



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

Phase I Findings Report



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

This report was prepared by the chair, members, and staff of the NCVHS ICD-11 Workgroup on Timely and Strategic Action to Inform ICD-11 Policy. See Appendix A for the Workgroup Roster.

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The National Committee on Vital and Health Statistics

The National Committee on Vital and Health Statistics (NCVHS) serves as the statutory [42 U.S.C.242(k)] public advisory body to the Secretary of the Department of Health and Human Services (HHS) in the areas of health data, standards, statistics, national health information policy, and the Health Insurance Portability and Accountability Act (HIPAA). In that capacity, the Committee provides advice and assistance to HHS and serves as a forum for interaction with relevant private sector groups on a range of health data issues. The Committee is composed of eighteen individuals from the private sector who have distinguished themselves in the fields of health statistics, electronic interchange of health care information, privacy and security of electronic information, population-based public health, purchasing or financing health care services, integrated health information systems, health services research, consumer interests in health information, health data standards, epidemiology, and the provision of health services. Sixteen of the members are appointed by the Secretary of HHS for terms of four years each. Two additional members are selected by Congress. <https://ncvhs.hhs.gov/>

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Table of Contents

ABOUT THIS REPORT	4
INTRODUCTION	4
EXECUTIVE SUMMARY	5
Figure 1: ICD-11 Workgroup Timeline	7
I. ICD-11 BACKGROUND	7
A. About ICD classification systems.....	7
Figure 2: The many uses of the <i>ICD</i> System in the U.S.	8
II. PHASE I WORKGROUP OBSERVATIONS.....	13
III. POTENTIAL BENEFITS OF U.S. ADOPTION OF ICD-11	14
A. Automation advantages – transformation to a 21 st century digital healthcare data infrastructure	14
B. Enhanced capabilities to capture clinically relevant details.....	14
C. Continuous Improvement	15
D. Avoidance of a Clinical Modification.....	15
E. Interoperability with other coding systems.....	15
IV. SYNOPSIS OF FIRST WORKGROUP REQUEST FOR INFORMATION (RFI).....	15
A. Introduction	15
B. General Themes In RFI Responses.....	16
V. AUGUST 3, 2023 ICD-11 EXPERT ROUNDTABLE MEETING	19
A. Expert Roundtable Summary of NIH research findings.....	19
B. Expert Roundtable Group Breakout Discussions	20
VI. ADDITIONAL INSIGHTS AND OBSERVATIONS FROM THE WORKGROUP.....	21
A. Learning from ICD-10-CM Implementation	21
B. Additional Expected Benefits: Growing Recognition of What is Different about ICD-11, and Transformational Opportunities.....	22
C. Summary of Key Findings for NCVHS Consideration.....	22
VII. NEXT STEPS FOR THE ICD-11 WORKGROUP.....	23
APPENDIX A: NCVHS ICD-11 Workgroup Members, Staff, and Federal Partners.....	24
Phase I Workgroup Roster.....	24
Phase II Workgroup Roster.....	27
APPENDIX B: ICD-11 Overview.....	31

ABOUT THIS REPORT

The purpose of this report is to provide a summary of findings from the initial six months (Phase I) of the National Committee on Vital and Health Statistics (NCVHS) Workgroup on Timely and Strategic Action to Inform International Classification of Diseases, 11th Revision (ICD-11) Policy. During the December 2022 public NCVHS meeting, the Committee approved establishment of the ICD-11 Workgroup in response to preliminary research and conversations with federal staff. In response to the World Health Organization's (WHO) adoption of ICD-11, the Committee identified the need for in-depth gathering and synthesis of information and evidence to inform development of timely and strategic recommendations. The Workgroup Charge [is available](#) on the Committee's website.

Jamie Ferguson and Margaret Skurka were selected to serve as Workgroup co-chairs by the Committee Chair. An additional five NCVHS members were identified to serve on the Workgroup: Val Watzlaf, Wu Xu, Denise Love, Vickie Mays, Rich Landen. Together they identified essential areas of expertise needed to enhance the Workgroup's capacity. Additionally, nine external subject matter experts (SMEs) were identified and served as members: Sue Bowman, Susan Fenton, Charles Hawley, Denise Love, Christopher Macintosh, Stella Onuoha-Obilor, Patrick Romano, Mary Stanfill, and Andrew Wiesenthal. Numerous federal staff also attended Workgroup meetings serving as liaisons between HHS programs and the Workgroup's information gathering work. In June 2023, two new Committee members – Michael Hodgkins and Cathy Donald – joined the Workgroup.

In October 2023, as the Workgroup entered Phase II, and additional external SMEs were identified and confirmed to fill gaps where additional expertise is anticipated to be essential. See Appendix A for the complete list of Workgroup members and federal SMEs.¹

INTRODUCTION

For more than a century, the International Classification of Diseases (ICD) has been the basis for comparable statistics on causes of mortality and morbidity. It has been almost 30 years since the WHO publication of ICD-10 (International Statistical Classification of Diseases and Related Health Problems, 10th Revision) for mortality and morbidity reporting. The U.S. adopted the WHO's ICD-10 for mortality reporting in 1999 yet only recently adopted a U.S. modification (ICD-10-CM) for morbidity reporting in 2015. These ICD-10 based reporting systems are still used today and are still based on the 1993 publication of ICD-10. WHO retired ICD-10 following its final update in 2019. The latest version of ICD is the eleventh edition (ICD-11), which was adopted by the World Health Assembly in 2019. ICD-11 went into effect on January 1, 2022² and world-wide implementation of ICD-11 began immediately (See Appendix B). According to WHO, over 22 countries had already implemented ICD-11 as of its 2022 release, and 64 countries are implementing its 2023 release for documentation and reporting purposes including: primary care, secondary care, and tertiary care health records; death certificates; reimbursement; vaccination certificates; traditional medicine; and essential medicines.³ While WHO member nations like the U.S. are required to implement ICD-11 for mortality reporting, countries also have committed to begin reporting morbidity statistics with ICD-11. Therefore replacing ICD-10-CM for

¹ Current ICD-11 Workgroup membership is available online here: <https://ncvhs.hhs.gov/membership/workgroup-on-timely-and-strategic-action-to-inform-icd-11-policy/>

² International Statistical Classification of Diseases and Related Health Problems (ICD) <https://www.who.int/standards/classifications/classification-of-diseases>

³ <https://www.who.int/news/item/14-02-2023-icd-11-2023-release-is-here>

U.S. morbidity reporting and related uses now must be considered. The big question before us is whether and how to adopt and implement ICD-11 in the U.S. for morbidity reporting.

While the National Center for Health Statistics (NCHS) continues to maintain ICD-10-CM with periodic updates, it relies on a significantly outdated terminology and classification system. In contrast, ICD-11 incorporates current medical science and enhanced clinical content. It is based on the latest knowledge in semantics, classification, and digital computing, designed to be continuously updated rather than depending on major upgrades as with previous versions of ICD. It is completely restructured to take advantage of today's digital capabilities, to improve coordination with and translations across other classifications and terminologies, improving the comparability of health information throughout the health care system. On-line services and tools are available to reduce the cost of ICD-11 implementation. In addition to offering more precise and expanded clinical content, ICD-11 has also been expanded to better capture social, community, and behavioral factors that may be critical to developing personalized care or evaluate health equity. ICD-11 is now available in 7 languages and WHO is developing versions in 23 more languages. Perhaps most importantly, in this time of increasing demands on clinicians that have contributed to historic levels of physician and nursing burnout, ICD-11 offers new opportunities to automate many of the manual tasks required for clinical documentation, coding for reimbursement, public health reporting, clinical quality and patient safety measurements, and population health analysis.

