**Department of Health and Human Services**
**NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS**
**June 17-18, 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 June 2020 meeting page.*

Due to the COVID-19 pandemic, the National Committee on Vital and Health Statistics was convened virtually via Zoom on June 17-18, 2020. The meeting was open to the public. Present:

**Committee Members**
William W. Stead, MD, Chair
Denise Chrysler, JD
James Cimino, MD
Llewellyn Cornelius, PhD, LCSW
Nicholas Coussoule
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

**Executive Staff**

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

**Lead Staff**
Lorraine Doo, MPH, *CMS*
Rachel Seeger, MA, MPA, *OCR*
Maya Bernstein, JD, *ASPE*

**Guest Presenters**
Paul Sutton, PhD, *NCHS*
Brian Moyer, PhD, *NCHS*
Chesley Richards, MD, *CDC*
Helen Nissenbaum, JD, *Cornell Tech*
Mark Rothstein, JD, *Univ. of Louisville*
Daniel Kalwa, *CMS*

In addition, 122 individuals – members of the public and other federal staff – virtually attended the meeting on day 1, and 62 attended virtually on day 2.

## —DAY ONE—

### Welcome, Roll Call and Agenda Review—Ms. Hines & Dr. Stead

Ms. Hines welcomed Committee members and members of the public, noting the especially challenging time during the pandemic. After conducting roll call, she turned it over to Dr Stead who welcomed new member Dr. James Cimino to his first NCVHS meeting, Dr. Stead reviewed the two-day meeting agenda and introduced Dr. Arnold.

### ASPE Update—Sharon Arnold, Executive Staff Director

Dr. Arnold noted that telework had just begun at HHS when NCVHS last met, in March. Most staff members are still working from home, though the Office of the Secretary and the Secretary's Operation Center at the Humphrey Building remain open. The Department is dealing with two public health emergencies, the COVID-19 crisis and the civil rights protests spurred by the death of George Floyd. She outlined a number of guidances issued by OCR, FDA, and CDC in response to these crises, in addition to ongoing data updates.

The CARES Act provided funding for many health and human services programs, including more than $1 billion for the Indian Health Service. Research activities include Operation Warp Speed, which aims to deliver 300 million doses of a safe and effective COVID-19 vaccine by January 2021. NIH launched a centralized, secure enclave to store and study medical record data for people diagnosed with the disease. HHS is using supercomputing facilities and personnel to help analyze the data. The Census deployed a household Pulse Survey via email and texts to study the impacts of the pandemic on households across the U.S. ASPE is also working on the FY2022 budget and preparing for hurricane season.

In closing, Dr. Arnold acknowledged the service of three retiring NCVHS members: Lee Cornelius, Alix Goss, and Bill Stead. She stressed Dr. Cornelius's contributions to the Committee's work on population health data and noted his lifetime achievement award from the Council on Social Work Education for his work on social and economic justice. She recognized Ms. Goss' leadership as co-chair of the Standards Subcommittee, notably around the Predictability Roadmap and burden reduction. Finally, she acknowledged Dr. Stead's visionary leadership as co-chair of the Subcommittee on Population Health for three years and then as Committee Chair since 2016. She noted his cultivation of enriching partnerships with many governmental and non-governmental entities and his emphasis on tangible recommendations that address near-term challenges while also bringing the long view. She expressed gratitude to all three retiring members for their accomplishments and service.

In the discussion period with NCVHS members, Dr. Arnold asked for the Committee's guidance on ways to share information on people's COVID-19 status to maximize transparency as well as privacy and confidentiality protection. She also asked for the Committee's guidance on using and protecting new data sources.

Members suggested a gap analysis on what other data is needed; noted deficiencies in race and ethnicity data and the need to standardize collection at the point of care; wondered about ways to improve data collection from the states as part of the modernization initiative; and asked about the usefulness to the Department of the 2018 NCVHS recommendations on the U.S. vital registration and vital statistics system.

**Update from the Director of the National Center for Health Statistics, Brian Moyer, Ph.D. (slides)**

Ms. Hines welcomed the new NCHS Director, Dr. Brian Moyer. He was previously Director of the Federal Bureau of Economic Analysis (BEA), where he oversaw innovation efforts to modernize statistical concepts, methods, and operations, including expanded use of big data. Dr. Moyer served at the BEA (the principal federal statistical agency that produces GDP measures for the U.S.) for 27 years and directed it for 10 years. He also served in the Commerce Department as Acting Undersecretary for Economic Affairs, with responsibility for the Census Bureau. He focused his NCVHS briefing on the Center's work on data modernization, workforce enhancements, and the response to the COVID-19 pandemic; he also touched on budget developments.

Data modernization and the future NCHS workforce future are key parts of the vision for NCHS. The data modernization initiative aims for progress in harnessing new data sources and techniques; expansion of the capacity for statistical analysis; and better connecting NCHS work with the broader CDC enterprise and federal statistical system. The vision for the NCHS workforce involves promoting more coordination and collaboration and encouraging more innovation across all staff.

