



Health Information Technology Advisory Committee

Meeting Summary

September 5, 2018, 9:30 am – 4:00pm ET

In-Person

The September 5, 2018, Health IT Advisory Committee (HITAC) meeting was called to order at 9:02 am ET by Lauren Richie, Designated Federal Officer, Office of the National Coordinator for Health IT (ONC).

ROLL CALL

(Members in attendance, representing)

Carolyn Petersen, Individual, HITAC Co-Chair

Robert Wah, DXC Technology, HITAC Co-Chair

Michael Adcock, University of Mississippi Medical Center

Christina Caraballo, Kizmet Health

Tina Esposito, Advocate Health Care

Cynthia A. Fisher, WaterRev, LLC

Valerie Grey, New York eHealth Collaborative

Anil Jain, IBM Watson Health

John Kansky, Indiana Health Information Exchange

Kensaku Kawamoto, University of Utah Health

Steven Lane, Sutter Health

Leslie Lenert, Medical University of South Carolina

Arien Malec, Change Healthcare

Denni McColm, Citizens Memorial Healthcare

Clem McDonald, National Library of Medicine

Aaron Miri, Imprivata

Brett Oliver, Baptist Health

Terrence O'Malley, Massachusetts General Hospital

Raj Ratwani, MedStar Health

Steve L. Ready, Norton Healthcare

Sasha TerMaat, Epic

Andrew Truscott, Accenture LLP

Sheryl Turney, Anthem BCBS

Denise Webb, Marshfield Clinic Health System

Federal Representatives

Ram Sriram, National Institute of Standards and Technology (NIST)

Members not in attendance:

Brad Gescheider, PatientsLikeMe



Kate Goodrich, Centers for Medicare & Medicaid Services (CMS)
Chesley Richards, Centers for Disease Control and Prevention (CDC)
Patrick Soon-Shiong, NantHealth
Lauren Thompson, Department of Defense/Department of Veterans Affairs (DoD/VA)

ONC Senior Staff

Jon White, Deputy National Coordinator (ONC)
Steve Posnack, Executive Director, Office of Technology
Elise Sweeney Anthony, Executive Director, Office of Policy
John Fleming, Deputy Assistant Secretary for Health Technology Reform
Seth Pazinski, Director, Office of Planning, Evaluation and Analysis
Lauren Richie, Designated Federal Officer

Welcome Remarks –

Jon White, Deputy National Coordinator (ONC)

Jon White welcomed the committee members to the meeting, especially with the excessive heat and humidity in Washington, D.C. He noted a full agenda for the day and mentioned the fall activities ahead for the members. The Interoperability Forum held on August 6, 2018 – August 8, 2018, was a well-attended and well-regarded event. Highlights from the Forum will be discussed later in the day by Steve Posnack. There will be a large portion of today's meeting focused on interoperability and open discussion.

He noted that ONC is working to revise and draft the Trusted Exchange Framework and Common Agreement (TEFCA) considering the public comments received. ONC is also working on a notice of funding opportunity (NOFO) for a cooperative agreement to select a recognized coordinating entity (RCE) to support TEFCA. The 21st Century Cures Act (Cures) requires ONC to engage in rule-making to help advance interoperability, the exchange of health information, and to address information blocking. ONC is undertaking the development of the notice of proposed rulemaking (NPRM) to outline proposed policy in Cures. These proposed policies will focus on provisions for conditions, and maintenance and certification requirements for health IT developers under the certification program. ONC is also working on the voluntary certification of health IT for use by pediatric healthcare providers, other specialty care and practice settings; as well as provisions related to information blocking and establishing definitions for reasonable and necessary activities that do not constitute information blocking.

He noted that ONC is in the process of rulemaking and acknowledged that it is not always a fast process, but ONC is working hard and as fast as possible. He stated that ONC is working to advance interoperability to support the access, exchange and use of health information through open application programming interfaces (APIs) and transparent, uninhibited data



sharing. The notice of proposed rule-making (NPRM) is anticipated to be published in the fall of this year. ONC is also working on another Cures provision to develop criteria that will eventually be included in the reporting program. A request for information (RFI) was released in late August to support this effort.

Jon then turned it over to John Fleming to speak about burden reduction efforts that he has been undertaking.

John Fleming shared that his project while at ONC has been to work towards physician administrative burden relief. He noted that this work has been broken into two areas. First is a report to Congress regarding suggested benefits and tactics for improvement; the other has been to work with CMS to look at the problematic issue of documentation burden. He noted that he is hopeful that providers are able to return to documentation for the benefit of the patient rather than for the benefit of billing. A proposed rule was released in July and will close on September 10, 2018. Once the comment period closes, discussions and finalization of the rule will begin. While not in the HITAC's specific purview, this may be of interest to the HITAC members.

Jon White then turned the meeting over to Elise Sweeney Anthony, Executive Director, Office of Policy.

21st Century Cures Update –

Elise Sweeney Anthony, Executive Director, Office of Policy (ONC)

Elise Sweeney Anthony thanked the members of the HITAC for traveling to DC, especially with the current steamy weather. She also thanked the committee for their work participating and traveling to meetings, as well as engaging in the work that results in draft recommendations from the workgroups/task forces. Elise went on to thank ONC's subject matter experts and staff leads for their work behind the scenes. Elise then specifically thanked Lauren Richie, Seth Pazinski, and Mitch Kost while also acknowledging the rest of the team for their work ensuring that meetings run smoothly.

She then went on to review the agenda for the day. She shared that the first item on the agenda is a deep dive on the EHR reporting program and a review of the RFI, to gather initial feedback from the committee. The goal of the RFI is to gather public input, identifying what is important to set-up the program, and identifying criteria that will be helpful for end-users and the purchasers of EHR systems. ONC is in the process of awarding a contract to help assist with the aggregation of public comments and execution of the program. Once all comments are received and consolidated, ONC will present findings to the committee, engaging members to assist in developing the reporting criteria.



The HITAC will then hear from the Interoperability Standards Priorities Task Force (ISPTF) and the Annual Report Workgroup (ARWG). Both groups will be continuing their work through the fall, working on components of Cures.

Additionally, highlights from the Interoperability Forum that was held in early August will be reviewed and discussed. With the committee together in-person, a discussion will be had to gather thoughts and feedback regarding different aspects of the interoperability conversation.

She then provided updates regarding work ONC is doing around Section 4006 of Cures, another component from Cures which focuses on patient access and education. This work has been done in collaboration with the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Office for Civil Rights (OCR). Of note, ONC released the **Get It. Check It. Use It.** resource. This is a tool that provides an easy way for patients to understand how to get their health information, how to update it, how to provide their input into a patient amendment, and how to use it in their care.

She went on to highlight a few items from Cures that provide an overarching view of Congress' thoughts about the importance of certification and health IT going forward. She noted items like information blocking, provisions around communication, and ensuring there is no special effort needed to access health information. These are sample items that ONC is thinking through as they develop the rule.

With a full agenda ahead, she thanked the HITAC members and stakeholders for their work on TEFCA and for their upcoming work. Elise then turned the meeting over to the HITAC co-chairs.

Review of Agenda and Approval of June Meeting Minutes – *Carolyn Petersen, co-chair and Robert Wah, co-chair*

Robert Wah welcomed the HITAC members to their third in-person meeting. He acknowledged the public in the room and on the phone. He went on to acknowledge that he and Carolyn appreciate all the work done to prepare for the meeting. He noted the effort made to have materials distributed in a relatively timely fashion, although it was a bit challenging being so close to a holiday weekend. He noted that this federal advisory committee is different than most as there is a prescriptive legislative agenda provided in Cures. He also noted that at the end of the day there would be time allocated for open discussion.

VOTE TO APPROVE MINUTES

Robert Wah called for a vote on the minutes from the June 2018 meeting. No comments or amendments were offered, and the minutes were approved.



He then thanked the committee for their participation and work, particularly those who have taken on the responsibility of leading or participating in a workgroup or task force. As was discussed at the first meeting, the task force is the place where much of the work gets done and that work needs to be acknowledged. He then turned it over to the Interoperability Standards Priorities Task Force (ISPTF) co-chairs for an update.

Interoperability Standards Priorities Force (ISPTF) Update –

Ken Kawamoto, co-chair and Steven Lane, co-chair

Steven Lane thanked the chairs for the opportunity to address the entire committee. He noted the TF membership is a mix of committee members and public members, representing a diverse mix of engaged stakeholders.

He then reviewed the charge of the task force which is to make recommendations on priority uses of health information technology, the associated standards and implementation specifications that support such uses.

The summer activities of the TF were reviewed:

- The TF kicked off on July 20
- An overview of Centers for Medicare & Medicaid Services (CMS) quality programs was presented by Elisabeth Myers (ONC) on July 31
- The TF discussed how best to prioritize discussions.
- The TF conducted a survey to determine which uses of health IT were the highest priority for the group to analyze.

Once the TF works through the prioritized uses, work will then shift to looking at the standards that exist and identifying opportunities where those standards might need to be evolved or made clearer. Limitations of those standards will be reviewed, identifying how they have or have not been implemented within the vendor community. The end goal will be to provide recommendations for industry/government action.