EXECUTIVE SUMMARY

The NCVHS Workgroup on Timely and Strategic Action to Inform ICD-11 Policy was established to gather information from a broad range of sources to bring to the full NCVHS Committee in its effort to develop advice and recommendations to Department of Health and Human Services (HHS) regarding adoption and implementation of ICD-11 as a Health Insurance Portability and Accountability Act (HIPAA) code set. This report provides a synopsis of the Workgroup's Phase I activities, from Spring 2023 through Fall 2023, which are serving as the basis to inform its Phase II activities.

NCVHS maintains from its work that immediate action is needed if the U.S. is to avoid repeating for ICD-11 the many costs and resource burdens that characterized the late implementation of ICD-10. Through this project, NCVHS supports HHS in leading the U.S. in preparation for policy and implementation decisions regarding ICD-11. The Workgroup intends for NCVHS to be well-positioned to develop recommendations to the HHS Secretary as a result of its work.

In its first phase, the Workgroup conducted an environmental scan of much of the research available in published literature as well as from other sources. The Workgroup then issued a Request for Information (RFI) in a Federal Register Notice (FRN) to gather information from the health care community and the public to provide a wide range of perspectives for the Workgroup's consideration.⁴

The Workgroup also identified over two dozen experts with a broad range of perspectives representing a variety of stakeholders to participate in a one-day ICD-11 Expert Roundtable Meeting held in-person at the Humphrey Building in Washington, D.C., August 3, 2023, with a hybrid (virtual) option.

⁴ NCVHS Request for Information (RFI) published in the Federal Register, June, 13, 2023: <https://www.federalregister.gov/documents/2023/06/13/2023-12617/national-committee-on-vital-and-health-statistics-meeting-and-request-for-information>

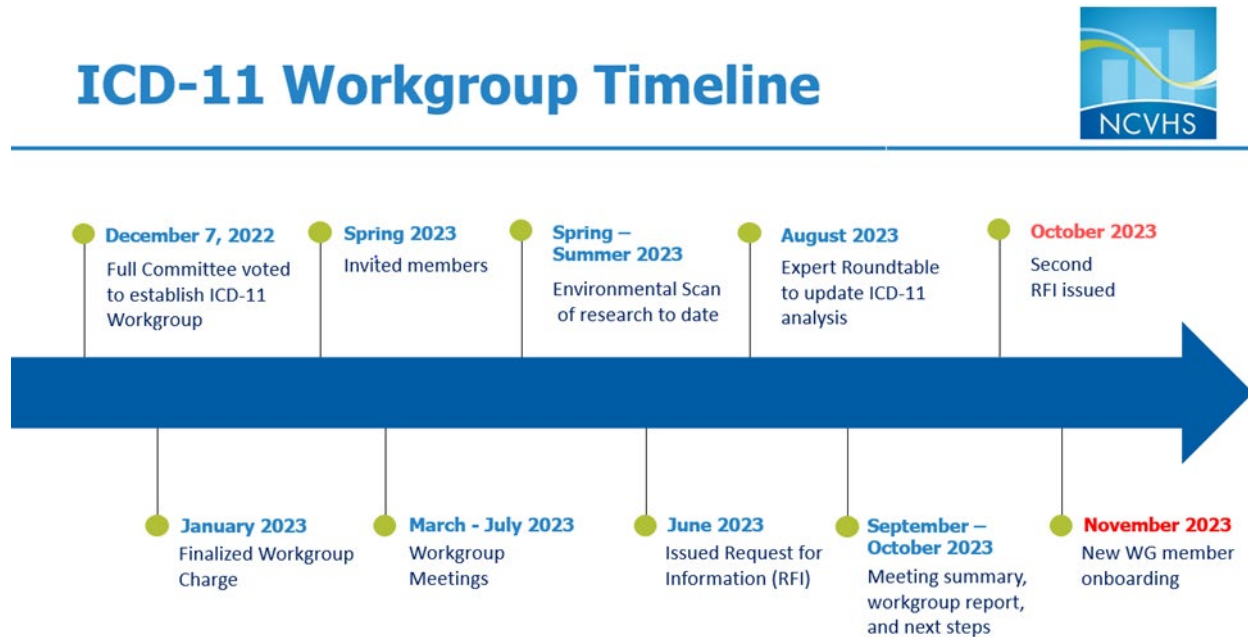
At a high level, the main themes that surfaced from the August expert roundtable include:

- a. Governance and funding for all aspects of ICD-11 adoption, its implementation, and its maintenance are needed with designation of a single central HHS coordinating entity with participation of all impacted federal agencies.
- b. There is strong interest and engagement in ICD-11 planning from organizations across the spectrum of health care, wellness, academia, public health, financing, and policy research.
- c. It will be possible for the U.S. to avoid a full clinical modification of ICD-11.
- d. There are significant gaps in currently available information and research essential for analysis and policy decisions on the U.S. approach to support adoption and implementation of ICD-11 for morbidity coding – including a lack of federal coordination of this much-needed research to inform decision-making. For example:
 - i. Additional ICD-11 content analysis is needed to identify and meet U.S.-specific needs.
 - ii. The process for U.S. maintenance and changes to the content must be better understood.
 - iii. Technical implementation must be better understood and communicated, including the technical implementation of post-coordinated expressions.
 - iv. The role of ICD-11 in clinical documentation, triggering patient interventions, and new or extended use cases, should be further explored.
 - v. With a modern online coding system, education and workforce changes could be significant.

Key Points of Discovery Identified by the Workgroup in Phase 1

- a. ICD-11 certainly can enable documentation and coding of more granular clinical detail. If its structure is properly leveraged by Electronic Health Record (EHR) data tables and documentation tools, capturing granular detail may be possible while reducing clinician coding/documentation burden, because most coding will be automated.
- b. Measurements that rely on coding—including reimbursement, public health reporting, clinical quality assessment, health systems research, and outcomes research—will be improved. The Workgroup has heard input to indicate that the cost of data acquisition (e.g., from the clinical observation to the coded record), is expected to be lower after initial implementation costs.
- c. Continuous evolution of the ICD-11 Foundation, derivatives, and tools will keep the online coding system current, and lower maintenance costs of both ICD-11 and systems that use ICD-11 due to the reduced disruption inherent in online updates.
- d. While some changes may be needed to meet all U.S. code content requirements, it is possible to avoid a full clinical modification, which would reduce U.S. costs.
- e. Potential for enhancing comparability with international data, reporting, and research will be enhanced when countries operate from the same ICD Foundation.
- f. Interoperation with other coding systems will be eased because ICD-11 will include mappings to terminologies such as the Systemized Nomenclature of Medicine – Clinical Terms (SNOMED CT).

Figure 1: ICD-11 Workgroup Timeline



I. ICD-11 BACKGROUND

A. About ICD classification systems

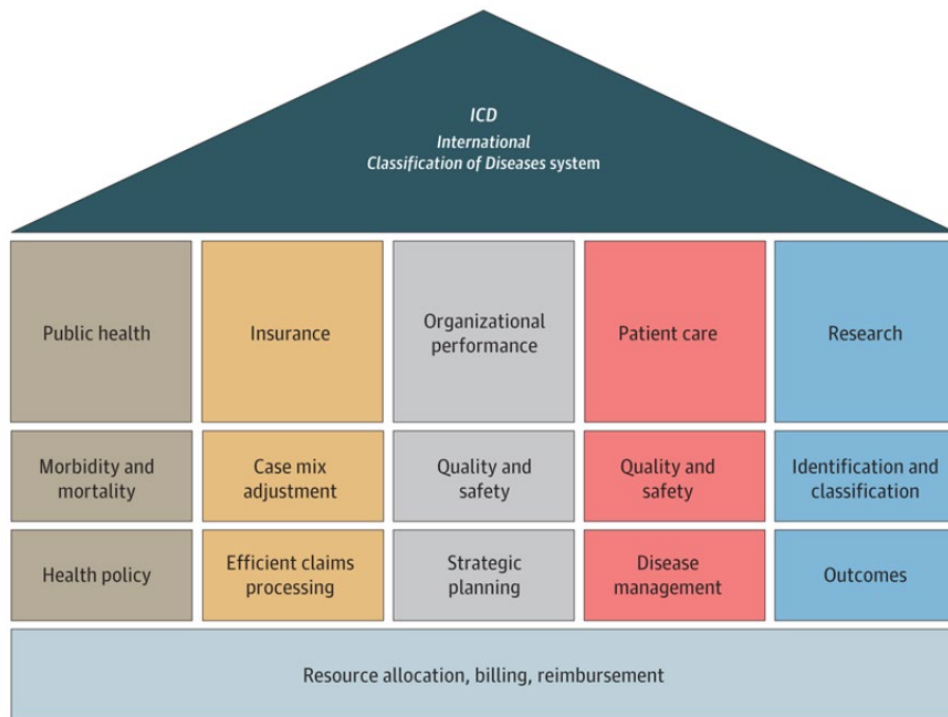
The WHO Family of International Classifications (WHO-FIC) includes three systems that serve as the international standards for health data, statistical aggregation and clinical documentation. The three systems include the:

