

Workgroup on Timely and Strategic Action to Inform ICD-11 Policy

ICD-11 Expert Roundtable Meeting

Meeting Summary

August 3, 2023

National Committee on Vital and Health Statistics (NCVHS)



NCVHS ICD-11 Workgroup Members in Attendance

Jamie Ferguson, Kaiser Permanente,* Workgroup Co-Chair

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Wu Xu, PhD, University of Utah*

Other NCVHS Members in Attendance

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Invited SMEs

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Linda Kloss, MA, Consultant and previous NCVHS member

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Public Attendees

In-Person

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Matthew Garnett, NCHS

Tara Rose, Optum

Vicki Rohrer, LabCorp

Cathy Sheppard, X12

L. Nell Smircina, American Acupuncture

Nancy Spector, American Medical Association (AMA)

Charles Stellar, Workgroup for Electronic Data Interchange (WEDI)

John Michael Villarama, American Osteopathic Association (AOA)

Virtual

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ICD-11 Workgroup Meeting Summary

[NOTE: all related meeting documents, including Powerpoint presentations are posted on the August 3, 2023 meeting page of the NCVHS website]

Action Items

- Invited experts and Workgroup members will bring the key themes identified during this meeting to confer with their respective organizations to obtain additional feedback for the Workgroup by email by September 15.
- Second, Workgroup members will send Ms. Hines their top three to five priority questions for the revised RFI by September 15.

Welcome and Introductions

Call to Order and Roll Call—Rebecca Hines, Executive Secretary/DFO

Ms. Hines invited NCVHS ICD-11 Workgroup members to introduce themselves and state any conflicts of interest pertaining to the meeting. Mr. Ferguson noted that his organization, Kaiser Permanente, submitted a response to the Request for Information (RFI) regarding the implementation of the International Classification of Diseases, 11th Edition (ICD-11). Thus, Mr. Ferguson recused himself from discussions relevant to the RFI response submitted by Kaiser Permanente. No other members stated any potential conflicts of interest related to the meeting's agenda.

NCVHS Priorities for ICD—Jamie Ferguson, Workgroup Co-Chair

ICD-11 was adopted by the World Health Organization (WHO) in 2019 and became effective on January 1, 2022. There are three components of ICD-11: (1) mortality reporting (e.g., cause of death); (2) morbidity coding (e.g., specific diagnoses) for health care and public health purposes; and (3) morbidity coding as a Health Insurance Portability and Accountability Act of 1996 (HIPAA)-mandated medical code set for health care billing and payment. As a member of WHO, the United States is treaty-bound to implement ICD-11 for mortality reporting, whereas usage of ICD-11 for morbidity reporting is not required for WHO members. NCVHS is currently evaluating the use of ICD-11 for morbidity coding purposes.

NCVHS's goal specific to ICD-11 is to offer recommendations to inform development of sound U.S. policy for adopting and implementing ICD-11. To achieve this goal, the NCVHS ICD-11 Workgroup has five objectives:

- 1. Develop advice and recommendations to HHS regarding adoption and implementation of ICD-11 for morbidity.
- 2. Avoid a repeat of the protracted and costly U.S. transition from ICD-9 to ICD-10 by identifying lessons learned from the ICD-10 planning process and transition, as well as how implementation of ICD-11 will differ from that of ICD-10.
- 3. Identify efforts (e.g., research, new stem codes, post-coordination strategies) to avoid the need for a full clinical modification (CM).
- 4. Conduct research to inform a relatively smooth transition from ICD-10-CM to ICD-11 for morbidity coding.
- 5. Identify key topics and messages for the U.S. health care industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

Previous NCVHS ICD-11 Activities

NCVHS held an ICD-11 expert roundtable meeting in August 2019 to discuss relevant issues and concerns regarding ICD-11 implementation. In November 2019, NCVHS recommended that HHS (1) evaluate impacts of different approaches for implementing ICD-11 for mortality and morbidity classification and (2) provide timely leadership on strategic outreach and communications to the health care industry regarding ICD-11 implementation. However, the COVID-19 pandemic hindered the evaluation of ICD-11. To restart this process, NCVHS sent a recommendation letter to the U.S. Department of Health and Human Services (HHS) in September 2021 with recommendations similar to those put forward in the 2019 letter.

NCVHS is now focusing on developing recommendations to inform development of sound U.S. policy for implementing ICD-11. On December 7, 2022, NCVHS established the ICD-11 Workgroup, which now includes 17 members, 8 of whom are NCVHS members and 9 who are external to the Committee. In spring 2023, NCVHS completed an environmental scan of published literature on ICD-11 to identify gaps in the knowledge base. Most of the ICD-11 studies identified in the environmental scan were conducted outside the United States; thus, more research is needed on how to best apply research findings and recommendations from other countries to the United States. On June 13, 2023, the ICD-11 Workgroup issued an RFI regarding ICD-11 implementation, and the Workgroup received 18 responses (posted on the NCVHS website.)

NCVHS ICD-11 Workgroup and Roundtable

Meeting Design and Anticipated Takeaways—Jamie Ferguson, Workgroup Co-Chair, and Valerie Watzlaf, Workgroup Member

This expert roundtable meeting has two primary and three secondary objectives:

Primary Objectives

- Identify ICD-11 adoption and implementation issues and research questions that are most critically important to study for informing ICD-11 policy recommendations.
- Obtain input from stakeholders to draft a collaborative plan, including a potential timeline and necessary resources, for ICD-11 implementation and establish an ongoing ICD-11 community of interest to inform recommendations.

Secondary Objectives

- Bring together diverse independent study efforts regarding ICD-11 to facilitate collaboration and coordination of current research efforts.
- Improve collaboration with the U.S. delegation to WHO on requesting any needed changes to ICD-11.

This meeting seeks to address how well ICD-11 can serve as a HIPAA code set and for other purposes. Actions to address this overall question include (1) assessing the costs and benefits of ICD-11 implementation; (2) identifying how many ICD-10-CM diagnostic classification codes commonly used in the United States can be translated to the ICD-11 foundation and a linearization or subset (either the existing ICD-11 Mortality and Morbidity Statistics (MMS) linearization or a new one) along with post-coordination; and (3) understanding how ICD-11 code set coverage for commonly used codes varies based on use cases (e.g., Medicare payment data, clinical research studies). This meeting will also focus on a potential ICD-11 research agenda, what is needed to confirm that the United States does not require a CM, and which benefits of ICD-11 for morbidity coding are most compelling for health care industry stakeholders.

