International Classification of Diseases, Eleventh Revision (ICD-11) Expert Roundtable

Preliminary Meeting Summary

Held August 6-7, 2019

Subcommittee on Standards

National Committee on Vital and Health Statistics (NCVHS)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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See Appendix B and C for a complete list of meeting participants.

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NCVHS—The National Committee on Vital and Health Statistics

NCVHS serves as the advisory committee to the Secretary of Health and Human Services (HHS) on health data, statistics, privacy, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. 242k[k]). The Committee also serves as a forum for interaction with interested private-sector groups on important health data issues. Its membership includes experts in health statistics, electronic interchange of health care information, privacy, confidentiality, and security of electronic information, population-based public health, purchasing or financing health care services, integrated computerized health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Sixteen of the 18 members are appointed by the HHS Secretary to terms of 4 years each. Two additional members are selected by Congress. The NCVHS website provides additional information: **www.ncvhs.hhs.gov**

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Overview of the Meeting and Background Information

The National Committee on Vital and Health Statistics (NCVHS) has two charges related to terminology and vocabulary data standards: (1) s*tudy* the issues related to the adoption of uniform data standards for patient medical record information and the electronic exchange of such information and report to the Secretary of the Department of Health and Human Services (HHS) recommendations and legislative proposals for such standards and electronic exchange, and (2) a*dvise* HHS on health data collection needs and strategies, and *review and monitor* HHS's data and information systems to identify needs, opportunities, and problems.

In partial fulfillment of these charges, on August 6–7, 2019, the NCVHS Subcommittee on Standards hosted an International Classifications of Diseases, eleventh edition (ICD-11) expert roundtable in Washington, DC. The group of invited experts represented government, academia, health industry associations, health care providers, and others. See Appendix A for agenda, Appendix B for the roster of invited experts, Appendix C for audience attendees, Appendix D for public comments, Appendix E for the final research questions, and Appendix F for a list of acronyms used. Audio recordings of the meeting are available on the NCVHS website at https://ncvhs.hhs.gov/meetings/subcommittee-on-standards-icd-11-evaluation-expert-roundtable-meeting/.

During this 2-day meeting, attendees discussed issues related to the adoption and implementation of ICD-11 in the United States, developed research questions that could produce answers to inform the process, outlined key communications topics and messages, and compiled points for consideration by NCVHS in its development of a recommendation letter to the HHS Secretary. NCVHS intends to advise the Secretary on this topic as it relates to the best interests of the United States. This report summarizes the discussions and identifies outputs from the meeting that will inform the Committee's recommendations.

Pre-meeting Materials

To support invited experts' preparation for the meeting, the following materials were distributed prior to the meeting:

- NCVHS February 13, 2019, Letter to the HHS Secretary regarding "Recommendations on Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards and Guidelines for Curation and Dissemination of these Standards."
- Meeting Report: July 2018 Expert Roundtable on Health Terminologies and Vocabularies.
- Timelines for the adoption and implementation of ICD-10, ICD-10-CM, and ICD-10-PCS. (add link)
- Literature review of the impact of the transition to ICD-10 and ICD-10-CM/PCS. (add link)
- Overview of ICD-11. (add link)

The ICD

According to the World Health Organization (WHO), the International Statistical Classification of Diseases and Related Health Problems (ICD) is the bedrock for world health statistics. The ICD "maps the human condition from birth to death: any injury or disease we encounter in life—and anything we might die of—is coded."[1]

WHO states that a country's health statistics are the true measure of its wellbeing and that "ICD allows a world of 7.4 billion people speaking nearly 7,000 languages to share a common vocabulary for recording, reporting, and monitoring health problems."[2] This shared standardization allows scientists to analyze global health data—for both diseases (morbidity) and for causes of death (mortality).

[1] See https://www.who.int/health-topics/international-classification-of-diseases
[2] Ibid.

Some countries analyze ICD codes to determine how to invest their health care resources. In the United States, ICD-10-CM codes are used to bill health insurance companies—in addition to other purposes, e.g., measuring quality and safety of patient care, assessing patient outcomes, monitoring resource and service utilization, public health surveillance, risk and severity adjustment, etc. These examples show the importance of the ICD in health care finances.

Mortality and Morbidity Data Collection

Before 1948, WHO only used the ICD system to collect and record mortality data. Morbidity codes were added in ICD-6. Currently more than 100 countries worldwide (i.e., approximately half of all countries) use the ICD system to report mortality data to track death and disease rates.

In the United States, the National Vital Statistics System (NVSS), which is a part of NCHS, oversees the collection and dissemination of the Nation's official vital statistics, including **mortality data.** It contracts with each state, two cities (Washington, DC, and New York City), and five territories (Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands) for registering births, deaths, marriages, divorces, and fetal deaths (Figure 1).

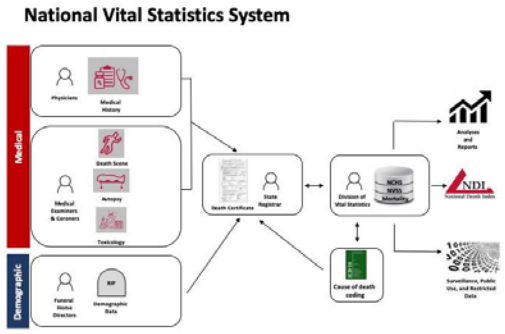

Figure 1. NVSS structure for collecting mortality data in the United States.

NCHS oversees the collection of **morbidity data** in the United States. It uses the ICD-10-CM system to code and classify morbidity data from the inpatient and outpatient records, physician offices, and most NCHS surveys. As the WHO Collaborating Center for the Family of International Classifications for North America, NCHS is responsible for coordinating all official disease classification activities in the United States, especially as they relate to the ICD and its use, interpretation, and periodic revision.[3]

Welcome and Introductions

To open the meeting on Tuesday, August 6, NCVHS Chair Bill Stead called roll, made introductions, and described the meeting objectives within the context of the overall charge of the Committee to advise the HHS Secretary on data standards and national health information policy. The meeting's objectives were to:

- Develop a shared understanding of lessons learned from the ICD-10 planning process/transition and the differences between ICD-10 and ICD-11;
- Reach consensus on the research questions to be answered to inform evaluation of cost and benefit of transition from ICD-10 to ICD-11 for mortality and morbidity—and to identify impacts of not moving to ICD-11 for morbidity; and
- Identify key topics/messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

[3] See https://www.cdc.gov/nchs/icd/index.htm

NCVHS ICD-11 Project and Roundtable Meeting Design

Rich Landen provided a brief overview of the NCVHS "Evaluating Pathways to ICD-11" project and noted that ICD-10, ICD-10-CM (U.S. clinical modification), and ICD-10-PCS (U.S. procedure coding system) are named code sets under the Health Insurance Portability and Accountability Act (HIPAA). As clarified in NCVHS's February 21, 2019, letter to the Secretary, ICD-10-PCS is completely separate from ICD-10 and will not be updated with the transition of ICD-10 to ICD-11. ICD-10-PCS is a procedure classification system designed by CMS for coding hospital-based procedures. This development was undertaken because WHO retired its procedure coding system with the 10th revision of ICD. Although many of the experts in attendance remember the process of adopting and implementing ICD-10, ICD-10-CM, and ICD-10-PCS, the process for ICD-11 will be different.

