Department of Health and Human Services
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
January 24-25, 2022
Virtual Meeting

MEETING SUMMARY

Note: *For details on this meeting, please refer to the transcript and slides posted here:* https://ncvhs.hhs.gov/meetings/full-committee-meeting-9/

The National Committee on Vital and Health Statistics (NCVHS) was convened virtually on January 24-25, 2022. The meeting was open to the public. Present:

Committee Members
Jacki Monson, JD, Chair
Tammy Banks, MBA, FACMPE
Denise Chrysler, JD
James Ferguson
Melissa Goldstein, JD
Richard Landen, MPH, MBA
Denise Love, BSN, MBA
Vickie Mays, PhD, MSPH
Margaret Skurka, RHIA, CCS, FAHIMA
Debra Strickland, MS
Valerie Watzlaf, PhD, MPH, RHIA, FAHIMA
Wu Xu, PhD

Invited Speakers
Shawna Webster, NAPHSIS
Jeff Greenland, NAPHSIS
Chris Muir, MPA, ONC
Katherine Sapra, PhD, MPH, CMS/CMMI
Reuven Pasternak, MD, MPH, MBA, Department of Homeland Security
Josh Corman, I am The Cavalry
Betty Bekemeier, PhD, MPH, University of Washington
Glen Mays, PhD, MPH, University of Colorado
Elizabeth Pathak, PhD, WiiSE
Ninez Ponce, PhD, MPP, UCLA
Seth Spielman, PhD, MS, Microsoft
David Van Riper, University of Minnesota

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

NCVHS Staff
Maya Bernstein, JD, HHS/ASPE
Lorraine Doo, MPH, CMS
Natalie Gonzalez, JD, LLM, CDC
Nate Kim, HHS/ASPE
Rachel Seeger, MA, MPA, OCR
Marietta Squire, NCHS

Other HHS Staff

Krycia Cowling, PhD, MPH, HHS
Kristen Miller, PhD, NCHS
Ryan Mintz, MS, HHS
Susan Queen, PhD, HHS/ASPE
Scott Stare, CMS/OMH

In addition to those individuals who presented virtually during the meeting (listed above), 69 people on day 1 and 115 people on day 2 attended the meeting virtually.

ACTIONS

1. The Committee unanimously approved the Subcommittee on Privacy, Confidentiality, and Security's letter and recommendations (with additional non-substantive refinements related to citations and formatting to be performed by the Subcommittee) to the Secretary on strengthening cybersecurity in health care.

2. The Committee reviewed the Subcommittee on Privacy, Confidentiality, and Security's letter and recommendations on data collection and use during a public health emergency and decided to review the updated version of the letter during a future ad hoc Committee meeting.

The final versions of the letters and attachments will be posted on the NCVHS website.

—DAY ONE—

Call to Order and Roll Call—Rebecca Hines, Executive Secretary and Designated Federal Officer

Ms. Hines invited National Committee on Vital and Health Statistics (NCVHS) members and speakers to introduce themselves and state any conflicts of interest that pertain to today's meeting. No members stated a conflict of interest.

Welcome Remarks and Agenda Review—Jacki Monson, Chair

Ms. Monson welcomed NCVHS Committee members and invited speakers to the meeting and reviewed the meeting agenda. The primary goals of today's NCVHS Committee meeting are to review, finalize, and approve recommendation letters from the Subcommittee on Privacy, Confidentiality, and Security and the Subcommittee on Standards. Ms. Monson acknowledged and thanked her predecessor, Mr. Nick Coussoule, for all of his contributions to the Committee during his tenure as Chair.

Update from the Office of the Assistant Secretary for Planning and Evaluation (ASPE) —Sharon Arnold, Executive Staff Director

The majority of the U.S. workforce continues to telework because of the ongoing COVID-19 pandemic, while government agencies and offices are planning for a return to in-person work. The Safer Federal Workforce Task Force is led by the White House COVID-19 Response Team, as well as the Office of Personnel Management, and General Services Administration, and provides federal agency leaders with ongoing guidance to keep their employees safe and agencies operating during the COVID-19 pandemic. The Department of Health and Human Services (HHS) recently announced a phased approach to returning to in-person work, which will begin during fall 2022.

As of January 20, 2022, greater than 80 percent of eligible individuals in the United States had received at least one dose of a COVID-19 vaccine. During September 2021, President Biden signed an Executive Order requiring all federal employees and on-site contractors to present proof of vaccination by November 2022. The Office for Civil Rights (OCR) recently released a report of best practices for improving access to COVID-19 vaccination programs and preventing discrimination on the basis of race or ethnicity. Continuing activities include HHS allocation of significant resources to support COVID-19 pandemic responses (including free at-home COVID-19 tests and masks); U.S. Food and Drug Administration (FDA) evaluation of the landscape of evolving COVID-19 therapeutic treatments; and the Centers for Disease Control and Prevention (CDC) provision of guidance as new COVID-19 variants emerge.

In addition to COVID-19, other diseases and conditions have emerged or remain high priorities for HHS. During 2021, President Biden signed an Executive Order adding measles to the list of communicable diseases that may require quarantine in the future. Further, HHS Secretary Becerra signed a renewal of the public health emergency (PHE) declaration regarding the ongoing opioid crisis. During October 2021, the HHS Secretary announced the launch of the HHS Overdose Prevention Strategy, which is designed to increase access to a full range of care and services for individuals with substance use disorders.

Since the last full NCVHS meeting, multiple personnel changes and new appointments have occurred within HHS, including the following:

- Dr. Rachel Levine, the Assistant Secretary of Health, was sworn in as an Admiral of the U.S. Public Health Service Commissioned Corps, making her the first openly transgender four-star officer across all of the U.S. Uniformed Services.
- Ms. Carol Johnson was named Administrator of the Health Resources and Services Administration.
- Dr. Lawrence Tabak is serving as the Acting Director of the National Institutes of Health as the search continues for a permanent successor to Dr. Francis Collins, who retired in 2021.
- Ms. Angela Ramirez was named HHS Deputy Chief of Staff.
- Dr. Susan Jenkins joined ASPE as Director of the Division of Evidence Evaluation and Data Policy.
- Ms. Rachel Seeger, who previously served as lead staff for the Privacy, Confidentiality, and Security (PCS) Subcommittee, is now a Senior Advisor for Communications at OCR.
- Natalie Gonzalez is now lead staff for the PCS Subcommittee.
- Dr. Vickie Mays and Ms. Denise Love have been appointed as Co-Chairs for the new Sexual Orientation and Gender Identity (SOGI) and Social Determinants of Health (SDOH) Data Workgroup.
- Mr. Nick Coussoule stepped down as NCVHS Chair after accepting a position at Horizon Blue Cross Blue Shield of New Jersey.
- Ms. Jacki Monson was appointed NCVHS Chair.

The Office of the National Coordinator for Health Information Technology (ONC) recently launched the Sequoia Project, which aims to support a nationwide health information exchange through a set of non-binding but foundational principles. In addition, ONC recently released a report on comprehensive assessments of scientific integrity policies and practices throughout the U.S. government. ASPE is responsible for leading the responses to that ONC report. Another major ASPE priority is developing the HHS Strategic Plan for 2022-2026, which is being finalized before release for public comment. ASPE continues work related to implementation of the Foundations for Evidence-Based Policymaking Act of 2018; ASPE has developed evidence-building and evaluation plans and a capacity assessment for review by the Office of Management and Budget (OMB) and then release. ASPE is also developing recommendations related to the Paperwork Reduction Act waiver process and processing waiver requests under the current PHE. ASPE has released several COVID-19-related reports, including one about vaccination of children aged 12-17 years and reasons for parental vaccine hesitancy.

