



Collaboration of the Health Information Technology Policy and Standards Committees

FINAL Summary of the March 30, 2017 Joint Meeting

KEY TOPICS

Call to Order

Michelle Consolazio, U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health Information Technology (ONC), welcomed participants to the Health Information Technology Policy Committee (HITPC) and Health Information Technology Standards Committee (HITSC) joint meeting. This was the final public, in-person meeting of the Joint Committee. She reminded the group that it was public meeting, conducted with two opportunities for public comment and that a transcript will be posted on the ONC website. She asked members to identify themselves for the transcript before speaking. Members introduced themselves for the roll call.

Remarks

P. Jon White, Acting National Coordinator, ONC, welcomed and thanked the members of the Joint Committee. He assured the members of the Joint Committee that the recently instated Secretary of HHS is committed to improving interoperability through Health IT and touched on the value of the continuing work on 21st Century Cures. He also introduced the New Deputy Assistant Secretary for Healthcare Information Technology (HIT) Reform John Fleming, who provided a brief overview of his career and policy goals with regard to HIT.

Review of Agenda

HITPC Co-chairperson Kathy Blake noted the two key agenda items for this meeting: presentation and approval of the Public Health Task Force (PHTF) recommendations and review of the Patient Generated Health Data Draft White Paper from the Consumer Task Force. Blake then asked for a motion to approve the minutes of the March 8, 2017, virtual meeting. A motion was made and the minutes were approved by majority vote.

Action item #1: The minutes of the March 8, 2017, virtual meeting were approved by majority vote.

HITPC Co-chairperson Paul Tang noted the importance of integrating public health and individual health before introducing the co-chairs of the PHTF.

Public Health Task Force Recommendations

Larry Wolf, PHTF Co-chair, thanked the Task Force members and their partners at ONC. The charge of the PHTF was to identify areas for which HIT tools can be used to prevent and/or assist in public health crises. The PHTF used Zika as a use case, and looked specifically at four different areas: capturing pregnancy status, sharing and sending data to public health agencies, considering the use of clinical decision support (CDS), and improving electronic initial case reporting (eICR). The Task Force aimed to adhere to the following principles:

- Clarity of purpose

- Bright spots (learning from examples of success and building on existing capabilities)
- Engage stakeholders
- Parsimony (recommend the minimum necessary)
- Generality (recommendations that apply to Zika, but are more broadly applicable in the long-term)
- Pragmatic
- Balance priorities
- National scale (working with a view toward nation-wide implementation)

Wolf provided an overview of the information flow among public health, laboratories, healthcare providers, and individual patients, particularly with regard to reporting and guidance.

Anne Fine, PHTF Co-chair, addressed the first charge of the Task Force: capturing pregnancy status. Pregnancy status is a critical data point for a number of reportable conditions, but there is no standardized method or set of data elements for the capturing of that data in electronic health records (EHRs). A report detailing the consensus reached concerning the data elements was circulated prior to this meeting. At the present time, standardized capture and transmission of pregnancy status data is not possible or realistic, so the PHTF recommends:

- Disseminating the prioritized data elements related to pregnancy status,
- Promoting Ask on Order Entry for transmission via electronic laboratory reporting (ELR) to capture pregnancy status for tests for reportable diseases where that data is relevant,
- Publishing pregnancy data standards in ONC's Interoperability Standards Advisory (ISA), and
- Exploring avenues for individual patients to electronically self-report pregnancy status and related data with the provider's EHR.

The second charge of the PHTF was to determine how to share and send pregnancy status and related data to public health. Public health currently does not receive this data in a consistent or complete way, even through ELR. eICR through EHRs is not a system in place. Pregnancy status is a key data element for prioritization and appropriate testing. The Task Force recommends:

- Promoting the transmission of pregnancy status for Zika and other reportable conditions where pregnancy status is relevant
- Expanding the use of ELR to transmit pregnancy status to public health for Zika and other reportable conditions, particularly in the short term, while other methods are developed
- Promoting a specific prenatal test for Zika to indicate pregnancy status
- Publishing pregnancy data standards for transmission in the ONC ISA
- Encouraging state and local jurisdictions to leverage existing public health authority to require the transmission of pregnancy status
- Promoting the use of ONC's Interoperability Proving Ground (IPG) as a mechanism for sharing information on public health interoperability projects.

