



National Committee on Vital and Health Statistics (NCVHS)
Project Proposal: Timely and Strategic Action
to Inform ICD-11 Policy
(12/15/2022)

Introduction

The NCVHS Subcommittee on Standards proposes a project to advance the national ICD-11 discussion, in follow up to its 2019 [ICD-11 expert roundtable findings¹](#) and the Committee’s 2019 and 2021 [recommendations to HHS²](#).

The World Health Organization (WHO) initially released ICD-11 in 2018, a scientifically updated, state of the art technology adopted by WHO to become the de facto global standard for health data disease classification. The Committee recognized that much is unknown about the implications for the United States around transitioning to this next version. The purpose of its recommendations to HHS was to outline an organized set of essential research questions, the answers to which will inform timely and rational development of U.S. policy for ICD-11 implementation.

NCVHS finds that action is needed now to avoid repeating for ICD-11 the many costs and resource burdens on the U.S. health care system that characterized its very late implementation of ICD-10. One important goal in the adoption of ICD-11 is to avoid using multiple versions. Another goal is to avoid, if possible, a U.S.-specific clinical modification as occurred for ICD-10. In its role as advisor to HHS, NCVHS intends for this project to support HHS in leading the U.S. in preparation for policy and implementation decisions regarding ICD-11.

Since the Committee’s 2021 recommendations were submitted, we have become aware of multiple academic and industry organizations in the U.S. that have independently initiated studies to better understand ICD-11. These efforts are not centrally coordinated, and the Committee is unable to ascertain the degree to which this work addresses ICD-11 research that the Committee identified as essential. Of note, these efforts are beginning to identify changes warranting submission of requests to WHO for modifications to ICD-11. WHO is requesting that countries submit requests for changes to WHO, which would update ICD-11 itself in order to avoid development of multiple national clinical modifications as happened with the US, Australia, Canada and other countries with the ICD-10 version.

National coordinated leadership is needed now to bring together and augment the current independent study efforts and to work with the U.S. delegation to WHO on requesting any needed changes to ICD-11 well in advance of the U.S. implementation. This project will form an NCVHS expert ICD-11 Workgroup that will collaborate with HHS, CMS OBRHI, NCHS, NIH/NLM, and other relevant federal agencies, as well as non-federal stakeholders as described in the “Membership” section below. The new Workgroup will perform an environmental scan on the ICD-11 research already conducted, develop goals and an agenda for an expert roundtable meeting, and launch a public/private collaborative to conduct the research identified during the expert roundtable meeting. The results of this research will facilitate development of sound U.S. policy for the transition to and implementation of ICD-11.

¹ NCVHS ICD-11 Expert Roundtable Meeting August 6-7, 2019: <https://ncvhs.hhs.gov/meetings/subcommittee-on-standards-icd-11-evaluation-expert-roundtable-meeting/>

² NCVHS Recommendations for Immediate Action on ICD-11 (Sept 10 2021): <https://ncvhs.hhs.gov/wp-content/uploads/2021/09/NCVHS-ICD-11-recommendations-for-HHS-Sept-10-2021-Final-508.pdf>

The scope of this proposed project would be limited to the Committee’s questions regarding U.S. implementation and use of ICD-11 for morbidity coding. This project would not address ICD-11 for mortality or changes to, nor the use of, the ICD-10 Procedure Coding System (ICD-10-PCS) which is a U.S. product not part of the International Classification of Diseases.

I. Project Proposal

1) Form an NCVHS ICD-11 Workgroup, in collaboration with HHS including CMS/OBRHI

Purpose. The primary purpose of the Workgroup is to provide NCVHS the necessary structure to support development of advice and/or recommendations to the Secretary regarding adoption of ICD-11 as a HIPAA code set. To accomplish this, the Workgroup intends to coordinate, facilitate, and/or review expert studies, research, and/or findings to answer the [Committee’s questions](#) about ICD-11.

Membership. In addition to Committee members with relevant expertise, the Workgroup will achieve balanced representation with nationally recognized subject matter expert perspectives with inclusion of members from: payers, providers, clearinghouses, public health jurisdictions, researchers, and population health, quality, equity, and/or tribal health programs. At the same time the size of the Workgroup needs to not be so large as to be unwieldy. In addition, selected subject matter experts (SMEs) from HHS Operating and Staff Divisions (OpDivs/StaffDivs) will be invited to attend Workgroup meetings to provide expertise and relevant information to inform the Workgroup’s activities.

