Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
June 5-6, 2019
Hubert H. Humphrey Building, Washington, DC

MEETING MINUTES

Note: *For details on this meeting, please refer to the transcript and slides posted at ncvhs.hhs.gov. See "Related Items" associated with the meeting agenda.*

The National Committee on Vital and Health Statistics convened on June 5-6, 2019, at the Department of Health and Human Services' Hubert H. Humphrey Building in Washington, DC. The meeting was open to the public. Present:

Committee Members
William W. Stead, MD, Chair
Nicholas Coussoule
Llewellyn Cornelius, PhD, LCSW
Alexandra (Alix) Goss
Linda Kloss, RHIA, CAE, FAHIMA (by phone)
Richard Landen, MPH, MBA
Denise Love, BSN, MBA
Vickie Mays, PhD, MSPH
Jacki Monson, JD (by phone)
Frank Pasquale, JD
Bob Phillips, MD, MSPH
Debra Strickland, MS

Lead Staff and Liaisons
Sharon Arnold, PhD, ASPE, Executive Staff Director
Rebecca Hines, MHS, NCHS, Executive Secretary
Lorraine Doo, MPH, CMS
Geanelle Herring, MSW, CMS
Rachel Seeger, MA, MPA, OCR
Maya Bernstein, JD, ASPE

NCVHS Staff
Debbie Jackson, MA, NCHS
Marietta Squire, NCHS
Geneva Cashaw, NCHS

Other Federal
Don Rucker, HHS
Marilu Hue, CMS
Michael Lincoln, VA
Robert N. Anderson, NCHS
Donna Pickett, NCHS
Steve Schwartz, NCHS

Natalie Gonzalez, CDC
Lisa Wagner, NCHS
Zoe Barber, ONC
Katherine Knapp, VHA
Amy Blum, NCHS
Cynthia Bush, NCHS

Others
Jean Narcisi, American Dental Assn.
Walter Suarez, Kaiser Permanente
Margaret Weiker, NCPDP
Erin Weber, CAQH CORE
Suzanne Niemeyer, Ketchum
Laura Hoffma, AMA
Aptta Bhutto, MHS
Manisha Khatt, MHS
Charles Stellar, WEDI
Nathan Tatro, APA
Anne McNedes, Kaiser Permanente
Michelle Dirst, APA
April Todd, CAQH

Contractor Support
Nathan West, RiverWest
Michelle Dillon, RLA
Ruth Bennett, RLA
Gregory Richards, RLA
Chandra Chhay, Caset
Susan Kanaan, writer

ACTIONS

The Committee approved the following two documents, which are posted on the NCVHS website:

1. Report—Health Information Privacy Beyond HIPAA: A Framework for Use and Protection
2. Letter to the Secretary with recommendations on actions the Department could take to improve privacy protections for health information not subject to HIPAA regulation

—DAY ONE—

Welcome and Agenda Review—Dr. Stead

After welcoming those present, Dr. Stead read a note he had sent to Dr. Bruce Cohen, who recently concluded eight years of service as an NCVHS member, thanking Dr. Cohen for being "a faithful servant to the country and a generous partner to [his] fellow Committee members." He then welcomed new member Frank Pasquale, the incoming Co-Chair of the Subcommittee on Privacy, Confidentiality and Security; and

he announced that Rich Landen would replace Nick Coussoule as Co-Chair of the Subcommittee on Standards. He then reviewed the agenda and outlined the priorities for the meeting.

ASPE Update—Sharon Arnold, Executive Staff Director

Dr. Arnold welcomed Mr. Pasquale to NCVHS, and thanked Linda Kloss and Dr. Phillips for their extended service on NCVHS in order to provide leadership for ongoing projects. She said ASPE is very focused on implementing the Evidence-Based Policymaking Act, which changes the paradigm of how government develops evidence and data. As a large and diverse Department, HHS is assessing how it identifies policy questions, what kind of data it has, how it uses data, and its staffing. The Data Council has three new workgroups to this end, on developing a 21st Century workforce of data scientists; data governance and the Department's data use agreements; and setting up a data inventory. This is a heavy budget season for ASPE, which is simultaneously implementing the FY2019 budget, working with Congress on the 2020 budget, and doing developmental work on the president's proposed 2021 budget. She predicted that HHS would continue to have extremely constrained resources.

