Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
March 24-25, 2020

MEETING SUMMARY – Held Virtually

Note: *For details on this meeting, please refer to the transcript and slides posted on ncvhs.hhs.gov. See "Related Items" associated with the meeting agenda on the March 2020 meeting page.*

Due to the COVID-19 pandemic, the National Committee on Vital and Health Statistics was convened virtually via Zoom on March 24-25, 2020. The meeting was open to the public. Present:

Committee Members
William W. Stead, MD, Chair
Nicholas Coussoule
Llewellyn Cornelius, PhD
Denise Chrysler, JD
Melissa M. Goldstein, JD
Alexandra Goss
Richard Landen, MPH, MBA
Denise Love, BSN, MBA
Vickie Mays, PhD, MSPH
Jacki Monson, JD
Frank Pasquale, JD
Margaret Skurka, MS, RHIA, CCS, FAHIMA
Debra Strickland, MS

Absent:
James Cimino, MD

Executive Staff

Sharon Arnold, PhD, ASPE, Exec. Staff Director
Rebecca Hines, MHS, NCHS, Exec. Secretary

Lead Staff
Lorraine Doo, MPH, CMS
Rachel Seeger, JD, OCR

Guest Presenters
Sharon Arnold, Ph., ASPE
Margaret Weiker, NCPDP
Alexandra Mugge, CMS
Mark Knee, ONC
Kate Tipping, JD, ONC
Naomi Lefkovitz, NIST
Edward H. You, HHS
Chris Muir, ONC
Stephen Konya, ONC

In addition, 74 individuals (i.e., members of the public and other federal staff), followed the meeting on day 1, and 35 followed on day 2.

ACTION

The Committee unanimously approved a motion to adopt the recommendations to the HHS Secretary outlined below, with a cover letter that acknowledges the possible impact of COVID-19 on timing of implementation.

1. Adopt as a HIPAA standard the NCPDP Telecommunications Standard Implementation Guide version F6 (to replace version D.0).

2. Promulgate and implement according to recommended timeline:
    - Proposed Rule (NPRM) to be published by the end of calendar year 2020.
    - Assuming favorable NPRM public comment, a Final Rule published by September 1, 2021.
    - A 3-year pre-implementation window following publication of the final rule, allowing (but not requiring) industry use beginning September 1, 2024 (This will allow sufficient time for planning and completion of necessary budget cycles).
    - Allow both versions (D.0 and F6) to be used for a 9-month period beginning September 1, 2024 and ending April 30, 2025 (This will enable an effective live-testing and transition period that allows the use of either the D.0 or F6.)
    - Require full compliance by the end of the third year (i.e., F6 only beginning May 1, 2025)

The final letter and recommendations are posted on the NCVHS website.

—DAY ONE—

Welcome and Agenda Review—Ms. Hines, Dr. Stead

Ms. Hines welcomed NCVHS members and the public audience and expressed appreciation for members' service during the current unprecedented circumstances. After roll call, Dr. Stead reviewed the agenda and noted the priorities related to updating retail pharmacy claim standards and advancing the collaboration with ONC and HITAC to enable convergence of administrative and clinical data.

New Member Introductions and Orientation—Ms. Hines

Ms. Hines welcomed the three new members able to attend this meeting and asked them to introduce themselves. (Refer to meeting transcript for further details.)

- **Denise Chrysler, JD,** is a public health attorney who worked for the Michigan State Health Department and now directs the Midstate Region of the Network for Public Health Law, located at the University of Michigan's School of Public Law.

- **Melissa Goldstein, JD,** is Professor of Law, Bioethics, and Health Policy at George Washington University and the Milken Institute School of Public Health. Previously, she worked on health IT in the area of privacy and security at the Markle Foundation, and she previously has served in the Federal Government.

- **Margaret Skurka, MS,** is a Professor Emerita at Indiana University, was President of AHIMA when former NCVHS member Linda Kloss was CEO and was active in the international HIM Association. One of her goals for her NCVHS participation is to help ease the transition to ICD-11.

Each of the ten current NCVHS members then briefly introduced themselves. Jim Cimino was absent.

