NCVHS
National Committee on Vital and Health Statistics

November 25, 2019

The Honorable Alex Azar II
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Preparing for Adoption of ICD-11 as a Mandated U.S. Health Data Standard

Dear Secretary Azar:

As stipulated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the National Committee on Vital and Health Statistics (NCVHS) monitors the continued effectiveness of adopted health data standards pursuant to the requirements of HIPAA's administrative simplification provisions. This includes making recommendations regarding adoption of the International Classification of Diseases, version 11 (ICD-11) in the United States.

The ICD is a classification system developed by the World Health Organization (WHO) to serve as the foundation for identifying health trends and statistics worldwide and the international standard for reporting diseases and health conditions. WHO published ICD-11 for review in 2018 and the World Health Assembly formally adopted this version on May 25, 2019 to be effective beginning January 1, 2022. Adoption of ICD-11 by the United States has two distinct dimensions:

- **First, adoption for mortality,** i.e., cause of death reporting is a condition of U.S. membership in the World Health Organization (WHO) contributing to worldwide surveillance. It is led by the National Center for Health Statistics (NCHS) in conjunction with state vital registration and statistics agencies.
- **Second, adoption for morbidity,** i.e., diseases, disorders, injuries and other health conditions, however, requires HHS rulemaking since ICD is a HIPAA-designated medical code set. Its use for morbidity is mandatory for hospitals, physician practices, and other health care provider and service settings. Uses include monitoring the incidence and prevalence of diseases, supporting claims for reimbursement, tracking of safety and quality guidelines, population health monitoring, research as well as state health data reporting.

The U.S. implemented ICD-10 for mortality reporting in 1999. It implemented it for morbidity in 2015, 25 years after it was endorsed by the WHO, and after a protracted regulatory process. As

a major code set standard, NCVHS's Subcommittee on Standards began studying ICD-11 in 2018 to inform a U.S. strategy for transitioning to this updated version of ICD.

In our letter of February 13, 2019, NCVHS recommended updated criteria for adoption of Health Terminology and Vocabulary Standards calling for adoption to be "supported by research confirming the benefits and estimates of cost, including burden of use, of adoption and implementation."[1] These criteria also are provided in Attachment A. To that end, NCVHS held a meeting of experts on August 6-7, 2019, to gain a deeper understanding of ICD-11 and to begin identifying research questions and communication topics necessary for development of the U.S. strategy for moving from ICD-10 to ICD-11. A summary of this meeting is available online.[2]

Why ICD-11 is a Major Advance

ICD-11 is designed to take advantage of today's digital capabilities to:

- be continuously updated in response to advances in biomedical and population health science and clinical practice;
- improve coordination with other classifications and terminologies;
- provide the flexibility to reduce the need for national clinical modifications;
- improve the comparability of translations; and
- support on-line services to reduce the cost of implementation.

Why Research and Evaluation of ICD-11 are Essential

The extent to which implementation and use of ICD-11 can be automated in real-world settings in the U.S. requires research and evaluation. The need for research is compelling given ICD-11 may, or may not, provide significant opportunity to reduce provider burden and increase interoperability of electronic health information – high priority goals for the U.S.

NCVHS studied historical adoption processes and timelines and took them into account in formulating the recommendations that follow. With its adoption of ICD-11, WHO is no longer updating ICD-10.[3] Considering the complexity of mortality and morbidity adoption in the U.S., and the potential for advances in productivity and interoperability, the Committee has determined there is urgency to commence the vetting of ICD-11. While adoption and implementation of ICD-11 will be a years-long process, the Committee encourages HHS to move forward with these actions to avoid a repeat of the protracted and costly transition from ICD-9 to ICD-10. An essential part of early planning is to begin informing and engaging industry stakeholders.

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[1] NCVHS Recommendations on Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards, February 13, 2019: https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf
[2] NCVHS ICD-11 Expert Roundtable Meeting Summary, August 2019: https://ncvhs.hhs.gov/2019-August-Meeting-Summary
[3] WHO is no longer updating ICD-10. ICD-10-CM and ICD-10-PCS continue to be maintained by the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services respectively.