Steven Lane reviewed a list of the priority areas identified by the task force, via a survey, to decide where the group should begin their work. The task force initially considered separating into smaller groups, but decided to start out collaboratively. The results of the survey are ordered below:

1. Orders & Results
2. Medication/Pharmacy Data
3. Evidence-Based Care for Common Chronic Conditions
4. Closed Loop Referrals
5. Other



6. Social Determinants of Health
7. Cost Transparency

The TF used the priority list as a starting place. Orders and results were the highest priority, which is where the task force will start. This was not to say that any of the other items are not important, but the group wanted to start somewhere, and through the balloting process, orders and results were at the top. This is an area ranging from laboratory, imaging, cardiac and pulmonary testing; medications, and prescriptions, as these are all types of orders. The TF started where the potential impact was the greatest, initially focusing on laboratory test. Many providers have difficulties moving discrete laboratory data with semantic interoperability between systems. The TF identified that there are barriers for everyone, including small offices, large systems, and patients getting access to their results. The TF is working to identify the largest problems with regard to orders and results and is working to understand where there are opportunities for improvement.

Ken Kawamoto added that this was an initial pass at identifying a place to focus, but the ISPTF is interested in identifying the problems that folks are facing with interoperability and clinical use cases and identifying potential solutions.

Steven Lane noted that the determination by the group was to start with orders and results, engaging the entire task force to develop an initial methodology. The work will then continue over the next few meetings and then potentially take two of the next domain areas and separate out into small groups and then work through them following the same methodology.

The co-chairs then opened the discussion up for comments and feedback from the HITAC members.

Discussion

- **Arien Malec** commented that in his time working with ONC and on a variety of federal advisory committees, he has seen the health IT community be able to make significant progress by focusing on a few areas- working in collaboration with the broader community; specifically health IT developers and provider organizations, in conjunction with CMS on specific policy levers that may be utilized in this area. He commended the work of the task force, but urged the HITAC to narrow the focus. The ISPTF is looking at new standards development for high-priority areas. There are some areas that currently need finishing, such as the move to “**Axe the Fax**”. There are issues with the overall end-end usability with existing forms of exchange (e.g., consolidated, CDA) and the need to have more focused clinical notes in the context of exchange of information. In summary, two items were highlighted:



- He recommended narrowing the focus on a few priority areas and convening the entire stakeholder community, in particular, the developers who need to implement them and provider organizations who need to use them.
- Areas that are high priority for the nation that warrant finishing, as they will help reach the goal.
- **Steven Lane** responded to Arien's comment, noting that depending on the domain, the need may be quite different. In the area of social determinants of health, as an example, this is an area where standards are not well developed. In other areas, it's about well-established standards, like Direct, that need to evolve.
- Another comment that was left out earlier was to note that Terry O'Malley is an ISPTF member who is one of the co-chairs of the USCDI task force. There have been discussions highlighting the importance of working in parallel and staying in alignment.
- **Ken Kawamoto** remarked that a year will go by very quickly; thus, the ISPTF needs to come up with something achievable, quickly. As an example, lung cancer is the number one cause of death for both men and women from cancer. To prevent it, there is a screening called lung cancer CT screening which is projected to save more lives than mammograms. Currently, there is less than a 5% adoption rate in the U.S. because data is needed on how many packs people are smoking. Currently, the data only includes if a patient is a smoker not how many packs. Collecting data and sharing what is already in the EHR is an example of what is achievable and in scope.

With no additional comments in the room or on the phone, **Robert Wah** turned the meeting over to the co-chairs of the Annual Report Workgroup.

Health IT Advisory Committee Annual Report Workgroup Update – *Carolyn Petersen, co-chair and Aaron Miri, co-chair*

Aaron Miri kicked off the discussion of the Annual Report Workgroup (ARWG). He noted that he and Carolyn would be providing a review of the membership and an update regarding the scope and progress of the ARWG.

Aaron noted that the membership of the ARWG is limited to HITAC members. Aaron acknowledged the ONC staff for their assistance and guidance. He went on to review the charge which is to inform, contribute to, and review the draft and final versions of the HITAC Annual Report to be submitted to the HHS Secretary and Congress each fiscal year. As part of that report, the ARWG will help track ongoing HITAC progress.

The detailed charge was reviewed. The AR-WG is to provide specific feedback on the content of the report as required by the 21st Century Cures Act including:

- Analysis of HITAC progress related to the priority target areas



- Assessment of health IT infrastructure and advancements in the priority target areas
- Analysis of existing gaps in policies and resources for the priority target areas
- Ideas for potential HITAC activities to address the identified gaps

The priority target areas noted in section 4003 of Cures covers:

- Interoperability
- Privacy and security
- Patient access
- Any other target area related to the above target areas that the HITAC identifies as appropriate

A diagram depicting the process for establishing the annual report was reviewed, and then a crosswalk was reviewed of priority target areas. The crosswalk will be used to ensure the ARWG is making a meaningful impact.

A three-dimensional crosswalk of the priority target areas will be used to identify the interests of key stakeholder groups, which adds another dimension to consider. The crosswalk will be used to identify challenges and issues to work through, making sure that less represented voices are considered.

Aaron then turned the discussion over to his co-chair, Carolyn Petersen.

Carolyn Petersen reviewed the ONC objectives and benchmarks. She noted that while the slides and legislation state benchmarks, it is the first year, so the group is establishing baselines. The purpose of HITAC's annual report, as stated in section 4003 of Cures, is for ONC to work in collaboration with the Secretary to establish appropriate objectives and benchmarks for advancing and measuring the advancement of the priority target areas.

ONC sets the objectives and the benchmarks that the ARWG are looking to use in the development of the annual report. This will align with the priority target areas in Cures, establishing a consistent measurement process over time. The objectives and benchmarks can be updated, as needed over time. ONC is open to feedback from HITAC members about the objectives and benchmarks. Carolyn encouraged participation in that discussion, which is held in a public forum.

For fiscal year 2018, ONC identified several objectives:

- Publish proposed regulation for implementation of the health IT provisions of the 21st Century Cures Act to drive access to clinical data by;
 - Advancing proposals related to application programming interfaces (APIs)
 - Identifying behaviors not considered information blocking, which will assist the HHS Office of Inspector General (OIG) in their enforcement of the Cures Act provisions that prohibit information blocking.



- Publish the draft Trusted Exchange Framework (TEF) to improve data sharing across disparate health information networks.
- Consider standards and implementation specifications to support priority uses of health IT based on HITAC recommendations, encouraging all stakeholders to implement and use as applicable to the specific interoperability needs they seek to address.

With regards to benchmark (baseline), for fiscal year 2018, there are several benchmarks:

- The proposed regulation covering APIs, info blocking, and other health IT topics to be published.
- Publication of the draft trusted exchange framework.
- Standards and specifications to promote priority uses considered.

Carolyn then presented the structure proposed for the annual report.

1. Executive Summary
2. Overview
3. Description of HITAC's Work in FY18
4. Health IT Infrastructure Landscape Analysis
5. Health IT Infrastructure Gap Analysis
6. Recommendations for Addressing Health IT Infrastructure Gaps
7. Suggestions for Additional HITAC Initiatives
8. Conclusion
9. Appendices

The Proposed Landscape Analysis Structure was presented:

- Overview
 - Legislative requirements
 - Current ONC and HITAC priorities
- For Each Priority Target Area:
 - Background
 - Current State
 - Describe Recent Progress for Various Topics
 - Show Examples from Stakeholder Groups

The proposed gap analysis structure for each of the priority target areas will include:

- Gaps identified
- Opportunities identified
- Recommendations for addressing gaps and opportunities.

The ARWG is completing the work in a flow cascade approach. Starting with the HITAC having the opportunity to review, as the workgroup begins working on the next item.



The ARWG has had three meetings and has begun building the overall structure and thinking about the landscape analysis and gap analysis.

- Later this month the workgroup will discuss the landscape analysis.
- In October, the workgroup will review the gap analysis and the outline of HITAC's progress for this year.
- In November, work will commence on the year-end review and the overall report outline.
- In December, the workgroup is expecting to review and work through the final draft.
- In the spring, the workgroup will begin working on the fiscal year 2019 report.

Carolyn shared that the ARWG will be touching base with the HITAC throughout the process.

- Today's goal is to provide the workgroup's approach.
- At the meeting next month there will be an opportunity to review and discuss the landscape analysis and gap analysis.
- In November, the year-end review and the overall report outline will be shared.
- In the winter/spring the HITAC will be reviewing and hopefully approving the annual report.
- The report will be submitted to the HHS Secretary and eventually to Congress.

Carolyn then opened up the discussion for comments and questions.

Discussion

John Kansky noted that the workgroup hasn't had the opportunity to talk about the landscape analysis and gap analysis, but asked about a vision for what will define future state and further gaps?

- **Carolyn Petersen** stated that they had not yet defined an ideal future state at this point or looked at a particular goal for the committee. The ARWG is looking at items that have been identified broadly through the committee and looking for things that have not been achieved or areas where further progress is necessary to further ONC and Congress's broad goals and objectives.
- **Aaron Miri** added that they are still in an information gathering stage.
- **Robert Wah** added that time will be dedicated at future meetings to review and comment on drafts, as this is a committee project that represents the committee's perspective as a whole.

Elise Sweeney Anthony thanked the co-chairs for their work and acknowledged Michelle Murray, ONC staff lead for her support. She noted that the landscape analysis and gap analysis would help inform, not only the annual report, but also ONC's work 5-6 years down the line. Also noting the work on the annual report will help ONC think about things on a longer scale.