Initial Activities. The Workgroup will conduct a roundtable meeting in the first half of 2023 to draw upon national expertise that will identify approaches to ensuring that essential research is conducted. The Workgroup also plans to conduct an environmental scan to inform its activities. A secondary project will be to begin to draft an initial outreach and communication plan for U.S. implementation of ICD-11.

Preparation activities of the Workgroup for the Spring 2023 expert roundtable meeting will include:

- a) Conduct an informal environmental scan on the research, outreach, and communication that has already been performed on ICD-11, potentially utilizing graduate students from identified university programs to assist in this process.
- b) Identify key stakeholders whose participation would lead to meaningful national dialogue, to invite to the Spring 2023 expert roundtable meeting.
- c) Identify specific deliverables, goals, and agenda for the roundtable meeting, such as to:
 - Identify opportunities and models for a formal “Collaborative” – i.e., a public-private partnership that would determine how to approach the priority areas of research and communication that need studying in the near-term to inform U.S. policy and decision-making for ICD-11.
 - Assess available evidence and make initial observations regarding whether a clinical modification to ICD-11 is necessary, or whether more research on this is needed, or whether WHO ICD-11 is adequate for US purposes.
 - Identify anticipated benefits, and costs of moving to ICD-11 for morbidity classification, including barriers to implementation, e.g., readiness as a reimbursement tool, effect on Diagnosis-related Groupings (DRGs) and grouper software, preparation of older databases to integrate ICD-11 with prior ICD-9 and ICD-10 data, etc.
 - Evaluate the impact of not moving to ICD-11 for morbidity coding.

- Appraise the ability of ICD-11 for public health applications e.g., accurate data that can be used to track and understand worldwide pandemic variants, design effective public health policies, epidemiological research, and the utmost in quality and patient safety in the prevention and treatment of health issues.
- Assess whether ICD-11 will reduce provider burden, increase interoperability of electronic health information, or promote health informatics.

II. Project Phases & Sequence

This project is proposed to be carried out in multiple phases:

Phase I – Establish Workgroup and Initiate Planning:

November-December 2022

Propose formation of an NCVHS ICD-11 Workgroup that includes members of the NCVHS committee as well as additional subject matter experts in ICD-11 from the relevant federal agencies, researchers, and in quality metrics as well as the healthcare and public health industry. Discuss with the full Committee at its December 6-7 meeting and bring to a vote for approval.

December 2022-January 2023

Identify specific goals and deliverables for the 2023 Roundtable Meeting, which would include a re-examination of the past work of the Committee as a springboard/starting place to focus ICD-11 research and communication needs.

Phase I Deliverables and Timeline:

1. Brief the full Committee and bring for a vote at the December 6 meeting of the full Committee to establish the ICD-11 Workgroup.
2. Establish a Workgroup charge and invite members in collaboration with HHS agencies.
3. Hold initial Workgroup meeting and initiate planning activities.
4. Brief the Standards Subcommittee on plans for the Spring 2023 expert roundtable Meeting.

Phase II – Plan for Spring 2023 Expert Roundtable Meeting including Environment Scan:

February – April 2023

A. Compile relevant research already conducted on ICD-11 to include but not be limited to its operational and economic impact of implementation in the U.S., potential drivers for a clinical modification, costs and benefits, application to public health, effectiveness as a reimbursement tool etc. In essence, creating a mini environmental scan of the transition and its impact.

B. Hold planning calls, identify roundtable meeting invitees, develop meeting agenda.

Phase II Deliverables and Timeline:

1. Brief CMS/OBRHI and other agency representatives on ICD-11 environmental scan results.
2. Publish full environmental scan as a report on the NCVHS website.
3. Organize Roundtable Meeting with ongoing collaboration with NCHS, CMS/OBRHI, NIH/NLM and other agencies as appropriate.

Phase III – Convene Spring 2023 Expert Roundtable Meeting:

May 2023

Convene expert roundtable meeting in collaboration with HHS partners including CMS/OBRHI to:

- Identify research questions that are crucial to inform the U.S. approach for ICD-11 adoption and implementation using previous NCVHS research outline as starting point, including identify impacts of not moving to ICD-11.
- Inform evaluation of benefits and cost of transition from ICD-10-CM to ICD-11 for morbidity.
- Explore formation of a public/private ICD-11 Collaborative to conduct a priority set of research questions to inform HHS policy and decision-making.

