HIT Policy Committee
DRAFT
Summary of the January 8, 2013 Meeting

ATTENDANCE

The following members were present:

- Farzad Mostashari
- Paul Tang
- Madhulika Agarwal
- Christine Bechtel
- Christopher Boone
- Arthur Davidson
- Connie White Delaney
- Paul Egerman
- Judith Faulkner
- Gayle Harrell
- Charles Kennedy
- David Lansky
- Deven McGraw
- Marc Probst
- Joshua Sharfstein
- Scott White

The following members were absent:

- David Bates
- Neil Calman
- Richard Chapman
- Patrick Conway
- Thomas Greig
- Frank Nemec
- Latanya Sweeney
- Robert Tagalicod

KEY TOPICS

Call to Order

MacKenzie Robertson, Office of the National Coordinator (ONC), welcomed participants to the 44th 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 reminded members to identify themselves for the transcript before speaking. She turned the meeting over to HITPC Chairperson and National Coordinator Farzad Mostashari.

Remarks

Mostashari reported on Jonathan Haidt's *The Righteous Mind*, relating Haidt's conclusions on competition and group selection to the task at hand. Talking about morality, social control, solidarity and authority, Mostashari recognized that not every problem can be solved via authority. Governmental regulation is one means of control, but may not be as effective as social norms. He declared that legal and right are different. ONC has called on the layer between self-interest and government regulation and is calling on moral behavior. He spoke of professionalism and fairness, cheating and harm, saying that he wishes to use all tools at his disposal to encourage societal enforcement of norms.

Review of Agenda

Paul Tang, Vice Chairperson, noted the items on the previously distributed agenda. There were no changes to the agenda. He asked for approval of the summary of the December meeting, saying that Christine Bechtel had requested several minor edits. It was moved and seconded to approve the summary and the motion was approved unanimously.

<p align="center">**Action item #1: The summary of the December 2013 HITPC meeting was approved.**</p>

Update from CMS

Robert Anthony presented slides showing the most recent numbers on registrations and payments for the EHR incentive program. Twenty-four months into the program, he concluded that the news was good. He noted the new report format for Medicaid. Several different reports are now available at the CMS website. The most recently available data show that 84% of EHs have registered. 64% of eligible EPs have registered. The denominator for EPs was revised to account for escalation. Nearly 65% of all eligible hospitals have received an incentive payment for either MU or AIU. Nearly 65% have made a financial commitment to put an EHR in place. He emphasized that reports, as well as the slides, differentiate total payments and unique payments. Approximately 25% of Medicare EPs are meaningful users of EHRs and approximately 33% of Medicare and Medicaid EPs have made a financial commitment to an EHR. 58% of Medicare EPs receiving incentives are non-primary care specialists. As of November 30, active registrants totaled 340,090. 96,426 EPs have received Medicare incentive payments. 65,625 unique Medicaid EPs have received incentive payments.

Members interrupted with questions. Judith Faulkner inquired about repeat payments to hospitals and wondered how close actual payments will come to estimated payments. Anthony responded that it is too early to make that assessment. Large numbers will come in during January and February. The report does not show number of repeat payments.

Characteristics of hospitals not yet registered are small size, rural location and "problems with infrastructure implementation." He indicated that CMS staff hopes that the RECs will help the hospitals with implementation challenges. Some providers may not register in advance of attestation.

What has been the impact of the HITPC on meaningful use and AIU? A subset of providers has reportedly said the incentives are not worth the effort: What is being done to engage them? Medicaid providers are making a commitment to the use of EHRs. CMS staff does not know how long it will take them to get to meaningful use. There are challenges for Medicaid providers. CMS has conducted a wave survey of this population. Their issues cluster on ROI and providers nearing retirement. This was anticipated and CMS is trying to design resources targeting this subset. A member asked that the HITPC provide advice on the issue. He wondered about the relevancy of the HITPC to AIU. Anthony opined that it depends on the provider; the driver is the incentive. Other providers are looking at the complexity of meaningful use. Mostashari interjected that for Medicaid providers, the AIU is the first payment and they do expect to continue to meaningful use. The legislation specifies that Medicaid EPs are not subject to

penalties as Medicare providers are. Therefore, they have less urgency to move to meaningful use. He said that he wants to assist them with meaningful use without delay.