Subcommittee on Privacy, Confidentiality, and Security's Draft Recommendations on Data Collection and Use During a Public Health Emergency

—Melissa Goldstein, Subcommittee Co-Chair

The PCS Subcommittee has drafted two letters of recommendations for the HHS Secretary, for review and approval by the full NCVHS Committee: "Data Collection and Use During a Public Health Emergency" and "Recommendations to Strengthen Cybersecurity in Health Care."

The objectives of the September 2020 PSC Subcommittee meeting were to understand current policies and practices involving data collection and use with respect to privacy and security during the COVID-19 PHE; understand challenges and potential areas of clarification in light of these practices, new and emerging technology developments, and new and evolving policy directions; and identify best practices and areas where additional technical assistance or guidance may be useful. During this meeting, the PSC Subcommittee identified several priority actions, as follows:

- Develop an overarching, integrated, and well-funded PHE data collection and use framework that as socially supported at the federal, state, and local levels
- Address health disparities and improve health equity
- Develop health data infrastructure for new forms of data collection during a PHE
- Remove data silos across public health and health care entities
- Create standardized data use agreements
- Collect and share complete race/ethnicity data
- Combine data and computing infrastructure to create a potential data commons
- Embed privacy and security guidelines
- Enhance data sharing within communities in a privacy-appropriate environment
- Reduce multiplicity of laws by developing a national policy standard
- Develop a broader definition of a Health Insurance Portability and Accountability Act (HIPAA)-covered entity
- Reconsider deidentification as a backbone of administrative data

Since the September 2020 meeting, the priorities have evolved as the COVID-19 pandemic has evolved. The PCS Subcommittee used the information gained during and after the Subcommittee meeting to develop five recommendations for the HHS Secretary, which are presented and discussed in the sections below.

Draft Recommendation 1: Develop a governance strategy specific to PHEs with associated methods to ensure the privacy and security of data that increases public perceptions of trustworthiness and measures to monitor and address public trust.

Ms. Love expressed support for the language of this recommendation. Mr. Landen also expressed support and suggested incorporating language related to the efforts of other Subcommittees (i.e., the letter focuses on privacy and security, but the strategy will also address standardization as directed by the Standards Subcommittee).

Ms. Goldstein confirmed that the supporting language for Draft Recommendation 1 explains data governance. Ms. Love suggested adding a citation to ONC standards to the second sentence of the supporting language.

In response to a suggestion by Mr. Landen to reference other types of PHEs in the supporting language, Ms. Bernstein updated the supporting language to state, "We have learned from other infectious outbreaks, *such as HIV, Ebola, and Zika virus epidemics, and other PHEs, including Hurricanes Katrina, Irma, and Maria*." Ms. Goldstein suggested inserting a footnote after that sentence that explains that the lessons learned differ by PHE because strategic approaches are tailored to the PHE (e.g., an infectious outbreak will likely require more health care system–specific strategies than a wildfire).

Draft Recommendation 2: Support the development of real-time, interoperable information sharing for PHEs that prioritizes privacy and security.

Ms. Banks suggested updating the language to "development of real-time *and use of* interoperable information." Ms. Love suggested changing "prioritizes" to "embeds" or "incorporates" in order to avoid possible conflicts connotated by the concept of prioritizing privacy and security (i.e., that prioritizing privacy and security will lead to intentional withholding or reduced sharing of data). Mr. Landen added that "prioritizing privacy and security" may imply that these capabilities are being increased. Ms. Bernstein suggested that updating "that prioritizes privacy and security" to "while providing good-faith protections" may alleviate concerns regarding "prioritizes." Ms. Chrysler emphasized the importance of recognizing tradeoffs in addressing privacy, security, and data sharing.

Draft Recommendation 3: Review the current process for issuance of PHE waivers, Notices of Enforcement Discretion, and sub-regulatory guidance.

Ms. Goldstein confirmed that this "review" covers evaluation of the process outcomes.

Ms. Bernstein suggested incorporating language related to the level of approval waivers and notices that must be received before full approval, and who will provide that approval. Ms. Goldstein noted that the intent of the recommendation is for waivers and notices to undergo multiple reviews, which may escalate if needed, to ensure that the correct individuals provide the final review.

Draft Recommendation 4: Address health disparities in and health equity of data collection and use at the federal, state, and local levels.

Dr. Vickie Mays suggested updating this recommendation to state "address inequities" and to specify the inequities of highest priority. Dr. Xu suggested revising the language to be more specific to PHEs because the current language is too general.

Draft Recommendation 5: Develop data stewardship responsibilities, based on principles of fair information practices, for entities collecting, using, and sharing data during a PHE, including responsibilities relating to privacy, security, lifecycle management, protection from re-identification, and responsible communication.

Meeting participants agreed with Dr. Vickie Mays' suggestion to replace the word "responsible" with "evidence-based." Ms. Banks suggested ending the recommendation after "PHE" and expanding on the remaining content in the supporting information; however, meeting participants decided to edit the language instead of removing it from the recommendation.

Dr. Xu suggested changing "Develop" to "Define." Participants also agreed to insert a footnote that references the NCVHS report, "Toolkit for Communities Using Health Data."

Dr. Love commented that "protection from re-identification" may raise issues about sharing substance abuse–related data; these types of protections are necessary for public reporting, but not for other activities such as contact tracing. Ms. Goldstein noted that the phrase is critical to the intent of the recommendation, but that the supporting language can provide clarifications regarding this concern.

Mr. Landen suggested narrowing the scope of this recommendation because it appears too broad, particularly the mention of "lifecycle management." Dr. Vickie Mays noted that each part of the recommendation may appear broad, but is actually focused directly on PHEs; for example, "lifecycle" refers to the lifecycle of the PHE, not of data. Committee members suggested changing this recommendation to become Draft Recommendation 2 to better connect it to Draft Recommendation 1;

Mr. Landen confirmed that this change would alleviate his concerns related to the scope of this recommendation.

Committee members agreed to insert a footnote into this recommendation letter that cites the HITAC Public Health Data Systems (PHDS) Task Force report.

Subcommittee on Standards—Rich Landen and Denise Love, Subcommittee Co-Chairs

Update on Convergence 2.0 Project

The Convergence 2.0 project aims to standardize information to reduce burden throughout the health care system in post-pandemic America. The Convergence 2.0 project builds on previous work of the Standards Subcommittee related to the Predictability Roadmap, which was launched to (1) envision industry-driven standards development and adoption, (2) provide timely standards-related updates, (3) enable pre-adoption testing and more value assessments, and (4) and enhance conformance with standards.

The Convergence 2.0 project includes two phases. Phase 1 involves assessing the current health data standards landscape by conducting Listening Sessions and reviewing Request for Written Comment (RFC) submissions; conceptualizing potential solutions to improve efficiency and reduce burden; and developing a Phase 2 workplan. Phase 2 is focused on developing and refining recommendations based on the information collected in Phase 1, as well as consultations with industry. Phase 2 also involves identifying other opportunities for standards optimization related to HHS priorities, such as consistency in reporting, exchange of social data, flow of health data beyond traditional HIPAA and Health Information Technology for Economic and Clinical Health (HITECH) Act partners, and sanctioned exceptions and alternatives to HIPAA transaction standards.

In Phase 1, the Standards Subcommittee has received 31 RFCs and has held four listening session panels with industry presenters. The Standards Subcommittee is now reviewing and analyzing the comments received and has identified several preliminary themes, including data sharing across all actors and data types, privacy and security beyond HIPAA, regulatory challenges, conformity assessments, and challenges and opportunities (e.g., patient matching, semantic harmonization). In addition to the comments and industry panels, the Standards Subcommittee has reviewed information from other inputs, including the HITAC Intersection of Clinical and Administrative Data Task Force, HITAC Public Health Data Systems Task Force, and the Electronic Prior Authorization (PA) Request for Information (RFI) Task Force.