She then invited questions and comments from the Committee. Asked about governing principles for privacy, she said ASPE looked forward to partnering with NCVHS in this area. Dr. Stead called attention to the Framework proposed in the draft report on privacy beyond HIPAA that is being reviewed at this meeting, along with the health data framework NCVHS put forward a few years ago, which shows ways to apply metadata at the level of data sets. Asked how NCVHS could help ASPE and NCHS ensure a focus on population and community health in the new Federal Data Strategy and Action Plan, she said she would think about that and she welcomed suggestions from the Committee.

Health Information Privacy and Security Beyond HIPAA—Ms. Kloss [SLIDES]

Ms. Kloss outlined the context and background for the report and letter being presented for review. She thanked Subcommittee members, Dr. Stead, and NCVHS staff for their contributions. The two documents are the result of a two-year journey led by the Subcommittee on Privacy, Confidentiality and Security to identify and describe the changing environment and the risks to privacy and security and confidential health information; to highlight promising policies, practices and technologies; to lay out integrative models for how best to protect privacy as it exists outside HIPAA protections; and to provide guidance for the Secretary, health data stewards, and the subjects of data. The project involved conducting an environmental scan in 2017-18 and holding a working meeting with subject matter experts in March 2019 to develop the Framework presented in this report. Ms. Kloss described how the thinking evolved over the two years of working on the project. The resulting report addresses multiple audiences and recommends both near-term and longer-term actions.

She then led the Committee through a discussion of the report, focusing in particular on the four sections on the "world beyond HIPAA," guiding principles for use and protection, a framework for use and protection, and the path forward. The Committee's comments and edits generated the most extensive discussion around three themes. The first discussion theme concerned the report's treatment of the topic of de-identification and how best to communicate its complexity. Members agreed that although the term is a misnomer, its usage is written into HIPAA and sufficiently common in the field that the report needs to use it while also providing caveats about the risks of re-identification. The second discussion theme related to the important differences between the commercial uses of health-relevant information and the uses for research. A cross-cutting point concerned the need for rigorous and ongoing consent processes as uses evolve. The third discussion theme concerned how the nation's health care providers and government can adequately educate patients about the risks to their health-related information and their

rights with respect to accessing and protecting that information. Ms. Bernstein reminded the group about the broad scope and intention of this report and its focus on the information and uses that lie outside HIPAA protections. For the full richness of this discussion, refer to the transcript posted on the website. The final version of the report also is available on the NCVHS website.

The group then turned to the letter to the Secretary that puts forward the Committee's recommendations for near-term actions that the Department could take. A few small modifications but no substantive issues were raised in the discussion of the letter. Ms. Kloss said she and Subcommittee staff would revise the report and letter based on the day's discussion and bring it back for review later in the meeting.

Committee Updates

NCVHS members reported on their participation in the following activities:

- Ms. Goss participated in the spring conference of the Workgroup for the Electronic Data Interchange (WEDI), which brought together perspectives on evolving API technologies and longstanding policy issues related to HIPAA. She presented the Committee's work on the Predictability Roadmap.
- Mr. Landen also presented at WEDI (but not as an NCVHS member per se) on the transition from ICD-10 to ICD-11. He stressed the importance of avoiding the lack of industry consensus that prolonged the adoption and implementation of ICD-10-CM.
- Ms. Hines reported that NCHS has hired a new outreach health policy expert to help raise awareness of NCHS's work. She also reported that the Committee's community health and well-being measurement framework is now fully launched: US News and World Report published an interview with Bruce Cohen and with her, and Dr. Cohen and Dr. Stout are planning to work on a paper together. Ms. Hines hailed this as a stellar example of NCVHS expanding its impact by collaborating with the private sector. She commended the Committee for this accomplishment.

ICD-11 Project: Evaluating Pathways to ICD-11—Mr. Landen and guest presenters [SLIDES]

The Committee devoted most of its afternoon session to delving into ICD-11, with an overview, review of the timeline and process, findings from a literature review, and summary of the changes from ICD-10 to ICD-11. Mr. Landen explained that ICD's three components are mortality, morbidity (associated with a clinical modification or CM), and (to date) procedural coding by hospitals. The Procedure Coding System [PCS] is not part of ICD, and NCVHS has recommended that it not be considered part of the adoption path to ICD-11.