Following this roundtable meeting, the ICD-11 Workgroup will develop a meeting summary and a report of Phase one Workgroup findings. This will be a detailed report with key takeaways and observations from the roundtable meeting, including key insights, knowledge gaps, relevant research areas, and next steps for ICD-11 implementation.

What We've Learned Thus Far—The Highlights

A Practical Strategy to Use ICD-11 for Morbidity Coding in the United States Without a Clinical Modification—Kin-Wah Fung, NLM, NIH

ICD-11 Overview

ICD-11 is now the official version of ICD coding that is supported by WHO. ICD-11 is used by at least 35 countries for a variety of coding purposes, including cause of death, cancer registries, primary care, and reimbursement. Compared to ICD-10, ICD-11 has 4,000 additional stem codes (i.e., a 40 percent increase). Unlike previous ICD versions, ICD-11 includes an underlying foundation knowledge base, which is a collection of ICD entities (e.g., diseases, disorders) and their relationships (e.g., one disease being a subtype of another disease). Specific classifications (i.e., linearizations) are derived from this foundation. ICD-11 also allows for post-coordination (i.e., cluster coding) and has more than 14,000 extension codes, which provides for potentially millions of extension code combinations.

In <u>NCVHS's ICD-11 2019 recommendation letter</u>, the prioritized research areas included whether ICD-11 can fully support morbidity classification without a U.S. CM (Clinical Modification). Avoiding a CM can provide multiple benefits, including the following:

- Avoids costs and delays associated with creation and maintenance of a CM.
- Enables earlier usage of updated ICD coding from WHO.
- Avoids potential differences in coding and incompatibilities between CM and ICD-11.
- Enables the United States to leverage ability of ICD-11 to align with other medical terminologies (e.g., Systemized Nomenclature of Medicine – Clinical Terms [SNOMED-CT]) and support automated coding.

Potential Approaches for Implementing ICD-11 for Morbidity Coding

Dr. Fung noted that the stem codes in the ICD-11 MMS subset are insufficient for coding all current ICD-10-CM codes. Options for expanding coverage without a CM include the following:

- Creation of U.S.-specific linearizations of ICD-11 by exposing additional foundation entities for coding, beyond the MMS subset used for mortality reporting.
- Apply post-coordination of codes, also known as clustering of codes, which may include the addition of U.S.-specific optional extension codes to existing ICD-11 foundation-derived codes.
- Addition of a small set of new stem codes not linked to the ICD-11 foundation, i.e., creating an "ICD-11-CM Lite" rather than a full CM.

Dr. Fung and his research team previously ranked these options based on the level of effort to develop and maintain these strategies, the ease of implementation by health care stakeholders, and the risk of each solution creating divergence (i.e., inconsistencies) between the U.S. coding approach to ICD-11 and the WHO ICD-11 core code set. Based on this ranking, Dr. Fung proposed a stepwise strategy for ICD-11 mapping with ICD-10-CM in which the United States would proceed in a stepwise approach until ICD-10-CM codes are covered (defined in this study as matching an ICD-11 stem code, foundation entity, and/or post-coordination cluster): use existing ICD-11 MMS codes (Step 1); use additional ICD-11 foundation entities (Step 2); apply post-coordination with existing ICD-11 extension codes (Step 3); apply post-

coordination with new U.S.-specific extension codes (Step 4); and create new U.S.-specific stem codes (Step 5).

Study Design

To examine the efficacy of the strategy described above and the coverage of ICD-10-CM by ICD-11, study researchers used two sampling strategies: (1) sampling a set of commonly used codes across all ICD-10-CM chapters (i.e., horizontal sampling) and (2) examining all codes within a single chapter (i.e., vertical sampling).

Horizontal Sample

For the horizontal sample, investigators identified the most commonly used ICD-10-CM codes from deidentified Medicare claims data. Because most Medicare beneficiaries are over 65 years old, Medicare data lack commonly used codes from three ICD-10-CM chapters: *Chapter 15: Pregnancy, childbirth and the puerperium; Chapter 16: Certain conditions originating in the perinatal period;* and *Chapter 17 Congenital malformations, deformations and chromosomal abnormalities*. To identify commonly used codes from these three chapters, researchers supplemented Medicare claims data with deidentified data from the University of Nebraska Medical Center. From these datasets, researchers identified 909 codes that cover at least 60 percent of usage in each ICD-10-CM chapter.

Vertical Sample

For the vertical sample, researchers chose ICD-10-CM codes *Chapter 11: Diseases of the digestive system*. This chapter was selected given its relatively even distribution of code usage within the chapter (rather than a few codes used significantly more than others), moderate coverage in existing ICD-11, and an ideal sample size of 817 codes for mapping analyses.

Mapping Approach

Researchers mapped the horizontal and vertical samples against ICD-11 using a search approach similar to the proposed strategy described earlier. For each ICD-10-CM code, researchers first searched for an exact match among ICD-11 stem codes. ICD-10-CM codes lacking an exact stem code match were then searched for matching ICD-11 foundation entity matches. ICD-10-CM codes still lacking coverage were then mapped for potential post-coordination using existing ICD-11 codes. Any codes that lacked coverage following all of these steps were then identified as needing a new ICD-11 stem code.

Existing ICD-11 stem codes and foundation entities were searched using the WHO Family of International Classifications (FIC) ICD-11 Maintenance Platform because this platform displays detailed information (e.g., inclusions, index terms) for ICD-11 foundation entities. Relevant foundation entities were identified based on their unique resource identifiers (URIs). Post-coordination of codes was not limited to options listed in the ICD-11 Maintenance Platform. In some cases, researchers used combinations of stem codes, extension codes, and foundation entities. Some new U.S.-specific extension codes were also proposed for some existing ICD-10-CM codes.

Recoding Results

For the horizontal sample (i.e., commonly used codes), 32 percent of sample codes are covered by existing ICD-11 stem codes, 6.4 percent by foundation entities, 53.1 percent by post-coordination using only existing extension codes, and 6.8 percent by post-coordination that includes a new extension code. Only 1.7 percent of the horizontal sample codes require a new ICD-11 stem code.