In assessing the overall health standards landscape, the Standards Subcommittee has identified multiple areas of consensus. One overarching point of consensus is that HIPAA’s standards adoption and regulatory processes are obsolete and require major updates. In addition, the Subcommittee identified the importance of allowing multiple standards to coexist and be used by stakeholders to effectively meet business needs; enabling multiple versions of a standard to be in production and used simultaneously; modifying the standards adoption process under HIPAA; and eliminating the opaqueness of the current standards development, readiness, and adoption processes to establish a predictable cycle for adoption. Other areas of consensus include the importance of amending the exception approval process for testing emerging standards to become less burdensome and proactively supportive of innovation; amending the Direct Data Entry (DDE) exemption to be more user-friendly and less burdensome to providers; developing, implementing, and funding a national system of standards testing; and developing and publishing criteria used to determine fiscal impact, value, and return on investment (ROI).

In addition, the Standards Committee agrees that HHS should act on previous NCVHS and industry priorities, particularly to adopt a standard for health care attachments and acknowledgements and to publish a regulation for the PA application programming interface (API). Additional actions for HHS include implementing a patient education campaign regarding applications and privacy policy; implementing training programs for providers on data exchange; implementing standards for payers to bidirectionally exchange information; supporting the capture of *International Classification of Diseases, Tenth Revision, Clinical Modification* SDOH data elements across the health care system; developing a solution for patient matching; engaging with state and territorial officials to provide guidance on health and wellness data systems; and working with the American National Standards Institute to identify methods for compensating standards development.

Areas that the Standards Subcommittee identified as needing further exploration include workforce training and development regarding emerging standards, collaboration among advisory committees, collaboration among standards development organizations (SDOs), after-the-fact enforcement relative to proactive conformance testing, clarification on whether Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR) standards will replace current X12 HIPAA standards for certain provider types, code set adoption and coding guidelines, the new app economy, collaboration between SDOs and coding bodies, approaches to expanding the concept of covered entities, and virtual credit cards and electronic funds transfer. The Standards Subcommittee posed the following questions to NCVHS Committee members:

- Are there points in this presentation that require more explanation?
- Given that the Standards Subcommittee expects to share recommendations during the next Committee meeting, are there concerns related to the areas of consensus and are there gaps?
- What should the Standards Subcommittee be aware of when continuing work in areas that require further exploration?
- What else should the Standards Subcommittee be mindful of?

Discussion

Dr. Watzlaf encouraged the Standards Subcommittee to further emphasize the importance of mitigating data flow challenges in preparation for future PHEs within its recommendations.

HITAC Public Health Data Systems (PHDS) Task Force Recommendations from 2021

The HITAC PHDS Task Force was charged with developing recommendations to inform HHS' response to President Biden's Executive Order titled, "Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats." To address this mission, the PHDS Task Force must (1) identify and prioritize policy and technical gaps associated with effectiveness, interoperability, and connectivity of information systems and (2) identify characteristics of an optimal future state for information systems relevant to public health. The PHDS Task Force developed 52 recommendations, many of which thematically overlap with consensus areas identified by the Standards Subcommittee in the Convergence 2.0 project:

- ONC should work with federal partners to create a preparedness plan and data standards for collecting information from within the health ecosystem during PHEs.
- ONC should collaborate with CDC and other public health jurisdictions to work with providers and standards communities to ensure that use of standards supports the collection of complete demographic and contact information elements.

- ONC should work with CDC and legal organizations (e.g., Network for Public Health Law) to identify policies that are preventing health departments from exchanging immunization data with other organizations across the health ecosystem.
- ONC should coordinate with CDC to support states in establishing infrastructure meeting state, tribal, local, territorial (STLT) and federal needs for collecting situational response and public health data and to support identified core public health data system functions.
- ONC should define a core standard set of data elements to support patient matching across public health and health care systems.
- ONC should collaborate with CDC to educate Congress on the need to authorize and appropriate robust, sustained, and consistent funding through CDC to support the development and maintenance of public health data systems and a workforce capable of supporting routine and large-scale responses.
- ONC should collaborate with CDC to encourage incorporation of equity considerations into funding models for public health data systems, including specific and direct investment in traditionally under-resourced communities.
- ONC should collaborate with CDC and OCR to develop and release best practices and guidance for applying the HIPAA Minimum Necessary standard with public health (PH) authorities.
- ONC should collaborate with CDC to support policies that facilitate data sharing and ensure that the appropriate access is provided to each level (e.g., federal, local) of PH authority.
- ONC should work with relevant HHS partners to support payor access where appropriate to public health reporting data to facilitate maintenance of complete patient health histories and clinical data sharing.
- ONC should collaborate with CDC, the Council of State and Territorial Epidemiologists, and STLT authorities to ensure consistent collection of agreed upon standards for certain health equity data elements.

Discussion

Dr. Vickie Mays noted that many of the presented recommendations include engagement with CDC and emphasized that other offices (e.g., Office of the Assistant Secretary for Preparedness and Response [ASPR]) and entities (e.g., Census Bureau) should be included in these recommendations to support specific data standard needs. Ms. Chrysler responded that the PHDS Task Force's recommendations were drafted with a narrower lens on public health systems and clinician needs, which led to a focus on CDC engagement.

Electronic PA RFI Task Force

ONC will soon issue an RFI to seek input on support for electronic PA processes and on how the ONC Health Information Technology (HIT) Certification Program could incorporate standards and certification criteria related to electronic PA. The Electronic PA RFI Task Force will launch this week to provide input and recommendations in response to the ONC RFI and will inform future rulemaking in the electronic PA space.

Reactor Panel

- **Shawna Webster, National Association for Public Health Statistics and Information Systems (NAPHSIS)**

Through the Epidemiology Laboratory Capacity grant mechanism, CDC has provided $77 million to help the National Vital Statistics System (NVSS) to adopt FHIR across jurisdictions. Approximately $1.3 million will be allocated to each NVSS jurisdiction, which cumulatively is the most funding that has been dedicated to vital records systems in more than 30 years. However, the COVID-19 pandemic has dramatically diverted jurisdiction resources, likely impacting their ability to implement FHIR within the grant's 2-year timeline. In addition, jurisdictions are expected to implement FHIR while fulfilling their other duties. The COVID-19 pandemic highlighted many gaps within the U.S. health care system, leading Congress to allocate more than $550 million to support data modernization efforts. However, the sense of urgency for these efforts appears to be waning, despite no reduction in need.

Ms. Webster emphasized that the current model for funding and maintaining vital records systems is unsustainable. The National Center for Health Statistics purchases vital records (including both birth and death information) from all 57 U.S. jurisdictions for approximately $21 million. Considering that one mid-sized U.S. state recently spent $8 million to update its electronic death registration system, the amount of funding provided to states (for implementing and maintaining data systems and purchased data) is not sufficient. Ms. Webster encouraged NCVHS and its subcommittees to recommend that HHS support efforts that improve vital records data systems and the flow of vital records data because all levels of government rely on these types of data.

- **Jeff Greenland, NAPHSIS**

Updating and maintaining current vital records systems requires significant action across all stakeholders. However, because vital records systems are not HIPPA-covered entities, many public health entities and departments cannot readily expand their efforts to maintain vital records when overwhelmed by other ongoing duties, including responses to the COVID-19 pandemic. The health care system has not allocated the staff and resources needed to improve the vital records systems. When HIPAA was first enacted, the major challenges to maintaining vital record systems were security and technology (e.g., how to secure information flow through phone lines or modems). However, the challenge now relates to people, specifically bad actors who can impose more damage than faulty or outdated technology. Providing more resources to support the preparation and updating of vital records systems will help protect these important datasets from possible threats.