NCVHS has already begun work on ICD-11, as part of its mandate. It conducted an environmental scan and held an expert roundtable in July 2018, both in the context of the NCVHS Health Terminology and Vocabulary initiative; as a result of that convening the Committee made recommendations on ICD-11 in a February 2019 letter to the Secretary. Among other things, NCVHS recommended defining a balanced set of priorities and alternative pathways toward adoption of ICD-11, with a plan for communicating them to industry. It also recommended regulatory simplification; assessing the fitness of ICD-11 for US adoption for mortality and morbidity and the likelihood of a need for a clinical modification; and assessing the potential costs and benefits of moving to a new version. In addition, the expert roundtable devised principles to guide adoption and updates. NCVHS will host an expert roundtable in August of this year to develop a set of research questions to inform the evaluation of using ICD-11 for morbidity and mortality in the U.S. The information being presented today as orientation will also serve as background for the August meeting participants.

- **ICD-10 Timeline and Process [SLIDES]**
  - Donna Pickett, MPH, Chief, CDC Classifications and Public Health Data Standards; Head, Collaborating Center for the WHO-FIC in North America.
  - Marilu (Mattie) Hue, CMS/CM/HAPG/DAC
  - Robert N. Anderson, PhD, Chief, Mortality Statistics Branch, Division of Vital Statistics; Co-Chair, ICD Mortality Reference Group

This segment focused on the major milestones in the development of ICD-10-CM and ICD-10-PCS, with particular attention to the role of NCVHS in the process. Ms. Pickett and Ms. Hue presented timelines that summarize the milestones, with links to the relevant documents by NCVHS and other entities. (These tables are posted with the materials for this meeting.) The Committee began work on ICD-10 in 1988 with hearings. The transition to ICD-10 was complicated by the concurrence of HIPAA adoption, a challenge that Ms. Pickett noted will not be present with the transition to ICD-11. ICD-10 was implemented for mortality in the U.S. in 1999. NCHS researched the need for a clinical modification for morbidity and developed ICD-10-CM over 1995-2002. Ultimately, the compliance date for morbidity use in the U.S. (ICD-10-CM) was October 1, 2015.

Ms. Hue reviewed the timeline for ICD-10-PCS. In the mid-1980s, a task force evaluated volume 3 of ICD-9 to determine the feasibility of a new procedure coding system and a set of objectives. NCVHS reported on the work on ICD by an NCVHS Subcommittee in its 1990 annual report, and further work on procedure coding and classification ensued. NCVHS issued recommendations for a single procedure coding system in 1993, and HCFA (the predecessor to CMS) contracted to develop such a system to replace ICD-9 Volume 3. The ensuing years were devoted to testing, rulemaking, education, outreach, and monitoring. ICD-10-PCS was adopted on the same timetable as ICD-10-CM.

Reflecting on this information, Dr. Stead observed that the National Committee's major work on ICD-10 and the transition from ICD-9 took place in the mid-1990s through the early 2000s. Looking ahead to the implications for the transition to ICD-11, he asked the presenters whether they thought the timing was right for NCVHS to start working on understanding the landscape, identifying the research and evaluation questions, and making industry more aware of ICD-11. Both Ms. Pickett and Dr. Anderson agreed that the timing was correct, at least with respect to mortality. Ms. Pickett said this transition should be simpler, now that the Committee knows what to expect; and she endorsed laying out the research questions now. Mr. Coussoule wondered whether industry is motivated to make this work, and she said she thought the Committee's process would help answer that question. Mr. Landen speculated that ICD-11 would enable greater value-generation for industry.

Dr. Stead then welcomed the presenters from the Vanderbilt University Medical Center's Center for Knowledge Management, via WebEx.

- **Findings from ICD-10 Literature Review—Sheila Koosner, PhD, and colleagues, VUMC Center for Knowledge Management [SLIDES]**

Dr. Koosner introduced her colleagues and co-authors, who collaborated in reviewing the published and gray literature on the impact of the transition to ICD-10-CM and -PCS in order to understand the benefits and challenges of ICD-10 implementation. The review was conducted from March to May, 2019. The findings will be submitted to the peer-reviewed journal *Medical Care*.

The team reviewed the websites of PubMed, Web of Sciences, and Business Sources Complete as well as those of professional associations, research groups, and others; and they conducted Google searches and hand searches. They were looking for articles addressing the impact of this transition, including benefits, costs, and resulting problems. The nine outcomes of interest on which they extracted data included training, productivity, staffing, system changes, reimbursement, coding accuracy, mapping between ICD-9 and ICD-10, disease surveillance/management, and "other." The team identified a total of 2,054 documents, and included 109 documents after screening on the basis of eligibility criteria. (Refer to the slides and transcript for details.)