- International Statistical Classification of Diseases and Related Health Problems (ICD)
- International Classification of Functioning, Disability and Health (ICF); and
- International Classification of Health Interventions (ICHI).

The NCVHS ICD-11 Workgroup on Timely and Strategic Action to Inform ICD-11 Policy group report's focus is on the ICD which has been the main system to provide statistics on the causes of mortality and morbidity for more than a century. The purposes and uses of ICD are many and include collection, analysis, interpretation and international comparison of mortality and morbidity data over time. As seen in the figure below, the ICD has many specific utilities in the U.S. that are essential to our healthcare, public health and research enterprise. It also works to ensure semantic interoperability and comparability for many different use cases such as reimbursement, decision support and resource distribution.⁵

⁵ International Statistical Classification of Diseases and Related Health Problems (ICD)
<https://www.who.int/standards/classifications/classification-of-diseases>

Figure 2 The many uses of the ICD System in the U.S.



ICD-11 adoption and publication by WHO

WHO began developing ICD-11 in 2007. Its goal was to examine the current classification system, ICD-10, and determine areas in which it could be enhanced based on changes in the clinical sciences and terminologies as well as improving the digital capabilities. Input was received from many classification experts via the ICD-11 online portal and a Joint Task Force was created to review the overall structure of ICD-11 to make sure it was usable and reliable. A preliminary version of ICD-11 was released in 2016 for WHO Member State comment, field trials were held for the WHO-FIC collaborating centers that same year and in 2017 more specialized field trials were held. In 2018, feedback from this work was incorporated into a new ICD-11 version that countries could use to begin preparation for implementation. The World Health Assembly formally adopted this version on May 25, 2019, and international reporting using ICD-11 began January 1, 2022.⁶

ICD-10CM and ICD-11 comparison

Previous versions of ICD were lists of classification codes. Each decade, the hierarchy of codes was expanded and reorganized to reflect changes in biomedical knowledge and clinical practice. ICD-11 is completely restructured to take advantage of today's digital capabilities and modern semantic modeling. Traditional code hierarchies in ICD-11 are derived from a more comprehensive underlying semantic network that improves coordination with other classifications and terminologies. This structure provides the flexibility to reduce the need for

⁶IFHIMA Fosters Planning for ICD-11 Adoption with Global Case Studies January 2021
https://ifhimasitemedia.s3.us-east-2.amazonaws.com/wp-content/uploads/2021/02/07232231/IFHIMA_ICD_WP_FINAL_02_06_2021.pdf page 3

national clinical modifications, to improve the comparability of translations, and to support on-line services that can reduce the cost of implementation. A linearization is a subset of the foundational semantic network of ICD-11 that is exposed for classification. Regulatory adoption of ICD-11 for morbidity coding means adopting a specific linearization with or without optional extension codes. This is a fundamental departure from past practices necessitated by the updated structure of ICD-11.

A comparison of the two systems is provided in the table below.⁷

ICD-10	ICD-11
<ul style="list-style-type: none"> ● List of classification codes for diseases and health conditions in a single hierarchy ● Expanded and reorganized each decade ● Code structure allows for a single code to capture multiple elements of a condition (pre-coordination) 	<ul style="list-style-type: none"> ● Digital representation of health terms and classes, and polyhierarchical relationships between terms and classes, in an underlying semantic network ● Designed to be continuously updated, potentially reducing the need for major upgrades in the future ● Code structure allows flexible clustering of stem codes and extensions (post-coordination) ● Purpose-specific classification hierarchies may be derived computationally ● Includes online tools and services designed to ease translation/mapping between ICD-10 and 11 and to work with other terminologies ● Includes digital tools and services to support implementation

Considerations related to ICD-11 adoption and implementation in the U.S.

a. ICD adoption as a HIPAA code set

Under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, any set of codes used for encoding data elements, such as a table of terms, medical concepts, medical diagnostic codes, or medical procedure codes make up a code set.⁸ There are many code sets that have been adopted as HIPAA standards. As a HIPAA-designated medical code set, the ICD-10-CM morbidity classification is an essential component of fee-for-service hospital and physician billing and payment processes for Medicare, Medicaid, and private insurance payers, among others. HHS programs and regulations make its use for morbidity coding

⁷ NCVHS Recommendations to the HHS Secretary, “Preparing for Adoption of ICD-11 as a Mandated U.S. Health Data Standard. (Nov 25 2019): <https://ncvhs.hhs.gov/wp-content/uploads/2019/12/Recommendation-Letter-Preparing-for-Adoption-of-ICD-11-as-a-Mandated-US-Health-Data-Standard-final.pdf> Attachment B page 1

⁸ Public Law 104-191—AUG. 21, 1996 Health Insurance Portability and Accountability Act of 1996 Subtitle F—Administrative Simplification <https://www.govinfo.gov/content/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf>

mandatory for hospitals, physician practices, and other health care provider and service settings.⁹

b. ICD adoption outside of HIPAA

ICD is used outside of HIPAA for both mortality and morbidity coding. As stated above, mortality (cause of death) reporting is a condition of U.S. membership in the WHO, contributing to worldwide surveillance and therefore is nondiscretionary. The WHO agreement is a U.N. treaty with implementation obligations led by the National Center for Health Statistics (NCHS) in conjunction with state vital registration and statistics agencies. NCHS is currently working toward adoption of ICD-11 for mortality reporting in the U.S.¹⁰

Morbidity reporting (diseases, disorders, injuries and other health conditions) is also used for international public health surveillance and statistical reporting. The ICD coding system also supports health care administration; quality and equity research; public health surveillance to monitor the incidence and prevalence of diseases; capture of data for patient safety and clinical quality measurements; and state and local health data reporting.¹¹ Unlike mortality reporting, the adoption of ICD for morbidity coding is discretionary, although WHO member countries have committed to start implementing and reporting morbidity statistics in ICD-11 to ensure global data comparability.¹²

c. Potential for additional uses of ICD-11

ICD-11 provides potential opportunities to advance the depth and breadth of representation of clinical data capture including data for quality and patient safety, behavioral, substance abuse and psychiatric disorder coding, improving ease and effectiveness of clinical data capture within the EHR, advancing Social Determinants of Health (SDOH) coding and improving the capture and utilization of important social and community risk factors needed across a diversity of populations in order to measure and achieve goals of health equity.¹³ Implementing these use cases and capturing their potential benefits in many cases will depend upon the linearization of ICD-11 used for morbidity coding, the implementation of ICD-11 in various systems, as well as workforce education, training, and readiness.