Based on its assessment, NCVHS advises HHS to take a proactive approach toward ICD-11, specifically recommending 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.**

   A key lesson identified by the Committee from the transition from ICD-9 to ICD-10 is that early and targeted research would have better informed the decision-making process and given stakeholders more realistic estimates of costs, benefits, public policy imperatives and opportunities presented by ICD-10. NCVHS has concluded that such research results would have facilitated rulemaking and smoothed the transition path for ICD-10 with significantly less controversy and burden to the industry.

   Since ICD-11 reflects current clinical knowledge, science, and computer processing capability, it is the Committee's assessment that there is strong potential for ICD-11 to provide more clinical relevance and improved support for achieving policy objectives. Evaluation of that potential, of course, requires further study to find a path forward that reduces the cost and burden to the U.S. healthcare system relative to the ICD-10 conversion.

   An outline of research questions is provided in Attachment B of this letter. The Committee calls on HHS to lead and support aspects of the research best handled by HHS and to engage experts from the healthcare industry and academia in other aspects of the research. This important work is best approached as an HHS/industry collaboration similar to that which guides its work in Promoting Interoperability, formerly Meaningful Use. Research topics the Committee recommends be explored include:

   ● The key use cases for ICD-11 for both mortality and morbidity and how well suited ICD-11 is to support these uses.
   ● Whether ICD-11 can fully support morbidity classification in the U.S. without development of a U.S. clinical modification (CM) and if not, are there areas to be targeted in a CM version. Development of a U.S. clinical modification for morbidity extends the implementation timetable and requires additional ongoing processes for curation of the classification.
   ● The cost and benefit estimates and opportunity costs of alternative timelines for transitioning from ICD-10 to ICD-11 for mortality and morbidity classification.
   ● The impact of the changes in ICD-11's code structure in different environments and on other health information standards designated in regulations under HIPAA or Promoting Interoperability.
   ● The quality of WHO mappings of ICD-10 to 11 for U.S. use cases.
   ● The potential of ICD-11 to support greater convergence of clinical and administrative standards for morbidity.

- Greater insight into how to derive benefit from the greater computer processing capability.

NCVHS recommends that HHS complete this research within the next 12-18 months because key questions regarding timely adoption and implementation will depend on the findings.

2. **HHS provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about the transition to ICD-11.**

Another important lesson from the transition of ICD-9 to ICD-10 was that every industry stakeholder was impacted to some degree by the changes—from solo practitioners to the largest industry payers; from state and federal agencies to private sector technology companies. Compounding the complexity, the transition from ICD-9 to ICD-10 involved NCHS developing and implementing a U.S. clinical modification, ICD-10-CM, for morbidity classification and CMS developing a new procedure coding system for use in the U.S. for inpatient services.

Large-scale change requires effective communications. A trusted source of truth for the industry would have helped to mitigate inconsistent messaging and misinformation in the protracted ICD-9 to 10 transition. Health care organizations have learned a great deal about succeeding with this type of complex change—these lessons can be strategically leveraged for the update to ICD-11.

Subject matter experts urged NCVHS to recommend that HHS take the lead in ensuring there is early and targeted communications about ICD-11 including the status of planning and research. Additional detail about communications goals, target audiences and media is provided in Attachment C. Experts urged that communications be tailored to address the concerns of each major stakeholder group and to engage stakeholders well in advance of the transition. The following have a stake in this transition:

- Patients and their advocacy organizations
- Providers/clinicians/caregivers and their professional associations
- Payers (operations and IT systems), intermediaries, and their associations
- Vendors and software developers
- State legislatures and agencies
- Policymakers – federal and state
- Coders and their associations
- Standards Organizations
- Quality, performance metrics developers
- Clinical content developers
- Researchers – both morbidity and mortality

As with the research, NCVHS recommends that HHS develop and execute a communication plan as early as possible, preferably running parallel with the research work over the next 12-18 months.

3. **The Secretary ensure appropriate federal priority, as needed, for the National Center for Health Statistics's (NCHS) efforts to negotiate the ICD copyright issues to ensure that copyright will not be a barrier to U.S. adoption and use of ICD-11.**

    While WHO has adopted ICD-11, it has not yet established copyright and use policies. Once these are established, NCHS will, as needed, negotiate an agreement on behalf of the U.S. to ensure appropriate access to ICD-11 and subsequent updates and modification that will be released from time to time. Early research will inform a decision about whether the U.S. will undertake a clinical modification, and thus inform NCHS negotiations.