Phase III Deliverables:

1. Convene Roundtable Meeting.
2. Publish meeting report with outcomes of roundtable discussions.
3. Develop plan to follow up on activities initiated as a result of roundtable meeting. This could include a plan for ongoing tracking and coordination of research together with a timeline for its completion.
4. Formulate draft outreach and communications plan in collaboration with relevant HHS agencies.

APPENDIX A – Project Rationale

Committee Charge

The NCVHS Charter calls for the Committee to “Study 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 Health and Human Services (HHS) recommendations and legislative proposals for such standards and electronic exchange.” Further, the Committee is to “Monitor the nation's health data needs and current approaches to meeting those needs; identify emerging health data issues, including methodologies and technologies of information systems, databases, and networking that could improve the ability to meet those needs.” Terminologies and vocabularies are also a dimension of the Committee’s charge as part of advising the Secretary and reporting to Congress on adoption of standards under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act (HIPAA).

Previous Committee Work on ICD-11

To advance these goals, the Committee held an in-depth expert roundtable meeting in 2019³ to:

- Avoid a repeat of the protracted and costly U.S. transition from ICD-9 to ICD-10 by developing a shared understanding of lessons from the ICD-10 planning process/transition, and 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 coding – and to identify impacts of not moving to ICD-11 for morbidity.
- Identify key topics and messages to communicate to the industry to foster early stakeholder engagement and preparation for the transition to ICD-11.

As a result of what the Committee learned, it issued a letter to the Secretary with two overarching recommendations. That:

1. HHS conduct research to evaluate the impact of different approaches to the transition and implementation of ICD-11 in the United States for mortality and morbidity classification to guide policy and decision-making
2. HHS provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about the transition to ICD-11

The letter included an outline of the specific research questions recommended for study based on input and discussions from the 2-day expert roundtable meeting.

In September 2021, the Committee issued a new letter with streamlined recommendations to bring the same concerns to a new administration.

The Secretary’s response was agreement that thoughtful consideration of the impact of a transition to ICD-11 on the healthcare industry and regular outreach and communications with the industry are critical – and that the Department looked forward to continued collaboration with the Committee as this important issue develops.

³ NCVHS Expert Roundtable Meeting (August 6-7, 2019): <https://ncvhs.hhs.gov/meetings/subcommittee-on-standards-icd-11-evaluation-expert-roundtable-meeting/>

Starting in 2021, the Subcommittee on Standards co-chairs initiated periodic meetings with CMS' Office of Burden Reduction and Health Informatics (OBRHI) leadership to engage and align current issues of focus for the Committee. Established recently as part of a CMS reorganization, OBRHI's focus is on reducing administrative burden and advancing interoperability and national standards – all of which aligns with the focus of the Subcommittee. The need for HHS leadership for the upcoming transition to ICD-11 was discussed during the July and September discussions. OBRHI, Subcommittee co-chairs and staff reached consensus on next steps for the Committee in the near-term. Uncertainties of federal funding for HHS could limit work on ICD-11 at HHS and impact the project scope for NCVHS.

ICD – Recent History

A review of recent history provides useful context. ICD-10 went into effect for mortality reporting in the US in 1999. On October 1, 2015, the ICD-10-CM, the US clinical modification for morbidity reporting was adopted as the updated medical code set under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), to replace version ICD-9. Another new coding system was developed by HHS' CMS that was used for acute care procedures since ICD-10-CM does not contain a procedure classification system. ICD-10-PCS went into effect in 2015. Thus, the US experienced a major, substantial transition in HIPAA-mandated code sets that constitute master data, touching virtually every clinical and administrative health system. Adoption in the US for morbidity reporting came 25 years after the system was adopted by the WHO. We note that after the publication of a CMS Final Rule setting an implementation date for ICD-10, that implementation date was subsequently postponed once by legislative action and twice by regulatory action. The postponements caused increased costs due to re-work and retraining, as well as other less tangible downsides. It is our opinion that the Workgroup approach may alleviate for ICD-11 transition the causes of those ICD-10 transition delays.

Background on ICD-11

The World Health Organization (WHO) released ICD-11 in June 2018 so countries could preview and begin their planning for implementation. In May 2019, the World Health Assembly voted on adoption of ICD-11 with an effective date of January 1, 2022. ICD-11 is intended by the WHO for use for both mortality (i.e., cause of death) reporting and morbidity (i.e., disease) reporting.