For the vertical sample (i.e., all codes from *Chapter 11: Diseases of the digestive system*), 38.7 percent of codes are covered by ICD-11 stem codes, 16.8 percent by foundation entities, 31.5 percent by post-coordination using only existing extension codes, and 7.4 percent by post-coordination that includes a new extension code. Only 5.6 percent of the vertical sample codes require a new stem code.

Among ICD-10-CM chapters, Chapter 19: Injury, poisoning and certain other consequences of external causes required the most post-coordination with other ICD-11 stem codes, extension codes, and foundation entities. Other ICD-10-CM chapters that benefit from post-coordination include Chapter 7: Diseases of the eye and adnexa, Chapter 12: Diseases of the skin and subcutaneous tissue, and Chapter 15: Pregnancy, childbirth, and the puerperium.

Among ICD-10-CM codes that require new extension codes, 28 percent of the new codes relate to anatomy/topography (e.g., fifth metatarsal bone); 14.4 percent relate to health devices, equipment, and supplies (e.g., urinary catheter); 9.6 percent to temporality (e.g., first trimester); 45.6 to severity scale values (e.g., loss of teeth, Class I); 1.6 percent to dimensions of injury (e.g., complex tear meniscus), and 0.8 percent to external causes (e.g., prolonged static or awkward postures).

Dr. Fung noted that post-coordination may reduce the number of new ICD-11 stem codes needed. For example, some ICD-10-CM codes use a similar pattern, such as *Z79.01 Long term* (current) use of anticoagulants, *Z79.4 Long term* (current) use of insulin, and *Z79.82 Long term* (current) use of aspirin. For these three ICD-10-CM codes, the closest existing ICD-11 stem code does not distinguish between current and previous usage of medicaments. For this case, Dr. Fung proposed a new ICD-11 stem code for "Long term (current) use of medicaments," which can then be post-coordinated with ICD-11 codes for specific medicaments (e.g., anticoagulants). Post-coordination with International Classification of Health Interventions (ICHI) can also reduce the number of new ICD-11 stem codes needed.

In 2.1 percent of codes sampled, one ICD-10-CM stem code can be mapped to more than one ICD-11 code (i.e., one-to-many matches). Similarly, in 3.4 percent of codes sample, multiple ICD-10-CM codes can be mapped to a single ICD-11 code (i.e., many-to-one matches). Many-to-one matches present a potential challenge for ensuring backward compatibility of ICD-11 coding with ICD-10-CM codes and will require further research.

Conclusions

Dr. Fung concluded his presentation by noting that the study's findings represent a best-case scenario for replacing ICD-10-CM with ICD-11; coverage by ICD-11 may differ among other ICD-10-CM chapters and codes that are used less frequently. Prerequisites for employing the strategy used in this study include the following:

- Post-coordination among ICD-11 stem codes, foundation entities, existing extension codes, and new extension codes.
- Compatibility for residual categories in ICD-10-CM
- Harmonized coding guidelines, including inclusions and exclusions to delineate when specific ICD-11 codes should be used.

Discussion

Dr. Newman noted that WHO did not seek to identically replicate ICD-10-CM when creating ICD-11, and in some cases, eliminated some ICD-10 codes based on updated research and clinical guidelines. Thus, this attendee asked whether the lack of coverage for an ICD-10-CM code automatically requires an approach to provide direct mapping with ICD-11 (e.g., new stem codes, post-coordination). This attendee also noted that the United States participated in the process of ICD-11 development and can coordinate with WHO to create new stem codes as needed. Dr. Fung replied that this study only examined backward compatibility with ICD-10-CM and is not meant to preclude other ICD-11 implementation approaches such as requesting new ICD-11 stem codes from WHO.

Ms. Kloss added that ICD-11 is designed to evolve as needed, which may include the creation of new stem and extension codes, to prevent the need for ICD-12. This continual evolution may reduce the

need for post-coordination or new U.S.-specific extension codes and help resolve other implementation challenges as they arise.

Mr. Linzer asked how the post-coordination approach will be used by physicians and other health care providers, who may lack expertise in detailed post-coordination and may need to apply regular codes in electronic health record (EHR) systems. Dr. Fung replied that some ICD-10-CM coding already includes post-coordination, and clinicians do not need to understand detailed post-coordination approaches to use these codes. Mr. Romano agreed and provided an example of ICD-10-CM using post-coordination to cluster an underlying code with a specific manifestation code. The challenge for implementing ICD-11 will be developing new relevant ICD-11 post-coordination approaches before these solutions are implemented among health care providers.

Workgroup Considerations

Themes from the 18 RFI Responses—Patrick Romano, Workgroup Member

On June 13, 2023, NCVHS issued an RFI regarding ICD-11 implementation, and the Workgroup received 18 responses. Mr. Romano highlighted themes from the responses to the 12 questions in the RFI.

Question: What would be the benefits of implementing ICD-11 for morbidity in your setting or organization?

Respondents highlighted multiple potential benefits, including the following:

- Enhanced alignment and integration with EHR systems and other relevant health care standards (e.g., SNOMED-CT).
- Increased ability to describe health conditions in greater detail through the combination of codes.
- Improved usage of medical coding for research collaborations.
- Improved reimbursement, risk adjusted quality measure reporting, and value-based care and payment models.
- Improved ability to capture relevant data regarding social determinants of health (SDOH).

Respondents also emphasized ICD-11's flexibility, including the increased emphasis on post-coordination, which will enable ICD-11 to evolve based on new medical discoveries and allow for more precise clinical coding.

Question: What information or research will your organization need in order to inform assessments of cost, benefits, implementation approaches, communications, and outreach regarding the transition to ICD-11?

Respondents noted a variety of needed research and information, including (1) how U.S.-specific coding needs will be met without a CM; (2) additional detail on how ICD-11 differs from ICD-10-CM; (3) comprehensive cost/benefit research on ICD-11 implementation, including impacts on payment, reimbursement, and new payment models; (4) detailed information on how ICD-11 will be implemented, including timeline and key milestones; (5) impacts of ICD-11 implementation on other code sets (e.g., SNOMED-CT); and (6) expected impacts and changes for EHR systems and other types of health care software.