Dr. Moyer then outlined some of the impacts of COVID-19 on NCHS work and described its response to the pandemic. Household surveys have been moved to the telephone, and N-HANES is out of the field until further notice. Most staff are working from home, and some are assisting with the CDC/federal government response. NCHS is accelerating the availability of its statistics (notably, with timely death counts), expanding its surveys with questions on COVID, and partnering with the federal statistical community (e.g., on the Pulse Survey). On the latter survey, he stressed the rapidity with which the statistical community has come together to put a survey in place and get the results out to the public. He then briefly commented on the FY2021 budget, which is still uncertain.

Returning to CDC modernization, he noted that Dr. Richards would talk later in the meeting about this initiative. CDC is allocating $500 million in funds for COVID-19 related modernization, and NCHS has made proposals that it hopes will be accepted as part of the broad CDC strategy. NCHS hopes to upgrade the Vital Statistics System, with attention to past NCVHS recommendations on this subject. It also proposes improvements to the modeling for forecasting the COVID spread and impact.

Dr. Stead thanked Dr. Moyer, stressed the Committee's interdisciplinary and diverse nature as a resource to NCHS, and expressed hope that this dialog can continue at subsequent NCVHS meetings.

**Subcommittee on Privacy, Confidentiality and Security Project Scoping — Mr. Frank Pasquale (slides)** *(Please refer to the transcript and slides for details.)*

This was the first of three sessions on privacy and confidentiality, facilitated by the PCS Subcommittee chair, Frank Pasquale. This session addressed project scoping for the Subcommittee, which Mr. Pasquale chairs. The second session featured presentations by two experts; and in the third, on day two of the meeting, the Committee discussed next steps.

As a near-term project, ASPE has asked NCVHS to recommend a toolkit for state and local health agencies on how to collect, use, protect, and share data responsibly during a pandemic. For the longer term, the Subcommittee is considering several possible projects, including 1) how to contribute to a trusted public health surveillance infrastructure in the face of new pandemic threats; 2) the unexpected or unintended consequences of interoperability rules requiring HIPAA-covered providers to transfer data to non-HIPAA

covered entities; and 3) five possible "secondary topics" that may be beyond the Committee's bandwidth (see slides for details).

Regarding the toolkit requested by ASPE, Mr. Pasquale outlined a number of relevant topics, including what *should* happen with data in an emergency, fair information principles for a pandemic, what data should be collected, and what best practices can be learned from. He noted that in 2015, NCVHS released a toolkit for communities using health data; if it provides a framework for analysis, he wondered how it might be updated or supplemented for the current public health crisis. He added that it would be important to look at case studies, to see the projects being proposed and the analyses being conducted.

After commenting briefly on waivers, data use agreements, accountable sharing, transparency, community involvement, and security, he invited NCVHS colleagues to discuss these ideas and project options, in order to determine what resonates with Committee members and is doable in 6-12 months.

- **Discussion**

In the highly appreciative discussion, a major theme was the importance, in Ms. Goss's words, of "finding the right slice of the pie" for moving forward with an impactful yet manageable project. Mr. Pasquale mentioned data use agreements as one possible focus; Dr. Mays pointed to contact tracing as an activity with the potential to "go off the rails." She noted the critical importance of training on protecting the data. Dr. Stead suggested trying to do something within a very few months and endorsed the intersection of contact-tracing and data use agreements as a fertile set of topics for a longer-term project. Ms. Love suggested a retrospective assessment of what worked and what didn't, with attention to public versus private roles in this area. Ms. Chrysler suggested "tracking the blow-back."

### NCVHS 14th Report to Congress—Mr. Coussoule (slides)

NCVHS is mandated to submit a regular report to Congress on the implementation of the administrative simplification provisions of HIPAA. The Committee began discussion of its preparations for the 14th report to Congress with a planned publication date falling in spring 2021. Mr. Coussoule explained that NCVHS has traditionally used the document to report on recent history – in the timespan forward from the 13th report – including the recent work of the Committee, and the opportunities and next steps that lie ahead. He outlined the major themes in the 12th (2017) and 13th (2019) reports, noting several that continue to be relevant. The 13th report was comprehensive, and stressed a call to action in several areas. It is expected that the 14th report will take a less holistic approach and will aim to lay out the work needed for improving administrative and clinical data coordination. He noted that NCVHS has had several significant accomplishments in 2019-20 related to privacy protections beyond HIPAA, the predictability roadmap, health terminologies and vocabularies, and recommendations on ICD-11. These will be covered in the 14th report. He suggested these major themes for the 14th report:

1. Update on the status of NCVHS recommendations on implementation of the HIPAA administrative simplification provisions and the impact of action or inaction on the furtherance of automation.