For each outcome of interest, Dr. Koosner described the findings, cited illustrative articles, and noted any limitations in the findings. Some of the limitations of the study as a whole were that only English articles were considered; the data on several topics were limited; and much of the literature was based on survey reports and qualitative criteria. She presented these conclusions from the study:

- This comprehensive review identified significant gaps in the literature for most outcomes of interest, revealing opportunities for future research/knowledge sharing.

- Much of the data were qualitative rather than quantitative, and reports often did not include full methodological details. The disease surveillance/management outcome was a notable exception to this finding.

In the discussion period, Mr. Pasquale wondered how "the jump from 10 to 11" compares to the one from 9 to 10. He also pointed out that the failure to quantify benefits (i.e., merely quantifying costs) can distort the policy-making process. On the first point, the presenters commented on the ways in which current technology could make the transition to ICD-11 easier than the previous one, given such factors as EHRs and computer-assisted coding.

- **Overview, and Highlights of Changes from ICD-10 to ICD-11—Ms. Pickett and Dr. Anderson [SLIDES]**

Ms. Pickett briefly reviewed the history of ICD-10, noting that there would be no more updates to ICD-10 after 2019. Because the U.S. adopted ICD-10 for morbidity late in the game, some Americans wondered why ICD-11 was needed; but "the rest of the world saw the gaps… that could not be addressed or fixed in 10." Work on ICD-11 began in 2007, and many U.S. representatives have been and are very involved in the revision process.

ICD-11 for Mortality and Morbidity Statistics (ICD-11 MMS) has new conventions, a new structure, new content, and new tools, and will require new thinking. However, there is structural consistency with ICD-10 wherever possible in order not to disrupt time series. She estimated that 20-25 percent will change. (Refer to the slides and transcript for details.) The classification attempts to harmonize with new clinical understandings of diseases and new methods. More of the codes are "pre-coordinated" instead of linking a series of codes to express concepts. The "foundation layer" has all the medical knowledge needed on any given concept, while the "classification layer" provides a unique code that, in Dr. Anderson's words, "allows you to put things in a particular bucket." A clinical modification could involve additions to the foundation and/or the classification. Some members expressed concerns about decisions to combine or expand specific concepts. This and other issues raised by members are summarized at the end of this section.

ICD-11 has 55,000 codes, in contrast with ICD-10's 14,000. (A subset of these, totaling about 8,000, is valid for mortality use.) ICD-10-CM had roughly 68,000 codes. Ms. Pickett described the ICD-11 coding structure in some detail, including the use of extension codes (which are not mandatory for reporting to WHO). She said WHO has a lot of information about ICD-11 on its web pages, and there is an implementation package. The 72nd World Health Assembly approved ICD-11 on May 25, 2019. WHO is aware that while there will be a few early adopters, few countries are likely to make the transition quickly.

Dr. Anderson then gave an overview of the transition to ICD-11 for mortality, which will be totally contained within NCHS from the standpoint of coding. He noted that as a signatory to the Nomenclature Regulations, the U.S. is obligated to make this transition; so it is only a question of when, not if. The U.S. uses the international version to code causes of death, not a clinical modification. It collaborates with the Iris Core Group, an international group concerned with automated coding, to ensure consistency. He reminded the Committee that the states provide mortality data to NCHS, which does the coding and uses the data for surveillance purposes, returning the death codes to the states. Currently, coding is automated for about 75 percent of records, and they hope to get that up to 90 percent.

The U.S. is part of the Joint Taskforce (JTF) on the ICD-11 along with Australia, Germany, Canada, and Japan. In late 2018, the JTF determined that ICD-11 is fit for purpose for both mortality and morbidity statistics, and NCHS believes that is the case and that it will be useful. In response to a follow-up question, Dr. Anderson clarified that the ICD-11 is fit for purpose "generally" for mortality, though not necessarily for certain unique national issues. He outlined the steps needed to be ready to implement for mortality, including revising the automated coding system and decision tables, retraining nosologists and coders, revising computer and database specs, a bridge coding study, and developing educational and promotional materials. He estimated that these steps would take a minimum of five to six years.