Question: What considerations affect the impact of ICD-11 on clinical documentation and payment processes including risk adjustment, public health, population health, and research?

Respondents expressed concern that current ICD-11 MMS codes do not provide sufficient granularity and detail necessary for many purposes, including public health surveillance, administrative workflows,

health care quality monitoring, payment and reimbursement systems, and health care research. Respondents also highlighted the importance of considering how ICD-11 interacts with other components of health care and HIPAA infrastructure, such as EHR system and mandated X12 transactions.

Question: What unique U.S. coding and terminology considerations are essential?

Respondents noted the need for a standardized approach for coding data related to SDOH and other relevant social and economic factors, including level of social support, lack of internet access, interpersonal violence, and socioeconomic status. Respondents also noted that ICD-11 implementation should consider the requirements and implementation timelines for other mandated regulatory changes, including No Surprises Act, Trusted Exchange Framework and Common Agreement (TEFCA) requirements, and interoperability standards.

Question: How should HHS implement ICD-11 in the U.S. for morbidity coding?

Respondents emphasized the importance of implementing ICD-11 slowly and carefully following development of a clear transition plan and implementation roadmap. Respondents recommended applying lessons from the implementation of ICD-10-CM but differed on how these lessons should be applied: some respondents advocated for a transition approach in which, at a set date, all HIPAA entities must stop using ICD-10-CM and start using ICD-11, whereas others advocated for a transition period during which both ICD-11 and ICD-10-CM would be used.

Question: What entity should be responsible for coordinating overall national implementation of ICD—11 for morbidity coding? What entity should be responsible for coordinating U.S. requests for updates or changes to ICD-11? How should this process be managed?

Respondents disagreed on who should manage ICD-11 implementation and coordination with WHO for changes and updates. Some respondents advocated having either the National Center for Health Statistics (NCHS) or the Centers for Medicare & Medicaid Services (CMS) lead ICD-11 implementation and management efforts with input from other agencies (e.g., National Library of Medicine [NLM], Office of National Coordinator for Health Information Technology [ONC]). Some respondents recommended expanding the role of NLM Office of Health Data Standards and Terminologies (HDST) to manage ICD-11 implementation and maintenance based on HDST's role as the National Release Center for SNOMED-CT. Other respondents recommended creating an ICD-11 national steering committee composed of representatives of key stakeholder groups, including government agencies, professional associations (e.g., American Medical Association [AMA]), health care organizations, and academia.

Question: What resources, tools, or support will your organization need for implementation? What kinds of technical resources, guidance, or tools should the U.S. Federal Government make available? Respondents emphasized the importance of timely release of ICD-11 policy guidance from federal agencies, including links to public and private resources for ICD-11 implementation. Respondents recommended that federal agencies collaborate with health care industry organizations to disseminate guidance and information regarding ICD-11, including mapping of codes between ICD-10-CM and ICD-11. Federal agencies should also consider the unique implementation needs and concerns of small physician practices, rural health care providers, and Medicaid plans.

Question: What other operational impacts of ICD-11 adoption and implementation should HHS consider?

Respondents stressed the wide-scale upheaval and costs involved with implementing ICD-11, including how ICD-11 implementation may overlap with other legislative and regulatory requirements (e.g., interoperability requirements). Many health care providers have limited resources for ICD-11 implementation, including updating all relevant systems (e.g., EHR systems), staff training, and changing administrative workflows. Thus, HHS should consider the impacts of ICD-11 implementation and provide

support to ease this transition. Respondents also stressed the need for frequent and continued testing of implementation approaches as well as dissemination of results from this testing.

Report-Outs from July 27 Pre-Work Breakout Groups—Rebecca Hines, Executive Secretary/DFO

These report-outs were prepared by ICD-11 Workgroup members and invited experts who met on July 27, 2023, to conduct preliminary discussions and brainstorming prior to this Expert Roundtable Meeting. Each breakout group from this July 27 meeting discussed key takeaways from their discussions (summarized below and PowerPoints available on the August 3, 2023 meeting page of the NCVHS website).

Group 1

Group 1 noted the importance of additional research on benefits of ICD-11 for specific use cases (e.g., coding SDOH, population health), as well as downstream impacts of ICD-11 implementation on public health surveillance, payment/reimbursement, and quality monitoring. Group 1 recommended a pilot implementation in a real-world environment (e.g., one health care system) to identify potential challenges and benefits of ICD-11 implementation. Group 1 also encouraged NCVHS to engage EHR and other health software providers for additional inputs on considerations relevant to ICD-11.

Group 2

Group 2 noted the importance of additional research on topics related to ICD-implementation strategies, including the degree of overlap between ICD-10-CM and ICD-11, expected costs and time required for different stakeholders (e.g., clinicians, payers) to implement ICD-11, and benefits and drawbacks of creating U.S.-specific linearizations. Group 2 recommended a federally funded pilot project to test maintenance and governance of ICD-11 within the United States, including interactions with WHO for additional or modified stem codes.

Group 3

Group 3 emphasized the need for stronger evidence that the United States does not require a CM for ICD-11. The group highlighted the importance of evaluating the impacts of not creating a CM for ICD-11, including examining code coverage between ICD-10-CM and ICD-11. Additional detail is also needed on ICD-11 governance, including how the United States would interact with WHO for code additions and modifications, the frequency of updates to ICD-11, and options for incorporating U.S.-specific clinical detail. Group 3 recommended additional representation on the NCVHS ICD-11 Workgroup, including practicing clinicians, EHR vendors, standards development organizations (e.g., X12), medical coding and billing companies, and representatives from Indian Health Service (IHS).

Group 4

Group 4 noted that many clinicians were vocal opponents of adopting ICD-10-CM because of the burden and costs associated with conversion. Thus, gaining support among clinicians will likely require mechanisms to reduce implementation costs for clinicians (e.g., federal financial support for implementation). Group 4 suggested highlighting the role of ICD-11 for modernizing health care and health information applications, including provider workflows. Group 4 also recommended conducting pilot (i.e., "sandbox") demonstrations of ICD-11 implementation for different segments of the health care industry (e.g., clinicians, EHR vendors) to demonstrate clear benefits to those specific segments.

