HIT Policy Committee FINAL Summary of the June 5, 2013 Virtual Meeting

ATTENDANCE

Members present:

- Madhulika Agarwal
- David Bates
- Neil Calman
- Arthur Davidson
- Connie White Delaney
- Paul Egerman
- Judith Faulkner
- Thomas Greig
- Gayle Harrell
- Deven McGraw
- Marc Probst
- Joshua Sharfstein
- Paul Tang

Members absent:

- Christine Bechtel
- Patrick Conway
- Scott Gottlieb
- Charles Kennedy
- David Lansky
- Farzad Mostashari
- Frank Nemec
- Alicia Staley
- Latanya Sweeney
- Robert Tagalicod

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 49th meeting of the Health Information Technology Policy Committee (HITPC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with two opportunities for public comment and that a transcript will be posted on the ONC website. She called the roll and instructed members to identify themselves for the transcript before speaking.

Remarks

David Muntz, Principal Deputy National Coordinator, ONC, remarked that many accomplishments have been made. The most recent EHR incentive program adoption numbers are astonishing. Consumers have also made positive steps. The progress was recognized in Tom Friedman's May 25th op-ed on health IT in

the New York Times (<a href="http://www.nytimes.com/2013/05/26/opinion/sunday/friedman-obamacares-other-surprise.html?ref=thomaslfriedman& r=0) as well as in the trade press. Participation in the June 3rd Datapalooza was inspiring. Data liberation is progressing. The establishment of the FDASIA Workgroup demonstrates collaboration across ONC, the Food and Drug Administration (FDA), and the Federal Communications Commission (FCC). Although there are criticisms, they are an opportunity to examine efforts. Care transformation requires people, process, and policy. He announced two recent appointments to the HITPC. The U.S. Government Accountability Office (GAO) appointed Alicia Staley, Boston, Mass., Co-chair, Tufts Medical Center Patient Family Advisory Committee, and Media Specialist, Staley Media Services, to fill a consumer representative slot. Senator Mitch McConnell, (R-KY), appointed Scott Gottlieb, M.D., American Enterprise Institute, to the slot allocated to the minority leader. Neither of the new members was present. The terms of Chris Boone and Richard Chapman have expired.

Review of the Agenda

Paul Tang, Vice Chairperson, asked for approval of the summary of the May meeting, which had been distributed with the meeting materials. Deven McGraw moved and Neil Calman seconded the motion to accept the summary with no amendments. The motion carried unanimously.

Action item #1: The summary of the May 2013 HITPC meeting was approved as distributed.

Tang noted that the meeting was intended to provide information rather than to take action. He mentioned each of the items on the previously distributed agenda.

Patient-Centered Outcomes Research Institute

Joe Selby, PCORI, reported on an initiative of his organization, which is an independent research organization, authorized by Congress as part of the 2010 Patient Protection and Affordable Care Act. PCORI funds comparative clinical effectiveness research that provides patients and those who care for them information to make better-informed health care decisions. He emphasized the practical nature of the research. PCORI is proposing a national Patient-Centered Clinical Research Network. Two funding announcements for up to \$68 million have been released for Clinical Data Research Networks (CDRN) and Patient-Powered Research Networks (PPRN). Letters of intent are due June 19. Many federal agencies, as well as private organizations, participated in a visioning conference in July 2012. He described the vision of network, which would have these characteristics: a network of networks; two types of component networks, systems-generated and patient driven; active involvement of health care systems, clinicians, and patients; a commitment to establishing interoperability and data-sharing across networks; and ready collaboration with the larger research community. And, ideally, a network would have the following capabilities: rich clinical data from electronic health records and other data sources stored in standardized, interoperable formats; capacity to conduct both observational studies and randomized trials embedded in clinical settings; rigorous practices for data security and confidentiality; appropriate IRB and human subjects oversight; utility for CER, safety studies, surveillance, etiologic research, and potentially for pre-approval trials; and a governing structure.

The availability of \$12 million to support up to 18 new or existing Patient-Powered Research Networks (PPRN) for 18 months was announced. Requirements are to have: patients with a single condition, interested in research participation; ability to increase size and diversity of patient membership; willingness to build a standardized database of patient-reported data; and willingness to explore collection of electronic clinical data.

The availability of \$56 million was announced to support up to eight new or existing Clinical Data Research Networks for 18 months. Requirements are: at least two health care systems engaged;

willingness and capacity to work toward data standardization with other awardees; willingness to participate in collaborative studies with data-sharing as part of a national research infrastructure; greater than or equal to 1,000,000 patients enrolled; data standardized within network and with other awardees' networks; patients, system, and clinicians engaged in governance and use; and capable of implementing clinical trials. He called these efforts a natural outcome of meaningful use.