Overview of Strategic Plan and Selection Criteria for Committee Projects—Dr. Stead (slides)

After noting and appreciating the diversity of NCVHS members' backgrounds and interests, Dr. Stead reviewed the NCVHS Strategic Plan (https://ncvhs.hhs.gov/strategic_plans/september-13-2017-ncvhs-strategic-plan/) and described how the Committee selects and carries out its projects. NCVHS has the capacity to "take a long lens" and develop near-term recommendations that reflect that long lens. He described the recent NCVHS work on health terminologies and vocabularies to illustrate its approach to its work. Most projects require 18 to 36 months, with incremental deliverables. The criteria used to select projects include being consistent with the NCVHS mission, appropriately scaled, complementary, and aligned; resulting in actionable information or recommendations; and having an urgency that justifies the use of limited resources. NCVHS is also required to do certain things, including submitting a periodic report to Congress on HIPAA implementation. It has submitted 13 such reports to Congress. The next report is due in FY2021.

NCVHS projects originate in the subcommittees and are outlined in the NCVHS workplan. Ms. Hines explained that projects begin with a draft scoping document that is discussed with the full Committee to benefit from the full breadth of member perspectives. The Committee works collaboratively with other bodies, notably HITAC, the ONC FACA, at present. Ms. Goss described the evolution of a collaboration with HITAC that grew out of the Standards Subcommittee/Review Committee's work on the Predictability Roadmap. The collaboration relates to the Intersection of Clinical and Administrative Data (ICAD) Project, with four NCVHS members serving on the ICAD taskforce (including Ms. Goss, who is Co-Chair). (See later agenda item for more on that project.)

ASPE Update—Sharon Arnold, Executive Staff Director

Dr. Arnold focused on what HHS and ASPE are doing around COVID-19, noting that "it is all COVID all the time right now." The activities include providing guidance from CDC to patients, the general community, and provider groups. Examples include CMS guidance on HIPAA compliance and waivers, SAMHSA guidance on services for persons with substance abuse disorder, guidance on civil rights protections related to the disclosures of PHI about infected individuals, and guidances to professional and health care organizations and commercial entities on operating in the current environment. HHS/ASPE is also gathering data and providing technical assistance to Congress on legislative proposals.

Asked how NCVHS can help, she said ASPE welcomes ideas on new data sources as the Department thinks about sources for monitoring trends and understanding the impacts of the coronavirus. Mr. Pasquale noted the need for new privacy, confidentiality, and security standards for the use of new sources and the disposition of data, and he suggested looking at international examples such as Singapore's use of the phone app TraceTogether and the uses of big data by South Korea and Taiwan.

In response to another question, Dr. Arnold said she had no status report on the Public Health Modernization Act; however, progress continues on the Evidence-Based Policymaking Act, and ASPE is moving ahead on developing evidence plans at Department and agency levels. Ms. Bernstein called attention to the latest OMB guidance on the Evidence Act.

NCPDP Change Request Submitted to NCVHS
—Ms. Goss and Mr. Landen; Margaret Weiker, NCPDP (2 sets of slides)

(Please refer to the transcript and slides for details of the presentations.)

Ms. Goss gave an overview of the change request from the National Council for Prescription Drug Programs (NCPDP), the ANSI-accredited developer of standards for the U.S. pharmacy service industry. The Designated Standards Maintenance Organization (DSMO) asked NCVHS to consider an upgrade to the named standard under HIPAA, produced by NCPDP. It is version F6.

NCVHS last considered a pharmacy-related standards upgrade, version F2, in 2018, recommending adoption of vF2 by 2021. However, the landscape has changed since then. The most significant change is that some new drugs are now priced at more than $1 million, and the current and recommended standards do not accommodate that many digits. Therefore, the industry collaborated on developing an update and asked NCVHS to update its prior recommendation to vF6, which includes all modifications since vD.0. (the version now in effect). Ms. Goss outlined the changes between versions D.0. and F2 and said the changes in F2 are incorporated into F6.