d. WHO-FIC network

The WHO-FIC Network includes WHO collaborating centers, non-government organizations (NGOs), and other experts that together support the work of WHO for international classification systems. The primary role of the WHO-FIC Network is to promote the implementation, use, maintenance, and updating of the WHO reference health classifications, which includes ICD-11. WHO-FIC operates a maintenance platform in which experts submit proposals to suggest changes to ICD-11 or enhance its content. In the

⁹ NCVHS Letter to the HHS Secretary, "NCVHS Updated 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>, page 2

¹⁰ Ibid

¹¹ Ibid

¹² World Health Organization, ICD-11 Implementation <https://www.who.int/standards/classifications/frequently-asked-questions/icd-11-implementation>

¹³ NCVHS Letter to the HHS Secretary, "NCVHS Updated 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>, pages 3, 7

- maintenance platform, the content areas of submitted proposals can be found as well as those that have been implemented. The proposal system supports content enhancement, such as expanding parent-child relationships, proposing a complex hierarchical change, and proposing new post-coordination rules or clusters and related value sets.¹⁴ At present, not all U.S. participation in the WHO-FIC network is coordinated centrally.
- e. Potential for integration with interoperable clinical coding standards
 One of the most important differences between ICD-11 and previous versions is its improved ability to be interoperable in digital health information environments. The information framework for ICD-11 has three main integrated parts: an underlying semantic network called the Foundation, classification hierarchies derived from the Foundation called linearizations, (e.g., the ICD-11 Mortality and Morbidity Statistics or MMS linearization), and a common biomedical ontology linked to the Foundation. ICD-11 MMS is the classification hierarchy closest to ICD-10 and it includes a subset of the ICD-11 entities from the ICD-11 Foundation with distinct parent relationships defined for the purpose of mortality and morbidity statistics (MMS). National implementations of ICD-11 may require different country-specific linearizations, however all will be based on the same ICD-11 Foundation. Therefore, ICD-11 will facilitate international standardization of morbidity data in a way that ICD-10 could not. Due to the semantic linkage with SNOMED-CT, which assists with the electronic exchange of clinical health information and the unique resource identifiers assigned to every ICD-11 entity, ICD-11 may further enable automated coding.¹⁵
- f. Potential for standards alignment, mapping across terminologies
 When transitioning to a new coding system, it is important to develop mapping tools across terminologies and classification systems for improved standards alignment. WHO has developed mapping tools in Excel that map from ICD-10 to ICD-11 from multiple categories, ICD-10 to ICD-11 to one category and ICD-11 to ICD-10 to one category. The ICD-11 implementation package includes all information, tools, training materials, mapping tables and more in support to use ICD.¹⁶ Also, the ICD-API supports each ICD-11 entity's Unique Resource Identifier (URI), and back-end web services provide easy access to ICD content as well as facilitating links to external terminologies.¹⁷ Researchers have also examined mapping options from ICD-10-CM to ICD-11 and found that sequential mapping through ICD-10 yielded better coverage and accuracy compared to mapping through SNOMED CT. However, there were limitations to the study such as using only a small proportion of ICD-10-CM codes and having the failure analysis conducted by only one terminologist. Therefore, more research is needed including a larger number of codes and using other methods of mapping between ICD-10-CM and ICD-11 such as lexical mapping and machine learning

¹⁴ WHO FIC Maintenance Platform <https://icd.who.int/dev11>

¹⁵ JAMA Healthcare Forum Preparing for the International Classification of Diseases, 11th Revision (ICD-11) in the US Health Care System Feinstein, J, Gill, PJ, Anderson, B, July 28, 2023 <https://jamanetwork.com/journals/jama-health-forum/fullarticle/2807690>

¹⁶ ICD-10 to 11 mapping tables <https://icd.who.int/browse11/l-m/en#/htp%3a%2f%2fid.who.int%2f%2fentity%2f1766440644>

¹⁷ IFHIMA Fosters Planning for ICD-11 Adoption with Global Case Studies https://ifhimasitemedia.s3.us-east-2.amazonaws.com/wp-content/uploads/2021/02/07232231/IFHIMA_ICD_WP_FINAL_02_06_2021.pdf page 7

approaches.¹⁸

g. Potential for improved data continuity and comparability

The data discontinuity that results from changing classifications systems may be less disruptive than the U.S. experienced in the transition from ICD-9-CM to ICD-10-CM. More research is needed, but initial studies are encouraging. When the U.S. implemented ICD-10-CM, only 24.3% of the ICD-9-CM codes had an exact match in ICD-10-CM. However, with post-coordination and just nine additional extension codes added, ICD-11 MMS can fully represent nearly 60% of the most frequently used ICD-10-CM codes. Furthermore, continuous maintenance and evolution of ICD-11, enabled through the online proposal platform, is expected to negate the need for disruptive ICD version changes.¹⁹ Instead, regular version updates will ensure the ICD-11 content reflects current scientific knowledge.

ICD-11 Additional Potential

ICD serves a broad range of uses globally and provides critical knowledge on the extent, causes and consequences of human disease and death worldwide via data that is reported and coded with the ICD. Clinical terms coded with ICD are the main basis for health recording and statistics on disease in primary, secondary and tertiary care, as well as on cause of death certificates. These data and statistics support payment systems, service planning, administration of quality and safety, and health services research. Because the ICD coding system is a starting point and key resource for these essential functions, an updated system is crucial in order to meet the capabilities to support an integrated, patient-centered health care system.

Potential changes when ICD-11 is adopted

The transition and implementation to ICD-11 for morbidity coding should be managed under a comprehensive plan that allows for the differences in coding guidelines and rules across sites of care and specialties, with specific considerations to accommodate primary care, solo providers, specialized care, and rural healthcare settings. Health information technology infrastructure investments for new software tools and revisions to database systems, automated coding systems, and maintenance of these systems will need to occur. Due to the enhancements in the digital capabilities of ICD-11, a new workforce with strong technical skills may be necessary. Education and training for coders and clinicians will require changes to existing coding policies, procedures, and priorities. Comparability studies need to be conducted to compare coding quality of ICD-10-CM to ICD-11 with both systems for a period of assessment before implementation.

WHO recommends that each country establish a national center of excellence to coordinate maintenance of existing systems during the transition, project management and strategic planning, self-assessment, dual coding studies, use of ICD-11 with terminologies and electronic health records, technical requirements, and management of health information system changes, tools, and case-mix groupers.²⁰ Other areas that will be needed include crosswalk mappings between ICD-11 and ICD-10-CM due to the extensive use of multiple post-coordination codes,

¹⁸ Xu, J., Fung, KW., Bodenreider, O., NLM/NIH Stud Health Technol Inform. 2022 June 06; 290: 96-100. doi:10.3233/SHTI220039.

¹⁹ WHO-FIC Maintenance Platform: icd.who.int/dev11.

²⁰ WHO ICD-11 Implementation or Transition Guide: https://icd.who.int/en/docs/ICD-11%20Implementation%20or%20Transition%20Guide_v105.pdf pages 14-17.

addressing SDOH and social needs coding challenges, and redesigning of billing and quality measure reporting. Due to the clustered code structure, data standards for EHRs will need to be changed to accommodate the longer character lengths in ICD-11. It is also very important to include a transparent, current communication plan to share with all stakeholders regarding the changes in standards, processes and systems.²¹

II. PHASE I WORKGROUP OBSERVATIONS

Based on initial activities, the Workgroup observed that ICD-11 has a number of characteristics that could be advantageous for morbidity reporting – enhanced and more precise clinical content, a design that is adapted to current technologies and meant to be continuously and seamlessly updated, greater ease of coordination with other classifications and terminologies (such as SNOMED CT), and the potential for the automation of clinical coding when used in the context of electronic health record documentation. Its more modern structure is intended to reduce or eliminate the need for national clinical modifications. After extensive field trials and refinement, international reporting with ICD-11 began January 1, 2022.