Faulkner declared that success of the program should be measured by the achievement of health goals. She recommended comparison charts to show where good is being done. Progress is not the same as results. A comparison of the attesters to non-attesters per results would be interesting, although there may be other factors to control for. What is the value of the investment? Christine Bechtel said that someone needs to think about indicators of good outcomes and to measure them. Anthony replied that CMS is beginning to begin to think about long-term analysis. He explained that timing must be taken into account in measuring impact. One would not expect observable impact until several years in the future. Bechtel urged CMS to work with the HITPC to identify outcomes and indicators per stage and to design an analysis. The program is under congressional scrutiny. Anthony agreed to initiate discussions although there may not be time to influence Stage 3. Mostashari interjected that from the beginning the program was designed with expected outcomes in mind. Perhaps they were not communicated sufficiently. If providers see the measures as a grab bag, they will not be enthusiastic about participation. He directed their attention back to the original categories and domains, saying that the Meaningful Use Workgroup has always focused on expected outcomes. Better communication may be needed in Stage 3. Expectations must also be considered, particularly the time required to observe effects: How long does it take to demonstrate effects? Gayle Harrell said expectations may not have been realistic. Quality measures will show the impact. Bechtel told Mostashari that she did not intend to imply the program had no goals and objectives. She wants everyone to be clear regarding the appropriate time for measuring quality. Tang emphasized that the process is a multi-year program. This is only Stage 1, and the point is to get nearly everyone to Stage 1. ONC commissioned a study of implementers prior to 2009. Having results by 2013 is not realistic.

Charles Kennedy talked about the public wanting proof. Pointing to the limitations of dashboard-type data, he explained the benefits of conducting a controlled study, starting now in order to inform later decisions. David Lansky advocated a CMS study tying payment and outcomes to the EHR functionalities. Meaningful use has been a low stakes, non-performance based program. Providers have tried to measure different things but the results are not reported. CMS does have other programs that are high stake. CMS should identify measures to evaluate the adoption of HIT, such as adverse events, which CMS intends to make central to payment programs, and conduct an evaluation.

Faulkner referred to vendors and stages – collection in Stage 1, interoperability in Stage 2 and outcomes in Stage 3, saying that most systems currently have all of these necessary functions. Therefore, the minute the systems are installed, one should begin to see results. Someone agreed. Benefits are being achieved. Tang clarified that no one is saying outcomes will not be seen until the completion of Stage 3. He reminded her that many, if not most, products had problems meeting Stage 1 requirements. Faulkner continued to talk about requirements constituting only a small subset of what systems provide.

Anthony pointed out that he had not been allowed to complete his presentation. He said he wanted to highlight that over half of EHs are attesting to meaningful use. These high performances are indicative of the early adopters.

HITPC Preliminary Priority Areas and Workplan

Tang presented the key topics for 2013. Regarding meaningful use, recommendations for Stage 3 objectives and quality measures will be finalized. Preparations for Stage 4 will commence toward a learning health system. Consideration will be given to creating a shared health record, patient-generated data and shared decision-making. He called out clinical documentation and the upcoming hearing. Safety-enhanced design of EHRs is another topic with a hearing scheduled for February 13. He moved to

measuring clinical quality. Facilitating a supply of de novo quality "measures that matter" to leverage clinical data from EHRs and PHRs is important. Facilitating incorporation of flexible platforms for measuring and reporting quality measures in HIT systems is another area. The role of data intermediaries and their sustainability must be discussed. "Near real-time" clinical quality dashboards for practitioners will be considered as well as connections to clinical decision support. The third major category of key topics is HIE. Subtopics include: the state of the field and best practices; the role of HIE in new payment models; facilitating greater exchange across organizational and geographic boundaries through policy and certification levers and standards development; governance models and principles to facilitate HIE; and ONC's EHR Safety Plan. Regarding the key topic of privacy, he delineated the following subjects: patient identities in cyberspace; consent and control of information in automated query/response exchanges; challenges of implementing minors' rights in cyberspace; personal representatives; cloud computing; and right of access in an electronic world. Another broad topic is consumer empowerment, which includes blue button; combining and sharing data from multiple sources; data overload; reconciliation of data; protecting downloaded patient data; and shared decision-making. He declared that the HITPC will also consider new models of care, such as accountable care; supporting population management; longitudinal data and shared care plans across the continuum (including wellness); supporting new payment models; and Medicare Shared Saving Program requirements.