Wolf addressed charge three: clinical decision support. He stressed the importance of integrating guidelines into the workflow of providers and of acknowledging the dynamic nature of public health crises and the guidelines that relate to them. Wolf also recognized that guidance has multiple sources at both the local and national levels. Use of CDS is sometimes complicated by the fact that existing guidelines for choosing the appropriate laboratory tests are often complex, which can lead to erroneous or missed diagnoses. In light of the emerging nature of CDS, the PHTF recommends:

- Following demonstration projects that have indicated how CDS from public health can be incorporated into EHRs to identify best practices for future recommendations
- Exploring the sharing of CDS implementations across provider locations by promoting the use of CDS Connect from the Agency for Healthcare Research and Quality (AHRQ) as a mechanism for sharing information on public health interoperability projects related to CDS
- Encouraging the use of CDS to improve access to human readable guidance and to identify patients at risk
- Exploring mechanisms that enable consumers to identify and document their own risks and share their data with their providers
- Exploring the use of open application program interfaces (APIs) for CDS.

The fourth charge of the PHTF dealt with eICR and electronic case reporting (eCR). The challenges with eCR are related to the fact that public health does not currently collect that data from EHRs.

Furthermore, many eCR projects are still in their infancy. The PHTF recommends:

- Incorporating Charge 1 recommendations for collection and sharing of pregnancy status data into the eICR
- Leveraging current work from existing eCR projects to promote best practices and standards for reporting as well as with follow-up and case management
- Exploring the use of new or maturing standards such as Structured Data Capture and SMART on FHIR as methods for eCR.
- Promoting the use of ONC's IPG as a mechanism for sharing information on interoperability projects related to eCR.

Wolf summarized the PHTF's process for developing recommendations and offered an overview of the additional topics of deliberation for the Task Force.

Fine summarized the deliberations related to each charge given to the PHTF. Highlights from the deliberations regarding Charge 1, the capture of pregnancy status, include a note on the critical nature of testing vulnerable pregnant women and following up on potentially exposed or infected infants and presentation of the priority data element specifications for Public Health. The virtual meeting of the Joint Committees on March 8 resulted in a comment regarding the surprising lack of involvement from the individual patients. In response, the Committee explored an application called [myhealthfinder](#) which provides tailored, interactive guidance to patients regarding their health inquiries; this could be rebranded, customized, and reapplied in various settings. The Committee would also like to explore ways patients can electronically self report data to the provider's EHR.

Fine then offered background regarding Charge 2, the sharing and sending of pregnancy status, paying particular attention to the public health authority for the receipt of pregnancy data. She also directed the Committee to ONC's [fact sheet](#) regarding permitted uses and disclosures of health data for public health activities. Fine reiterated that Ask on Order Entry is the best short-term option for capturing and sending this data to public health through EHRs, despite of some of the challenges facing full implementation of Ask on Order Entry as a reporting tool.

Wolf addressed the deliberations regarding Charge 3 and CDS. These deliberations functioned primarily as a reminder that the guidelines CDS works with are incredibly complex. Wolf reminded the Joint Committee of the process for integrating effective CDS into provider workflow. The public hearing resulted in several sets of comments regarding what CDS for public health and emerging risks should

accomplish. It should identify at risk individuals, ensure correct test ordering, provide clinical management and patient education, provide guidelines for reporting to public health, and provide stable URLs for guidance from federal and other public health agencies. With regard to external stakeholders, CDS Hooks has provided a good model for describing how an EHR can use a remote decision support service through prototype implementations, and the Argonaut Project has chosen to focus on CDS in 2017. The PHTF recommends exploring the use of open APIs and the use of CDS for consumer self-identification of risks.