Q&A

ONC is represented on the steering committee. There will be challenges such as interoperability, patient consent and participation, and hosting of randomized trials. Paul Egerman said that implementation of a common data model will be difficult. Selby responded that a meeting in conjunction with the Institute of Medicine on a common data model is planned. Discussions on how to move toward learning health systems will also take place. McGraw reminded members that they had made recommendations on the common rule and participation in federally-sponsored research. She expressed hope of returning to issues pertaining to research protections.

Judy Faulkner wondered how work on a common data model and a learning system could proceed simultaneously since a data model is static and a system for learning requires change. Selby disagreed that the two were contradictory. Learning health systems can only learn from research across systems. A common data model has utility, even within a single system. A common data model will have to evolve across systems. A steering committee comprised of members committed to working together on research has been established. Selby agreed to provide frequent updates and to solicit advice from the HITPC. Egerman suggested that he involve the Information Exchange Workgroup.

CMS Update

Robert Anthony, Centers for Medicare and Medicaid Services (CMS), moved through his updated slides, describing registration and payment through April 2013. There are nearly 395,000 active registrants. There is a trend toward transition to payments. For Medicare EPs, 61 percent are non-primary care physicians. Seventy-five percent of eligible EPs are registered and more than 50 percent have been paid. Seventy-seven percent of all EHs have received an EHR incentive payment for either meaningful use or AIU. Approximately 50 percent of Medicare EPs are meaningful users of EHRs. Approximately 63 percent of all Medicaid EPs have received an EHR incentive payment and 10 percent are meaningful users. At the time of the analysis, 194,080 EPs had attested, 193,867 successfully. For hospitals, 2,977 had attested successfully.

Drug formulary, immunization registries and patient list are the most frequently selected menu objectives by EPs, and for EHs, advance directives, clinical lab test results, and drug formulary are the most frequently selected. Transition of care summary and patient reminders were the least frequently selected menu objectives for EPs, and for EHs, least selected were transition of care summary and reportable lab results. Anthony observed that since transition of care summary will be a core objective in Stage 2, CMS staff is anticipating that providers will need with the objective.

Looking at EPs performance in 2011, 2012, and the first 90 days in 2013, he concluded that the latecomers were generally performing as well as the early adopters.

Members asked no questions.

Data Analytics Update

Jennifer King, ONC, described EH progress in meaningful use as of April. Sixty percent of 5011 hospitals have attested; another 19 percent have received AIU payments only and an additional 4 percent have participated in a REC. Sixty-nine percent of large hospitals have attested, compared to 66 percent of

medium sized hospitals. Forty-nine percent of small urban hospitals have attested compared to 68 percent of small rural hospitals and 56 percent of CAHs. CAHs have relatively high rates of REC participation. Attestation rates vary little by type of ownership. With regard to EPs, as of April, 43 percent had attested; 14 percent had received AIU payments only, and another 20 percent had registered for the EHR incentive program. The overwhelming proportion of participation of EPs is by physicians. Pediatricians are slightly under-represented. Among ambulatory physicians, rural – urban location was not related to attestation or registration.

King went on to show slides on trends in attestation and payment after registration, indicating that about 80 percent of EP registrants have attested. For Medicaid EP registrants, about 80 percent have been paid. Looking at attestation status for the 2012 program year among providers that completed 90-day attestation in the 2011 program year, as of April 2013, attestation progressed for 94 percent of EHs. Attestation progressed for 83 percent of EPs. King concluded that these data indicate that registrants are progressing to attestation. Regarding objective scores reported by EHs at attestation, scores greater than 90 percent were reported for the majority of objectives. However, patient-specific educational resources, med reconciliation, and transition of care summary scores were considerably lower. Among EPs, 48 percent reported a 100 percent score on transition of care summary.

Q&A

Tang suggested a change in colors on the graph slides. He declared that the findings are good. Egerman wondered about the prevalence of EHRs among the entire U.S. population. King referred to data from one of the NCHS surveys, indicating that in 2012, 72 percent of office-based physicians had some kind of EHR, but not necessarily one certified for meaningful use. But she said that she knew of no data on patients having access to EHRs. It may be possible to generate an estimate using size of physician panel data. Egerman referred to then-President Bush's goal for every "American" to have an EHR. King agreed to work on an estimate. Faulkner said that estimates from her clients summed to about 178 million with adjustments for overlaps. David Bates agreed that this information would be useful. Tang wondered about obtaining information from the Consumer Empowerment Workgroup or an advocacy organization. King said that ONC staff is partnering with other organizations to obtain information on consumer perceptions of the usefulness of EHRs.