Identifying how the benchmarks crosswalk to the priority target areas is important.

Denise Webb thanked the chairs for their work. She noted that the structure and approach make sense, but she was having a little trouble with the term benchmark. ‘Benchmark’ seems to be related to measurements. She noted it is likely that Congress would like to see how the HITAC is moving the needle in the priority areas. She recommended concrete measurement in terms of baselines and targets, in each of the priority areas.

Aaron Miri acknowledged Denise’s comment and noted that her feedback going forward would be appreciated.

Ken Kawamoto commented that he believed it was the job of the HITAC to discuss things that can be leveraged (e.g., the National Academy of Medicine, future of EHRs), identifying a vision where the use of health IT is not a source of frustration and patients receive all the care needed. Maybe it is not achievable in one or two years, but hopefully, it will not be another 15 years away.

Andrew Truscott thanked the chairs for taking this work forward. He noted that much had been written about the landscape, but not much seems to change. He commented that it is about the gaps and where progress needs to be made. Secondly, when it comes to targets, he recommended being clear about what is realistic and what is a stretch target. Identifying something empirical to measure against, as opposed to identifying what could have been achieved. He also noted that the HITAC needs to be critical because as a community they are good about making aspirational goals, but not as good at hitting them.

Sheryl Turney commented that a great structure for the development of the annual report had been laid out, but she challenged the group to quantify a better picture of how interoperability is defined. From the perspective of this annual report, interoperability should be defined by the way the solution is delivered. The definition of interoperability looks very different across stakeholders. She noted that interoperability should be patient-centered and from the patient’s perspective. Hopefully in the future patients will be able to get the right information to coordinate with their provider, in one place. That should be everyone’s goals, at the same time physicians need to be properly compensated for the work they do. She shared her personal experience where she had physicians support her daughter’s condition who went unpaid because there was no code, no process for physicians from Yale, University of California Irvine and Mayo Clinic to work together on something because currently in today’s world, that is not compensated. She noted her pleasure to see that the CMS rules have more of that coming forward for the future. Regarding research, she noted the need to embrace and demonstrate the importance of research. The more participation in research, the more solutions there will be for the patient’s lifetime of issues; there are use cases that demonstrate that as well. There is still a



struggle between what data people can use and what data they cannot use based on protecting the individual's identity. She noted that there are many challenges that are dealt with in her organization's research arm, regarding what they are allowed to do with the data and what they can do even with the patient's permission. That is something that needs to be in that picture.

- **Carolyn Petersen** responded to comments noting that the definition of interoperability is a really good point and well taken. With regard to comments about interoperability, she suggested putting that on hold until Steve Posnack's review of the Interoperability Forum later in the day.
- **Aaron Miri** agreed with Carolyn's comments and added the importance of past FAC and ONC work.
- **Elise Sweeney Anthony** noted a definition of interoperability from Cures in Section 4003 and reviewed the three-pronged definition: The first part focuses on enabling the care exchange of our electronic health information. The second part is on allowing for complete access and use. The final part focuses on not constituting information blocking. This was just a short version of the definition laid out in Cures, but reviewed for the HITAC's awareness.

Clem McDonald noted that he would prefer to not define anything. He proposed that a goal be to push data to all patients, all test results sent to patients. This means there is a need for structure and coding.

Robert Wah noted that the HITAC was a little behind the original agenda and turned it over to Lauren Richie who turned the meeting over to Seth Pazinski, the director of strategic planning and coordination division at ONC and Michael Wittie who is the program lead for the EHR reporting program.

Discussion of EHR Reporting Program and Criteria Development – *Seth Pazinski, Director, Strategic Planning & Coordination Division (ONC)* *Michael Wittie, EHR Reporting Program Lead (ONC)*

Seth Pazinski thanked the HITAC for the opportunity to present and noted he was looking forward to introducing HITAC to this new program. A request for information (RFI) was released to gather public input, and ONC is looking forward to getting initial feedback. As mentioned at the beginning of the meeting, the 21st Century Cures Act (Cures) requires that ONC develop EHR reporting criteria through a public, transparent process, through two mechanisms:

- 1) Rulemaking on conditions of certification
- 2) Engaging stakeholders to develop and implement the EHR reporting program

The program intends to make public information available to compare certified health IT. The information from the source includes both users of the technology and developers of



certified health IT. It will be important to hear about existing sources of data that can be leveraged and feedback on ways to minimize any potential burden participating in the program. He then turned it over to Michael Wittie who provided an overview of the RFI.

Michael Wittie noted that ONC is very focused on implementing the provisions of Cures to improve health IT, interoperability, and reduce provider burden. A number of topics are focused on patient access, burden reduction, and enhancing the certification process. The program is going to ultimately reflect input from the developers of certified health IT and voluntary input from users, providers, and patients, etc. about criteria related to security, usability, interoperability, performance certification and other areas that stakeholders identify as appropriate. The Cures Act requires that ONC engage the public in a transparent process to inform what those criteria should be and how the program should work.

In 2016 there was a report for Congress on the feasibility of mechanisms to assist providers in comparing and selecting certified EHR technology products based on market analysis and subject research. ONC released the RFI which is the first step in developing the criteria and gathering input from the public on what would be useful and implementable from the perspective of both users, purchasers, and also on the part of developers to avoid being overly burdensome.

The RFI is seeking input on reporting criteria that have the following characteristics:

- Show distinct, measurable differences between products
- Describe the functionalities of health IT products varying by the setting where implemented (e.g., primary versus specialty care)
- Provide timely and reliable information in ways not unduly burdensome to users or to small and/or start-up developers
- Comparatively inform acquisition, upgrade, and customization decisions that best support end users' needs beyond currently available information
- Support analysis for industry trends with respect to interoperability and other types of user experiences

The RFI has two sections that include the following:

- Cross-Cutting Topics
 - Existing Data Sources
 - Data Reported by Health IT Developers versus End-Users
 - User-Reported Criteria
 - Health IT Developer-Reported Criteria
- Categories for the EHR Reporting Program
 - Security
 - Usability and user-centered design
 - Interoperability
 - Conformance to certification testing



- Other categories, as appropriate to measure the performance of certified EHR technology

Cures requires the following:

- ONC to conduct a stakeholder-driven process and
- An independent entity to develop each criterion using stakeholders' input through a convening process, resulting in the development of draft criteria that will be published publicly.

Next steps for the HITAC include

- Initial feedback from HITAC received today
- HITAC will be provided an update on:
 - A summary of public comments received on the RFI
 - A summary of feedback received through the required stakeholder engagement process
- HITAC will review and submit recommendations on the draft reporting criteria

ONC will be awarding a contract to an independent contractor soon. Once the comments from the public and stakeholders are aggregated, the independent entity will draft criteria proposals. ONC will then come back to the HITAC and present the draft criteria and seek further recommendations. ONC will seek HITAC comments at the same time that the public is providing their comments. This feedback will then be incorporated into what becomes the EHR reporting program. The deadline to submit comments to the RFI is October 17, 2018. In addition to any feedback today, members are welcome to submit through the formal RFI process.

Michael Wittie then turned the meeting back over to the HITAC co-chairs for discussion and questions.

Discussion

John Kansky commented that it is not Congress's intent that the federal government take a position that one product is better than another. He questioned how to describe the intent of the program. He also wondered if there was precedent from another agency in the federal government doing a similar analysis.

- **Seth Pazinski** responded to the first point, noting that the main goal is transparency of the information. Regarding the government favoring one product over another, it is about making available the comparative information so that there is improved transparency. ONC is interested in learning about particular areas of most interest with regards to this program and whether ONC can potentially address some of those transparencies or gaps.



Ken Kawamoto noted that perhaps this is something that can be used to foster change. If ONC conducts a qualitative analysis, maybe ONC can get to something actionable that the vendors can use to improve their system.

- **Michael Wittie** responded that he thinks this is part of the second aim. The first part is informing the acquisition and decisions, the second part of the intent is the trending concept.

Steven Lane noted his appreciation for taking on this work. He noted the importance of this work which can help in acquisition decisions, many of which have already been made, but implementation as well. Providers are already using a system and the more they know about capabilities will help them. Most understand that the burden to providers is already high and asking providers do something more with an unfunded mandate is going to be tough. With vendors, even small vendors, this is the cost of doing business. He recommended asking vendors to bake tools into their system so it's not extra work to be able to do reporting and metrics, but instead these will show up automatically in the process of use. There are key metrics to answer questions. With usability there are key issues; if clinicians do the wrong thing, it suggests the system is not supporting them in doing the right thing. He suggested looking for these artifacts without creating an undue burden. Some of the systems are already measuring things like how much time a clinician is spending interacting with the patient or interacting with the patient's data as opposed to doing busy administrative work. He suggested metrics that all of the vendors have to report. In regards to interoperability, there's the ability to ask how frequently there are patient queries, how often, and was one of them data exchange. How much of that data is incorporated on a discrete level and how much of it is used by clinicians? There have been other discussions about how to measure interoperability, and it seems those discussions should apply to this effort.