Mostashari talked about grouping the topics and focus. There are opportunities in meaningful improvement for everyone. One group of topics may be learning how to use technology to improve care (CDS, dashboards and registries). Second, meaningful interoperability and exchange must be a focus, taking into account effective implementation and practice. Third, meaningful consumer empowerment, including access, participation and action, will require a shift in attitudes.

Discussion

Marc Probst voiced approval of the list of priorities but urged that timing be incorporated into plans. He reported that people are not commenting on the Stage 3 RFC because they are too busy trying to implement Stage 1. Discussions on climbing the ladder are needed. He favored a broad emphasis on security, especially since HIPAA is now being interpreted differently. The impact of those changes should be discussed.

Kennedy asked that ONC consider calling out efficiency and effectiveness. ACOs do not understand meaningful use from a risk management perspective. The technology is needed to manage financial risk.

Josh Sharfstein noted the absence of any mention of public health. He urged recognition of its super structure benefit, for example, in a nationwide response to a flu outbreak.

Harrell commended the list of priorities but said that more definition is needed. Breaches have escalated recently and security must be increased. Greater involvement of patients will require looking at PHRs. Recognizing that they are not within the purview of the HITPC, she asked that guidance on PHRs be considered.

Paul Egerman declared the list to be an excellent one. Nevertheless, he thought that insurance exchanges should be added: What can creatively be done with information exchange and insurance exchanges?

Chris Boone wanted the topic of data intermediaries clarified.

Deven McGraw observed that the list was daunting. Thought must be given to its management. She noted that a consumer workgroup is being formed and asked about plans for dividing the topics among existing workgroups and teams and coordinating their efforts. Perhaps additional workgroups are needed.

Bechtel noticed that the topic of health disparities is missing. Nothing substantial was done to advance equity in Stage 2. Although disparities can be identified via the listing function, nothing more was

accomplished. Disparities are applicable to several of the key topics. Perhaps a disparities workgroup should be convened. An ONC staff person reported that a roundtable on e-health equity is planned for February with the consumer empowerment workgroup charged with following up with recommendations. Bechtel went on to describe another priority—dialogue with the HITSC. She reported that in working with the Meaningful Use Workgroup subgroups to propose Stage 3 measures, members requested and received advice from the HITSC on standards readiness. In a number of cases, members were surprised about the lack of standards. She said that she wanted to review the list of measures for which standards were reportedly not ready and prioritize them for development.

Faulkner declared that the list of priorities may indicate arrogance in telling vendors this is what they must work on. Opportunity costs are involved. Vendor groups are meeting continuously to identify what is needed for the best interests of the country, not for their own profit. In the early 1970, several companies started EHRs. They did this without FACAs. She announced a lengthy list of innovations by vendors: post visit recap, interoperability, patient portal, smoking cessation, CDS, childhood obesity, mobile patient portals, natural language support, telemedicine, device integration and many more. All of this was done to save lives. The HITPC may squish innovation and drive out small vendors. Mostashari informed her that the priorities are topics for discussion by the HITPC, not what is planned for another stage. He said, for example, that it is important for HITPC members to understand potential uses of EHR data for research.

Madhulika Agarwal requested greater emphasis on telemedicine and mobile applications. A staff member talked about bringing experts in to inform members on topics without the expectation that recommendations will result. Bechtel wondered why anyone would want discussion without recommendations: What would be the action? She declared her interest in having an impact, not just engaging in discussion. She asked ONC to define the action pathways.

Harrell reported that providers are feeling some of same frustrations described by Faulkner. The HITPC needs to hear from users and to refocus. Faulkner suggested that committee members attend user groups and listen. Harrell agreed with Mostashari on the role of government. The society, the community will have the most impact.