2. Original HIPAA Administrative Simplification regulations have been an accelerant for driving transaction automation and reducing burden on payers and providers.

3. The world has changed in multiple ways that make the existing regulatory process and structure a barrier to improvement instead of an accelerant. In particular, there is a need for a more cohesive and aggressive integration between clinical and administrative functions and attendant data, with resulting burden reduction.

Finally, Mr. Coussoule described the timeline for this project: outlining during the summer, drafting beginning in the Fall – with substantive contributions from each Subcommittee – refinement in the early winter, and finalization of the document in late winter 2021.

NCVHS members then discussed this approach. Ms. Goss suggested addressing the fact that the Committee's extensive work on the Predictability Roadmap, with significant input from the industry, has not yet generated traction in terms of the federal response. This topic would include understanding the barriers encountered by federal partners. Mr. Landen noted that there will be new members in Congress, and a narrower focus for the report will be appropriate. Dr. Stead pointed out that in their planning for projects and deliverables, subcommittees should bear in mind that the 14th report will cover NCVHS work through 2020.

Ms. Hines said that in the next few weeks, Subcommittee leaders would be asked to help think through the framing of the report and to contribute to its content.

**NCHS Update: National Vital Statistics System's Response to COVID-19—Paul Sutton, Ph.D. (slides)**
*(Please refer to the transcript and slides for details.)*

Dr. Sutton is Deputy Director of the NCHS Division of Vital Statistics (DVS). He noted that DVS has been working for a number of years on modernizing the system to improve timeliness and efficiencies, such as those related to electronic death registration and interoperability; and these improvements are very relevant to the demands imposed by responding to COVID. Having gained experience in releasing provisional data and quarterly estimates, the Division is more flexible, timely, and responsive to major events than in the past.

Awareness of COVID began at NCHS in early February, with the expectation that it could have major significance. The DVS released its first preliminary guidance on how to certify a COVID-19 death on March 4, 2020. A new cause of death, with a new ICD-10 code, had to be established, and a new COVID-19 page. In mid-April, DVS did a webinar for thousands of clinicians who would be certifying deaths. Manual coding was initially prioritized because of the anticipated high volume. The certification guidance addressed special issues such as the use of abbreviations and reporting the cause of death as "probable." Cause of death coding practices at NCHS had to be modified and updated. For example, manual coding had to be managed, as the number of records that had to be coded by NCHS nosologists nearly doubled. Over time, auto-coding increased.

NCHS began releasing provisional data on COVID-19 deaths in early April, with weekly updates. Dr. Sutton stressed that the data are "largely incomplete," because of the time it takes to complete death certificates, exacerbated by the extra time it takes to code COVID deaths. Provisional data are by definition subject to change. Because the data are incomplete, DVS has tried to assess the excess mortality resulting from COVID-19. It also has continually expanded the amount of detail in its updates, such as by adding tables related to sex, age, race and Hispanic origin, and geographic detail, with distributions of deaths across groups. Staff are looking at ways to better present and control for confounding factors such as age. Working with the National Center for Immunization and Respiratory Diseases in Atlanta, DVS is monitoring and reporting the rate of excess deaths due to the pandemic. There is an effort to put

together visualizations to show the excess mortality from this cause, both for the U.S. as a whole and for specific jurisdictions. COVID-19 death counts are reported on four CDC/NCHS websites, with download and APIs for automatic access. (See slide.)

- **Discussion**

Members had a number of questions and comments for Dr. Sutton. Asked about the possibility to decouple reporting the fact of death from the other information, to increase timeliness, he said this idea had not been discussed but that it was potentially problematic in his view. To another question, he commented on the possibility of publishing confidence intervals for provisional data. He added that he saw this as DVS's next big challenge, if provisional data is used increasingly even after COVID-19 recedes. Dr. Mays engaged him on the likelihood that modernization will improve the speed of access to race and ethnicity data in mortality data, especially in relation to epidemics, for example in Puerto Rico. They also discussed the disconnects between NCHS systems and the National Violent Death Reporting System, a CDC system. He acknowledged that "there's still a lot of progress to be made" in these areas, although work has begun on them. Ms. Love pointed out that state hospital discharge data reporting systems and the NUBC DR code will ultimately be rich sources for validating death coding. Dr. Sutton said that NCHS is starting to look at more options for linking vitals to other data sources.

### CDC Public Health Data Modernization Initiative—Chesley Richards, MD, MPH

*(Please refer to the transcript for details.)*

Dr. Richards, Deputy Director for Public Health Science and Surveillance at CDC, advises the CDC director and senior leadership about data modernization. His remarks covered the following topics: the vision, the data modernization initiative, the impact of COVID-19, and common themes that CDC and public health agencies are wrestling with.