Arien Malec referred to the policy background that led to the program. He noted that an early draft of 21st Century Cures had language about a Stars Rating program following the Prescription Drug Program and Medicare Advantage Stars Rating approach. The final draft pulled out the stars rating approach and put in this language that calls on ONC or allows ONC to work with an outside organization to establish certification criteria. It seems there is a perspective by Congress that there is some sort of market failure relating to the existing mechanisms for providing public information. There are some well-known programs out there that provide information on usability, ratings, user ratings, analyst ratings, EHR technology, and other health information technology. Looking at some of the language in 21st Century Cures it seems like some of the market failure addresses some of the specific concerns about access to information for small provider organizations, as well as access to smaller developers. He framed up the policy question for ONC related to choice. His interpretation of the language was ONC is not locked into choosing an outside agency. Instead, ONC is able to create a star rating kind of approach or picking an outside firm to address the market failures. Anything that ONC does has to come along with a funding model, a taxpayer-based funding model. He noted that it seems as if ONC may be setting up



the stars program, but it's not clear that it's necessarily the right approach and that policy approaches should be considered to work with an outside firm on addressing some of the barrier burdens and market failures attached to that outside firm.

- **Elise Sweeney Anthony** commented that she appreciated the comment and would like to provide background regarding how ONC is thinking about implementation. ONC is open to implementation which is why ONC is putting out the RFI to gain insight on how the public sees this provision and how it will be most helpful to them. As noted, earlier versions of Cures included a star rating program. However, that did not get finalized, so ONC is staying close to the language that was finalized. One of the big messages that comes through is around transparency, and the stakeholder engagement and the importance of having outside entities help us with the development of that process. That is part of why ONC is looking to bring on a contractor, hopefully in the next two or three weeks or so, to help with the process. At the same time, comments in the public and what ONC hears today will help us think through how ONC goes forward with implementation of the program.

Andrew Truscott noted that the subject area is both incredibly mundane and fascinatingly contentious in equal measure. He suggested looking at the UK and Australia, as they have similar programs because of the way their health system works nationally. He noted the distinction between product capabilities and implementation capacity - not all products or implementations were created equal. He noted he does not have a problem with burden; it is important, provided it's reasonable. The word "meaningful" was used and he noted he would like to add "useful" to that, as this reporting should not be a box on a piece of paper. This will be used as a proxy for competency; it will provide the ability for an organization to correctly curate and care for patients and their information. This is something that has to be done, but should not cause undue burden.

- **Michael Wittie** noted his appreciation for the comments and believes looking at the UK and Australia is a great suggestion. He reminded everyone to look at the RFI and if they feel inspired, to send some comments. He asked the HITAC to help ONC think through what the pitfalls are in doing this. What is an undue burden, he asked? Are there things to keep in mind like past experiences with something, if not similar and analogous, in another field or topic? Or is there something ONC should avoid?
- **Andrew Truscott** commented that there is a desperate need for this and ONC could get it wrong on the first cut. Get the first cut out there, and then things can be updated. If created in a vacuum, it won't be successful.

Raj Ratwani noted he had a lot of comments given that this is usability-related. The focus needs to be on the usability side, not the user-centered side. When it comes to user-centered design, everyone will raise their hand and say they do it. When pushed for evidence, they're going to show evidence, and it is difficult to detect variability in the user-centered design process. He emphasized the need to focus on core usability. When it comes to core usability,



this ties back to the burden points Steven and Andrew made; it's going to be easy to decide to put out a survey instrument to assess usability, but that only gets to the perception of usability. There is value in that, but he recommended focusing on the harder part which introduces the burden, which is getting to performance-based usability. He pushed the point around performance-based usability and making sure it is done in a way such that things can be compared equally. It has to be on the implemented product, where there is still huge variability in optimization, upgrades, and so forth. He also noted that this should not be just on provider facing components of the EHR, but also the areas that the patient is touching. Finally, and most importantly, approaching this whole project or process with a focus on usability user-centered design and talking to the stakeholders iteratively. Identifying what would be the most useful for them in regards to transparency. Put pilot data in front of them and ask providers how that data would change their decision-making. Keep iterating throughout the process to see it is done right this time.

Robert Wah noted some members were still in the queue waiting to speak; to make sure there is time for all to have input, he noted he would take the chair's prerogative and allow the questions/comments without immediate response to each.

Leslie Lenert highlighted the importance of the aspirational nature of this; this is where EHRs will be influenced to make them what we want them to be. Secondly, usability statistics have effects on the healthcare processes as outlined and described by Raj. That includes a focus on productivity metrics coming out of the EHRs and using them as tools to see how the healthcare system is performing. What's the rate of rejection of insurance claims? How long does it take the average primary care visit? There are many things that can come out of the EHRs that explain these processes. The last point he made was about the notion that going forward there are enormous amounts of data about the organization that is linked to the EHR and captured simultaneously. Without the organizational characteristics, qualities, and other data, results can't be interpreted. Based on the particular types of activities that providers are engaged in and the culture of the organization, quality ratings may differ. To interpret quality rating, enormous amounts of data needs to be provided.

Aaron Miri first noted that this needed to be done yesterday and is going to be messy. There is a lot of tribal warfare that occurs with product usage within the provider community and there's a lot of misinformation about what products can and cannot do. He noted on the CIO and provider side contracts limit the ability to talk about certain features typically because of competitive concerns. There are a lot of things that an organization may not be able to articulate back because of contract agreements.

Cynthia Fisher noted that she represents the voice of patients and caregivers. She noted that this should be about the patient and caregiver. Isn't it about the practicality of how care is managed, she asked. Is it not HITAC's job to make transparency a verb, rather than a noun? Thinking about it from a patient perspective, when identifying the costs of the



system, the cost of lost days and time away from work or parking aren't even accounted for. The mobile world works with us today for banking, flying, and every other facet of life. Why is it that the EHR community has yet to deliver it to the patient in a consolidated, human-readable form that can also be machine-readable and analyzed? She noted it is our job to make it happen. At the 30,000-foot level, \$36 billion has been applied to the hospital systems and provider networks to have the EHRs in place today, yet it took her 45 minutes to get her Partners portal password at which point, she gave up. Many members of the HITAC have children and aging parents; it would be nice to have all their information in one place as appointments and care are managed. It is all doable. Why not leverage business models that exist today? It is done in every other facet of our lives, she stated. This can happen soon - open the APIs, and let it be free to the patient, she suggested. The patient has paid for it through insurance, through taxes, and through care. Why not use the condition of participation? CMS and HHS basically make participation in interoperability and transparency of pricing throughout the healthcare system, deliver that to the patient as a condition to participate in any federal benefits plan. Finally, in order to get paid, as a condition of payment, the patient must receive their information in the repository of their choice using the levers that are in place, the tools available, and HHS leaders to make it happen. If it were a condition of payment, everyone would be interoperable. Ultimately, the patient should be able to rate price, performance and quality, just as they do in other apps (e.g., Amazon, Uber). The patient and consumer can then make informed choices. Net prices should be posted. HHS and the HITAC can make it happen. Citizens and taxpayers are begging for the game of healthcare to change.

Christina Caraballo noted that when looking at the evaluation of the technology, it is very helpful to consider what's being used in the market. The vendor community is supporting API, and Fast Healthcare Interoperability Resources (FHIR), but that doesn't mean the market is using it. There is a need to understand what is in use versus what is available. To understand the technology providers are using, noting what is available and what they have turned on. This will help address interoperability and patient access at the same time.

Tina Esposito noted that this will also reveal to some extent what EMRs don't do, and what they should not do. Sometimes the EMR is not in the position to do what is wanted, and that should not be lost. It should be as explicit as possible. To some extent, it is just as important to understand what the systems should not be doing or what they are not in the position to do.

Arien Malec noted that his first comments were about setting up the policy choices, the second round of comments are going to be more prescriptive. The committee in its comments seems not to be aware that there are existing rating systems for EHRs. They are pretty discriminatory; they provide clear distinctions between the top or top three categories and bottom categories. There should be a compelling reason for this if it is believed that the private market rating system that exists is insufficient and there is a need to set-up a public competitor to that private rating system. It should be clear that a



materially better rating system is being provided and will be used preferentially to achieve policy outcomes. The costs of setting up a private or public/private competitive rating system should not be underestimated. There is a lot that goes into a rating agency around fairness, transparency and addressing organizations that attempt to game the system. If it is not possible to do a significantly better job than the existing agency, then work should be done with the current existing agency to address what is perceived or believed as the deficiencies of the organization. In reality, you're putting an agency out of business and setting up a public competitor. If that is done, it needs to be very deliberate and needs to be clear that a better approach is being taken than what currently exists.

Robert Wah noted that one of the dilemmas as chair is to have a robust discussion without being limiting. There are a few people who have spoken already. He asked for individuals on the phone to speak up with comments, as it is hard to recognize them.

Raj Ratwani noted that private sector groups are measuring or attempting to measure usability now. Having attempted this in lots of ways, it is incredibly difficult to do at scale. There are different ways being attempted to do it, but they aren't actually measuring true usability which is what the market wants. At the very least that data needs to be available so the private sector can get access to it. That is the huge burden. Some of that ties back to language in the contracts signed with vendors, or access to source data, or access to log data.

Andrew Truscott questioned whether ONC reviewed what currently exists, identifying the pros and cons before releasing the RFI. Identifying whether there is something that needs to be taken on. If there is insight into something that might be more appropriate to take on as a baseline, perhaps it should be accelerated and moved forward more quickly.