Probst acknowledged that Stage 1 did present development challenges for vendors. They are less impacted now and can consider the use of the technology. He urged members to be careful about adding new functions. Meaningful use may have created challenges, such as patient identification and security. Consideration should be given to helping resolve these challenges. He reported that he perceived the priority list as opportunities rather than new requirements. But he urged everyone to be realistic about time expectations.

Tang called on Jodi Daniels, ONC, to present slides with the preliminary work plan. She showed a slide that listed six workgroups and teams in rows with four quarterly columns and some specific activities in the corresponding cells. Several hearings are planned for the Meaningful Use Workgroup. Data intermediaries is assigned to the Quality Measures Workgroup and the safety plan to the Certification and Adoption Workgroup. Nominations have been requested for the consumer empowerment workgroups, one for HITPC and one for HITSC. The nomination period will close January 14. Many activities have been designated for these workgroups. She announced that a new workgroup, Accountable Care, will be formed. Several emerging issues, such as quality improvement and big data, have yet to be assigned. Staff will try to incorporate issues raised during the earlier discussion into the plan and will present a relived plan at a later meeting.

Discussion

Bechtel acknowledged that the plan was overwhelming. She reiterated her earlier comment that health disparities must be called out specifically.

Privacy and Security Tiger Team Recommendations on Patient Identify Proofing and Authentication

Deven McGraw, Chairperson, reminded the members that she had presented and explained preliminary recommendations at the December meeting and said that the team had made few changes since that presentation. The overarching recommendation is that ONC should develop and disseminate best practices for identity proofing and authentication for patient access to portals (MU2 view, download, and transmit capability); such best practices should be disseminated to EPs, EHs and CAHs sufficiently in advance of the onset of stage 2 to enable planning. Best practices should be consistent with the following principles:

- Protections should be commensurate with risks
- Simplicity and ease of use for patients and consistent with what they are willing to do‖
- Flexibility in methods offered
- Leverage solutions in other sectors, such as banking
- Accompanied by education that makes these processes transparent to the patient
- Build to scalable solutions (e.g., greater use of voluntary secure identity providers)
- Solutions need to evolve over time as technology changes
- To further manage risks, couple with out-of-band confirmation (using an independent/different channel to confirm identity).

Regarding authentication, the team reviewed its previous recommendation in light of testimony at the recent hearing and recommended that ONC should strongly encourage providers to use more than user ID and password and, at least initially, drive toward protections analogous to those used in online banking. The Tiger Team considered whether it should encourage the HITSC, though the Privacy and Security Workgroup, to consider certification standards in this area. However, the team concluded that certification standards may not be the best approach at this time. ONC should also disseminate, at a minimum, the latest best practices in password management. Technology options for authentication continue to evolve; ONC should continue to monitor and update policies as appropriate to reflect improved technological capabilities. Given the risks associated with credentialing patients for view/download/transmit and the critical importance of educating patients about the use of these functions, ONC should respond to previous HITPC recommendations regarding transparency of risks and benefits of V/D/T to patients. She went on. The Tiger Team also considered whether it needed to make additional recommendations on the use of the DIRECT protocol when patients use the function to authorize transmission of their information to a PHR or other third party. The Tiger Team concluded that DIRECT is moving forward in way that is consistent with these recommendations. NSTIC, which would provide for credentials that could be re-used for a range of online purposes, should provide a more scalable solution for patient authentication in the future. ONC should continue to work with NIST to ensure that any issues unique to the health care environment are addressed in the development of the NSTIC approach.

Discussion

Paul Egerman, Co-Chairperson, emphasized that the team is recommending only that ONC establish best practices, not requirements for certification..

Someone asked about level of assurance 2.5. Egerman responded that it is not an official level. It is between level 2 and level 3 and, for example, can be based on responses to questions. Level of assurance is defined by NIST. McGraw said that level 2.5 refers to something higher than username and password.

Banks look at how accounts are accessed. She acknowledged the need to solicit and identify best practices. She clarified for Mostashari that level has to do with authentication, not identify proofing. Mostashari observed that most providers incorporate identify proofing into their care processes.

