⁹ Rasch, Elizabeth & Brandt, Diane & Chan, Leighton. SSA-NIH-BU collaboration to improve the disability determination process: A conceptual and operational approach based on contemporary paradigms and novel assessment methods. 139st American Public Health Association Annual Meeting and Exposition, 2011, Oct 29-Nov 2; Washington Convention Center, Washington DC. Washington DC: APHA, 2011.

⁴⁰ Centers for Medicare & Medicaid Services. Functional Reporting [Internet]. Baltimore, MD: The Centers for Medicare & Medicaid Services; [updated 2014 May 01; cited 2018 Jul]. Available from: <https://www.cms.gov/Medicare/Billing/TherapyServices/Functional-Reporting.html>.

⁴¹ Vreeman DJ, Richoz C. Possibilities and implications of using the ICF and other vocabulary standards in electronic health records. *Physiother Res Int* [Internet]. 2015 Dec [cited 2018 Aug];20(4):210-219. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3907616/>.

⁴² Eliason MJ. An exploration of terminology related to sexuality and gender: arguments for standardizing the language. *Soc Work Public Health* [Internet]. 2014 Jan 9 [cited 2018 Jul]; 29(2):162-175. Available from: <https://www.tandfonline.com/doi/abs/10.1080/19371918.2013.775887>.

⁴³ Lee JG, Ylioja T, Lackey M. Identifying Lesbian, Gay, Bisexual, and Transgender Search Terminology: A Systematic Review of Health Systematic Reviews. *PLoS ONE* [Internet]. 2016 May 24 [cited 2018 Jul]; 11(5):e0156210. available from: <http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0156210&type=printable>.

⁴⁴ Office of the National Coordinator (US). 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications [Internet]. Final rules. *Fed Regist*. 2015 Oct 16;80 FR 62601: 62601-62759. [cited 2018 Jul]. Available from: <https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base>.

endeavor which aims to understand how the genetics, environment, and lifestyle of a person can determine the best approach to prevent or treat disease, motivate the use of standards for genomic content in EHRs.⁴⁵ The commonly used standard terminologies for EHRs have not historically included genomic content. The complexity, variety, and relatively rapid nature at which genetic information is achieved, adds to the difficulties in terminology coverage and standardized adoption for this domain.

The Human Phenotype Ontology (HPO) is a regularly used terminology for recording clinical phenotypes in research. HPO is used for the representation of phenotypes in the NIH-funded Undiagnosed Diseases Network and in ClinVar. The ontology was added to the UMLS Metathesaurus in 2015.⁴⁶ The integration of HPO within the UMLS could allow for synonymous linking between other terminologies such as SNOMED CT, with which much of clinical data are encoded, and LOINC for laboratory data. Furthermore, SNOMED International is working on an agreement with HPO to leverage the UMLS work and to provide stronger links between HPO and SNOMED CT data.

Gene Ontology (GO) is a collaborative project of ontologies describing molecular functions, biological processes, and cellular components. The GO is widely used for the functional annotation of gene products in humans and across a large variety of model organisms.⁴⁷ GO has been integrated into the UMLS Metathesaurus and there is currently less than 1% overlap with any other UMLS Metathesaurus resources.⁴⁸

Following the completion of the Human Genome Project in 2003, NLM started the development of Genetics Home Reference, a consumer health website that provides information for the general public about the effects of genetic variation on human health. GHR now covers over 1200 conditions and 1400 genes. GHR conditions are linked to standard terminologies including ICD, SNOMED CT, Orphanet, and OMIM.

Online Mendelian Inheritance in Man (OMIM) is a comprehensive, authoritative compendium of human genes and genetic phenotypes developed at Johns Hopkins University. The OMIM vocabulary has long been integrated in the UMLS. Along with other resources, it is used for the representation of medical phenotypes in ClinVar.

LOINC contains terms for genetic test orders and observations, including cytogenetic or mutation analysis tests, specific chromosomal alteration or mutation testing, and fully structured discrete genetic test reporting. The most current HL7 version 2 specifications for laboratory reporting includes guidance

⁴⁵ Genetics Home Reference. What is the Precision Medicine Initiative? [Internet]. Bethesda (MD): The U.S. National Library of Medicine, Lister Hill National Center for Biomedical Communications; 2015 Apr [updated 2018 May 29; cited 2018 May]. Available from: <http://ghr.nlm.nih.gov/primer/precisionmedicine/initiative/>.

⁴⁶ The U.S. National Library of Medicine. NLM Health Data Standards Executive Summary for 2015 [Internet]. Bethesda (MD); The U.S. National Library of Medicine. 2016 Jan 15 [cited 2018 May]. Available from: <https://www.nlm.nih.gov/healthit/executive-summaries/2015/index.html#umls/>.

⁴⁷ GeneOntology. GO FAQ [Internet]. Gene Ontology Consortium; 2006 Jun 06 [updated 2018 Mar 20; cited 2018 May]. Available from: http://wiki.geneontology.org/index.php/GO_FAQ/.

⁴⁸ Unified Medical Language System. GO (Gene Ontology) – Synopsis [Internet]. Bethesda (MD): The U.S. National Library of Medicine; 29 Sep 2008 [updated 2018 May 07; cited 2018 May]. Available from: <https://www.nlm.nih.gov/research/umls/sourcereleasedocs/current/GO/>.

for reporting clinical genetics tests, including discrete variants, complex variants, and pharmacogenomics studies. The implementation guide requires the use of LOINC, for identifying the tests being resulted and depending on the specific observation being reported, coded result values are drawn as appropriate from SNOMED CT, HPO, ICD, HGVS (Human Genome Variation Society) expressions, ISCN (International Sustainable Campus Network), COSMIC (Catalogue of Somatic Mutations in Cancer), or LOINC Answer codes.⁴⁹

Recently CPT has added the ability to report laboratory testing related to genomics, including codes for Proprietary Laboratory Analyses (PLA), Molecular Pathology (MoPath), Multianalyte Assays with Algorithmic Analyses (MAAA), and Genomic Sequencing Procedures (GSP).⁵⁰ Tests included in the PLA section must be commercially available in the U.S., and the PLA codes are available to any clinical laboratory or manufacturer that wants to specifically identify their tests. MoPath procedures involve the analyses of nucleic acids to detect genes variants that may be indicative of germline or somatic conditions, or to test for histocompatibility antigens. MAAAs are procedures that utilize multiple results derived from panels of analyses of various types, including molecular pathology assays, fluorescent in situ hybridization assays, and non-nucleic acid-based assays. And GSPs are DNA or RNA sequence analysis methods that simultaneously assay multiple genes or genetic regions relevant to a clinical situation.

The National Center for Biotechnology Information (NCBI), a center at NLM, has several resources that are used in biomedical research. ClinVar, which has been mentioned previously, aggregates information about genomic variation and its relationships to human health. The database facilitates access to and communication about the relationships asserted between human variation and observed health status, and the history of that interpretation. ClinVar processes submissions reporting variants found in patient samples, assertions made regarding their clinical significance, information about the submitter, and other supporting data. The alleles described in submissions are mapped to reference sequences, and reported according to the HGVS standard.⁵¹ Another resource, the Single Nucleotide Polymorphism database (dbSNP), is a collection of simple genetic polymorphisms (including single-base nucleotide substitutions, small-scale multi-base deletions or insertions, and retroposable element insertions and microsatellite repeat variations).⁵² The NCBI gene coding system coverage includes links to genetic diseases, and many of the genes included in the databases are prior to registration to HUGO Gene Nomenclature Committee (HGNC).

⁴⁹ Health Level Seven International. HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm [Internet]. Ann Arbor, MI: Health Level Seven International; [cited 2018 Jul]. Available from: http://www.hl7.org/implement/standards/product_brief.cfm?product_id=279.

⁵⁰ American Medical Association. Newly released codes [Internet]. Chicago, IL: American Medical Association; [cited 2018 Jul]. Available from: <https://www.ama-assn.org/practice-management/newly-released-codes>.

⁵¹ National Center for Biotechnology Information. What is ClinVar? [Internet]. Bethesda, MD: National Center for Biotechnology Information, National Library of Medicine; [updated 2016 Sep 1; cited 2018 Jul]. Available from: <https://www.ncbi.nlm.nih.gov/clinvar/intro/>.

⁵² National Center for Biotechnology Information. The NCBI Handbook - Chapter 5: The single nucleotide polymorphism database (dbSNP) of nucleotide sequence variation [Internet]. Bethesda, MD: National Center for Biotechnology Information, National Library of Medicine; [updated 2011 Feb 2; cited 2018 Jul]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK21088/>.

Finally, the HGNC is responsible for the syntax including unique symbols and names for human loci, and includes protein coding genes, ncRNA genes and pseudogenes. The HGNC is supported by the National Human Genome Research Institute (NHGRI), an Institute of the National Institutes of Health an agency of the U.S. Department of HHS.⁵³ A key aspect of -omic content is the fact that concept/term and code are not always sufficient in standardizing. The use of a series of approved symbols to define a functional or structural gene family is often utilized and currently the HGNC is the major player in the field with primarily researchers utilizing the standard gene nomenclature.

While many resources are available for researchers and clinical medicine, the current gap is in a clear recommendation or coordination surrounding the adoption of a standard(s) for genetics and genomics nomenclature.

Medical Devices

Medical devices cover a vast range of equipment and are essential for patient care. The WHO defines a medical device to mean any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for a specific purpose.⁵⁴

While FDA Unique Device Identifiers (UDI) is the standard for medical device identification in the U.S., the current gap is in the adoption of a standard for device nomenclature. Within the U.S. and internationally a few medical device terminologies are utilized for different use cases including Universal Medical Device Nomenclature System (UMDNS), Global Medical Device Nomenclature (GMDN), the unique device identifier (UDI), and SNOMED CT. UMDNS is an international nomenclature and coding system for the identification, processing, filing, storing, retrieving, and communication of data about medical devices. GMDN provides a classification system for medical devices and diagnostics and helps to facilitate data exchange between the manufacturers and regulators. And SNOMED CT is a used to encode clinical records, including medical procedures and devices, and the terminology and is linked to UDIs through a SNOMED-GMDN collaborative effort.

Through the SNOMED CT and GMDN harmonization effort, a portion of GMDN medical devices have been incorporated into SNOMED CT terminology and an equivalency table is available for those with a SNOMED CT Affiliate License and GMDN License. However, this table is not readily available due to GMDN licensing. Furthermore, the agreement ended in April 2017 and the justification for continued collaboration has not been strongly demonstrated. Currently the AccessGUDID system, the public application for obtaining device identification information submitted to the FDA, utilizes the equivalency map between SNOMED CT and GMDN for the UDI link.

⁵³ HUGO Gene Nomenclature Committee. FAQ about gene nomenclature [Internet]. Cambridgeshire, UK: European Bioinformatics Institute; [cited 2018 Jul]. Available from: <https://www.genenames.org/about/faq>.

⁵⁴ World Health Organization. Medical Device Regulations: Global overview and guiding principles [Internet]. Geneva, Switzerland: World Health Organization; 2003 [cited 2018 Aug]. 43 p. Available from: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf.

Mental Health

On-going concerns about the lack of approved standards for mental health continue to concern many. Two major manuals: International Classification of Diseases (ICD) and the Diagnostic and Statistical Manual of Mental Disorders (DSM), provide classification systems relevant to public health, clinical diagnosis, service provision, and research in the mental health domain. The National Institute of Mental Health's Research Domain Criteria is a framework based upon behavioral and neuroscience research. The DSM, currently in its 5th edition, is the most recognizable resource in the mental health domain. However, concerns regarding the validity and reliability of the diagnostic categories, as well as the way in which the latest edition was developed, continue to render the manual from being readily adopted.⁵⁵

Substance Abuse

Substance abuse is an area that spans disciplines including clinical (physical symptoms), mental health, and public health. Codes to document substance abuse need to cover both the classification (diagnosis of substance abuse as a condition) as well as the specific substance that is being abused (down to the chemical level). The substance being abused may or may not be a drug. If it is a drug, it may or may not be illicit.

Current named standards (such as ICD-10-CM and SNOMED CT) have some codes, but they are not created on a consistent basis to cover the full spectrum of the problem. Codes are available to capture the class of the disorder, but not necessarily down to the specific chemical, particularly where illicit drugs are concerned. Some suggest expanding RxNorm to cover all illicit drugs as it is designed to show not only chemical substances but also their relationship through categorization. This avenue is not being pursued since it goes beyond the current scope of RxNorm to cover prescription medicines that are approved for use by the FDA. NLM and NCHS are working to address the issue from a public health perspective. A consistent approach to cover all perspectives is needed.

Public Health

Public health practice has historically assessed population health status and problems through measures such as surveys, and vital statistics reporting. Some of these are data reported by healthcare professionals and aggregated across systems. Health information exchange (HIE) has allowed for more comprehensive clinical data to be made available to public health agencies in a timelier manner, however, the full potential of HIE has yet to be realized. Current EHR systems and most health terminologies have been primarily clinical in focus rather than for public health. Additionally, healthcare focus has begun shifting from simply treating the sick to including the affected, vulnerable, and healthy, with increasing demand for preventative and predictive care. One barrier to better integration has been due to the ambiguity of terminology within the public health domain.^{56 57 58} For example, it appears that

⁵⁵ Insel T. Post by Former NIMH Director Thomas Insel: Transforming Diagnosis [Internet]. Bethesda (MD): National Institute of Mental Health; 2013 Apr 29 [cited 2018 June]. Available from:

<https://www.nimh.nih.gov/about/directors/thomas-insel/blog/2013/transforming-diagnosis.shtml>.

⁵⁶ Chute CG, Koo D. Public Health, Data Standards, and Vocabulary: Crucial Infrastructure for Reliable Public Health Surveillance. J Public Health Manag Pract [Internet]. 2002 May 01 [cited 2018 Aug]; 8(3):11-17. Available from:

<https://www.ncbi.nlm.nih.gov/pubmed/15156620>.

⁵⁷ Revere D, Hills RH, Dixon BE, Gibson PJ, Grannis SJ. Notifiable condition reporting practices: implications for public health agency participation in a health information exchange. BMC Public Health [Internet]. 2017 Mar 11 [cited 2018 Jun]; 17:247. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28284190>.

the definition of many fundamental public health concepts (such as ‘health disparities’, ‘health inequalities,’ or ‘health equity’) are still up for debate and reaching consensus on standard terminologies would be helpful.^{59 60 61}

Rare Diseases

The domain of rare diseases has been suggested as a gap in terminology content coverage. In the United States, a rare disease is defined as a condition that affects fewer than 200,000 people. In the European Union, a disease is defined as rare when it affects fewer than 1 in 2,000 people.⁶² Increased attention on rare diseases has also resulted from an improved genetic, molecular, and biochemical understanding resulting from recent scientific and technological advances.⁶³ But, as similar with genomic terminology, the complexity, variety and rarity of these disease states, adds to the difficulty in coverage for this domain. Orphanet (maintained by INSERM) is a resource that provides information on rare diseases to a variety of stakeholders. The Orphanet Rare Disease Ontology (ORDO) is a structured vocabulary for rare diseases derived from the Orphanet database. In 2014, the European Commission Expert Group for Rare Diseases adopted a recommendation for EU member states to introduce Orpha codification (codes from Orphanet) in health information systems.⁶⁴ In May 2015, SNOMED International and INSERM signed an agreement to add rare disease content into SNOMED CT and to provide a complete linkage between SNOMED CT and Orphanet. This will allow for recording of rare diseases in the EHR and allow for linkages to rare disease data in other gene ontology databases (such as GO).

⁵⁸ McCullough JM, Goodin K. Clinical Data Systems to Support Public Health Practice: A National Survey of Software and Storage Systems Among Local Health Departments. *J Public Health Manag Pract* [Internet]. 2016 Sep 30 [cited 2018 Jun]; 22(Suppl 6):S18-S28. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27684613>.

⁵⁹ Braveman P. Health Disparities and Health Equity: Concepts and Measures. *Annu Rev Public Health* [Internet]. 2006 Apr 21 [cited 2018 Jun]; 27:167-194. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/16533114>.

⁶⁰ Braveman P. What Are Health Disparities and Health Equity? We Need to Be Clear. *Public Health Rep* [Internet]. 2014 Jan-Feb [cited 2018 Jun]; 129(Suppl 2):5-8. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24385658>.

⁶¹ Olsen J, Baisch MJ. An integrative review of information systems and terminologies used in local health departments. *J Am Med Inform Assoc* [Internet]. 2013 Sep 13 [cited 2018 Jun]; 21(e1):e20-e27. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24036156>.

⁶² Genetic and Rare Diseases Information Center. FAQs About Rare Diseases [Internet]. Gaithersburg (MD): Genetic and Rare Diseases Information Center; [updated 2017 Nov 30, cited 2018 Aug]. Available from: <https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases/>.

⁶³ Field MJ, Boat TF. Rare Diseases and Orphan Products: Accelerating Research and Development [Internet]. Washington (DC): National Academies Press (US); 2010 [cited Jul 2018]. 420 p. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK56189/>.

⁶⁴ Commission Expert Group on Rare Diseases. Recommendation on Ways to Improve Codification for Rare Diseases in Health Information Systems. European Commission [Internet]; 2014 Nov 13. [cited 2018 Jul]. Available from: http://ec.europa.eu/health/sites/health/files/rare_diseases/docs/recommendation_coding_cegrd_en.pdf.

Social Determinants of Health

Social and behavioral determinants of health is an emerging area with wide implications for both individual and population health management and research. According to the WHO⁶⁵ and Department of Health and Human Services *Healthy People 2020*,⁶⁶ “The social determinants of health are the conditions in which people are born, grow, live, work and age. These circumstances are shaped by the distribution of money, power and resources at global, national and local levels. The social and behavioral determinants of health contribute to health disparities - the unfair and avoidable differences in health status seen within and between countries.”

Social and behavioral determinants are different from some other clinical tests because they usually cannot be measured directly. They are social constructs experienced by an individual that are commonly captured through surveys, as a self-report with validated question sets where the answers are converted into a score, or through inference from geocoded data sets.^{67 68} The 2015 Meaningful Use program defined a certification criterion to enable a user to record, change, and access key patient social, psychological, and behavioral data that are in LOINC terms (and UCUM for units of measure).⁶⁹

Currently, there is a small set of codes within ICD-10-CM which are used for collecting data on social determinants of health.⁷⁰ ICD-10-CM code categories Z55 to Z65 identify problems related to education, employment, occupational exposure, housing and economic circumstances, social environment, and social support networks.

⁶⁵ World Health Organization. Social determinants of health [Internet]. Geneva, Switzerland: World Health Organization; [cited 2018 August]. Available from: http://www.who.int/social_determinants/sdh_definition/en/.

⁶⁶ Office of Disease Prevention and Health Promotion. Social Determinants of Health [Internet]. Rockville (MD): Office of Disease Prevention and Health Promotion; [cited 2018 August]. Available from: <https://www.healthypeople.gov/2020/topics-objectives/topic/social-determinants-of-health>.

⁶⁷ Committee on the Recommended Social and Behavioral Domains and Measures for Electronic Health Records; Board on Population Health and Public Health Practice; Institute of Medicine. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 1 [Internet]. Washington (DC): National Academies Press (US); 2015 Jan 8 [cited 2018 May]. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/24757748>.

⁶⁸ Committee on the Recommended Social and Behavioral Domains and Measures for Electronic Health Records; Board on Population Health and Public Health Practice; Institute of Medicine. Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2 [Internet]. Washington (DC): National Academies Press (US); 2015 Jan 8 [cited 2018 May]. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK268995/>.

⁶⁹ Office of the National Coordinator (US). 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications [Internet]. Final rules. Fed Regist. 2015 Oct 16;80 FR 62601: 62601-62759. [cited 2018 Jul] Available from: <https://www.federalregister.gov/documents/2015/10/16/2015-25597/2015-edition-health-information-technology-health-it-certification-criteria-2015-edition-base>.

⁷⁰ American Hospital Association. ICD-10-CM Coding for Social Determinants of Health [Internet]. Washington DC: American Hospital Association; 2018 Apr [cited 2018 Jul]. Available from: <https://www.aha.org/system/files/2018-04/value-initiative-icd-10-code-social-determinants-of-health.pdf>.

Potential Solutions to Gaps in Coordination Efforts

In addition to the examples above, the recent NCVHS letter to the ONC identified cognitive status, family health history, and functional status (amongst others) as data classes in the USCDI that are not adequately covered by health terminology and vocabulary standards.⁷¹ However, it should be noted that the USCDI mechanism can be used going forward to identify and prioritize these health terminology standard gaps. In general, gaps may be addressed by:

Expanding a Current Standard

Current named standards don't cover an area but could easily be expanded to cover the domain. This may mean creating new codes in the standard(s) or incorporating an existing terminology into a named standard. The second may be accomplished through mapping (not the most cost-effective solution) or by merging the two.

Naming an Additional Standard

Current named standards don't cover an area but there is an existing terminology that does cover the domain. In this case the existing terminology should be considered for identification as a named standard after it is fully vetted.

Developing New Terminologies

Current named standards don't cover a domain and can't be expanded to cover the domain. No existing terminologies cover the domain. In this case a new terminology may need to be developed that will then be chosen as a named standard after it is fully vetted. RxNorm was developed along these lines.

As new needs are identified, users should be encouraged to, whenever possible, first work with the named standards to determine if they can be expanded to meet their needs rather than developing a new approach.

Governance and Coordination of Standards

This section describes the current health terminology and vocabulary governance and coordination environments. Governance is concerned with "how political and administrative decisions get made, how governmental systems work, and why both formal and informal institutions matter in how things get done."⁷² The term coordination is also used here because many of the current mechanisms operate to ensure that stakeholders have say in how systems move forward, a purpose less formal than overall

⁷¹ National Committee on Vital and Health Statistics. Letter to National Coordinator for Health Information Technology [Internet]. Washington DC. 2018, Mar 15 [cited 2018 Jul]. Available from: <https://ncvhs.hhs.gov/wp-content/uploads/2018/08/USCDI-Comments-on-LtrHead-March-19-1-1.pdf>.

⁷² Grindle MS. Good Governance, R.I.P.: A Critique and an Alternative. *Governance: An International Journal of Policy, Administration, and Institutions* [Internet]. 2017 Jan 30(1) [cited 2018 Jun]:17-22. Available from: <https://onlinelibrary.wiley.com/doi/epdf/10.1111/gove.12223>.

governance of complex systems or regulations. Governance and coordination are important to ensure fair and consistent process, system coordination, responsiveness to end users, and the overall value of named and other standards.