Arien Malec noted that the rating system that currently exists, KLAS, does a reasonable job of discriminating one EHR versus another in terms of provider-driven characteristics. There is good information on usability and okay information on interoperability. If there was a magically better rating system, we may magically have interoperability, that isn't the way that organizations end up buying a product. He noted that he does not believe that it is possible to set up a public rating agency or public-private rating agency that will do a significantly better job than the one that currently exists. A better policy approach to work with the agency is to find the market failure points that are high-priority. Good suggestions were discussed today (e.g., considering patient input on the ability of portals to be more standardized in terms of how to assess usability of EHR products, do a better job of measuring interoperability). These are all considerations to take to an organization that currently exists, suggesting that if they do a better job of measuring certain attributes, there might be a material benefit to participating if these attributes are improved. This is his preferred policy stance; noting concerns of taxpayer burden to set-up an independent competing system. He noted that he wants to be as deliberate as possible as a committee providing advice to ONC to consider the concerns with setting up a competing system



versus going where the market is and address the incremental market failures (e.g., patient usability, access to information, interoperability, and better structured information on usability).

Clem McDonald noted the ratings are difficult; rating agencies don't want to be too strict or tough, as their customers are also the companies they are rating, to some degree. Whether there are items to narrow down and measure and invest in developing some proven measures, usability comes down to time, the time to learn it, the time to do things. He suggested a sample of people set-up for a specific test for three or four things which could be different and hard, but perhaps investing in something like that would be a fair measure of the actual time it takes to do stuff under reasonable circumstances across systems. He also expressed support for Cynthia on her mission, the mechanism is easy to assert, but the idea of getting data pushed to the patient is a very good one.

Robert Wah: Noted that per the agenda, the meeting was at the published time for public comment. To stay on track with the schedule, he deferred to Lauren to open the meeting for public comment.

Lauren Richie opened up the lines and the opportunity in the room to provide public comment.

Public Comment

Tommy Flushing, Director of Government Affairs, LAPIS Corporation of America: So much has been written about interoperability but point-of-care has received less attention. What are the goals moving forward to outline or mandate capturing information at the point of care? Based on the approach of the statements made by certain individuals, that maybe had to get redundant testing, or images were lost. Again, the takeaway, the reality is, outside EHR, there are more benefits to capture information. Why are we not mandating capturing at the point of care?

Robert Wah noted that the committee will collect the comments, but will not have a direct response to the question.

There were no further comments in the room or on the phone.

Recap of ONC Interoperability Forum – Interoperability Efforts and Barriers– *Steve Posnack, Executive Director, Office of Technology (ONC)*

Robert Wah noted his appreciation for staying in-line with the published time for public comment, as it is important to respect the fact a promise was made to the public even



though it breaks the rhythm of the meeting. Steve will recap the Interoperability Forum discussion.

Steve Posnack noted his thanks for the opportunity to present and that he would do his best to compress his comments as his time to present what shortened by previous comments. Today's presentation is to provide a sense of the topics covered, issues, highlights, and challenges that emerged from the Interoperability Forum held in Washington, DC on August 6 - 8, 2018. There will be ample time for input later this afternoon. He noted that this was the second Interoperability Forum and there was a lot of engagement. He thanked everyone who helped set it up. He specifically mentioned his lead staff, Caroline Coy and Vaishali Patel who worked with the team of experts behind the scenes.

The two goals of the forum were to learn about recent advances and to identify concrete actions in response to interoperability. Various speakers covered a variety of topics, including improving patient access, addressing public health, and reducing provider burden. Many of the demos had a dimension in which the patient was involved in their care.

There were various keynotes and other speaking opportunities, as well as a demo from the **CMS Blue Button 2.0** team that highlighted some of its new technology and interactivity. **The National Partnership for Women and Families** released a new video on how caregivers and women and families play important roles in providing care and access to health information.

There were 400 in-person attendees and over 600 on the web. There was also an international audience. There were 21 breakout sessions, numerous presenters, panelists, and the hashtag #InteropForum was trending. There were seven tracks across the broad spectrum of different interoperability topics that included:

- Patient Matching
- Interoperability Measurement
- Security
- Content Interoperability
- Clinician Experience with Interoperability
- Interoperability Infrastructure
- Using Standards to Advance Research

Patient Matching

Leaders from the private sector and staff facilitated discussion. Key points raised were:



- Inaccurate matching is not just a technology problem; there are a lot of human dimensions that can impact patient matching. Accurate dimensions in terms of workflow and data capture and data quality can affect patient matching.
- An important take away was about having a better understanding of matching definitions, metrics, being able to promote transparency about matching related aspects and patient records, numbers and a better understanding of how to deal with pediatric populations. Matching techniques currently being deployed in the field were reviewed. There also was discussion about referential matching and other types of consumer interactions.

Interoperability Measurement

- From an interoperability perspective, the goal was to identify current state, gaps, and look at actions taken. In summary, there is a limited amount of data that can be accessible to people who do this work. There also is a limited amount of understanding of where across the whole spectrum, from the action that has started to the outcome we would like to be able to measure, and all those intermediate steps in-between. We are working to understand how to best get at data that may be relevant to interoperability measurement. To gain an understanding of how to look at other ways to get access to data and how to look at testing novel approaches that will help facilitate understanding related to interoperability measurement activities.

Security

- From a security perspective, identity, and trust were discussed, as well as the ability for patients to have a role in managing and maintaining access and control of their information. Looking to an API oriented ecosystem with more patient-directed and mediated exchange. Digital identity was discussed, as well as areas for multiple stakeholders to collaborate.

Content Interoperability

- This session focused on core interoperability; its maturity, and its representation into predominant standards: consolidated CDA and FHIR. There was also an opportunity through that track to look at current validation test tools and explore opportunities for continuous improvement.
- A baseline for certification was reviewed. Certification is often done before deploying to the customer. Once certified, tweaks are often made to the system. Understanding how issues are being handled, at the developer level, was encouraging. Issues that are brought up are not just isolated to one particular provider, instead solving issues across the developer's deployed portfolio.
- Expectations are increasing, exchange is taking place and data transmissions deployed, but the next level of functionality and the next level of performance that requires more standardization and constraint is needed. Interesting points made earlier today align with this track; the opinion of the participants in this track was not to expand too quickly or do too much more than what is available right now.



There was a preference to finish what has been started and get a handle on what is currently deployed. There are questions of whether to go narrow and deep or wide and shallow. There were discussions about what the best approach is and identifying whether more data is needed and how it is going to be collected.

- There was an interesting track on clinician experience with interoperability that covered long-term and short-term duties. There was a demo on a project that has been going on for about five years called 360X which is an amalgamation of different standards including Direct and HL7v2 messages about how to handle closing the referral loop and automating the processes between referring and receiving providers.
 - Numerous health IT developers and clinical teams presented on the third day and during the track. Clinical decision support, CDS hooks, FHIR, and behavioral health-oriented data were discussed. A key action coming out of this session was the need to look at ways to improve processes to ensure better data quality and that the data is going to the right places so that it can be reused.

Interoperability Infrastructure

- Interoperability infrastructure was well attended. There was a lot of discussion about the nationwide health information exchange infrastructure, the current trajectory, and where various networks are going. Carequality, ehealth Exchange, Commonwell, Strategic Health Information Exchange Collaborative (SHIEC), and the Sequoia project presented an update on what their infrastructure is doing and various efforts to ensure connectivity among the networks. There also was discussion about the cost of business models and modes of exchange, including consumer access as part of the exchange infrastructure. There also was a discussion of business models. As apps are connecting via various points in the network, there is greater assurance around the practices that are used by consumers. Who will play the relevant role in determining trustworthiness? Last but not least, another refrain about focusing on and using existing standards, making sure they are deployed in an efficient and effective manner, and an acknowledgment that when looking to having other data, there are some things to think about. When someone ships the data from one point to another, the ability to store that data is not always available with current functionality built into systems.

Using Standards to Advance Research

- There was a refrain associated with research needing a cohesive set of standards, but also recognizing that clinical care requires a certain level of data accuracy and research needs data granularity. When it comes to standards available, research does not necessarily need new standards; they want to be able to use and participate in the current clinical ecosystem where standards are already. There



seems to be a convergence between clinical users and those focused on research. The research community is interested in collaborating.

Steve thanked everyone again for their participation and noted the ONC annual meeting, which is a broader scope of topics including the policy, and interoperability aspects is scheduled for November 29-30, 2018. More information will be available soon.

Robert Wah: Asked the members to return by 12:55 PM, noting a little bit shorter than planned lunch.

Discussion of Interoperability Efforts and Barriers-

Carolyn Petersen, co-chair

Robert Wah, co-chair

Steve Posnack, Executive Director, Office of Technology (ONC)

Carolyn Petersen thanked everyone for returning after lunch. She recapped the agenda, noting a series of briefings and reports, and then concluding with a recap of the interoperability forum. She noted that this time would be used to continue the interoperability discussion and then identify topics of future work for HITAC. She kicked off the discussion beginning with interoperability and barriers, and turned the discussion over to Robert Wah.