Group 5

Group 5 noted that many of the benefits of ICD-11 that have been highlighted so far are more relevant to many secondary users of coding data (e.g., health care quality auditors, researchers) rather than stakeholders that are required to directly input ICD-11 codes (e.g., health care providers). Thus, health

care providers and other stakeholders that bear the cost and burden of implementation may be more resistant to ICD-11 implementation than other stakeholders. For example, large system vendors (e.g., large EHR vendors, clearinghouses) are likely to resist ICD-11 implementation because of the cost and effort required to restructure their systems and workflows for ICD-11. Similarly, payers may resist implementation if they do not see clear evidence of benefits for payment models (e.g., improved ability to detect fraud or abuse).

Group 5 recommended that NCVHS issue another RFI with a 60- or 90-day comment period and request information about benefits more relevant to specific stakeholder groups (e.g., payers). For example, NCVHS can ask whether ICD-11 has benefits relevant to risk management, which may be relevant to payers.

Group 6

Group 6 highlighted relevant research questions related to ICD-11 including additional research on potential gaps between ICD-10-CM and ICD-11 and prospective studies on post-coordination strategies. This research will be crucial for demonstrating feasibility of ICD-11 and post-coordination approaches, including changes to administrative and coding workflows.

Additional research is needed on the approach to post-coordination, including determining what U.S.-specific extension codes are needed, as well as feasibility testing of post-coordination approaches. ICD-11 should also be tested for its ability to accommodate longer code clusters and free-text extensions.

When asked about stakeholders likely to resist ICD-11 implementation, Group 6 noted that physicians and other health care providers are likely to resist unless ICD-11 offers additional quality and clarity compared to ICD-10-CM. Physicians, patients, and other stakeholders may also resist ICD-11 implementation out of concerns that new coding approaches may lead to additional denials of reimbursement claims and prior authorization requests. Automated coding may reduce this concern by introducing more consistency in ICD-11 coding and reimbursement processes.

Group 7

Group 7 stressed the importance of determining the return on investment (ROI) of adopting ICD-11 for morbidity reporting, including what broader health care industry needs are met by ICD-11. To determine the need for an ICD-11 CM, Group 7 recommended examining ICD-10-CM usage, including how much ICD-10-CM differs from ICD-10 and how many of those different codes are frequently used, to determine whether an ICD-11 CM is needed.

Group 7 also noted that some health care stakeholders are likely to resist ICD-11 implementation, including many physicians, hospitals, EHR vendors, payers (e.g., insurance companies), and medical coders. Group 7 recommended highlighting benefits relevant to these specific stakeholders, such as the ability of ICD-11 to improve reimbursement processes.

Group 8

Group 8 noted that some health care providers are enthusiastic about ICD-11 implementation, including the ability of WHO to continually adapt and update ICD-11 based on new discoveries and clinical practices. The ability of ICD-11 to be modified and updated will also reduce the likelihood of the need for future versions of ICD coding (e.g., ICD-12). Group 8 members suggested exploring the potential of artificial intelligence (AI) to assist with implementation and reduce the implementation burden on health care providers. Group 8 concluded their remarks by suggesting that federal agencies should provide funding to assist with ICD-11 implementation to health care industry stakeholders with limited resources.

Breakout Groups—Morning Session

Workgroup members joined their assigned breakout sessions to discuss two questions: (1) What are the most important research questions remaining? and (2) What is needed to accomplish a national ICD-11 research agenda in a timely manner? Following these discussions, breakout groups then shared the following summaries with other meeting attendees.

Report-Outs to Full Group

Group A

Group A advocated for expanding the NLM study presented by Dr. Fung to complete mapping of all codes between ICD-10-CM and ICD-11. Mapping coverage between ICD-10-CM and ICD-11 should also account for which ICD-10-CM codes are frequently used and are U.S.-specific, which can reveal benefits and drawbacks of implementing ICD-11. Additional research is also needed on how AI systems can be leveraged to assist with ICD-11 implementation. To ensure that research is conducted in a timely manner, Group A recommends an additional RFI with a longer response time to capture additional responses from different health care stakeholders. Group A also emphasized the importance of dedicated ICD-11 research funding, including for research by hospitals, payers, and other health care stakeholders.

Group B

Group B emphasized the importance of additional information regarding ICD-11 governance, including whether implementation and usage of ICD-11 is overseen by WHO or a U.S. federal agency (e.g., HHS). Additional research is needed to assess whether the United States can use SNOMED-CT rather than ICD-11 for morbidity coding, including whether SNOMED-CT can be used to create datasets in a similar format as ICD-11. Additional research is also needed on how post-coordination will be applied, particularly when many health care systems (e.g., EHRs, billing systems) require pre-coordinated codes. Group B noted the importance of identifying how ICD-11 implementation will be funded and coordinated. Finally, ICD-11 implementation will likely require legislation to mandate ICD-11 adoption because voluntary adoption is unlikely to achieve sufficient compliance.

Group C

Group C noted the importance of additional research on the coverage of ICD-11 codes for U.S.-specific coding needs, including rare diseases and specific populations (e.g., racial and ethnic minorities). Research should also be conducted to determine ideal post-coordination combinations of stem codes, foundation entities, and extension codes to meet U.S.-specific coding needs. Based on Dr. Fung's report post-coordination will certainly be required and this will complicate ICD-11 implementation. More research is needed on how ICD-11 implementation will impact other clinical documentation standards (e.g., SNOMED-CT, RxNorm). Accomplishing this research will require additional research funding as well as centralized coordination of research activities.

Group D

Similar to Group A, Group D advocated for expanding the NLM study to conduct a complete mapping between ICD-10-CM and ICD-11, including how ICD-11 maps to commonly used EHR fields. This expanded study should also incorporate additional data sources such as all-payer claims databases (APCDs) and assess whether ICD-11 provides greater clinical accuracy than ICD-10-CM. Group D encouraged CMS to identify ICD-11 research priorities based on its strategic roadmap. Group D also noted the importance of a central U.S. coordinating entity or authority to manage implementation of ICD-11. This entity and authority should oversee high-level messaging and education regarding ICD-11 and have statutory authority to mandate compliance with ICD-11.