It is the Committee's assessment that taking a proactive approach to research, communications, and copyright for the transition to ICD-11 for mortality and morbidity classification in the U.S. will enable the U.S. to identify the optimal path forward, maximizing benefit and minimizing cost.

NCVHS wishes to thank you for the opportunity to submit these recommendations and is available to answer questions and provide any additional information and guidance regarding next steps.

Sincerely,

/s/
William W. Stead, M.D., Chair
National Committee on Vital and Health Statistics

CC: HHS Data Council Co-Chairs

Attachments:

    A. February 2019 NCVHS Recommendations: "Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards"
    B. ICD-11 Research Questions
    C. ICD-11 Communications Plan

Attachment A:

**Criteria for Adoption and Implementation of
Health Terminology and Vocabulary Standards[4,5]**

HHS will encourage its agencies and programs to use the following criteria to assess and make recommendations for adoption and implementation of standards for health terminologies and vocabularies for use in the U.S.

Health terminology and vocabulary standards should be:

1. Clear in purpose, expected outcomes, boundaries, and guidelines for use and designed to perform well for its stated purpose.
2. Supported by research confirming the benefits and estimates of cost, including burden of use, of adoption and implementation.
3. Sponsored by organizations such as ANSI (American National Standards Institute) or other ISO-accredited (International Organization for Standardization) standards development organizations, or other private or public organizations that will assure transparent practices, open well-documented processes for input and appeal, permitting broad participation from relevant communities of practice, resources, continuity and efficient maintenance and update of the standard over time.
4. Sponsored by an entity with sustainable resources sufficient to keep pace with advances in the medical and health science domain for which the new standard or an update to a named standard is designed and to support implemented standards.
5. Developed by the range of experts required to precisely and unambiguously define and represent the scope and detailed content of the standard using accepted content development practices that optimize data quality.
6. Designed to complement and integrate with related standards to minimize the unnecessary duplication and redundancy and reduce the burden of mapping.
7. Designed to be vendor-and technology independent with explicit semantics.
8. Designed to minimize the need for mapping and translation.

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[4] These Criteria replace the "Guiding Principles for Selecting PMRI Standards" approved by NCVHS on July 6, 2000. National Committee on Vital and Health Statistics, "Report to the Secretary of the U.S. Department of Health and Human Services on Uniform Data Standards for Patient Medical Record Information." https://www.ncvhs.hhs.gov/wp-content/uploads/2014/08/hipaa000706.pdf

[5] Terminology and vocabulary standards that are specifically identified in federal regulations or sub-regulatory guidance requiring their implementation by the parties set forth in the regulation for purposes or circumstances denoted in the regulation. The NCVHS Environmental Scan report lists the terminology and vocabulary standards designated in regulations under HIPAA (Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996) or Promoting Interoperability ("PI," formerly the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, commonly known as Meaningful Use).

Implementation of adopted standards should be supported by:

1. Where mapping is essential to use, maps are tested and available.
2. No or low cost ways of obtaining standards, implementation guides and maps.
3. Documented lines of responsibility among stakeholders including terminology and vocabulary sponsor, regulators, vendors and end user organizations.
4. Plans and processes for implementation suitable for the terminology and vocabulary standard, considering vendor and user readiness and aligned with overall standards adoption roadmap.

Outline of Research Questions to Evaluate Benefits and Costs of the Transition to ICD-11 for Mortality and Morbidity in the U.S.[1]

Background

The International Classification of Diseases (ICD) is a classification of causes of death and health conditions developed by the World Health Organization (WHO) to serve as the foundation for identifying health trends and statistics worldwide. WHO initiated development of ICD-11 in 2007. Experts from the U.S and over 90 countries participated in the Joint Task Force and Topic Advisory Groups developing ICD-11's structure and content. WHO published ICD-11 for review in 2018 and the World Health Assembly adopted ICD-11 on May 25, 2019 to be effective beginning January 1, 2022.