Finally, Ms. Pickett showed a slide listing items that are in ICD-10-CM but "may not be in 11." She noted the need to figure out how to address those gaps; also, there will need to be discussions with the standards organizations. The timeframes for transition, which may be affected by the NCVHS recommendation to modify the regulatory process, are unknown.

Discussion

Members raised a number of concerns and suggestions with Ms. Pickett and Dr. Anderson during their presentations. They are summarized below, as possible lessons for the future.

- (Ms. Love) The lumping that happened between ICD-9 and -10 in some areas caused problems for surveillance and public health activity, and some good work was lost. Some public health groups and governmental divisions did not initially understand the need to be involved in the developmental process.
- (Ms. Strickland) There has to be a predictable set of delimiters to avoid issues with validation. This will have to be worked out with standards organizations, which need to come together to figure out how to make this work.
- (Ms. Goss) Is NCHS the entity trying to bring the industry around this implementation opportunity, and is it asking for support from NCVHS? Who is on point to ensure that collaboration is occurring? Ms. Pickett replied that in the transition from 9-CM to 10-CM, NCVHS was at the center of some but not all of the collaborative work; some was handled through SDOs and the DSMO process. There should probably be early conversations to ensure that everyone is on the same page about what needs to happen. This answer applies to morbidity, not mortality.

- (Dr. Phillips) Speaking as a clinician about the more elaborate codes ["laterality"] in ICD-11, if there is no return on the investment in the data, there is less incentive to do it correctly. So it is important to turn these data into tools/information that help the people collecting the data as they care for patients, such as in clinical decision support tools.
- (Ms. Love) The bridge study for ICD-9-to-10 was very useful; could one be built in for morbidity the next time around?

Follow-up on the Beyond HIPAA documents—Ms. Kloss

Ms. Kloss presented revised versions of the report on Health Information Privacy Beyond HIPAA and the letter to the Secretary that the Committee discussed and provided input on earlier in the day. She highlighted the substantive changes made to the versions discussed earlier. Members responded positively to the proposed revisions, and made a handful of minor modifications to the new versions. The Committee then voted unanimously to approve the report and the letter, subject to minor edits.

—DAY TWO—

Subcommittee on Standards: Predictability Roadmap Next Steps—Ms. Goss, Mr. Landen [SLIDES]

The purpose of this session is to provide an update on the Predictability Roadmap initiative and to set the stage for the July 10-11 visioning meeting. The purpose of the Predictability Roadmap initiative is to improve the cadence (pace) and predictability of standards development, adoption, and implementation. In established practice, SDOs advance their requests to a Designated Standards Maintenance organization (DSMO), which then sends a recommendation to NCVHS.

As part of the Roadmap process, NCVHS held an appreciative inquiry visioning session in 2017, followed by a forum with end users in 2018. On that basis, it drafted 23 recommendations that it put out to industry for feedback, with a robust hearing in December 2018. Based on the feedback, NCVHS narrowed the 23 to 5 recommendations that were sent to the HHS Secretary in a February 2019 letter. Ms. Goss reviewed the recommendations, the fifth of which is to "re-evaluate the function and purpose of the DSMOs."

Mr. Landen described the conditions that applied when national standards were "a new thing." These led to creation of the DSMOs (comprising three SDOs and three content committees) as a bridge to help keep everyone on the same page. Between 2001 and 2009, the DSMOs played important roles; but after that, the number of request changes they handled dropped dramatically because the six DSMO organizations had created a more efficient process and culture. Through the Roadmap process described above, NCVHS reached the understanding that the DSMO had accomplished its mission and that its value for the industry going forward was in question; hence the Committee's fifth recommendation. Mr. Landen quoted and summarized several of the comments received from the public about that recommendation (refer to the slides for details). He noted that the Committee wants to create a clear path for the industry, consistent with all the NCVHS recommendations; the path for the DSMO is not predetermined.

The Subcommittee on Standards has created a project scoping statement for evaluating the function and purpose of the DSMO. This subject will be the focus of the July 10-11 visioning meeting, which will be facilitated by experts from the HHS IDEA Lab and Innovation Office. A maximum of 25 participants

representing a cross-section of stakeholders will be invited. Ms. Goss said the ideal outcome from her perspective would be to arrive at enough clarity around a consensus vision that the Committee could then draft a letter to the Secretary. However, it is more likely that more than one vision or path will emerge and need to be further explored and mapped out, possibly through a subsequent working meeting. The Subcommittee will also seek input from others who do not attend the visioning meeting.