Previous versions of ICD were lists of classification codes. Each decade, the list of codes was expanded and reorganized to reflect changes in biomedical knowledge and clinical practice. ICD-11 is designed to take advantage of today's digital capabilities; to be continuously updated in response to advances in biomedical science and clinical practice; to improve coordination with other classifications and terminologies; and to provide the flexibility to reduce the need for national clinical modifications and improve the comparability of translations and on-line services to reduce the cost of implementation.

What We've Learned Thus Far—the Highlights

Learning from the ICD-10 Process and Timeline

Almost 30 years after it endorsed ICD-10, the World Health Assembly (WHA) endorsed ICD-11, and WHO is planning for ICD-11 to be available for implementation in January 2022. WHO published ICD-11 for review in 2018 prompting NCVHS to begin the process of studying and preparing for adoption and implementation of ICD-11 in the United States. To provide the historical background for the ICD-11 evaluation process, Bill Stead reviewed the timeline for the U.S. implementation of ICD-10. He used Figure 2 to summarize this complex process, which took approximately 25 years, from 1990 to 2015, including 5 years devoted to HIPAA rulemaking.

Figure 2. ICD-10 Implementation Timeline

Year	**Initiator**	**Action**
1988	NCVHS	• Recommended that WHO not copyright ICD-10 because it would impede its use in U.S.
1990	World Health Assembly	• Endorsed ICD-10 for both mortality and morbidity
1990	NCVHS	• Conducted initial review of ICD-10 (mortality and morbidity) • Reviewed CPT-4 and ICD-9-CM (procedure coding), found structural problems • Recommended that Health Care Finance Administration (HCFA*) evaluate the feasibility of a uniform procedure code
1993	NCVHS	• Recommended that HCFA study the feasibility of implementing ICD-10 for morbidity • Held three meetings and three working sessions to develop recommended steps to create a single procedure coding system for multiple purposes in U.S.
1994	NCHS	• Awarded contract to the Center for Health Policy Studies to evaluate ICD-10 compared to ICD-9-CM for morbidity • Developed prototype of ICD-10-CM morbidity only; mortality on separate pathway and does not modify ICD-10 unless updated by WHO
1995-1997	NCHS	• Developed phase 2 ICD-10-CM → public comments • Developed phase 3 ICD-10-CM, 3-month open public comment on tabular list
1997	NCVHS	• Held hearings on initial candidate code sets to be adopted under HIPAA • Recommended adopting code sets already in use, then update by adopting ICD-10 related code sets for morbidity and procedures

1998-2003	HHS	● HIPAA rulemaking
1999	NCHS	● Implemented ICD-10 for mortality in U.S.
2002	NCHS	● Posted pre-release of ICD-10-CM (morbidity) on website
2002	NCVHS	● Held hearing on ICD-10-CM – majority → implementation challenging but feasible with 2-3 years lead time for system changes ● Blue Cross Blue Shield of America (BCBSA) → NCVHS should evaluate impact on all aspects of the industry before making a recommendation
2003	DSMOs	● Requested modification of the American National Standards Institute (ANSI) Healthcare Task Group of the Insurance Subcommittee (X12N) and National Uniform Billing Committee (NUBC) to accommodate ICD-10-CM and ICD-10-PCS
2003	American Health Information Management Association (AHIMA)/AHA	● Conducted pilot test of ICD-10-CM
2003	NCVHS	● Contracted with RAND Corporation to study cost and benefits of moving to ICD-10 code sets ● Held three meetings to review RAND Corporation study plan, preliminary results, and final results ● Recommended that HHS initiate rulemaking for concurrent adoption of ICD-10-CM and ICD-10-PCS, use rulemaking to invite comments on key issues, allow 2 years after the final rule for implementation
2008	HHS	● Published Notice of Proposed Rulemaking (NPRM)
2009	HHS	● Published final rule, required HIPAA-covered entities to transition to ICD-10-CM and ICD-10-PCS by October 2013
2015	HHS	● Actual transition occurred October 2015 after two delays

* Predecessor agency to CMS.

What We Know from the Literature

Sheila Kusnoor and her colleagues at Vanderbilt University Medical Center (VUMC) Center for Knowledge Management conducted a literature review of publications on the impact of the adoption and implementation of ICD-10, ICD-10-CM, and ICD-10-PCS. Dr. Kusnoor summarized findings from the research team's final comprehensive report:

- Kusnoor and colleagues conducted online searches from March to May 2019 for published and gray literature. The sources included PubMed, Web of Science, Business Source Complete, government websites, association websites, and news websites. They also used Google to find additional white papers and presentations. They searched the references from each source by hand.
- The team screened and categorized the more than 2,000 articles produced via the search parameters. The main screening criterion was whether the article addressed the impact of the coding transition. The final set of 78 reports covered the following broad areas of impact: morbidity surveillance (24), reimbursement (16), productivity (13), mortality surveillance (13), coding accuracy (12), costs (7), mapping between versions (4), patient care (2), and staffing (1). The majority of the literature was related to the ICD-10-CM and ICD-10-PCS transitions.
- The team drew conclusions about some of these areas of impact:
  - Implementing morbidity surveillance impacted some health outcomes.
  - Reimbursement impact was varied, but some reported little impact.

  - Productivity was impacted by an initial loss then recovery.
  - Cost impact was varied, but the delays increased costs.
  - Mapping was impacted because many codes lacked straightforward mapping.
  - Implementation had a negative impact on patient care.
  - The articles contained insufficient data to measure the impact on staffing or coding accuracy.
- One article found that the coding transitions caused discontinuities in cause-of-death trends that impacted the top causes of death rankings. Another article found overestimates for diabetes and underestimates for heart disease and cerebrovascular mortality rates after the coding transition.
- The team identified the following knowledge gaps with regard to coding transition literature:
  - Costs for organizations of various sizes
  - Impact on staffing
  - Impact on coding accuracy
  - Impact on patient care
  - The extent of disruptions in morbidity and mortality surveillance
- The team members identified significant gaps in the literature that revealed opportunities for future research and knowledge sharing. They also noted that much of the data was qualitative, with the exception of morbidity and mortality surveillance. Finally, they identified a need for better reporting of data.

Development and Structure of ICD-11

Bob Anderson and Donna Pickett, both with NCHS, described the process that WHO used to develop ICD-11. The presentation included the following key points:

- ICD-11 was created to capture advances in health science and practice, make better use of the digital revolution, address multiple topics, improve and fill persistent major gaps in basic use for mortality statistics, improve morbidity statistics, become easier to use, manage national clinical modifications in a more effective manner, improve integration with other classifications and terminologies, and improve comparability of translations.
- ICD-11 has been designed to be fully integrated with other classification systems, including the International Classification of Functioning, Disability, & Health (ICF); the International Classification of Health Interventions (ICHI); the International Classification of Primary Care (ICPC); the International Classification of External Causes of Injury (ICECI); the Anatomical, Therapeutic, Chemical (ATC) classification system with Defined Daily Doses (DDD); and ISO 9999 Technical aids for persons with disabilities—Classification and Terminology.
- ICD-11 has been designed to be fully integrated with other terminologies and derived classification systems, including SNOMED CT; the International Classification of Diseases for Oncology, Third Edition (ICD-O-3); the ICD-10 Classification of Mental and Behavioral Disorders; Application of the International Classification of Diseases to Dentistry and Stomatology, Third Edition (ICD-DA); Application of the International Classification of Diseases to Neurology (ICD-10-NA); and ICF, Children & Youth Version (ICF-CY).
- The process for building ICD-11 employed the use of a revision steering group (RSG) and cross-cutting topic advisory groups (TAGs) to develop its content and structure. A joint task force (JTF) composed of experts in mortality, morbidity, and statistics provided input and review. Six experts from the United States participated in the TAGs and the JTF.
- The U.S. experts who participated in the JTF assessed ICD-11's ability to capture mortality statistics. The JTF determined that ICD-11 would be fit for this purpose by late 2018, and NCHS outlined a plan for implementing ICD-11 in the United States for mortality while considering licensing implications, a limited ability to make national modifications, and needed revisions to existing HIPAA standards.
- ICD-11's content includes a foundation layer, descriptions, and content model parameters. It also has linearizations for (1) mortality and morbidity statistics (MMS), (2) primary care, and (3)

quality/patient safety. This means that ICD-11 has a foundation layer that contains the semantic network of terms and meaning plus derivative linearizations that are built on that foundation but that function independently.[4] For example, as a derived linearization, ICD-11 MMS is based on the foundation component but incorporates advances in science and medicine, is structurally consistent with ICD-10 where possible, and provides a better representation for public health prevention. Its migration is expected to be less expensive than previous migrations because of new automation tools.

- The foundation of ICD-11 is based on four principles:
  - To be the knowledge base for all of its reference and derived classifications.
  - To constantly change in response to advances in science and medicine.
  - To allow flexibility (e.g., multiple classifications and tabulation lists can be derived from the foundation).
  - To create consistency throughout all derived classifications.
- ICD-11 has a more simplified code structure than ICD-10. It uses extension codes and code clustering. The extension codes allow for a high level of customization across many parameters.
- ICD-11 uses new rules, methods, and tools for coding. It includes tabular lists and new content (it has grown to 27 chapters). The number of codes has grown from 14,400 in ICD-10 to 55,000 in ICD-11, and the coding structure has been updated.
- ICD-11 is compatible with multiple computer systems and includes a coding tool, browser, web services with full functionality in the software of choice, online services, offline services on a local computer with updates when the internet is available, output files in multiple formats (e.g., comma-separated values [CSV], Microsoft Excel [.xls], classification mark-up language [ClaML], and others), and a print version that can provide the look and feel of the past.
- The ICD-11 implementation package comes with advocacy and training materials, a quick guide, maps to and from ICD-10 (transition tables), and a training and test platform.
- The process of adopting and implementing ICD-11 began at the 72nd WHA in May 2019. It is scheduled to come into effect on January 1, 2022. WHO noted that the switch to ICD-11 would likely be a slow process.

What Has Changed from ICD-10 to ICD-11?

Olivier Bodenreider, from the National Library of Medicine, presented the results of his collaborative work with Kin Wah Fung and Julia Xu to compare ICD-11 to both ICD-10 and ICD-10-CM.

Differences between ICD-10 and ICD-11

- The comparative analysis aimed to describe and quantify the changes from ICD-10 to ICD-11 and evaluate whether ICD-11 could replace ICD-10-CM, which significantly increases granularity and scope of coding.
- Bodenreider and colleagues obtained data files for ICD-11 MMS (the 2018 MMS linearization) as well as three files that mapped codes from 10 to 11, from 11 to 10, and from 10 to multiple codes in 11. Additional resources included the ICD-11 Reference Guide, the ICD-11 Implementation or Transition Guide, access to the ICD-11 MMS Browser, an ICD-11 MMS Coding Tool, an ICD-11 Foundation Component Browser, the ICD Application Programming Interface (API) (which provided access to linearization and Foundation Component along with post-coordination support/allowable axes and values), the 2019 version of ICD-10-CM, and the Unified Medical Language System (UMLS) meta-thesaurus and lexical tools.
- Although ICD-11 documentation states that it has 55,000 codes, this number refers to entities in the Foundation Component, which are not all unique codes. The analysis found ICD-11 to have 32,160 leaf codes, which are used for coding, but 15,106 of them (47%) are found in three chapters that fall outside the scope of ICD-10 (i.e., Chapter 26—Supplementary chapter on

[4] Chute CG. The rendering of human phenotype and rare diseases in ICD-11. J Inherit Metab Dis. 2018;41(3):563–569. doi:10.1007/s10545-018-0172-5.

traditional medicine conditions, Chapter V—Supplementary section for functioning assessment, and Chapter X—Extension codes for support of post-coordination). The actual total number of usable ICD-11 codes is 14,622, which is a 20% increase over ICD-10 (i.e., ICD-10 has 12,187 codes used for coding purposes).

- It is difficult to determine what has or has not changed between ICD versions because ICD-11 uses different codes and coding syntax (e.g., Huntington disease: G10 in ICD-10, 8A01.10 in ICD-11). In ICD-11, names may change without a change in meaning, and vice versa. This is due to the overall change in organizing principles and in its chapter delineation. The maps provided by WHO do not provide equivalence because narrow to broad maps are common, and the maps can be one-to-many.
- Roundtrip mapping analysis produced 4,820 equivalent code pairs (33% of ICD-11 codes used for coding purposes).
- Some codes moved from one chapter to another. This reflects different organizing principles or a new understanding of diseases, but it may result in incorrect coding if coders are not aware. It can also lead to missed codes (e.g., value set curators may overlook some codes if they are placed in a different chapter).
- ICD-11 has seven new chapters:
  - Chapter 3 Diseases of the blood or blood-forming organs
  - Chapter 4 Diseases of the immune system
  - Chapter 7 Sleep-wake disorders
  - Chapter 17 Conditions related to sexual health
  - Chapter 26 Supplementary chapter traditional on medicine conditions
  - Chapter V Supplementary section for functioning assessment
  - Chapter X Extension codes

Differences between ICD-10-CM and ICD-11

- ICD-10-CM has 71,932 existing (pre-coordinated) codes; ICD-11 has 14,622 of them; however, with post-coordination, the possible number of codes could be much higher. ICD-11 allows for two kinds of post-coordination:
  - Two or more stem codes (connected by "/").
  - Stem codes with one or more extension codes (connected by "&").
- Use of normalized lexical matching to ICD-10-CM produced 3,211 ICD-11 codes for coding purposes (from chapters 1–25). These were mapped to 2,315 ICD-10-CM codes for coding purposes and 1,577 ICD-10-CM codes that are *not* for coding purposes.
- Using a manual matching process for six disease categories, the team sought to determine whether the meaning of an ICD-10-CM code could be fully represented by a pre-coordinated ICD-11 code, fully represented by post-coordination, or only partially represented even with post-coordination. The results produced 9%, 49%, and 43% representation, respectively, for each type of coordination. It was noted that post-coordination coverage could increase to 76% if ICD-11 added three extension codes for episode of care (thus covering all 105 fracture thumb codes).

Comparison of Content Coverage of ICD-11 to ICD-10-CM and SNOMED -CT

Christopher Chute described his analysis of ICD-11 MMS, the product that would be used to replace the 2012 version of ICD-10-CM:

- In 1994, to determine how well clinical classifications worked, researchers at the Computerized Patient Record Institute (CPRI) evaluated coding efficacy for measuring content capture. They used various sources of clinical text from five large medical centers to create 3,000 concepts that were then subjectively scored into three categories: 0, Not in Classification; 1, Vaguely Represented; or 2, Represented.