Previous versions of ICD were lists of classification codes. Each decade, the list of codes was expanded and reorganized to reflect changes in biomedical knowledge and clinical practice. ICD-11 is completely restructured to take advantage of today's digital capabilities; to improve coordination with other classifications and terminologies; to provide the 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. Changes in the structure of ICD-11 include:

ICD-10	**ICD-11**
• List of classification codes for diseases and health conditions	• Digital representation of health terms and classes, and relationships between terms and classes
• Expanded and re-organized each decade	• Designed to be continuously updated, potentially reducing the need for major upgrades in the future
• Code structure allows for a single code to capture multiple elements of a condition (pre-coordination)	• Code structure allows clustering of stem codes and extensions (post-coordination)
	• Purpose-specific classifications may be derived computationally
	• Includes tools and services designed to ease translation/mapping between ICD-10 and 11 and work with other terminologies
	• Includes tools and services to support implementation

In February 2019, NCVHS recommended updated criteria for adoption of Health Terminology and Vocabulary Standards to the Secretary of HHS. These criteria call for adoption to be "supported by research confirming the benefits and estimates of cost, including burden of use, of adoption and

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[1] This attachment is included as part of the Letter to the Secretary with Recommendations for Preparing for Adoption of ICD-11 as a Mandated U.S. Health Data Standard, November 25, 2019: https://ncvhs.hhs.gov/reports/recommendation-letters/2019-November-Letter-to-the-Secretary

implementation." [2] With these criteria as a guide, NCVHS convened a roundtable of experts and formulated the following outline of research questions to evaluate benefits and costs of transition to ICD-11 for Mortality and Morbidity in the U.S. HHS, through the National Library of Medicine, has already begun some of this research.

Adoption of ICD-11 by the U.S. has two distinct dimensions. Adoption for cause of death (mortality) reporting is a condition of U.S. membership in the World Health Organization (WHO) contributing to worldwide surveillance. It is led by the National Center for Health Statistics (NCHS) in conjunction with state vital statistics agencies. Adoption of ICD-11 as a standard for classification of health conditions (morbidity), however, involves broad participation from public and private health industry stakeholders including providers and

Overview of Research Areas
I. Research to develop U.S. specific use cases to guide evaluation of ICD-11 for mortality and morbidity in preparation for implementation.
II. Research to evaluate content, consistency and stability of ICD-11.
III. Research to inform HHS decisions about the process and timeline for implementing ICD-11 for mortality in the U.S.
IV. Research to inform HHS decisions regarding adoption and implementation of ICD-11 for morbidity in the U.S.

payers and is governed by regulations under HIPAA (Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996) and Promoting Interoperability (PI; formerly the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, commonly known as Meaningful Use).

Research Areas and Questions

The first two research areas apply to both mortality and morbidity, the third area is specific to mortality and area four addresses morbidity.

I. Research to develop U.S. specific use cases to guide evaluation of ICD-11 for mortality and morbidity in preparation for implementation:

  1. What are the most important perspectives to consider, based on the anticipated impact, when developing use cases for ICD-11? For example:
      a. Health care delivery perspectives
      b. Coverage and payment perspectives
      c. Population health and public health perspectives
      d. Safety perspectives
      e. Research and evaluation perspectives

  2. For each perspective, which uses are appropriate for ICD-11? Which uses are not? For example, for the health care perspective:
      a. What level of detail is needed to document clinical care and to support clinical decision-making? Can ICD-11 provide for this level of detail?

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[2]NCVHS Recommendations on Criteria for Adoption and Implementation of Health Terminology and Vocabulary Standards, and Guidelines for Curation and Dissemination of these Standards, February 13, 2019: https://ncvhs.hhs.gov/wp-content/uploads/2019/03/Recommendation-Letter-Criteria-and-Guidelines-for-Health-T-V-Standards.pdf

       i.   Are the answers to these questions different for primary care and specialty care?

     ii.   Is the change to ICD-11 an opportunity to harmonize with sector-specific terminologies e.g., ICPC, to better support primary care while enabling ICD-11 adoption or outputs

b. How does ICD-11 coordinate with detailed clinical documentation? Such as:

       i.   SNOMED CT coded observations in direct care.

     ii.   Clinical registries, e.g., 2,000 terms in echo-cardiography dictionary.

3. **For the appropriate uses within a perspective, what are the use cases that would demonstrate the greatest impact (benefit or burden) of the transition to ICD-11?**

    a. What benefit(s) would each sector find compelling for change?

    b. For the health care sector, what do EHR and health information technology vendors estimate the cost of conversion to be – for them and for customers?