Robert Wah noted that the chairs wanted to leave some time as a committee to discuss an important issue, using Steve's presentation on the Interoperability Forum as a lead-in. He noted that there is not a specific format in mind, it is just an opportunity to have a full and rich discussion on barriers to interoperability, identifying issues that need to be brought forward. With that as an introduction, he welcomed comments. The time will be used to discuss the barriers to interoperability and where the committee wants to go with their work going forward. If one ends up being shorter than the other, the committee can move into the second discussion. The goal is to make sure there is plenty of time for the members to share input.

Carolyn Petersen noted one topic that came up in the morning discussion was about interoperability and the notion that there are a variety of missions put forth by different organizations and stakeholders. She suggested starting with a review of the interoperability definition in Cures and then launch from that point into the discussion.

Discussion

Clem McDonald commented that he didn't think it was worthwhile to spend the whole day talking about a definition, noting that there are other things to discuss.



Carolyn Petersen noted that consideration of the definition and how it is expressed and operationalized among different sectors has relevance to the work going forward. She noted it will benefit the committee to at least have a recap of the definition from ONC, as it is something that has an impact on the report and future fiscal years.

Elise Sweeney Anthony read the definition that is laid out in section 4003 of Cures. The term 'interoperability', with respect to health information technology, means such health information technology that:

- a) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;
- b) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and
- c) does not constitute information blocking as defined in section 3022(a).

Carolyn Petersen suggested starting with taking five minutes to discuss any concerns or issues people have around the way people interpret interoperability. Asking the members what other pieces should be thought about as they try to formulate a streamlined, effective strategy for dealing with interoperability in the future.

Cynthia Fisher commented that when looking at usability and the stakeholders, she questioned whether it was the committee's role to deliver best practices, at the lowest possible price, and at the most interchangeable fees for improving healthcare, and mitigating costs to the consumer, to the employer, and to the taxpayer. She noted that there is a race for big data. The providers, insurers, the clearinghouses, and EHR vendors are all in a race to control and silo the data. She noted that as an outsider, it is very discouraging to know that federal tax dollars of \$36 billion were used through the providers to get EHRs in place, and now providers of information are looking to have ownership interest and are charging significant fees to get access to the data. In this scenario, there is no longer a free system, and price increases are being encouraged. She questioned what can be done at ONC to stop this. She encouraged using the levers in place (e.g., conditions of payment and participation) to allow for interoperability and to know that doctors don't leave their jobs because they are frustrated they cannot do their job and can't get access to information to see the whole patient. She encouraged the group to look at the whole system and look at mitigating costs to the taxpayer across the system. Revisiting what was talked about earlier around the RFI, in the end, what does that matter? Why spend taxpayer dollars when Consumer Reports can rate it? Once the job of interoperability is accomplished, ratings won't be needed any longer because at some point all caregiver records (e.g., parent, children) will be available on mobile devices, just as other transactions are currently on mobile devices.



Arien Malec noted that there is actually language in Cures that addresses the notion of permitted purposes and one of the issues that needs to be ironed out in interoperability is that it is such a squishy unknown thing; in people's minds it works all the time, in every context. Yet when looking at aspects of clinical medicine, clinicians just don't agree on certain things (e.g., physicians can't even agree on what a problem is). Permitted purposes needs to be narrowed, and it needs to be recognized that in the real world not everything can be accomplished. The definition of interoperability is secondary to the actual clinical workflows that permitted purposes are embedded in. For example, what is required in a transition of care may not be required in an emergency department context of use, both under a broad treatment purpose and both may be different than what may be required for public health or research. This is a plea to design the high-priority purposes of use, follow clinical and research practice backward to the data that needs to flow and the kinds of data that needs to flow and then get interoperability working backward from that. In terms of measurement he noted that in general, the best measurement is one that is outcome driven, rather than process driven. Multiple groups have noted outcome driven measurements are much harder to do and more process intensive, whereas, a process-based metric is much easier and cheaper and may get about 75 percent of the way there. Measuring the outcome is much harder than a process measure. He summarized that focusing on permitted purposes, making sure the definition is secondary to what is clinically important in that use case or in that purpose of use, and to the extent possible, measure interoperability by the outcome achieved. He also noted that cheap and easy process-based measures are good too.

Steven Lane noted that his practice is highly interoperable, he has benefited from making connections with other organizations in the region, lots of tools, standards-based, and a very cooperative vendor. At the committee meeting he hears all the barriers, but 90 percent of his patients are online. It is important moving forward to learn from those who have been most successful and figure out how to bring those lessons forward to others to close the gap. The big challenge seems to be with the cross-vendor exchange; there are real challenges that standards and the work of the HITAC can help to mitigate. When talking about a definition of interoperability, there are many stages like making connections, laying the pipes, and pushing the payload. When it comes down to usability of the data (e.g., point of care, population health, research), you have to get down to the granular level and figure out where the value is to make the data most useful. There are big challenges, but getting down to solutions leading practices need to be promulgated, work done on cross-vendor or cross-network exchange, and getting down to the granular molecular usability of the data being exchanged.

John Kansky responded to the concerns in the way that people are thinking about interoperability; he encouraged a sensitivity to balance for two channels of interoperability. He noted that there may be people around the table that two channels make sense to and others that might think it sounds weird. There seems to be a focus by CMS and ONC to want to establish the patient as a channel for interoperability, something



that needs to be done. This means making the patient an active vehicle to move their data among the healthcare system to get things done. Meanwhile, for the last 30 years, the industry has been trying to build the provider-to-provider, payer-to-provider through HIE, Commonwell, Carequality, DirectTrust, etc. The industry is trying to figure out what works through the healthcare system channel. He noted that he is appealing to not forget about that channel and certainly not making it harder for that channel to be successful. Whatever is done, (TEFCA, HITAC) both channels need to be promoted and advanced.

Clem McDonald noted that everyone makes it too complicated too often. He agreed with the emphasis of the two channels. Stimulating the sources of the data to deliver in a standard format with enough coding and structure that it can be filed anywhere it goes, it will solve everybody's problem. He suggested requiring that all electrocardiograms (EKGs), x-rays, and all lab tests are presented in a certain way and sent to the patient as a push. In Indiana, 30 hospitals were connected. They had to put it in a standard format, it took a day and a half at each system, but it happened. He emphasized the need to think simply. Just get it to the patient as the driving force and then there will be a way to get it to other parts of the system that need it.

Leslie Lenert, noted his concern of unintended consequences, the industry is introducing more and more information that could be partially corrupted as it moves around. He suggested focusing on a standard for de-duplication of data, as there is no standardized approach currently available. It could be one of the biggest problems faced, as an example, there could be 20 CCDs from 10 organizations, and they may only have 20 percent overlap, and it will be unknown what data is accurate. An approach is needed to manage information as it is moved and shared to support de-duplication.

Andrew Truscott noted there is a difference between accuracy and precision. There is accuracy, but not precision. He noted that he hears that Meaningful Use (MU) has gone away and customers seem to be moving away from those requirements as those items are no longer required. The requirements didn't go away; there is just no longer a stick anymore. Organizations are noting that TEFCA doesn't apply and it isn't something they need to do. Clarity is needed around who and what is covered and how to demonstrate how compliance will be useful. This committee is on the hook to make recommendations to ONC on what the requirements should be, though he noted he could be interpreting incorrectly. Just because MU dropped, it does not mean that nothing needs to be done. There are incentives and punitive measures. There are a large group of standards organizations; he recommended asking them to inform policy moving forward. The absence of saying anything is a barrier at the moment.

Ken Kawamoto noted that he heard a lot of very similar thoughts. He emphasized sharing data, but he agreed that duplication is a problem and could become a total mess. He suggested as a low bar to identify ten pieces of information that look the same or different. For true interoperability, he suggested getting more target based, starting with use cases.



He agreed with earlier comments that healthcare is very expensive and there is poor value for the current costs.

Sheryl Turney noted that she was adding to Leslie's comments. As a payer, some of the challenges are a little different. She highlighted that payers not only have to abide by state and national rules but also association rules; therefore, interoperability becomes very complicated. One of the venues that has been collecting data for the past few years are the state all-payer claims databases (APCD). As an example, Massachusetts is challenging Patient-Centered Outcome Research Institute (PCORI) regarding the reuse of data without getting permission. There are some uses of the data that are not prescribed based on the particular state laws. Interoperability is complicated when considering secondary uses. There isn't any player in the market that doesn't want to monetize that data in some way; this is a challenge that needs to be dealt with. She emphasized ONC's tool on secondary uses as it is very helpful and includes education. There are many stakeholders who want to use data for secondary purposes that potentially were not intended.

Steven Lane noted that it seems to be low hanging fruit to bake in requirements so that patients can subscribe to their data and receive an update from any data source automatically. To Les' point, there will be a huge challenge because once connections are established, and data is flowing, the amount of data is overwhelming. De-duplication is just one piece of the larger challenge of data curation which includes prioritizing, sorting, and identifying gaps - there are a lot of pieces there. Whether discussing handing all the data to the patient or on their iPhone or members of the care team, there is the same challenge. He stressed that he hopes the work of the committee could help support the notion of the app ecosystem. The idea that there are smart developers out there, who once they have the data, will be able to utilize artificial intelligence and machine learning to start to do some of that work of reconciliation. Speaking as a clinician that has tried to do the work manually, it could take forever. Technology needs to be leveraged to derive meaning from the data.

Clem McDonald noted that he has not been talking about secondary use or sending insurance data. CCDs adds complexity, that being the primary delivery mechanism. There are real challenges passing data from A to B and B to C. If the originator sent to the patient and then possibly to other users like the physician of record, the complexity is lost.