In summarizing the deliberations around Charge 4, eICR, Wolf noted the potential value of eCR to the work of public health. He also addressed the differences between eICR and eCR. eCR is the fully or semi-automated generation and electronic transmission of reports of potential cases of reportable diseases and conditions from an EHR or health IT system to appropriate public health authorities, replacing the historically paper-based process. eICR, on the other hand, is a first step in implementation of eCR. The eICR will convey a standard set of data elements, vocabularies and value sets to Public Health Agencies (PHAs) for all reportable conditions in all jurisdictions. It is termed “initial” as the report may be the first report made to public health from the clinical provider, containing just enough pertinent data for PHAs to initiate investigation or other appropriate public health activities as necessary. In the short-term, the PHTF recommends incorporating Charge 1 recommendations for the collection of pregnancy status into the eICR. The mid-term approach involves following Digital Bridge using Reportable Condition Knowledge Management System (RCKMS) and other eCR projects for Zika reporting. In the long-term, the goal is to move toward bi\directional data exchange with eCR, case management, and integrated CDS.

Before opening up to discussion, Fine highlighted best practices in which data reflecting the mother’s pregnancy status and prenatal Zika tests was integrated into the newborn’s EHR.

Discussion and Q&A

Paul Tang, HITPC Co-Chairperson opened the floor to discussion.

Arien Malec noted that common APIs and content standards enable more general capabilities. He called for continued efforts to make CDS and API developments that can be applied in both specific and general settings in a proactive manner in order to create more flexibility in public health.

White thanked the PHTF Co-chairs, as well as external and federal partners for their work. He then asked for a drilldown regarding pregnancy status reporting standards. Wolf noted that depending on the context, there was a great deal of potential variability with regard to reported information and the way it is coded in EHR. This is why the PHTF recommended sharing the standards through the ISA. Fine added that the Task Force focused on improvements to the EHR's ability to capture pregnancy status data.

Gayle Harrell strongly encouraged the Committee to consider and address the variance in state laws regarding levels of consent for reporting in the case of a terminated or aborted pregnancy. How will state privacy laws impact reporting to public health via EHR, given that there are specific levels of consent required before health data can be transmitted? Harrell pointed out that she did not believe pregnancy qualified as a reportable condition. Tang encouraged the PHTF Co-chairs to incorporate these considerations into their recommendations.

Aaron Miri added to Harrell's point about privacy and consent, asking the Task Force to consider the issue of consent with regard to reporting the health data of minors.

Andy Wiesenthal clarified the differences between reportable conditions and patient status relevant to care.

Leslie Kelly Hall suggested that the standardized assessment tool is also used for self-assessment so that patients can participate and be educated along the way, self-assess, and communicate both with their providers and with public health. Fine voiced her support regarding the importance of Hall's observation, and briefly discussed the paper solution being used in New York City. An electronic solution would be even better.

Anne LeMaistre asked that software be used to help alleviate and streamline the burden of data capture.

Lorraine Doo raised the issue of HL7's personal health record (PHR) system functional model. Doo believes that the PHR model could meet some of the needs addressed here. With reference to the Centers for Medicare and Medicaid Services (CMS) Alternative Payment Models, has the Task Force looked at the maternity action collaborative models?

Floyd Eisenberg called attention to the lack of definition around inclusion for chronic reportable diseases. How can identification be streamlined to make it easier for vendors to connect them?

Paul Egerman echoed Harrell's questions about privacy, noting that pregnancy status is not a legally required reportable item in most states. How do privacy considerations impact the work of the Task Force? Is there a need for special privacy rules around this information? Wolf noted that this issue could be discussed further, and should be explicitly addressed in the letter of transmission.

Jitin Asnaani commended the Task Force for thinking in terms of practicality and what will actually encourage adoption and usage of these guidelines and their outcomes at the provider level. Interoperability must be a big part of the data capture, because patients may not always be aware of the data they need to self report, either through the EHR or directly to their provider. Additionally, it would be beneficial to have health risks presented by travel (such as Zika) become a consideration in the normal consumer workflow. Fine noted that myhealthfinder includes information for those who are traveling as well as those who are pregnant. It is likely that bundling the information together with other kinds of health concerns for an individual is the most effective means of communicating with the patient.

Chelsey Richards, CDC, encouraged the Task Force to recognize that local and state public health organizations do a great deal of the heavy lifting in public health crises; how can local, state, and federal organizations work towards becoming a "one public health" mechanism? Richards recommends making guidelines in CDS more easily adjustable.

Eisenberg reminded the group that health guidance for travelling consumers is available online, while also noting that it can sometimes be difficult to exactly pinpoint the epicenter of an outbreak.