II.   **Research to evaluate content, consistency and stability of ICD-11:**

1. **Conduct an independent U.S. verification and validation of ICD-11 content and methodologies for post-coordination[3] and curation.** For example:

    a. Maps from ICD-10 to 11 and from ICD-11 back to ICD-10, given:

       i.   Only about 33% of codes have one-to-one mapping between ICD-10 and ICD-11.

     ii.   One-to-many and many-to-one mappings are problematic in longitudinal databases in which data coded in two different versions are merged. Few systems are able to convey data provenance indicating whether the ICD code is original or was generated by mapping from another version.

    b. Content and methodologies. Representative questions include:

       i.   Does ICD-11 have redundancy? How does it address this?

     ii.   Does ICD-11 have ambiguity? How does it address this?

    iii.   If names of ICD codes change, are meanings changed?

    iv.   Does ICD-11 delete codes? If so, how is this handled with regard to pre-existing data?

     v.   If a term's classification changes, does its code change?

    vi.   What will be the impact of semantic drift of "NEC" (not elsewhere classified) terms over time?

    vii.   Does post-coordination support complete and safe retrieval of encoded data with respect to recognizing concept equivalence & content coverage?

    viii. What will happen when a pre-coordinated[4] term is added to ICD-11 that corresponds to a concept previously represented with post-coordinated codes?[5]

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[3] Post-coordination is an ad-hoc cluster of codes to represent a single clinical concept, e.g., "arm" plus "left" for laterality.
[4] Pre-coordination is a pre-assembled single code that represents a single clinical concept, e.g., "left arm."
[5] NLM is addressing aspects of these questions.

  ix. How will multiple synonymous post-coordinated expressions be recognized?[6]

  x. How will the completeness of multiple classification be assured and what will be the cost of missing classifications?

  xi. Could ICD-11 be transformed so that a formal software classifier could be used to handle redundancy, e.g., to ensure pre-coordinated codes are used when they exist, to avoid developing post-coordinated codes when not needed?

2. **Evaluate mechanisms of covering content gaps.** For example:
   a. Mandated post-coordinated extensions
   b. Addition of base concepts (stem codes or extensions)
   c. Leveraging related terminologies for domain-specific concepts such as signs, symptoms, medications, toxins, and devices via enhanced integration and compatibility
   d. Alternative approaches to accommodating regional and urgent codes (stem or extension) without compromising consistency

3. **Evaluate alternative approaches (methods & infrastructure platforms) to support semantic comparability studies.** For example:
   a. ICD-11 vs ICD-10
   b. Each incremental revision to ICD-11 vs the previous version

III. **Research to inform HHS decisions about the process and timeline for implementing ICD-11 <u>for mortality</u> in the U.S.:**

1. **Compare coding quality, project cost and time required to implement automated ICD-11 coding of death certificates with i) natural language processing (NLP) based on data from past cases[7] to ii) NLP based on the ICD-11 foundation[8].** For example:
   a. How many past cases required to train the NLP?
   b. Does combination of NLP with the ICD-11 foundation reduce the decision logic required to assign primary cause of death, and as a result improve the quality of auto coding and reduce the cost/time to convert and maintain?
   c. What lessons from NLP-based coding for mortality are applicable to morbidity?

2. **Evaluate costs and benefits of transitioning from ICD-10 to ICD-11 for mortality in 3 versus 6 years:**
   a. What are the costs for each timeframe?

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[6] NLM is addressing aspects of these questions.

[7] NCHS is targeting 2021 for implementation of an upgrade to the ICD-10 NLP coding system to improve the % of death certificates that are auto coded. Feasibility of NLP based on the ICD-11 foundation should be evaluated in parallel with that implementation and the comparison should take place after the implementation.

[8] The ICD-11 Foundation Component is the underlying ontological database containing all ICD entities: diseases, disorders, injuries, symptoms and so on, from very broad to finely specified. This content is the equivalent of the Tabular List and Alphabetic Index in ICD10. The Foundation is structured in a standardized manner to facilitate point-of-care data capture but also provides terminology for diseases and related health conditions, and the structures necessary for incorporation into digital health information systems.