- The researchers then applied their scoring system to ICD-9-CM, the 2012 version of ICD-10-CM, and ICD-11 to determine whether ICD-11 performed better than its previous versions in the areas of diagnosis, findings, modifier, other, and overall. Procedures were included in the overall totals.
- Researchers concluded that, in terms of content coverage, ICD-11 is significantly better than ICD-10-CM and comparable to SNOMED CT.

Reflections on Adoption and Implementation of ICD in the United States

Bill Stead reflected on the lessons learned from implementing ICD-10 in the United States and suggested the following implications for research questions to prepare for implementation of ICD-11:

Lessons Learned

- Historically, the ICD update occurred without problems or too much difficulty every 9 to 10 years from 1900 to 1975, even during World War I and World War II.
- WHA took 15 years to endorse ICD-10, and the timespan between the ICD-10 and ICD-11 endorsement was 30 years.
- These lengthening transitions have coincided with the invention of computer systems and national modifications to handle morbidity and procedure coding.
- The United States spent 9 years implementing ICD-10 for mortality; 13 years (from 1990 to 2003) for evaluating ICD-10, developing modifications, and rulemaking; and 12 years for implementing ICD-10-CM and ICD-10-PCS.

Implications for Potential Research Questions

- The estimated costs associated with adopting and implementing ICD-10 for morbidity and procedure coding were off by at least an order of magnitude. This was largely because the RAND study did not take into account that almost every system and every interface would have to be modified.
- The development of ICD-11 spanned 12 years (from 2007 to 2019) with the intent of leveraging an informatics foundation to make the transition and subsequent updates less difficult and timely. Specific research could determine whether ICD-11 will work as intended. If so, will the cost/benefit and optimal timeline for implementation change? In addition, the factors that might again lead to incorrect cost analysis should be investigated.

Research Questions—Breakout Sessions 1 & 2

Breakout Session Process, Results, and Summary of Expert Input

NCVHS' recommended criteria for the adoption and implementation of health terminology and vocabulary standards states that "[h]ealth terminology and vocabulary standards should be supported by research confirming the benefits and estimates of cost, including burden of use and of adoption and implementation." During this next segment of the meeting, invited experts were divided into five panels (breakout groups) to develop specific input for the Committee's consideration and use. Invited experts were seated in groups of six or seven by area of expertise so that each panel could develop targeted input. The groupings and proposed research categories were aligned as follows:

- Clinical scope and use (2 panels)
- Training and implementation, including staff productivity
- Technology issues and opportunities
- Mortality as it pertains to each of the other three categories

Categories of Research Questions

To set the stage, Rich Landen presented a draft set of potential ICD-11 research categories developed by the Subcommittee. These draft categories were based on NCVHS criteria, the 2018 expert roundtable

meeting findings, VUMC Research, and a previous Rand Corporation research on ICD-10. The categories included the following:

1. Clinical scope and use, to include representation of current medical, behavioral, health care, and public health delivery as well as impact on productivity, including documentation and decision support
2. Training and implementation, to include impact on productivity, cost of access and dissemination, and support for automatic updates
3. Technical issues and opportunities, to include system changes for implementation, artificial intelligence for computer-assisted coding, and automated classification and mapping
4. Benefits in supporting major purposes, to include classification of diseases (or cause of death) across all care settings, quality measurement (surveillance), research, and payment and pricing
5. Adoption pathways and timetable, to include stakeholder engagement, the vetting process, lead times, and the window of implementation opportunity
6. Impact on related standards, to include administrative standards (e.g., X12, NCPDP, HL7, CAQH CORE, NACHA) and updates to other terminologies and vocabularies
7. Other

Breakout: Roundtable Session #1: Research Questions for Focus Areas and Major Uses

After discussion within their panels for just under an hour, meeting participants reconvened as a full group to report each roundtable's consensus input on the most important research questions.

Clinical Scope and Use

- What is the impact of implementing ICD-11 on provider effort, burden, and workflow across all health care settings and systems? How will implementing ICD-11 impact productivity (e.g., will it increase or decrease documentation effort)?
- What tools are needed to support a highly effective implementation of ICD-11 in clinical practice (e.g., interface terminologies, computer-assisted coding), reduce burden, and better incorporate coding into the workflow?
- What benefits could accrue to stakeholders across the health care ecosystem? Is it possible to enhance productivity by generating administrative codes from clinical data in an accurate and useful manner? Could implementing ICD-11 improve quality outcomes and value? If so, how could these benefits be communicated to providers?
- What are the specific implications for implementation of post-coordination (e.g., optional post-coordination and use of extension codes)? Will the base code require so many extension codes as to impact readability and data quality?
- When reviewing the content and categories in ICD-11, can clinicians and other stakeholders identify missing elements (e.g., U.S. Clinical Modification, linkages to the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition [DSM-V] for behavioral health)?
- With regard to major uses:
    - What is the impact of returning to pre-coordinated terminologies, especially on use cases?
    - How well will ICD-11 support algorithms for risk adjustment and quality measures? Will ICD-11 be at least as good as the current ICD-10 in this area?
    - How will ICD-11 support the generation of real-world evidence for device surveillance and quality improvement?
    - How will the changes in ICD-11 stability and maintenance impact users? How will ICD-11 be updated and maintained over time, and what are the implications for its various uses?
    - How can ICD-11 be used to bridge the gap between fine-grained data for research versus large groupings for administrative purposes? Is it possible to use SNOMED and EHR problem lists to code or to assign a symptom without losing an administrative translation? Will evidence of care or other utilities be lost?

  - With regard to decision support, is ICD-11 sufficiently updated to be used to define cohorts and interventions? Can ICD-11 be used to integrate external determinants of health to improve the utility of decision support? Can ICD-11 be used in all aspects, by all specialties? If not, what is its deployment scope (e.g., dentistry does not use ICD codes)?

Training and Implementation

- Will ICD-11 require a US Clinical Modification? If so, will the CM use pre-coordinated codes, as ICD-10-CM does or use post-coordinated codes as ICD-11 does? This is the primary question that impacts training needs.
- Which categories of optional ICD-11 extension codes will be adopted by the U.S? This also highly impacts training needs.
- What innovative training approaches (e.g., virtual, economic, and scalable tools) could be used to implement ICD-11?
- What computer system changes will be needed to implement ICD-11? Will improved convergence of administrative and clinical codes be needed?
- Is sophisticated computer-assisted coding possible with ICD-11? What would incentivize vendors to quickly develop NLP and artificial intelligence (AI) coding tools for this use?
- Would controlled field testing be helpful in implementing ICD-11? If so, what type of field testing? Is the University of Calgary's process a useful model?
- With regard to major uses, what are all of the potential uses for ICD-11, including new concepts?
- How might the role of the coder change under ICD-11? If there is an opportunity for increased automation, what new skills may coders need to develop and what new roles might they take on?
- Will the law to consider codes for new diseases twice a year need to change with continuous addition of codes to ICD-11 by WHO?