Ms. Weiker, NCPDP's Vice President for Standards Development, described NCPDP and its consensus-based operations and described the changes that have occurred since vF2 was developed. She outlined the technical changes in the standard and the activities to which it would apply, including eligibility verification, claims, billing, and prior authorization. She enumerated the changes in vF6 in addition to changing the dollar fields. She then discussed the benefits of the proposed change, which include better functionality; enhanced patient safety processes; reduced burdens for IT development, testing, and implementation; and expedited patient access to care. In addition to recommending that HHS name vF6 in a proposed rule, NCPDP recommended that the final rule be published no later than August 2021. If the timeline is not met, a number of workarounds will be necessary, and it will not be possible to process some claims. Finally, Ms. Weiker thanked NCVHS for acting expeditiously on the DSMO request.

Mr. Landen then described the processes NCVHS has undertaken to evaluate and consider stakeholder feedback on the NCPDP change request, leading to the recommendation being put forward today. NCVHS posted a Federal Register Notice on February 27 containing seven questions to request written input from stakeholders. The questions pertain to the expected enhancements, the timeframe, workarounds in the meantime, barriers and costs of implementation, and testing. NCVHS received written input from 10 national stakeholder organizations. Nine expressed general support for the adoption of vF6 because of the anticipated enhancements; one expressed neutrality. An important theme of the responses was that the timely adoption of the standard by HHS is critical. (The themes of the responses are summarized in the slides posted on the website.)

Mr. Landen then invited attendees on the live webcast to give oral comments, but no public comments were offered. He then outlined the recommendation from the Subcommittee on Standards, which is that the Full Committee recommend the following to HHS:

1. Adopt as a HIPAA standard the NCPDP Telecommunications Standard Implementation Guide version F6 (to replace version D.0).

2. Promulgate and implement according to recommended timeline:

    - Proposed Rule (NPRM) to be published by the end of calendar year 2020.

- Assuming favorable NPRM public comment, a Final Rule published by September 1, 2021.
- A 3-year pre-implementation window following publication of the final rule, allowing (but not requiring) industry use beginning September 1, 2024. (This will allow sufficient time for planning and completion of necessary budget cycles.)
- Allow both versions (D.0 and F6) to be used for a 9-month period beginning September 1, 2024 and ending April 30, 2025 (This will enable an effective live-testing and transition period that allows the use of either the D.0 or F6.)
- Require full compliance by the end of the third year (i.e., F6 only beginning May 1, 2025).

NCVHS members discussed the proposed recommendations, with Ms. Goss and Mr. Coussoule explaining the thinking behind the recommended duration of the implementation period. Dr. Stead thanked NCPDP, the DSMO, and the Standards Subcommittee for the roles they played in expeditiously moving this forward. Ms. Goldstein expressed concern that the proposed timeline is too ambitious in the light of current circumstances; Mr. Landen noted that this is merely a recommendation, and HHS will modify the timeline if necessary. In that case, NCVHS would work with industry to adjust the timeline.

The Committee then unanimously approved a motion to adopt the recommendation as stated above, with a cover letter that includes acknowledgement of the possible impact of COVID-19 on timing.

Update: New Interoperability Rules

(Please refer to the transcript and slides for details of the presentations.)

- **CMS Interoperability and Patient Access Final Rule—Alexandra Mugge, Deputy Chief Informatics Officer, CMS (slides)**

Ms. Mugge discussed the attributes, timeline, and impacts of the new CMS interoperability rule, noting that it and the ONC rules (described in the next presentation) "mark the beginning of a new data exchange landscape."

CMS initiated the rule writing process because the lack of data exchange and transparency in health care has led to a fractured system in which data does not flow seamlessly among patients, providers, and payers. The goal of the rules is a connected health care system that works for these stakeholders as well as for researchers, developers, and others, thus providing the foundation for value-based care, documented in comprehensive patient records. A foundation of privacy and security underpins all the policies in the rule. Ms. Mugge stressed that "interoperability is a journey" in which the CMS and ONC rules are a step, not an endpoint.