The CDC vision is "real-time data for real-time action." This will require improvements across the U.S. in the public health workforce and in technologies and tools. The CDC surveillance strategy, starting in 2014, aimed to improve the crosscutting data streams on which the agency depends. Despite limited funding, Dr. Sutton along with Delton Atkinson and Charlie Rothwell made progress on electronic death reporting and registration, among other areas that include syndromic surveillance. In 2018, such efforts crystalized into the Data Modernization initiative, a priority of current CDC Director Dr. Redfield, with Congressional support. Although the vision was for a $1 billion investment in public health data over 10 years, it got a $50 million appropriation in 2020. Funds have been going out to the states, and some used for CDC modernization. The Digital Bridge initiative also improved electronic case reporting, especially relevant for the COVID response. The Robert Wood Johnson Foundation funded the initial efforts, championed by RWJF Vice President and former NCVHS Chair John Lumpkin.

In response to COVID-19, CDC received $500m through CARES legislation. The idea is to invest in a data infrastructure at CDC and in public health to create a data superhighway in place of the sometimes "archaic" ways data are moved today. One advance has been creation of a "data analytic data lake" to leverage more than 200 data streams. HHS now manages a computing environment for performing integrated analyses. One concern is the continuing costs that will be needed to continue progress beyond COVID-19. The President's 2021 budget includes $30m for the data modernization initiative.

Key activities include supporting the states, and through them local public health agencies as well as nongovernmental organizations, with technical support, partnering with academic institutions and the private sector. CDC will accelerate its data ecosystem, upgrade its own data science workforce and tools,

and support innovation. This includes using artificial intelligence decision support to better predict and plan for what is coming.

Finally, Dr. Richards turned to the common themes that must be wrestled with. First is the tension between the national scale and local control. The second is workforce issues and the tools available to incoming workers. Another is a systems issue related to the balance between integration and the ability to understand individual diseases, which can lead to silos. Other issues include costs and how to resource public health activities; standards development and adoption; data collection versus harvesting the data in other sources including EHRs; and questions of data ownership and control.

- **Discussion**

Dr. Stead responded that Dr. Richards' comments align well with NCVHS's thinking in its deep dive into vital records and statistics systems. He asked how NCVHS could be helpful. Dr. Richards thanked the Committee for its recommendations based on that study. He suggested that NCVHS continue to make its recommendations for federal leadership and investment in a more resilient and coordinated system "an important part of what you tell the Secretary." He added that people at the federal level should not simply impose things on states and locales in a heavy-handed way; there must be a partnership, with benefits at all levels of the system. This has been evident in the work on COVID-19.

Noting the large variations among state capacities, Dr. Mays suggested creating an analysis or model to help identify the specific gaps for specific states that need to be fixed, to inform Congress and others. Dr. Richards welcomed this idea. He also commented on the potential to use tools like natural language processing and decision support to improve accuracy and timeliness of birth reporting and improve the NVDRS. Ms. Love called attention to all-payer claims data bases as a potentially useful data source on public health, and they discussed the potential state uses of synthetic data.

Mr. Landen pointed to the work by ONC on harnessing the data in EHRs, practice management systems, and other sources. Dr. Richard said CDC has a good and strengthening relationship with ONC. He asked the Committee to offer advice on fruitful approaches in this realm that are relevant to public health. Ms. Goss noted that Dr. Richards' comments and vision with respect to public health have implications for widening the scope of the Standards Subcommittee's project on clinical/administrative data convergence. Ms. Goldstein raised the issue of public trust and privacy protection with respect to surveillance data.

Finally, from the audience, Nancy Kreiger of Harvard School of Public Health sent a comment about how the aggregations in the reporting of age-specific death rates for COVID-19 obscure significant findings about racial and ethnic inequities. Dr. Sutton said NCHS is aware of this and related issues, and is looking for ways to expand data on race without compromising privacy and confidentiality.

### Privacy, Confidentiality, and Security Perspective on Data Collection and Use During the COVID-19 Public Health Emergency

Mr. Pasquale introduced this session, which featured two expert presenters. He said Dr. Nissenbaum's co-authored work on "privacy disaster or disaster for privacy" is relevant to the thinking about data use in the context of emergencies, as well as to broader questions related to data misuse.

- **Understanding Privacy through the Lens of Contextual Integrity—Helen Nissenbaum, PhD (slides)** *(Please refer to the transcript and slides for details.)*

Dr. Nissenbaum is Professor of Information Science at Cornell Tech. Her work spans the societal, ethical, and political dimensions of information technology and digital media. She introduced the Committee to the theory of contextual integrity as a way of understanding privacy, particularly in relation to digital technology. This approach is relevant to COVID contact tracing and Google/Apple's APIs, and provides a way of querying what is going on.