Technical Issues or Opportunities

- Can interoperable representation of research and clinical term/classifications/nosologies be used to simplify distribution and deployment?
- Can a post-coordination model support complete and safe retrieval of encoded data with respect to recognizing concept equivalence and content coverage?
- Can ICD coding for reimbursement or quality control be implemented as a computable service on top of standardized clinical statements captured by EHR during the process of clinical care?
- Major uses also include intellectual property, maintenance updates, and extension sharing. Would it be helpful to create matrices of research questions versus major uses?

Mortality

- What are the real differences between ICD-10 and ICD-11 for mortality, especially on a detailed level? Could a comparability study with ICD-10 assess the design process more efficiently? To reveal additional specificity provided by ICD-11, what percentage of codes are "unspecified" or "other specified" in ICD-10 versus ICD-11?
- Would analyzing the WHO mapping between versions prove which maps are useful? Will new cause of death lists need to be created?
- Drug detail is a gap in ICD-10 (e.g., it cannot determine the number of deaths due to fentanyl), so a workaround is needed. ICD-11 has drug extension codes. How good are they, and are they adequate?
- Will implementing ICD-11 have an impact on data quality?
- What are the costs for switching to ICD-11, and what are consequences of not switching? How are the costs defined?
- Does ICD-11 provide new data or details that could create novel avenues of mortality research?
- Comparability studies were not done for mortality when transitioning from ICD-9 to ICD-10. Would it be useful to do them when transitioning to ICD-11? Although it would be challenging to

create a dual-coded dataset, a synthetic dataset might show the differences and allow analyses of representativeness and broad sets of clinical conditions while avoiding privacy concerns.

An integrated summary of the final research questions that participants deemed most important is attached as Appendix E.

Background: Pathways and Timetables

Adoption of ICD-11 by the United States has two distinct dimensions. Adoption for cause of death (mortality) reporting is a condition of U.S. membership in the World Health Organization (WHO) contributing to worldwide surveillance. It is led by the National Center for Health Statistics (NCHS) in conjunction with state vital statistics agencies. Adoption of ICD-11 as a standard for classification of health conditions (morbidity), however, requires HHS rule making since ICD is a HIPAA-designated medical code set that is mandatory for use in hospital, physician and some dental and pharmacy billing as well as state and other population health data reporting. In terms of timing, WHO has indicated that ICD-11 will be available for implementation in 2022. NCVHS is interested in developing and outlining steps to be completed before then, including the initiation and completion of the aforementioned research to inform the path forward for the U.S.

Breakout: Roundtable Session #2: Adoption Pathways and Timetables, Impact on Related Standards

During the second breakout session, attendees met for 1 hour to identify issues and develop suggestions for potential pathways and timetables for the adoption and implementation of ICD-11 in the United States. As a secondary consideration, the groups discussed possible impacts of ICD-11 on related standards. Invited experts remained within their original groups to develop input on these topics (i.e., clinical scope and use, training and implementation, technology issues/opportunities, and mortality). The entire group then reconvened to share their input.

Adoption Timeline Issues and Ideas

Meeting attendees identified and discussed the following issues and ideas regarding the establishment of an ICD-11 adoption and implementation timeline:

- **International adoption:** It might be helpful to learn the implementation goals of other countries and glean insights from their plans, if applicable. For example, many countries use automated coding systems for capturing mortality data (Europe and Australia use a system called IRIS). The United States should implement ICD-11 for mortality within 1 to 2 years of other countries to allow for data comparison. For morbidity, other countries have national modifications, legislative parameters, stakeholder engagement, impacts on national statistics, and reimbursement issues.
- **Mapping:** An evaluation of how much of the pathway for implementing ICD-11 depends on mapping and interoperability would be helpful. Because it is the default approach, evaluating patient safety and quality as they relate to mapping might be prudent.
- **Post-coordination:** No EHR supports post-coordination in meaningful way. Although there is pressure to meet clinical needs, adding complex expressions to terminologies adversely impacts data quality. The group discussed sharing post-coordination libraries and problem lists. If EHRs cannot support post-coordination, how would this problem be mitigated? A predominant EHR is EPIC, which has implemented PROMIS measures—a post-coordination adaptive process. The case should be made that post-coordination is needed to enhance workflow and cognitive support.
- **Stakeholder engagement and buy-in:** Systematic and conscientious needs assessments should be conducted with all stakeholders (e.g., providers, insurance companies, states, and regulators) to gather their input on the desired state and how to get there. The process to develop testing tools could be used to assess whether stakeholder needs are being addressed.
- **Cost effectiveness:** Research efforts to demonstrate the cost-effectiveness of adoption and implementation would be valuable.

- **Automation:** ICD coding might be implemented as a computable service on top of standardized clinical statements captured in the EHR using Promoting Interoperability Standards. If feasible, humans would no longer assign ICD codes. Research to support algorithmic coding could then obviate the need for post-coordination work. Human resources could be used to audit, analyze, and conduct quality assurance on automated coding processes.

Expert Input on Adoption Timeline and Impact on Related Standards

Invited experts provided the following input regarding the timeline for the adoption and implementation of ICD-11 and its impact on related standards. Similar to the first breakout session, the subheadings align with the topic assigned to each table (i.e., clinical scope and use, training and implementation, technology issues/opportunities, and mortality data). The potential impact on related standards is the final subheading.

Clinical Scope and Use

- Determine what is needed to hold stakeholders to a 5-year process for implementation.
- Determine whether the vetting process of ICD-9 and ICD-10 is appropriate for ICD-11.
- Determine whether a U.S. CM will be needed. If so, can ICD-11 be adopted while the CM is being developed?
- Describe how lessons learned in pilot programs could be generalized for broad implementation.
- Identify all stakeholders (e.g., coders, national organizations) and determine whether it is possible to develop an implementation strategy that is diverse enough to meet the needs of all stakeholders. Outline what each stakeholder group needs to achieve implementation.
- Identify resources for change and barriers to change.
- Study different models of care to identify windows for opportunity.
- Determine whether ICD-11 is fit for purpose with regard to payment models.
- Identify current costs for the implementation of code sets, including training, system upgrades, and any other related costs. Describe what it takes to build tools in terms of time and costs.
- Determine how using ICD-11 would affect electronic transactions and paper forms.
- Determine how current standards would handle post-coordination.
- Determine whether dual coded studies would be needed to study impact.
- Describe changes (up or down) to the clinical burden versus changes in quality and value of data.
- Describe the process for transforming coders into auditors.

Training and Implementation

- Urgently determine whether a U.S. CM will be needed (i.e., extensions and post-coordination) because this question must be answered to determine an implementation timeline.
- Implement ICD-11 before knowledge gained during the transition to ICD-10 is lost. Identify the different efficiencies for ICD-11. ICD-10-PCS was the most difficult transition, so moving to ICD-11 "should" be relatively easier.
- Create early engagement with physicians at every level.
- Be aware of concerns about the quality of coded data, especially physician data.
- Engage stakeholders in all research under consideration. Create a plan to disseminate research results and then engage stakeholders in evaluating the results.
- Continually track lessons learned.
- Evaluate methods of comparing longitudinal data that do not involve mapping. Reduce reliance on mapping because it is overused with poor results.

Technical Issues or Opportunities

- Determine and describe the implications of the technical changes (e.g., technical structures and code lengths).

- Create and use a pilot evaluation testing program with a body of research to explore across a spectrum of uses.
- Integrate ICD-11 into the vendor EHR and terminology service application products.
- Systematically evaluate the consequences of mapping on quality and safety.