To be used for morbidity coding in fee-for-service reimbursement, ICD-11 must be adopted in regulation as a HIPAA code set. Beyond mortality and morbidity reporting, ICD-11 may be used to capture data related to social risk, social and community health factors to inform research and interventions in support of health equity and overall better health.

The Workgroup expects that continued refinement of ICD-11 will happen through the WHO Family of International Classifications (WHO-FIC) Network. NCHS centrally coordinates with WHO-FIC for the U.S. government, however it appears to the Workgroup that activities of other U.S. participants in related WHO activities are not centrally coordinated. Enhanced central coordination would better enable U.S. stakeholders to utilize the array of implementation tools, training materials, mapping tables, and other support materials and tools that are provided by the WHO. Central coordination would also facilitate input from other government agencies with responsibilities that benefit from the ICD. As these ICD-11 materials and tools are improved by research here and in other countries, a single point of coordination and dissemination and support center or network in the U.S. would be useful.

Migrating current morbidity coding uses to ICD-11 will require planning that addresses the needs of all end-user communities. Investment in health information technology infrastructure will be needed, as will continuing investment in assessment of coding quality and outcomes as the transition proceeds. A national center of excellence might support these functions. It could support the redesign of billing systems and quality measures, it could facilitate the migration of data standards to be incorporated into EHR systems and disseminate research evidence on beneficial uses of ICD to track public health surveillance and social and community health factors. As with any such comprehensive change, clear and continuous communication of goals, progress, problems, and solutions to all stakeholders will be a key success factor.

²¹ JAMA Healthcare Forum Preparing for the International Classification of Diseases, 11th Revision (ICD-11) in the US Health Care System Feinstein, J., Gill, P.J., Anderson, B. July 28, 2023:
file:///C:/Users/VALGEO/Downloads/feinstein_2023_vp_230017_1689789183.23721.pdf

III. POTENTIAL BENEFITS OF U.S. ADOPTION OF ICD-11

A. Automation advantages– transformation to a 21st century digital healthcare data infrastructure

The rich Foundation and the underlying ontological structure of ICD-11 support the development of automated coding capabilities that leverage advanced techniques such as natural language processing (NLP), machine learning (ML) and artificial intelligence (AI). Fully automated or machine-assisted coding will contribute to burden reduction and prevention of burnout of care providers.

WHO already has developed and provided digital tools including a browser, a coding tool and a suite of APIs (application programming interfaces) to ease adoption.

ICD terms can be used to drive automation in order sets, patient alerts, care pathways, and other best practices for clinicians. The ICD can become a trigger for an intervention in the system that drives patients, nurses, and physicians to act. These and other process automation rules can be built on ICD, and most of them can be maintained at a local level.

B. Enhanced capabilities to capture clinically relevant details

There is new content in ICD-11 that covers new disease categories or medical disciplines (e.g., sleep-wake disorders, sexual health, traditional medicine). Some chapters and disease areas (e.g., mental, behavioral and neuro-developmental disorders) have undergone comprehensive review to align with the latest advances in medical knowledge. The Foundation significantly increases the number of potentially codable conditions (e.g., incorporating 5,500 rare diseases from Orphanet²²), as Foundation entities can be exposed for coding in any specific linearization. Post-coordination (or code clustering) provides a parsimonious way to add specificity to existing codes and avoids combinatorial explosion. One example of post-coordination is the three-part model for capturing healthcare-related harm or injury.²³

The enrichment of clinical content in coded data will not only benefit direct patient care, but also other use cases which depend on ICD coding, such as:

1. Reimbursement— more accurate and timely reimbursement, potential for reduction in fraud, more precise risk adjustment, better support of value-based care
2. Public health – better disease reporting, epidemics tracking, antibiotics resistance monitoring
3. Observational research – improved capture of SDOH data will benefit data analytics investigations such as predictive modeling
4. More precise clinical quality measures with improved international comparability.

²² Rare diseases in ICD-11 <https://www.who.int/standards/classifications/frequently-asked-questions/rare-diseases>

²³ Southern, D.A., Harrison, J.E., Romano, P.S. *et al.* The three-part model for coding causes and mechanisms of healthcare-related adverse events. *BMC Med Inform Decis Mak* 21 (Suppl 6), 376 (2021). <https://doi.org/10.1186/s12911-022-01786-w>

C. Continuous Improvement

The online maintenance platform supports an open, transparent and continuous update process. Impending changes can be previewed before official release.

Due to its design, ICD-11 potentially can be the last major (disruptive) version change of ICD. In the future, incremental changes may be sufficient.

D. Avoidance of a Clinical Modification

Due to the expanded content coverage, continuous updates, and flexible structure of ICD-11 including post-coordination and the expectation of additional linearizations, ICD-11 may replace ICD-10-CM directly, avoiding the development of a full national clinical modification (CM) for the U.S.

This can save years of implementation time and resources and allow earlier adoption of ICD-11 for morbidity coding. Ongoing savings associated with avoidance of CM maintenance will be significant.

Interoperability will be enhanced at a lower cost, without the U.S. needing to develop and maintain unique methods to use a CM with all other international health data standards. As other countries are also using ICD-11 without national modifications, international comparability of statistics, analyses, and research will be greatly enhanced, in addition to international interoperability.

E. Interoperability with other coding systems

The logical underpinnings of ICD-11 will facilitate the alignment of ICD-11 with other coding systems. This will enable better integration and translation of coded data between clinical and administrative systems. For example, reporting of SDOH data, (e.g., food, transportation and housing) for some quality measures (e.g., the Healthcare Effectiveness Data and Information Set/HEDIS) can be facilitated by translating ICD-coded information into SNOMED CT or LOINC (Logical Observation Identifiers, Names, and Codes) codes.

IV. SYNOPSIS OF FIRST WORKGROUP REQUEST FOR INFORMATION (RFI)

A. Introduction

NCVHS published a Request for Information (RFI) addressing the potential use of ICD-11 for morbidity coding in the U.S. in the June 13, 2023 issue of the Federal Register (FR).²⁴ Industry stakeholders, interested individuals and organizations, and any members of the public were encouraged to respond. While respondents were invited to comment on any aspect of ICD-11, the following 12 questions were provided as a guide to information the Workgroup would find particularly helpful:

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

²⁴ Federal Register Notice, [FR Doc. 2023-1261] published June 13, 2023: <https://www.federalregister.gov/documents/2023/06/13/2023-12617/national-committee-on-vital-and-health-statistics-meeting-and-request-for-information>

2. 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?
3. What considerations affect the impact of ICD-11 on clinical documentation, payment processes including risk adjustment, public health, population health, or research?
4. What unique U.S. coding or terminology considerations are essential? For example, coding or terminology related to community health, social determinants of health, essential human needs, sexual orientation, gender identity and expression, obesity, external cause of injury, and information about mental, behavioral, or neurodevelopmental disorders including alignment with DSM-5 (Diagnostic and Statistical Manual of Mental Disorders – Fifth Edition)?
5. How should HHS implement ICD-11 in the U.S. for morbidity coding?
6. WHO recommends establishing a national center for ICD-11 implementation. What entity should be responsible for coordinating overall national implementation of ICD-11 for morbidity coding, and how should the implementation be managed?
7. ICD-11 uses an open process in which WHO encourages requests for updates and changes, thus eliminating the main drivers of national clinical modifications. What entity should be responsible for coordinating U.S. requests for updates or changes to ICD-11? How should this process be managed?
8. What resources, tools, or support will your organization need for implementation?
9. What kinds of technical resources, guidance, or tools should the U.S. Federal Government make available?
10. What workforce, workforce planning, or training will your organization need to support implementation?
11. What are your organization's requirements for ICD-11 mapping to other coding systems and terminologies, including value sets?
12. What other operational impacts of ICD-11 adoption and implementation should HHS consider?

B. General Themes In RFI Responses

The number of responses and level of detail in respondents' comments were limited by the short response time between RFI publication and the comment deadline. While only 19 responses were received by the due date, these responses provided useful perspectives and insights, and served as a guide for publication of a second RFI in October 2023.