The theory of contextual integrity frames privacy as "appropriate flow" that conforms with "legitimate contextual informational norms." The contexts referred to are social domains such as health care, education, and politics, each with its own goals and norms. The theory, or lens, seeks to understand what people mean when they say their privacy is at risk or has been violated by technologies. Dr. Nissenbaum used the example of "assisted health surveillance." The issue in using mobile phones for contact tracing is how to avoid "Trojan horses." After showing the technological process for such tracing as proposed by Apple and Google, she raised a number of questions such as who maintains the database and benefits from the knowledge it accumulates, where the processing is done, and what informs the decision to alert a person that s/he has been infected.

Contextual integrity offers new ways to think about privacy other than simply in terms of control, secrecy, sensitive information, and consent; again, it frames privacy as appropriate information flow. To assess this, the flows are mapped in terms of five active parameters: the three actors (data subject, sender, recipient), information types, and transmission principles. These are compared with entrenched information norms and assessed with respect to contextual ends, purposes, and values. The norms of legitimate information flow protect the interests of all concerned, and serve specific articulated values such as equity and the curing of disease. Dr. Nissenbaum described the assessment as an empirical process with "actual discovery."

To illustrate, she referred to an assessment of 15 disaster apps that she conducted with colleagues Madelyne Sanfilippo et al, recently published in *The Journal of the Association for Information Science and Technology*. In conclusion, she said that to evaluate the contextual integrity of contact tracing apps, it is necessary to have information about how the apps work in order to map the flows, identify the risks, and determine whether public health authorities can benefit from the knowledge.

- **Mark Rothstein, JD**

Mr. Rothstein has a joint appointment at the University of Louisville's Brandeis School of Law and School of Medicine. His research concentrates on bioethics, genetics, health privacy, public health law, and employment law. He was Chair of the NCVHS Subcommittee on Privacy, Confidentiality and Security from 1999 to 2008. His remarks are also in a forthcoming editorial of *The American Journal of Public Health*.

The fundamental ethical, legal, and policy challenge in public health is balancing public and individual interest. The conflict between these interests that is now evident in the context of COVID-19 has long existed with respect to the collection, use, and disclosure of health information. The ethics and policy issue today is whether—and if so, how—to permit the use of technologies to help control the pandemic.

Mr. Rothstein proposed four criteria for answering this question: 1) necessity and effectiveness, 2) proportionality and minimal infringement, 3) purpose limitation, and 4) justice.

1) Necessity and effectiveness: No public health intervention should be introduced without compelling evidence of its necessity and effectiveness. With the current deadly pathogen, some clinical and information-gathering measures have been implemented without clear evidence of their necessity or effectiveness. Citing thermal screen as an example of a measure with no proven effectiveness, he asserted that the stakes are too high to employ measures whose main value is symbolic.

2) Proportionality and minimal infringement: Public health interventions should be proportional to the risk, with consideration for the value of the information to public health. The degree of infringement relates to the sensitivity of the information, the presence or absence of consent, and the availability of less intrusive means. The principles of minimum necessary and least-identifiable form are relevant, along with the need for security measures.

3) Purpose limitation: Data collected for a specific purpose should be used only for that purpose. This requirement may conflict with big data analytics and other health surveillance technologies. It also raises questions about contact tracing that is not voluntary, uses invasive technologies, or leads to stigmatization. The use of data from other sources for public health uses is especially problematic, particularly if they involve sensitive data.

4) Justice: Fairly allocating the burdens and benefits of health information policies requires consideration of information practices in a broader context, notably the impact on vulnerable populations. This criterion requires attention to racial disparities, criminal justice, economic inequities, and other types of vulnerability. Will any health benefits derived from collecting and using health information extend to all members of society?

Mr. Rothstein concluded that whatever aggressive public health data practices are deemed necessary in response to COVID-19 should be continually evaluated using these four criteria. And when the emergency ends, intrusive health information practices initiated during the pandemic that are no longer necessary should be discontinued.

- **Discussion**

The first discussion theme to arise was the need to look at the cultural and legal differences among societies when considering the applicability of screening and contact tracing models used successfully in other countries. Technological approaches require suitable constraints, though questions were raised about the feasibility of constraining the uses of the data once "the barn doors are open" in the words of Mr. Coussoule. Members expressed concerns about the limitations on public acceptance and trust in the current, politicized environment in the U.S. Responding to an observation about younger Americans' greater relaxation with the uses of their data, Mr. Rothstein attributed this difference to their stage in the life cycle—their youth—rather than to fundamental and permanent differences between the generations. Commenting on Mr. Rothstein's third criterion, Ms. Love pointed out the socially positive uses of repurposed data for managing public health, and cautioned against a wholesale rejection of repurposing. He explained that the need for constraints depends on the sensitivity of the data and the intended

purpose. Dr. Nissenbaum noted that contextual integrity "forces a different kind of thinking" with respect to these issues. She added that Fair Information Practice Principles are problematic because the legitimacy of the intended purpose also needs to be evaluated. Dr. Mays noted the additional concerns present when the subjects of the data are vulnerable.