- **Katherine Sapra, PhD, Centers for Medicare & Medicaid Services (CMS)**

Congress established the CMS Innovation Center (CMMI) in 2010 through the Patient Protection and Affordable Care Act to identify methods that improve health care quantity; reduce costs related to Medicare, Medicaid, and children's health insurance programs; and accelerate the shift from a health care system that pays for volume to one that pays for value. CMMI develops and tests new health care payment systems to promote patient-centered practices. These alternative payment models reward health care providers for delivering high-quality and cost-efficient care to patients. Nearly 70 percent of Medicare Part A and Part B eligible beneficiaries receive care through Medicare Advantage or an Accountable Care Organization (ACO). These organizations are responsible for coordinating all care for that beneficiary to reduce fragmentation and costs, as well as improve quality of care. CMMI aims for all

Medicare Part A and Part B eligible beneficiaries to receive care from either Medicare Advantage or an ACO by 2030.

A major requirement of accountable health care includes giving providers incentives, tools, and data that are necessary to providing high-quality care at low cost. The large volume of data generated by health care systems can overwhelm providers; therefore, tools for quickly summarizing and analyzing these data are critical. Dr. Sapra noted that one challenge with alternative payment models relates to the tension between retaining the privacy of patient health data and sharing those data to improve care coordination across providers, systems, and other settings—particularly data related to SDOH. CMS aims to better integrate health and social services to address SDOH and health disparities, but data sharing can be complicated for social service providers. For example, a social service provider may receive information that is protected under HIPAA, but some organizations lack the resources to safeguard such data. Opt-in and opt-out policies also challenge data sharing. With opt-out policies, more information is collected, but patients may not be fully aware that their data are being shared and would opt-out if they were aware. Finally, current federal regulations prohibit sharing of substance abuse insurance claims data with ACOs, which means that providers may lack vital data needed to care for their patients.

In addition, the health care field has made significant progress in terms of data interoperability. For example, the Gravity Project is developing standards to optimize sharing of SDOH data among a patient's providers. SDOH data must be updated regularly because any changes may be critical for patient care. Proxy measures of demographic data may help reduce the burden of SDOH data collection, but these measures have limitations, including that they usually measure neighborhood-level, rather than individual-level, outcomes. Proxy measures can also introduce variability when data are compared across states with different policies.

- **Chris Muir, MPA, Office of the National Coordinator for Health Information Technology (ONC)**

Since 2020, ONC's top priority has been to respond to the COVID-19 pandemic and to ensure that public HIT infrastructure can support responses to the current and future pandemics. ONC and CDC are working together to formulate a response to President Biden's Executive Order "Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats." ONC and CDC are reviewing the recommendations provided by the HITAC PHDS Task Force, as well as other sources, in order to draft and publish a final response. Another priority for ONC is to address health equity and disparities related to race/ethnicity, sexual orientation, and gender identity. ONC has adopted robust and flexible standards related to race and ethnicity and, along with federal partners, is developing guidance on best practices to collect this type of data, as well as data on sexual orientation and gender identity. ONC has drafted data elements related to race/ethnicity, sexual orientation, and gender identity for inclusion in the United States Core Data for Interoperability standard; ONC is currently awaiting comments and feedback on these data elements. ONC is collaborating with H7 on the Gender Harmony project, which aims to develop inclusive gender- and sex-related standards to improve data collection and care for gender-marginalized individuals. ONC also continues to collaborate with H7 on the Gravity Project.

Mr. Muir emphasized that in addition to its COVID-19 response and health equity efforts, ONC continues its work to improve administrative transactions and intersections with clinical data, reduce provider burden, advance health care reform efforts, and include PA in guidance documents. Finally, ONC encourages the standards field to continue testing of existing guides to implementing FHIR to identify possible gaps that may impede adoption.

Discussion

Dr. Xu emphasized the importance of the vital records systems, their interoperability, and the coordination needed to ensure their efficient operation. Dr. Xu encouraged (1) CDC to provide more coordination in this area (particularly at the state level) with additional support from ONC and the Association of State and Territorial Health Officials and (2) NCVHS to continue to work with CDC to advocate for funding for vital records systems. Mr. Greenland seconded Dr. Xu's recommendation that federal-level support is needed to coordinate vital records systems across the country.

Mr. Landen asked Ms. Webster to describe how federal leadership could optimally support vital records systems. Ms. Webster replied that federal leadership could facilitate coordination by supporting the vital records data collection and delivery systems, which may require funding of these systems through state budgets instead of fees.

Ms. Love asked Dr. Sapra whether CMS has issued guidance to help community-based organizations avoid activities that raise HIPAA concerns and thus require HIPAA compliance, which many lack the resources to achieve. Dr. Sapra could not confirm the existence of such guidance and added that CMS does not provide legal advice to any organization.

Subcommittee on Privacy, Confidentiality, and Security Review of Recommendations to Strengthen Cybersecurity in Healthcare—Jacki Monson, Chair

The PCS Subcommittee has incorporated feedback received to date from the NCVHS Committee into the "Recommendations to Strengthen Cybersecurity in Healthcare" letter to Secretary Becerra. During this session, the PCS Subcommittee aims to perform a final review of the letter with the full NCVHS Committee and finalize the draft for transmittal. Ms. Monson presented each of the four recommendations in the letter and asked Committee members to share any feedback and remaining concerns.

General Feedback
Mr. Landen suggested deleting the word "herculean" from the draft. Mr. Landen expressed concern with the recommendation to enact more cybersecurity mandates when many organizations lack the ability or resources to comply with current cybersecurity mandates; he emphasized the need to reconcile these two concepts. Ms. Monson noted that language related to the Meaningful Use program is intended to provide a successful example of an incentive approach. Mr. Landen noted that the Meaningful Use program is voluntary and provides financial incentives, whereas HIPAA compliance is not voluntary and does not involve financial support.

Recommendation 1: We recommend HHS strengthen the HIPAA Security Rule.

- *a) Make the addressable provisions of the HIPAA Security Rule mandatory.*
- *b) Including additional minimum cybersecurity hygiene requirements.*

Mr. Laden suggested deleting the word "addressable" because it implies three possible options: (1) comply with the requirements, (2) do not comply but provide an alternative approach, and (3) do not comply and do not provide an alternative. The recommendation must eliminate the possibility of option (3). Participants agreed to update the recommendation to the following, which will also include a footnote to the OCR FAQ page: "(a) Eliminate from the HIPAA Security Rule's addressable category, the choice to not comply—requiring compliance or a documented reasonable alternative [Option C from the FAQs]."

Committee members discussed whether the supporting language for this recommendation should list possible suitable alternatives or recommend that the HHS generate those alternatives.

Recommendation 2: HHS, in partnership with other appropriate government agencies, should consider mandating basic cybersecurity requirements for any organization that is a recipient of federal funds.

Committee members agreed with the language of this recommendation and did not provide any additional updates.

Recommendation 3: We recommend HHS further enhance communication and education about the HIPAA Security Rule and security threats and incidents.

- *a) Provide more robust guidance regarding enterprise-wide risk analysis and risk mitigation requirements in the HIPAA Security Rule to ensure covered entities and business associates understand the full breadth of the expectations and requirements.*
- *b) HHS and other appropriate government agencies should facilitate more coordination and collaboration among public and private sector parties during incidence, including work to coordinate the identification of threats to critical infrastructure.*

Committee members agreed with the language of this recommendation and did not provide any additional updates.

Recommendation 4: HHS and other appropriate government agencies should consider developing programs to assist healthcare entities in meeting the enhanced minimum-security requirements and upgrading or replacing high-risk legacy technology that cannot meet the minimum-security requirements needed to keep the technology safe and secure.

Committee members reviewed and tentatively updated Recommendation 4 to the following: "HHS and other appropriate government agencies should consider *evaluating the level of compliance and* developing programs to assist healthcare entities *with the greatest need* in meeting the enhanced minimum-security requirements and updating or replacing high-risk legacy technology that cannot meeting the minimum-security requirements needed to keep the technology safe and secure." The evaluation mentioned in this recommendation would involve an initial literature search and a business need analysis to identify programs that should be developed to provide necessary assistance.