NCVHS members were asked to comment on the plans and the topic.

Discussion

Regarding the project scoping document, Ms. Love observed that the terms "administrative and clinical" are too narrow when talking about the convergence of data sources and streams; it is really about administrative billing data and "everything else," in view of the many types of information now deemed relevant to health and the care process. Mr. Landen hailed "this kind of blue-sky thinking" as just what is needed in the visioning session.

Dr. Stead suggested asking some or all of the six DSMO entities two questions: 1) what they can do now "if we just get out of the way," and 2) where could an oversight and coordination body be helpful. He also suggested asking HHS for its comments on the Committee's other four recommendations and whether they resonate or raise concerns. Dr. Mays seconded the idea of asking HHS for insights, including asking for suggested issues for the visioning process.

Ms. Love pointed out that with the move toward value-based purchasing, the information traditionally available from administrative data will have to be captured in other ways; and in general, the field is adapting to a new environment. That reality is also embedded in these discussions. Mr. Coussoule noted that with so much changing and so many moving pieces, a scenario planning exercise would be useful, to consider alternate scenarios. Ms. Kloss agreed.

Ms. Doo said she believed NCVHS would be receiving a response letter from HHS regarding the aforementioned recommendations. She cautioned against assigning roles to entities that they cannot perform under current regulations. Ms. Goss suggested creating a fact sheet outlining the current roles and responsibilities of the respective DSMOs.

Plans for the Expert Roundtable on ICD-11—Mr. Landen

Mr. Landen reminded the group that the purpose of the August 6-7 meeting is to identify the research questions to inform evaluation of the cost and benefit of transition from ICD-10 to ICD-11 for mortality and morbidity; to determine the need or lack thereof for a U.S. clinical modification; and to consider the timing of the paths for mortality and morbidity uses. Invitations have been sent to a diverse set of experts in both areas.

Dr. Stead described the anticipated National Library of Medicine (NLM) contribution, new design principles and quantitative and qualitative analyses by Clem McDonald and Oliver Bodenreider's team. These inputs will be ready by early August for NCVHS to draw upon and inform the roundtable, including as pre-reads for the expert panel. Their full research will be published later as a journal paper.

Mr. Landen described the structure for the roundtable, with a level-set in the morning followed by breakout sessions to work on drafting the categories for research questions and then key communication

topics and messages to engage key stakeholders sooner rather than later. There will be separate paths for mortality and morbidity.

Dr. Stead remarked on the striking finding from the VUMC literature review about how little evaluation has been done on the transition from ICD-9 to ICD-10. He stressed his hope that research questions could be framed that would lend themselves to a methodology to evaluate costs and benefits of the next ICD transition and to inform iterative evaluation and improvement going forward in a more continuous evaluation process. This, he said, would be a service to the country. Others agreed, with Mr. Landen noting that there was no follow-on to the RAND study, the primary research document on ICD-10 implementation.

Members briefly brainstormed about representative categories and topics for the roundtable, and raised the following topics and questions:

- Assuming that clinical data will be captured in the standards promoting interoperability, can the ICD foundation layer be automated and mapped to the classification to be used?
- Identify the questions for determining the value of building a U.S. clinical modification.
- Plan to build in models and simulations of evaluation over the long haul and identify who will do this.
- There was surprise that it could take up to seven years to transition to ICD-11 for mortality use. What questions would inform understanding of the relative costs of shorter vs. longer transitions, to help determine the optimal timeline?
- Look at the experience of other countries as they move to mortality.

NCVHS and ONC/HITAC Collaboration Update—Don Rucker, National Coordinator for Health Information Technology

Dr. Stead welcomed Dr. Rucker and Dr. Mason, ONC's Chief Medical Officer. He provided an update on the recent collaboration between ONC/HITAC and NCVHS – with NCVHS being invited to attend the March 20 hearing on information gathering around prior authorization held by the Health Information Technology Advisory Committee (HITAC). He noted that NCVHS has been assessing the potential for convergence of administrative and clinical standards and for burden reduction around approaches to prior authorization. The goal for the latter, he said, is to align the standards so that a clinician's information system can submit a request for prior authorization of a service to a payer who can adjudicate the request without needing a manual intervention. At present, real harm is occurring in patient care because of delays.