**—DAY TWO—**

### Welcome, Roll Call and Opening Remarks—Ms. Hines & Dr. Stead

After a welcome and roll call, Ms. Hines turned the floor over to Dr. Stead who welcomed participants and reviewed the agenda.

### Subcommittee on Standards—Ms. Goss, Mr. Landen (slides)

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

This session covered three topics: 1) an update on the Committee's March 2020 recommendations for adoption of updated NCPDP HIPAA standards; 2) an update on the HITAC Task Force on Intersection of Clinical and Administrative Data (ICAD); and 3) plans for the August 25-26 NCVHS hearing on CAQH CORE Operating Rules proposed for federal adoption.

(1) At its March 2020 meeting, NCVHS deliberated the NCPDP F6 standard, and voted to make two recommendations to the Secretary on NCPDP HIPAA standards: adoption of F6, and a timeline for its adoption. Subsequently, the Executive Subcommittee approved a letter to HHS adding a third recommendation clarifying the status of the NCVHS recommendations on Batch Version 10 and Medicaid Subrogation that had been associated with the May NCVHS 2018 recommendation to adopt F2. The letter was submitted to HHS on April 22, 2020 and acknowledged by the Department on June 9.

(2) The NCVHS Subcommittee on Standards and the ONC Health Information Technology Advisory Committee (HITAC) have joined forces to work on the Intersection of Clinical and Administrative Data, coordinated by ONC/HITAC task force by that name (ICAD). Ms. Goss co-chairs it with Sheryl Turney, and four NCVHS members with varied expertise sit on the task force. The traditional NCVHS focus on administrative data and the HITAC focus on EHR clinical data complement each other; and both are interested in facilitating the convergence of these data to improve data interoperability and support clinical care, reduce burden, and improve efficiency. The use case chosen for the project is prior authorization, which has been a difficult-to-solve source of burden for providers; however, the project is intended to inform the larger conversation about convergence.

ICAD began weekly meetings in March, and created several offline work groups to address various topics. It will produce a report to HITAC in the Fall that will inform the NCVHS Standards Subcommittee's work on its own, larger convergence project. The NCVHS work will leverage input from the community and considerable background work by NCVHS and HITAC.

After summarizing the timeline and process for the work of the task force, Ms. Goss invited the other NCVHS ICAD members to add their comments. Mr. Landen stressed the leadership by industry stakeholders in addressing these issues and sharing their findings. He also noted the direct patient involvement in the deliberations, due to the fact that, in contrast with other transactions, they are directly affected by prior authorization. He predicted that the mechanisms for getting patients' input can be leveraged for other transactions in the future. Ms. Strickland praised the effective approach developed by

the co-chairs. Ms. Monson expressed excitement about the idea of "privacy and security by design" that is built into the approach.

Looking ahead to future work by the Standards Subcommittee, Ms. Goff noted the previous day's discussion of public health reuse of data. She suggested, with Mr. Landen's concurrence, that at its November meeting the Subcommittee talk about expanding the scope of its convergence project to incorporate this dimension.

In a discussion of the convergence topic, Dr. Mays affirmed the need to transcend the "siloed buckets" of clinical, administrative, and public health data, and other members agreed. This led to a thoughtful extended discussion about how to get providers and payers to collect the data needed to address public health, notably data on race and ethnicity. Noting that NCVHS needs a Subcommittee on Population Health again, Dr. Stead stressed the convergence of public health, health care, and mental health and the fact that the root causes for all are the same. In that context, though, he asserted that standards work should continue its focus on enabling meaningful data to "move through the pipelines." He also wondered if the NCVHS convergence project can resume soon enough to generate something to report in the 14th Report to Congress.

While agreeing about the need for a Population Health Subcommittee, Dr. Mays and others asserted that from a strategic standpoint, it is better to approach these questions about data on the social determinants of health through a standards lens, with an emphasis on making the business case for collecting such data.

(3) Regarding the Operating Rules hearing, Mr. Landen said that CAQH CORE has asked NCVHS to consider three new operating rules for adoption by HHS as national mandatory standards. A virtual hearing is scheduled for August 25-26. The Subcommittee on Standards has invited about 20 organizations to testify and submit written comments, and an additional 10 organizations to submit written comments. The meeting will be announced in the Federal Register as well as on the NCVHS website, and Ms. Hines indicated all are welcome to send written comments. Mr. Landen summarized the plans for the meeting. After the hearing, the Subcommittee will deliberate and draft recommendations that will be presented to the Full Committee.

**Division of National Standards Update—Daniel Kalwa, CMS Division of National Standards**

Mr. Kalwa is a Policy Advisor with the Division of CMS Division of National Standards (DNS), which is responsible for writing and enforcing regulations around HIPAA administrative simplification. Its main means of communicating to the public around its regulatory actions is in the Unified Agenda on the OMB website (reginfo.gov). This normally happens twice a year, but COVID-19 has slowed the pace. The next update will come out shortly after this meeting, although it won't be entirely up-to-date. The DNS is working on three regulatory activities: modification of use of the NCPDP D.0. standard, which is still on track; continuing to pursue updating the NCPDP standards to F6, as recommended by NCVHS; and work toward the delayed NPRM on attachments.