Troy Seagondollar pointed out that the data gathered from federally funded community health centers, as well as the Title X and planning clinics, may be at risk if the funding dissolves. Did the Task Force make any provisions for populations that may be affected by a change in funding status? Wolf responded that changes to policy were not in the charge of the PHTF. Fine agreed that while the PHTF did not specifically address the federal funding of health care institutions, Seagondollar's point is a good one. She hopes that some of the advances in CDS and eCR could reduce the reporting burden on providers in publically funding care settings. Wolf added that there has been a highly interactive, coordinated effort between the public and private spheres in addressing these challenges.

Harrell highlighted the lack of funding allowances for public health in the HIT for Economic and Clinical Health (HITECH) Act. Funding for state public health agencies must be addressed.

Tang thanked the PHTF and its Co-chairs, indicating the continued importance of the unification public and individual health. Sharing of data, interoperability of systems, and information management remain areas of growth. Before calling for a vote on the recommendations of the PHTF, Tang asked for a motion to discuss and phrase an amendment to the recommendations per Harrell's earlier comments. Discussion to include a provision for the discussion of the privacy and consent issues at the state level that surround the reporting of terminated pregnancies ensued. Weisenthal moved to approve the current recommendations, contingent upon e-mail approval of language to be submitted regarding pregnancy and privacy concerns. A motion to approve the recommendations with further instructions to the PHTF to develop precise language passed. The Joint Committee approved the recommendations.

Action item #2: The Public Health Task Force recommendations were approved, with further instructions to the Task Force to develop precise language regarding pregnancy and privacy concerns.

Prior to Public Comment, White clarified the structure and hierarchy of ONC while the agency experiences a period of transition.

Public Comment

There was no public comment, and the Committee broke for lunch.

Consumer Task Force Update: Summary of Feedback on the Patient-Generated Health Data Draft White Paper

Background

Malec introduced the Consumer Task Force (CTF) Draft White Paper on the use of Patient Generated Health Data (PGHD), as well as presenters Leslie Kelly Hall and Emily Mitchell (Hall was standing in for PTF Chair Patty Sengstack, who could not attend this meeting). Hall began by reviewing the current charge of the CTF, which was to provide feedback on the PGHD White Paper.

Elise Sweeney Anthony, ONC, touched on the potential value of PGHD at all levels of care. PGHD are health-related data created, recorded, or gathered by or from patients or their authorized representatives to help address a health concern. The information included in PGHD can be diverse, including health and treatment histories, biometric data, symptoms, and lifestyle choices. This data is the responsibility of the patient, both in terms of the capture and recording, as well as the sharing and

distribution of that data. PGHD keeps the person at the center of care by increasing patient engagement and providing more information on a daily basis, particularly in the case of ongoing or chronic conditions. It also creates opportunities to reduce costs and readmissions.

The 2015 Edition HIT Certification Criteria included a criterion (§170.315(e)(3)) for patient health information capture. This criterion was purposefully broad to account for the functional diversity of information and channels of communication, while still allowing flexibility for vendors, providers, and patients. The criterion involves two key components: (1) the ability to identify, record, and access information directly and electronically shared by the patient or authorized representative; and (2) references and links to patient health information documents. Anthony recognized the continuing work of both CMS and ONC related to incorporating PGHD in the care continuum.

Summary of the Draft White Paper

The Program Manager for the PGHD project, Emily Mitchell, Accenture, introduced the [White Paper](#): “Conceptualizing a Data Infrastructure for the Capture, Use and Sharing of Patient Generated Health Data in Care Delivery and Research through 2024,” published on January 10, 2017. The focus of the work was on investigating best practices, opportunities, and gaps in the use of PGHD in care delivery and research. Industry outreach, environmental scans, and literature reviews were incorporated into the drafting process. ONC requested that the research on PGHD focus on seven key topics:

- 1) Collection and validation of data and tools
- 2) Ability to combine PGHD with medical record data in multiple ways
- 3) Data interoperability
- 4) Big data analysis
- 5) Data donation
- 6) Regulatory overview
- 7) Patient recruitment for research, studies, and trials

Initial observations and trends indicate that the use of PGHD can have a positive impact on patient satisfaction and experience. Successful PGHD implementations tend to focus on a specific disease or population segment, use some form of data analytics, and include simplified user interfaces, designed for the patient’s consumption of information. Successful implementation was also noted where organizations were adapting to the necessary changes in workflow or creating data triage teams that lessen the burden on the physicians. The research also indicated several opportunities for key stakeholder groups that result from PGHD integration:

- Patients and caregivers are more likely to engage in healthy behaviors, increase treatment adherence, and improve overall health outcomes.
- Clinicians make timelier and better informed decisions, improving collaboration with patients to create personalized treatment plans.
- Researchers may increase their access to large amounts of data as well as connect with patients directly for studies and trials.