Mr. Landen expressed concern about the recommendation's direct mention of "replacing high-risk legacy technology" when that component is only one potential issue that should be corrected to enhance security; he suggested deleting the reference to legacy technology in the recommendation, while maintaining that language in the supporting content, so that the recommendation can be broad. Committee members suggested revising the recommendation to state, "HHS and other appropriate government agencies should consider evaluating the level of compliance with the HIPAA Security Rule and providing assistance to healthcare entities with the greatest need in meeting the enhanced minimum security requirements" and to include the example of updating legacy technology only in the supporting content.

Public Comment—Rebecca Hines, Executive Secretary and Designated Federal Officer

Mr. Andrew Tomlinson, Director of Federal Affairs at the College of Healthcare Information Management Executive (CHIME), emphasized support for NCVHS' efforts to strengthen cybersecurity and cyber-resilience across the health care sector. Mr. Tomlinson encouraged NCVHS to advocate for the expeditious implementation of Public Law 116-321, previously known as HR 7898, which will mandate the use of an industry standards cybersecurity framework and best practices to obtain relaxations on breach-related HIPAA penalties. This law will help to incentivize providers to adopt cybersecurity best practices and protect their organizations and patients.

The Committee then recessed for the following day.

—DAY TWO—

Call to Order and Roll Call—Rebecca Hines, Executive Secretary and Designated Federal Officer

NCVHS Committee members and speakers introduced themselves and stated any conflicts of interest. No members stated a conflict of interest.

Welcome Remarks and Agenda Review—Jacki Monson, Chair

Ms. Monson welcomed NCVHS Committee members and invited speakers to the meeting and reviewed the meeting agenda.

Follow-Up Panel on COVID-19: Capacity, Gaps, and Quality in Collection of Race/Ethnicity Data —Moderators: Vickie Mays and Denis Love

- **Elizabeth Pathak, PhD, Women's Institute for Independent Social Enquiry (WiiSE)**

The mission of the Coronavirus in Kids Tracking and Education (COVKID) Project is to monitor and compile epidemiologic surveillance data on COVID-19 in children and teens within the United States. Understanding COVID-19 incidence, severity, and mortality—as well as racial and ethnic disparities for each of these parameters—in children and teens requires the review of multiple types of data, including testing, cases, hospitalization, intensive care admissions, and death certificate data. COVKID has extracted cumulative case counts from each state through December 24, 2021, yielding 9,305,171 cases (with varying age ranges), whereas CDC has extracted 8,409,230 cases through December 23, 2021 (including a Restricted File release on January 10, 2022). These counts should be the same, but they are not because of different reporting practices, such as different definitions for age ranges.

Currently, the percentage of U.S. children and teens (aged 0-19) with COVID-19 whose race/ethnicity data are missing from the CDC Restricted File is 29 percent; some states have higher (e.g., 52 percent in New York) and lower (e.g., 9.8 percent in Vermont) rates of missing data. The need to obtain race/ethnicity data in the context of COVID-19 is particularly critical because research suggests that Hispanic and Black individuals are more likely to experience poor COVID-19 outcomes. For example, data extracted from the Virtual Pediatric Systems (VPS) COVID-19 Dashboard on March 28, 2021, reveal that of children admitted to an intensive care unit, 37.1 percent were Hispanic and 27.7 percent were Black. Despite the importance of collecting pediatric COVID-19 data, the VPS COVID-1 Intensive Care Registry ceased operations on April 1, 2021, because of insufficient funding.

COVKID, the CDC Restricted File, and CDC WONDER are major sources of death certificate data reporting; however, different input data lead to different case counts. For example, through December 2021, COVKID reported 782 COVID-19-related deaths, the CDC Restricted File reported 1,500 COVID-19-related deaths, and CDC WONDER reported 992 COVID-19-related deaths in children and teens (aged 0-19); some of these discrepancies are due to omission of COVID-19 on an individual's death certificate. CDC WONDER data highlight the disproportionate impact of COVID-19 on children and teens (aged 0-19) from racial/ethnic minority groups. Through December 2021, COVID-19 mortality rates were 46.6 percent for Native Hawaiians and Other Pacific Islanders (NHOPI), 24.9 percent for American Indians/Alaskan Natives, and 22.3 percent for Blacks—compared to 8.6 percent for Whites. Further, mortality rates for Hispanic children are almost double those for White children, and the rates for Black children are more than double those of Hispanic children.

Overall, these statistics and analyses highlight the importance of collecting race/ethnicity information in order to better understand the impact of COVID-19 in underrepresented populations. In addition, race/ethnicity data must be stratified by age to be useful, missingness of race/ethnicity should be investigated and corrected, and excessive suppression of data, particularly death counts at the state level, must end. Priorities for each state include expanding dashboards to include reporting on children; using standardized thresholds and definitions to improve comparability across states; including vaccination, testing, case, hospitalization, and death data in collection approaches; and reporting all data items by race and ethnicity.

- **Seth Spielman, PhD, MS, Microsoft and David Van Riper, University of Minnesota**

The two major sources of race and ethnicity data are the American Community Survey (ACS) and the Decennial Census. The ACS is a sample of approximately 3.5 million housing units with a response rate of 60 percent. Its population counts are estimates and therefore carry a level of uncertainty. The Decennial Census is a complete enumeration of the U.S. population, with all responses obfuscated to prevent reidentification after publication of the data. In addition, the 2020 Decennial Census included a formal privacy framework, which injected noise into the collected data to further enforce privacy of the responses.

An analysis of the margins of error of ACS estimates reveals substantial uncertainty about the quality of the race/ethnicity data at the census tract level. The quality improves for larger geographic units, such as county, suggesting that scale matters. ACS analyses can also be performed on specific population by U.S. county, which can illustrate major variations in uncertainty associated with rural or urban communities, and by demographic parameter (e.g., such as gender or income), which can illustrate unique areas of uncertainty. For example, an analysis of ACS data indicated that Hispanic females over age 65 exhibit significantly higher coefficients of variation in terms of median household income, compared to all females, all individuals over age 65, and all Hispanic individuals, suggesting that this group's estimates likely carry more uncertainty. Methods to improve the collection of race/ethnicity data and reduce uncertainty include using geodemographic data and generating optimal, or "goldilocks," geographies based on user-defined constraints (e.g., margin of error, population size); this method enables the review of more meaningful and reliable data that have not lost socio-spatial variation.

The Decennial Census delivers three main products: (1) PL94-171 redistricting data, which are typically used for legislative and congressional redistricting; (2) demographic and housing characteristics (DHC; formerly known as Summary File 1); and (3) detailed DHC (DDHC; formerly known as Summary File 2). The 2020 PL94-171 data were released in August 2021, the DHC will be released in late 2022 (approximately a 1-year delay), and the DDHC does not yet have a release date. Delays in these data releases are directly related to the COVID-19 pandemic, which has significantly altered the Census Bureau's data collection schedules and, in turn, the data processing and quality control procedures. Another cause of the delay is a change in the Census Bureau's disclosure avoidance process, which includes resetting algorithms and parameters for each of the three major data products; still in testing, this new process will result in release of a demonstration DHC product, which will be compared to past data releases. Further, the Census Bureau has proposed substantial changes to its data products. The Census Bureau plans to release new census block tables in the DHC (including sex information in 5-year ranges and more race/ethnicity information), reduce the geographic detail of the reports (by shifting from census blocks to counties), and eliminate 169 DHC tables and 67 out of the 71 DDHC tables. The tables containing single year of age information by race/ethnicity, as well as information related to specific Hispanic subpopulation related to origin, will no longer be available. In addition, the change to present data at the county level may increase uncertainty in data for cities with larger populations.

Overall, the ACS and Decennial Census provide sufficient city-level rates and population estimates, but more granular estimates (such as within-city or county level) contain significant levels of uncertainty. This observation highlights the importance of geographic and demographic resolution for population estimates. Areas or subgroup with higher numbers of counts will be more accurate overall than smaller areas or populations.