Governance and coordination of individual vocabularies and terminologies

As noted in the overview of recent history and the detailed descriptions of named standards in the appendices, each vocabulary and terminology has its own governance and coordinating mechanisms. Depending on ownership, governance may be public or private or a combination for certain functions such as maintenance. Mechanisms are in place for federal agency-to-agency and for federal to private coordination. Private organizations offer a path for general input from stakeholders. The following examples apply to specific vocabularies or terminologies:

- ICD-10-CM/PCS is maintained and funded by NCHS and CMS. Both federal agencies co-chair the ICD Coordination and Maintenance Committee (C & M Committee), who is responsible for approving coding changes, developing errata, addenda and other modifications to the then current ICD standard.
- CPT is owned, licensed, and maintained by the AMA. CPT's maintenance process permits any interested party to submit proposed changes. CMS and AMA coordinate the release of HCPCS Level and I and II codes.
- LOINC is owned, licensed, and maintained by the Regenstrief Institute. The National Library of Medicine, additional federal agencies, and other groups, contribute to funding the standard. The LOINC maintenance process accepts submitted content changes from users and editorial and technical development is guided by advisory groups.
- SNOMED CT is owned, licensed, and maintained by SNOMED International. The National Library of Medicine, on behalf of the U.S. Department of Health and Human Services, sits on its governing body and contributes funding as the U.S. Member. Members (countries, territories, and some companies) license the terminology and contribute to funding the standard. SNOMED CT (International and US Edition) maintenance process accepts submitted content changes from users. Editorial and technical development for SNOMED CT International Edition is maintained by SNOMED International with guidance from the Advisory Groups and the Chief Terminologist. SNOMED CT US Edition is maintained by the NLM SNOMED Content Manager.
- CDT is owned, licensed, and maintained by the ADA. The ADA's Code Maintenance Committee is the decision-making body of organization that considers requests from any interested party.

Cross-standard governance and coordination

Regarding more comprehensive cross-standard governance and coordination mechanisms, several approaches have been tried. Some have stood the test of time, others have evolved or been replaced. Their evolution reflects evolving technology, the changing stages of adoption of health IT, inventiveness of experts, and shifting federal priorities.

- As the central coordinating body for clinical terminology standards within HHS, NLM coordinates with SDOs to provide access to current versions of named standards including SNOMED CT, LOINC, RxNorm, and other commonly used terminologies and vocabularies that are not named standards. The NLM maintains the UMLS, which includes the Metathesaurus and UMLS Terminology Services (UTS), to harmonize and provide access to terminologies and to help advance biomedical and informatics research.
- HHS modeled agency-to-agency standards coordination through its Consolidated Health Informatics Initiative (CHI).
- HHS modeled public-private collaboration for standards development and adoption through the work of the American Health Information Community (AHIC) in the period leading up to passage of the HITECH Act.
- Under HITECH, the ONC appointed the Health Information Technology Standards Panel (HITSP), a public-private mechanism later replaced by the Health Information Technology Standards Committee (HITSC), a federal advisory committee. The Health Information Technology Advisory Committee (HITAC) replaced earlier standards advisory committees at ONC.
- ONC, leveraging its authority, worked with CMS to specify the use of vocabulary and terminology standards through EHR certification and Meaningful Use.
- The newly instituted Interoperability Standards Advisory (ISA) appointed in 2017 is to be a resource to help the industry determine the best standard to be used to address specific clinical health information interoperability needs.
- Since 1949, NCVHS has advised the Secretary on patient medical record standards, a charge made statutory by the HIPAA law specifically regarding administrative and code set standards. The Committee assists and advises the Secretary and has no authority for action, instead the Committee coordinates with other FACAs and scientific advisors (such as HHS Council).
- Many SDOs coordinate with one another to ensure compatibility, harmonization, and or alignment. Collaborative partnerships are highlighted in Appendix 1 and 2 for each respective SDO.

Current governance and coordination strengths and weaknesses

Table 2, provides a summary of the strengths and weaknesses regarding governance and coordination of terminology standards revealed through this environmental scan.

| Strengths | Weaknesses |
|--|---|
| Several iterative changes in governance and coordination have been made in response to changing contexts. | The current state remains fragmented with no overall coordinating mechanism at the federal level. |
| Some federal levers are available to advance research, development, dissemination, adoption and enforcement. | Research, testing, education, and enforcement are siloed, not necessarily coordinated and have not advanced a common strategic and integrated set of goals. |
| There are several notable public-sector innovations that have become the industry standard, e.g. RxNorm. | Financing, particularly from the public sector, is not predictable nor is it adequate to support research, development, dissemination, adoption, or enforcement. |
| Public-private collaboration has advanced adoption. For example, projects such as the Healthcare Services Platform Consortium's System of Logical Representation (SOLOR), or the SNOMED CT and terminologies efforts in the EHR implementation at the Nebraska Medical Center at the University of Nebraska. Both projects demonstrate the value of an integrated, description-logic-based system. | Political, intellectual property, and other private interests conflict with public interests in standards; collaboration efforts have not yet been sufficient to create an integrated, safe, and effective way of representing and exchanging patient's detailed clinical data. |
| The U.S. efforts are appropriately linked to global terminology and vocabulary efforts | Private sector initiatives have not necessarily driven innovation because there is often no viable market; terminologies and vocabularies are foundational. |
| | There is currently no generally understood health terminology and vocabulary vision to unify efforts and guide adoption. |

| Strengths | Weaknesses |
|-----------|--|
| | There are currently no generally adopted practices to ensure consistency and rigor in system development and maintenance and no requirements or funding for rigorous efficacy and safety evaluation. |
| | No standardized representation model, no standardized contribution model, and very little attention to metrics of quality and life-critical system practices exist. |

Table 2. Strengths and weaknesses of current governance and coordination in the health terminology and vocabulary standards space.

In a 2006 white paper *Healthcare Terminologies and Classifications: An Action Agenda for the United States*, an AMIA and AHIMA Task Force identified the need for stronger policy coordination and a more centralized and simplified governance of terminologies and vocabularies.⁷³ The Task Force recommended the establishment of a centralized public-private oversight authority to advance greater consistency in processes, system coordination and responsiveness to end users, and to facilitate improved uniformity of adoption. Recommendations also urged that U.S. governance make provision for robust coordination and collaboration with international terminology and classification development and maintenance efforts. This is part of ongoing work of NCHS with WHO's Family of International Classifications, the ICD-11 development efforts, and the NLM's role with SNOMED International and Regenstrief Institute. It is not clear whether these efforts are resourced at the right level.

A confounding variable regarding governance and coordination is the prevalence of licensing arrangements to protect the intellectual property of standards development organizations and fund development and ongoing maintenance. Maintenance of a standard requires a steady funding source which is obtained, in many cases, through usage fees. The 2000 PMRI recommendations called for federal licensing of all named systems for U.S. use to ensure they are freely available to U.S. users without the need for usage fees. This happened for SNOMED, but not other systems. Federal licensing for LOINC was already established in 1999 as part of NLM contract support to ensure the free distribution of LOINC. RxNorm, developed in 2003 after the PMRI recommendations, was designed from the start to be freely available from the NLM. In spite of these efforts, proprietary issues confound international relationships as well as placing practical limits on how much coordination can be achieved in the U.S. For example, the SNOMED license allows affiliates (aka licensees) to use SNOMED CT in Member countries at no charge but use in non-Member countries may incur usage charges. This limit of

⁷³ American Medical Informatics Association (AMIA) and American Health Information Management Association (AHIMA) Terminology and Classification Policy Task Force. *Healthcare Terminologies and Classifications: An Action Agenda for the United States* [Internet]. 2006 Nov [cited 2018 Aug]. Available from: <http://bok.ahima.org/PdfView?oid=67607>.

the SNOMED license presents a barrier to its use for open science internationally with some organizations, at the urging of their constituents, choosing named standards that are freely available, named standards that are a better fit for purpose.

Governance may be improved through incremental solutions to specific problems. It may also address some of the larger macro-political issues. Examples can be cited of incremental improvements over the nearly 20 years since the PMRI Report was issued. Still, governance and coordination remain fragmented and the environment has become more complex raising several important strategic questions:

- On the current path, will vocabularies and terminologies be capable of optimally serving the needs of health improvement and the healthcare industry?
- What incremental or macro change pathways are most likely to lead to improved value of vocabularies and terminologies?
- What types of improved coordination is needed from governmental agencies?
- How might the private and public sectors work more effectively to advance the common goal of better integrated terminology standards which would provide a consistent foundation for interoperability, research and the many other uses for standardized health information?

Maintenance and Dissemination of Standards

This section summarizes approaches to maintaining vocabulary and terminology standards and releasing version updates. The U.S. has multiple named standards and additional voluntary vocabularies and terminologies, each with its own maintenance processes, methods for dissemination and approaches to supporting those who must use the standards. Technology companies and end users must understand and accommodate a broad range of approaches. Stakeholders seeking additions, changes or clarifications or answers to questions must work through the channels prescribed by respective governing authorities. The PMRI Report recommended that, for each named standard, HHS fund conformance testing, uniform implementation guides, and other assists to ensure that there was up to date information on system capability and performance.

Overview of approaches and services

All terminologies require regular updating. Table 3 summarizes maintenance and release approaches used by U.S. named standards authorities. Greater detail can be found in the description of standards in appendices 1 and 2. Solid progress has been made in upgrading maintenance and making it more transparent and accessible. Some systems have also made maintenance processes more responsive by handling requests and issuing changes more frequently. Nevertheless, the current environment remains uneven and approaches to requesting additions or modification to the terminologies range from web-based to hard copy requests. As is true with all standards development processes, seeking new codes or code changes requires knowledge of how the submission process works.

What is less clear from the Table 3 descriptions is that some terminologies like LOINC, SNOMED, and RxNorm have updates that show what changed and how the old and new versions relate to each other. In contrast there have been instances when ICD maintenance has changed the meaning of codes and new terms may be added in ways which can change the meanings of other terms (e.g., “not elsewhere classified” terms).⁷⁴

Release schedules range from annual to semi-annual to weekly, monthly, and daily. While the UMLS Terminology Services (UTS) provides electronic access to all the named standards, developers and commercial entities offer a variety of alternative dissemination methods ranging from apps to print materials. For ICD and CPT particularly, these resources represent substantial revenue for nonprofit stakeholders and commercial entities.

| Named Standard | Request for Change or Add | Update Schedule | Access and Funding |
|----------------|--|--|---|
| CDT | Change requests using a template on the ADA site that is emailed to the ADA. Decisions to accept requests are made by the ADA’s Code Maintenance Committee, according to the published schedule. | Annual update, effective January 1 of each year. | Access: <ul style="list-style-type: none"> ● Official files from ADA. ● License for commercial use is required. ● Data are also available from NLM via UMLS Metathesaurus. ● Annual update of code system available via PDF or book from ADA. Funding by ADA through usage charges. |
| CPT | New or revised code applications submitted to the CPT Editorial Panel according to a published schedule and via email. | Release schedule by category: Category I annual (provision for certain types of codes to be “early released” (e.g., vaccine products, Molecular Pathology); Category II – released 3 times year (March, July, and November); | Access: <ul style="list-style-type: none"> ● Official files from the AM. ● License for commercial use is required. ● Data are also available from NLM via UMLS Metathesaurus. |

⁷⁴ Cimino JJ. An approach to coping with the annual changes in ICD9-CM. *Methods of Inf Med.* 1996 Sep;35(3):220.

| Named Standard | Request for Change or Add | Update Schedule | Access and Funding |
|------------------------|--|---|--|
| | | <p>Category III – released biannually (January and July); PLA - released quarterly (January, April, July, and October); and MAAA - released March, September, and December.</p> | <ul style="list-style-type: none"> ● Print and digital versions available from publishers under licensing arrangement with AMA. <p>Funding by ADA through usage charges.</p> |
| <p>HCPCS II</p> | <p>Hard copy applications with supporting documentation must be sent via USPS to each member of the HCPCS workgroup. Updates may take the form of permanent national codes or temporary codes.</p> | <p>Quarterly with annualized compilation.</p> | <p>Access:</p> <ul style="list-style-type: none"> ● Official files from CMS. ● CPT (Level I) is available via from AMA; license for commercial use is required. ● CDT (Level II) is available from ADA; license for commercial use is required. ● Data are also available from NLM via UMLS Metathesaurus. <p>Funding:</p> <ul style="list-style-type: none"> ● Overall provided by CMS. ● CPT (Level I) funded by AMA through usage charges. ● CDT (Level II) funded by ADA through usage charges. |

| Named Standard | Request for Change or Add | Update Schedule | Access and Funding |
|----------------------------|---|---|---|
| ICD-10 CM & PCS | Requests for coding changes are submitted to the Coordination & Maintenance Committee that meets in the Spring and Fall. Questions regarding coding guidelines are handled by the ICD Coding Clinic sponsored by the AHA. Coding Clinic advice is the result of unanimous decisions of the Cooperating Parties. | Annual updates effective October 1 of each year. There is a way to expedite the release of procedure codes for new technologies with an April 1 release. To date, this expedited release has not been employed. | <p>Access:</p> <ul style="list-style-type: none"> ● Official files for ICD-10-CM from NCHS (CDC) at no charge. ● Official files for ICD-10-PCS from CMS at no charge. ● Data are also available from NLM via UMLS Metathesaurus. ● Print and digital versions available from a range of for-profit and nonprofit publishers. <p>Funding:</p> <ul style="list-style-type: none"> ● Licensing for ICD-10-CM established and funded by NCHS as part of their role as the North American representative to WHO-FIC. ● ICD-10-PCS funded by CMS. |
| LOINC | Request for change process at LOINC website and via RELMA. | Released in June and December. | <p>Access:</p> <ul style="list-style-type: none"> ● Official files from the Regenstrief Institute at no charge. ● Data also available from NLM via UMLS Metathesaurus. <p>Funding:</p> <ul style="list-style-type: none"> ● Primary funding through contract support from NLM. ● Regenstrief Institute. |

| Named Standard | Request for Change or Add | Update Schedule | Access and Funding |
|------------------|---|---|---|
| NDC | Labeler submits new SPL to update the information via the Drug Registration and Listing System (eDRLS). | NDC Directory is updated daily. | <p>Access:</p> <ul style="list-style-type: none"> ● Official files from FDA's electronic NDC Directory that may be browsed or downloaded at no charge. ● Data also available from NLM as part of RxNorm and via the UMLS Metathesaurus. ● NDC codes available via mobile apps. <p>Funding provided by FDA.</p> |
| RxNorm | Structured product labeling (SPL) submitted by drug manufacturers to FDA. Change requests to existing codes can be sent to rxnorminfo@mail.nih.gov. | New drug information released weekly; full release of RxNorm each month. | <p>Access:</p> <ul style="list-style-type: none"> ● Official files from NLM through the UTS at no charge. ● Data also available from NLM via the UMLS Metathesaurus and RxNorm APIs. <p>Funding provided by NLM.</p> |
| SNOMED CT | US Change Request System for modifications to U.S. Extension or International SNOMED CT core. | The U.S. Edition is released twice a year – March 1 and September 1. The International Edition is released twice a year January 31 and July 31. | <p>Access:</p> <ul style="list-style-type: none"> ● Official International and U.S. Editions of SNOMED CT files from NLM through the UTS. ● International and U.S. Editions of SNOMED CT available at no charge to U.S. users. ● U.S. Edition data also available from NLM via the UMLS Metathesaurus. |

| Named Standard | Request for Change or Add | Update Schedule | Access and Funding |
|----------------|---|---|--|
| | | | Funding provided by NLM through contract support to cover the annual SNOMED International Membership fee. |
| UDI-DI | Labeler must apply UDI to label of device in human readable and machine-readable format (for devices meeting compliance dates), and submit a set of required fields to GUDID via a web interface or HL7 SPL within 15 days of being in commercial distribution. | GUDID and AccessGUDID are updated daily | Access to official files from NLM through AccessGUDID at no charge. Funding: <ul style="list-style-type: none"> ● Funding to maintain UDI files provided by FDA. ● Funding to maintain AccessGUDID provided by FDA and NLM. |

Table 3. The varying maintenance and release approaches used by U.S. named standards authorities.

Support for users

While not shown on the table above, each SDO provides varying levels of support to users. The user base ranges from policy/governance, developers/IT, clinician/healthcare providers, coders, and researchers. Additionally, the types of support that is provided can include: assistance in understanding of requirements and use of terminology, process for the maintenance and release, submission of new content or change requests, and technological implementation. Again, there is significant variability in the level of support available and approach. Furthermore, some take the approach that the education and/or support for the users are not provided by the SDO but by another partner.

Current maintenance and dissemination strengths and weaknesses

Regarding maintenance and dissemination, the current environment reveals a very broad range of issues, some strengths and some weaknesses. On balance, the amount of variation in maintenance and dissemination approaches of named standards undoubtedly inhibits innovation and adds to administrative burden and cost.

| Strengths | Weaknesses |
|---|---|
| The current version of named standards may be available from multiple commercial sources with formats ranging from print to electronic. These variations provide business and revenue opportunities for commercial entities who provide flexibility for the user community. | The current version of named standards may be available from multiple commercial sources with formats ranging from print to electronic. While this provides flexibility, it can also put financial burdens on some users. |
| UMLS Terminology Services (UTS) is a source for current versions of named standards. | Cost effective approaches may not be pursued due to proprietary interests. |
| Most maintenance processes have adopted more responsive, transparent and open processes available to stakeholders who may not be “members” or “customers.” | Classification algorithms, terminology development infrastructure, source codes, and other underlying methods for named standards are not universally open-sourced. |
| Users can choose a preferred source and method for getting updates, applying and using vocabulary and terminology tools. | UMLS requires a no fee license which engenders some complaints. |
| Maintenance calendars are explicit and generally highly reliable. | Maintenance timelines vary greatly from daily (NDC) to annually (ICD). There is no one size fits all, but timeliness is important particularly for devices and procedures. |
| High level of expertise involved in the maintenance processes. | There is no uniform measure or test of quality control across sources to ensure that they conform to the official standard. |
| | There are no industry adopted, best practice standards, for maintenance or support and no comparative evaluation. |
| | Semantic continuity continues to be an issue with some standards. NDC regularly re-issues old codes for new or different drugs. |
| | There is an integration and integrate-ability of content where the terminology equivalent of “building codes” |

| Strengths | Weaknesses |
|-----------|---|
| | starts to drive unproductive variation in terminology structure and process which becomes evident when integrating content. |
| | Users may need more support resources than are available. |

Table 4. Strengths and weaknesses of the current terminology standards maintenance and dissemination practices.

Terminology maintenance best practices requires a strong content management process with quality control, engagement of subject matter experts, and editorial oversight. This combination can also help address dissemination. There may be much to be learned by sharing best practices and gaining a greater understanding of the resources required for lifecycle management and maintenance of a vocabulary and terminology. Considering the lessons learned by developers and by end users over the past 10-20 years, several important strategic questions are suggested:

- What would a world class vocabulary and terminology maintenance process look like? What barriers can be addressed through federal action? Through private initiative?
- What would a world class process for dissemination look like? What barriers can be addressed through federal action? Through private initiative?
- What are reasonable standards for customer support to process questions about the application of the standards and how well are these being met?
- What governance and coordinating mechanisms may be critical to improving on the current state of maintenance, dissemination and support?

Adoption of Standards

Taking a broad view, adoption of vocabulary and terminology standards within the U.S. includes rule-making processes and adoption and use by the industry. Effective implementation of these complex standards also extends to how well system users are supported in their use.

ICD-10-CM & ICD-10-PCS as an illustrative case study

The current state is well illustrated by the recent U.S. experience in adopting ICD-10-CM and ICD-10-PCS. The WHO approved ICD-10 in 1990. The U.S. then began building the clinical modification and the U.S. commissioned development of a procedure coding system to replace ICD-9 Volume 3. NCVHS

recommended HHS begin rule-making for adoption of ICD-10-CM and PCS in 2003. The notice of proposed rulemaking (NPRM) was published in 2008 and a final rule published on January 15, 2009 set an implementation date of October 1, 2013, which was later revised to 2014, before final implementation in October 2015. The U.S. adopted native ICD-10 for mortality reporting in 1999.

Since HIPAA named code sets were initially adopted as standards in 2004, only the update from ICD-9-CM to ICD-10-CM/PCS has required full rulemaking for adoption. Other named standards such as CPT, SNOMED CT, and LOINC issue periodic updates under the same system name and hence, are covered by the rule in effect. Because ICD-9-CM was specifically named in regulation and because WHO's approach calls for a formal name change (ICD 9th edition becomes ICD 10th edition) ICD updates require regulatory adoption. ICD-10-CM represented a significant expansion in detail, but it retained a familiar hierarchical structure. ICD-10-PCS, on the other hand, involved design of an entirely new system. A regulatory change will be required for the U.S. to move from ICD-10-CM to ICD-11 unless the adoption process for this standard is amended to permit the change to be handled as a version update.

It took seven years to go from NPRM to effective date including two delays. In a recent listening session with healthcare CIOs about HIPAA administrative standards, NCVHS heard that deferments put CIOs in the position of "crying wolf" to their organizations about the need for resources for standards adoption. They urged predictable and reliable adoption schedules. Implementing ICD-10 was often compared to Y2K because diagnosis and procedure codes are master data used by all HIPAA covered entities for a range of critical operations across supporting technologies. For many covered entities and their technology and service partners, successful implementation required complex, multi-year project management. For HHS and all federal health systems, state agencies, health providers, payers and clearinghouses, this adoption demonstrated the value of end-to-end testing, extensive communications, and tailored levels of education.

Lifecycle terminology and vocabulary standards management

NLM maintains the most complete information on terminology use cases as reported in the UTS annual reports.⁷⁵ Less is known about how--and how well-- terminologies and vocabularies are routinely managed and used by individual covered entities, yet these practices are key to accurate capture, processing, and interpretation of data. To achieve interoperability within and across various systems and applications, free text and structured clinical information needs to be organized, mapped, and managed even as terminologies and vocabularies and their uses evolve.

The vision for PMRI standards contemplated automatic code assignment and mappings in the EHR happening behind the scenes. The technical capability to produce SNOMED CT concepts for problem lists and other EHR data capture uses is improving. While not all codes can be successfully mapped,

⁷⁵ National Library of Medicine. Unified Medical Language System (UMLS) Terminology Services [Internet]. Bethesda, MD: The U.S. National Library of Medicine; [cited 2018 Jun]. Available from: <https://uts.nlm.nih.gov/home.html>.

many SNOMED concepts have been mapped from and to ICDs for billing and other uses.⁷⁶ There is proof of concept, but it is not clear what approaches will be most reliable and cost effective. Also, there is not wide implementation at this time. This may be an area where focused research can produce evidence that could provide significant impact on realizing the vision for optimizing the value of PMRI standards.

Most organizations also lack tools, technological expertise, funding or data governance platforms to manage terminology and vocabularies, maps, and other terminology resources such as value sets, reference sets, or APIs. While they have expertise in specific systems, organizations may not have staff skilled in working across systems in new roles such as terminology asset manager, terminology mapping specialist, or terminology educator reference roles.⁷⁷

Some of the key functions required for effective use of terminology and vocabulary standards at the local level include maintaining current versions of standards, mappings and the technology tools that support them, establishing internal mapping guidelines and use cases, maintaining measure logic and value sets, and serving as a knowledge expert. These roles have potential to break down silos that too often exist between experts in a terminology or vocabulary and a use (billing versus clinical, ICD and SNOMED) and approach.