Research and outreach for the White Paper occurred between the Fall of 2015 and the Fall of 2016, during which the key findings were synthesized into a draft PGHD White Paper that discusses emerging trends that enable PGHD and provides a vision for the future that enables the capture, use, and sharing of PGHD. The White Paper also describes opportunities, challenges, and enabling actions for stakeholder groups to support that future vision. Those stakeholder groups include: patients and caregivers,

clinicians, researchers, policymakers, technology developers, standards bodies, and payers and employers.

In terms of specific opportunities garnered through the integration and use of PGHD, the White Paper identified three key categories: (1) patients, (2) clinicians, and (3) researchers. Patients' experiences improved, and they increased their ability to engage in shared decision-making. Furthermore, there was a reduction in the time, effort, and cost of patients visiting a clinical setting or research site, which resulted in improved workflow efficiencies. Clinicians enjoyed increases in visibility into their patients' adherence to treatment plans, the ability to intervene in a timely fashion, and the opportunity to develop more personalized care plans. Researchers had access to larger pool of participants and the subsequent data, as well as the ability to monitor adherence to study protocols.

The overall efficacy and feasibility of PGHD is impacted by the lack of a clear business case for clinician implementation. PGHD is further challenged by concerns over the accuracy of the data coming from consumer-grade devices, concerns about privacy and security policies, and the health literacy of patients and their comfort level with the necessary technologies. This is compounded by concerns over use authentication, interoperability, data provenance, and cultural challenges.

The PGHD draft White Paper detailed several enabling actions for various stakeholder groups. Patients and caregivers are encouraged to collaborate with clinicians and researchers to determine how capturing, using, and sharing PGHD can be valuable for managing their health. Clinicians should share their own observations regarding the benefits, challenges, and best practices of PGHD use. The White Paper calls for an increase in funding for research regarding the benefits, challenges, and outcomes surrounding PGHD. Policymakers should encourage collaborating with industry to strengthen model practices, and consumer education and outreach, as well as review medical malpractice and liability laws related to PGHD. Technology stakeholders should continue efforts to improve usability and accessibility as well as implement user-centered design principles into products that capture PGHD. Payers and employers should continue to motivate clinicians to capture PGHD through reimbursement programs.

Two pilot demonstrations, both of which started in late summer 2016, have been used to test the policies and workflows identified in the White Paper. Validic (with Sutter Health in Northern California) and TapCloud (with AMITA Health in the Chicago area) have been working with personalized diabetes care plans using remotely gathered PGHD from patient devices. The findings from these pilots should inform updates to the draft White Paper. The [White Paper](#) can be accessed online, and is open for public comment through May 8, 2017. Comments may be emailed to ONC-PGHD-Policy@hhs.gov.

Feedback on the Draft White Paper

Members of the Committee offered feedback regarding the White Paper. There is a distinct need to identify priority use cases and to develop proof of concept(s) in order to inform standards. Some patient populations have barriers that prevent their access to or use of devices that collect PGHD. Many members believe that conversation about PGHD collection should expand to include trending data. Furthermore, interdisciplinary collaboration across the various stakeholder groups is critical for advancing the use of PGHD.

The White Paper succeeded in being well written and clear, in including different stakeholder groups, and in listing enabling actions and some real-world examples. The White Paper could incorporate more real-world examples, use more plain language, and incorporate a narrative that reflects a coordinated

approach with all of ONC's efforts. Several questions were raised regarding the definition of PGHD: should definition be broadened to include other data sets? Will the definition of PGHD vary by care setting? Should the term be changed to "person generated health data" to expand the scope beyond the clinical setting? Members of the Committee suggested rewriting the future scenario to focus more on people and less on EHRs. Members were divided on the extent of change in future vision; some members imagined more automation and suggested including emerging technologies.