Faulkner suggested that patients be given a choice about preferred level of access. McGraw said that it is important to make providers aware of alternative approaches.

Harrell pointed out that identify proofing may not always happen in person because of a time lapse in seeing a provider. She said that provider and patient education is important. RECs have a role in education but more is needed.

Tang called for a vote on acceptance of the recommendations. The recommendation of the Privacy and Security Power Team were unanimously approved as submitted.

> **Action item #2: The recommendations of the Privacy and Security Power Team on patient identify proofing and authentication were unanimously approved as submitted.**

Public Comment

Carol Bickford, American Nurses Association (ANA) asked that the priority for 2013 include health promotion and wellness in conjunction with consumer engagement. Management of records in the cloud, including their retirement, should be another priority. Depar

e-Consent Project

Kathryn Marchesini, ONC, described the pilot project undertaken by ONC. The expected outcome is innovative ways to: educate patients about their option to make an individual choice (or patient consent) about whether or not their health care provider can share/access their health information through a health information exchange organization (HIE); assess patients' knowledge gained and their individual satisfaction with the educational material and associated electronic delivery method; and electronically capture and record a patient's choice. The project was described as having five phases: obtaining patient input; design of materials; design open source tool; pilot of solution at a health care site; and analysis and finalization of tools. Surveys and focus groups conducted in the first phase revealed that patients are: interested in knowing how people accessing their health information will use it; concerned with misuse of information, privacy, and how information is secured; and want to know if information will be shared with health insurance companies. They prefer to receive education from their providers.

The pilot was launched on October 22, 2012, at four health care facilities in western New York. Patients have the option of using a tablet computer to view interactive educational material and electronically make a consent decision, which is captured.

Q&A

The patient education videos are not yet on the website. Data were not collected to evaluate providers' response to their patients' choices.

ONC Update – Safety Plan

Jodi Daniels, ONC, reviewed the patient access safety plan, which was developed as a result of Institute of Medicine (IOM) recommendations. The plan was released (http://www.healthit.gov/policy-researchers-implementers/health-it-and-patient-safety) on December 21, 2012 for public comments due by February 4th. She invited members' comments. She anticipates a final plan by early summer 2013. Items in the plan include:

- Encourage and facilitate clinicians reporting of health IT – related safety events
- Encourage health IT developers to embrace their shared responsibility for patient safety
- Incorporate health IT into existing safety programs of PSOs/AHRQ, ONC and CMS

ONC will propose to use certification criteria to ensure EHRs facilitate the use of AHRQ Common Formats. AHRQ will provide technical support to PSOs to incorporate health IT expertise and PSOs will work with clinicians. ONC will collaborate with health IT developers to develop a Health IT Developer Code of Conduct, which will subsequently be incorporated into accreditation and certification programs. CMS will provide guidance to surveyors and accreditation organizations to recognize health IT–related adverse events when conducting surveys on CMS' behalf. ONC-ACBs will conduct live testing in clinical environments to determine whether clinician safety complaints are addressed and whether EHR safety features are performing adequately. She emphasized ONC's intent to work with state governments and the private sector on these efforts.

ONC Program Updates—2012 Accomplishments

Daniels continued her presentation. She showed slides that repeated much of the information presented by Anthony. Regarding the regional extension program, which she declared was hugely successful in helping EPs, a GAO study found that 47% of providers who received AIU payments had been helped by RECs. 94% of pharmacies are actively e-Prescribing, and 43 states and territories have directed exchange with 60,359 clinical and administrative staff nationwide having access to directed exchange. During Q3 2012 there were 79,957,695 directed exchange messages. Twenty states have statewide query-based exchange.

She noted several successes of the Beacon Community including that all 17 communities have at least two measures trending positively and the launch of new exchange capabilities in communities like New Orleans and San Diego. The collaboration has enabled 51 primary care practice locations representing 432 providers and 447,000 patients to exchange a consistent patient summary care document to better manage transitions of care and to populate community data repositories or registries.

Regarding workforce development, as of November 30, 21,917 people have been enrolled in community college training with an attrition rate of 29.5%. There have been 981 students who have graduated from university-based programs. More internships and hands on experience opportunities are needed to improve these programs.