<blockquote>
<blockquote>
i. To NCHS for implementation of the back-end coding infrastructure

ii. To states for database conversions and correction of statistical analyses

iii. To the industry for database conversion and training
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b. What are the benefits of switching from ICD-10 to ICD-11 for mortality by applicable use case in each timeframe?

c. How does the cost benefit ratio change across the two timeframes?

d. What are the key barriers to achieving the earlier target dates?

IV. Research to inform HHS decisions regarding adoption and implementation of ICD-11 <u>for morbidity</u> in the U.S.:

1. **Evaluate the feasibility of using ICD-11 for morbidity without a U.S. Clinical Modification (CM).** For example:

    a. Develop clear criteria for ascertaining whether ICD-11 is – or isn't – sufficient for morbidity.

    b. Develop explicit U.S. criteria for use of extensions and post-coordination.[9]

    c. Use the criteria to evaluate the feasibility of the U.S. implementing ICD-11 for morbidity and improving its fitness for U.S. purposes with U.S. post-coordination requirements and extensions over time?

       ▪ In addition to evaluating current content, assess the fitness of the WHO update processes and schedules for U.S. purposes

    d. If it is not feasible for the U.S. to implement ICD-11 for morbidity, how long will it take to develop a U.S. CM?

       ▪ How much will it cost to develop, implement and maintain?

2. **Evaluate fitness of ICD-11 for morbidity to contribute to convergence of clinical, social, and administrative health information standards.** For example:

    a. Can EHRs and related software support ad-hoc post-coordination, or sharing of post-coordinations among partners?

    b. Can ICD coding be implemented as a computable service on top of standardized clinical statements captured by EHR using the Promoting Interoperability Standards to record clinical care?

    c. Can interoperable representations of research and clinical terms/classifications/nosologies simplify distribution and deployment of health terminology and vocabulary standards?

    d. What are the costs of supporting a-c above by use case?

    e. What are the benefits by use case?

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[9] The preferred pathway is working through the WHO's processes to add new concepts to ICD-11 rather than U.S. specific extensions. Editorial guidelines for U.S. extensions to SNOMED-CT provide an example.

3. **Evaluate the impact of using ICD-11 for morbidity on burden, efficiency, workflow, and consider the implications for documentation quality by use case and stakeholder.** For example:
    a. What are changes to clinical burden vs. changes in quality and value of data? Who bears the burden and who receives the benefit?
    b. What tools and methods for analysis are needed to reduce work flow burden and improve documentation quality?
        i. Costs and benefits of implementing these tools in EHRs etc
        ii. Human factors

4. **Evaluate alternative approaches to training/ongoing support for using ICD-11 for morbidity (costs & benefits by use case).** For example:
    a. Innovative training approaches
    b. Computer assisted coding and coding quality assurance
    c. Workforce role changes, i.e., coders becoming coding coaches/quality assurance managers, as the nature of the work evolves.

5. **Evaluate the interrelationships between ICD-11 and other HIPAA & Promoting Interoperability (PI) standards.** For example:
    a. What are the implications of technical changes, such as technical structures and code lengths to the HIPAA-specified transactions and operating rules, i.e., X12, Health Level Seven (HL7), National Council for Prescription Drug Programs (NCPDP), CAQH/CORE and National Automated Clearing House Association (NACHA)?
    b. What will the role of PI standards be relative to ICD-11? Can entities code in one of those standards and then translate to ICD-11?[10]
    c. What are overlaps with other code sets? (Note: procedural coding and ICD-10-PCS are out of scope) Can ICD-11 be coordinated or integrated with other terminologies to manage overlap and contribute to post-coordination?
    d. Evaluate the feasibility of computer assignment of ICD codes from EHR data and content vs manual entry of ICD codes.

6. **Evaluate feasibility of different timeframes for transitioning to ICD-11 <u>for morbidity</u>.** For example:
    a. Evaluate the costs and benefits of transition to ICD-11 for morbidity in 2025, 2027, 2030.
    b. Evaluate alternative guard rails (carrots & sticks) to hold stakeholders to an implementation time-line to avoid costly delays.
    c. Evaluate alternative approaches to scaling lessons learned in pilots for broad deployment across the health system.
    d. Evaluate the feasibility of re-purposing and re-using for ICD-11 the same test beds, tools, databases and techniques as were used for the conversion to ICD-10.

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[10] NLM is addressing aspects of these questions.