Hall then discussed the specific feedback on the treatment of the key stakeholder groups. The Committee felt there should be greater emphasis on caregivers, identified the need to better understand patient motivation, and asked for more discussion regarding PGHD as it relates to better quality of life outcomes. On the clinician side, the White Paper should offer a stronger business case, as well as address clinician concerns like multiple data types and liability. Researchers should be encouraged to demonstrate the value of collection and meaningful feedback regarding the use of collected data. Patients should have an increased role in research that uses PGHD. Further clarification regarding the responsibilities of the researchers using PGHD is needed. For the sake of policymakers, more information regarding how federal agencies should be supporting PGHD, as well as guidance on funding and incentives, is needed. Clarity regarding the role of policymakers at the state and local levels is also desirable. In terms of the technology stakeholders, there is a need to broaden opportunities beyond technology standards. Members noted the importance of usability not just for technology, but also for the integration and presentation of PGHD in EHR; along those lines, human-centered design should be a focus. Finally, greater attention to the incentives provided by payers and employers is necessary. There should also be an emphasis on the privacy and discrimination concerns expressed by patients.

Although possibly outside the scope of the White Paper, members had additional suggestions for tools and resources that could encourage PGHD collection and use:

- Develop a table that illustrates types of PGHD by technologies and devices that collect these PGHD.
- Provide actionable advice and guidance on how different stakeholder groups can integrate and use PGHD in their work.
- Create more educational materials on PGHD for different stakeholder groups.
- Identify relevant and actionable information related to PGHD capture, use, and sharing as it relates to new policies and rules supporting MACRA/MIPS and 21st Century Cures.

Discussion and Q&A

Malec opened the discussion with comments regarding the potential of systems with secure messaging with attachments for the future of PGHD, making reference to Kaiser Permanente and the Department of Defense. It is vitally important that local decision-makers have agency with regard to the way PGHD is used as a tool for driving better clinical care.

Wiesenthal pointed out that any patient history qualifies as PGHD—the question is in who is responsible for recording, maintaining, and applying that information in a clinical care setting. He does not see the importance of stressing the business case for PGHD, as he sees the country moving quickly toward value-based care. Hall agreed, adding that value-based care only improves when patients participate in divulging their medical information. Wiesenthal stressed that integrated records are integral to capturing and understanding patient behaviors.

Kim Nolen noted that medication adherence or primary non-adherence is something to pay attention to with regard to shared decision-making, and that PGHD is useful for keeping tabs on a patient in-between visits. She also stressed the importance of making the volume of data consumable and usable for the patient. Hall agreed: when people participate in shared decision-making, the cost-saving and care-adhering decisions are not necessarily mutually exclusive. Mitchell noted that dashboards and carefully crafted user interfaces are effective means of communicating data and making it usable for the patients.

Harrell called for a more in-depth review of liability issues. Mitchell agreed that a greater understanding of liability and privacy issues is important for setting patient-provider expectations.

HITSC Co-chairperson Lisa Gallagher reminded the Committee of the work completed by the Data Provenance Task Force in January 2015, as its findings and reporting may be relevant here. Wolf agreed that data provenance is a key element, regardless of the initial source of the data.

Wolf continued by explicating the acronym of PGHD. The data is intended to help manage health care issues. Research on the determinants of health has suggested that what happens in the health system accounts for 10 – 20% of what matters; the other 80% occurs outside the boundaries of the health system. This makes engaging patients outside of their traditional care environments critical for quality of care and reduced cost. In that vein, it is important to give patients context for their medical information.

Carolyn Petersen encouraged the group to consider the role of patient as researcher. This may improve rates of adherence to care plans, as it will help mitigate instances where the patient and the provider have decided that there are two different health problems or questions at hand. Co-research allows for a drastic and meaningful increase in patient engagement.

Doo noted that medication compliance is an important contributing factor to the reliability of PGHD. Has the Workgroup discussed issues of liability and use of information that may be incomplete or inconsistent, either because of lack of patient follow-through or because of specific omission the provider has made? What goes into the chart—is all PGHD actionable? Hall responded that there must and will be more discussion of liability. The question of what kind of information goes into the patient's chart is left to the provider. Hall believes that closer relationships between patients and providers in building a health record that involves PGHD will help care teams identify voids in the information that may be necessary for care.