Mortality

- Because U.S. states and territories are the stakeholders that use ICD for mortality, they will have to modify their systems to accept new codes, and they will receive new specifications. Determine the cost to states to prepare for the transition.
- For mortality, the window of opportunity is flexible (i.e., 2025 vs 2027 may not matter). Determine and describe any benefits to earlier implementation. If there are benefits, determine whether increased resources would lead to earlier implementation.
- Assess whether any interoperability issues exist between electronic death registration systems and coroner reporting systems (i.e., HL7 and FHIR).

Impact on Related Standards

- Identify all standards that could be impacted by ICD-11, including content standards, terminologies, decision support, content-related standards, consumers of patient data, and report definitions.
- Describe the role of SNOMED CT as it relates to ICD-11. Determine whether SNOMED CT code translates to ICD-11 or whether ICD-11 would make SNOMED CT obsolete.
- Determine whether and how ICD-11 would coordinate with X12. Determine whether and/or how ICD-11 would work alongside fast health care interoperability resources (FHIR).
- Determine how ICD-11 would overlap with other code sets and whether it would coordinate with others for post-coordination.
- Determine how ICD-11 would coordinate with detailed clinical documentation (e.g., there are 20,000 terms in the echocardiography dictionary).
- Consider billing and insurance processes, including non-covered entities such as Workman's Compensation.
- Determine how ICD-11 would leverage related terminologies for domain-specific concepts (e.g., medications, toxins, devices).
- Evaluate methods to accommodate regional and urgent codes without comprising consistency.

Recap of Insights from the Day and Discussion

To complete the first day of the meeting, Bill Stead and Rich Landen described and outlined their key take-aways and "gold nuggets" on the proposed research questions. After creating further discussion with attendees to clarify several points, they asked the group to continue to comment and provide input on each priority area throughout the remainder of the conference. The final list of research questions is attached as Appendix E.

Closing Remarks and Adjournment

Rich Landen outlined the day 2 agenda, asked the group to reconvene at 8:30 am, and adjourned the meeting.

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Welcome Back and Call to Order

To open the meeting on Wednesday, August 7, 2019, NCVHS Chair Bill Stead called roll and reviewed the morning work plan. The day's objectives were to recap day 1, complete roundtable break out session #3, report out to the group, and synthesize key communication topics and messages with the top priority research questions. The day would conclude with a Standards Subcommittee working session to review roundtable findings, outline a draft letter to the Secretary, and determine next steps. Finally, public comment was taken after the working session and then the meeting was adjourned.

Recap from Day 1

Bill Stead and Rich Landen presented the next draft of the document synthesizing the first day's discussion and asked the group to once again collectively review and refine the proposed research questions. A list of the top 11 research questions considered most important and relevant to informing adoption and implementation of ICD-11 is included as Appendix E and will be attached to the letter to the Secretary with the committee's recommendations.

Break Out: Roundtable Session #3: Key Communication Topics and Messages

The Subcommittee determined that communications surrounding the adoption and implementation of ICD-11 in the United States will be important for a smooth and less problematic transition. The subcommittee members noted that HHS and other entities will play an essential role in disseminating clear and timely information about the transition.

Identification of the Issues

Rich Landen introduced the communication topic to meeting participants by presenting the following example questions that could be answered and tailored to stakeholder groups:

- What is an ICD?
- Why is it necessary for WHO to update the ICD every decade or so?
- How is ICD-coded data used in the United States? (Explain for morbidity and mortality.)
- Didn't we just do this? Describe how ICD-11 would not be like the transition to ICD-10.
- What was learned from the ICD-10 implementation experience? Describe productivity, end-to-end testing, and any available data on how the transition would impact major users.
- What is the process for determining when ICD-11 will be implemented? Describe how the morbidity and mortality paths are independent.
- How can we begin preparing: what information does my organization need to begin to prepare for ICD-11 implementation?
- Isn't this just a billing question?
- Isn't this just a code set mapping technical issue?
- What is the relationship(s) to other standards, code sets, and vocabularies (e.g., EDI, SNOMED, PCD, HIPAA, ONC's ISA)?

Breakout Session Results and Summary of Expert Input

Invited experts met for 1 hour within their panels to identify and define important communication topics and key messages regarding the adoption and implementation of ICD-11 in the United States. The full group then reconvened and outlined the most important themes and messages for the Committee to consider. These communications topics and messages are outlined below.

1. **Urgency of a path forward and a timeline for key decisions:**
   a. Will the United States support post-coordination for mortality?
   b. Which extensions will the United States adopt for mortality?
   c. Does the United States require a CM?

   d. Will the United States proceed with a regulatory path forward for morbidity?
      i. Will it be the path recommended by NCVHS or will it be the same NPRM/final rule path that was used for ICD-10?
      ii. What will the timing be for morbidity?

2. **Which ICD-10 transition tactics will be effective for ICD-11 and which no longer apply?**
3. **What are the implications of ICD-11 for related standards and services?**
   a. Transport standards X12, NCPDP, HL7, Operating Rules
      i. Support for stem codes
      ii. Support for extensions
      iii. Guard rails for extensions and post-coordination
   b. FHIR, decision support, report definition standards
   c. Terminology server vendors
   d. EHR, billing and practice management software developers
   e. Clearinghouses and health information exchanges
4. **ICD-11 is intended to be the last "decadal" update of the classification from WHO.**
   a. What is the plan for continuous incremental updates?
5. **Quality and safety costs of mapping, repetitive mapping in particular.**
6. **Consider that different agencies have different priorities and interests** (e.g., the Agency for Healthcare Research and Quality [AHRQ] aims to reduce burden).

An integrated summary of the final communication topics that participants deemed most important is attached as Appendix F.

Synthesis: Refined Research Questions and Key Communication Topics

After the morning report-out session, Bill Stead led the group through final discussions and additions to the meeting's two main output documents: the research questions and the key communication topics. Two further themes that arose during the meeting were the identification and listing of key stakeholders and suggestions for creating a change management strategy. These concepts are further described below.

Key Stakeholders

Throughout the meeting, attendees identified the key stakeholders in the process of adopting and implementing ICD-11:

- Patients
- Physicians
- Hospitals and patient care centers
- Insurers/payors
- Drug and device manufacturers
- Physician and health care professional organizations
- Other terminology server vendors and standards organizations
- EHR, billing, and practice management software developers
- Clearinghouses and health information exchanges
- Other insurance entities, such as Workers Compensation and automobile liability/no-fault

Change Management

Because change management will be an important component for implementing ICD-11, attendees made the following suggestions:

- For each use case, map barriers to change, resources available to support change, and implementation tactics.
- Develop tactics to address participants in transactions that are not HIPAA-covered entities (i.e., ways to successfully encourage entities such as Workers Compensation and Automobile Liability/No-fault to adopt and use ICD-11 despite lack of federal mandate to do so).
- Engage stakeholders from the use cases at every step.
- Design end-to-end testing into the implementation and continuous refinement cycle.

NCVHS Standards Subcommittee Working Session

After lunch, the Subcommittee gathered for a working session to review roundtable findings, outline a letter to the Secretary, determine next steps, and listen to public comment. They also discussed the suggestions and points raised by invited experts along with their own contributions.