She outlined a five-stage implementation process for the CMS rule, with the first policy going into effect in the Fall of 2020 (6 months from publication of the rule in the Federal Register). "The rubber hits the road for patient access" on January 1, 2021. At that point, patients will be able to access information on their claims and encounters plus some clinical information in a usable format on their chosen app, via their payers' APIs. Provider directories also will be available. In January 2022, all payers will be required to exchange data at a patient's request when the patient changes to another payer; and in April of that year, state Medicaid offices will have to exchange certain enrollee and eligibility information with CMS daily for the dual-eligible population. Ms. Mugge noted that the rule crosses the gamut of everyone CMS regulates.

After describing the privacy and security provisions in the rule, she highlighted the anticipated impacts for patients, providers, and payers. As a few examples, patients will benefit from access to improved provider directories and better care coordination; providers will have access to new data about patients; and payers will have easier data exchange with the providers seeing their enrollees. Finally, she referred to this source for additional resources: https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index.

- **21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule—Kate Tipping, JD, Branch Chief, and Mark Knee, Senior Policy Advisor, ONC Office of Policy (slides)**

Ms. Tipping noted that recordings and slides from ONC webinars on the present topic are available on the ONC website, to supplement this high-level presentation. She focused on the updates to the 2015 edition certification criteria, conditions, maintenance of certification, and enforcement.

The 21st Century Cures Act of December 2016 included Title IV, which deals with health IT and includes some regulatory requirements. ONC's March 2019 Notice of Proposed Rulemaking (NPRM) generated more than 2000 comments conveying a broad array of stakeholder feedback. The final rule supports the roles of patients, physicians, hospitals, developers, and the American public. Ms. Tipping reviewed the criteria and approach for updating the 2015 edition certification criteria. The new version removes or time-limits some criteria, revises some, and adds some (see slide).

The United States Core Data for Interoperability (USCDI) standard will replace the Common Clinical Data Set definition 24 months after publication of the final rule. ONC will establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.

Section 4002 of the 21st Century Cures Act requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program. The Conditions and Maintenance of Certification express initial and ongoing requirements for health IT developers and their certified Health IT Module(s). Noncompliance with the proposed Conditions and Maintenance of Certification requirements is subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program. Regarding enforcement, ONC is leveraging the directory view process already used for overall ONC surveillance. A non-conformity would result in a corrective action plan, with a certification ban as a consequence of failure to follow it.

Mr. Knee then talked about information blocking, reiterating the reference to ONC webinars and fact sheets for further information. Information blocking is defined as "a practice that is likely to interfere with the access, exchange, or use of electronic health information." He noted that "there are essentially two rules," one covering the topics covered by Ms. Tipping and one for information blocking. The Cures Act (Section 4004) defines information blocking as well as the reasonable and necessary activities that do not constitute blocking. It authorizes ONC to further identify situations in each category and the HHS Office of the Inspector General to investigate claims and address implementation and enforcement issues. It also establishes a penalty structure.

The Cures Act identifies four groups of actors that are regulated by the information blocking provision: developers, health information networks, health information exchanges, and health care providers; ONC in its rule combines networks and exchanges into a single category. In some cases, different criteria pertain to different actors (e.g., a higher threshold for providers regarding requisite knowledge).

Mr. Knee then outlined the compliance timeline and discussed some of the key terms and ideas in the regulations, noting in particular the importance of the definition of electronic health information. He then outlined the eight exceptions—i.e., reasonable and necessary activities that are not considered information blocking—and commented further on the "content and manner" exception (see slides). Finally, he pointed to the resources available at www.HealthIT.Gov/CuresRule.

In the discussion period, NCVHS members offered comments and questions on the applicability of other countries' laws; the advisability of sharing learnings with states working on all-payer claims databases and health data exchanges; and the evidence about the efficacy of patient/consumer education about apps, API usage, and other topics. Ms. Tipping promised to follow up with Ms. Goldstein on the latter topic, which Ms. Hines explained is a focus of the Subcommittee on Privacy, Confidentiality and Security.

Project Update: Convergence of Clinical and Administrative Data—Mr. Landen (slides)

Mr. Landen reported that the ONC's HITAC Intersection of Clinical and Administrative Data (ICAD) Task Force has just gotten off the ground to work on a vision, shared by both HITAC and NCVHS, for what NCVHS calls *convergence* and ONC refers to as *intersection*.