Current adoption strengths and weaknesses

Regarding rulemaking and implementation for use, high level strengths and weaknesses include:

| Strengths | Weaknesses |
|---|--|
| As a result of the transition to ICD-10, there is greater industry awareness of what it takes to upgrade a pervasive standard that impacts EHRs, billing, payment, analytic and other critical systems. | Due to the artifact of the naming conventions, full rulemaking is required for adoption for new versions of ICD. |
| Though deployment lags, technology and informatics know how are now more widely available for lifecycle management of terminologies and vocabularies by users than in the past. | The lag time from publication of an updated version of ICD by WHO and the U.S. modification and regulatory adoption, means this is at least a half decade process. |
| New technology is maturing that will at least in part automate the assignment of codes for billing. | End user generally lack the expertise and tools to manage the lifecycle across vocabulary and terminology standards. |

⁷⁶ National Library of Medicine. Metathesaurus - Mapping Projects [Internet]. Bethesda, MD: The U.S. National Library of Medicine; 2016 March 31 [cited 2018 Jul]. Available from: https://www.nlm.nih.gov/research/umls/knowledge_sources/metathesaurus/mapping_projects/index.html.

⁷⁷ Hyde L, Casto AB, Koehler M, Peterson K. Clinical Terminology: Expanding Career Pathways for HIM Professionals. J AHIMA [Internet]. 2017 Sep;88(9) [cited 2018 Jul]:50-55. Available from: <http://bok.ahima.org/doc?oid=302254>.

| Strengths | Weaknesses |
|---|---|
| Automated assignment of SNOMED concept codes and ICD translation is increasingly feasible though not yet able to be mainstreamed. | Use of vocabulary and terminology standards remain siloed in much of their application. |

Table 5. Strengths and weaknesses of the current rulemaking and implementation procedures.

The following strategic questions can be examined regarding how to handle regulatory and operation adoption in the years ahead:

1. Could the regulatory process be modified to ease regularly scheduled updates? If so, what may be options to make the process the most efficacious?
2. What can be done to avoid the protracted and expensive experience of adoption of ICD-10?
3. What are the essential elements of effective lifecycle management for stakeholders who use vocabulary and terminology standards? What steps would improve fuller adoption of automated encoding to improve usability while reducing administrative burden?

Summary of Themes for Evaluation and Improvement

This NCVHS environmental scan provides a contemporary look at the current landscape of the health terminology and vocabulary space. While the U.S. has made progress in electronic health data exchange, this review brings to light several opportunities to improve regulatory and sub-regulatory adoption, governance and coordination, maintenance, and end user support. It also identifies gaps in terminology standards coverage and, at the same time, areas of redundant and overlapping content.

This report identifies the need for more comprehensive and coordinated planning, resourcing, research, and evaluation to guide adoption, maintenance, dissemination and use of terminology and vocabulary standards that are the foundation for health and health system improvement.

The following are overarching themes that will benefit from further exploration to identify helpful short-term incremental improvement and longer-term direction.

1. Build consensus on the direction forward

When the current standards were adopted in the U.S., it was envisioned that there would be ongoing evaluation to guide adjustments based on experience and changing requirements. The mix of standards adopted in 2004, coupled with the 2015 updates to ICD, require ongoing evaluation to inform consensus building processes for the best paths forward. This focus on direction forward should be based on

contemporary principles and should consider how best to pace change, address gaps and leverage technology.

Example 1: The move from ICD-9-CM to ICD-10-CM and ICD-10-PCS readdressed the then current issues relating to outdated clinical concepts, the lack of expansion capability, and brought the U.S. back into alignment with international standards. In the U.S., the debates leading up to this transition revealed the need for greater clarity on how terminologies and vocabularies work together. ICD-11 is being designed to facilitate mapping to SNOMED CT and advance machine coding. Modeling these capabilities will be important to understanding future opportunities.

Example 2: When implemented in 2015, ICD-10-PCS represented a major new classification system design to capture inpatient services. As more procedures shift from inpatient to ambulatory, and for reasons relating to quality, safety, and efficacy, it will be beneficial to gain a clearer understanding of how procedure data are captured in PCS and CPT and how differences impact interpretation and uses of data. Looking forward, will the nature of the service determine the code set regardless of the care setting?

2. Expand understanding that redundant health terminologies present a barrier to interoperability

Terminologies and vocabularies grow from a user's need for a controlled nomenclature to facilitate workflows and provide positive outcomes. Most users, new to the world of standard terminologies, follow natural instinct and develop a new terminology to meet these needs. With little exposure and training in development of terminologies to support interoperability they end up creating a niche vocabulary with little, if any, connection to existing named standards. Over time, these niche vocabularies tend to have small but strong user bases and find harmonizing with larger or other terminologies difficult as they work to protect the vocabulary they have created. However, if the overall goals are for data interoperability, the need for collaboration and compromise should be a priority.

Lacking are educational materials describing the preferred approach (as discussed above) of first trying to expand a current standard, naming an additional standard if the current standards won't work, or, as a last resort, developing a new terminology to meet the user's needs. Introductory or educational materials providing one clear description of the overall process and access points is not available. The best location and mechanism for presenting this information, including an explanation of the challenges that are generally encountered when niche vocabularies are unnecessarily developed, should be explored.

The following examples describe challenges resulting from creation of multiple niche vocabularies within a domain.

Example 1: Clinical Care Classification System (CCC), International Classification of Nursing Practice (ICNP), North American Nursing Diagnosis Association International (NANDA-I), Nursing Interventions

Classification System (NIC) and Nursing Outcomes Classification (NOC), Omaha System (OMS), and Perioperative Nursing Data Set (PNDS), are all commonly used nursing terminologies and code sets, each developed independently to meet the specific needs of their intended users. This independent approach has made it difficult to share and compare nursing data.

In 2015 the American Nursing Association (ANA) recognized two reference terminologies (SNOMED CT and LOINC), eight interface terminologies (CCC, ICNP, NANDA-I, NIC, NOC, Omaha System, PNDS, and ABC Codes), and two minimum data sets (Nursing Minimum Data Set (NMDS), and Nursing Management Minimum Data Set (NMMDS)).^{78 79} The ANA recently reaffirmed support for use of recognized reference terminologies for coding nursing problems, interventions and observations (SNOMED CT) and in nursing assessments and outcomes (LOINC).⁸⁰ Maps from nursing-specific terminologies to SNOMED CT or LOINC are needed to achieve interoperability. CAP provided these maps between SNOMED CT and the interface terminologies when they owned SNOMED CT, however ownership of the maps did not transfer to SNOMED International since the maps were considered U.S. specific. CAP ceased production of the maps in 2013 shortly before they dissolved their terminology services. The intent was for interface terminology owners to make use of the NLM UMLS Metathesaurus to find Concept Unique Identifiers (CUIs) and extract concept-level synonyms between SNOMED CT, LOINC, and their nursing terminologies. However, mapping work is expensive and takes more resources (both funding and expertise) than were available. Some nursing-specific terminologies for assessments and outcomes (e.g. CCC, Omaha System), and the NMMDS have been directly integrated into LOINC or SNOMED CT. While readily available, users of these nursing-specific outcome and assessment terminologies are encouraged to translate them to LOINC when exchanging data with another setting. The nursing community continues to work towards resolving the issues.

3. Mitigate the consequences of redundant terminology and vocabulary efforts

With the use of reference terminologies and domain-specific ontologies, some overlap is inevitable. However, significant content coverage duplication where it becomes redundant and pushes the variation in conceptual models across terminologies may increase costs while adversely impacting data integrity and interoperability. Research in the areas of concept organization may need to be expanded to better inform development and adoption of standards going forward.

⁷⁸ American Nurses Association. Position Statement: Inclusion of Recognized Terminologies Supporting Nursing Practice within Electronic Health Records and Other Health Information Technology Solutions [Internet]. Denver (CO): Association of Perioperative Registered Nurses; 2015 Mar 19 [cited 2018 May]. Available from: <https://www.aorn.org/-/media/aorn/guidelines/position-statements/posstat-endorsed-ehr-hit-terminologies.pdf>.

⁷⁹ The Office of the National Coordinator for Health Information Technology. Standard Nursing Terminologies: A Landscape Analysis [Internet]. Washington (DC): The Office of the National Coordinator for Health Information Technology (U.S.); 2017 May 15 [cited 2018 May]. 44 p. Available from: https://www.healthit.gov/sites/default/files/snt_final_05302017.pdf.

⁸⁰ American Nurses Association. ANA Official Position Statements [Internet]. Silver Spring (MD): American Nurses Association (US); Effective date 2018 April 19. [cited 2018 June]. Available from: <https://www.nursingworld.org/practice-policy/nursing-excellence/official-position-statements/>.

Example 1: As adoption of SNOMED CT has increased globally, there is increased demand for expansion of SNOMED CT to cover additional areas of medicine and health beyond the current scope of the terminology. This idea to make SNOMED CT the primary terminology, eliminating the need for additional terminologies and classifications, has been debated both within the U.S.⁸¹ and globally.^{82 83 84} Proponents of this idea envision SNOMED CT expanding to cover additional areas (either directly in the terminology or through formal extensions or modules maintained by other SDOs) including devices, tumor staging, pathology and laboratory observations, functioning, genomics, and social determinants of health. Recently, a SNOMED International Member stated their country designated SNOMED CT as *the* primary standard terminology for health data interoperability.⁸⁶ This Member's stance emphasizes the need for consensus on this issue. While this approach may be perceived as consolidating expenses for Member countries (if they only need to pay for one terminology), and simplifying implementation (if they only need to interact with and use one terminology), it presents a problem for SNOMED International management who encounter copyright and intellectual property rights of other terminologies preventing them from meeting this request of some SNOMED International Members. While the debate continues, SNOMED International continues actively working with other SDOs to find ways to harmonize work efforts to eliminate redundant duplication and facilitate interoperability wherever possible.

Example 2: NLM conducts and supports research and development related to the representation, interpretation, and use of biomedical knowledge in various electronic forms including EHRs. Development of the UMLS evolved from this work to provide system developers with a suite of tools to build and enhance electronic information systems. It has always been known that "one size does not fit all" where vocabularies are concerned and the NLM supports coordination when possible. But the "UMLS approach assumes continuing diversity in the formats and vocabularies of different information sources and in the language employed by different elements of the biomedical community. It is not an

⁸¹ Campbell WS, Karlsson D, Vreeman DJ, Lazenby AJ, Talmon GA, Campbell JR. A computable pathology report for precision medicine: extending an observables ontology unifying SNOMED CT and LOINC. *J Am Med Inform Assoc* [Internet]. 2017 Sep 13; 25(3) [cited 2018 May]:259-266. Available from: <https://academic.oup.com/jamia/article-lookup/doi/10.1093/jamia/ocx097>.

⁸² Kalra D, Schulz S, Karlsson D, Stichele RV, Cornet R, Goeg KR, Cangili G, Chronaki C, Thiel R, Thun S, Stroefmann V. Assessing SNOMED CT for Large Scale eHealth Deployments in the EU: ASSESS CT Recommendations [Internet]. Bonn: ASSESS CT (DE); 2016 Dec [cited 2018 Jul]. 23 p. Available from: http://assess-ct.eu/fileadmin/assess_ct/final_brochure/assessct_final_brochure.pdf.

⁸³ Australian Digital Health Agency. Australia's National Digital Health Strategy [Internet]. Sydney: Australian Digital Health Agency (AU); 2017 Aug 2 [cited 2018 Jul]. 63 p. Available from: https://conversation.digitalhealth.gov.au/sites/default/files/adha-strategy-doc-2ndaug_0_1.pdf.

⁸⁴ Ministry of Health. SNOMED CT Implementation in New Zealand [Internet]. Wellington: Ministry of Health (NZ); 2017 Feb 27 [cited 2018 June]. Available from: <https://www.health.govt.nz/nz-health-statistics/classification-and-terminology/new-zealand-snomed-ct-national-release-centre/snomed-ct-implementation-new-zealand>.

⁸⁵ Arora J. Electronic Health Record (EHR) Standards for India [Internet]. New Delhi: Ministry of Health and Family Welfare (IN); 2016 Dec 30 [cited 2018 Jul]. 45 p. Available from: https://mohfw.gov.in/sites/default/files/17739294021483341357_1.pdf.

⁸⁶ Downs D. SCCI0034: SNOMED CT: Product Specification [Internet]. Leeds: The Health and Social Care Information Centre (NHS Digital) (UK); 2016 Feb 11. [cited 2018 Jul]. 25 p. Available from: <https://digital.nhs.uk/binaries/content/assets/legacy/pdf/o/e/0034352016req-spec.pdf>.

attempt to build a single standard biomedical vocabulary.”⁸⁷ While the UMLS is a way to find synonymy between terminologies, it is not clinically validated, and rather, should be used as a tool in the harmonization of terminologies rather than as the sole source.

4. Resource the maintenance and dissemination of named standards

Adequate resources are required to develop and maintain standards and support end users. Resources include not only direct funding but also funding to ensure a technical infrastructure to support these processes, a workforce trained and experienced in the development and maintenance of controlled vocabularies, and research and evaluation to inform decisions going forward. Whether funding comes from the government (to ensure named standards are freely available) or the private sector (generally to meet the needs of a professional association), these funds must be reliable and at an appropriate level to assure continued maintenance and dissemination of named standards without placing an undue burden on the user community through usage fees. Federally supported systems requiring adequate resourcing include:

- ICD-10-CM and ICD-10-PCS and the North American representation to the work of the WHO. The resources for maintenance of CM and PCS may need to support an agile maintenance process.
- Funding to ensure the ongoing maintenance and free distribution of the core terminologies (LOINC, RxNorm, and SNOMED CT (both International and US Editions)).
- NLM’s UMLS, UTS, and terminology research to help develop targeted research to ensure that alternatives are being considered and that decisions are supported by evidence.

5. Improve governance and coordination across named terminology and vocabulary standards

In the U.S., there are currently multiple named health terminology standards and over a dozen federal agencies and non-federal SDOs working in a loosely coordinated effort. Many of the issues identified throughout this scan suggest the need for stepped up governance and coordination. Terminologies and vocabularies represent a highly specialized arena that requires a range of experts. The scope of governance functions should span the lifecycle of the named standards and address at least the following: the process for addressing gaps, timing, process and impact for standards updates, best practices in maintenance, dissemination, support, and priorities for research.

⁸⁷ Humphreys BL, Schuyler PL. The Unified Medical Language System: Moving beyond the vocabulary of bibliographic retrieval. In: Broering NC, editor. High- Performance Medical Libraries: advanced information management for the virtual era. Westport (CT): Meckler; 1993. p. 33.

Example 1: Encoding and exchanging imaging findings is an important aspect of medical practice, quality, and safety. Unfortunately, there has not been a consistent push for a terminology standard for radiological imaging. SNOMED CT, Radiology Lexicon (RadLex), ICD, and National Cancer Institute Thesaurus (NCIT), LOINC or CPT have all been used and studied for use in radiology imaging practice.^{88 89}
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Both SNOMED International and the Regenstrief Institute (owners of SNOMED CT and LOINC respectively) have entered into separate agreements with radiology SDOs.

- SNOMED International is working with Digital Imaging and Communications in Medicine (DICOM), an international medical image standard owned by the National Electrical Manufacturers Association.⁹¹ With this agreement SNOMED International allowed a set of SNOMED CT codes and descriptions to be used in DICOM standards.
- The DICOM part 20 standard for sending Imaging Reports using HL7 Clinical Document Architecture (CDA) requires a LOINC term for labeling the imaging procedure report, as does the Diagnostic Imaging Report template in HL7's Consolidated CDA standard. Regenstrief is working with RadLex, a North American radiology lexicon, owned by the Radiological Society of North America. With this agreement, a unification between LOINC and the RadLex Playbook has created a new radiological procedures concept model.⁹²

Thus, two named reference terminologies have different (with some potential overlapping) use cases that might or might not complicate interoperability.

Example 2: As noted earlier, there is great variability by which SDOs maintain and disseminate standards that is a barrier to implementation making it difficult for users to know where and how to request new codes. As an example, LOINC, and SNOMED CT allow online submission of change requests. The process for addressing content requests vary by SDO. On one hand, the ease of submitting modification requests online is beneficial to users. On the other end of the spectrum, HCPCS

⁸⁸ Yan Z, Lacson R, Ip I, Valtchinov V, Raja A, Osterbur D, Khorasani R. Evaluating Terminologies to Enable Imaging-Related Decision Rule Sharing. AMIA Annu Symp Proc [Internet]. 2017 [cited 2018 Jul];2016:2082-2089. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28269968>.

⁸⁹ Warden GI, Lacson R, Khorasani R. Leveraging terminologies for retrieval of radiology reports with critical imaging findings. AMIA Annu Symp Proc [Internet]. 2011 [cited 2018 Jul];2011:1481-1488. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/22195212>.

⁹⁰ Wang KC. Standard Lexicons, Coding Systems and Ontologies for Interoperability and Semantic Computation in Imaging. J Digit Imaging [Internet]. 2018 Jun [cited 2018 Jul];31(3):353-360. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29725962>.

⁹¹ SNOMED International. New Global Licensing Agreement for SNOMED CT Code Inclusion in the DICOM Standard [Internet]. London: SNOMED International (UK); 2016 Mar 2 [cited 2018 Jun]. Available from: <https://www.snomed.org/news-articles/new-global-licensing-agreement-for-snomed-ct-code-inclusion-in-the-dicom-standard>.

⁹² Vreeman DJ, Abhyankar S, Wang KC, Carr C, Collins B, Rubin DL, Langlotz CP. The LOINC RSNA radiology playbook – a unified terminology for radiology procedures. J Am Med Inform Assoc [Internet]. 2018 Jul 1 [cited 2018 Aug];25(7):885-893. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29850823>.

It requires 36 hard copies of a change request, with supporting documentation, sent via USPS to each of the 36 members of the HCPCS workgroup. Greater coordination would simplify the process for both SDO and users.

Example 3: The FDA Code of Federal Regulations (21 CFR 207.35 (ii))⁹³ states that when a registrant has discontinued a drug product, its product code may be reassigned to another drug product five years after the expiration date of the discontinued product, or, if there is no expiration date, five years after the last shipment of the discontinued product into commercial distribution. NDC codes have been applied to different ingredients, routes and strengths within the five-year stipulations. This combined with the fact that the FDA NDC has run out of available codes, means the NDC format will need to be revised.⁹⁴ These rules and issues impede progress toward a digital health information world.

Example 4: The Health Information Technology Standards Committee recommended that electronic clinical quality measures (eCQMs) use SNOMED CT codes to specify clinical findings such as TNM bladder cancer staging. TNM staging is a scoring system to describe the amount and spread of cancer in a patient's body. The American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) have developed a TNM staging system to describe most cancers. AJCC owns the intellectual property rights and has established a licensing model to allow access for use. While this licensing model meets the needs of their primary customers, their approach to licensing makes it difficult to incorporate their content into named standards such as SNOMED CT.

For the 2015 Meaningful Use Stage 2 eCQM requirements, NLM worked with AJCC to include TNM codes for colon, breast, and prostate cancer from the 7th edition for inclusion into the US Edition of SNOMED CT as required for eCQMs. Requirements for new eCQMs, regular TNM updates, and AJCC's current approach to licensing, necessitate establishing a new agreement for each new set of codes needed in future editions of SNOMED CT. Similar negotiations are taking place between AJCC and the Regenstrief Institute (for LOINC) and HL7. The eCQM rules are generally established with short turnaround times for obtaining the needed codes. The rules are thus difficult to implement as they require use of proprietary codes and yet do not specify who pays for licensing, harmonizing, and coordinating between SDOs intellectual property. Coordinated negotiations to cover as many as practical of the named standards that need to include AJCC codes are being discussed.

⁹³ U.S. Food and Drug Administration. CFR – Code of Federal Regulations Title 21 [Internet]. Silver Spring (MD): U.S. Food and Drug Administration (US); 2017 Apr 1 [updated 2017 Aug 08, cited 2018 Jun]. Available from: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfrcfr/CFRSearch.cfm?CFRPart=207>.

⁹⁴ U.S. Food and Drug Administration. Public Hearing: Future Format of the National Drug Code [Internet]. Silver Spring (MD): U.S. Food and Drug Administration (US); 2018 Aug 7 [cited 2018 Aug]. Available from: <https://www.fda.gov/Drugs/NewsEvents/ucm574488.htm>.

Appendix 1: Named Health Terminology Standards

Unified Medical Language System (UMLS) Metathesaurus data referenced in Appendix 1 was pulled from the 2018AA version.

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| Name | <p>CDT</p> <p>Current Dental Terminology (also known as Code on Dental Procedures and Nomenclature)</p> <p>https://www.ada.org/en/publications/cdt</p> |
| Purpose | <p>The CDT Code's purpose is to achieve uniformity, consistency and specificity in accurately reporting dental treatment. One use of the CDT Code is to provide for the efficient processing of dental claims, and another is to populate an EHR. This code set is used to enable accurate, consistent, and uniform reporting of dental treatment. Used for both electronic and paper dental claims.</p> <p>The CDT Code is included in Level II of the Healthcare Common Procedure Coding System (HCPCS) as HCPT (Current Dental Terminology in HCPCS).</p> |
| Usage | CDT codes are only available for distribution in the U.S. and internationally. |
| Named Standard? | <p>Named HIPAA standard (August 17, 2000) - any claim submitted on a HIPAA standard electronic dental claim must use dental procedure codes from the version of the CDT Code in effect on the date of service.</p> <p>The CDT Code is also used on paper dental claims, and the ADA's paper claim form data content reflects the HIPAA electronic standard.</p> |
| Ownership | American Dental Association (ADA) |
| Development Principles | The ADA's Council on Dental Benefit Programs (CDBP) has the responsibility for CDT Code maintenance. The CDBP established a multi-stakeholder body, the Code Maintenance Committee (CMC), that includes representatives from various sectors of the dental community (e.g., ADA; dental specialty organizations; third-party payers). CMC members, by majority vote, determines which of the requested actions are accepted as submitted, accepted with amendments, or are declined. All accepted actions are incorporated into the CDT Code. |
| Coverage | Dental procedures and services. |
| Out of Scope | No documentation found. |
| Development & Maintenance | The CDT Code maintenance process is open to submissions from any interested party. CMC deliberations and decisions are made during the committee's open annual meeting, where non-member observers have the opportunity to offer comment on any requested action before a vote is taken. Complete documentation of the maintenance process (e.g., CMC composition, timeline, action request form and completion instructions, request evaluation guidelines, etc.) are posted on the ADA's website: www.ada.org/cdt . |

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| Requesting New Content | <p>New content may be a request for a complete new entry, revision to an existing entry, or deletion of a current entry. The “CDT Code Action Request Form” along with a signed “Copyright Assignment Agreement” constitute a complete submission for consideration by the CMC.</p> <p>Requests can be submitted at any time, with the date received determining the CDT Code version that may incorporate the requested action. The annual closing date for submissions is November 1st and all received by that date are on the agenda for the next CMC annual meeting. Any requests received after the closing date will be addressed in the next annual maintenance cycle. The CDT Code’s maintenance timeline is posted on the CDT Code’s web page.</p> <p>The action request template is a MS Word® document provided on the ADA site for download, completion, and return via email to the ADA - dentalcode@ada.org.</p> |
| Release & Dissemination | <p>Annual update, effective January 1 of each year.</p> <p>Official file share provided by the ADA</p> <ul style="list-style-type: none"> ● Individual CDT Code users (e.g., dentists) or interested parties may purchase a copy of the current version in the form of a printed manual, eBook (PDF) or mobile device app. ● Licensed commercial users (e.g., federal agencies, dental benefit plans, practice management system vendors) receive the current version as an ASCII text file from ADA. <p>Data available from NLM (via UMLS).</p> <p>Annual update of code system available via PDF or book from ADA.</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <p>83.6% Current Dental Terminology in HCPCS 21.7% MEDCIN 12.5% SNOMED CT 8.3% HCPCS Hierarchical Terms 2.9% Consumer Health Vocabulary</p> |
| Harmonization & Collaborations | <p>None stated</p> |

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| Name | CPT⁹⁵ Current Procedural Terminology https://www.ama-assn.org/practice-management/cpt-current-procedural-terminology |
| Purpose | Code set used to report ambulatory and hospital outpatient medical procedures and services by physicians and other healthcare professionals. |
| Usage | Primarily U.S. but used (but not named as standard) in other countries. |
| Named Standard? | Named HIPAA Standard as HCPCS Level I. Named standard for 2014 ONC EHR certification criteria - MU Stage 2. |
| Ownership | American Medical Association (AMA) developed, copyrighted, and maintains the code set. |
| Development Principles | Three types of CPT code – Category I, Category II, and Category III. American Medical Association (AMA) Board of Trustees appoints the CPT Editorial Panel who has final authority for updates. The CPT Editorial Panel, who maintains CPT, is aided by the CPT Advisory Committee. The members of this committee are primarily physicians nominated by the national medical specialty societies represented in the AMA House of Delegates. This committee provides advice on procedure coding and appropriate nomenclature as relevant to the member's specialty. The responsibility to update or modify code descriptors, coding rules, and guidelines for the CPT code set lies with the AMA CPT Editorial Panel, authorized by the AMA Board of Trustees. This ongoing process has a schedule for submission deadlines and meetings of the CPT Panel, which can be found on the AMA site. An application form must be filled out completed and sent via email. |
| Coverage | Medical procedures and services. |
| Out of Scope | DMEPOS – durable medical equipment, prosthetics, orthotics, and supplies Ambulatory services. |
| Development & Maintenance | CPT codes are divided into 3 categories: Category I – codes assigned to procedures that are deemed to be within the scope of medical practice across the U.S. Services supported in the medical literature and have clearance from the U.S. FDA. The Relative Value Scale (RVS) Update Committee (RUC) process assigns relative value units (RVUs) for all Category I CPT codes. |

⁹⁵ The American Medical Association. CPT (Current Procedural Terminology [Internet]. Chicago (IL): The American Medical Association; [cited 2018 May]. Available from: <http://www.ama-assn.org/practice-management/cpt-current-procedural-terminology/>.