Richards observed that public health was not mentioned as a key stakeholder group, and asked the CTF to consider how PGHD is a potential goldmine for the prevention and identification of nascent epidemics or health emergencies. Hall agreed that public health should be considered more thoroughly as a stakeholder in this conversation.

Karen van Caulil added that the payer and employer stakeholder group has found that incentives around PGHD must be for both the physician and the patient, and they must be aligned—this alignment is key to shared decision-making. Has the Committee discussed the typically low level of health literacy across the general population and how that may impact the collection of PGHD, conversations about shared decision-making, or incentive alignment? Hall noted that “incentive” does not always refer to a monetary incentive. She also agreed that shared decision-making creates more opportunities for patient education.

Jamie Ferguson discussed the three categories of PGHD that Kaiser Permanente has identified: one-time electronic questionnaires, data from consumer-grade general wellness devices, and data from professional-grade monitoring devices for remote monitoring. The only evidence of clinical efficacy came from the professional-grade monitoring of people with serious conditions such as diabetes or congestive heart failure. Distinguishing among the different kinds of PGHD and their use cases is important.

Tang noted that convenience is key—avenues for PGHD must be convenient if the patients are going to buy-in. He also said that physicians must be at the point of need, not necessarily the point of care, which is confined to most traditional care environments. Finally, he agreed that the language “person generated health data” should be considered more carefully, as it reflects a person-centered care mindset. Aligning HIT with communication is an effective means of integrating healthcare into a life and a community.

Kay Eron suggested that the Task Force pursue medication adherence and clinical trials as important elements of the PGHD equation. Standardizing the data sets for capture is important to the re-usability of information in trials and research later down the line. Hall agreed that the taxonomy, vocabulary, and nomenclature around patient context is a gap that needs closing.

Miri encouraged members to take a second, more concentrated look at the language around who owns the data; looking at the granularities of security and privacy is important. Additionally, how can the clinical relevancy of certain kinds of data be ensured? The data must tell a story. Finally, Miri noted the challenges in trusting the data, particularly data generated from consumer-grade devices—they are not always accurate.

The difference in the data generated by consumer-grade products versus that of industry-grade products is a key challenge, Seagondollar agreed. How can providers and care professionals trust that data without that it is correct and that the device has been through some kind of quality assurance validation? Did the Task Force discuss some type of an approval, validation, or accreditation process for consumer-grade devices that can be used to generate PGHD that is usable for clinical decision-making? Hall explained that this was discussed, but no solutions were offered in this draft White Paper, as it was out of the scope of the CTF charge.

Malec encouraged the Committee to review former Surgeon General Hohoro’s talk on white space to help further consider ways of framing patient engagement and access.

Nancy Orvis agreed that Hohoro’s perspective is a valuable one. With regard to responsibility, the key is not necessarily who generated the data, but who controls it—is it perhaps better to discuss patient controlled data instead? How are data integrity, provenance, and accuracy maintained in a patient-controlled data setting? What kind of policy should be written around linking EHR and patient-controlled data? The VA’s Office of Connected Care has conducted important work in this space. Malec agreed, and offered the ONC report on non-HIPAA covered data as another resource for use cases.

Josh Mandel highlighted a best practice for providers: providing a “dashboard” not only for patients, but also for providers, as well as keeping track of the underlying data that support the conclusions made on that dashboard. Is there a way to standardize the flow of raw data?

Wanmei Ou asked if the Task Force considered how to guide standard and governance structures for raw data versus the more clinically relevant information. Hall explained that work completed in HL7 and under the Consolidated CDA has moved some of those standards forward outside of the charge of this Task Force.

Public Comment

Dan Rodie strongly encouraged the Task Force to directly address the issue of certification or accreditation of consumer-grade PGHD collection devices, particularly through the lens of privacy, security, and accuracy of information.

Lindsey Hoggle thanked and congratulated the Committee for their hard work over the years.