The National Center for Health Statistics (NCHS) (within HHS' Centers for Disease Control and Prevention) serves as the WHO Collaborating Center for the Family of International Classifications for North America and is responsible for coordination of all official disease classification activities in the United States relating to the ICD and its use, interpretation, and periodic revision. As with ICD-10 and previous versions of ICD, in its role as advisor to HHS, NCVHS is considering fitness for use of the new ICD-11 versions for mortality and morbidity and the timing for adoption in the US.

The U.S. must act quickly if it is to avoid repeating for ICD-11 the many costs, resource burdens, and missed opportunities that characterized its very late implementation of ICD-10. An important goal in the timely adoption of ICD-11 is to avoid using multiple versions, specifically and most importantly to avoid, if possible, a national clinical modification of the entire classification system. Thirty-five countries are already using ICD-11⁴ and others such as Canada and Australia are organizing their transition now. Those countries also are following the recommendations of the WHO by not making plans to develop a separate national clinical modification. The WHO has said that if something is

⁴ WHO ICD-11 2022 release: Better Health with Better Information <https://www.who.int/news/item/11-02-2022-icd-11-2022-release>

identified by a country as missing, they can provide feedback now and the changes will be incorporated into ICD-11. A great benefit of ICD-11 is its unique proposal platform that allows stakeholder participation in keeping ICD-11 up-to-date, and therefore there should be no need for national clinical modifications. It is, therefore, critical for HHS to exercise leadership at this stage to study ICD-11 and enable an immediate, coordinated and comprehensive transition to ICD-11 across the nation.

National coordinated leadership is imperative. Multiple academic and industry organizations in the U.S. have initiated independent studies to better understand ICD-11 and identify changes that WHO would need to make to avoid alternative versions. These efforts are not centrally coordinated, and the Committee is unable to ascertain the degree to which this work addresses ICD-11 research that the Committee requested.

APPENDIX B – Relevant Publications

1. Kin Wah Fung, Julia Xu, Olivier Bodenreider, The new International Classification of Diseases 11th edition: a comparative analysis with ICD-10 and ICD-10-CM, *Journal of the American Medical Informatics Association*, Volume 27, Issue 5, May 2020, Pages 738–746, <https://doi.org/10.1093/jamia/ocaa030>
2. Kin Wah Fung, Julia Xu, Shannon McConnell-Lamptey, Donna Pickett, Olivier Bodenreider, Feasibility of replacing the ICD-10-CM with the ICD-11 for morbidity coding: A content analysis, *Journal of the American Medical Informatics Association*, Volume 28, Issue 11, November 2021, Pages 2404–2411, <https://doi.org/10.1093/jamia/ocab156>
3. Harrison JE, Weber S, Jakob R, Chute CG. ICD-11: an international classification of diseases for the twenty-first century. *BMC Med Inform Decis Mak*. 2021 Nov 9;21(Suppl 6):206. doi: 10.1186/s12911-021-01534-6. PMID: 34753471; PMCID: PMC8577172.
4. Chute CG, Çelik C. Overview of ICD-11 architecture and structure. *BMC Med Inform Decis Mak*. 2022 May 16;21(Suppl 6):378. doi: 10.1186/s12911-021-01539-1. PMID: 35578335; PMCID: PMC9109286.
5. Susan H Fenton, Kathy L Giannangelo, Mary H Stanfill, Preliminary study of patient safety and quality use cases for ICD-11 MMS, *Journal of the American Medical Informatics Association*, Volume 28, Issue 11, November 2021, Pages 2346–2353, <https://doi.org/10.1093/jamia/ocab163>
6. Reza Golpira, Zahra Azadmanjir, Javad Zarei, Nasim Hashemi, Zahra Meidani, Akram Vahedi, Hooman Bakhshandeh, Esmaeil Fakharian, Abbas Sheikhtaheri, Evaluation of the implementation of International Classification of Diseases, 11th revision for morbidity coding: Rationale and study protocol, *Informatics in Medicine Unlocked*, Volume 25, 2021, 100668, ISSN 2352-9148, <https://doi.org/10.1016/j.imu.2021.100668>. (<https://www.sciencedirect.com/science/article/pii/S2352914821001532>)