Group E

Group E highlighted multiple areas that require needed research. More research and guidance are needed on post-coordination, including how post-coordination will be used to meet U.S.-specific coding needs and establish clear guidance for using extension codes. Additional research is needed on ideal approaches to ICD-11 implementation (e.g., phased versus simultaneous implementation) as well as technology needs for implementation. More information is needed on the governance of ICD-11, particularly how the United States will coordinate with WHO for maintaining and updating ICD-11 codes and related infrastructure. Group E emphasized the importance of prioritizing ICD-11 research and a complete roadmap of ICD-11 implementation.

Group F

Group F suggested examining which ICD-11 research questions can be answered using retrospective data rather than requiring live data and pilots of ICD-11 workflows and coding systems. Relevant research needs identified by Group F include (1) the ability of ICD-11 to capture SDOH data; (2) the educational resources needed for medical coders; and (3) the level of funding needed to ensure that ICD-11 implementation represents all health care stakeholders. Group F also recommended careful and inclusive development of use cases for guiding ICD-11 research and implementation efforts.

Group F listed multiple factors required to accomplish ICD-11 research in a timely manner, including (1) significant (up to \$50 million) in research funding; (2) request for proposals (RFP) for multidisciplinary ICD-11 research that involves key health care stakeholders; (3) RFP for development of ICD-11 education and training materials; (4) identification of ICD-11 pilot system participants and target dates for pilot testing; and (5) shared knowledge base for research data.

Group G

Group G discussed multiple factors necessary to accomplish a national ICD-11 research agenda. First, more information is needed on ICD-11 governance, including what U.S. entity (e.g., federal agency, public-private partnership [PPP]) will coordinate with WHO and oversee post-coordination approaches. Additional information is needed on post-coordination, including whether some use cases require precoordination. Group G suggested a complete mapping of code coverage between ICD-11, ICD-10-CM, and SNOMED-CT. Group G highlighted the need for a dedicated PPP or other organizing body (e.g., office within federal agency) within the United States to oversee ICD-11 implementation.

Discussion

Dr. Hodgkins advocated for the establishment of a Public Private Partnership (PPP) to oversee and manage U.S. implementation of ICD-11 and to ensure interoperability with other regulations and mandated code sets (e.g., SNOMED-CT). Ms. Kloss noted that NCVHS previously considered potential ICD-11 governance approaches in 2019, including the establishment of a PPP to coordinate coding terminology, implementation, and interactions with WHO. She recognized that governance remains a significant unknown for ICD-11 implementation.

Dr. Mays noted that Group B highlighted the need for legislation to mandate ICD-11 adoption and asked how this mandate would be applied. Ms. Stanfill replied that ICD-11 would most likely be mandated as a HIPAA code set rather than a specific transaction level (e.g., payment and reimbursement) to avoid inconsistent usage across federal stakeholders.

Continuity and Sustainability: Formation of a Sustainable Community of Interest—Susan Fenton, Workgroup Member

Dr. Fenton identified four questions regarding the ICD-11 implementation and sustainability efforts in the United States that the afternoon breakout groups are encouraged to discuss:

- 1. Who is best positioned to lead the overall project or specific parts of the project?
- 2. Are there organizations that *must* be included for the longitudinal success of ICD-11 implementation?
- 3. What is needed in the United States that is fundamentally different from other countries?
- 4. What are the essential next steps in priority order?

Ms. Hines reminded breakout groups that NCVHS operates strictly in an advisory capacity to HHS regarding the adoption of ICD-11 as a HIPAA code set; the Committee does not engage in implementation or operational endeavors.

Breakout Group Report Outs—Afternoon Session

Workgroup members joined their assigned breakout sessions to discuss the questions mentioned above and then shared key recommendations and findings (summarized below) with the full Workgroup.

Group A

Group A proposed that a PPP, similar to Cooperating Parties, lead the ICD-11 implementation and sustainability efforts. However, specific parts of these efforts may be led by other agencies, as needed. ICD-11 implementation and sustainability efforts should engage key stakeholders, including NCHS, CMS, AHIMA, AMA, IHS, American Heart Association (AHA), United States Department of Veterans Affairs (VA), Agency for Healthcare Research and Quality (AHRQ), American Chemical Society, American Academy of Family Physicians, Advisory Committee on Immunization Practices, American College of Obstetricians and Gynecologists, health information technology and EHR vendors, and clinical data scientist organizations. Ensuring longitudinal success requires the continued engagement of the same groups presently involved while considering the inclusion of additional groups as the implementation process progresses.

Group A advocated for the creation of a U.S.-specific CM that would include different information (e.g., SDOH) not captured in ICD-11 MMS. Additionally, Group A noted that the ICD-11 clinical diagnosis definitions could put clinicians at risk of misdiagnosis; thus, implementation efforts should integrate the concept of "highest level of clinical certainty" as a determinant of diagnosis.

Group B

Group B proposed that NLM may be ideally positioned to assume a leadership role for the ICD-11 implementation and sustainability efforts because of its impartial agenda, compared to other government or external entities, and proficiency in a range of terminologies. In the future, a new entity can eventually be created to serve as a neutral third party that oversees data management and evaluates key stakeholder agendas, ensuring that all efforts are aligned with the broader objectives of the effort.

Group B suggested that all federal agencies involved in health care should be included in the ICD-11 implementation and sustainability efforts, including a wide range of stakeholders, such as health plans, academic institutions, health information management systems, and EHR vendors. Furthermore, communication with other vendors, such as AI partners and prominent technology companies (e.g.,

Google), is integral to the development and dissemination of products related to ICD-11 implementation.

Group B highlighted the need for a more extensive RFI process to obtain the necessary information to support NCVHS' ICD-11 recommendations to HHS.

Group C

Group C proposed that the coordination and sustainability of the ICD-11 efforts should be facilitated at the federal level. This effort should be led by HHS, with ONC, CMS, CDC, and AHRQ as necessary stakeholders.

Group C emphasized the need for continued engagement from Workgroup member organizations to produce a comprehensive recommendations report for the NCVHS Full Committee, which will outline a proposed schedule of regular meetings and work sessions. In addition, securing sustained funding and resource allocation is key to ensuring the longitudinal success of the ICD-11 efforts. The ICD-11 implementation and sustainability efforts should also focus on expanding the range of participating stakeholders to ensure diverse representation and contribution to the effort's success.

Group C suggested enhancing the current NCVHS ICD-11 Workgroup website by exploring collaboration tools for continuous communication between meetings.