Arien Malec noted that business model issues in regards to primary drivers of interoperability hadn't been talked about. He noted that while it might be surprising, he does not see any technical barriers to interoperability. He noted this based on his experience working in the industry (e.g., building systems, Direct, Commonwell). He emphasized that given that there aren't that many technical barriers the remaining barriers have to be economic, and the business model issues need to be discussed. He once recommended jokingly to Farzad Mostashari, former National Coordinator, that primary care should be destroyed. Looking at the way interoperability is done, it is much easier to get two large systems to talk to each other; the current interoperability ecosystem is driven



around the needs of large systems. There is a need to identify the economics that work for small and independent practices. It isn't clear that physicians are willing to go through some of the painful practices that are required for interoperability. The forcing function for driving interoperability works too slowly and inefficiently to get the incremental improvement needed; this is a business model issue. It is an issue that the U.S. healthcare system is too big, too safety critical, and too distributed in its economics (large systems, independent practices, chain, and independent pharmacies) to get all the things done, all at once. He recommends going deliberately slow through systems to get it done. Without addressing the business model drivers, there will be a model that works for large institution, but leaves out the small and independent practices.

Cynthia Fisher asked the group to imagine looking at the broken interoperability and healthcare system as a restaurant. Asking the group to imagine a menu with transparent prices, where the service and information is provided and pushed to the patient in real-time. Healthcare EHRs were built on top of payment systems. The business model is important to have a competitive market as a consumer and taxpayer. She also provided a personal story to emphasize the importance of empowering care givers, enabling interoperability. She encouraged the committee to do the right thing and make it happen. She noted that Arien confirmed the technology is available and Clem is impatient about it. She joined Clem's impatience and begged the committee to do the right thing.

Sheryl Turney asked to differentiate price transparency with interoperability. Interoperability is the sharing of the data, but the cost and price transparency discussion should be separated because it gets complicated. She recommended that a better analogy for the healthcare system would be like going to a lawyer, not a restaurant. Lawyers are paid on an hourly rate, and it is unknown how long it will take to be resolved and there are unforeseen circumstances. Don't want physicians to be making decisions about healthcare based upon price. Healthcare services are something separate and should be put to the side.

Christina Caraballo noted her agreement with looking at the business case. She noted she was initially excited about TEFCA, but as she spoke with others in the industry, she started to hear about state law, privacy & security, and patient matching concerns and noted the need to look at these concerns and work on addressing them. As a committee, it would be helpful to help identify funding that might be available to support ONC to get out and talk to the players in the market. Looking at the qualified health information networks (QHIN) identified in TEFCA, these networks can provide an access point for patients that allows a marketplace for applications where data can be accessed in one space. If the infrastructure is there, then providers can subscribe to applications for patients to interact with.

Sasha TerMaat noted that the most important thing for the committee is to measure what they are going to do, but no clear measurement has been identified. It is unclear where the committee is looking to go within a year or five years to assess progress. It is unclear if the



committee will be able to achieve the end goals that committee members have in mind. It could be disappointing for members if centralized measures aren't identified.

Carolyn Petersen asked members who hadn't provided feedback to provide what he or she perceives as the primary challenge and the primary opportunity related to interoperability. Once everyone is heard from there will be a shift to start proposing what the HITAC should focus on or areas of work.

Michael Adcock noted that his focus is on telehealth. There are 243 sites in his home state of Mississippi, and only six of them are interoperable with the medical center. He noted that his biggest challenge is being able to get information between providers and pushed to patients. There are a lot of opportunities in Mississippi, as many providers in the state can't afford to purchase an EHR, but there is a need to better communicate with providers and patients.

Tina Esposito noted the challenge of pulling together the picture of the patient, noting issues that exist are the quality of the information and patient matching – a unique identifier is needed. It is important for the HITAC to keep different points of view in mind, for example, the outcome for the consumer is different than for a health system.

Valerie Grey shared that she is listening and learning in these meetings because she is new to this space. She noted that she agreed with everyone on the points that had already been discussed and it is difficult to identify the top challenge. She noted that HIEs have been trying to solve the interoperability problem for some time. She expressed that in the future it would be valuable to talk about patient consent and there is a need to reconcile state differences at the national level. She also noted that data quality and completeness is important, as well as the need to standardize information. TEFCA is important, but in New York, there are vendors who seem to be on hold connecting to state HIEs because they are waiting for the national solution. There seems to be a lot of state-level work that is moving slowly because of TEFCA. She also noted that she would appreciate more discussion about social determinants of health, understanding the need to focus on clinical information, but that other information is quite important.

Anil Jain noted that the business cases are misaligned. There also is inconsistent use of standards, even if standards exist, there are barriers to access the data. He noted the need to identify a focus and move quickly, but to do so without boiling the ocean. He also noted that he would like to focus on APIs solving problems and the use of free, unfettered data.

Denni McColm noted that her biggest challenge is getting the information needed from the state HIE and the biggest opportunity is to move to a consent to access approach, noting that confirming consent would be a good future discussion topic.



Aaron Miri provided a few stories to help describe the problems he has experienced in the field. In summary, he identified three areas of focus; standards, encouraging organizations to share information, and security.

Brett Oliver shared that he does a lot of learning, listening and compiling thoughts during meetings. He noted usability and the value of the data that gets pushed forward as priorities. Sharing data helps the patient, but usable information is needed. He provided a different perspective than some of the others on the committee, as many in his system are still faxing. He emphasized the importance of the basics, focusing on both technology and cultural changes.

Terry O'Malley noted his interest in interoperability is about how it makes his work better and safer for patients. There are a lot of shiny objects, but echoing Clem, this needs to be simplified. The basics (i.e., unique patient identifier, permitted use and authorization, and high-value use cases) need to be the focus. Focusing on results, as the ISPTF co-chairs suggested, is a high-value use case. Standardizing results and how to push them and share them will go a long way in improving care. They need to build the policy and business case in parallel with the standards needed. Interoperability is a local issue; it is a care ecosystem issue before a national issue. Suggest letting local care providers identify what their care priorities are.

Carolyn Petersen noted a challenge around the heterogeneity of patients. There are distinct groups that manage their disease without technology. There is a need to find ways to help these patients even when not looking to use data. On the opportunity side, interest in using data to help individuals with atypical situations (e.g., rare diseases, people who are isolated in some way, people with lack of bandwidth). There is a need to help people manage their care day-to-day.

Raj Ratwani noted a concern related to the usefulness of the data and relation of usefulness and the financial barriers. Looking for innovative solutions, but the costs associated with APIs are shocking. In agreement with Sasha, he also would like to have a better understanding of measuring and how the committee will see advancement.

Robert Wah noted it is worth being more explicit about the business barriers to interoperability. Patients are a revenue source for providers of care, so sharing of patient information seen as a potential leakage of revenue. There is a need to address that discomfort. He compared the vendor space to the cell phone industry which used to be siloed as part of the business model. It was hard to call from one network to another. He submitted that when full interoperability came and it was seamless to call across networks, all boats floated higher, much higher. Identifying the silo issue is the first step. Regarding solutions, there is a need for interoperability at the data level, going beyond that there needs to be a layer of insight where data can be analyzed. The last layer is the layer of engagement where getting the right information to the right person at the right time is



critical, including payers, providers, and researchers. Need insights delivered in a way that people can use. On a related issue, outside of the U.S., there is the General Data Protection Regulation (GDPR), and the need to be mindful about where the general public, regulators and the industry are at currently around the issue of access to data.

Denise Webb noted that she echoed a lot of the previous comments made from others at provider systems and she also noted she is in a rural part of Wisconsin where there is pressure to manage the cost of care. In her area, it is challenging when it comes to exchanging health information across different products. She emphasized the need to solve the issue of getting patient data to new providers of care; this is a priority for the patient, as the provider may need it to provide care. She noted that exchange across vendor products is difficult, but this is not a technical issue, but more of a political and competitive forces issue. There has been a lot done around providing broadband, but it is still expensive. Some patients travel over two hours for care, and it would be helpful to care for those patients using telemedicine. There is an opportunity in work done with USCDI and providing patients' access to data in the apps of their choice. If all else fails, it is important that patients have their data with them.

Carolyn Petersen announced that the committee would be taking a short 15-minute break.

Carolyn Petersen, reconvened the meeting after the break and introduced Steve Posnack to make a few comments.

Steven Posnack provided comments noting his appreciation for the interoperability barrier discussion, noting how valuable it is for members to share their experience with each other and ONC. As was discussed earlier, there is a need to identify impactful measurement points to monitor progress. There were many things identified as important throughout the day, but there is a need to identify priority. He noted that the committee needs to be mindful of the time it takes to make impactful changes, setting clear goals and outcomes for the industry. He also noted that at times there could be educational challenges spreading policy changes across the country and the committee can be a powerful way to help share that information. He noted that there are a lot of dimensions involved in interoperability and the members have valuable contributions to provide based on their experiences.

Clem McDonald commented that there needs to be a focus on getting the data out. Today, data isn't free and fungible. There is a need to focus on getting the data out; the market will create what is needed to use it in other ways.

Sheryl Turney questioned what levers or recommendations could be made to push the business model problem around interoperability. There is a need to address the workflow



and business model issues, and she suggested that perhaps that should be a priority for 2019.