Dr. Rucker said ONC has been focused on provider burden, and it is charged under 21st Century Cures with reporting to Congress on the problem. At his request, Dr. Mason described a series of listening sessions ONC and CMS have held with the clinical community regarding their top burdens. The top three proved to be documentation requirements related to ambulatory visit notes, prior authorization, and lack of interoperability. This led to a draft report that sparked more than 200 public comment letters that are now being incorporated into the final report.

Dr. Rucker noted that national demand has led to a search for value in health care that he sees as the context for these issues. Information on value involves three unconnected information flows: financial data, clinical data, and quality measures. The task at hand—"the homework problem for NCVHS"—is how to merge financial and clinical data streams into a single computable space. There is considerable interest in the field in doing this; he cited work by CAQH Core, the DaVinci Project, CMMI, and the CMS Standards

Group. The challenge for the prior authorization system today is that the data are inadequate, so people supplement it in various ways. What is needed is a detailed description of the patient to which a rich set of decision logic can be applied, in conjunction with decision information. What that information is and where it goes is part of what has to be figured out. He noted that prior authorization and clinical decision support need essentially the same things, from a data and computing point of view. The third information area relates to price; and there is tremendous attention to price in the U.S. these days. The questions to get to valid and stable price transparency are similar to those already noted: what information is needed, how do you get it, and how do you use it in a reliable way?

The other "monster elephant in the room," said Dr. Rucker, is new technology. Consumers want to be part of the game; and in this world, FHIR[1] and smartphones are a given. He asserted that the integration of clinical and financial data has to be done in "this sort of modern FHIR-type of way"; and the "FHIR stuff" should be piggybacked onto X12 messages to get the best of both worlds. This will generate the granularity needed to provide the instantaneous yes/no information that clinicians and patients want. In sum, "FHIR will be the fuel to merge financial and clinical data." Noting the mandates from 21st Century Cures, he proposed that prior authorization is a good place to start; and it is in everyone's interest to do this voluntarily. He expressed gratitude for the opportunity to collaborate with NCVHS on these issues, and again noted the work already underway.

Discussion

NCVHS members had a lively conversation with Dr. Rucker on these topics. Ms. Love pointed to the work under way in the states and called for involving the states and using an approach that is scalable from the ground up. Dr. Rucker agreed, and noted that a draft Senate bill has language about a national all-claims payer database.

Regarding quality measures, the third data stream, Dr. Phillips wondered about a way to avoid prior authorization for physicians with high value practices that could also use the data to drive decision-making. Dr. Rucker pointed to the rich analysis and statistical stability enabled by using FHIR-based APIs, something CMMI and the CMS Standards Group are starting to look at.

Mr. Pasquale asked for thoughts on priorities for the Subcommittee on Privacy, Confidentiality and Security, and Dr. Rucker stressed the "deep privacy issues" related to secondary uses of data from social media, the Internet of Things, and so on. Ms. Kloss briefed him on the just-completed NCVHS report on health information privacy "Beyond HIPAA." In response to a question from Ms. Monson, Dr. Rucker said the diversity of state privacy laws and their implications for interoperability are on his and ONC's radar.

He then talked with Mr. Coussoule about payer needs and perspectives and how technology can enable faster data flow, which payers also want. He noted the relevant work of WEDI and CAQH and suggested that BlueCross plans help work out the mechanics of that as a next step. Asked by Ms. Strickland to comment on leveraging FHIR technology, he noted several opportunities including advances in the

[1] Fast Healthcare Interoperability Resources (FHIR) is a draft standard describing data formats and elements (known as "resources") and an application programming interface (API) for exchanging electronic health records. *Source: Wikipedia, accessed 6/22/19*

modern computing environment and the need for specific use cases to generate a proof of concept, possibly using the advanced imaging topic that is on the CMS agenda, mapping that onto FHIR.

Ms. Goss commented on the challenges for the field stemming from the need to comply with laws and regulations and their significant past investments in systems and ways of doing things over the past two decades. She expressed concern about pressures to do things that have high overhead but won't bring value. Dr. Rucker agreed, but said he still saw a path forward. Mr. Landen pointed to the barriers such as regulations and insurance contracts that impede the effort to reduce burden.