The NCVHS Charter notes the scope of the Committee's advisement to HHS around HIPAA; and when HIPAA was passed, there were no clinical standards. Today, however, technology and health care culture are "ripe to start merging" clinical and administrative data. The lack of harmonized clinical and administrative data standards and policy creates ecosystem burdens including inefficient workflows impacting patient outcomes, time-consuming discovery of payer specific requirements, and technical barriers related to vendor support and integrated platforms. All this impacts patient safety and the quality of health care delivery.

NCVHS and ONC/HITAC started exploring opportunities for collaboration toward these goals in March 2019. In the policy landscape, HIPAA, the Medicare Modernization Act, ARRA HITECH, and 21st Century Cures Act all encourage exchange of data and reduction of burden; and the Cures Act specifically asks ONC and NCVHS to intersect around this work. One challenge is that standards rulemaking authorities are separate across different programs.

The HITAC ICAD Task Force was created to support the convergence of clinical and administrative data in order to improve interoperability, support clinical care, reduce burden, and improve efficiency. As noted, four NCVHS members, representing both the standards and privacy subcommittees, serve on the task force. The NCVHS representatives to ICAD will brief NCVHS on its activities at full Committee meetings. Later in the meeting, Mr. Landen and Dr. Stead explained that NCVHS believes the resources available through the collaborative ICAD project will strengthen the Committee's ability to pursue its goals with regard to convergence.

The ICAD Task force will meet weekly, and all meetings are open to the public. The Task Force will produce recommendations for submission to HITAC, which in turn will make recommendations to ONC. It will share its deliverables with NCVHS, which will use it in the project described below. ICAD will also identify patient- and process-focused solutions. After completing its activities (by September 2020), ICAD will make public a summary of its findings.

Turning to the NCVHS project into which the integration/convergence initiative feeds, Mr. Landen noted that the convergence of clinical and administrative data emerged as a major priority in the NCVHS work on the Predictability Roadmap. He briefly reviewed the major themes of the Roadmap.

The Standards Subcommittee chose prior authorization as a test case or "exemplar" of convergence because it requires both clinical and administrative data, and today's fragmentation makes this very difficult for payers, providers, and patients. The Subcommittee aims to develop recommendations to support convergence, with an initial focus on prior authorization transactions and workflow. In collaboration with ONC, the Committee aims to identify and recommend a path toward convergence of administrative and clinical data standards, using the prior authorization processes of industry as an exemplar, thus to better understand and guide convergence paths for health care policy and standards. The project will have three phases over the coming year: information-gathering, analysis, and development of proposals for submission to HHS and industry. This work will be informed by the work of the ICAD Task Force, which reports to ONC's advisory committee, HITAC.

Finally, Mr. Landen reviewed the scoping document for this project. After brief discussion in which it was suggested that the project also identify best practices, NCVHS members agreed that the project is on the right track.

Committee Discussion—Dr. Stead

Dr. Stead reported that NCVHS received a letter from WEDI expressing strong support for the NCVHS letter to the Secretary on ICD-11 and offering WEDI's help in three areas. In addition, NCVHS received a letter from a French government agency, offering the assistance of people working in its health terminology management center as part of a collaborative effort in this area. Dr. Stead hailed these two communications as good signs that "the industry is engaging."

Finally, members shared their appreciation for the way this meeting was conducted and for the supporting technology, while expressing their strong preference for meeting in person. There being no public comment at this point, they recessed until the following day.

—DAY TWO—

Opening Remarks—Dr. Stead

Dr. Stead expressed gratitude to NCVHS members for making time to do the Committee's work while trying to "stay well, take care of their families, and deal with the crisis in the health system." He then reviewed the agenda and welcomed the first speaker.

NIST Privacy Framework-Naomi Lefkovitz, National Institute of Standards and Technology (slides)

(Please refer to the transcript and slides for details of the presentation.)