Comments were submitted via the web meeting chat. Jonathan Nebeker wrote, “There is a standard for getting human-readable guidance called InfoButtons. VA is now using this. Many vendors support it. Regarding the inconsistency of standards, this is exactly the work that Health Services Platform Consortium is doing by integrating work from CIMI and SOLOR. There is current work in collaboration with the American College of Obstetrics and Gynecology for maternal-fetal health and registry reporting that directly addresses some of the issues relevant to Zika. Steve Hasley is the ACOG contact for the standards work. I do think that the whole group needs to hear the HSPC comment. Infobuttons just needs to be specifically referenced in the report.”

And Margaret Lampe (CDC) wrote, “Consent is not required to transmit HIV reporting information. It can be required for HIV *exposure*, i.e., an infant with unknown infection status who is born to an HIV+ woman. We have some experience with reporting pregnancy status with positive Hepatitis B surface antigen tests via commercial labs. An important lesson learned there is that reporting to public health needs to be done in ONE way.”

Remarks

Tang thanked the ONC participants and volunteers for their time and effort on the Committees. He gave a brief retrospective of his understanding about how HITECH and these two FACA Committees came about. The progress that has been made in the HIT sector since the passing of HITECH and the American Recovery and Reinvestment Act (ARRA) is staggering; much of that progress is due to the dedication and hard work of the FACA Committee members, as well as strong leadership at the helm of ONC. Tang recognized the efforts of Jon White, Elise Sweeney Anthony, and Michelle Consolazio, specifically. He expressed gratitude for the strong and meaningful collaboration of both public and private partners in this work.

Gallagher, HITSC Co-chairperson, offered profound thanks to everyone who participated in the work of HITSC. She specifically thanked Dr. DeSalvo, Jon White, Michelle Consolazio, Lucia Savage, Jodi Daniel, Elise Sweeney Anthony, Steve Posnack, and Dixie Baker. She reminded the Committees that cyber security remains a serious and ever-changing challenge for the future of healthcare. Cyber security and the needs of the industry must be at the forefront of HIT work going forward.

Malec also thanked everyone involved at ONC, and in HITPC and HITSC. He recognized the alacrity with which Meaningful Use (MU) was initially implemented and the ways in which it was stalled. The healthcare system in this country is large, complicated, and slow moving, but the progress that has been made in the last 5 or 6 years is profound and meaningful. Widespread implementation and use of EHRs,

health exchange networks, public and private partnerships, emerging API access to EHRs, have all been integrated into the HIT landscape in a relatively short timeframe. The majority of this integration has been backed by standards and policies that are the direct result of the work of these Committees and Workgroups. The new HIT Advisory Committee (HITAC) is operating in a HIT landscape that is much improved.

Harrell thanked everyone involved, and offered specific thanks to Paul Tang and Paul Egerman. She highlighted the importance of interoperability, privacy and security, and data availability, as HITAC moves forward and as the industry moves to value-based care.

Anthony thanked everyone who worked on the subgroups and task forces, those who worked on deep technical issues—without that work, ONC would not have been able to move forward. She also offered thanks to the various stakeholder groups for their input. In particular, the members of Workgroups who do not sit on the Committees were offered her thanks. She also recognized the importance and value of public comment. Anthony then moved to a brief discussion of HITAC and its role in 21st Century Cures, noting that the structure of HITAC will differ in scope and focus. The GAO has started the appointment process with 14 appointees listed on the *Federal Register*; the deadline is April 14th. ONC may appoint 3 members to HITAC, and the houses of Congress may appoint a combined 8 members.

Hall thanked Michelle Consolazio for her work.

White offered remarks detailing and praising the work of Paul Tang, Kathy Blake, Arien Malec, and Lisa Gallagher. He then discussed the substantive and meaningful nature of the work these Committees have accomplished and offered profound thanks.

Committee members toasted the health of the Nation.

Consolazio offered profound thanks to the members of the Committees for their hard work before closing the meeting.

SUMMARY OF ACTION ITEMS

Action item #1: The minutes of the March 8, 2017 virtual meeting were approved by majority vote.

Action item #2: The Public Health Task Force recommendations were approved, with further instructions to the Task Force to develop precise language regarding pregnancy and privacy concerns.

Meeting Materials

- Agenda
- Summary of the December 6, 2016, joint meeting
- Presentations and reports slides