Art Davidson agreed with Tang about changing the color of the graph lines. Regarding the transition of care summary being one of the least frequently reported objectives, he noted an inconsistency in King's and Anthony's data. King said that her data were restricted to those providers that selected that menu item and their reported results. Of those who selected the item, 48 percent reported a score of 100 percent. Anthony interjected that the CMS data indicate that when selected, the results are high. Thus, their data are consistent.

Gayle Harrell asked why providers drop out. King responded that they have not necessarily dropped out; they may eventually attest. Staff is examining the characteristics of providers that are slower to attest. They are working with RECs to identify issues. Anthony reported that CMS had surveyed that set of providers and the findings were presented at a previous HITPC meeting. Reasons for delayed attestation included: delayed implementation because of the product used and post-implementation workflow challenges. He said that a significant number of providers registered without being informed on what was required in the program. Resources were directed to this group.

Privacy and Security Tiger Team Update

Deven McGraw, Chairperson, reported on the team's review of comments received in response to questions asked in the Stage 3 RFC. Comments were reviewed to determine whether there were relevant policy considerations to discuss, and whether previous recommendations addressed the questions.

Regarding re-use of third party credentials for identity management, she said that the team's September 2012 recommendations on provider user identity management, adopted by the Policy Committee, already address this issue. The recommendations urged multi-factor authentication at NIST Level of Assurance (LoA) 3 for remote access to PHI; entities covered by HIPAA should also, as part of their security risk assessment, identify other access environments that may require multiple factors to authenticate an asserted identity. Provider users should continue to be identity-proofed in compliance with HIPAA. Work being done as part of NSTIC to establish trusted, third-party credentials is ongoing, but such solutions are not yet widely available and may not be by Stage 3. Consequently, as recommended by the HITPC, ONC's efforts on this issue should continue to be informed by NSTIC developments, including (but not limited to) the work being done in the NSTIC pilots.

McGraw moved to certification criteria for testing authentication, saying that since the question does not request a policy-based response, it would be best answered by the HITSC Privacy and Security Workgroup. On the question about stand-alone certification, she reported that ONC should permit certification of both a stand-alone EHR and an EHR along with a third-party authentication service provider. On the attestation for security question, the team concluded that it would like to further investigate methods beyond attestation to call greater attention to existing HIPAA requirements, such as risk assessments, through meaningful use. A subgroup has been convened to consider the issues and to examine the effectiveness of the attestation process.

McGraw moved to the certification standard for audit logs, which she suggested be submitted to the HITSC Privacy and Security Workgroup to address whether it is feasible to certify compliance of EHRs with the prescribed ASTM audit log standard. Some team members also questioned the adequacy of the standard. Regarding attestation for length of time for audit logs, she reported that the HIPAA Security Rule does not require that audit logs are maintained for a specific period of time. Consequently, there is no reason to require additional policy specifying a timeframe. Covered entities will make their own decisions on audit trail maintenance periods.

With regard to a standard format for audit logs, McGraw said that though there are arguments in favor of standardizing formats for log files, this is a lower priority discussion in the context of meaningful use. She recommended following the guidance of the HIPAA Security Rule, which does not require any particular audit trail format. The HITSC Privacy and Security Workgroup can determine whether particular specifications should be required for EHR certification.

Concerning the three questions on patient consent, the team referred to its recent recommendations (adopted by the Policy Committee) on query/response re: technical mechanisms to support communication of patient consent requirements that data holders and requesters should comply with. Applicable law and policy and should have a technical way to communicate applicable consent or authorization needs and requirements. They should also have a means to maintain a record of such transactions. The HITSC should further consider technical methods for giving providers the capacity to comply with applicable patient authorization requirements or policies. She noted that the team has deferred further discussion on data segmentation until it has received an update on the DS4P Initiative pilot projects from ONC.

She reported that a virtual hearing on non-targeted query has been organized for June 24 to uncover what sort of policies are deployed to ensure that a non-targeted query for a patient record is appropriate, legal, and authorized. Such policies may include limitations on who can conduct the query, the purposes for which a query can be conducted, and geographic or other limits intended to help assure proper access to a patient's records. The team also wants to learn about the thought processes behind the development of any such policies.

Discussion

Members made no comments in response to Tang's call for discussion. Robertson called for a change in the order of the agenda items since the meeting was running ahead of schedule and not all presenters were present.