Ms. Lefkovitz, a Senior Privacy Policy Advisor for NIST, said the institute developed the Privacy Framework in response to requests for a framework for privacy similar to its Cybersecurity Framework. It is a voluntary tool. NIST released v1.0 in January 2020 after disseminating a request for information and months of conducting public workshops and webinars. The Framework is intended as a tool to help organizations manage privacy risk and make ethical decisions, to optimize the beneficial uses of data and minimize adverse consequences. It will also help organizations fulfill their compliance obligations. It is also meant to facilitate internal and external communication about privacy risk in a way that extends beyond cybersecurity risk, with which it shares some but not all characteristics. She noted the existence of both individual and organizational risks.

The Privacy Framework provides more information and guidance than the Cybersecurity Framework does, and includes a section on privacy risk assessment that helps in evaluating the trade-offs between the benefits and risks of data use and mitigating the risks to an acceptable level. NIST stresses the importance of privacy risk assessment to building customer trust, and Appendix D of the Framework suggests key privacy risk management practices and resources. Ms. Lefkovitz noted that assessment and control are an iterative process.

The Framework structure aligns with the three key components of the Cybersecurity Framework: the core, profiles, and implementation tiers. The core provides a granular set of activities and outcomes to enable an organizational to dialogue about managing privacy risk. The profiles drive the risk-based approach of the Framework and are a way to prioritize activities and outcomes for managing privacy risks. The implementation tiers are a set of benchmarks for thinking through whether processes and resources are sufficient for achieving the goals. The cross-cutting functions in the structure are "identify, govern, control, communicate, protect."

NIST chose to "meet organizations where they are today" and to show flexibility in how they can use the two NIST frameworks together. The idea is to enable a conversation inside organizations about the resources they need in order to achieve a given target profile with respect to cybersecurity and privacy. NIST expects to have an ongoing conversation with stakeholders about how to simplify and align the approaches in the two frameworks. They are designed to be agnostic to any specific laws or regulations. There is a resource repository on the NIST website to which stakeholders are invited to contribute.

As next steps, Ms. Lefkovitz stressed the hope that the Privacy Framework will be adopted, and that NIST will receive implementation feedback. It created a companion roadmap to highlight areas of continuing challenge, including privacy risk assessment, emerging technologies, inventory and mapping, and international developments.

Discussion

In the brief discussion period, NCVHS members praised the NIST Framework, noted its potential usefulness in the public health arena, and expressed concern that small providers and other entities in the health care ecosystem will not have the bandwidth or expertise to take advantage of it. Ms. Seeger said OCR wants to help get the Framework out, and that while it does not map directly to the OCR audit protocol, OCR and NIST are talking about a crosswalk from the NIST Framework to the HIPAA privacy rule. Ms. Lefkovitz invited advice from NCVHS about dissemination of the Framework.

Safeguarding the Bioeconomy—Edward H. You, HHS Office of National Security (slides)

(Please refer to the transcript and slides for details of the presentation.)

Mr. You is a Supervisory Special Agent with the FBI's Weapons of Mass Destruction Directorate who is detailed to HHS to look at the growing biotechnology challenges. He uses the term "bioeconomy" to expand the scope of thinking about what constitutes a biological threat, given that such threats pose risks to multiple sectors and thus to the national economy. The health sector is one of the fastest growing areas in biotechnology, notably through personalized medicine and the generation and use of genetic information. Data has become "the new oil"—the resources upon which new technologies and applications are built. The combination of longitudinal and genetic data facilitates personalized treatments. The federal government is leading the effort, with the NIH *All of Us* program and the Department of Veterans Affairs' Million Veteran Program. The private sector is also jumping on board,

with direct-to-consumer resources such as 23andMe. There are evolving connections between data and clinical services; for example, 23and Me has invested heavily in pharmaceutical design and development using the data to which it has access.

Mr. You stressed that the combination of biologically relevant longitudinal data with genetic data creates risks that go far beyond potential privacy and fraud issues. He cited a number of examples of partnerships between U.S.-based companies and government entities and enterprises in China and elsewhere, and stressed that access to such data by foreign entities can give them considerable economic power and lead to dependency on "a foreign supply chain" by U.S. citizens and organizations. (As one example of "insidious" data abuse, he said China used 140,000 prenatal clinical samples to identify ethnic Uighurs.) He questioned how many U.S. companies have foreign investments or partnerships, and whether consumers understand the potential uses of their data when they use these companies' services. He pointed to the failure to recognize "the true nature and value of health data," especially from a national security standpoint, with consequences for the cooptation of business models and job opportunities among other risks. He cited several existing partnerships between U.S. and Chinese entities in the health arena, and said the Chinese government is now clamping down on sharing biological material and data. He pointed out the need to support innovation as well as to address security.