Key Points for Letter to the Secretary

Subcommittee members reviewed and discussed the input, feedback, and considerations raised by invited experts in combination with their own contributions. Members discussed and debated important elements to include in an NCVHS' letter to the Secretary regarding the adoption and implementation of ICD-11. This discussion produced the following outline for the letter:

- Describe NCVHS' Charge related to ICD-11 adoption
- State that NCVHS recommends urgently conducting research to inform the path forward for adopting and implementing ICD-11 in the United States
- Describe the urgency based on the following rationale:
  - WHO no longer updates ICD-10, and ICD-10 no longer reflects the reality of present-day clinical knowledge and practice. ICD-10 was developed based on research from the 1980s.
  - As the international community transitions to ICD-11, now is the time to develop plans for the transition to ICD-11 in the United States.
  - ICD-11 includes important enhancements: it was specifically created for EHRs and modern computability.
  - Quickly adopting and implementing ICD-11 may be an important opportunity for HHS to save national resources while meeting the needs of the U.S. health care system for interoperability and population health improvement.
  - The evaluation approach recommended by NCVHS is based on an assessment of how to improve on the transition from ICD-9 to ICD-10. For example, beginning with a robust research plan was not done for the last transition. This is a key insight of the Committee.
  - The costs of not moving forward may be significant.
- State that the WHA has adopted ICD-11. Describe the differences between adoption and implementation for mortality versus morbidity. Explain why the path for morbidity is more complex. With regard to the project scope, clarify that NCVHS recommended that ICD-10-PCS can be excluded from the transition process (and reference previous letter).
- State that near-term research to determine the benefits and costs of different implementation approaches and timeframes, beginning with mortality, should begin immediately. This research should also determine the costs and implications of not implementing ICD-11 in a timely manner.
- Include a statement regarding the importance of a strategic communication process and immediate engagement of key stakeholders.
- Highlight extensive work done to inform recommendations about research questions and communication topics.
- Reference the NCVHS Criteria for Adoption and Guidelines for Curation and Dissemination.

The group reached consensus that NCVHS should recommend that HHS take a proactive approach toward ICD-11 and engage stake holders in the process. The members agreed that this letter[5] to the Secretary should include the following two attachments:

1. The list of research questions and key communication topics.
2. NCVHS recommendations for: "Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards" and Guidelines for Curation and Dissemination of Health Terminology and Vocabulary Standards"
3. The August 6-7, 2019 ICD-11 Expert Roundtable Meeting Summary (this document).

Public Comment

At the end of the meeting, two individuals offered public comments, which were transcribed and are presented in Appendix D.

Closing Remarks and Adjournment

Bill Stead and Rich Landen thanked attendees for their valuable participation and contributions. The NCVHS Expert Roundtable on the adoption and implementation of ICD-11 achieved its stated goals. Invited experts contributed significant input to support the Committee's development of research questions regarding a pathway to adoption, timetable to adoption, and key communications topics and messages. The Subcommittee began the process of drafting the key elements of a letter to the Secretary to outline recommendations for proceeding on the adoption and implementation of ICD-11.

[5] Link to the final letter

Appendix A: Agenda

National Committee on Vital and Health Statistics (NCVHS)

ICD-11 Expert Roundtable Meeting

August 6-7, 2019

HHS Headquarters, Hubert Humphrey Building
200 Independence Avenue, SW, Room 705-A
Washington, DC 20201

Meeting Objectives

- Develop a shared understanding of lessons from the ICD-10 planning process/transition and the differences between ICD-10 and ICD-11.
- Reach consensus on the research questions to be answered to inform evaluation of cost and benefit of transition from ICD-10 to ICD-11 for mortality and morbidity – and to identify impacts of not moving to ICD-11 for morbidity.
- Identify key topics/messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

Tuesday August 6

9:00 am	**Welcome and Introductions** • Call to Order & Roll Call • NCVHS Terminology & Vocabulary Agenda • Introductions and anticipated meeting takeaways	Bill Stead, MD, NCVHS Chair Rich Landen, Co-chair, Standards Subcommittee
9:20 am	**NCVHS ICD-11 Project and Roundtable Meeting Design**	Rich Landen
9:30 am	**What We've Learned Thus Far – The Highlights:** • Learning from the ICD-10 process and timeline • What we know from the literature	Bill Stead, MD Sheila Kusnoor, PhD, Vanderbilt University Medical Center's Center for Knowledge Management
10:25 am	Break	

10:40 am	**What We've Learned Thus Far – The Highlights:**
	• What has changed from ICD-10 to ICD-11?
	  • Development and structure of ICD-11
	  • Analysis of resulting product
		Bob Anderson, PhD & Donna Pickett, RHIA, MPH/NCHS
		Olivier Bodenreider, MD, PhD, NIH/NLM

11:30 am	**Research Questions – Breakouts 1 & 2** • Introduction of working draft categories of research questions • Initial reaction and feedback	Rich Landen & ICD workgroup
12:15 pm	Lunch	
1:15 pm	**Breakout Group Assignments and Instructions**	Rich Landen & ICD workgroup

1:20 pm	**Breakout: Roundtable Session #1** • Research questions for focus areas + major uses	Expert Panelists
2:15 pm	**Report Outs to Full Group**	NCVHS members with Expert Panelists
3:00 pm	Break	
3:15 pm	**Breakouts: Roundtable Session #2** • Adoption pathways and timetable • Impact on related standards	Expert Panelists
4:15 pm	**Report Outs to Full Group**	NCVHS members with Expert Panelists
5:00 pm	**Recap of Insights from the Day & Discussion** • Flag top priority research categories and questions	NCVHS members with Expert Panelists
5:30 pm	**Closing Remarks & Adjourn**	Rich Landen & Bill Stead

Wednesday August 7

8:30 am	**Welcome Back and Call to Order** • Roll call • Review morning work plan	Bill Stead & Rich Landen
8:45 am	**Recap from Day 1** • Refinement of research questions with input from Expert Panelists	Rich Landen & ICD-11 workgroup
9:15 am	**Roundtable Session #3** • Introduction of working draft key communication topics and messages	NCVHS members with Expert Panelists
10:15 am	Break	
10:30 am	**Report Outs to Full Group**	NCVHS members with Expert Panelists
11:15 am	**Synthesis: Key Communication Topics for NCVHS Consideration** • Flesh out top priority research questions & communication topics	Rich Landen, Bill Stead, NCVHS members with Expert Panelists
12:30 pm	Lunch	
1:15 pm	**NCVHS Standards Subcommittee Working Session** • Review Roundtable Findings ● Research categories and questions ● Key communication topics and messages • Outline draft letter to the Secretary • Next steps	Rick Landen & Alix Goss NCVHS members Expert Panelists who wish to participate
2:45 pm	**Public Comment**	Rebecca Hines, NCVHS Executive Secretary/Designated Federal Officer
3:00 pm	**Closing Remarks and Adjourn**	Bill Stead & Rich Landen

National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

Appendix B: Invited Experts

August 6-7, 2019

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Elitsa Evans
Erin Fernandez
Carissa Haney
Holly Hedegaard, CDC
Katherine Isbell
Ankur Jain
Lolita Jones
Gail Kocher
Ellen Kramarow
Shannon M. Lamptey
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Anne McNealis
Henry Olaisen
Yurly Plylypchuk
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Jim Seidler
Stephanie Smith
Brenda Sokol
Nancy Spector
Merri-Lee Stine
Jagan Sukumar
Nikki Taylor
Kathryn Williamson