Attachment C:
ICD-11 Communications Plan

Introduction

In prior deliberations, the National Committee on Vital and Health Statistics (NCVHS) reflected on the industry experience with the adoption and implementation of ICD-10. One major finding was that **inadequate communication with industry stakeholders led to decisions that resulted in increased cost and burden to the industry.** Inadequate communication and information contributed to misperceptions of ICD-10 capabilities, limitations, costs and benefits. Those misperceptions led to polarization of positions resulting in a failure to achieve industry consensus around adoption.

In August 2019, NCVHS convened industry experts to conceptualize a scenario that would avert problems encountered during adoption of ICD-10. Based on their input, NCVHS developed three recommendations regarding the transition to ICD-11.[1] This plan communicates the details underlying Recommendation 2 that:

- **HHS provide timely leadership on strategic outreach and communications to the U.S. healthcare industry about the transition to ICD-11**

The goal of this outreach and communications plan is to promote industry awareness and consensus-building around an optimal implementation pathway for ICD-11, for both mortality and morbidity. **A proactive and strategic approach developed in partnership with key industry organizations will help reduce the cost and burden of transitioning to ICD-11.**

Pursuant to the Committee's Recommendation 2, the following themes and suggestions were identified as key elements that HHS should include in its strategic outreach and communications plan in support of the upcoming transition to ICD-11.

I. Communications Approach

1. Begin communication now.
2. Utilize a professionally developed marketing and communications strategy including:
    a. Conduct targeted focus groups for professionals and stakeholders. Solicit their lessons learned and incorporate findings into communications stream.
    b. Use passive communications (pull) like websites, Wikipedia-like information sources that stakeholders can find.
    c. Use active communications (push) that send information to target audiences.
    d. Link all communications to the official U.S., NCHS and WHO ICD-11 websites and maintain a library of education packets, recorded webinars, and tools.

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[1] This attachment is included as part of the Letter to the Secretary with Recommendations for Preparing for Adoption of ICD-11 as a Mandated U.S. Health Data Standard, November 25, 2019: https://ncvhs.hhs.gov/reports/recommendation-letters/2019-November-Letter-to-the-Secretary

e. Link outreach initiatives to feedback channels to learn from/improve adoption path or outreach efforts.

3. Share the HHS research plan and findings as they become available going forward with full transparency:
    a. Manage expectations, basing promises on vetted research results.
    b. Do not promise saving lives or reducing health care costs.
    c. Describe what ICD-11 will mean in terms of clinician workflows, operations, coding and implementation costs, including how it will and will not interact with Promoting Interoperability, electronic health records, practice management systems and payers' automated eligibility, authorization and adjudication software.
    d. Identify and encourage potential authors to submit articles to journals, publications, and other media.
    e. Promote the need for supporting research regarding ICD-11 to potential funding agencies e.g., NIH, AHRQ, SAMHSA, associations.
4. Target each stakeholder audience:
    a. Communicate across all healthcare and public health settings, not just physicians, hospitals, health plans and researchers, e.g., dentists, pharmacists, skilled and custodial care organizations, rehab and therapy workers, social workers, psychologists, counselors, patient advocates, public health agencies, nurses, etc.
    b. Motivate stakeholders to engage in demonstrations or tests that prove the values and clarify the real costs.
    c. Consider competitions to demonstrate new capabilities of ICD-11, with publicity and prizes.
5. Use multiple communication channels including:
    a. Organizations and institutions:
        i. Medical and Nursing schools
        ii. Professional training/accreditation programs
        iii. Advocacy organizations
        iv. Professional and trade journals, blogs, etc.
        v. Federal agencies and vehicles, e.g. CMS, AHRQ, VA
    b. Media:
        i. Internet, YouTube, blogs, webinars, podcasts, webcasts
        ii. Social media
        iii. Seminars, meetings and conferences
        iv. TV, radio, newspaper, mail
        v. Journals

II. <u>Essential Messages to Convey</u>

1. ICD-11 is coming and all stakeholders need to commence planning for how they (or their membership) will address the anticipated implementation:
    a. What you need to do now and down the road to get ready – activities and timeframes.
    b. Leverage ICD-10 conversion experience and personnel.