The DNS is also working on educating and revitalizing interest in using an exception to the process included in the HIPAA regulations, which allows covered entities to request an exception to test or pilot new standards and new approaches to HIPAA transactions. It recently released a memo with information on the process and how to extend the exception, which is time-bounded. Mr. Kalwa said he is excited about this opportunity because it is a way to start testing emerging standards and getting hard data.

Requests for an exception go to the Secretary and will also come to the NCVHS Subcommittee on Standards.

- **Discussion**

Ms. Goss, too, expressed excitement about the exception process, as testing has been a longstanding issue for industry. She asked whether DNS has an overarching testing strategy an intended role in advancing new and emerging standards that have industry backing. Mr. Kalwa said the exception process would be the mechanism, adding that there is no funding for pilot projects; that would require statutory change. Mr. Landen asked about enforcement, and Mr. Kalwa offered to have the appropriate DNS staff person speak to NCVHS another time on that topic.

As a public comment, audience member David Wilderman raised a question about adoption of a new version of the X12 transaction. This led to a series of questions from the public and a discussion between NCVHS members and Mr. Kalwa about the confusion and issues around conflicting versions (5010 and 6020), stemming from language in the Affordable Care Act. Ms. Goss noted that the industry will have to be prepared to comment when they see the proposed DNS text; and she added that this also has implications for forthcoming work on prior authorization and the larger conversation about the intersection of clinical and administrative data. Mr. Kalwa said the DNS is looking for industry feedback on its proposed solution (the timing of whose release is undetermined).

Members asked Mr. Kalwa to report on these issues at the November Full Committee meeting; and Dr. Stead suggested that in the meantime, the Standards Subcommittee work on the issues with DNS.

**PCS Subcommittee Project: Privacy, Confidentiality and Security Considerations for Data Collection and Use During a Public Health Emergency—Mr. Pasquale (slides)**
*(Please see slides and transcript for details.)*

Mr. Pasquale outlined the possibilities and next steps for a short-term NCVHS/PCS project, as informed by the previous day's discussion about what resonated with members and what is doable in the Committee's bandwidth. The proposed short-term project is in response to an ASPE request for NCVHS guidance on data collection during a pandemic. The slides outlined nine questions that might be considered in addressing this topic. In their previous discussion, NCVHS members expressed particular interest in revising or amending the NCVHS *Toolkit for Communities Using Health Data* in ways relevant to the pandemic, such as with respect to data use agreements, wider dissemination ("popularization") of data protection principles such as data minimization, and training on data protections for contact tracing.

Mr. Pasquale then commented on several key privacy-related topics including data use agreements, accountability, security, non-covered entities, data stewardship, and purpose specification that may be part of a longer-term project. He noted useful literature on the subjects where relevant. He asked members to comment on these topics and possibilities.

- **Discussion**

In response to a question about "popularizing" key privacy principles, Mr. Pasquale illustrated with an image of "the overworked general counsel" in a relatively small entity with limited bandwidth; this type of person/role is a potential audience for clear, straightforward information on data privacy protection principles during the pandemic. Other potential audiences include people in tech firms and regulators.

There was considerable discussion of data use agreements (DUAs), with some members noting their experience with the limitations of DUAs. Ms. Love stressed that they are only "one leg of the privacy-protection stool," along with statistical and management controls. The discussion returned again and again to the need for consumer education about the uses of their data and what they are being asked to agree to.

Regarding project scoping, Mr. Coussoule suggested keeping in mind the end game and what NCVHS is trying to influence. Ms. Goss noted that the range of topics under consideration overlaps with work under way by ONC in response to the 21st Century Cures Act.

Mr. Pasquale and others pointed to the complexity of these privacy issues, the amount that is not understood about the health data ecosystem and risks to privacy, and the way business models are changing as data is harnessed and technologies advance. COVID is accelerating private sector interest in public data and its repurposing in ways that present both risks and opportunities.

Dr. Cimino pointed to questions about the enforceability of DUAs between outside researchers and institutions (e.g., "special volunteers" with access to NIH patient data). Mr. Pasquale noted that the development of further guidance on accounting for disclosures is in the PCS parking lot for possible future work.

Returning to the subject of DUAs, members discussed the idea of a database or taxonomy of DUAs to assist entities in designing useful ones for themselves. Ms. Bernstein said a project similar to this is under way at ASPE.

In conclusion, Mr. Pasquale outlined possible next steps for the Subcommittee on this short-term project. One is to create a scoping document and literature review, including an updated NCVHS toolkit for communities using health data. The other step is hosting a hearing in September to canvas experts' latest views on these topics that are not yet reflected in the literature.