The main priority for the ICD-11 implementation and sustainability efforts is to define the scope of ICD-11 implementation, which involves delineating use case scenarios, including considering whether the ICD-11 implementation scope extends beyond HIPAA requirements to address broader considerations. For example, the effort should consider clinical documentation use cases, especially in behavioral and mental health domains, social and community health, and the potential impact of ICD-11 on quality measures and reporting.

Group D

Group D noted that the lead entity on the ICD-11 implementation and sustainability efforts will have several roles, including building relationships, coordinating efforts, developing the effort, and managing funding opportunities. This lead entity must be inclusive, involving both government and nongovernment stakeholders. Group D agreed that the HHS Secretary should appoint an individual or a group to make initial operational decisions. Organizations that could oversee ICD-11 implementation and sustainability efforts include the National Academies of Engineering, Sciences, and Medicine.

For continued success, key stakeholders such as WHO, federal agencies, clinical and coding societies, and standards organizations should be involved in ICD-11 implementation and sustainability efforts.

A distinct feature in the United States is the complexity and fragmented nature of health care delivery, funding, and reimbursement systems such as diagnosis-related groups and value-based care. Other unique U.S. challenges include the need to address SDOH, sexual and gender identity, language differences, and cultural diversity.

The next steps in this effort include the need to appoint a lead entity, outline legislation, secure funding, and start building necessary structures.

Group E

Group E proposed that HHS would be suitable for funding the initial coordination of the ICD-11 implementation and sustainability effort, potentially facilitated through the NCVHS Committee. However, the Committee would need to be staffed with a coordinator and expanded with task forces to (1) identify ICD-11 implementation gaps; (2) devise a governance mechanism to ensure ICD-11

sustainability; and (3) monitor clinical efficacy efforts. Group E also deliberated on the political and funding challenges associated with long-term project coordination, suggesting the potential creation of a new PPP to oversee sustained implementation. Additionally, Group E highlighted the need for the coordination of terminologies and classifications among agencies that oversee ICD-11 implementation and sustainability (e.g., HHS, NLM, CMS, AMA, and SNOMED), which is integral for ensuring sustained success.

The ICD-11 implementation and sustainability efforts should engage key stakeholders such as providers, payers, policy makers, technology vendors, and public health representatives.

The initial steps of ICD-11 implementation and sustainability efforts in the United States involve a comprehensive analysis of the implementation progress thus far, which would require collaboration with WHO. Existing studies, particularly those pertaining to Canada, could serve as valuable references for this analysis and provide insights into the specific needs of the United States.

Group E defined a priority order for next steps to ensure a systematic progression toward the project's objectives:

- Funding a NCVHS coordinator and staff to facilitate the expanded Committee's efforts.
- Designing a governance mechanism for the project.
- Identifying implementation gaps and developing a roadmap to guide the project's progress.
- Creating a technology-focused component, involving the identification and resolution of associated challenges and development of a toolkit for effective implementation.
- Deploying pilot studies targeting all users, accompanied by phased and audience-based educational initiatives.

Group F

Group F proposed several potential candidates to lead the ICD-11 implementation and sustainability efforts, including public health agencies (e.g., CMS and CDC), research institutes (e.g., National Institutes of Health), specialty societies (e.g., AMA), VA and active military, disability rights organizations, EHR vendors (e.g., Epic and Cerner), health research organizations (e.g., Association of American Medical Colleges), software developers and terminology maintainers (e.g., 3M), and Congress. Collaboration and engagement from these various entities will be instrumental in achieving the desired goals and ensuring the success of the ICD-11 implementation and sustainability efforts.

Regulation of ICD-11 will require a governmental agency (e.g., CDC, CMS, or ONC) to reflect on prior ICD-10 gaps. This process will involve examining previous source documents to inform ICD-11 decisions. Additionally, creating a PPP will expedite progress and broaden participation, thus enhancing inclusiveness.

Establishing the necessary governance structure, new roles, and funding, alongside coordination with WHO, will help achieve the effort's objectives. Furthermore, a comprehensive approach must be adopted for inclusive partnership and participation across all sectors, including public, private, current ICD-10 partners, and state and local entities.

Group G

Group G proposed that a PPP, involving both federal and non-federal representation, could lead the ICD-11 implementation and sustainability effort, which is separate from Rulemaking. Group G suggested the possibility of forming a consortium of agencies, including health information networks and representation from tribal and territorial groups, under the lead agency.

The strategy for identifying crucial organizations and agencies for the ICD-11 project revolves around evaluating functions such as code set updates and maintenance, understanding the potential impact of restructuring on involved parties, and defining the specific roles of cooperating parties (e.g., AHA, AMA, CDC, and CMS).

Group G emphasized the need to address financial aspects and conduct a full assessment of information needs to inform proactive educational and communication strategies. These efforts will be crucial to convey the values and opportunities aligned with the ICD-11 transition. Lobbyists, trade associations such as health insurance trade associations will need to be involved in order to communicate ICD-11 benefits and advocate for sustainable implementation funding. How do we get these groups engaged and involved in supporting implementation efforts?

A distinct feature in the United States is the absence of a centralized health care governing body because of the complexity of the health care system and the involvement of numerous stakeholders.

Moving forward, the focus of the effort should shift to identifying an entity to fund and coordinate the research efforts. The White House assumes a crucial role in designating the lead federal agency to determine the need for CM, complete the mapping process, and establish a clear timeline and roadmap for ICD-11 implementation and sustainability.

Discussion

Dr. Andrew Wiesenthal suggested that ICD-11 implementation with increased automation could alleviate burdens on the U.S. health care delivery system in terms of funding, billing, and data requirements, which could reduce the complexity of the U.S. health care system.

Public Comment—Rebecca Hines, Executive Secretary/DFO

L. Nell Smircina, American Acupuncture

Ms. Nell Smircina emphasized the significant potential impact of ICD-11 on her acupuncture profession. ICD-11 presents an opportunity to substantially improve patient access to acupuncture services, which could dispel misconceptions and validate acupuncture as a legitimate and valuable medical practice. Notably, more than 100 VA facilities offer acupuncture, illustrating its demand. ICD-11 could also bridge communication gaps and enhance education for insurance providers, various health care professionals, and patients, resulting in enhanced benefits for all involved.