General themes that emerged from the responses to the RFI included:

1. The migration to ICD-11 code sets will have a major impact on business and administrative operations and require significant financial and human resources for successful implementation.
2. Research is needed around the benefits and costs of adopting ICD-11.
 - a. ICD-11 should be implemented only after an assessment of the long-term return on investment provides estimates to indicate there is economic and social value in using the updated codes set for morbidity, thus justifying the implementation costs.

- b. The expected wide-scale upheaval and significant cost that may occur with the implementation of ICD-11 should be closely monitored, as do the expected benefits, so that recommended policy adjustments might be identified.
3. Lessons learned from the ICD-10 implementation should be reviewed to identify best practices for use with ICD-11.
4. An analysis should be conducted to understand the impacts of ICD-11 implementation on other adopted code sets such as codes other than ICD when used in HIPAA transactions.
5. ICD-11 must be implemented properly to ensure required data is encoded, which means adopting and mandating a U.S. version ("linearization").
 - a. Advance notice to the industry is needed as to whether a U.S. clinical modification of ICD-11 will be developed, what a U.S. linearization might include, and how the U.S.-specific coding needs will be handled.
 - b. The maintenance process must be evaluated to ensure the U.S. coding or terminology considerations are addressed.
6. All systems and processes leveraging ICD-10-CM codes will need to be evaluated for impact on transitioning to ICD-11: payment systems, public health, social service entities, population health and research.
7. There is a need to understand how post-coordination will be used effectively throughout the healthcare ecosystem, and assess what data infrastructure could be used to support post-coordination and how it would be developed.
8. U.S. coding and reporting guidelines must be defined. For example, the definition of a complete ICD-11 code for reporting is necessary. What is the level to which stem and extension codes must be applied to be considered a complete code?
9. A governance model to coordinate coding solutions and consolidate terminologies used in clinical practice in U.S. (e.g., stages of disease) should be established.
10. The fitness of ICD-11 for morbidity should be assessed in the convergence of clinical, social, and administrative health information standards.
11. Information is needed on expected software changes to accommodate ICD-11 in EHR and practice management systems, and estimated vendor implementation timelines and costs. ICD codes are used to drive rules in EHRs that can be maintained at a vendor, instance, and local level for care delivery through orders, medication, and outreach for example.

12. Expected costs should be assessed for staff training and expected changes to data collection and reporting, including quality measures, value-based programs, clinical research, and other clinical programs need to be communicated to industry stakeholders.
13. HHS should develop a detailed roadmap and transition plan for adopting and implementing changes to ICD-11 content.
14. Details are needed about the anticipated U.S. ICD-11 implementation timeline with major milestones and key deliverables.
15. Requirements and timelines of other mandated regulatory changes and updates need to be taken into consideration and coordinated in the implementation of ICD-11, including interoperability standards, No Surprises Act, HIPAA standards and operating rules, and Trusted Exchange Framework and Common Agreement (TEFCA), etc.
16. It is critical that ICD-11 implementation involve coordination across all authoritative agencies and entities involved in health care and public health regulation in order to prevent significant disruption due to unintended misalignment of code sets or associated policies.
17. Workforce investment grants should be considered. An upskilled workforce will be needed since ICD-11 may result in coding professionals moving to higher-level roles such as validation and auditing.
18. HHS should consider other legislative and regulatory requirements and deadlines that will overlap with the implementation period for ICD-11 in order not to overburden systems or clinical providers.
19. HHS should work with the appropriate standards organizations such as HL7 (Health Level 7) and X12 (Accredited Standards Committee X12) to ensure standards and implementation guides which currently depending on ICD-10 or ICD-10-CM codes are updated to include ICD-11 well in advance of any implementation deadlines.
20. HHS should establish a dedicated section of its website to post rules, guidance, frequently asked questions, and government and private sector resources for the implementation of ICD-11.
21. The availability of the following tools and resources are important for successful implementation:
 - a. Extensive coding mapping and crosswalks between ICD-11 and ICD-10-CM and other U.S. adopted code standards and terminologies;
 - b. Tools for automating coding;
 - c. Testing tools are also needed;
 - d. EHR implementation standards and tools to support ICD-11 code sets;

- e. Guidance and publications on the use of U.S. specific ICD-11 post-coordination, extension codes, or linearizations;
- f. Access to a digital code set once it is approved with live workflow, software updates, and a crosswalk identifying changes between ICD-10-CM and ICD-11; and
- g. For small rural hospitals or under resourced over-burdened hospitals in impoverished areas, staff training materials and funding to support staff who work on the revenue cycle and billing, coding, and informatics, as well as providers and other clinical staff.

V. AUGUST 3, 2023 ICD-11 EXPERT ROUNDTABLE MEETING

Preceding the Expert Roundtable Meeting, a virtual pre-work meeting was convened on July 27, 2023 to inform agenda development. Findings from break-out sessions in this pre-work meeting provided context and foundation for the hybrid (in-person and virtual) Expert Roundtable meeting held in Washington, D.C. on August 3, 2023.

During the Expert Roundtable meeting, breakout sessions were designed to explore approaches and issues likely to lead to a collaborative plan, potential timeline, and necessary resources for ICD-11 implementation in the U.S. as well as inform NCVHS recommendations. Seven in-person and three-virtual breakout groups met in both the morning and afternoon sessions to capture salient points, identify key themes, and highlight divergent opinions to the full roundtable group. A complete meeting summary can be found on the NCVHS website, together with a synthesis of both the morning and afternoons small group discussions.^{25,26}

A. Expert Roundtable Summary of NIH research findings

Senior researchers from the National Library of Medicine (NLM) and NCHS shared results of a collaborative study on the use of ICD-11 directly for morbidity coding without creating a Clinical Modification.²⁷

Based on a sample of 1,725 ICD-10-CM codes, covering the most commonly used codes from all ICD-10 chapters and the complete chapter of digestive diseases, a stepwise method was used to map to ICD-11. Starting with the stem codes from MMS, followed by exposing Foundation entities, then adding post-coordination (with existing codes and adding new stem codes if necessary), with creating new stem codes as the last resort. Overall, the stem codes level covered 35.2% of ICD-10-CM codes. Exposing the Foundation increased coverage to 46.5%. Post-coordination further increased this to 89.4%. 7.1% of codes require new extension codes and 3.5% require new stem codes.

²⁵ NCVHS ICD-11 Expert Roundtable Meeting Summary (August 3, 2023): https://ncvhs.hhs.gov/wp-content/uploads/2023/10/2023-August-3_NCVHS_ICD-11-Expert-Roundtable-Meeting-Summary-FINAL-508.pdf.

²⁶ NCVHS ICD-11 Expert Roundtable Meeting Small Group Discussion Synopses: <https://ncvhs.hhs.gov/wp-content/uploads/2023/11/Presentation-ICD-11-Expert-Panels-Summary-of-Research-Topic.pdf> and <https://ncvhs.hhs.gov/wp-content/uploads/2023/11/Presentation-ICD-11-Expert-Panels-Summary-of-Sustainability-Topic.pdf>.

²⁷ Fung KW, Xu J, McConnell-Lamptey S, Picket D, Bodenreider O. A practical strategy to use the ICD-11 for morbidity coding in the United States without a clinical modification. *J Am Med Inform Assoc*. 2023 Jul 5:ocad128. doi: 10.1093/jamia/ocad128. Epub ahead of print. PMID: 3740727.