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| | <p>Category II – tracking codes designed for the measurement of performance improvement.</p> <p>Category III – temporary codes for new or emerging technology or procedures. For data collections and serve to support the inclusion (or exclusion) of new or emerging technology in standards medical practice. Category III codes are not assigned a value through the RUC process.</p> |
| Requesting New Content | <p>Any individual QHP, medical specialty society, hospital, third-party payer, and other interested party may submit an application for changes to CPT for new or revised codes to the CPT Editorial Panel. The AMA staff reviews the code proposal and then CPT Advisory Committee reviews the proposal. This part of the process is not open to the general public. The Editorial Panel then reviews the code proposal and the advice from the CPT Advisory Committee at its regularly scheduled meeting. The group can approve the code, table the proposal, or reject the proposal.</p> |
| Release & Dissemination | <p>Category I – Released annually but certain category I codes are “early released” to become effective 6 months after release date (e.g., vaccine products, Molecular Pathology); other category codes may be early released to capture reporting for evaluation.</p> <p>Category II – released 3 times year (March, July, and November)</p> <p>Category III – released biannually (January and July)</p> <p>Proprietary Laboratory Analyses - released quarterly (January, April, July, and October)</p> <p>Administrative MAAA - released 3 times year (March, September, and December)</p> <p>Official files are from the AMA. Data available from NLM (via UMLS).</p> <p>No documentation on file specification found.</p> |
| Overlap | <p>Overlap statistics from UMLS: 42.5% CPT in HCPCS 12.7% SNOMED CT 8.5% MEDCIN</p> |
| Harmonization & Collaborations | <p>CPT is HCPCS Level I</p> |

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| Name | HCPCS-Level II ⁹⁶ Healthcare Common Procedure Coding System https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/index.html |
| Purpose | Codes used to identify products, supplies, and services such as ambulance and durable medical equipment and supplies when used outside a physician's office. |
| Usage | HCPC-Level II are a standardized coding system used in the U.S. for billing and identifying items and non-physician based services. Level II of the HCPCS is primarily used to identify products, supplies, and services not included in the CPT code set jurisdiction, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office. |
| Named Standard? | Named standard for HIPAA (1996). Public and private insurers were required to be in compliance with the August 2000 regulation by October 1, 2002. Named Standard for the 2014 ONC EHR certification criteria - MU Stage 2. |
| Ownership | In October of 2003, the Secretary of HHS delegated authority under the HIPAA legislation to CMS to maintain and distribute HCPCS Level II Codes. |
| Development Principles | CMS HCPCS Workgroup responsible for decisions about additions, revisions, and deletions. Workgroup comprised of representatives of CMS, CMS contractors, consultants from Federal agencies and Medicaid, private insurance, and the Department of Veterans Affairs. All complete recommendations are distributed to all reviewers; placed on HCPCS Meeting Agendas and reviewed at regularly scheduled meetings by a panel whose membership includes representatives of all government and non-government insurance sectors, including Medicaid, Medicare, the private insurance sector, and the Department of Veterans Affairs. All external recommendations (i.e., requests not generated internally) presented during the HCPCS Public Meetings to provide an open forum for interested parties to make oral presentations or to submit written comments in response to published preliminary coding decisions. The Public Meetings are not decision-making meetings, they are to provide an opportunity for applicants and the general public to react to preliminary coding decisions and share additional information with decision makers prior to final decisions. A summary of all external applications, including CMS' final decisions and rationale, are published on the CMS website. |
| Coverage | Ambulance services. |

⁹⁶ Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures [Internet]. Baltimore (MD): Centers for Medicare & Medicaid Services (U.S.); 2015 [cited 2018 Jun]. 12 p. Available from: <https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelII CodingProcedures7-2011.pdf>.

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| | DMEPOS - durable medical equipment, prosthetics, orthotics, and supplies when used outside a physician's office. |
| Out of Scope | CPT content |
| Development & Maintenance | <p>HCPCS codes represent 6,000 separate categories of like items or services for millions of products from manufacturers.</p> <p>A HCPCS code is a five-digit alpha-numeric number. The first letter of the code identifies to which category the item or service belongs. HCPCS codes are not brand specific – many different products can fall under the same HCPCS.</p> <p>CMS provides rules for code assignment and extensive review process for HCPCS maintenance. HCPCS updates include both permanent national codes as well as temporary codes. When assigning an existing “Temporary” or “Permanent” code, CMS will assign items to the existing code category, and ensure that the coverage indicator assigned to the code category accurately reflects Medicare policy regarding payment for the item. When assigning a new “Temporary” or “Permanent” code, CMS determines that the new code category is appropriate and will make effort to establish, publish, and implement the new code at the time of the final coverage determination is made.</p> |
| Requesting New Content | <p>Requests for/to establish, revise, or discontinue a code must include a form filled out in ink with supporting documentation, plus 35 copies of the entire original recommendation information packet (36 applications in total). The packets are sent to the HCPCS workgroup members. Application packets must be sent in paper form through the mail at the address indicated, not hand delivered.</p> <p>HCPCS updates include both permanent national codes as well as temporary codes. Permanent national codes are updated annually – code requests have to be received by January 3 of the current year to be considered for the next January 1 update. Temporary codes can be added, changed, or deleted on a quarterly basis. Once established, Temporary codes are usually implemented within 90 days. CMS does not have an external request mechanism for Temporary codes.</p> |
| Release & Dissemination | <p>Quarterly with annualized compilation.</p> <p>CMS releases: HCPCS Annual update – downloadable zip file New established Temporary Codes and effective dates – downloadable zip file Online look up Code list PDF downloads</p> <p>CPT (Level I) is available from AMA (see above for more details) CDT (Level II) is available from ADA (see above for more details)</p> <p>Data available from NLM (via UMLS).</p> |
| Overlap | There is some overlap between HCPCS codes and National Drug Code (NDC) codes, with a subset of NDC codes also in HCPCS, and vice versa. The CMS maintains a crosswalk from NDC |

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| | <p>to HCPCS in the form of an Excel file. The crosswalk is updated quarterly.</p> <p>Current Dental Terminology (CDT) codes are a separate category of national codes, copyrighted to the American Dental Association (ADA), are considered HCPCS Level II codes.</p> <p>Overlap statistics from UMLS: 5.5% Current Procedural Terminology 1.7% SNOMED CT 1.6% MEDCIN 1.4% Consumer Health Vocabulary</p> |
| Harmonization & Collaborations | <p>HCPCS Level I is CPT CDT codes incorporated into Level II</p> |

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| Name | <p>ICD-10</p> <p>International Statistical Classification of Diseases and Related Health Problems 10th Revision</p> <p>http://www.who.int/classifications/icd/en/</p> |
| Purpose | <p>To promote international comparability in the collections, classification, processing, and presentation of mortality statistics. It is used to track epidemiological trends and to assist in medical reimbursement decisions. Replaced ICD-9.</p> |
| Usage | <p>Global, with national/regional versions (for U.S. see ICD-10-CM below)</p> <p>Available in 42 different language translations.</p> |
| Named Standard? | <p>Cause of death coding from death certificates and mortality data; in use in U.S. since 1999 (statutory basis).</p> |
| Ownership | <p>World Health Organization (WHO)</p> |
| Development Principles | <p>ICD is developed collaboratively between the WHO and the 10 International centers (including the National Center for Health Statistics (NCHS) Center for Disease Control and Prevention (CDC) for U.S.).</p> <p>The 1993 ICD-10 release had major restructuring changes in the classification from version 9. The changes were driven by the need to expand categories, use of new code labels (alpha-numeric), expanded use of families (ability to drill down), and an improved consistency in classification structure.</p> <p>ICD is revised periodically and is currently in its tenth revision with an eleventh in progress. Annual updates and triennial major updates are provided for each edition.</p> <p>Two separate bodies manage the updating process: the Mortality Reference Group (MRG) and Update and Revision Committee (URC).</p> |

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| Coverage | Covers the main parameters of health system related to death and disease – mortality and morbidity. |
| Out of Scope | Functioning and disability (ICF) Health Interventions (ICHI) |
| Development & Maintenance | <p>With the 10th revision it was determined that the regular 10-year interval between revisions was too short. Thus, creation of ICD-10 took a little longer than expected. However, ICD-10 expanded the classification beyond ICD-9. ICD-10 is a variable-axis classification with structure of the classification grouped by: epidemic diseases, constitutional or general diseases, local diseases arranged by site, developmental diseases, and injuries.</p> <p>The basic ICD is a single coded list of three-character categories, each of which can be further divided into up to 10 four-character subcategories. In place of the purely numeric coding system of previous revisions, the 10th revision uses an alphanumeric code with a letter in the first position and a number in the second, third and fourth positions. The fourth character follows a decimal point.</p> <p>The classification is divided into 22 chapters (e.g., Chapter II – Neoplasms), roughly grouped into medical diseases.</p> <p>Two separate bodies manage the updating process: The Mortality Reference Group (MRG) and Update and Revision Committee (URC). They ensure all new or removed content adheres to the WHO conventions of ICD.</p> |
| Requesting New Content | <p>Changes must be sponsored by one of the WHO Collaborating Centers for Classification of Diseases.</p> <p>The URC receives proposals via the update proposal platforms for the Family of International Classifications (FIC). The URC considers the proposals and submits recommendations on proposed updates to the WHO-FIC Network who makes recommendations to WHO.</p> |
| Release & Dissemination | <p>Tabular list is updated every three years for major changes, annually for minor changes.</p> <p>Index list published annually for changes that do not impact on the structure of the tabular list.</p> <p>Minor updates are accepted each October at the annual Network meeting and published the following year in the WHO website before implementation in January of the year following publication.</p> <p>Major updates are accepted each October at the Heads of Centers meeting and published the following year before implementation in January of the year designated as major.</p> <p>Online browser. ICD-10 data files are available from WHO and CDC. Data available from NLM (via UMLS).</p> <p>The classification releases consist of 3 volumes:</p> |

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| | <p>Volume 1: Tabular list – the main classifications Volume 2: Instruction manual – the guidance for users Volume 3: Alphabetical index – classification index</p> <p>A SNOMED CT to ICD-10 map is available from SNOMED International (via SNOMED CT International and US Editions).</p> |
| Overlap | <p>Overlap statistics from UMLS: 83.9% SNOMED CT 70.6% ICD-10-CM 45.9% MEDCIN 38.4% ICPC-2 36.8% MedDRA 32.0% ICD-9-CM 21.3% Consumer Health Vocabulary 15.9% NCI Thesaurus</p> |
| Harmonization & Collaborations | <p>WHO collaborates with Member governments, non-governmental agencies, other agencies, SDOs, as well as divisions and units of WHO.</p> |

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| Name | <p>ICD-10-CM⁹⁷</p> <p>International Statistical Classification of Diseases - Clinical Modifications</p> <p>https://www.cdc.gov/nchs/icd/icd10cm.htm</p> |
| Purpose | <p>U.S. specific Clinical Modification of ICD-10. Used for diagnosis coding in clinical and outpatient settings.</p> |
| Usage | <p>U.S. code system - also used in other countries (Spain, Belgium).</p> |
| Named Standard? | <p>HIPAA standard for morbidity in outpatient, inpatient and other care settings.</p> |
| Ownership | <p>WHO has authorized the development of an adaptation of the ICD-10 for use in the United States for U.S. government purposes.</p> <p>The National Center for Health Statistics (NCHS), the U.S. Federal agency responsible for use of the International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) in the United States, has developed a clinical modification of the classification for morbidity purposes.</p> |
| Development Principles | <p>All modifications to the ICD-10 must conform to WHO conventions for the ICD. ICD-10-CM was developed following an evaluation by a Technical Advisory Panel and consultation with</p> |

⁹⁷ Centers for Medicare and Medicaid Services and National Center for Health Statistics. ICD-10-CM Official Guidelines for Coding and Reporting FY 2018 [Internet]. Atlanta (GA): Centers for Disease Control and Prevention (U.S.); 2018 [cited 2018 Mar]. 117 p. Available from: https://www.cdc.gov/nchs/data/icd/10cmguidelines_fy2018_final.pdf.

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| | <p>physician groups, clinical coders, and other stakeholders for clinical accuracy and utility.</p> <p>Maintenance of ICD-10-CM and ICD-10-PCS is through the ICD-10 Coordination and Maintenance Committee (C&M) is a Federal interdepartmental committee comprised of representatives from the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS). The C&M Committee receives and considers code change proposals through an open process and receives advice from the Cooperating Parties.</p> <p>The Cooperating Parties is comprised of NCHS, CMS, AHA, and AHIMA advise on changes and develop coding guidelines. Cooperating Parties serve as Editorial Advisory Board (EAB) to Coding Clinic sponsored by AHA. AHA maintains the central office on ICD-10-CM for handling coding questions from the field.</p> <p>NCHS leads responsibility for ICD-10-CM maintenance for diagnoses and CMS leads responsibility for ICD-10-PCS for inpatient acute care procedures.</p> |
| Coverage | <p>The disease classification has been expanded to include health-related conditions and to provide greater specificity at the sixth and seventh character level. The sixth and seventh characters are not optional and are intended for use in recording the information documented in the clinical record.</p> |
| Out of Scope | <p>No documentation found.</p> |
| Development & Maintenance | <p>NCHS leads responsibility for ICD-10-CM maintenance. However, because the ICD-10-CM represents the best in contemporary thinking of clinicians, nosologists, epidemiologists, and statisticians from both public and private sectors, when future modifications are considered, advice will be sought from all stakeholders. Additionally, the WHO conventions for the ICD are adhered to during maintenance.</p> <p>ICD-10-CM is released in the Alphabetical Index or Tabular List. The ICD-10-CM the Alphabetical Index, is an alphabetical list of terms and their corresponding code, and the Tabular List, is a structured list of codes divided into chapters based on body system or condition. The Alphabetical Index consists of the following parts: the Index of Diseases and Injury, the Index of External Causes of Injury, the Table of Neoplasms and the Table of Drugs and Chemicals.</p> <p>The ICD-10-CM Tabular List contains categories, subcategories and codes. Characters for categories, subcategories and codes may be either a letter or a number. All categories are 3 characters. A three-character category that has no further subdivision is equivalent to a code. Subcategories are either 4 or 5 characters. Codes may be 3, 4, 5, 6 or 7 characters. That is, each level of subdivision after a category is a subcategory. The final level of subdivision is a code. Codes that have applicable 7th characters are still referred to as codes, not subcategories. A code that has an applicable 7th character is considered invalid without the 7th character.</p> <p>The ICD-10-CM uses an indented format for ease in reference.</p> |
| Requesting | <p>Suggestions for modifications come from public and private sectors. Modifications proposals</p> |

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| New Content | <p>must be submitted prior to a scheduled meeting. The Committee provides a public forum to discuss proposed changes to ICD-10. The first day of the meeting is devoted to procedure code issues and is led by CMS. The second day is devoted to diagnosis code issues and is led by CDC. Tentative agendas for the meetings are posted one month in advance of the scheduled meetings.</p> <p>The committee is responsible for approving coding changes, developing errata, addenda and other modifications. Requests for coding changes are submitted to the committee for discussion at either the Spring or Fall C&M meeting.</p> <p>Final decisions on code revisions are made through a clearance process within DHHS. No final decisions are made at the meeting.</p> |
| Release & Dissemination | <p>Annual updates effective October 1 of each year.</p> <p>Official release files on NCHS (CDC) website. Files are also available from CMS and via NLM UMLS.</p> <p>A SNOMED CT to ICD-10-CM map is available from NLM. The map is based on the SNOMED CT US Edition. Available for free with a UMLS Metathesaurus License.</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 12.9% MEDCIN 12.5% SNOMED CT 8.0% ICD-10⁹⁸ 6.8% MedDRA 6.7% ICPC-2 5.6% ICD-9-CM |
| Harmonization & Collaborations | <p>Guidelines for the use of ICD-10-CM in coding and reporting is approved by a collaborative group - the Cooperating Parties for the ICD-10-CM: the American Hospital Association (AHA), the American Health Information Management Association (AHIMA), CMS, and NCHS.</p> |

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| Name | <p>ICD-10-PCS⁹⁹</p> <p>ICD-10 Procedure Coding System</p> <p>https://www.cms.gov/Medicare/Coding/ICD10/2019-ICD-10-PCS.html</p> |
| Purpose | <p>U.S. code system for hospital reporting of procedures performed in hospital inpatient health care settings.</p> |

⁹⁸ Note numbers obtained from the UMLS 2018AA version which included 1998 version of ICD-10 and the 2017 version of ICD-10-CM. ICD-10-CM is a much larger, more granular classification code system (with 178,446 atoms in 102,038 CUIs) to ICD-10 (with 13,505 atoms in 11,552 CUIs).

⁹⁹ Brooks P, Butler R. ICD-10-PCS. Presented at: National Committee on Vital and Health Statistics Full Committee Hearing [Internet]; 2017 June 21-22 [cited 2018 Mar]; Washington, DC. Available from: https://ncvhs.hhs.gov/wp-content/uploads/2017/06/Day1-Pat-Brooks-and-Rhonda-Butler-ICD_10_-PCS.pdf.

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| Usage | U.S. code system - also used in other countries (Portugal, Spain, and Taiwan). |
| Named Standard? | Named HIPAA standard for inpatient procedures. |
| Ownership | Centers for Medicare and Medicaid Services (CMS). CMS is the U.S. governmental agency responsible for overseeing all changes and modifications to the ICD-10-PCS. |
| Development Principles | <p>Maintenance of ICD-10-CM and ICD-10-PCS is through the ICD-10 Coordination and Maintenance Committee (C&M) which is a Federal interdepartmental committee comprised of representatives from the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS). The C&M Committee receives and considers code change proposals through an open process and receives advice from the Cooperating Parties.</p> <p>The Cooperating Parties is comprised of NCHS, CMS, AHA, and AHIMA advise on changes and develop coding guidelines. Cooperating Parties serve as Editorial Advisory Board (EAB) to Coding Clinic sponsored by AHA. AHA maintains the central office on ICD-10-CM and ICD-10-PCS for handling coding questions from the field.</p> <p>NCHS leads responsibility for ICD-10-CM maintenance for diagnoses and CMS leads responsibility for ICD-10-PCS for inpatient acute care procedures.</p> |
| Coverage | In-patient procedures. |
| Out of Scope | Diseases Outpatient procedures |
| Development & Maintenance | <p>ICD-10-PCS has specific key attributes including:</p> <ul style="list-style-type: none"> • Structured to be expandable - As new procedures are developed the structure of ICD-10-PCS should allow them to be easily incorporated as unique codes. • Completeness – all substantially different procedures must have a unique code. • Multi-axial terminology – each axis specifies same type of information within a section. • Standardized definitions – each term has a single meaning. <p>The codes are comprised of seven components of meaning – each component is referred to as a “character”</p> <ul style="list-style-type: none"> • Individual expression of a character, represented by a letter or number is called a “value” • 34 possible values for a character within a given context, such as root operation <p>Table Structure</p> <ul style="list-style-type: none"> • 17 top level subdivisions called Sections – each section defines varying numbers of root operation tables. Each table contains four columns and varying numbers of rows. <p>ICD-10-PCS release comes in several different types of files:</p> <ul style="list-style-type: none"> • ICD-10-PCS Coding Guidelines • ICD-10-PCS Code Tables and Index (zip file of xml, xsd, and pdf) |

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| | <ul style="list-style-type: none"> • ICD-10-PCS Codes File (zip file of txt and pdf) • ICD-10-PCS Order File (zip file of txt and pdf) • ICD-10-PCS Final Addenda (zip file of pdf and txt) • ICD-10-PCS Conversion Table (zip file of xls, txt, and pdf) |
| Requesting New Content | <p>Suggestions for modifications come from public and private sectors. Modifications proposals must be submitted prior to a scheduled meeting. The Committee provides a public forum to discuss proposed changes to ICD-10. The first day of the meeting is devoted to procedure code issues and is led by CMS. The second day is devoted to diagnosis code issues and is led by CDC. Tentative agendas for the meetings are posted one month in advance of the scheduled meetings.</p> <p>The committee is responsible for approving coding changes, developing errata, addenda and other modifications. Requests for coding changes are submitted to the committee for discussion at either the Spring or Fall C&M meeting.</p> <p>Final decisions on code revisions are made through a clearance process within DHHS. No final decisions are made at the meeting.</p> <p>An implementation exception is for procedure codes capturing new technology. If a clear and convincing case is made that the new code is needed to capture new technology, this new code may be implemented on April 1 of the following year.</p> |
| Release & Dissemination | <p>Annual addenda October 1.</p> <p>Release files include Core content (ICD-10-PCS Tables, Index, Definitions), Official ICD-10-PCS Coding Guidelines, update summary. Files are available in a machine-readable format (for technical purposes) and PDF (for coders).</p> <p>Releases available from CMS. Data available from NLM (via UMLS).</p> |
| Overlap | No documentation. |
| Harmonization & Collaborations | Guidelines for the use of ICD-10-PCS in coding and reporting is approved by a collaborative group - the Cooperating Parties for the ICD-10-PCS: the American Hospital Association (AHA), the American Health Information Management Association (AHIMA), CMS, and NCHS. |