### Committee Reflection: What Have We Learned?—Dr. Stead, Ms. Hines

For their final session, NCVHS members participated in a round-robin session in which they shared their impressions of what they had learned and were taking away from this meeting. This summary presents a distillation of the key points.

- Dr. Mays: Hold on to the idea of making a business case for standardized collection of race and ethnicity data, framed in the context of clinical and administrative issues.
- Dr. Cornelius: It's good that the use of artificial intelligence (natural language processing) arose in the meeting's discussion of federal data collection because AI will shape future discussions of federal data.
- Mr. Coussoule: The topics addressed at this meeting are highly intertwined and cross subcommittee domains. NCVHS may be able to leverage these overlaps.
- Ms. Goss: Trust is the beacon and goal for the work on data and communities. In the face of the tremendous complexity of what NCVHS is addressing, it is a good aspiration to make it work in the daily lives of citizens. The Committee is pivoting from standards to a philosophical privacy focus in the next phase, opening new opportunities for service.

- Mr. Landen: Many new perspectives arose in this meeting in the light of COVID-19. The Committee needs to think through the issues strategically to make near-term progress that has the potential to become sustainable longer-term solutions. The Standards Subcommittee needs to augment its approach to convergence to include the public health data issues discussed at this meeting.
- Ms. Strickland: It's good that ASPE is taking on the effort to create models to drive good, understandable data use agreements.
- Mr. Pasquale: The PCS Subcommittee, which benefitted from the comments on its projects, needs to engage more with the clinical/administrative data-sharing proposals. There are interesting opportunities for cross-pollination among all the dimensions of the Committee's work—privacy, standards, and population health. It would be useful for NCVHS to pay attention to the conversation in Congress now about new privacy legislation.
- Ms. Monson: There are many connections between privacy and standards, topics that have monopolized this meeting. And NCVHS needs its Subcommittee on Population Health back.
- Ms. Chrysler: Public health has a special role and broad power to collect and use information. In responding to the ASPE request for guidance, the Committee needs to maintain the balance between this special data stewardship and the importance of privacy; and risk tolerance needs to be reevaluated.
- Ms. Skurka: It is hard to be a new NCVHS member without having met other members face-to-face. The forthcoming work on ICD-11 is exciting. And the Procedure Classification System has nothing to do with ICD-10 and should be renamed. (Response: The recent NCVHS recommendation to this effect got somewhat watered down; this can be revisited.)
- Dr. Cimino: In the era of COVID-19, it is necessary to standardize data collection processes as well as the data themselves. In this pandemic, there are urgent struggles to identify patients with COVID-19 and to tease this information from the EHR. Can NCVHS originate recommendations? (Response: Yes.)
- Ms. Goldstein: Over the last six months, public reactions to data collection and other aspects related to COVID-19 have varied widely. The Committee needs to consider what it can recommend that is balanced, practical, doable, and useful and minimizes blowback.
- Dr. Stead: Dr. Moyer is bringing a fresh lens to NCHS with his "outsider view" and interest in cross-sector approaches and alternative data capture strategies. That is a good direction.
- Ms. Hines: NCVHS has had a liaison to the NCHS Board of Scientific Counselors, and now needs a volunteer to play this role. Dr. Cornelius, who chaired the BSC for six years, described the benefits of attending its meetings; and Dr. Mays, who served as liaison, said the two bodies should be sharing back and forth.

### Public Comment

There was no public comment at this stage of the meeting.

### NCVHS 2020-21 Workplan Review

The Committee discussed its workplan, with input from each of the subcommittee chairs and other members.

### Final Words from Outgoing Members

Ms. Hines noted that this is the final Full Committee meeting for Dr. Stead as NCVHS Chair and for Dr. Cornelius and Ms. Goss.

Recalling Debbie Jackson's statement that "NCVHS is a family," Dr. Stead reflected on the Committee's history during his tenure as a member, Co-Chair of the Subcommittee on Population Health, and NCVHS Chair. He thanked each member for their collegiality and for many memorable experiences.

Dr. Cornelius observed that many members and staff "go above the call of duty and really dive in"; and observers may be unaware that the public face of what happens is only the tip of the iceberg. He stressed the long-term legacy of the Committee and the fact that it can take a long time to bring about positive change.

Ms. Goss, echoing the family theme, commented on "this intellectual exercise among really good-hearted, very smart, very hardworking and dedicated individuals." The work they do together is a great responsibility. She thanked her colleagues for helping her grow through this experience.

In closing, Dr. Stead thanked the subcommittees for their thoughtful planning and work, the staff of the subcommittees, the NCHS team, the ASPE staff, the logistics contractor, and Ms. Hines "for the help she gives each and every one of us at all hours of the day." 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/

Chair Date