While the results are encouraging, they likely represent the best-case scenario. To achieve good results, post-coordination is essential, without which the coverage will be significantly reduced. Post-coordination has never previously been used in ICD coding. Although post-coordination is widely implemented in SNOMED-CT, which is mandated for the problem list in U.S.-certified EMRs, most electronic health data and messaging standards do not currently support post-coordination. Implementation of post-coordination will present additional challenges in tooling and user training. Other prerequisites include the alignment of residual categories and coding guidelines (definitions, inclusions, exclusions and index terms) to ensure equivalent meaning between ICD-11 and ICD-10-CM when needed. The study is based on a limited sample of ICD-10-CM codes. More research with larger samples covering more disease areas is needed.

B. Expert Roundtable Group Breakout Discussions

Two sets of small discussion groups were held; there were seven breakout groups in total and each was assigned a facilitator. Groups focused their input guided by the following questions:

1. What are the most important research questions remaining—what information is missing and what is needed to support policy recommendations?
2. What is needed to accomplish a national research agenda in a timely manner?
3. What are the essential next steps in priority order?
4. Who and what organizations need to be involved moving forward – are there specific agencies and organizations whose involvement is needed for specific studies?
5. How to coordinate and sustain this community to obtain needed information to support NCVHS recommendations to HHS?

Detailed reports given by each breakout group, describing their discussions, analyses, and findings, can be found in the expert roundtable meeting summary report²⁸ and in the meeting report-outs.²⁹

The following themes emerged from breakout group reports:

1. Additional research is needed on benefits, costs, impacts of ICD-11 on providers and other stakeholders.
2. HHS should coordinate and ensure federal funding of an additional national ICD-11 research agenda that may involve multiple agencies and departments, including unique U.S. needs for:
 - a. managing/ integrating complex and fragmented health care delivery
 - b. funding and reimbursement systems
 - c. addressing SDOH, sexual and gender identity, language differences, and cultural diversity
 - d. maintaining ICD-11 content without a full clinical modification

²⁸ NCVHS ICD-11 Expert Roundtable Meeting Summary (August 3, 2023): <https://ncvhs.hhs.gov/wp-content/uploads/2023/10/2023-August-3-NCVHS-ICD-11-Expert-Roundtable-Meeting-Summary-FINAL-508.pdf>.

²⁹ NCVHS ICD-11 Expert Roundtable Meeting Small Group Discussion Synopses: <https://ncvhs.hhs.gov/wp-content/uploads/2023/11/Presentation-ICD-11-Expert-Panels-Summary-of-Research-Topic.pdf> and <https://ncvhs.hhs.gov/wp-content/uploads/2023/11/Presentation-ICD-11-Expert-Panels-Summary-of-Sustainability-Topic.pdf>.

3. U.S. ICD-11 governance options should be evaluated for their potential to best manage and coordinate with WHO-FIC and oversee implementation, including linearizations, post-coordination, and optional extension content, for all use cases.
4. The potential of artificial intelligence and automation for burden reduction deserves extra attention.
5. The ICD-11 transition needs strategies for pilot testing, education, and communication.
6. A second, more extensive federal Request for Information (RFI) by the Workgroup with a longer response period is needed.
7. A lead entity should secure funding and start building necessary structures.

Summary reports from the break-out groups reflected general agreement about the needs related to the critical role of additional research, sustainable funding, centralized and coordinated governance, and pilot testing. One of the greatest areas of variation in viewpoints of participants was input on what entity will be best suited to lead the U.S. effort. Suggestions for a lead entity ranged from specific agencies or a combination of federal agencies (CMS, CDC, ONC, NIH, White House) to a new public-private partnership entity or a new or existing specialty society.

VI. ADDITIONAL INSIGHTS AND OBSERVATIONS FROM THE WORKGROUP

A. Learning from ICD-10-CM Implementation

1. ICD-11 maintenance processes will have to be well understood and managed for the U.S.
2. ICD-10-CM maintenance processes should be reviewed to identify learnings for ICD-11.
3. Specific circumstances where U.S. needs warrant an update to ICD-11 prior to the WHO update cycle to ICD-11 is a challenge that must be better understood. Collaboration with WHO will be essential.
4. Control of code updates will change from ICD-10-CM processes. There is a need for assurance on the responsiveness of any new U.S. maintenance process to requests for changes.
5. Profitable, existing systems and processes built up around ICD-10-CM will undergo significant change, making ICD-11 a “disruptive” technology.
6. The costs associated with transition – IT, education, and training will be significant. Grants for small entities to implement would be helpful.
7. Many benefits of ICD-10-CM implementation were derived from the updated clinical content reflected in the increased granularity and specificity. The benefits of ICD-11 are similar as there are substantial content updates, however, benefits of ICD-11 also include the digitization of ICD. The costs to implement ICD-11 may partially be informed by the ICD-10-CM implementation history as some of the same factors will apply (in respect to the improved/modernized clinical content). The digital format of ICD-11, however, may result in additional implementation costs as

well as additional burden reduction and automation benefits. One of the most attractive benefits of ICD-11 – the ability to embed ICD-11 within the electronic clinical documentation process – will require revisions to software applications. Furthermore, the current EHR environment is very different than when ICD-10-CM was implemented.

8. Consistent application, capture, and storing post-coordinated code clusters will require both technology modifications and standardized processes/procedures, as well as end-user training.
9. Additional informatics challenges will have to be understood. For example, it will be important for ICD-11 content to be available via an HL7 FHIR (HL7 Fast Healthcare Interoperability Resources) terminology server – not only Foundation and linearizations but concept maps as well.

B. Additional Expected Benefits Growing Recognition of What is Different about ICD-11, and Transformational Opportunities

1. Automation and artificial intelligence could be game changers if facilitated by a digital ICD-11.
2. The pace of technological change continues to accelerate with more powerful and flexible tools emerging. The most recent of these was generative AI, specifically large language models (LLMs). These deep learning algorithms summarize, translate, predict, and generate content based on patterns in extremely large datasets. For medical coding, the summarizing and translating are particularly important since this is what medical coders do every day. Combining the ICD-11 Uniform Resource Identifiers (URIs) with speech recognition to turn voice into words with accuracy and then using LLMs to assign the codes for human review has the potential to reduce provider burden and increase efficiency, while also resulting in improved accuracy over time.
3. Impact on greater awareness and better understanding of health (in)equality. Early examination of voluntary use of ICD-11 for non-clinical codes, such as SDOH, will be essential.
4. Potential for ICD-11 to contribute to higher quality and lower cost in the U.S.
 - a. If automation can be used in ways that are ethical and inclusive of differences in population health social risks, and capture all of the relevant entities in a clinical note, this will increase the details available for research and study as well as care delivery.
 - b. As an example of the potential for research and study, automated ICD-11 coding may increase detailed data by reducing the use of unspecified codes. In this way, the use of technology will enable the assignment of more detailed codes.
 - c. Consistent documentation of non-medical drivers of health could result in adjustments to the standards of care, for example, including access to transportation for health care appointments.

C. Summary of Key Findings for NCVHS Consideration

1. Need for designation of a central U.S. coordinating entity.
2. Need to understand U.S. ICD-11 governance and management in the WHO context.

3. Funding is needed for research, coordination, and planning:
 - a. ICD-11 cost and benefits analyses (research)
 - b. Additional content analysis (research)
4. Stakeholder engagement is needed to build a community of interest for coordination in the U.S.
5. Standards integration and technical implementation must be well-coordinated.

VII. NEXT STEPS FOR THE ICD-11 WORKGROUP

1. Publish a second Request for Information (RFI) to obtain additional input from the public on questions specific to anticipated uses of ICD-11 for morbidity coding in the U.S. [Note, this was accomplished on October 16, 2023.³⁰]
2. Determine Workgroup Phase II Agenda and Workplan (in progress).
3. Provide a detailed update to members of NCVHS at the November 29-30 meeting of the full Committee. [Note, this occurred on November 30, 2023.³¹]

³⁰ NCVHS Request for Information (RFI) published in the Federal Register, October 16, 2023: <https://www.federalregister.gov/documents/2023/10/16/2023-22753/national-committee-on-vital-and-health-statistics>.