ONC Updates

Jodi Daniel, ONC, repeated Muntz's announcement of the two new appointees to the HITPC. She went on to announce that the GAO had reappointed David Lansky to another three-year term as an employer representative. Speaker of the U.S. House of Representatives John Boehner reappointed Gayle Harrell to represent consumers. She noted that more consumer products were presented at the recent Health Datapalooza IV compared to previous years. ONC issued a new challenge for tools. People can describe what they want and then developers will design the tools. Voting is open on the website through June 11.

The third-annual two-day Health Privacy Summit opened June 5 in D.C. The U.S. Chief Privacy Officer Todd Park and the European Union's Data Protection Supervisor, Peter Hustinx, are scheduled speakers. CMS and ONC will sponsor the eHealth Provider Webinar on Advancing Interoperability. Approximately 1800 individuals registered at:

https://www150.livemeeting.com/lrs/8000055450/Registration.aspx?pageName=1683xk04vdc7880m.

The Beacon Community Experience report and a video cast of issues learned were published May 22. The National HIE Governance Forum for HIE governing entities was created under the National eHealth Collaborative cooperative agreement with ONC. More information is available at: http://www.nationalehealth.org/hie-governance-forum. Over 30 organizations representing HIEgoverning bodies are participating. A steering committee was established. She noted several recent reports. Consumer eHealth Unintended Consequences Report was written by Westat under contract by ONC. This report includes a list of strategies for achieving the benefits of e-health and preventing or mitigating adverse events. The report is available at: http://www.healthit.gov/sites/default/files/final report building better consumer ehealth.pdf.

HIE Unintended Consequences Report was also prepared by Westat. The report identifies seven categories of unintended consequences: incomplete, inaccurate or untimely data provided by HIE; problems related to data presentation, including data overload; heterogeneity of use of HIE; patient perceptions or concerns about HIE; reputational and financial risks to organizations and providers engaged in HIE; vulnerability to technically related unintended consequences; and unintended consequences of administration of HIE. The report is available at:

http://www.healthit.gov/sites/default/files/hie uc workgroup final report.pdf.

Another report on Advice to HIOs and HISPs for MU2 Transition of Care Measure was prepared by Audacious Inquiry. The purpose of the report is to advise HIOs and HISPs on how to support the transitions of care measure 2. The report is available at:

http://www.healthit.gov/sites/default/files/key considerations for hios stage 2 toc final.pdf.

HITECH Report: Understanding the Impact of Health IT in Underserved Communities and Those with Health Disparities was released May 10. It is available at:

http://www.healthit.gov/sites/default/files/hit disparities report 050713.pdf.

Videos on Consolidated CDA Overview were posted. They walk the viewer through the basic concepts of the HL7 Consolidated-CDA standard and how it can be used to meet 2014 Edition EHR Certification Criteria. The videos review core features of the standard and requirements placed upon the use of the standard by certification criteria, as well as the nuts and bolts of how certification testing is performed for these certification criteria. Watch the videos at: http://www.healthit.gov/policy-researchers-implementers/consolidated-cda-overview. Finally, ONC contracted with NORC to convene advisory groups in support of patient centered research. It is a 10-month project to develop infrastructure for the research.

Q&A

Tang asked how the NORC contract relates to the PCORI projects. Daniel said that ONC is working on the infrastructure and coordinating with PCORI staff to ensure complementary efforts. The contract is to develop a strategic plan for what HHS will do with regard to the PCORI projects.

Harrell said that Daniel had mentioned a lot of links. (The links were shown in Daniel's slides and in the meeting materials distributed in advance of the meeting.) She requested that they be sent to her by e-mail. Regarding the PCORI and ONC-supported research, she wondered whether EHRs will be used. Daniel explained that the research will likely use data from various sources, EHRs, claims, and patient responses. One goal is to reduce the time from research findings to practice.

Health IT Workforce Update

Larry Wolf, Co-Chair, reported that at its May meeting, the HITPC's discussion of the workforce recommendations indicated that HITPC members could benefit from information on the results of ONC's workforce development efforts. Subsequently, ONC staff and select grantees prepared a presentation. Chitra Mohla, ONC, reported that curriculum development centers had produced 20 components for dissemination. A community college consortia implemented programs at 82 member colleges, resulting in the capacity to train 10,500 persons annually. Training roles included practice workflow redesign, clinician practitioner, implementation support specialist, implementation manager, technical software support specialist, and trainer. Degree programs were established at nine universities from which 1,258 students have graduated. They are expected to fill the following roles: clinician and public health leader; health information management and exchange specialist; health information privacy and security specialist; research and development scientist; programmers and software engineers; and health IT subspecialist. A competency exam was developed. Training material developed by grantees is freely available on the Department of Energy's National Training and Education Resource site: https://www.nterlearning.org/.