The group then moved to considering next steps for a collaboration between NCVHS and HITAC around these issues and opportunities. Ms. Goss stressed the importance of leveraging the work of various industry segments in this space. Dr. Stead suggested getting industry input on an idea put forward by Dr. Rucker: asking payers to identify the top five use cases and whether there is a common set of information on these use cases, and also looking at what FHIR resources exist and what could be added. If willing payers would come to the table, they could work on one or more of the use cases to identify the information set and the decision logic; this would enable providers to implement the logic as decision support, enabled by FHIR. Dr. Mason said ONC's conversations with experts working in this area has found a common view that more must be learned about the clinical data that need to be exchanged to better automate the process.

Ms. Goss proposed taking a first step forward on these questions together. Regarding the frame, scope, and starting point, Dr. Rucker suggested identifying one or more use cases and understanding what information is needed and how it can be gotten. He noted that WEDI, CAQH CORE and DaVinci have already done relevant work. Ms. Doo added that X12 might be able to identify data elements. Asked for his thoughts on the ONC role in such a project, he said he envisioned NCVHS as a good vehicle, and that ONC could assist or do it jointly and would help NCVHS with access to the stakeholders. The parties agreed to time it after October 1. Dr. Rucker suggested using the broad scope of ways to bring clinical and financial data together, with prior authorization as a use case.

Subcommittee on Population Health Update—Dr. Phillips

Dr. Phillips celebrated the results of a successful partnership experience: on June 3, the IHI 100 Million Healthier Lives released the Well-being in the Nation, or WIN, Measurement Framework, which is based on the NCVHS Measurement Framework for Community Health and Well-being that the Committee published in 2017. The WIN Framework was developed over two years of work with stakeholders, led by Dr. Soma Stout.

The Federal Data Strategy Draft Action Plan was also just released, with a request for feedback by July 5. Bob raised the question whether NCVHS should plan to develop a response. The Draft Action Plan is the focus of any comments. Dr. Phillips described the structure of the document and enumerated the 16 action steps. He then flagged five that he saw as having particular relevance for NCVHS – actions 3, 4, 9, 15, and 16 – noting the completion deadlines specified for each one. In the population health area, data access is the major concern after the loss of four data systems, with most of their data contents pulled into federal research data centers to which communities, in particular, have limited ability to work with.

The group discussed the potential focal issues, what avenue(s) of communication NCVHS should use, and a process for generating comments and reviewing them before the deadline. There was strong support among members for writing a letter, with Dr. Stead also suggesting supporting key HHS staff who are

tasked with moving the action plan forward. Dr. Phillips offered to draft the letter, and Ms. Kloss and Mr. Pasquale agreed to assist with drafting content. Members suggested that the letter also applaud the initiative, highlight relevant NCVHS work and publications, and highlight the Committee's role as an ongoing advisor to HHS on data and information policy. Ms. Hines will work to adjust the date of the next Executive Subcommittee call from July 8 to before July 5 so that action can be taken on the letter in time to meet the due date.

2019/2020 NCVHS Workplan

Committee members reviewed and updated the NCVHS workplan for each of the subcommittees, focusing on the next four months.

Public Comments

Ms. Hines reported that 55 people were present on the WebEx on Day One of this meeting. She read a question submitted about whether the VUMC Knowledge Management Team in its literature review found any information on institutions. In response, the Team provided a few citations but stated that "in general, there was a lack of strong, quantitative data reporting the impact of the ICD-10 implementation on the productivity of institutions as a whole… that could be used to inform next steps."

Audience member Laura Hoffman, Assistant Director of Federal Affairs for the American Medical Association, said the AMA has been focusing on privacy, and the new ONC/CMS rules on interoperability are shifting the paradigm of how information will be shared within the health system. The AMA has suggested to ONC that it require apps to check for an attestation of whether the app has been developed in accordance with best practices and in a transparent manner. Second, the AMA has concerns with respect to prior authorization that new technologies and other factors will lead to overreach in which third parties use information-blocking rules to gain access to excessive amounts of information, infringing on clinician decision-making. Third, she urged that volume reduction be considered in the efforts to automate information flow for prior authorization. Finally, the AMA wants the ONC "Consent to Share" tool to be mandatory, to give patients more control over who gets access to their information.

Closing Remarks—Dr. Stead

In closing the meeting, Dr. Stead thanked the staff of all the Subcommittees, the NCHS team, the ASPE staff and leadership, and RLA for their meeting support. He then adjourned the meeting.

I hereby certify that, to the best of my knowledge, the foregoing summary of minutes is accurate and complete.

/s/ 08/15/2019
Chair Date