Eighty-eight million U.S. consumers have access to Blue Button, resulting in 1.4 million Blue Button downloads. Four hundred and fifty organizations have joined the Blue Button Pledge Program. Among many other activities, ONC sponsored a pilot to evaluate the role of patients in improving accuracy of information in their medical records. Information on 29,110 certified projects is available on the CHPL. She also described a number of CQM developer and implementer tools.

Doug Fridsma, ONC, reported on standards. Twelve hundred individuals from 400 organizations participate in the S&I Framework. Many national standards have been established as a result. They are in various stages from development to balloting. SDO activities include the successful balloting of IGs lab results interface and transitions of care. HQMF V2 is under ballot. Other projects are progressing – esMD, LOI/eDOS, Query Health pilots, longitudinal care coordination and PHRI. As at previous meetings, Fridsma reported that resources for standards development have decreased by 80%, and emphasis will change as a result. He called out several specific challenges in standards development:

- Testing of standards occurs for the first time during pilot demonstration
- Testing of standards occurs much too late in the process to influence standards development
- Changes to standards made during pilots don't get back into improving standards in a timely manner
- Implementing untested standards introduces business risk to pilot organizations

He continued to list activities, saying that in 2013 efforts will be aligned with stage 3 needs.

Q & A

McGraw asked about e-Health Exchange and alignment with NwHIN since the decision to not issue a final rule has been made. Mostashari responded that ONC still has responsibility for standards and an implementation guide for exchange. Activities, in addition to governance, will be undertaken.

Faulkner asked about the number of reported queries: Does the number refer to documents or specific patients? Mostashari replied that the count is on the receiving side. Pursuing a broader paradigm was mentioned. Someone talked about putting together, in cooperation with vendors, a dashboard that presents county data.

Regarding workforce development, Faulkner asked about graduates' success in finding jobs. Staff responded that data on jobs were not collected except in a few programs. University-based programs appear to be more successful, possibly because participants are already employed or at least have completed some basic education and training. In contrast, community colleges may target unemployed persons. Mostashari repeated that the training programs are challenged by their participants' need for on-the-job training and internships.

Harrell reported hearing from trainees about their dissatisfaction with online training and the lack of hands-on experience; Mostashari informed her that most of the programs are not online.

Faulkner asked Fridsma about the development of lab, clinical, administration and medication standard vocabularies, wondering what will be done with them since there are existing vocabularies. He explained that nothing new was created; standards were identified among existing options in order to promote consistent use.

Someone suggested building on existing programs, such as the Epic training program. Mostashari acknowledged that since resources have declined, ONC with have to work with partners. Staff is working with representatives from the Department of Labor to link with apprenticeship programs and to develop a curriculum.

Tang asked for an assessment of the HITPC's attempt to coordinate Stage 3 preliminary work with HITSC. Fridsma indicated that it worked well. The HITSC is currently commenting on the RFC with respect to the availability of standards. Staff also coordinated across policy and standards activities. Standards are ready for some of the proposed measures, but not for all. Consideration will be given to an incremental approach and to the use of building blocks. Thought must be given to whether the CCDA is final or an incremental step. Mobiles, platforms and modularity are other considerations. Regarding home monitoring devices, some progress has been made on taxonomies.

Faulkner suggested taking more of a global or international approach with standards.

Public Comment

Bickford read a comment written by Robin Raiford on priorities and the work plan for patient engagement and care coordination. People need to listen to patients and not treat them as body parts. She (a nurse herself) related a recent, horrible, personal experience with hospitalization. There was no care coordination across hospitals. There was no med reconciliation across hospitals and encounters.

Robertson reminded her of the three-minite comment limit. Raiford herself came on the phone to invite McGraw and Bechtel to lunch to discuss consumer issues.

Bickford offered anyone who was interested a button saying, "We've always done it this way."

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the December 2013 HITPC meeting was approved.

Action item #2: The recommendations of the Privacy and Security Power Team on patient identify proofing and authentication were unanimously approved as submitted.

Meeting Materials

- Agenda
- Summary of December 2012 meeting
- Presentations slides
- Tiger Team report