³¹ NCVHS Meeting, November 30, 2023 Agenda: <https://ncvhs.hhs.gov/meetings/full-committee-meeting-15/>.

APPENDIX A: NCVHS ICD-11 Workgroup Members, Staff, and Federal Partners

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APPENDIX B: ICD-11 Overview Key Facts, History, and References³² September 2023

Introduction – What is ICD?

The International Classification of Diseases and Related Health Problems (ICD) is a classification system developed and copyrighted by the World Health Organization (WHO). ICD is the international standard for reporting mortality, morbidity and other conditions affecting health. ICD serves as the foundation for identifying health trends and statistics worldwide. The tenth version (ICD-10) was used for this purpose from January 1993 until January 2022. The WHO began development of the eleventh version (ICD-11) in 2007. Experts from the United States (U.S.) and over 90 countries participated in the Joint Task Force and Topic Advisory Groups to develop ICD-11's structure and content. WHO published ICD-11 for review in 2018, and the World Health Assembly adopted ICD-11 in May 2019 to be effective beginning January 1, 2022.³³ ICD-11 is presently being adopted by WHO member countries.

New Developments In ICD: An Overview of ICD-11

Previous versions of ICD were hierarchical lists of classification codes as described below. Each decade, the list of codes was expanded and reorganized to reflect changes in biomedical knowledge and clinical practice. However, the WHO's ICD-11 classification is completely restructured to take advantage of today's digital capabilities; to improve coordination with other classifications and terminologies; to provide flexibility to reduce the need for national clinical modifications and to improve the comparability of translations and support on-line services to reduce the cost of implementation. ICD-11 incorporates not only current medical science and enhanced clinical content but also the latest knowledge in classification design and digital computing.

Unique features of ICD-11 include:³⁴

Modern technology and user interfaces. Digital representation of health terms and classes, and relationships between terms and classes.

Changing to reflect medical knowledge. The ICD-11 foundation uses a comprehensive semantic model designed to be continuously updated, potentially reducing the need for major upgrades in the future.

Post-coordination. This is a feature of ICD-11 that allows clustering of codes with optional extensions to achieve necessary specificity. This provides flexibility without predefining every combination that may possibly be needed.

Linearizations. These are subsets of the ICD-11 foundation that are exposed to users for specific purposes. A linearization is used for international mortality reporting and another one is anticipated to be derived for U.S. morbidity coding.

³² This information was developed by the National Committee on Vital and Health Statistics (NCVHS) ICD-11 Workgroup on Timely and Strategic Action to Inform ICD-11 Policy and is available on the NCVHS website here: <https://ncvhs.hhs.gov/NCVHS-WG-ICD-11-Overview-September-2023>

³³ World Health Organization, International Statistical Classification of Diseases and Related Health Problems (ICD) <https://www.who.int/classifications/classification-of-diseases>

³⁴ WHO Reference Guide <https://icdcdn.who.int/icd11referenceguide/en/html/index.html>

Freely available online tools and services ICD-11 is designed to ease translation and mapping between ICD-11 and other terminologies and coding systems.

Additional tools and services to support implementation.

Clinical content updates in ICD-11 include:³⁵

Significant detail to classify rare diseases as well as social, community, and behavioral health.

Codes for antimicrobial resistance.

Codes for full documentation of patient safety.

Necessary detail for cancer registration fully-embedded.

Specific coding for clinical stages of HIV.

More clinically relevant coding for complications of diabetes.

Codes for common skin cancers basalioma, and melanoma subtypes.

Classification of heart valve disease and pulmonary hypertension, matching current diagnostic and treatment capacity.

New chapters for disease of the immune system, sleep-wake disorders, and conditions related to sexual health.

Incorporation of traditional medicine diagnoses.

Supplementary section for assessment of functioning.

HISTORY: ICD-10 and ICD-10-CM

In the U.S., ICD is a HIPAA-designated medical code set. When the ninth and tenth versions of ICD were implemented, the WHO authorized development of adaptations by member countries to meet their specific statistical classification needs for mortality reporting, as well as morbidity coding use cases.

- The National Center for Health Statistics (NCHS), the Federal agency responsible for publishing ICD in the U.S., determined that modifications of the WHO's ICD versions nine and ten were necessary to meet the data classification needs in the U.S.
- Thus, NCHS developed the International Classification of Diseases, tenth revision, Clinical Modification (ICD-10-CM).³⁶
- The U.S. implemented the WHO ICD-10 classification for mortality reporting (cause of death coding) in 1999.
- In 2015, the U.S. implemented ICD-10-CM for morbidity reporting (e.g., coding on healthcare claims).
- ICD-10-CM includes changes to WHO's ICD-10 with expansion of specific codes to achieve the specificity required for morbidity reporting in the U.S.

Though the U.S. adopted ICD-10-CM fairly recently, it was developed based on the 1990s version of the WHO ICD-10, which is now outdated. The WHO adopted ICD-11 for worldwide implementation in 2019. As of January 2022, the WHO will report global health statistics in ICD-11. WHO member countries have committed to start implementing and reporting morbidity statistics in ICD-11 to ensure global data comparability.³⁷ The WHO has retired and is no longer supporting ICD-10. NCHS continues to maintain

³⁵ WHO ICD-11 Fact Sheet <https://www.who.int/publications/m/item/icd-11-fact-sheet>

³⁶ National Center for Health Statistics, International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) <https://www.cdc.gov/nchs/icd/icd-10-cm.htm>

³⁷ World Health Organization, ICD-11 Implementation <https://www.who.int/standards/classifications/frequently-asked-questions/icd-11-implementation>

ICD-10-CM independently, while the U.S. evaluates and considers the use of ICD-11 for mortality and morbidity data classification needs specifically in the U.S.

Implementation of an updated ICD classification system has far-reaching impacts in the U.S. where there are multiple uses of ICD embedded in a variety of software, systems, and processes. Thus, there are multiple stakeholders who need to be involved, consulted, and informed in this evaluation. Not the least of which are health care providers, who bear the burden of documentation to derive ICD codes for reimbursement in fee-for-service or volume-based plans.

THE WORK AHEAD

The clock is ticking on a series of critical decisions for the U.S., such as assessing when ICD-11 should replace ICD-10 for cause of death coding (i.e., mortality reporting). Regarding how ICD-11 should be adopted and implemented with sufficient detail to meet U.S. needs for morbidity classification without a full clinical modification, several analyses are needed. Regulatory adoption must consider other related standards updates. Selection of implementation methodologies must consider the role of automation in ICD-11 to reduce the burden of clinical documentation or to improve the accuracy and utility of coding for reimbursement, and how ICD-11 will be used to drive interventional action to patients.

Additional Resources and References on ICD-11:

NCVHS Updated recommendations for immediate action on ICD-11 to HHS Secretary, September 10, 2021 <https://ncvhs.hhs.gov/wp-content/uploads/2021/09/NCVHS-ICD-11-recommendations-for-HHS-Sept-10-2021-Final-508.pdf>

NCVHS Recommendation to HHS Secretary on Preparing for Adoption of ICD-11, November 25, 2019 <https://ncvhs.hhs.gov/wp-content/uploads/2019/12/Recommendation-Letter-Preparing-for-Adoption-of-ICD-11-as-a-Mandated-US-Health-Data-Standard-final.pdf>

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

NCVHS Recommendation to HHS Secretary on Regulatory Simplification of the ICD, February 21, 2019 <https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Regulatory-Simplification-of-ICD.pdf>

WHO ICD-11 page and fact sheet <https://icd.who.int/en>,

https://icd.who.int/en/docs/icd11factsheet_en.pdf

IFHIMA ICD-11 Perspectives <https://ifhima.org/publication-resources/articles/icd-11/>

AHIMA Latest on ICD-11 <https://www.ahima.org/news-publications/trending-topics/icd-11/>

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