Discussion of Health IT Advisory Committee Future Topics –

Carolyn Petersen, co-chair

Robert Wah, co-chair

Steve Posnack helped transition the conversation to hearing from the committee regarding their ideas for future discussion topics, noting that ONC is listening and wanted to provide an opportunity for free-flowing discussion. ONC is using this information to inform future work, and a means to identify possible solutions to challenges that are identified. ONC's programmatic leadership team is in attendance, listening, and wants to be able to convey concerns to others within ONC and at sister agencies. ONC will use these comments and share with colleagues ensuring that everyone is aware of what is happening in the field to help everyone do better.

Carolyn Petersen transitioned the conversation to Robert Wah regarding the future direction discussion for the committee.

Robert Wah noted that Cures dictated a list of items that the committee needs to focus on, but members also need the opportunity to discuss their additional ideas and issues. He emphasized that today's discussion does not necessarily mean that these are items that the committee will take on going forward.

Steven Lane questioned what the committee could actually do, noting that there are many things that he would like to see happen, but he would like the committee to invest wisely. He expressed concern for ONC being able to implement overly optimistic ideas of the committee.

Robert Wah noted that there needs to be a balance between optimism and realism, but for the moment he would like to have the conversation and see how the conversation evolves.

Arien Malec noted that if the group tries to go everywhere all at once they will go nowhere. If there are specific deliverables and the work is limited at one particular time, a lot of progress can be made in ten years. He pushed the committee to finish what was started and take on one, maybe two new things and steadily and maybe even more slowly than some would like, move the ball down the field.

John Kansky commented that TEFCA would be the new way that is designed for the country to interoperate. He noted there would be challenges and this group should be focused on attacking the obstacles.



Andrew Truscott noted that the committee was charged with privacy and security and there is opportunity to assist in privacy enhancing technologies as noted in Cures. This ties into the third charge of enabling proxies to gain access to information about a third party. Protecting privacy laws and protecting access where appropriate, this is an appropriate area to investigate further.

Leslie Lenert suggested focusing on population health, regional health, and public health opportunities raised by interoperability and the creation of both push/pull networks under consideration by TEFCA. Noting that there is no strategy for dealing with this in this country. There are opportunities to create regional systems to cross healthcare organizations and can help take the risk out of healthcare. He emphasized that there is a lot that can be done with population health efforts, but there are no guidelines or boundaries that have been discussed. He suggested starting with the national needs and then moving beyond traditional public health issues where there are opportunities that are raised by TEFCA and other approaches.

Raj Ratwani mentioned the pediatric certification program as a place he would like to see a group formed to support the effort.

Sheryl Turney suggested that with TEFCA representing the pathway forward, there should be a way for stakeholders to participate in a pilot and work out the business model issues and address how current HIEs can bridge the process to a future model. That will be a quantifiable, focused project that will provide a great deal of value.

Clem McDonald mentioned that he was not sure if the USCDI was completed and if not, it should be completed. When the patient checks-in there should be a field to determine where the patient identifies they want their information to go. There needs to be something to identify a place for patients to receive and organize information. The political push for getting this done is the patient, getting information to the patient will help spread the information.

Terry O'Malley commented that he would like to think about how to intertwine the policy and payment levers for the committee's work. He wondered if there was a group that collaborated between ONC and CMS that works together to help drive interoperability.

Elise Sweeney Anthony noted that the information they are hearing from the members is helpful, she then responded to some of the committee member comments noting areas where ONC is currently working.

- Regarding Sheryl Turney's comment on business drivers, this is something that ONC is thinking about in regards to the conditions of certification. Also, thinking about information blocking, identifying things that are impeding. There will be an opportunity for the committee to inform some of that work.



- She noted that Raj Ratwani mentioned pediatric settings. ONC is thinking about this, and this is something that ONC is planning to address in the rule which the committee will be informing.
- Regarding Sheryl Turney's other comment on the TEFCA pilot program, ONC is thinking about what pilots could support implementation, as this is a requirement within Cures.
- Following up on Terry O'Malley's question, ONC and CMS collaborate often and there are formal mechanisms that ONC leads around health IT within HHS. There is a lot of time spent coordinating with CMS.

Steve Posnack added that CMS has many more statues that they are responsible for tracking.

Ken Kawamoto commented that he would like to start to think about what is achievable in the next year and over the next ten years.

Aaron Miri would like to work on a strategy for identifying patients. He would also like to encourage a mini-hackathon to figure out ways to solve problems that haven't been thought about. He also expressed a need to think about workforce development as there is currently a deficit of talent.

Jon White noted his appreciation for the variety of recommendations from practical to optimistic. He went back to the point of overestimating what can be done in a year and underestimating what can happen in ten, noting that a lot can change in ten years and it is difficult to anticipate how things will change in that amount of time.

Steven Lane mentioned that the work done on USCDI should not be lost, noting that that work needs to move along, as it is a great opportunity to do good.

Robert Wah provided an opportunity for committee members to provide their feedback, noting that it was important to have a conversation of ideas outside of what was in Cures.

Cynthia Fischer commented that the delivery of the information to the patient is a priority. The privacy issue can be addressed by the patient, as the patient will want to share it with the appropriate caregivers. She envisions a way to possibly share health IT data easily with each physician. She stressed the need to get to a point where there is openness and information is shared easily so we can have the best health system delivered to the patient community.

Robert Wah noted his appreciation for today's discussion and said that this will be an ongoing process to inform ONC regarding committee ideas and issues.



Aaron Miri asked if leaders from other agencies could share their perspective on related topics. He provided hearing from CDC in regards to Zika during a previous Health IT Policy meeting as an example.

Robert Wah noted that there is coordination with CMS' advisory committee, National Committee on Vital Health Statistics (NCVHS) and there will be future opportunities to collaborate with them.

Elise Sweeney Anthony confirmed that there will be future opportunities to hear from other agencies. There is opportunity to think of the long game, but also enabling space for the HITAC to get involved in urgent issues, such as Zika, going forward.

Ram Sriram noted the need to look into interoperability of EHRs with Medical Devices and with other sensors, as the future will be Smart and Connected Health with social networks playing a role.

Public Comment

Julia Skapik, Cognitive Medical Systems, I appreciate very much the discussion about metrics and interoperability. ONC is in an excellent position to be able to gather richer metrics about interoperability, for example what information is actually viewed and what information can be confirmed by a receiver that they actually received it. These are pieces of information that are generated at the point of the exchange and don't actually add any burden. That being said, it's exciting that there's going to be availability of the 2015 edition, more rich narrative content, health concerns, plans, and assessment sections. Is that content going to be made available to users immediately? If not, why not? Can they do some sort of tracking of systems to make sure users are getting that information exchange?

From the standpoint of users and usability, the priority of my vendor seems to be on my user feedback when it takes me over 20 minutes of clinical time to be on hold and provide them with feedback. Yesterday, I was on a used auto parts site and a person was available waiting to help me and live chat.

The other thing ONC can do to make a difference is require the availability of feedback from users on a myriad of issues that include: safety, usability, functionality, interoperability as a point of the use of the system. To report those metrics and also how they are being adjudicated by the vendor will at least give the user a sense they can reasonably, without taking an hour out of their day, provide feedback to the system and let them know that someone is listening. It also may help to add some additional information to the objectives metrics that are being generated in the private sector.



The following public comments were received in the chat feature of the webinar during the meeting:

Gary Dickinson: What is the best method to provide feedback on priorities?

CentriHealth/UHG 2: The HL7 EHR Work Group is compiling topics and recommendations for "Reducing Clinician Burden". This is a work in progress, but comments and reference sources are welcome. Here's the link:

http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG#Reducing_Clinician_Burden

Gary Dickinson - CentriHealth/UHG 2: Categories for the EHR Reporting Program should include: 1) patient safety faults; 2) interoperability deficiencies; 3) care coordination challenges; 4) work flow anomalies; 5) patient identity matching faults.

Gary Dickinson - CentriHealth/UHG 2: In our reading of the 21st Century Cures Act "interoperability" definition, the terms "complete" and "all" apply to health information technology and thus require that health information: 1) SHALL be rendered for purposes of "interoperability" (including "access, exchange and use"); and 2) SHALL be rendered as originated (captured) and as presented to the originating author, verifier and/or attester; and 3) SHALL have the capability to be rendered as whole ("all" and "complete"): without alteration, reduction, omission, derivation or transformation; and 4) SHALL thus be equivalent to the content of traditional health records captured manually (e.g., on paper) then reproduced or propagated via photocopier or fax machine as an identical rendition of the original.

Closing Comments

Robert Wah noted his appreciation for everyone coming to the meeting prepared. He hoped the conversation was productive for everyone and welcomed feedback for improvement by whatever means members feel most comfortable. He noted that the group has come together well and there doesn't seem to be any reluctance to speak up during meetings. He thanked the ONC team for all of their help and all of the contributions by members on the workgroups and task forces.

Carolyn Petersen thanked the members for their willingness to engage and for traveling to the meeting. She also thanked the ONC team for their help getting everyone together to do productive work.

Lauren Richie noted the next HITAC meeting will be held on **October 17, 2018**. She also noted that members and the public can find all of the HITAC meetings on the calendar posted on healthIT.gov.

Lauren Richie adjourned the meeting at 3:51pm ET.