- ***Betty Bekemeier, PhD, MPH, RN, University of Washington***

Gaps in collecting public health data in rural areas are caused by limited access and resources, data unavailability or low-quality data, and variable data needs. The Solutions in Health Analytics for Rural Equity across the Northwest (SHARE-NW) project aims to identify, gather, and visualize data with public health leaders to more effectively address rural health disparities and achieve health equity in Washington, Oregon, Idaho, and Alaska. In 2021, SHARE-NW investigators interviewed public health leaders, who reported that they are overwhelmed by the high volumes of data generated and that they lack the capacity to assess and ensure data quality, which has implications for data trustworthiness. The public health leaders also reported a general lack of data on underserved groups. Both administrative and community public health data are critical to addressing health equity in rural areas. However, administrative data exhibit common inconsistencies across reporting agencies, which have been exacerbated during the COVID-19 pandemic, and lead to a lack of comparable data and subsequently a lack of resources to inform data-driven decisions for resource allocations.

To address the challenges to collecting and reporting data from rural areas, SHARE-NW aims to reduce the gap between practice and research through development and dissemination of supportive resources, including data capture tools, linked datasets, user-center data dashboards, and training on data use. Through its various efforts, SHARE-NW has identified several modifiable solutions to help address gaps in addressing equity: (1) access to datasets and dashboards with visualizations/infographics; (2) training on how to collect and use data effectively and creatively, how to use an equity lens in decision-making, how to analyze data to identify alternative sources of data, and how to evaluate data quality; and (3) incentivize communities to collect better data. The SHARE-NW website features a data dashboard that allows users to review general demographic data, as well as more specific topics, such as mental and behavioral health and tobacco use. SHARE-NW also hosts multiple training sessions on, for example, understanding population health concepts, communicating effectively, and visualizing data stories.

The effects of declining funding for public health efforts have become pronounced during the COVID-19 pandemic. During the past 5 years, the Public Health Activities and Service Tracking (PHAST) team developed the Uniform Chart of Accounts (UCOA), which is a standard method of reporting public health finance information (including the amount of funding required to support specific programs, such as noncommunicable disease control). Ready availability of these reports can help public health leaders advocate for the funding and staffing required to facilitate necessary programs. Recent analysis—performed collaboratively by PHAST, de Beaumont, Public Health Accreditation Board, and Public Health National Center for Innovations through the Staffing Up initiative—determined that the nation's public health workforce should increase by 80 percent to provide the minimum set of services that each community requires. Agencies are using the UCOA to quantify the financial impact of the COVID-19 pandemic; understand funding sources for public health services; identify programs at risk during funding cuts; demonstrate the value and function of public health to funders, elected officials, and the public; and develop the Staffing Up Workforce calculator.

Overall, addressing public health equity in rural areas requires improvements in data accessibility, more training, and resources for oversampling, data collection, and tracking of highly affected COVID-19 hotspots. To improve public health administrative data specifically, the public health field requires more standardization, resources and time, coordination, and incentives.

- **Glen Mays, PhD, MPH, University of Colorado**

The Robert Wood Johnson Foundation supports three major research initiatives that provide community- and county-level public health data: (1) National Longitudinal Survey of Public Health Systems (NLSPHS), which is a national cohort of 600 local public health jurisdictions that has been sampled since1988; (2) National Health Security Preparedness Index (NHSPI), which is an annual county-level survey that provides estimates of preparedness and response capabilities across all 50 states; and (3) Systems for Action Research Program, which involves community-level studies of cooperation across medical, social, and public health delivery systems. A review of data from these three sources reveals that most local public health jurisdictions have not realized improvements in access or use of race/ethnicity data. The most progress has been observed in the collection of hospitalization and vaccination information, but collection of other data points, such as occupational exposures and unmet social needs, continues to lag. In addition, jurisdictions continue to experience data missingness or incomplete data and limited access to administrative data sources and regional and social health information exchanges.

Approximately 53 percent of local public health agencies report no or limited ability to examine racial equity as part of community health needs assessments, and 63 percent report no or limited ability to allocate resources based on analyses of racial equity in priority health needs. Rural jurisdictions are up to 21 percent more likely than urban areas to report limited capacity to consider racial equity in assessments and resource allocation. Further, COVID-19 mortality rates were 13-21 percent higher in jurisdictions that were unable to consider racial equity in resource allocation. Improving local public health access requires (1) expanded staffing of local public health workers with data science training; (2) more training for staff on data collection, access, and use; (3) improved data infrastructure to support local access to state and regional data systems; and (4) enhanced statistics capacity to fulfill local data requests (e.g., related to staffing, protocols).

- **Ninez Ponce, PhD, MPP, University of California, Los Angeles**

Data desegregation and equity are imperative to health equity. During previous presentations to the NCVHS Committee, Dr. Ponce emphasized that some place-based equity algorithms may be missing key data inputs, leading to some communities being overlooked during resource allocation. Developers must enhance place-based equity algorithms, possibly by including data from available vulnerability measure indices, that is, Social Vulnerability Index, Area Deprivation Index, Social Deprivation Index, and the Medical Vulnerability Index. However, only two of these indices (Social Vulnerability Index and the Medical Vulnerability Index) collect race, ethnicity, and language information. Overall, these place-based indices must better address underlying causes of structural racism, discrimination, and biases that may be indicated in non-health-sector databases. In October 2021, the California Pan-Ethnic Health Network released the "Nothing About Us Without Us: Can Area-based Social Indices Effectively Advance Health

Equity?" report, which provides the following suggestions to better capture race, ethnicity, and language information in indices:

- Directly factor in race, ethnicity, language, and other domains relevant to measuring health disparities
- Even when an index does factor in race, ethnicity, and language, determine impact on communities that are small in size, heterogeneous, displaced, or geographically dispersed
- Pair indices with other tools and strategies, including authentic, targeted community engagement and long-term structural reforms
- Match indices with SDOH addressing specific policy issues that those policies aim to solve
- Consider whether relevant domains are available at the block level

Dr. Ponce and colleagues recently published a journal article on data reporting gaps for NHOPI individuals. They found that greater than 30 percent of the federal data resources reviewed for the publication failed to properly disaggregate NHOPI data from the broad Asian category, despite an Office of Management and Budget (OMB) mandate from the late 1990s to do so. This lack of compliance is a form of structural racism that disproportionately affects 1.4 million Americans through an inability to advocate based on population data evidence, a lack of resources, and limitations to political power. Next steps to improve data and health equity include improving tools, as well as conducting trainings, that focus on understanding and evaluating race/ethnicity data.

Discussion

Dr. Vickie Mays noted that the Grantmakers in Health released a report on modernizing race/ethnicity data across federal health programs, particularly during the COVID-19 pandemic. She added that HHS released a report on how to collect race/ethnicity data in 2011 and has not updated this report since.

Dr. Glen Mays emphasized that social health information exchange systems are growing, but require many improvements (e.g., access to public health regional systems) to ensure the collection of sufficient race/ethnicity data. Dr. Ponce suggested that nongovernment funding could catalyze this work. Dr. Bekemeier agreed that nongovernment funding is helpful, but stressed that the government must provide support as well facilitate and scale up these activities.

Dr. Pathak emphasized that COVID-19 is "a disease of the working class," in that mortality and disease severity disproportionately impact the working class (particularly workers who are Black, Hispanic, AI/AN, or NHOPI). In addition, children, particularly minority children, are more likely to be in working class families. Dr. Pathak noted that investigation of the intersection of health and work requires the integration of health and social data. Dr. Pathak noted that mandates offer one approach to achieving successful health and social data collection and integration, such as those issued by CMS to hospitals that receive Medicare-related funding.