William Hersh, Oregon Health and Science University (OHSU), reported on the HIT curriculum. ONC funded cooperative agreements to five universities to support health IT curriculum development that ran from April 2010 to March 2013. Recipients were: Duke University, Columbia University, Johns Hopkins University, OHSU, and University of Alabama Birmingham. OHSU received additional funding to serve as the National Training and Dissemination Center (NTDC). The third and final version (Version 3) materials are currently housed on the NTDC site, awaiting final disposition. The curriculum consists of components supporting instruction in 20 content areas: Introduction to Health Care and Public Health in the U.S., The Culture of Health Care, Terminology in Health Care and Public Health Settings, Introduction to Information and Computer Science, History of Health Information Technology in the U.S., Health Management Information Systems, Working with Health IT Systems, Installation and Maintenance of Health IT Systems, Networking and Health Information Exchange, Fundamentals of Health Workflow Process Analysis and Redesign, Configuring EHRs, Quality Improvement, Public Health IT, Special Topics Course on Vendor-Specific Systems, Usability and Human Factors, Professionalism and Customer Service in the Health Environment, Working in Teams, Planning, Management and Leadership for Health IT, Introduction to Project Management, and Training and Instructional Design. Each component consists of 8-12 units. Each unit contains 1-4 lectures, each with voice-over PowerPoint Flash presentation, slides, MP3 audio file, and transcript of audio. He emphasized that the primary audience is educators, not students. To obtain the curriculum materials, anyone can go to: http://www.onc-ntdc.info, set up a profile, and download components or units. Per the original funding announcement, universities own the intellectual property for their components. For public rollout, they adopted a Creative Commons Attribution Non-Commercial ShareAlike 3.0 Unported License. This means that all users can use, share, and adapt the materials, but they must attribute the originator of the work, use the material only for non-commercial purposes, and share any changes made under the same license.

Patricia Dombrowski, Bellevue College, reported on the adaptation of the curriculum for rural physician practices in rural and migrant clinics and for the VA. A five-hour online class was designed that VA employees could take, but on their own time. Nevertheless, the demand was high. An adaption is being designed for community colleges to use with veterans with funding from the Department of Labor.

Norma Morganti and Rita Horwitz, Cuyahoga Community College, talked about role-based workforce competencies for patient-centered care via HIT and focusing on PCMH, HIE, meaningful use, and population management. The design is based upon input from subject matter experts and was facilitated with a partnership with Better Health Greater Cleveland. The resources were built to be widely distributed and used by educators and health care organizations that are ready to move to patient-centered care supported by health IT. For each role, there are competencies, learning objectives, and resources.

Discussion

Harrell asked for certification and employment results. Mohla replied that the grantees had not been required to collect tracking data. However, grantees have offered anecdotal data saying that graduates are finding jobs, though students need hands-on experience with EHRs. Hersh talked about research by someone at ONC who documented an increase in online job postings. Harrell suggested that ONC staff track outcomes and conduct follow up assessments to determine whether funds were well spent. Mohla informed her that an evaluation contract is nearing completion.

Connie Delaney commented on the importance of obtaining an overview of and tracking the insatiable work force demand. McGraw inquired about the inclusion of privacy and security training in the training roles, noting that the slides did not show that as a topic. Hersh responded that although privacy and security was not a specific component, the topic is embedded in several components. Privacy and security leaders at ONC were involved as subject experts. McGraw commented on the difficulty of understanding the HIPAA rules as well as establishing a culture to support privacy and security in organizations. She asked for more details on what students are taught about the latter. Hersh noted that since funding has ended, the more recent HIPAA regulations are not included in the training materials, nor are there plans for doing so.

ONC Updates Continued

ONC staff showed slides with data on participation in the numerous S&I Framework efforts and referred to the status of the 13 initiatives as depicted in the portfolio slide.

Harrell expressed concern about PDMP, which was scheduled for completion in March. Staff responded that the contract ended. Harrell probed for more information. Daniel interjected that staff are working to find funds to continue the PDMP work. Harrell declared it to be important.

Public Comment

Robertson announced the three-minute limit and reminded everyone that comments do not require responses. There was no public comment.

Another Item Added

Tang reminded members that from now on, approximately 50 percent of the HITPC meetings will be convened virtually. He asked for members' opinions on virtual meetings. He said that the agenda will influence decisions on whether to hold a virtual or an in-person meeting. Some discussions require a face-to-face meeting.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the May 2013 HITPC meeting was approved as circulated.

Meeting Materials

- Agenda
- Summary of May 2013 meeting
- Presentations and reports slides