Mr. You hosted a series of workshops with AAS and the National Academy of Sciences that convened representatives from major technology and telecommunications companies to talk about where the U.S. economy is going with biological data. The conclusion was that while the U.S. is doing a lot in privacy policy with respect to clinical data, it is not doing much to address national security. A series of short meeting reports were generated that have helped change legislation; and both Congress and the Defense Department have "woken up." The workshops led to a National Academy of Sciences consensus study report, "Safeguarding the Bioeconomy," released in February 2020. After commenting on the COVID-19 pandemic from this perspective, he warned that we may be "giving them the keys to the kingdom if we don't understand the value of our data today." Finally, he noted that Russia, Iran, and other countries are in this space (which he later called "a biological space race") as well as China and are potential competitors of the U.S., unless they can become strategic partners.

Discussion

NCVHS members engaged in rich discussion with Mr. You about his presentation. Asked for his policy recommendations, he pointed to the recommendations in the National Academy study report. He reiterated the need for a perspective that "overlays" privacy protection with national security. Mr. Pasquale proposed that given China's key role in developing essential technologies, it is advisable to create cooperative approaches that protect U.S. interests rather than blocking access to data. Mr. You agreed, but stressed the need for due diligence and reciprocity. He added that some best practices have been implemented in the U.S. Ms. Goss commented on the importance of citizen involvement, education, and awareness, to encourage consumers to become active and astute participants in this endeavor; however, others noted that few consumers are equipped to make the necessary decisions. Finally, Mr. You asked NCVHS to help raise awareness of the concerns he has outlined, and Ms. Hines suggested that the Committee think about how it might encourage strategic thinking in this area.

Subcommittee on Privacy, Confidentiality and Security (PCS) Workplan Discussion—Mr. Pasquale (slides)

Mr. Pasquale, who co-chairs the PCS Subcommittee, presented a set of possible themes for the Subcommittee's 2020-21 work plan for discussion by the Full Committee. Subcommittee members have identified these two priorities: 1) trusted public health surveillance infrastructure in the face of new pandemic threats, and 2) unexpected or unintended consequences of interoperability rules requiring HIPAA-covered providers to transfer data to non-HIPAA covered entities. In addition, they have identified several secondary topics, including artificial intelligence, data on opioid and substance use disorder, and a research agenda on de-identification.

The aspects of the first topic, a trusted public health surveillance infrastructure, include technology (including international examples and domestic proposals), emergency exceptions, secondary uses, ethics and bias, data security, and the patchwork of laws. Mr. Pasquale commented briefly on each of these. The second proposed topic, unintended consequences of interoperability, addresses concerns articulated in the NCVHS *Beyond HIPAA* initiative. He proposed the possibility of the Subcommittee having a primary and a secondary focus encompassing both topics, in each case starting with an environmental scan to determine what other work is going on in these areas and where the relevant expertise exists. He then asked for discussion of these ideas.

Members expressed support for the two identified priorities, and suggested ways to shape or focus them as well as ways to think about the Subcommittee's work in general. The comments included these:

- The key is to recognize the dynamic nature of the environment and to be nimble and strategic.
- Frame the task for topic 1 as finding the (appropriate) scope of public health surveillance.
- Identify potential operating partners for the project.
- Look at state-level epidemiology and public health databases.
- Take a multi-layered approach to stewardship rules, and use multifaceted thinking.
- Take into consideration past NCVHS work in PCS, vital records, and population health.
- Bear in mind that public health reporting in the future will involve two directions that need to be complementary: 1) getting robust vitals and related data based on identified data collected and maintained in a secure, privacy-enhanced fashion, and 2) strengthening the ability to use non-identified signals to determine patterns.
- Explore novel data sources such as social media.
- Pay attention to international issues and possible partnerships with WHO and PAHO as well as the National Academy of Medicine.
- Include the issue of erratic redactions of sensitive information by payers and providers.
- As part of the environmental scan, convene a roundtable early in the next federal fiscal year to look at the data coming out of third parties and to explore industry perspectives.