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| Name | <p>LOINC</p> <p>Logical Observation Identifiers Names and Codes</p> <p>https://loinc.org/</p> |
| Purpose | A universal standard for identifying health measurements, observations, and documents. |
| Usage | Global - Available in the following translations: Chinese, Dutch, Estonia, Belgian French, Canadian French, French, Swiss French, Austrian German, German, Swiss German, Greek, |

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| | Italian, Swiss Italian, Korean, Brazilian Portuguese, Russian, Argentinian Spanish, Mexican Spanish, Spanish, Turkish |
| Named Standard? | Yes – LOINC is a named standard for Meaningful Use in the United States. The final rule for Meaningful Use Stage 2 specifies LOINC should be used for the electronic exchange of laboratory test results and clinical observations such as vital signs, social, psychological, and behavioral data, and documents such as care/referral summaries. |
| Ownership | LOINC is owned and maintained by Regenstrief Institute, funded primarily by the National Library of Medicine. |
| Development Principles | LOINC data structure is based on the LOINC concept model. The LOINC terminology is maintained by the LOINC Committee, who defines the overall naming conventions and policies for the development process. The LOINC Committee is comprised of the members of its composite committees of Laboratory LOINC, Clinical LOINC (and the Nursing Subcommittee), and LOINC/RadLex. Includes laboratory, clinical, and nursing subgroups. Committee representatives are domain experts primarily from the U.S., but also from other countries. |
| Coverage | <p>Overall scope is anything you can test, measure, or observe about a patient. All observations reported by clinical laboratories.</p> <p>Two major divisions of LOINC content: Laboratory (chemistry, hematology, serology, microbiology (including parasitology and virology), toxicology, cell counts and antibiotic susceptibilities) and Clinical (vital signs, hemodynamics, intake/output, EKG, obstetric ultrasound, cardiac echo, urologic imaging, gastro endoscopic procedures, pulmonary ventilator management, radiology studies, clinical documents, select survey instruments, and other clinical observations).</p> <p>Additional areas within scope: Some veterinary medicine Order sets, panels, forms, and other enumerated “collections” of observations.</p> |
| Out of Scope | Clinical medicine |
| Development & Maintenance | <p>LOINC employs content editors to model new content based on submissions requested by users and new collaborative agreements between Regenstrief and other SDOs and organizations. LOINC adheres to a specific modeling process for the structure of the concept as well as modeling into the code system. A Committee defines overall naming conventions and policies for the development process; Committee has laboratory, clinical, and nursing subgroups to provide guidance and advises how content shall be modeled.</p> <p>The LOINC code is a unique permanent identifier. The LOINC code ends with a check digit preceded by a hyphen(dash). The hyphen, as well as the numbers, is part of the LOINC identifier and must be included in all electronic transmissions.</p> <p>Part of LOINC modeling includes the fully specified name which has five or six main parts: the name of the Component or Analyte measured, the Property observed, the Time Aspect of the measurement, the type of System or same, the Scale of measurement, and (where relevant) the Method of the Measurement.</p> |

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| | <p>As LOINC is a concept-based terminology, two important attributes include a Short Name and Long Common Name. LOINC has maintained a set of editorial policies that guide adherence to the concept-oriented practice.</p> <p>LOINC data releases are produced by Regenstrief. LOINC data are released in LOINC Table Core (csv file), LOINC Table File (csv file or Microsoft access format), LOINC Table Changes File (Microsoft access format), and LOINC Table Changes Report (pdf). Each release typically contains around 1,400 new terms.</p> |
| Requesting New Content | Any LOINC user can submit a request for changes (new and updates) to the terminology via the formal request for change process accessible from the LOINC website. Regenstrief also provides webpages showing term requests currently in the queue, those that have passed the quality assurance process and will be included in the next release, and a variety of request processing statistics. |
| Release & Dissemination | <p>LOINC data releases are produced by Regenstrief. The LOINC terminology is released twice a year - in June and December. It is available for free via Regenstrief.</p> <p>LOINC data are released in LOINC Table Core (csv file), LOINC Table File (csv file or Microsoft access format), LOINC Table Changes File (Microsoft access format), and LOINC Table Changes Report (pdf). Each release typically contains around 1,400 new terms. There is a pilot Fast Healthcare Interoperability Resources (FHIR) Terminology Services API (including the CodeSystem, ValueSet, and ConceptMap resources) for programmatic access to LOINC content.</p> <p>LOINC is also now available, with the use of RELMA software, to help users map their local terms or lab tests to LOINC codes. Apps aid use of LOINC by developers.</p> <p>Data also available from NLM (via UMLS).</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 6.6% SNOMED CT 4.0% Consumer Health Vocabulary 3.7% NCI Thesaurus 3.7% MeSH |
| Harmonization & Collaborations | LOINC (Regenstrief) has extensive partnerships and collaborations with many SDOs and organizations including: HL7, IEEE Standards Association, SNOMED International, Radiological Society of North America, and Health Standards Collaborative. |

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| Name | <p>NDC</p> <p>National Drug Codes</p> <p>https://www.fda.gov/drugs/informationondrugs/ucm142438.htm</p> |
| Purpose | A universal product identifier for prescription medications approved for human consumption. The NDC code denotes labeler, product, and commercial package size. |

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| Usage | <p>The NDC code is present on all nonprescription (OTC) and prescription medication packages and inserts in the U.S.</p> <p>The NDC code is used for billing and reimbursement purposes varies depending on payer. And the NDC information and listing in the NDC Directory are used in the implementation and enforcement of the Act.</p> |
| Named Standard? | <p>A named HIPAA standard. CMS's 11-digit NDC derivative format adopted by data standards selected pursuant to HIPAA regulation.</p> <p>The Drug Listings Act of 1972 required registered drug establishments to provide the Food and Drug Administration (FDA) with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distributions. Drug products are identified and reported using the NDC. The information submitted as part of the listing process, the NDC number, and the NDC Directory are used in the implementation and enforcement of the Act.</p> <p>Section 510 of the Federal Foods, Drug and Cosmetic Act (Act), 21 U.S.C. §360, requires a registered drug establishment to provide the FDA with a current list of all drugs manufactured, prepared, propagated, compounded, or processed by it for commercial distribution. A 2007 update required the submission to be electronic.</p> |
| Ownership | <p>Product labeler/manufacturer assigns two segments of the code and FDA assigns one. FDA produces the National Drug Code Directory.</p> |
| Development Principles | <p>The labeler code is assigned by the U.S. FDA, and the product and package codes are assigned by the company.</p> <p>As of July 1, 2011, only drugs for which electronic listings (Structured Product Labeling or SPL) have been submitted to FDA are included in the NDC Directory.</p> |
| Coverage | <p>In scope – human prescription drug, OTC, or insulin product.</p> |
| Out of Scope | <p>Out of scope – animal drugs, blood products, or human drugs, that are not in final marketed form are not included in the NDC directory.</p> |
| Development & Maintenance | <p>The NDC code includes 3 parts – the labeler, product, and package sections make up an NDC code. The labeler code is assigned by the U.S. FDA, and the product and package codes are assigned by the company.</p> <p>NDC numbers can vary depending on when the code was first assigned by the FDA. Many labeler codes consist of 5 digits but some may only be 4.</p> <p>To standardize between pharmacies and CMS, many manufacturers add an eleventh number to the NDC. It is usually a leading zero, which can be inserted into the labeler, product, or package size portion of the NDC. This helps to accommodate for variations between sections. The 11th digit acts as a placeholder to help maintain consistency.</p> |

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| | The FDA publishes the listed NDC numbers and the information submitted as part of the listing information in the NDC Directory which is updated daily. Only information on final marketed drugs submitted to FDA in SPL electronic listing files by labelers are included. Only the outermost packages and dispensable inner layer packages, reported by firms as part of their product listing submission to the FDA, are included. |
| Requesting New Content | To add a new entry, or to correct erroneous or incomplete product data in the NDC Directory, a labeler needs to submit a new SPL to update the information via the Drug Registration and Listing System (eDRLS). As of July 1, 2011, only drugs for which electronic listings (Structured Product Labeling or SPL) have been submitted to FDA are included in the NDC Directory. |
| Release & Dissemination | NDC Directory is updated daily. The downloadable data file is offered in SAS, Stata, and CSV formats. National Drug Code Directory (a browsable database) NDC Database File (downloadable format) FDA publishes electronic NDC Directory. RxNorm and UMLS (NLM) also includes NDC codes. NDC codes are available via mobile apps. |
| Overlap | There is some overlap between HCPCS codes and NDC codes, with a subset of NDC codes also in HCPCS, and vice versa. The CMS maintains a crosswalk from NDC to HCPCS in the form of an Excel file. The crosswalk is updated quarterly. RxNorm distributes and normalizes NDC codes to RxNorm clinical drug concepts. |
| Harmonization & Collaborations | No documentation found. |

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| Name | RxNorm https://www.nlm.nih.gov/research/umls/rxnorm/ |
| Purpose | RxNorm is a normalized naming system for generic and branded drugs; and a tool for supporting semantic interoperability between drug terminologies and pharmacy knowledge base systems. |
| Usage | U.S. – Represents U.S. drug market, but available internationally. |
| Named Standard? | Yes - The drug terminology is a named standard for Meaningful Use in the United States. The final rule for Meaningful Use Stage 2 specifies RxNorm in the communication of medication data and medication allergies. |
| Ownership | RxNorm is owned and maintained by the National Library of Medicine. |
| Development Principles | The terminology is derived by normalizing drug data from other commonly used public and private drug terminologies. Changes compiled from these data sources are generally received |

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| | monthly. Exceptions include FDA Structured Product Labeling data, which are updated daily. An internal team of RxNorm editors and pharmaceutical experts provide the editorial policies for the terminology. New and major editorial policy changes are informed by user community feedback. |
| Coverage | RxNorm contains the names of prescription drugs and many over-the-counter drugs available in the U.S. RxNorm includes generic and branded: <ul style="list-style-type: none"> • Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic intent • Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specific sequence. |
| Out of Scope | Non-therapeutic radiopharmaceuticals, bulk powders, contrast medical, foods, dietary supplements, and medical devices, such as bandages and crutches. |
| Development & Maintenance | <p>Derived from other commonly used public and private drug terminologies. Generally, the following five basic steps are involved in RxNorm production:</p> <ol style="list-style-type: none"> 1. Group source data into collections of synonyms (called concepts). 2. Create an RxNorm normalized name for each concept (if the concept is in scope and unambiguous). 3. Assign an RxNorm concept unique identifier (RXCUI) to each concept and an RxNorm atom unique identifier (RXAUI) to each concept or string. 4. Include relationships and attributes from source data. 5. Create related RxNorm names and relationships. <p>RxNorm terminology is modeled such that the name and relationships are normalized with the simple pattern of Ingredient, Strength, and Dose Form, and Brand Name.</p> <p>The full monthly RxNorm release is produced by the National Library of Medicine. The release includes 9 data files (pipe-delimited, text files).</p> |
| Requesting New Content | Drug manufacturers should submit structured product labeling (SPL) to the FDA for inclusion of their drug information in RxNorm. |
| Release & Dissemination | <p>RxNorm is available for free from the NLM.</p> <p>RxNorm new drug information is released weekly (every Wednesday) with newly-approved drug information from the FDA Structured Product Labels source vocabulary. The full RxNorm data set is released monthly - generally on the first Monday of each month.</p> <p>Data also available from via UMLS.</p> <p>NLM also provides a number of RxNorm APIs, an RxNav Browser, and a UMLS Metathesaurus Browser. The RxNorm APIs and RxNav Browser are available without UMLS licensing restrictions.</p> |
| Overlap | Overlap statistics from UMLS: 18.6% Multum |

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| | <p>13.8% FDA Structured Product Labels 12.6% Micromedex 9.8% FDB MedKnowledge 9.7% Gold Standard Drug Database 8.3% National Drug File - Reference Terminology 8.0% National Drug File 6.8% SNOMED CT 3.9% NCI Thesaurus</p> |
| Harmonization & Collaborations | <p>Because RxNorm harmonizes sources, these sources are represented in RxNorm: Anatomical Therapeutic Chemical Classification System Vaccines Administered DrugBank Gold Standard Drug Database Medi-Span Master Drug Data Base* Multum MediSource Lexicon Micromedex RED BOOK Medical Subject Headings (MeSH) CMS Formulary Reference File FDA Structured Product Labels FDB MedKnowledge (formerly NDDF Plus) Veterans Health Administration National Drug File - Reference Terminology NDFRT FDASPL relationships NDFRT FMTSME relationships US Edition of SNOMED CT (drug information) Veterans Health Administration National Drug File</p> <p>*Discussions are ongoing to include Medi-Span Master Drug Data Base in RxNorm in the near future.</p> |

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| Name | <p>SNOMED CT</p> <p>SNOMED was originally an acronym for Systematized Nomenclature of Medicine, it lost that meaning when SNOMED was combined with CTV3 in 2002. The merged product was called SNOMED Clinical Terms, which was shortened to SNOMED CT. SNOMED International considers SNOMED CT to be a brand name, not an acronym.</p> <p>There are two different terminology releases, SNOMED CT International Edition, produced by SNOMED International, and SNOMED CT US Edition (which combines the International edition with the US Extension) produced by the National Library of Medicine.</p> <p>https://www.snomed.org/</p> |
| Purpose | <p>Clinical terminology enabling automation of reasoning and analytical approaches to processing EHR data.</p> |
| Usage | <p>Global</p> |

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| | Available in the following translations: Australian English, Canadian English and Canadian French, Danish, Dutch, Spanish, Swedish, UK English |
| Named Standard? | Yes – the U.S. Edition of SNOMED CT is a named standard for Meaningful Use in the United States. In Stage 1 of Meaningful Use it was required that EHR systems must encode problem list data in either SNOMED CT or ICD-9-CM. The final rule for Meaningful Use Stage 2 (and in the 2014 EHR Certification Criteria) expanded use of SNOMED CT and required EHR systems to use SNOMED CT for documenting problem lists, procedures, and some clinical findings such as smoking status. |
| Ownership | International Health Terminology Standards Development Organisation, trading as SNOMED International (SI). SNOMED International is an international, non-profit organization. The National Library of Medicine, on behalf of the Department of Health and Human Services, is the Member for the United States. |
| Development Principles | <p>SNOMED CT is developed with a strong adherence to the SNOMED CT Editorial Policies, based on a conceptual model utilizing description logic. Guidance for Editorial Policies is provided by international Advisory Groups (editorial, terminology release and content), and Clinical Reference Groups (to expand dialogue with specialists and address emerging uses).</p> <p>SNOMED CT International Edition content work is guided by the Members of SNOMED International. Annually the Members (via the Member Representatives, the National Library of Medicine on behalf of the U.S.) inform SNOMED International and the other Members of current country initiatives and areas of interest for content development and maintenance work.</p> <p>The US Edition adheres to the International Edition Editorial policies and works with users and U.S. constituents to ensure coverage for U.S. needs are met.</p> |
| Coverage | <ul style="list-style-type: none"> ● Clinical findings, including disorders ● Procedures, broadly defined as including all health-related activities such as history taking, physical examination, testing, imaging, surgical procedures, disease-specific training and education, counseling, and so forth. ● Observable entities which, when given a value, provide a specific finding or assertion about health-related information. Examples include the names of lab tests, physical exam tests, dates of significant events, and so forth. ● Anatomy, morphology, and other body structures ● Chemicals and other substances of relevance to health and health care, including generic drug ingredient names, generic drug products (virtual medicinal products) ● Generic physical devices relevant to health care, or to broad categories of injury or accident ● Organisms relevant to health and health care of humans and animals ● Other etiologies of disease, including external forces, harmful events, accidents, genetic abnormalities, ● Functions and activities ● Social contexts relevant to health, including general categories of status of |

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| | <p>employment, education, housing, care provision, family Relationships, and so forth.</p> <ul style="list-style-type: none"> ● Types of clinical records, documents, certificates and other records and record components relevant to health care. ● Staging, scales, classifications, and other miscellaneous health information ● Attributes and values necessary to organize and structure the terminology <p>US Edition (Extension) content coverage allows an even broader scope of concepts, terms, and components.</p> |
| Out of Scope | <ul style="list-style-type: none"> ● Non-human concepts (post 2014 versions) ● Content deemed appropriate not at the International level but for local extensions. ● Units of measure |
| Development & Maintenance | <p>SNOMED International employs content editors to model new content into SNOMED International Edition and create new reference sets (mappings and other derivatives) based on direction and initiatives put forth by the Members of SNOMED.</p> <p>All editorial direction is under the auspices of the Chief Terminologist – with guidance from the SNOMED CT Editorial Policy and advice from the International Advisory Groups for editorial, terminology releases, and content. Clinical reference groups expand dialogue with specialists and address emerging uses such as precision medicine.</p> <p>New content is created from one of two ways – directly from the content requested by users (via the formal request for change process), or from International collaboration work with other SDOs.</p> <p>The National Library of Medicine maintains the SNOMED CT U.S. Edition. A content manager models user requests. Those applicable only to U.S. interests will be modeled into the US Extension while those applicable to the international Members will be forwarded to the International Core. The NLM also works with SI (via Managed Service) to maintain the SNOMED CT to ICD-10-CM map and to create the U.S. Edition release.</p> |
| Requesting New Content | <p>SNOMED CT has a formal change request process. Any SNOMED CT user can submit for changes (new and updates) to the terminology via the formal request for change process. The National Library of Medicine utilizes an application (U.S. Content Request System) for any user requirement for SNOMED CT terminology changes. These changes can be made directly in the U.S. Extension or submitted to the International SNOMED CT core.</p> |
| Release & Dissemination | <p>The International Release of SNOMED CT is released twice a year – January 31 and July 31.</p> <p>The U.S. Edition of SNOMED CT includes the most recent version of the International Release, combined with the U.S. Extension (additional content relevant to the U.S.). The U.S. Edition is released twice a year – March 1 and September 1.</p> <p>Additional mapping files, reference sets, and derivatives are released throughout the year.</p> <p>SNOMED CT is released in Release Format 2 (RF2), a SNOMED CT release specification. All derivatives should also be released in RF2. And SNOMED CT also produces a script for users</p> |

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| | <p>to produce an OWL format of SNOMED CT.</p> <p>SNOMED International has a Terminology Release Advisory Group (TRAG) to provide guidance on new editorial and technological rules that may impact (or advance) the terminology.</p> <p>SNOMED International also has available many tools (i.e., SNOMED CT Browsers, Distribution Service, OWL and SQL load scripts), educational and technical resources, as well as translated Starter Guide and Sets (currently available in Spanish, French, German, Chinese, and Japanese).</p> <p>The National Library of Medicine, as the U.S. National Release Center, makes the International Edition (January 31 and July 31) as well as other International created derivatives (e.g., Nursing refsets and equivalency maps, LOINC-SNOMED files, Dentistry refsets) available free of charge to UMLS Licensees via the UMLS Terminology Services (UTS). The NLM maintains and distributes the SNOMED CT US Edition two times a year (March 1 and September 1). The US Edition includes content specific for the U.S. (US Extension) combined with the most recent International release.</p> <p>Non-Members pay a fee directly to SNOMED International.</p> <p>Data also available from via UMLS.</p> |
| <p>Overlap</p> | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 11.5% MEDCIN 9.4% Consumer Health Vocabulary 7.8% MeSH 6.4% NCI Thesaurus 5.7% MedDRA 5.4% NCBI Taxonomy 4.3% National Drug File - Reference Terminology 3.7% RxNorm 3.4% ICD-10-CM 3.4% ICPC-2 <p>Current overlap (or potential future overlap) to be aware of:</p> <ul style="list-style-type: none"> LOINC – clinical laboratory, physical exam observation, and cancer synoptic reporting content New SNOMED CT drug development work will overlap with some of RxNorm & AMT Potential content overlap with ICD-11 Radiology work |
| <p>Harmonization & Collaborations</p> | <p>SNOMED International has extensive partnerships and collaborations with many SDOs and organizations including: ADA, AMA, DICOM, Global Alliance, GMDNA, GS1, HL7, IBM Watson Health, ICN, JIC, LOINC, Trillium Bridge, WHO</p> |

Appendix 2: Additional Health Terminologies

Unified Medical Language System (UMLS) Metathesaurus data referenced in Appendix 2 was pulled from the 2018AA version.