June Bronnert, Intelligent Medical Objects (IMO)

Ms. June Bronnert, Vice President, Global Clinical Services at IMO, commended the proactive role that NCVHS has undertaken in initiating ICD-11 discussions and the substantial efforts invested thus far. These initiatives have highlighted the complexity of ICD-11 and revealed the diverse ways in which data are utilized across the health care landscape, which will significantly contribute to the advancement of ICD-11 implementation and sustainability.

Katherine Isbell, Lexico

Ms. Katherine Isbell emphasized that the medical community should assume a significant leadership role in the ICD-11 implementation, because practitioners possess an unparalleled understanding of medicine. She also noted that a coding language that matches clinical documentation would be immensely beneficial for ICD-11 implementation, which would not only enhance clarity but also eliminate ambiguity and thus streamline the process and improve overall communication.

Recap of Insights and Next Steps

Morning Session Recap—Jamie Ferguson

The primary purpose of NCVHS's efforts is to obtain a wide range of perspectives to inform policy recommendations concerning the adoption and implementation of ICD-11. A recurring theme in morning session discussions was the need for effective post-coordination, which helps organize core diagnostic concepts into predefined code sets to minimize disruptions for clinicians, coders, and systems. The importance of substantiating the benefits of ICD-11 and identifying the distribution of these benefits across the health care ecosystem also emerged as a key knowledge gap. Additionally, coordinated governance involving both governmental and private entities was consistently highlighted as essential to ICD-11 implementation. Discussions also emphasized the need to accommodate a diverse array of use cases beyond those of ICD-10-CM. Moreover, the Workgroup raised questions about the significance of ICD-11 compared to its predecessor, warranting clarification on the new or additional information within ICD-11 that enables valuable applications. The discussions also touched upon regulatory measures and potential incentives to facilitate broad national adoption, all of which revolve around the interplay of benefits, costs, and funding considerations.

Recap of Insights from the Day—Patrick Romano

Three prominent themes and associated actions (summarized below) could inform a national research agenda for ICD-11 adoption in the upcoming years.

- Content and Mapping, which involves continued/expanded comparisons between ICD-11 and ICD-10-CM, as well as SNOMED CT, probing gaps and weaknesses, particularly distinguishing true gaps from pseudo gaps, exploring/testing alternative linearization approaches and associated coding rules, and addressing governance issues related to linearization alternatives.
- Tools (especially post-coordination), which includes testing and implementing user interface for code assignment, testing and implementing AI using structured fields/natural language processing (NLP) using free text, addressing heterogeneous needs (e.g., rural hospitals, solo practices), and evaluating usability, accuracy, and training needs.
- Value and Impact, which involves effective strategies to conduct demonstrations and pilots (retrospective and prospective), estimate costs and benefits for different stakeholders, determine ways to mitigate costs and the need for financial incentives, and assess workforce implications (educational resources, productivity, and burnout).

Next Steps

Mr. Ferguson asked each breakout group facilitator to identify a single priority next step that NCVHS should focus on when developing advice and recommendations to HHS regarding ICD-11 implementation:

- Group A: design an ICD-11 governance mechanism.
- Group B: develop an extensive RFI process.
- Group C: continue and expand stakeholder collaboration.
- Group D: designate a new entity to oversee the implementation process.
- Group E: expand NCVHS with task forces and fund additional staff support.
- Group F: designate an entity to lead implementation efforts.
- Group G: designate a lead federal agency and establish a timeline.

Discussion

Research Incentives

Dr. Mays emphasized that ICD-11 discussions should include approaches to fund and incentivize the collection of research data within the ICD-11 framework across different agencies. Mr. Ferguson stated that the Workgroup's discussions have not addressed this topic but acknowledged the need to incentivize social, population health, equity, and policy research. These facets are crucial to the timely and rational development of U.S. policy for ICD-11 implementation.

ICD-11 Workgroup Message

Dr. Tcheng stated that the NCVHS Workgroup should establish a clear and concise message about the purpose of ICD-11, especially considering that the primary audience is clinicians and hospitals. To effectively convey its message, the Workgroup must emphasize that ICD-11 serves as an upgraded classification system for medical diagnoses, one that will ultimately replace the existing system. Focusing on this fundamental purpose of ICD-11 will be essential in avoiding any confusion or resistance. Additionally, while designating a new entity has been heavily discussed, the Workgroup should consider including certain entities that the medical community are familiar with (e.g., NCVHS, CDC) to facilitate smooth collaborations and engagements, as well as promote greater support and understanding of ICD-11 implementation.

Sharing ICD-11 Insights with Stakeholders

Dr. Mays suggested asking stakeholder representatives to share the presentation slides from this meeting to allow them to delve deeper into the insights and outcomes presented and encourage dialogue within their respective organizations. The feedback and comments received from these organizations will serve as a valuable input to NCVHS' ongoing efforts and will be considered by the Workgroup as it develops its report to the full NCVHS Committee. Mr. Ferguson confirmed that all the materials, including the slides from this meeting's sessions and the report outs, will be made available on the meeting webpage. Mr. Ferguson asked members to share the feedback from their respective organizations with the Workgroup by September 15.

Federal vs. Public-Private Governance

Dr. Swanson highlighted the need for a federal governance structure rather than a PPP to guide ICD-11 implementation efforts. He explained that a government agency will be trusted to prioritize the integrity of the decision-making process, with the ultimate goal of improving health care.

Refined RFI

Dr. Romano proposed a more focused and targeted approach for the next RFI to engage additional stakeholders and gather input from more diverse perspectives. Earlier discussions prior to this meeting suggested a 90-day comment period to gather meaningful input through a well-structured RFI process, which is feasible. Ms. Hines asked the Workgroup members to send her their top three to five priority questions for the revised RFI by September 15; these questions will help streamline the discussion in future meetings and gather specific and valuable input from stakeholders.

Adjourn

Mr. Ferguson thanked attendees and stated that the Workgroup will review the discussions, insights, and observations presented during this meeting, with the ultimate goal of developing preliminary recommendations to present to the full NCVHS Committee.

I hereby certify that, to the best of my	knowledge, the foregoing summary of
minutes is accurate and complete.	
/s/	04-October-2023

Jamie Ferguson, NCVHS ICD-11 Workgroup Chair

Date