Mr. Pasquale said the discussion had provided the outlines of a project scoping document. Asked about the choice between a single project or two projects, Mr. Pasquale proposed being in a monitoring mode on the *Beyond HIPAA* implications of interoperability. Several members spoke in favor of a dual track of some sort. Ms. Bernstein shared her sense that NCVHS could make meaningful contributions in the proposed areas, and she reminded the Committee of Dr. Arnold's request for ideas about novel data sources.

Update on FHIR At-Scale Task Force (FAST)—Chris Muir and Stephen Konya, ONC (slides)

(Please refer to the transcript and slides for details of the presentations.)

Mr. Muir, who directs ONC's Standards Division, discussed the context for FAST. He outlined the multiple collaborative efforts that are developing solutions in the context of the HL7 Fast Health Interoperability Resources (FHIR) initiative, including the Argonaut project, the DaVinci Project, and the Care Alliance. The FAST Initiative addresses the infrastructure challenges holding back the deployment and adoption at scale of such solutions. ONC convened a broad group of health care industry stakeholders and health IT technical experts in the FAST task force to analyze FHIR scalability gaps and barriers and identify ways to accelerate adoption at scale. ONC is focusing on the mandates and goals laid out in the Cures Act, in order to enable providers to spend more time caring for their patients and patients to have more active roles in their health care decisions and health management. ONC's rulemaking is directed at achieving these goals. FAST will help ensure that the new API ecosystem is scalable and allows third party apps to enhance information sharing and use.

Mr. Konya, a Senior Innovation Strategist at ONC and Lead for the FHIR FAST taskforce, described the project. The FAST initiative is "smoothing the runway" for the rollout of APIs to scale, for better access to data. He stressed that antitrust laws are strictly observed in its proceedings. FAST is the new name of the former P2 FHIR Task Force, which worked on payer and provider data-sharing. The name was changed to shift the focus to FHIR scalability issues and to be open to any stakeholder group with this concern.

The FAST Initiative was launched in January 2019. The organization has three key layers, supported by an external fourth one. There are seven Tiger teams, with 8 to 15 members each, which meet individually, biweekly. The Coordinating Committee has 30 to 40 members and meets monthly to guide the work of the Tiger teams. The Executive Steering Committee meets four to five times a year and is composed of C-suite-level representatives of participating organizations. Periodically, FAST checks its work with an external Technical Learning Community that is part of a listserv with several hundred members. Anyone can join it, and Mr. Konya encouraged NCVHS members to do so. This body serves as a way of building awareness and eliciting input to be sure the initiative stays on the right track.

He enumerated a number of technical and other barriers to information flow and outlined some of FAST's projects. In general, FAST tries to come up with solutions to technical issues and common scalability approaches to functional use cases that emerge from ecosystem projects such as Argonaut and DaVinci. One tiger team will design pilots to evaluate the solutions and move them toward adoption. Mr. Konya described a number of specific solutions that have been proposed to date. All content including the FAST annual report is available at https://tinyurl.com/ONC-FAST. FAST also will present its work at several industry events.

When asked about the anticipated timeline for launching solutions, Mr. Konya said some solutions may be piloted by the end of 2020. Dr. Stead noted that the challenge for the FAST Initiative is the transition from "the use case-based FHIR world to something that has to be predictable at scale."

2020 NCVHS Workplan

Members and staff briefly reviewed the NCVHS workplan.

Public Comments

There were no public comments.

Closing Remarks—Dr. Stead

Dr. Stead thanked everyone for engaging productively in this meeting, and thanked Ms. Hines for being "an unbelievable champion" in organizing it. Ms. Hines thanked the NCVHS staff and meeting logistic support for their contributions to this "team sport."

Dr. Stead then adjourned the meeting.

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

/s/	June 11, 2020
Chair	Date