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| Name | AJCC Cancer Staging ^{100,101} American Joint Committee on Cancer https://cancerstaging.org/references-tools/Pages/What-is-Cancer-Staging.aspx |
| Purpose | A classification system for describing the extent of disease progression in cancer patients. It utilizes the TNM scoring system: Tumor size, Lymph Nodes affected, Metastases. The TNM classification system is used as a tool for doctors to stage different types of cancer based on certain, standardized criteria. |
| Usage | Global |
| Named Standard? | Colon, breast, and prostate cancer codes from the 7th edition were incorporated into the US Edition of SNOMED CT for use in electronic clinical quality measures. TNM bladder cancer stage codes in SNOMED CT are required for a CMS eQIM. Currently no agreement is in place for the incorporation of these codes into SNOMED CT. |
| Ownership | The TNM Staging System was developed and is maintained by the AJCC and the Union for International Cancer Control (UICC). |
| Development Principles | To develop the 8 th edition, AJCC is worked with a community of experts (surveillance community, pathology community, and clinical decision support software developers). Development of staging system is based on characterizing the: Stage – the stage is based on (T) tumor primary site, (N) regional lymph nodes, (M) distant metastasis, and grouping cases with similar prognosis. Anatomic extent of the disease – which is specific for tumors at different anatomic sites. Each cancer type has its own classification system, letters and numbers do not always mean the same thing for every kind of cancer. Once the T, N, and M are determined, they are combined, and an overall <i>stage</i> of 0, I, II, III, IV is assigned. Sometimes these stages are subdivided as well, using letters such as IIIA and IIIB. |

¹⁰⁰ Amin MB, Greene FL, Edge SB, Compton CC, Gershenwald JE, Brookland RK, Meyer L, Gress DM, Byrd DR, Winchester DP. The Eighth Edition AJCC Cancer Staging Manual: Continuing to build a bridge from a population based to a more “personalized” approach to cancer staging. CA: A Cancer Journal for Clinicians [Internet]. 2017 Mar [cited 2018 Jun]; 67(2):93-99. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/28094848>

¹⁰¹ Asare EA, Gress DM, Greene FL, Winchester DP. Cancer registry data: Engaging the clinician to improve quality. Cancer [Internet]. 2015 Sep 1 [cited 2018 Jun]; 121(17):2866-2867. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/26018328>

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| Coverage | No documentation explicitly states what's in scope or out of scope. |
| Out of Scope | No documentation explicitly states what's in scope or out of scope. |
| Development & Maintenance | No documented description of maintenance process. |
| Requesting New Content | None |
| Release & Dissemination | The implementation of the 8 th Edition began on January 1, 2018. Updates are published on the AJCC website. New editions are published every couple to several years. Cancer Staging resources are available for purchase from AJCC. Books and references (staging forms) are available from AJCC for purchase. The 8 th Edition Cancer Staging System is available in XML format. |
| Overlap | Some of the AJCC 7 th Edition was harmonized and modeled into the US Extension of SNOMED CT (agreement between NLM and AJCC). This was for the use of TNM coding in meeting eQMs for colon, prostate, and breast cancer. The full text definitions were included in the code/term modeling. These are not included in the International Edition, only US Extension. |
| Harmonization & Collaborations | No documentation |

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| Name | CCC ¹⁰² Clinical Care Classification System https://www.sabacare.com/ |
| Purpose | CCC consists of two components, 1 – a standardized terminology that provides a coding structure to assess, document, and classify patient care, and 2 – an information model for electronic documentation of clinical nursing practice. |
| Usage | Global The CCC System has been translated into Korean (version 2.0), Norwegian (version 2.0), Persian/Farsi (version 2.5), Portuguese (version 1.0), Spanish (versions 1.0, 2.0, 2.5), Slovene (versions 1.0, 2.5 newsletter), Turkish (version 2.0), Chinese (version 2.5). |
| Named Standard? | No but recognized by American Nursing Association and Department of Health and Human Services for nursing. |

¹⁰² Saba VK. Clinical Care Classification System [Internet]. SabaCare Inc.; [updated 2017; cited 2018 May]. Available from: <http://www.sabacare.com/>

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| Ownership | Virginia Saba and colleagues at the Georgetown University School of Nursing developed the Home Health Care Classification (HHCC) System, now known as the Clinical Care Classification (CCC) System. |
| Development Principles | <p>The CCC System uses a five alpha-numeric character code, similar to ICD-10. The code thus implies meaning:</p> <ul style="list-style-type: none"> ● First position: One alphabetic character code for Care Component (A to U); ● Second and Third positions: Two-digit code for a Core Concept (major category) followed by a decimal point; ● Fourth position: One-digit code for a subcategory, if available, followed by a decimal point; ● Fifth position: One-digit code for: one of three Expected or Actual Outcomes and /or; one of four Nursing Intervention Action Types. <p>The terminology model relates nursing diagnoses and outcomes with nursing interventions and actions. The relations are designed to be bi-directional allowing for flow and feedback between the concepts.</p> |
| Coverage | Nursing diagnoses, interventions, outcomes. |
| Out of Scope | No documentation found. |
| Development & Maintenance | No documentation found. |
| Requesting New Content | The National CCC Advisory Scientific Board, part of SabaCare Incorporated, meets annually to review all submitted concepts, terms or labels for consideration. However, the terminology is not regularly published. Recommendations regarding development of new versions are made only after the Advisory Board has evaluated new ideas. CCC is considering the release of a Plan of Care (PoC) and a Workload Actions Measures Method for new users in the future. |
| Release & Dissemination | <p>No documented updated schedule found. CCC System National Scientific Advisory Board meets annually.</p> <p>Available for free from SabaCare.</p> <p>Data also available from NLM (via UMLS).</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 83.7% SNOMED CT 83.2% MEDCIN 49.9% Consumer Health Vocabulary 48.9% LOINC 39.3% ICNP 34.3% Medical Entities Dictionary 25.9% NANDA-I 21.2% Patient Care Data Set 15.1% NCI Thesaurus 14.8% Alcohol and Other Drug Thesaurus |

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| | <p>14.6% Alternative Billing Concepts</p> <p>13.6% CRISP Thesaurus</p> <p>13.3% ICPC-2 Plus</p> <p>13.3% Nursing Interventions Classifications</p> |
| Harmonization & Collaborations | Mapped to SNOMED CT, LOINC, and ICNP. |

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| Name | <p>CDISC Terminology</p> <p>Clinical Data Interchange Standards Consortium</p> <p>https://www.cdisc.org/</p> |
| Purpose | <p>CDISC standards are used for study planning and data collection, tabulation, analysis, and submissions to the U.S. Food and Drug Administration (FDA) and other regulatory agencies internationally.</p> <p>CDISC Controlled Terminology is the set of CDISC-developed and adopted standard expressions within CDISC-defined datasets. The primary objective is to define and support the terminology needs of the CDISC models across the clinical trial continuum.</p> |
| Usage | Global |
| Named Standard? | CDISC Standards are required for regulatory submissions to FDA (U.S.) and PMDA (Japan), endorsed by China FDA, and requested for use by the European Innovative Medicines Initiative (IMI). |
| Ownership | CDISC is a 501(c)3 global, non-profit charitable organization that develops data standards to streamline clinical research and healthcare. |
| Development Principles | <p>Terminology development is consolidated across all CDISC standards development governance into one decision-making body (the Global Governance Group (GGG)). The GGG meets weekly and is open to all active volunteers.</p> <p>The GGG consists of appointed representatives from each Foundational Standards team who review and approve normative (domains, variables and classes) and informative (examples, text explanations) content prior to internal review, public review and publication.</p> |
| Coverage | No documentation explicitly states what's in scope or out of scope. |
| Out of Scope | No documentation explicitly states what's in scope or out of scope. |
| Development & Maintenance | No documentation explicitly documents the development of the CDISC Controlled Terminology. |
| Requesting New Content | Online submission portal for new requests or requests for changes to the terminology. The CDISC New Term Request Page is hosted by NCI-EVS. |

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| Release & Dissemination | <p>CDISC Controlled Terminology is maintained and distributed as part of the NCI Thesaurus (ncit.nci.nih.gov) on an NCI File Transfer Protocol (FTP) site and is available for direct download from the cancer.gov CDISC terminology resources page. It is available in Excel, text, odm.xml, pdf, html and OWL/RDF formats.</p> <p>The CDISC Terminology is updated annually as part of the NCI Thesaurus. CDISC Terminology is freely available, without licensing restrictions from the National Cancer Institute (NCI).</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <p>25.6% SNOMED CT</p> <p>15.1% Consumer Health Vocabulary</p> <p>12% MeSH</p> |
| Harmonization & Collaborations | <p>Many partners/collaborators listed – but no information on what the collaborative work entails.</p> |

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| Name | <p>DSM-5¹⁰³</p> <p>Diagnostic and Statistical Manual of Mental Disorders, 5th ed</p> <p>https://www.psychiatry.org/psychiatrists/practice/dsm</p> |
| Purpose | <p>Common language and standard criteria for the classification of mental disorders. Primarily covers mental disorders recognized in the U.S.</p> |
| Usage | <p>In U.S. – some hospitals, clinics, and insurance companies require a DSM diagnosis for patients treatment.</p> <p>DSM-5 translations are in progress.</p> |
| Named Standard? | <p>No</p> |
| Ownership | <p>American Psychiatric Association (APA)</p> |
| Development Principles | <p>New edition was created following a DSM-5 Research Planning Conference, resulting in work groups surrounding Nomenclature, Neuroscience and Genetics Developmental Issues and Diagnosis, Personality and Relational Disorders, Mental Disorders and Disability, and Cross-Cultural issues. Most of development process was made under working group members signing a nondisclosure agreement.</p> <p>Decisions to include a diagnosis in DSM-5 were based on a careful consideration of the scientific advances in research underlying the disorder, as well as the collective clinical</p> |

¹⁰³ Clark LA, Cuthbert B, Lewis-Fernández R, Narrow WE, Reed GM. Three Approaches to Understanding and Classifying Mental Disorder: ICD-11, DSM-5, and the National Institute of Mental Health's Research Domain Criteria (RDoC). Psychological Science in the Public Interest [Internet]. 2017 Dec 06 [cited 2018 Jun]; 18(2):72-145. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29211974>.

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| | <p>knowledge of experts in the field.</p> <p>During development of the 5th edition, the APA periodically listed sections of the DSM-5 on the website for review and discussion.</p> |
| Coverage | A manual for assessment and diagnosis of mental disorders. |
| Out of Scope | Does not include information or guidelines for treatment of any disorder. |
| Development & Maintenance | Maintenance of DSM-5 is overseen by a Steering Committee of experts in psychiatric nosology, research, and practice. Changes resulting from submitted proposals, are made on a rolling basis. The Steering Committee determines the proposals to forward to the Review Committee who then considers the evidence in support of the proposed change. The Review Committee also undertake additional research and summarize the findings. The APA Board of Trustees will provide the final approval, and if approved, the Review Committee will develop the text changes for the DSM update. The Steering Committee will review and approve the changes and include it in a future updated version of the DSM. |
| Requesting New Content | Online submission of proposal for changes to DSM-5 are allowed. Changes are made to the DSM on a rolling basis. The revision process is overseen by a Steering Committee and be reviewed by the Review Committee. |
| Release & Dissemination | <p>The 5th edition has been revamped to include more frequent updates to keep up with the science of mental health (evident with the drop of the Roman numeral and use of Arabic). But no publicized update schedule.</p> <p>Book available for purchase.</p> <p>Data also available from NLM (via UMLS).</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <p>32.1% ICD-10-CM</p> <p>18.3% SNOMED CT</p> <p>16.8% MEDCIN</p> <p>11.9% MedDRA</p> |
| Harmonization & Collaborations | DSM-5 also contains both ICD-9-CM and ICD-10-CM codes. |

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| Name | <p>GMDN</p> <p>Global Medical Device Nomenclature</p> <p>https://www.gmdnagency.org/</p> |
| Purpose | To provide health authorities and regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and |

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| | support patient safety. |
| Usage | Global |
| Named Standard? | In the U.S., the GMDN Code is needed for FDA GUDID submission. The code can be used as part of the UDI rule. |
| Ownership | Global Device Nomenclature Agency (GMDNA) |
| Development Principles | GMDN is a list of generic terms for all medical device products. The terminology includes the Code, a 5-digit numeric code, cross-referenced to a Term Name and Definition. |
| Coverage | Device products used in the diagnosis, prevention, monitoring, treatment or alleviation of disease or injury in humans. |
| Out of Scope | None listed. |
| Development & Maintenance | <p>New and updated GMDN terms are published on the member website, the GMDN Database.</p> <p>The GMDN Code is a 5-digit numeric code, cross-referenced to a Term Name and Definition.</p> <p>GMDN Term development: 1) Request assessment and assignment – about 4 – 7 days; 2) Additional information gathering - depends on timeliness of manufacturer’s response; 3) Processing and quality control - 7 – 10 days depending on complexity of existing terms in the device area; 4) Requester approval - depends on timeliness of manufacturer’s response; 5) Finalizing term - 1 day (the 14 day public review period may be selected by some manufacturers).</p> |
| Requesting New Content | The GMDN is updated by member change requests. |
| Release & Dissemination | <p>Access to the GMDN Database is priced according to organization size.</p> <p>Membership provides a licence and to access the GMDN Database (provides GMDN Term Names) that group medical device products according to licensed content.</p> <p>All the GMDN Term Names and definitions are available to all users. The GMDN Code is provided for licensed content.</p> <p>From GMDNA: “The GMDN Database remembers the GMDN Terms of interest to you. Thereafter, we monitor these in your ‘My Terms’ list and let you know if their status changes in the future, for example if the Terms Definition is updated or we decide the description is no longer accurate and we need to make the GMDN Term obsolete.”</p> |
| Overlap | Some GMDN terms have been incorporated into SNOMED CT. |
| Harmonization & Collaborations | <p>Association of British HealthTech Industries (ABHI)</p> <p>Agency for Electronic Government and the Information and Knowledge Society (AGESIC)</p> |

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| | <p>Belgium Federal Public Service of Health, Food Chain Safety and Environment</p> <p>The British In Vitro Diagnostic Association (BIVDA)</p> <p>European Health Industry Business Communications Council (EHIBCC)</p> <p>Federal University of Itajubá</p> <p>Global Medical Technology Alliance (GMTA)</p> <p>GS1</p> <p>International Council for Commonality in Blood Banking Automation ICCBBA</p> <p>SNOMED International</p> <p>United Nations Standard Products and Services Code (UNSPSC)</p> <p>US National Library of Medicine</p> <p>WHO</p> |
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| Name | <p>GO</p> <p>The Gene Ontology</p> <p>http://www.geneontology.org/</p> |
| Purpose | <p>GO is a collaborative effort to address the need for consistent descriptions of gene products in different databases. The current ontologies of the GO project are molecular function, biological process, and cellular component.</p> |
| Usage | <p>Global</p> |
| Named Standard? | <p>No</p> |
| Ownership | <p>Produced by the GO Consortium</p> |
| Development Principles | <p>GO collaborators are developing three structured, controlled vocabularies (ontologies) that describe gene products in terms of their associated biological processes, cellular components and molecular functions in a species-independent manner. GO includes cross-links between the ontologies and the genes and gene products in the collaborating databases, and tools that facilitate the creation, maintenance and use of ontologies.</p> <p>The GO ontology is a logical structure of the biological functions ('terms') and their relationships to one another, manifested as a directed acyclic graph. It is designed to be species-agnostic, and includes terms applicable to prokaryotes and eukaryotes, and single and multicellular organisms. Documentation of the development and maintenance of the ontologies is available for public viewing.</p> |
| Coverage | <p>Molecular function, biological process and cellular components.</p> |

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| Out of Scope | GO does not include genes names or gene products. It does not provide structured vocabularies beyond its three domains: molecular function, biological process and cellular component. |
| Development & Maintenance | A team of senior ontology editors help to maintain the reviewing of new content. Ontology updates are made collaboratively between the GOC ontology team and scientists who request the updates. Most requests come from scientists making GO annotations. Occasionally domain experts are needed to review and revise an entire “branch” of the ontology with a large change. |
| Requesting New Content | Anyone can submit new or modifications to the ontology. |
| Release & Dissemination | GO is updated regularly throughout the year. The Gene Ontology vocabularies and gene product annotations are available to all public and private sector users, with no licensing requirements. GO is released in OBO Format (OBOF), a GO file specification. OBO is also available in OWL Data also available from NLM (via UMLS). |
| Overlap | Overlap is less than 1% with all other UMLS sources. |
| Harmonization & Collaborations | GO is an open science, international, collaborative effort. |

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| Name | HL7 Vocabulary http://www.hl7.org/ |
| Purpose | HL7 provides standards for the exchange, management and integration of data to support clinical patient care and the management, delivery and evaluation of healthcare services. The HL7 vocabulary is created to support HL7 transaction standards where vocabulary standards do not already exist. |
| Usage | Global |
| Named Standard? | No |
| Ownership | Health Level Seven International |
| Development Principles | The HL7 vocabulary consists of hierarchical Concept Domains, which are categories of like concepts that will be bound to one or more coded elements; code systems, which are the contexts in which concepts are defined; and value sets, which are lists of intended values for a Concept Domain or sub-domain. |

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| Coverage | HL7 is used in a variety of clinical and healthcare applications to support administrative and clinical processes. HL7 vocabulary is created to support HL7 transaction standards where vocabulary standards do not already exist. |
| Out of Scope | Not specified. |
| Development & Maintenance | <p>The categorization of Concept Domains is hierarchical allowing for further constraint on the breadth of the semantic category covered by the Concept Domain. Such constrained domains are known as “sub-domains”. Sub-domains allow for further specialization (constraint) on the intended values for a domain.</p> <p>A list of intended values for a concept domain or sub-domain is referred to as a value set. A value set consists of one or more coded concepts. These are the possible concept codes that can be carried in an HL7 Version 3 message in a coded data type. When a value set is associated with given concept domain or sub-domain, this is called "binding". Different value sets can be associated with the same concept domain in different circumstance.</p> <p>A concept code is only unique within a particular context.</p> |
| Requesting New Content | <p>Fill out a request form and it goes to ballot.</p> <p>Fully described in the HL7 Working Group: http://confluence.hl7.org:8090/display/VOC/Decision+Making+Practices</p> |
| Release & Dissemination | <p>The HL7-defined vocabulary tables that have been developed for coded class attributes are stored in the HL7 repository.</p> <p>FHIR resources have been created for many of the value sets.</p> <p>Data also available from NLM (via UMLS).</p> |
| Overlap | <p>HL7 Vocabulary Version 3.0</p> <p>18.6 % National Cancer Institute Thesaurus</p> <p>12.7 % US Edition SNOMED CT</p> <p>7.8 % Consumer Health Vocabulary</p> <p>7.6% LOINC</p> <p>4.9 % MeSH</p> <p>Value Sets: unknown</p> |
| Harmonization & Collaborations | <p>HL7 works with many SDOs on the Reference Information Model (RIM) a model for specification of the information content of HL7 messages.</p> <p>http://www.hl7.org/events/harmonization/index.cfm?ref=nav</p> |

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| Name | HPO ¹⁰⁴ Human Phenotype Ontology https://hpo.jax.org/app/ |
| Purpose | HPO is a formal ontology of human phenotypes. The ontology can be used for clinical diagnostics, mapping between phenotypes of model organisms, and as a standard vocabulary for clinical databases. |
| Usage | Global Chinese translation of HPO is available. |
| Named Standard? | No The European Commission recommends the adoption of Orphanet for rare diseases, and HPO has been incorporated into Orphanet. |
| Ownership | HPO is developed at the Charité Berlin with the Monarch Initiative, and logical definitions for HPO terms are being developed using PATO. |
| Development Principles | The three main components of the HPO project are the phenotype vocabulary, disease-phenotype annotations, and the algorithms that operate on these. In the HPO terminology, the terms describe clinical abnormalities and are arranged in a directed acyclic graph and are connected in an is-a hierarchy. The relationships are transitive, meaning that they are inherited up all paths to the root. Terms also include synonyms. Phenotypic abnormality is the main subontology of the HPO and contains descriptions of clinical abnormalities. Additional subontologies are provided to describe inheritance patterns, onset/clinical course and modifiers of abnormalities. HPO is maintained by a team of senior ontology editors. Ontology updates are made collaboratively between the GOC ontology team and scientists who request the updates. |
| Coverage | Terms describing these aspects of clinical abnormalities (sub-ontologies): <ul style="list-style-type: none"> • Phenotypic abnormality • Mode of Inheritance • Clinical Modifier |

¹⁰⁴ Kohler S, Vasilevsky NA, Engelstad M, Foster E, McMurry J, Ayme S, Baynam G, Bello SM, Boerkoel CF, Boycott KM, Brudno M, Buske OJ, Chinnery PF, Cipriani V, Connell LE, Dawkins HJS, DeMare LE, Devereau AD, de Vries BBA, Firth HV, Freson KF, Greene D, Hamosh A, Helbig I, Hum C, Jahn JA, James R, Krause R, Laulederkind SJF, Lockmuller H, Lyon GJ, Ogishima S, Olry A, Ouwehand WH, Pontikos N, Rath A, Schaefer F, Scott RH, Segal M, Sergouniotis PI, Sever R, Smith CL, Straub V, Thompson R, Turner C, Turro E, Veltman MWM, Vulliamy T, Yu J, von Ziegenweid J, Zanki A, Zuchner S, Zemojtel T, Jacobsen JOB, Groza T, Smedley D, Mungall CJ, Haendel M, Robinson PN. The Human Phenotype Ontology in 2017. *Nucleic Acids Res* [Internet]. 2016 Nov 24 [cited 2018 Jul]; 45(Database issue): D865-D867. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/27899602>

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| | <ul style="list-style-type: none"> • Mortality/Aging • Frequency |
| Out of Scope | No documentation found. |
| Development & Maintenance | <p>HPO release is a tab-delimited file designed to be as similar as possible to the format used by the Gene Ontology consortium.</p> <p>The Gene document describes the process of assigning HPO terms to disease entities such as Mendelian disorders from OMIM or Orphanet. Each line in the annotation file represents a link between a disease entity such as Noonan syndrome and one of the clinical features characteristically seen in that disease. Each of the features of a disease is to be listed on a separate line. Note that this file (and format) is intended to be used for the annotation of disease entities (e.g. Noonan syndrome) and not individuals (such as a person that has been diagnosed with Noonan syndrome).</p> |
| Requesting New Content | Requests are frequently submitted by biology domain area expert scientists. Submissions go through GitHub. |
| Release & Dissemination | <p>Continuously update.</p> <p>The HPO vocabularies, annotation files, tools and documentation are freely available.</p> <p>Available on GitHub and from NLM via UMLS.</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 38% OMIM 28.3% SNOMED CT 22.5% MedDRA 21% Consumer Health Vocabulary 20.4% MEDCIN 16.4% ICPC-2 15.0% NCI Thesaurus 11.4% ICD-10-CM |
| Harmonization & Collaborations | <p>HPO is mapped to the categories of the London Dysmorphology Database.</p> <p>HPO to MedDRA mapping.</p> <p>HPO to Orphanet mapping – with an ongoing partnership in Orphanet’s re-annotating the database with all diseases including HPO terms.</p> <p>Data also available from NLM (via UMLS).</p> <p>SNOMED International and HPO are working on a collaboration.</p> |

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| Name | ICD-O-3 ¹⁰⁵ International Classification of Diseases for Oncology, 3 rd Edition http://codes.iarc.fr/ |
| Purpose | Classification of neoplasms |
| Usage | Global - Cancer registries to record incidence of malignancy and survival rates. Available in the following translations: Published: Chinese, Czech, English, Finnish, Flemish/Dutch, French German, Japanese, Korean, Portuguese, Spanish, Romanian, Turkish |
| Named Standard? | Not in U.S. |
| Ownership | World Health Organization (WHO) |
| Development Principles | Two axes (coding systems) to describe the tumor. <ol style="list-style-type: none"> 1. Topographical code – to describe the anatomical site of origin (organ system) of the tumor 2. Morphological code – to describe the cell type (histology) of the tumor. Also includes the behavior of the tumor (malignant or benign). <p>Updates (in 2011) approved the WHO/IARC Committee (ICD-O-3 First revision (ICD-O-3.1).</p> <p>ICD-O code terms aligns with the nomenclature appearing in the World Health Organization <i>International Histological Classification of Tumours</i> series (WHO “Blue Books”).</p> |
| Coverage | Topography and morphology of neoplasms. |
| Out of Scope | No explicit documentation found. |
| Development & Maintenance | ICD-O is a dual classification code system for both topography and morphology. The topography code describes the anatomical site of origin of the neoplasm. The morphology code describes the characteristics of the tumor, including the cell type and biological activity. The topography code uses the same three- and four-character categories as ICD-10 for malignant neoplasms (C00–C80), extending the specificity for the site of nonmalignant neoplasms. WHO created a correspondence table between ICD-O revisions and between ICD-O revisions and ICD-9 and ICD-10. |
| Requesting New Content | No process identified. |

¹⁰⁵ Fritz A, Percy C, Jack A, Shanmugaratnam K, Sobin L, Park DM, Whelan S. International Classification of Diseases for Oncology. 3rd ed. 1st rev [Internet]. Geneva, Switzerland: World Health Organization; 2013 [cited 2018 Jul]; 242 p. Available from: <http://apps.who.int/iris/handle/10665/42344>.