Ms. Love asked about the extent to which the law is considered during the development of local public health data infrastructures. Drs. Bekemeier and Mays noted that consideration of the law is inadequate and agreed on the need for more training of public health professions on legal requirements. Dr. Mays added that public health professions are not covered by loan repayment programs, suggesting an area where the federal government could incentivize engagement.

Committee Discussion and Follow-Up on Workgroup to Assess SOGI and SDOH Data and Measure Definition, Collection, and Use—Vickie Mays and Denise Chrysler, Workgroup Co-Chairs

The SOGI/SDOH Data Workgroup is charged with the following:

- Identify considerations and options to define methodologically sound categories for framing sources of SOGI/SDOH data (e.g., survey, administrative, clinical, vital records, and public health surveillance)
- Identify domains of SOGI/SDOH data that should be collected by data category, including suggestions for prioritization among the domains in the case that limited data can be collected
- Conduct an assessment of best practices for how these data should be collected, including findings on specific data elements, data standards, the order of questions, public trust, and any other findings regarding options or alternatives to improve HHS' ability to improve data equity and aid equitable evidence-based decision-making
- Provide findings to the NCVHS Committee about specific privacy considerations for use and linkage of SOGI/SDOH data in each setting, including considerations for potential use of SOGI and SDOH data (e.g., administrative, clinical, public health, and research purposes)

The different aspects of SOGI information require the adoption of a use case approach. Multiple types of SOGI information are available, including recorded sex or gender, sex for clinical use, and gender identity. Typically, recorded sex or gender information is extracted from vital records. Sex for clinical use information relates to medical observations; HL7's categories for this type of information are male, female, or other, and currently no category for intersex or transgender status exists. However, many larger medical institutes use Systemized Nomenclature of Medicine–Clinical Terms (SNOMED-CT) codes to standardize the documentation of intersex and transgender status, in addition to other clinical sex categories. Gender identify information relates to an individual's personal sense of being a man, woman, or non-binary, and this information can only be obtained by asking the individual. ONC requires the ability to collect SOGI information through electronic health records (EHRs), but the range of values for EHR SOGI data has not been standardized. Standardization is imperative to improving data flow from EHRs to either electronic laboratory reporting or case reporting. Electronic laboratory reports do not require extensive gender information and typically include only information on medical tests ordered or performed. Case reports include information collected during interviews with the patient, including self-reports on the individual's gender identify and sexual orientation.

Mr. Ferguson emphasized that the SOGI/SDOH Workgroup must consider expanding the sex for clinical use category to include fields related to intersex and transgender status, as well as validating all possible sexual orientation categories to support the collection of that information. Mr. Ferguson also recommended that the SOGI/SDOH Workgroup identify methods to standardize the collection of clinical encounter information and evaluate the feasibility of expanding the standardized use of electronic case reporting.

The SOGI/SDOH Workgroup proposes to address standardization of SOGI and SDOH information first in clinical data types, followed by administrative data, survey data, and funded research data. It plans to begin by addressing clinical data because many current EHRs are being updated to collect SOGI information and to standardize clinical SOGI data. The SOGI/SDOH Workgroup will identify other needed supports for standardization, including data systems (e.g., hospitals, labs, insurers) and data integrity processes. The SOGI/SDOH Workgroup will engage with experts and organizations that are significant contributors of policy related to clinical SOGI data.

Discussion

Dr. Arnold explained that the primary objective of the SOGI/SDOH Workgroup is to identify high-priority gaps and to provide guidance in the form of recommendations (which will likely be released in approximately 1 year). During recent listening sessions held by the Standards Subcommittee, Ms. Love noted that many industry organizations also emphasized the importance of obtaining guidance related to SOGI/SDOH information collection. Mr. Landen noted that the Standards Subcommittee could work with the SOGI/SDOH Workgroup if specific ICD-10 code sets require updating. Ms. Skurka confirmed that SOGI is not captured in code sets, likely because these codes are not imperative for reimbursements.

Mr. Landen asked whether the SOGI/SDOH Workgroup has identified where SOGI and SDOH information should be captured, suggesting their possible incorporation into the ONC EHR as a primary repository. Mr. Ferguson agreed that ONC EHRs may be the primary repository for SOGI information, but will likely not be sufficient for SDOH information.

Dr. Vickie Mays noted that some related recommendations by external committees emphasize the need to amend HIPAA to enable better data sharing across the health care system, as well as social services and the justice system. Ms. Love added that the change to implement HIPAA requirements across more covered entities may also provide another approach to collecting data elements related to SOGI/SDOH data.

Ms. Love recommended that the SOGI/SDOH Workgroup contact CMS, which is developing value-based purchasing approaches to collecting SOGI and SDOH data. Committee members recommended that the SOGI/SDOH Workgroup consider other settings beyond the traditional clinic that could provide important data, including post-acute care facilities, home-health agencies, community health centers, and federally qualified health centers.

Dr. Vickie Mays asked Committee members to identify sources of established or standardized SOGI and SDOH information. Participants recommended the following: SDOs, HL7, SNOMED, National Quality Forum, Joint Commission, Logical Observation Identifiers Names and Codes (LOINC), National Committee for Quality Assurance, Federal Committee on Statistical Methodology, National Association for Home Care and Hospice, National Council for Prescription Drug Programs. They also suggested that the SOGI/SDOH Workgroup engage with the following experts and entities: Rob McClure (American Health Information Management Association), Ninez Ponce (UCLA), Dr. Bob Phillips (American Board of Family Medicine/American Academy of Family Physicians), and National Association of Country and City Health Officials (to help engage with a large urban area health department, possibly New York City), Jim Case (SNOMED), Marjorie Rollins (LOINC), Jeff Swanson (Kaiser Permanente), and the World Health Organization.

Panel on the Impact on Cyberattacks and Pandemic Stress on Healthcare

- **Reuven Pasternak, MD, MPH, MBA, Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security**

The mission of CISA is to partner with industry and government to understand and manage risk to U.S. critical infrastructure, with two major goals: defend against urgent threats and hazards and strengthen critical infrastructure and address long-term risks. CISA's National Risk Management Center (NRMC) is a planning, analysis, and collaboration center that analyzes strategic risks to U.S. critical infrastructure; leads public-private partnership initiatives to manage priority areas of national risk; and collaborates with private-sector and other stakeholders to better understand future threats. Through its efforts, CISA protects the 55 national critical functions (NCF), which are government and private-sector functions that are so vital to the United States that their disruption or dysfunction would have a debilitating effect on security, national economic security, national public health, or safety. The 55 NCFs can be divided into four major sections: (1) connect (e.g., provide cable access network services), (2) distribute (e.g., maintain supply chains), (3) manage (e.g., provide medical care and insurance services, and (4) supply (e.g., supply water). The NCF framework recognizes that critical infrastructure relies on cross-talk with other sector activities and systems and that a siloed approach to protecting NCFs is not sufficient to manage risks, particularly cybersecurity risks; thus, this framework focuses on key assets, systems, and networks that support the NCFs, as well as technologies and dependencies that enable their continue operation when a critical element is no longer functional. CISA monitors the risk status of each NCF, which are characterized as low, medium, or high risk (ranging from low to a greater than moderate chance of national scale disruption) according to various risk driver factors.

A threat that causes major dysfunction within the health care sector would have an immediate, pervasive, and profound impact on the hundreds of public and private health care systems within the United States, each with its own complex structures. The health care sector is challenging to protect because of the high volume of data created and shared across hospital systems. CISA aims to instill resilience within the health care sector to help prepare for the impact and stress of future pandemics (e.g., sudden high rates of hospitalizations with the same number of staff). CISA has developed a conceptual model of COVID-19 surge cascading effects, which starts with unaffected operations and ends in regional degradation. Within this model, the three major stressors on the health care system are increased demand for treatment and hospital care, commodity shortages, and workforce shortages, which can exert major cascading effects on each other. As any of these stressors escalate, the hospital must evaluate its options to prevent further degradation and a possible crisis. CISA has created the Disruptive Event Level System, where Level 1 indicates normal operations and Level 5 indicates rendering of a system unable to provide services because of compromised infrastructure. This level system, in addition to the available conceptual model, can help public health leaders to understand and monitor potential threats in order to inform protective and preventative strategies.