Appendix D: Public Comments

Amy Blum, from NCHS: "I'm speaking as a classification person with the Division of Healthcare Statistics, but also as a health information management professional and a member of AHIMA. I have been a classification specialist at NCHS since 1991, and I was a project officer for the development of ICD-10-CM, which began in 1994. I was involved in the entire 22-year implementation process. I am currently on the technical services branch of the Division of Healthcare Statistics. We run ambulatory and inpatient healthcare surveys. I would like to respond to some comments made by Committee members. The first group I met with at the start of the ICD-10-CM implementation development was the Worker's Compensation community. Their first request was for laterality. Their second request was to expand the external cause codes for injuries related to animals and machinery, where a large number of worker's compensation claims occur. So, yes, we did separate crocodile and alligator for a reason. We might have gone too far, but it was asked for. The injury community requested that the concepts of initial encounter, subsequent encounter, and sequelae so as not to lose information on the original injury if a patient was seen at a later date for an "old injury" visit. The American College of ACOG requested the fetal numbering codes. Every code in the ICD is there because a constituent asked for it. Any codes currently in ICD-10-CM missing from ICD-11 would need to be added. Although a CM has been created for ICDs in the past, it really should not be needed for ICD-11, however, the annual updates and the coordination and maintenance process does need to continue. The classification is dynamic and must be updated. The U.S. will always have to be independent of the WHO in maintaining the ICD-11 for morbidity. Just like with ICD-9, ICD-10, and ICD-11, things do get old and out of date, and I suspect that someday we will be here talking about ICD-12. A much more efficient and effective implementation process is essential for ICD-11; however, as a Federal standard, some rulemaking must occur. A proposed rule, a public comment period, and a final rule must be published to prevent litigation that can delay further implementation. Once an implementation date is set, however, it should be adhered to. Multiple administrations and many classes of NCVHS committee members will pass before ICD-11 is implemented, so a long-range plan is essential. Nothing in ICD-11 in the U.S. should be optional. What is optional will not be captured. Much of the original objection of ICD-10-CM was the cost of converting legacy systems. The conversion to ICD-11 will be more challenging and expensive. Therefore, it must be required that all extensions are required to ensure that they are programmed into all systems. There is an issue of principal diagnosis, the official coding guidelines, you need the 1500s, survey tools, all of those things that need to be decided when you have a code that does not have a fixed length. Those are very important considerations. The cost/benefit analysis is really somewhat questionable. What are we going to measure and how can it be quantified? The Committee needs to design and test an in-house project that somehow is designed to support implementation. I don't know what that would be, but that is something that the private sector does need to consider. We really don't have any way of measuring ICD-11 or its validity just yet. It must always be remembered that first and foremost the ICD is a statistical classification with the function of providing usable, reliable data on health care for all users. ICD-11 is a technically sophisticated product but unless it can fulfill its purpose, there cannot be a case for its implementation. And right now, we really don't know what that is. Although I do think that it's a very fascinating classification. I hope that someday it does get implemented. Thank you."

Suzy Roy, from SNOMED International, submitted an online comment. She is the customer relations lead for the Americas and a collaboration specialist. Her statement read, "On behalf of SNOMED International, I would like to thank the NCVHS for allowing us to listen in to the ICD-11 Expert Meeting. Most here know that SNOMED International is a member-based, not-for-profit standards organization that owns and maintains SNOMED CT, a clinical terminology that focuses on providing the encoding needs of all healthcare professionals for capturing, sharing, and analysis. We currently have 39 member countries, including the U.S., whom we work with and support. Based on the past two days, we would like to remind that SNOMED is currently implemented in the U.S. in the EHR and beyond (FDA devices, and biologic clinical application forms, for example). And SNOMED CT is used in over 80 countries. SNOMED is

designed as an ontology with a concept model based on description logic. The terminology has grammar and machine-based rules. Post-coordination is a key component of the design. We work with other standards to ensure that data can be shared and reused in a safe way and that the meaning is not changed. We have tried and tested processes and tools—from the ability to receive requests for change to editorial, technical, and educational training and advisory groups—supporting a community of users, and we have an established and stable update and release delivery. Finally, we are here because we are committed to supporting our members, the U.S. included, and of course we will continue our collaborative efforts with other standards development organizations, such as WHO, to ensure that our standards work together according to their different purposes and scope, as well as with clinical groups to ensure that SNOMED remains clinically up to date and relevant.

Appendix E: Final Research Questions

[Will be inserted when final]

Appendix F: ICD-11 Communications Plan

[Will be inserted when final]

Appendix G: List of Acronyms

AHA	American Hospital Association
AHIMA	American Health Information Management Association
AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
AMA	American Medical Association
ANSI	American National Standards Institute
API	Application Programming Interface
ATC	Anatomical, Therapeutic, Chemical classification system
BCBSA	Blue Cross and Blue Shield Association
CDC	U.S. Centers for Disease Control & Prevention
CMS	Centers for Medicare and Medicaid Services
CPRI	Computerized Patient Record Institute
DDD	Defined Daily Dose
DSM-V	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
EHR	Electronic Health Record
FDA	U.S. Food and Drug Administration
FHIR	Fast Healthcare Interoperability Resources
HCFA	Health Care Financing Administration, predecessor agency to CMS
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
ICD	International Classification of Diseases
ICD-10-CM	International Classification of Diseases, 10th Revision, Clinical Modification
ICD-10-NA	Application of the International Classification of Diseases to Neurology
ICD-10-PCS	International Classification of Diseases, 10th Revision Procedure Coding System
ICD-11	International Classification of Diseases, 11th Revision
ICD-11 MMS	International Classification of Diseases, 11th Revision Mortality and Morbidity Statistics
ICD-DA	International Classification of Diseases to Dentistry and Stomatology, 3rd Edition
ICD-O-3	International Classification of Diseases for Oncology, Third Edition
ICECI	International Classification of External Causes of Injury
ICF	International Classification of Functioning, Disability, & Health
ICF-CY	International Classification of Functioning, Disability & Health for Children & Youth
ICHI	International Classification of Health Interventions

ICPC	International Classification of Primary Care
ISO 9999	Technical Aids for Persons with Disabilities – Classification and Terminology
KBS	Knowledge Based Systems
NCHS	National Center for Health Statistics
NCVHS	National Committee on Vital and Health Statistics
NEC	Not Elsewhere Classified
NIH	National Institutes of Health
NLM	National Library of Medicine
NLP	Natural Language Processing
NPRM	Notice of Proposed Rulemaking
NUBC	National Uniform Billing Committee
NVSS	National Vital Statistics System
OIIG	Office of Informatics and Informatics Governance
PI	Promoting Interoperability
RSG	ICD-11 Revision Steering Group
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms (name no longer used, acronym considered a brand name)
TAG	ICD-11 Topic Advisory Group
UMLS	Unified Medical Language System
U.S.	United States
VHA	Veterans Health Administration
VUMC	Vanderbilt University Medical Center
WHA	World Health Assembly
WHO	World Health Organization
X12N/TG2	The Healthcare Task Group (TG2) of the Insurance Subcommittee (X12N) of the Accredited Standards Committee X12 (ASC X12) chartered by the American National Standards Institute