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| Release & Dissemination | <p>ICD-O-3 available since 2000 (print) Updated in September 2011</p> <p>WHO - as a csv file with the alphabetical index for topography and morphology from WHO.</p> <p>Online search available from IARC.</p> <p>SNOMED CT to ICD-O mapping file available as historical artifact from SNOMED International and NLM (with UMLS Metathesaurus License).</p> |
| Overlap | By agreement with the College of American Pathologists, the morphology section of ICD-O is incorporated into the Systematized Nomenclature of Medicine (SNOMED) terminology as the neoplasm section of the morphology field. |
| Harmonization & Collaborations | SNOMED International continued to map SNOMED to ICD-O until the January 2017 SNOMED International Release, which included the final update of the SNOMED CT to ICD-O mapping reference set. Currently in maintenance until a new ICD-O or ICD-11 is released. |

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| Name | <p>ICF¹⁰⁶</p> <p>The International Classification of Functioning, Disability & Health</p> <p>ICF-CY (International Classification of Functioning, Disability & Health for Children and Youth) was derived from ICF. In 2012, in the interest of a streamlined, comprehensive ICF which adequately addresses all aspects of functioning across the lifespan, the relevant stakeholders agreed to merge the two classifications back into one.</p> <p>http://www.who.int/classifications/icf/en/</p> |
| Purpose | A classification of diagnoses of the health components of functioning and disability. Functional status is not included. |
| Usage | Global – ICD and ICF constitute the core classifications in the WHO Family of International Classifications (WHO-FIC). |
| Named Standard? | Not in U.S. – in May 2001, ICF officially endorsed by WHO Member States as the international standard to describe and measure health and disability. |
| Ownership | World Health Organization (WHO) |
| Development Principles | In 2006 the WHO Family of International Classifications (WHO-FIC) Network established the Functioning and Disability Reference Group (FDRG) to advise on functioning, disability and health classification and coding issues. The FDRG has developed a work program to enable it to provide well researched advice. Topics include coding guidelines, ICF updates, ICF-ICD joint |

¹⁰⁶ Kostanjsek N. Use of The International Classification of Functioning, Disability and Health (ICF) as a conceptual framework and common language for disability statistics and health information systems. BMC Public Health [Internet]. 2011 [cited 2018 Jul]; 11(Suppl 4):S3. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/21624189>

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| | <p>use, education, ethical use of ICF, measurement and environmental factors. The FDRG works collaboratively with other committees and reference groups in the WHO-FIC Network to address these issues. The FDRG prepares updates to the ICF and makes annual recommendations to the URC.</p> <p>Updates go through the Update and Revision Committee (URC), who supports WHO-FIC. See information in the ICD sections regarding the Update and Revision process.</p> |
| Coverage | The ICF conceptualizes functioning and disability in the context of health. |
| Out of Scope | ICF does not cover circumstances that are brought about solely by socioeconomic or cultural factors. |
| Development & Maintenance | <p>ICF is focused on the impact of functioning of the individual. The classification organizes information in two parts. Part 1 deals with functioning and disability while part 2 covers contextual factors. Each part has two components:</p> <ul style="list-style-type: none"> • Functioning and Disability: <ul style="list-style-type: none"> ○ Body Functions and Body Structures ○ Activities and Participation • Contextual Factors: <ul style="list-style-type: none"> ○ Environmental Factors ○ Personal Factors. <p>Each ICF component consists of multiple domains, and each domain consists of categories that are the units of the classification. The ICF provides textual definitions as well as inclusion and exclusion terms for each class.</p> <p>WHO-FIC produces the releases.</p> |
| Requesting New Content | <p>The ICF Update Platform is a web-based system that allows users to enter and review proposals for ICF review. Anyone can access the system to view.</p> <p>A general user can create an update proposal. There is a Moderation layer where the URC Secretariat reviews the proposal (ongoing). The Initial Review Group layer occurs Jan – Feb, FDRG layer (march – April), Open discussion (May – June), Closed Discussion layer (July – September), the URC Secretariat then provides WHO with the list of approved updates.</p> |
| Release & Dissemination | <p>Updated annually</p> <p>Releases available: Health and Disability Assessment (pdf) ICF checklist (pdf) ICF guide (pdf) Practical Manual (pdf) Code list browser (online)</p> <p>Via WHO or NHCS (CDC) ICF online browser</p> <p>Data also available from NLM (via UMLS).</p> |

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| Overlap | Overlap statistics from UMLS: 20.0% Consumer Health Vocabulary 19.0% SNOMED CT 16.0% MeSH 15.5% NCI Thesaurus 14.0% Alcohol and Other Drug Thesaurus |
| Harmonization & Collaborations | None explicitly stated. |

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| Name | ICHI ¹⁰⁷ International Classification of Health Interventions http://www.who.int/classifications/ichi/en/ |
| Purpose | Code system being developed to provide a common tool for reporting and analyzing health interventions for statistical purposes. |
| Usage | Still in beta release (2017 beta release) |
| Named Standard? | No – still in beta |
| Ownership | World Health Organization (WHO) |
| Development Principles | Derived from the Australian Classification of Health Interventions (ACHI), a portion of the ICD-10-AM. A health intervention is an act performed for, with or on behalf of a person or population whose purpose is to assess, improve, maintain, promote or modify health, functioning or health conditions. The classification built on three axes: Target (entity on which the action is carried out), Action (deed done by an actor to a target), and Means (the processes and methods by which the action is carried out). |
| Coverage | ICHI covers interventions carried out by a broad range of providers across the full scope of health systems including acute care, primary care, rehabilitation, assistance with functioning, prevention and public health. |
| Out of Scope | Not explicitly stated |
| Development & Maintenance | The latest draft was released in 2015 with input from the WHO-FIC network. Active review and development of content is continuing to develop ICHI Alpha version 2016. The completeness of this content will be tested during later reviews and field testing. Once finalized, ICHI will be freely available for adoption by Member States. |

¹⁰⁷ Fortune N, Madden R, Almborg A-H. Use of a New International Classification of Health Interventions for Capturing Information on Health Interventions Relevant to People with Disabilities. *Int J Environ Res Public Health* [Internet]. 2018 Jan 17 [cited 2018 Jul];15:145. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/29342077>

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| Requesting New Content | Still in beta release – field testing was to start in 2017, now in 2018 |
| Release & Dissemination | Still in beta release - Available from WHO. |
| Overlap | Currently unknown |
| Harmonization & Collaborations | No documentation found. |

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| Name | ICNP¹⁰⁸ International Classification of Nursing Practice http://www.icn.ch/what-we-do/international-classification-for-nursing-practice-icnpr/ |
| Purpose | A classification of nursing phenomena, nursing actions, and nursing outcomes that describes nursing practice. A code system used to classify patient data and clinical activity within the nursing domain. |
| Usage | Not in U.S. but used globally. Available in the following translations: Brazilian Portuguese, Canadian French, Chinese (simple), Chinese (Traditional), English, Farsi (Persian), French, German, Icelandic, Indonesian, Italian, Japanese, Korean, Norwegian, Polish, Portuguese, Romanian, Spanish, Swedish |
| Named Standard? | Not in U.S. WHO accepted ICNP within the WHO-FIC to extend coverage of the domain of nursing practice (2009). |
| Ownership | International Council of Nurses (ICN) |
| Development Principles | A combinatorial terminology that provides a framework for local languages and existing nursing vocabularies and classifications to cross-map to. In the cross-mapping of ICNP with other nursing terminologies, suggestions to add to or modify the ICNP code system are considered. All changes and updates go through the ICNP review process (see 'Requesting New Content' section) provides opportunities for individuals and groups to review terms and concepts. |
| Coverage | Includes nursing diagnoses, nursing-sensitive patient outcomes and nursing interventions. Describes nursing care of people in a variety of settings and enables comparison of nursing data across clinical populations, settings, and geographical areas and time. |

¹⁰⁸ Park HA, Lundberg C, Coenen A, Konicek D. Evaluation of the content coverage of SNOMED CT representing ICNP seven-axis version 1 concepts. *Methods Inf Med* [Internet]. September 2011 [cited 2018 Jul];50(5):472-478. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/21947166>.

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| Out of Scope | No documentation found. |
| Development & Maintenance | <p>ICNP structure is multi-axial, meaning terms from different axes are combined to create a concept.</p> <p>Three primary elements of ICNP:</p> <ol style="list-style-type: none"> 1. Nursing phenomena (focus of nursing – nursing diagnosis) 2. Nursing Interventions (action or activities nurses perform) 3. Nursing Outcomes (results of nurse’s actions in terms of change in the focus at a specific time). <p>New content and changes terminology go through a vigorous review process which includes ICN staff as well as experts in nursing as well as technical informatics. New content and terminology maintenance occurs through user requests (via online submissions) or through content harmonization efforts with ICN collaborations.</p> |
| Requesting New Content | <p>Online concept addition, modification or inactivation accepted. The ICN staff review suggestions and, if approved, send it on to nursing practice expert reviewers and/or technical and informatics experts. From there, the ICN staff will review the recommendations from the expert panel and decide to make or reject the request for addition or change.</p> <p>www.icn.ch/what-we-do/icnpr-concept-submission-a-review-process-model</p> |
| Release & Dissemination | <p>Released once every two years (in May or June) in both tabular format and OWL representation.</p> <p>ICNP online browser Next planned update: June 2019 ICN Nursing diagnoses equivalency table between ICNP and SNOMED CT, released as a reference set twice a year following the SNOMED CT International Edition release.</p> <p>Data also available from NLM (via UMLS).</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 42% SNOMED CT 16.4% Consumer Health Vocabulary 13.9% MEDCIN 10.8% LOINC 10.2% NANDA-I |
| Harmonization & Collaborations | <p>Cross-mapping between ICNP (DC and IC) and SNOMED CT – includes content development and mapping</p> <p>CCC – mapping and integration</p> <p>International Classification of Health Interventions – evaluation of content and content development</p> |

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| Name | ICPC ^{109,110} International Classification of Primary Care http://www.who.int/classifications/icd/adaptations/icpc2/en/ |
| Purpose | A classification method for primary care encounters. It allows for the classification of the patient's reason for encounter (RFE), the problems/diagnosis managed, primary or general health care interventions, and the ordering of the data of the primary care session in an episode of care structure. |
| Usage | Global - ICPC is available in Catalan, Chinese, Croatian, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Japanese, Norwegian, Portuguese, Romanian, Russian, Serbian, Slovenian and Spanish. |
| Named Standard? | Not in the U.S. |
| Ownership | Developed by WONCA International Classification Committee (WICC) currently accepted under the World Health Organization's (WHO) Family of Classification of Diseases. |
| Development Principles | ICPC is maintained and updated by the International Classification Committee (WICC) of Wonca. Local support is given by individual members of the Wonca International Classification Committee. |
| Coverage | No documentation found. |
| Out of Scope | No documentation found. |
| Development & Maintenance | <p>ICPC is maintained and updated by the International Classification Committee (WICC) of Wonca.</p> <p>ICPC has a biaxial structure and includes 17 Chapters and within each chapter, 3 components come from 3 different classifications:</p> <ul style="list-style-type: none"> ● Reason for Encounter Classification (1981) ● International Classification of Process in Primary Care (IC-Process-PC) (1985) ● International Classification of Health Problem in Primary Care (ICHPPC-2-d) (1976, 1983) <p>The first version of ICPC published in 1987 is referred to as ICPC-1. The version in the 1993 publication "The International Classification of Primary Care in the European Community: With a Multi-Language Layer" is known as ICPC-E. The 1998 version 2 is referred to as ICPC-2. ICPC-2-E refers to a revised electronic version released in 2000. Subsequent revisions of</p> |

¹⁰⁹ Olagundoye OA, van Boven K, van Weel C. International Classification of Primary Care-2 coding of primary care data at the general out-patients' clinic of General Hospital, Lagos, Nigeria. J Family Med Prim Care [Internet]. 2016 Apr-Jun [cited 2018 Jul]; 5(2):291-297. Available from: <http://www.jfmpc.com/article.asp?issn=2249-4863;year=2016;volume=5;issue=2;spage=291;epage=297;aulast=Olagundoye>

¹¹⁰ Verbeke M, Schrans D, Deroose S, De Maeseneer J. The International Classification of Primary Care (ICPC-2): an essential tool in the EPR of the GP. Stud Health Technol Inform [Internet]. 2006 [cited 2018 Jul]; 124: 809-814. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/17108613>.

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| | <p>ICPC-2 are also labelled with a release date. ICPC is used when referring to the generic classification.</p> <p>The full revision cycle is currently 11 years however mapping to other classifications may be reviewed at shorter intervals to adjust for changes in other classifications and changed usage. WICC has been active since 1972 and currently has 40 members from 23 different countries. WICC is partially funded by Wonca and the participation of some members is supported by their national governments.</p> |
| Requesting New Content | No process identified. |
| Release & Dissemination | <p>Each of the 17 chapters are each divided into 7 components dealing with symptoms and complaints (comp. 1), diagnostic, screening and preventive procedures (comp. 2), medication, treatment and procedures (comp. 3), test results (comp. 4), administrative (comp. 5), referrals and other reasons for encounter (comp. 6) and diseases (comp. 7).</p> <p>The ICPC releases are published in excel, ClAML, and some files in Access-ready files.</p> <p>WHO Mapped SNOMED GP/FP subset to ICPC-2 Data also available from NLM (via UMLS)</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 49.1% SNOMED CT 48.5% ICPC-2P 40.9% Consumer Health Vocabulary 40.0% MedDRA 35.6% MEDCIN 31.0% ICD-10-Cm 29.0% NCI Thesaurus 26.2% Clinical Problem Statements 25.0% ICD-10 24.6% COSTAR |
| Harmonization & Collaborations | <p>ICPC-2 was last revised in 2015, and was carefully mapped to ICD-10. Whilst ICPC is a full classification system, the mapping extended the use to include ICD-10 disease classification system.</p> <p>Ongoing cooperation between WONCA and the WHO-FIC network exists for the revision of ICD-10 to ICD-11 and harmonization with ICPC.</p> |

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| Name | MedDRA ^{111,112} Medical Dictionary for Regulatory Activities, v20 https://www.meddra.org/ |
| Purpose | An international medical terminology dictionary used by pharmaceutical industry regulatory authorities for regulating pre-marketing to post-marketing activities. |
| Usage | Global Translations: Portuguese, Dutch, English, French Czech, Chinese, German, Hungarian, Italian, Japanese, Spanish |
| Named Standard? | Mandated in Europe and Japan for safety reporting. Recommended in Canada for adverse reaction reporting and Product Monograph (labeling). |
| Ownership | The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is the Trustee of the International Conference on Harmonization (ICH) Steering Committee and holds the intellectual property rights (ownership) of MedDRA. |
| Development Principles | MedDRA is a multi-axial terminology – terms are represented in multiple system organ classes (SOC). The use of SOCs allow for grouping by classification and retrieval. The editorial rules for MedDRA to model content into: System Organ Class (SOC) → High Level Group Term (HLGT) → High Level Term (HLT) → Preferred Term (PT) → Lowest Level Term (LLT). All maintenance of MedDRA is managed by MSSO (Maintenance and Support Services Organization). |
| Coverage | Medical conditions – signs, symptoms, diseases, diagnoses (therapeutic) Indications Investigations (tests, results) – names and qualitative results Medical and surgical procedures Medical, social, family history Medication errors Product quality issues Device-related issues Pharmacogenetic terms Toxicologic issues Standardized queries |
| Out of Scope | Drug/product terminology Equipment/device/diagnosis products |

¹¹¹ Medical Dictionary for Regulatory Activities. Introductory Guide MedDRA Version 21.0 [Internet]. McLean (VA); Medical Dictionary for Regulatory Activities (U.S.); 2018 Mar [cited 2018 Jul];82 p. Available from: https://www.meddra.org/sites/default/files/guidance/file/intguide_21_0_english.pdf.

¹¹² Medical Dictionary for Regulatory Activities. MedDRA Coding Basics [Internet]. McLean (VA): Medical Dictionary for Regulatory Activities; 2016 Jun 10 [cited 2018 May]. Available from: https://www.meddra.org/sites/default/files/training/file/6275-1901_meddra_coding_basics.pdf.

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| | <p>Patient Demographic terms Clinical trial study design terms Frequency qualifiers Numerical values for results Severity descriptors Not an equipment, device, diagnostic product dictionary</p> |
| Development & Maintenance | <p>Each MedDRA term is assigned an 8-digit numeric code (starts with a '1').</p> <p>The MedDRA terminology is hierarchical, and terms can be included in multiple SOC's. System Organ Class (SOC) → High Level Group Term (HLGT) → High Level Term (HLT) → Preferred Term (PT) → Lowest Level Term (LLT). The Lowest Level Terms (LLTs) are very specific "granular" terms that serves to record the reporter's words (verbatim terms). LLTs linked to parent terms (Preferred Terms, PTs). This allows for SOCs to be used for grouping in classification and retrieval.</p> <p>The MedDRA Pro-active Approach to Maintenance is the official method of maintenance. All corrections and improvements are made by the MSSO. General changes are suggested by users. And other ideas and suggestions can be submitted to Help Desk and an evaluation of proposals can occur but MSSO is not obligated to respond. Each MedDRA release is audited by an external physician that reviews a random sample of change requests processed by the MSSO with that release.</p> <p>Occasionally MedDRA codes are reused (in the corrections of spellings or terms are renamed).</p> |
| Requesting New Content | <p>Core and basic subscribers can submit up to 100 change requests per month. Submissions are sent via a web-based tool for change requests (https://mssotools.com/webcr/). And these go to the MSSO for review.</p> <p>For simple changes (PT and LLT levels), notification of final disposition within 7 – 10 working days. Complex changes above PT level received all year and posted for subscribers' comments mid-year.</p> |
| Release & Dissemination | <p>Weekly supplemental changes posted on MSSO website. Subscribers can use MedDRA Desktop and a web-based browser to view MedDRA terminology.</p> <p>MedDRA English release files are available 2 times a year: September 1, X.1 release – simple changes only March 1, X.0 release – complex and simple changes</p> <p>MedDRA is distributed as sets of extended ACCII delimited files for English and Western European languages. Other languages are distributed in different formats.</p> <p>MedDRA Term Selection: Points to Consider (MTS:PTC) – a guide to provide term selection advice for industry and regulatory purposes.</p> <ul style="list-style-type: none"> ● Developed by a working group of the ICH Steering Committee ● Updated 2x year (update goes with the MedDRA release) |

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| | Data also available from NLM (via UMLS). |
| Overlap | Overlap statistics from UMLS: 39.7% SNOMED CT 24.9% MEDCIN 24.2% Consumer Health Vocabulary 15.8 % NCI Thesaurus Some ICD-9 terms were incorporated into the first implementation of MedDRA. |
| Harmonization & Collaborations | WHO-ART Bridge – collaborative effort between the ICH and Uppsala Monitoring Centre (UMC) of the WHO to implement MedDRA in the WHO global safety database. A mapping bridge is updated by WHO and ICH (through MSSO). CTCAE – Since CTCAE (Common Terminology Criteria for Adverse Events) Version 4.0 (May 2009), all terms used by the U.S. National Cancer Institute are inserted into MedDRA as LLTs. NICHD Pediatric Adverse Events Terminology – The National Institute of Child Health and Human Development, the National Cancer Institute Enterprise Vocabulary Services, and the MSSO, developed a mapping of the NICHD Pediatric Adverse Event Terminology to MedDRA to support the reporting of adverse events in the pediatric population. |

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| Name | NANDA-I North American Nursing Diagnosis Association International http://www.nanda.org/ |
| Purpose | To allow nursing to identify and classify health problems within the domain of nursing. The taxonomy supports evidence-based care, allows for quantitative staffing and evaluation measures and supports evidence-based clinical decisions for electronic health records. |
| Usage | Global Translated into 18 different languages. |
| Named Standard? | No |
| Ownership | NANDA International, Inc. produces the International Nursing Diagnoses: Definitions and Classification. |
| Development Principles | The Diagnosis Development Committee (DDC) formulates and conducts review processes of proposed diagnoses and revisions of diagnoses. DDC reviews the literature and submissions and follows a formal process to ensure that new terminology is reflective of correct standards of care. The standard is revised every three years. |
| Coverage | No documentation found. |

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| Out of Scope | No documentation found. |
| Development & Maintenance | Follows a formal process with the DDC reviewing and making the updated changes. Not information regarding file formats and release development. |
| Requesting New Content | No process identified. |
| Release & Dissemination | <p>Recently produced NANDA International Nursing Diagnoses: Definitions and Classification 2018-2020, Eleventh Edition. It is updated every three years.</p> <p>Electronic version available with a license. Text format is available without a license.</p> <p>Files can be downloaded from NANDA-I. Data also available from NLM (via UMLS).</p> |
| Overlap | <p>Overlap statistics from UMLS:</p> <ul style="list-style-type: none"> 22.0% SNOMED CT 19.5% Consumer Health Vocabulary 15.5% MedDRA 14.0% MEDCIN 12.3% NCI Thesaurus 10.2% ICPC-2 10.2% Clinical Problem Statements |
| Harmonization & Collaborations | NANDA-I is commonly used with Nursing Interventions Classification (NIC) and (NOC), referred to as NANDA/NIC/NOC (NNN), as a means of providing comprehensive, research-based, standardized classifications of nursing diagnoses, nursing interventions and nursing sensitive patient outcomes. These classifications provide a set of terms to describe nursing judgments, treatments and nursing-sensitive patient outcomes (NANDA-I NIC NOC for Safe Patient Care, n.d.). |

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| Name | <p>NIC and NOC</p> <p>Nursing Interventions Classification System and Nursing Outcomes Classification</p> <p>https://nursing.uiowa.edu/cncce/nursing-interventions-classification-overview</p> <p>https://nursing.uiowa.edu/cncce/nursing-outcomes-classification-overview</p> |
| Purpose | <p>NIC and NOC are comprehensive, research-based, terminologies and standardized classifications of nursing interventions and nursing-sensitive patient outcomes. The use of NIC and NOC provides terms for documenting nursing care, including:</p> <ul style="list-style-type: none"> ● Communicating nursing care across settings ● Evaluating outcomes |

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| | <ul style="list-style-type: none"> ● Conducting effectiveness research ● Measuring nursing productivity ● Evaluating nursing competencies ● Facilitating reimbursement ● Designing curriculum |
| Usage | <p>Global</p> <p>NIC and NOC have both been translated into Chinese (simplified and traditional), Dutch, French, German, Indonesian, Italian, Japanese, Korean, Norwegian, Portuguese, and Spanish</p> |
| Named Standard? | No |
| Ownership | NIC and NOC are developed at the University of Iowa College of Nursing but are published and copyrighted by Elsevier. |
| Development Principles | <p>NOC outcomes are grouped hierarchically into 31 classes within seven domains. NIC interventions are grouped hierarchically into 30 classes within seven domains.</p> <p>NIC and NOC are continuously refined by teams of nurse researchers, faculty, graduate students, and expert clinicians.</p> |
| Coverage | <p>Coverage for NOC includes nursing outcomes in these domains: Functional Health, Physiologic Health, Psychosocial Health, Health, Knowledge and Behavior, Perceived Health, Family Health, and Community Health</p> <p>Coverage for NIC includes nursing interventions in these domains: Behavioral, Community, Family, Health System, Physiological: Basic, Physiological: Complex, and Safety.</p> |
| Out of Scope | No documentation. |
| Development & Maintenance | No documentation. |
| Requesting New Content | Submissions for terminology refinement are accepted. |
| Release & Dissemination | <p>It is updated every five years.</p> <p>NIC and NOC are available from Elsevier publishing.</p> <p>Books of codes are available for purchase from Elsevier.</p> <p>Data also available from NLM (via UMLS).</p> |
| Overlap | <p>NOC Overlap statistics from UMLS:</p> <p>18.1% SNOMED CT</p> <p>14.5% Consumer Health Vocabulary</p> <p>7.6% MedDRA</p> <p>7.1% NCI Thesaurus</p> <p>7.1% MEDCIN</p> |

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| | <p>5.3% Alcohol and Other Drug Thesaurus</p> <p>5.3% LOINC</p> <p>NIC Overlap statistics from UMLS:</p> <p>4.8% SNOMED CT</p> <p>2.0% Consumer Health Vocabulary</p> <p>1.4% Alternative Billing Concepts</p> <p>1.1% MEDCIN</p> |
| Harmonization & Collaborations | <p>NANDA-I is commonly used with Nursing Interventions Classification (NIC) and Nursing Outcomes Classification (NOC), referred to as NANDA/NIC/NOC (NNN), as a means of providing comprehensive, research-based, standardized classifications of nursing diagnoses, nursing interventions and nursing sensitive patient outcomes. These classifications provide a set of terms to describe nursing judgments, treatments and nursing-sensitive patient outcomes (NANDA-I NIC NOC for Safe Patient Care, n.d.).</p> |

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| Name | <p>OMS¹¹³</p> <p>Omaha System</p> <p>http://www.omahasystem.org/</p> |
| Purpose | <p>Omaha System is a “research-based, comprehensive practice and documentation standardized taxonomy” designed with three relational components 1 – problem classification scheme: client assessment, 2 – intervention scheme: care plans and services, and 3 – problem rating scale for outcomes: client change/evaluation component. The Omaha System is used to document client needs, describe practitioner interventions, and measure client outcomes.</p> |
| Usage | <p>U.S. based</p> <p>The terms, definitions, and codes have been translated in: Arabic, Chinese, Czech, Dutch, Estonian, French, German, Greek, Japanese, Korean, Norwegian, Slovene, Spanish, Swahili, Swedish, Thai, and Turkish.</p> |
| Named Standard? | No |
| Ownership | <p>The Omaha System was developed by the Visiting Nurse Association of Omaha in Nebraska and is maintained by the Omaha System Board of Directors. The OMS is free under public domain.</p> |
| Development Principles | <p>The Omaha System is a terminology and an implicit information model.</p> <p>The update process is a multi-step, triangulated approach, and includes the presentation of user-submitted suggestions at the biennial Omaha System International Conference. In</p> |

¹¹³ Martin KS, Monsen KA. The Omaha System [Internet]. Omaha (NE): Health Connections Press; 1975 [updated 2017; cited 2018 May]. Available from: www.omahasystem.org.