2. ICD-11 is "not your father's ICD":
    a. ICD-11 was designed to work with electronic health records and live in an electronic world. Digital tools have been built to support implementation.
    b. ICD-11 represents best current clinical knowledge and research (developed in 2015-2019), in contrast with ICD-10 (developed in the 1980s).
    c. ICD-11 may trade off investment in computing technology in exchange for reducing coding by providers or staff.
    d. ICD-11 may provide coders the opportunity to advance their skill set.
3. Explain why the U.S. needs to change so soon after ICD-10 implementation:
    a. ICD-10 was transitional—consider it a pathway.
    b. The ICD-11 transition does not include ICD-10-PCS.
    c. ICD-11 is designed for incremental updates potentially reducing the need for major upgrades in the future.
4. The U.S. is doing research to evaluate ICD-11 for use in the U.S., to determine the costs and benefits of implementation and to inform decisions about the best path forward:
    a. Research results will be shared with all stakeholders transparently.
    b. Stakeholders need to actively engage in research and demonstration projects.
    c. Evidence of benefits and cost will guide the adoption and implementation path as well as the timeline.
5. Mapping implementations and considerations:
    a. Only about 33% of codes have one-to-one mapping between ICD-10 and ICD-11.
    b. One-to-many and many-to-one mappings are problematic in longitudinal databases in which data coded in two different versions are merged.
    c. Few systems are able to convey data provenance indicating whether the ICD code is original or was generated by mapping from another version.
6. If a U.S. clinical modification (CM) is determined not to be needed, it will be important to explain why to industry:
    a. Ensure that the industry understands that implementation of ICD-11 for morbidity is a federal mandate whether or not the U.S. decides a CM is necessary.
    b. Communicate how U.S. stakeholders will make requests for modifications to ICD-11, e.g., the process for submission to WHO, the WHO approval process and timeline, and how it may differ from current processes.

III. <u>Mortality Specific Messaging</u>

Use of ICD-11 for mortality involves fewer stakeholders than morbidity. ICD codes are not used in states' death reporting to NCHS – rather are used in the NCHS reports back to the states. Priority target audiences for mortality messaging include states, researchers and policymakers as follows:

1. **States** – Provide states with rollout messaging and realistic timeline:
    a. Ensure enough advance notice for state agencies to plan, budget and be able to secure any necessary legislative authorizations

     b. Ensure transparency around timelines and that they are realistic given how fast states can be expected to move

     c. Ensure solid NCHS communication with States:

          i. What and when any NCHS tools will be made available

          ii. What state system changes will be necessary

          iii. Clarify NCHS responsibilities vs. state responsibilities for the transition

2. **Researchers** – Ensure messaging and timeline transparency similar to states:

     a. Ensure outreach on mapping and bridging

     b. Encourage use of public websites to share trend analysis

3. **Policymakers**:

     a. Emphasize that ICD-11 will provide more specificity on cause of death, which will be beneficial to state policy initiatives around key disease management, e.g., opioids, mosquito-borne illnesses and harmful algae blooms

     b. Convey thoughtful discussion of the features of ICD-11 including improvements and changes

IV. <u>Key Stakeholder Audiences for Morbidity</u>

1. Patients and their advocacy organizations
2. Professional associations:

     a. Physician professional associations and specialty societies

        ▪ Focus on aspects of specific interest/utility to their membership scope

     b. Behavioral, mental and social health associations

     c. Dental professional associations and specialty societies

     d. Nursing associations

     e. Hospital, long term care, home care, ambulatory/practice group, and associations for other provider stakeholders

     f. Health information management, financial management and coding associations

     g. Informatics, information systems and health IT associations

3. Payers:

     a. Operations

     b. IT and systems

     c. Payer trade associations

4. Vendors, developers and intermediaries:

     a. EHRs, billing, practice management, coding systems

     b. Clearinghouses

     c. Health Information Exchanges

     d. Clinical content developers

     e. Clinical decision support developers

5. States:

     a. Government – Ensure enough advance notice for state agencies to plan, budget and be able to secure any necessary legislative authorizations

     b. State Medicaid programs

      c. State data agencies
6. Policy Makers – manage expectations; make needs/value known but do not over-promise:
      a. State and federal
7. Standards Organizations
8. Coders
9. Quality, performance metrics developers
10. Software engineers and developers
11. Clinical content developers
12. Researchers