- **Josh Corman, I am The Cavalry and the CISA COVID-19 Task Force**

I am The Cavalry is a grassroots organization focused on the intersection of digital security, public safety, and human life. This organization is concerned with the nation's dependence on IT that enables any single outlier to have a profound and asymmetric impact on human life, as well as national and economic security. I am The Cavalry developed the Hippocratic Oath for Connected Medical Devices, which outlines five guiding ethical principles for manufacturers, organizations, and individuals delivering care through connected medical devices. The oath's principles can serve as a roadmap to follow in many other health care-related situations.

Mr. Corman served on the Health Care Industry Cybersecurity Task Force, which sought to improve cybersecurity practices across the health care industry. This task force developed a report for Congress in 2017, which emphasized five critical findings (shown below).

- The majority of health delivery organizations lack full-time qualified security personnel.
- Many organizations rely on legacy equipment that run on old, unsupported, and vulnerable operating systems.
- "Meaningful use" requirements drive hyper-connectivity without secure design and implementation.

- Vulnerabilities impact patient care.
- Organizations may contain equipment with known vulnerabilities and are not acting on it.

Mr. Corman emphasized that hospital systems should not use equipment and systems that cannot be adequately protected because that use can endanger future patient care. Shortly after publication of the 2017 Health Care Industry Cybersecurity Task Force report, large-scale cyberattacks caused unprecedented disruptions to U.S. and U.K. health care delivery systems, as well as billions of dollars in damages. Another recent cyberattack led to the death of an infant, proving that cyber-attacks impact not only patient privacy, but also patient lives. During the 2017 CyberMed Summit, Mr. Corman and colleagues performed an emergency room simulation whereby an insulin pump was hacked, leading the device to empty its contents, and the patient, who was currently driving a car, to crash and lose consciousness. Mr. Corman and colleagues' investigations of cybersecurity practices have led the FDA to recall approved devices, including an infusion pump and a subdural pacemaker.

Mr. Corman and colleagues recently published an article in *Morbidity and Mortality Weekly Report* on the impact of hospital strain on excess deaths during the COVID-19 pandemic; this report included a review of CDC data that revealed that an intensive care unit's optimal rate of bed utilization is 75 percent and that any increases in that rate are associated with increased COVID-19-related excess deaths. Further investigations identified that hospitals targeted by ransomware attacks were more likely to observe higher rates of COVID-19-related excess deaths that persisted longer than non-affected hospitals; these analyses further emphasize the importance of enacting cybersecurity practices across the health care system to protect patient lives.

Discussion

Ms. Monson asked both panelists to share their top priorities that the PCS Subcommittee should consider when refining their letters of recommendation. Mr. Corman noted that only 200 of the 5,600 hospitals in the United States have elected to use CISA's free services. Mr. Corman added that maintaining the current status quo of cybersecurity in the health care system is exceedingly dangerous and that gaps must be corrected to enhance protection. In addition, CISA has developed a catalog of cybersecurity bad practices for organizations to avoid. Dr. Pasternak emphasized the importance of establishing cybersecurity standards that are based on evidence and the needs of patients.

Mr. Landen asked whether CISA has discussed the consequences of overconnectivity with ONC, as well as possible mitigation strategies. Mr. Corman confirmed that, to his knowledge, this discussion has not occurred.

Ms. Love noted that most patients are likely unaware that cybersecurity attacks could impact their ability to receive medical care because they assume that hospitals are conducting quality security procedures. Mr. Corman added that progress will involve making society more aware of these types of these attacks and in turn accountable for their actions that may cause an attack.

Subcommittee on Privacy, Confidentiality, and Security Final Review of Recommendations to Strengthen Cybersecurity in Healthcare Letter —Jacki Monson, Chair

Meeting participants reviewed the updated PCS Subcommittee letter titled, "Recommendations to Strengthen Cybersecurity in Healthcare." Ms. Bernstein presented a list of changes made to the supporting content of Recommendation 1, including a reference to a recent CHIME report and to 2013

OCR guidance regarding the difference between a required and addressable implementation specification.

Ms. Hines suggested reformatting the recommendations within the executive summary portion to remove the word "should" and begin the statement with the verb of the recommendation; for example, "*Mandate* basic cybersecurity requirements for any organization that is a recipient of federal funds, in partnership with other appropriate government agencies," instead of "HHS, in partnership with other appropriate government agencies, should mandate basic cybersecurity requirements for any organization that is a recipient of federal funds."

Mr. Ferguson suggested updating one of the cybersecurity hygiene requirements to state "Installation of critical patches and addressing known vulnerabilities within a reasonable timeframe."

Committee members reviewed the supporting language in the document and rephased sections related to Recommendation 1 stating that "covered entities and business associates *should not be given the option to choose not to implement* the provisions of the HIPAA Security Rule" and that "we recommend that an entity *document* how they considered the requirement and adopted a reasonable alternative." Committee members agreed to include information from CISA's Cyber Hygiene Services webpage within the supporting content for Recommendation 2.

Ms. Strickland suggested updating "healthcare infrastructure" to "healthcare ecosystem" within the second paragraph of the cover letter.

Participants updated the recommendations according to these suggestions and the finalized recommendations are as follows:

1. Strengthen the HIPAA Security Rule by:
    a. Eliminating the choice not to implement an addressable specification or alternative, thus requiring covered entities to either implement the specification in the Rule or to adopt a documented reasonable alternative, and
    b. Including additional minimum cybersecurity hygiene requirements.
2. Mandate basic cybersecurity requirements for any organization that is a recipient of federal funds, in partnership with other appropriate government agencies.
3. Further enhance communication and education regarding the HIPAA Security Rule and security threats and incidents by:
    a. Providing more robust guidance regarding enterprise-wide risk analysis and risk mitigation requirements to ensure covered entities and business associates understand the full breadth of the Security Rule's expectations,
    b. Facilitating, with other appropriate government agencies, more coordination and collaboration among public and private sector parties during incidents, including work to coordinate the identification of threats to critical infrastructure,
    c. Leveraging, in partnership with other appropriate government agencies, the OCR cybersecurity newsletters as real-time playbooks on common cybersecurity incidents, and
    d. Encouraging entities to undergo the CISA certification audit and use CISA's free services to discourage bad practices.
4. Evaluate in concert with other appropriate government agencies the level of compliance with the HIPAA Security Rule and provide assistance to healthcare entities with the greatest in meeting the enhanced minimum security requirements.

Ms. Strickland made a motion to approve the recommendation letter (with additional non-substantive refinements related to citations and formatting), which was seconded by Dr. Watzlaf. Ms. Hines called for a vote of NCVHS Committee members; 11 members voted in favor of approving the letter and thus the letter was approved (with non-substantive changes).

Subcommittee on Privacy, Confidentiality, and Security's Data Collection and Use During a Public Health Emergency Letter Draft Update—Melissa Goldstein, Subcommittee Co-Chair

The PCS Subcommittee has updated the "Data Collection and Use During a Public Health Emergency" letter and recommendations according to feedback received on Day 1 of this meeting. The PCS Subcommittee will provide an overview of the changes made during an ad-hoc Committee meeting to be held before the next full Committee meeting.

Public Comments

No public comments were provided during this session.

Closing Remarks—Ms. Monson, Chair

Ms. Monson noted that the 2022 Workplan will be discussed in an upcoming Executive Subcommittee meeting. Ms. Monson thanked subcommittee staff members, invited speakers, the NCVHS team, and the RLA team for their support and adjourned the meeting.

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

/s/	October 3, 2022
Chair	Date