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| | addition, a 12- member international board of directors reviews and revises Omaha System on an ongoing basis using the results of current research, expert opinion, and user experience and feedback. |
| Coverage | The Problem Classification Scheme provides a structure, terms, and system of cues and clues for a standardized assessment of individuals, families, and communities. |
| Out of Scope | No documentation for out of scope information. |
| Development & Maintenance | A 12- member international board of directors reviews and revises Omaha System on an ongoing basis. No additional information on maintenance is available. |
| Requesting New Content | Submitters can send requests for new content additions or changes to the terminology. |
| Release & Dissemination | It is reviewed every two years. The OMS is freely accessible. Last publication in 2005 included a book and electronic version of code set. Available in the Health Connections Book, from Omaha Systems. Available in publication, online. Data also available from NLM (via UMLS). |
| Overlap | Overlap statistics from UMLS: 42.1% SNOMED CT 30.3% Consumer Health Vocabulary 19.6% NCI Thesaurus 18.6% Alcohol and Other Drug Thesaurus 12.5% Psychological Index Terms 11.7% Clinical Problem Statements 11.% Library of Congress Subject Headings 10.8% ICPC-2-Plus 9.8% NANDA-I |
| Harmonization & Collaborations | No documentation. |

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| Name | PNDS ¹¹⁴ Perioperative Nursing Data Set https://people.duke.edu/~newki001/ |
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¹¹⁴ Association of Perioperative Registered Nurses. Standards of Perioperative Nursing [Internet]. Denver (CO): Association of Perioperative Registered Nurses; 2009 Nov [cited 2018 Jul]; p 16. Available from: https://www.aorn.org/-/media/aorn/guidelines/aorn-standards/ii-01_standards_2015.pdf.

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| Purpose | PNDS is a standardized perioperative nursing vocabulary that describes diagnoses, interventions, and patient outcomes. |
| Usage | Global |
| Named Standard? | No |
| Ownership | PNDS is maintained by the Association of periOperative Registered Nurses. |
| Development Principles | A change in evidence-based practice per AORN standards and guidelines will trigger a need for an update to the data set. Once a change is identified, the AORN PNDS team will review the concepts for relevance and appropriateness, retire outdated concepts, edit existing concepts, or develop new concepts, as appropriate. The updated/new/retired concepts are then either: 1 - Reviewed by an AORN-PNDS task force, or 2 - Reviewed at the AORN Annual Conference by the Educator Specialty Assembly, which rates new concepts for their relevance and appropriateness to perioperative practice. The AORN board members then have the last review of the concepts for relevancy either approves or rejects the changes. |
| Coverage | No documentation. |
| Out of Scope | No documentation. |
| Development & Maintenance | No documentation. |
| Requesting New Content | No documentation. |
| Release & Dissemination | It is updated every five years. Data also available from NLM (via UMLS). |
| Overlap | Overlap statistics from UMLS: 37.9% SNOMED CT 12.1% ICNP 5.6% Consumer Health Vocabulary 5.1% MEDCIN 3.0% NCI Thesaurus |
| Harmonization & Collaborations | PNDS is the only nursing language focused on perioperative nursing process and practice and most of the PNDS concepts were created in SNOMED CT specifically for the PNDS language. The 3rd version of the PNDS was mapped to SNOMED CT in 2011. The SNOMED CT mappings were reviewed and validated in 2012 with no corrections and they are currently (2017) undergoing a review cycle. |

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| Name | UCUM The Unified Code for Units of Measure |
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| | http://unitsofmeasure.org/ |
| Purpose | UCUM is a syntax for representing units of measure for use with numerical references and values. It is not an enumerated set of codes. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. |
| Usage | Global |
| Named Standard? | No |
| Ownership | Regenstrief Institute, Inc. and The UCUM Organization |
| Development Principles | |
| Coverage | All units of measures used in international science, engineering, and business. |
| Out of Scope | Display units Full name and print symbols that are defined by other bodies and out of scope for UCUM. |
| Development & Maintenance | No information documented regarding the current management procedures for UCUM. |
| Requesting New Content | Requests for new or changes to UCUM are welcome. Once a request has been submitted a board member will review the request(s) and determine if it is to be accepted or rejected. First time users making a request will have a limited status to provide input. |
| Release & Dissemination | The pace of change in units of measure is much slower than other clinical vocabularies, thus UCUM has not established a regular release cycle. Periodic updates have been made when updates to the standard have been approved. UCUM is available free of charge from Regenstrief. Data also available from NLM (via UMLS - Via NCI Thesaurus). |
| Overlap | Overlap statistics from UMLS: 100% NCI Thesaurus 86.7% C-DISC 26.2% SNOMED 10.1 % Consumer Health Vocabulary |
| Harmonization & Collaborations | No documentation found. |

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| Name | UDI Unique Device Identification https://www.fda.gov/medicaldevices/deviceregulationandguidance/uniquedeviceidentification/ |
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| Purpose | UDI is a system to identify medical devices through their distribution and use. |
| Usage | U.S. |
| Named Standard? | Yes |
| Ownership | U.S. Food and Drug Administration The FDA has accredited 3 UDI Issuing Agencies: GS1, Health Industry Business Communications Council (HIBCC), International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA) |
| Development Principles | <p>The UDI is a unique numeric or alphanumeric code that provides:</p> <p>1 - A device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device, and</p> <p>2 - a production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:</p> <ul style="list-style-type: none"> - the lot or batch number within which a device was manufactured; - the serial number of a specific device; - the expiration date of a specific device; - the date a specific device was manufactured; - the distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device. <p>All UDIs are issued under a system operated by an FDA-accredited issuing agency.</p> |
| Coverage | <p>In the U.S., the label of most devices will include a unique device identifier (UDI) in human- and machine-readable form.</p> <p>As of September 24, 2018, is:</p> <ul style="list-style-type: none"> ● The UDI compliance date for direct marking of class II devices ● The date the UDI will be required for most kits with at least one class III, I/LS/LS or class II device within the kit ● The date the UDI will be required for most co-packaged and cross-labeled combination products with a device constituent ● The expiration date of the 801.30(a)(1) (three year "grandfather") I/LS/LS inventory exception ● The UDI compliance date for class I/unclassified devices for labeling and GUDID submissions |
| Out of Scope | No information provided. |
| Development & Maintenance | The systems for the issuance of UDIs that are operated by FDA-accredited issuing agencies and conform to certain international standards (21 CFR 830.20). Additionally, the FDA-accredited issuing agencies fulfill responsibilities and regularly apply for renewal of their accreditation. Labelers who license Universal Product Codes (UPCs) directly from an FDA-accredited issuing agency need proper controls over UPC assignment and use which advances the goals of the UDI program. While a UPC may serve as the UDI for class I devices if a UPC is present on the device label and device packages (21 CFR 801.40(d)), the labeler may choose to use the full UDI (device identifier (DI) + production identifier (PI)) to take advantage of the |

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| | <p>PIs in UDI (e.g., expiration date, lot, serial number) and to meet customer requirements.</p> <p>As part of the system, the device labelers are required to submit information to the FDA-administered Global Unique Device Identification Database (GUDID). The GUDID includes a standard set of basic identifying elements for each device with a UDI, and contain the DI, which serves as the key to obtain device information in the database. PIs are not part of the GUDID.</p> <p>Users of medical devices can use AccessGUDID to search or download information about devices. FDA transmits a file to NLM each day and NLM publishes the records to AccessGUDID.</p> |
| Requesting New Content | FDA has accredited the three UDI Issuing Agencies (GS1, Health Industry Business Communications Council (HIBCC), International Council for Commonality in Blood Banking Automation, Inc. (ICCBBA)). Labelers need to contact a UDI Issuing Agency (IA) directly if they are interested in using the IA's system for the issuance of UDIs. |
| Release & Dissemination | <p>Device labelers must submit certain information about each device to FDA's Global Unique Device Identification Database (GUDID). The public can search and download information from the GUDID at AccessGUDID.</p> <p>AccessGUDID is the public portal for the GUDID data submitted to the FDA by the labelers. AccessGUDID features include simple search, advanced search, web services/APIs and downloads.</p> |
| Overlap | Unknown |
| Harmonization & Collaborations | <p>FDA works with the three UDI Issuing Agencies.</p> <p>FDA works with the National Library of Medicine on AccessGUDID.</p> |

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| Name | <p>UMDNS</p> <p>Universal Medical Device Nomenclature System</p> <p>https://www.ecri.org/components/UMDNS/Pages/default.aspx</p> |
| Purpose | An international standard nomenclature and computer coding system for medical devices to assist with the identifying, processing, filing, storing, retrieving, transferring, and communicating of data about medical devices. |
| Usage | Global |
| Named Standard? | No |
| Ownership | ECRI Institute |
| Development | UMDNS content includes preferred terms, codes, entry terms and relationships (cross |

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| Principles | references). The content is organized in a hierarchy and includes attributes, definitions and linkages to other standards. |
| Coverage | Coverage includes all medical devices and supplies, clinical laboratory equipment and reagents, selected hospital furniture, systems and test equipment. New terms also include disposables, molecular diagnostic tests, emergency preparedness, medical software and emerging technologies. And a related dataset includes 30,000 device manufacturer/supplier/servicer company names and their associated 6-digit codes. |
| Out of Scope | Not documented. |
| Development & Maintenance | Not documented |
| Requesting New Content | Via online request form. |
| Release & Dissemination | Content can be licensed from ECRI. A free version is available to certain organizations (government agencies, hospitals, manufacturers) and available via website. Data also available from NLM (via UMLS). |
| Overlap | Overlap statistics from UMLS: 9.7% SNOMED CT 4.6% Consumer Health Vocabulary 4.2% Standard Product Nomenclature |
| Harmonization & Collaborations | Not documented. |

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| Name | UMLS Unified Medical Language System https://www.nlm.nih.gov/research/umls/ |
| Purpose | The purpose of the Unified Medical Language System (UMLS) is to facilitate the development of computer systems that behave as if they "understand" the meaning of the language of biomedicine and health. The UMLS Knowledge Sources (databases) and associated software tools (programs) for use by system developers in building or enhancing electronic information systems that create, process, retrieve, integrate, and/or aggregate biomedical and health data and information, as well as in informatics research. |
| Usage | Global |
| Named Standard? | No - the UMLS is not a clinically validated standard. |

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| Ownership | U.S. National Library of Medicine |
| Development Principles | <p>The Metathesaurus is a very large, multi-purpose, and multilingual vocabulary database that contains information about biomedical and health related concepts, their various names, and the relationships among them. It is built from the electronic versions of many different thesauri, classifications, code sets, and lists of controlled terms used in patient care, health services billing, public health statistics, indexing and cataloging biomedical literature, and /or basic, clinical, and health services research. In this documentation, these are referred to as the "source vocabularies" of the Metathesaurus. In the Metathesaurus, all the source vocabularies are available in a database format.</p> <p>The Semantic Network is a consistent categorization of all concepts represented in the UMLS Metathesaurus and to provide a set of useful relationships between these concepts. All information about specific concepts is found in the Metathesaurus; the Network provides information about the set of basic semantic types, or categories, which may be assigned to these concepts, and it defines the set of relationships that may hold between the semantic types.</p> <p>The SPECIALIST Lexicon has been developed to provide the lexical information needed for the SPECIALIST Natural Language Processing System (NLP). It is intended to be a general English lexicon that includes many biomedical terms. Coverage includes both commonly occurring English words and biomedical vocabulary. The lexicon entry for each word or term records the syntactic, morphological, and orthographic information needed by the SPECIALIST NLP System.</p> |
| Coverage | The scope of the Metathesaurus is determined by the combined scope of its source vocabularies. Many relationships (primarily synonymous), concept attributes, and some concept names are added by the NLM during Metathesaurus creation and maintenance, but essentially all the concepts themselves come from one or more of the source vocabularies. Generally, if a concept does not appear in any of the source vocabularies, it will also not appear in the Metathesaurus. |
| Out of Scope | Not documented. |
| Development & Maintenance | <p>NLM staff work with research and development contractors and external medical informatics groups on the various UMLS products.</p> <p>The Metathesaurus has a team of staff who work on the inverting of various terminologies into a single format, so terms can be inserted and edited within the Metathesaurus.</p> |
| Requesting New Content | Terminology developers and owners can submit a request to have their vocabulary included in the UMLS. |
| Release & Dissemination | <p>Requires a free license and annual usage reporting.</p> <p>The Metathesaurus is released twice a year and is available to license holders via NLM.</p> <p>Users can access the UMLS resources using the UMLS Terminology Services (download, application programming interface (API) or a web browser).</p> |

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| Overlap | The UMLS Metathesaurus is a harmonization of 150+ vocabularies based on synonymy. |
| Harmonization & Collaborations | The NLM works with many organizations, SDOs, associations, government agencies (domestic and international) on various aspects of the UMLS. |

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| Name | WHO Drug Global https://www.who-umc.org/whodrug/whodrug-portfolio/whodrug-global/ |
| Purpose | International standard of medicinal product information. |
| Usage | Global |
| Named Standard? | No |
| Ownership | Uppsala Monitoring Centre - a WHO Collaborating Centre (one of five dedicated to pharmacovigilance). |
| Development Principles | Twenty five pharmacists, medicinal chemists and IT specialists, collect, validate and classify drug information from multiple international sources. The validation of trade names, inclusion of MAH information, identification of substances and determination of ATC assignments are among the essential tasks. Changes to already existing records in WHODrug are made or logged to meet defined coding conventions. |
| Coverage | Conventional medicines and herbal remedies. The conventional medicines include prescription-only products, over-the-counter (OTC) and pharmacist-dispensed preparations, as well as biotech and blood products, diagnostic substances and contrast media. Products and substances registered by the U.S Food and Drug Administration (FDA) and the European Medicines Agency (EMA) are also routinely recorded. |
| Out of Scope | No documentation. |
| Development & Maintenance | No documentation. |
| Requesting New Content | No documentation. |
| Release & Dissemination | WHODrug Global subscription also provides access to the WHODrug Standardised Drug Groupings (WHODrug SDGs) and the analytical tools, WHODrug Insight and WHODrug CAT. |
| Overlap | No documentation. |
| Harmonization & Collaborations | No documentation. |

Appendix 3: Guiding Principles for Selecting PMRI Standards¹¹⁵

The NCVHS will use the criteria in these Guiding Principles to make recommendations for PMRI standards that:

1. Improve the efficiency and effectiveness of the health system for delivering high quality care.
2. Meet the data needs of the health community, particularly providers, patients, health plans, clearinghouses, and public health organizations.
3. Will support making patient data available in the least personally-identifiable form practical when used or disclosed for intended purposes.
4. Will include strong protections for privacy of patients where applicable.
5. Will be consistent with the other HIPAA standards.
6. Have low additional standards development and implementation costs relative to the benefits of using PMRI standards.
7. Will be supported by an ANSI-accredited standards development organization, or other private or public organization that will assure continuity and efficient update of the standard over time.
8. Have timely developmental, testing, implementation, and updating procedures to achieve benefits faster.
9. Are vendor-neutral and technologically independent of the computer platforms and transmission protocols used in the electronic exchange of PMRI.
10. Are precise and unambiguous but as simple as possible.
11. Keep additional data collection burdens on users as low as is feasible.
12. Incorporate flexibility to more easily adapt to changes in the healthcare infrastructure (such as new services, organizations, and provider types) and changes in information technologies (such as new forms of data capture, knowledge representation, and information presentation).
13. Are consistent with the characteristics and attributes for clinically specific PMRI terminologies. Examples of these characteristics include in-depth and comprehensive coverage of a clinical area, the ability to map to broader statistical and reimbursement classifications, formal and systematic definitions, internal consistency and non-redundancy, and the capacity to evolve, change, and remain usable over time.
14. Are consistent with features and characteristics of data quality, including accessibility, accuracy, comprehensiveness, consistency, currency, definition, granularity, precision, relevancy, and timeliness.
15. Consider the degree to which the market has accepted each candidate PMRI standard.

¹¹⁵ National Committee on Vital and Health Statistics. Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information [Internet]. Washington DC: National Committee on Vital and Health Statistics: 2000 [cited 2018 Jul]. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf>.

Appendix 4: NCVHS Recommendations from the Report to the Secretary of HHS on Uniform Data Standards for Patient Medical Record Information¹¹⁶

The NCVHS Report on PMRI reflects the belief that significant quality and cost benefits can be achieved in health care if clinically specific data are captured once at the point of care and that all other legitimate data needs are derived from those data. The standards for patient medical record information that will result from the recommendations in this Report will be consistent and compatible with the HIPAA financial and administrative transaction standards, including the upcoming claims attachment standards.

In consideration of broad industry testimony on these key issues, the NCVHS recommends that the Secretary of HHS:

1. Adopt the Guiding Principles for Selecting PMRI Standards as the criteria to select uniform data standards for patient medical record information (PMRI). These Guiding Principles are based on those published in the notice of proposed rulemaking for selecting financial and administrative transaction standards, which have been modified by adding characteristics and attributes that specifically address interoperability, data comparability, and data quality.
2. Consider acceptance of forthcoming NCVHS recommendations for specific PMRI standards. The first set of these recommendations will be delivered to the Secretary eighteen months following submission of this Report and will include suggested implementation timeframes that consider industry readiness for adoption. For each recommendation for PMRI standards, NCVHS encourages the Secretary to provide an open process to give the public an opportunity to comment on the PMRI standards proposals before final rules are adopted.
3. Provide immediate funding to accelerate the development and promote early adoption of PMRI standards. This should take the form of support for:
 - a. government membership and participation in standards development organizations
 - b. broader participation of expert representation in standards development
 - c. enhancement, distribution, and maintenance of clinical terminologies that have the potential to be PMRI standards through:
 - (1.) government-wide licensure or comparable arrangements so these terminologies are available for use at little or no cost.

¹¹⁶ National Committee on Vital and Health Statistics. Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information [Internet]. Washington DC: National Committee on Vital and Health Statistics; 2000 [cited 2018 Jul]. Available from: <https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf>.

(2.) augmentation of the National Library of Medicine's Unified Medical Language System (UMLS) to embody enhanced mapping of medical vocabularies and classifications. PMRI Report, July 6, 2000 Page 8

(3.) development and testing of quality measures and clinical practice guidelines, such as published in the Agency for Healthcare Research and Quality (AHRQ) clearinghouses, and patient safety measures for their compatibility with existing and developing healthcare terminologies.

(4.) development and testing in multi-agency projects, such as GCPR (Government Computer-based Patient Record) framework project.

d. coordination of data elements among all standards selected for adoption under HIPAA through the development and maintenance of an open meta-data registry and working conferences to harmonize message format and vocabulary standards.

e. improvement of drug data capture and use by:

(1.) requiring the Food and Drug Administration (FDA) to make publicly available its National Drug Codes (NDC) database registry information

(2.) requiring the FDA to develop a drug classification system based on active ingredients so that all drugs that fall into a given category can be identified by the name of that category.

(3.) encouraging the FDA to participate in private sector development and ongoing maintenance of a reference terminology for drugs and biologics that promotes the ability to share clinically specific information.

f. early adoption of PMRI standards within government programs to provide broadened feedback to the standards development community.

4. For each standard recommended by NCVHS, commit funding for development of a uniform implementation guide, development of conformance testing procedures, and ongoing government licensure of, or comparable arrangements for, healthcare terminology standards.

5. Support demonstration of the benefits and measurement of the costs of using uniform data standards for PMRI that provide for interoperability, data comparability, and data quality.

6. Support increases in funding for research, demonstration, and evaluation studies on clinical data capture systems and other healthcare informatics issues.

7. Accelerate development and implementation of a national health information infrastructure. HHS should work in collaboration with other federal components, state governments, and the private sector on demonstration and evaluation projects and test beds.

8. Promote United States' interest in international health data standards development through HHS participation in international healthcare informatics standards development organizations and, in cooperation with the Secretary of the Department of Commerce, through monitoring the activity of U.S. healthcare information system vendors abroad.

9. Promote the equitable distribution of the costs for using PMRI standards among all major beneficiaries of PMRI. This may take the form of incentives for submission of data using the PMRI standards that can support a variety of purposes, including quality improvement.

10. Encourage enabling legislation for use and exchange of electronic PMRI, including:

a. comprehensive federal privacy and confidentiality legislation. This would ensure that all health information in any medium, used for any purpose, and disclosed to any entity receives equal privacy protection under law.

b. uniform recognition by all states of electronic health record keeping; and national standards for PMRI retention and electronic authentication (digital signatures).