Health Information Technology Advisory Committee

Meeting Summary - April 18, 2018

IN-PERSON

The April 18, 2018, Health IT Advisory Committee (HITAC) was called to order at 9:30 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
Christina Caraballo, Get Real Health
Tina Esposito, Advocate Health Care
Cynthia A. Fisher, WaterRev, LLC
Brad Gescheider, PatientsLikeMe
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, RelayHealth
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
Patrick Soon-Shiong, NantHealth
Sasha TerMaat, Epic
Andrew Truscott, Accenture LLP
Sheryl Turney, Anthem BCBS
Denise Webb, Marshfield Clinic Health System

Federal Representatives
Kate Goodrich, Centers for Medicare and Medicaid Services (CMS)
Chesley Richards, Centers for Disease Control and Prevention (CDC)
Ram Sriram, National Institute of Standards and Technology (NIST)
Lauren Thompson, Department of Defense/Department of Veterans Affairs (DoD/VA)

Members not in attendance:
Michael Adcock, University of Mississippi Medical Center

ONC Staff
Elise Sweeney Anthony, Director of Policy, ONC
John Fleming, Deputy Assistant Secretary for Health Technology Reform, HHS/ONC
Genevieve Morris, Principal Deputy National Coordinator, ONC
Steve Posnack, Director, Office of Standards and Technology, ONC
Seth Pazinski, Director, Office of Planning, Evaluation and Analysis, ONC
Lauren Richie, Designated Federal Officer, ONC
Don Rucker, National Coordinator, ONC
Jon White, Deputy National Coordinator, ONC

Welcome Remarks
Donald Rucker, National Coordinator (ONC)
John Fleming, Deputy Assistant Secretary for Health Technology Reform (HHS/ONC)

Donald Rucker: Interoperability is part of a much larger national debate, and I appreciate the Task Force and ONC staff's work. ONC has received a good basis for TEFCA from the panels and now has the Draft USCDI.

Kate Goodrich: Interoperability is a top priority for the CMS Administrator and the White House. We are collaborating with ONC and the VA. CMS is considering its levers and thinking about how to promote interoperability. Patients need access to their data in a manner that is secure, timely, usable.

Rucker: CMS is effectively the lever for much of what HITAC does.

John Fleming: We need to lower the cost of healthcare, and interoperability is one way to do it. But as you do your work in this area, please keep in mind the burden on the practitioner.

Rucker: That perspective is very important because smaller practices are the source of much innovation.

REVIEW OF AGENDA, APPROVAL OF MINUTES
Carolyn Petersen: HITAC members approved Minutes from the March 21, 2018, HITAC meeting by voice vote. No members objected; none abstained.

Presentation 1: Precision Medicine Initiative, All of Us Research Program and Sync for Science

Teresa Zayas Cabán, Chief Scientist, ONC

Cabán: I lead the Office of the Chief Scientist. Our office's role is not to do research, but to direct research and development projects that leverage the Health IT (HIT) infrastructure and HIT investment that this country has already made to support biomedical and health research enterprise. Projects under the precision medicine initiative or PMI include a portfolio of patient-centered outcomes research projects. My office also leads ONC's international portfolio. The PMI was launched in 2015 with the goal of discovering a way to individuals, based on their lifestyle, preferences, and their genomes. The cornerstone of the PMI is the All of Us Research Program, led by NIH.

All of Us is a program to enroll 1 million or more people who will donate their health data for science. Participants will be responding to surveys. They will allow the collection of biospecimens and their health records will be included as part of the cohort data. The data will then be curated and made available to individuals to do research. Another goal is to share the data back with patient participants.

Sync for Science is a cutting-edge, FHIR-enabled way of sharing data. All of Us is a use case for Sync for Science. If you go to the website https://healthit.gov/topic/precision-medicine you can see a demo of the system and a testing tool for developers participating in the pilot to test an API to make sure it is meeting the project requirements.

We also have Sync for Genes, our attempt to make it easy to share standardized genomic information at the point of care, using HL7 FHIR. We finished phase 1 last summer and put a report on the HealthIT.gov website. We will complete five different pilots looking at data and use cases. We recently launched phase 2.

Rucker: I want to add one editorial comment. Some of this may sound like a lot of deep science. These APIs and transmission modes, we believe, will form the basis of modern medical care going forward.

Presentation 2: ONC Guide to Getting and Using Your Health Records

Lana Moriarty, Director, Consumer eHealth & Engagement (ONC)

Moriarty: One of ONC's newest resources, launched on HealthIT.gov on April 4, is the Guide to Getting & Using Your Health Records. This is a measure of interoperability and a cornerstone of ONC's work toward patient engagement, improving health outcomes, and advancing patient-centered care. We have seen great progress here. Here are some data points from a survey we conducted, beginning in 2017: Over half of individuals who were offered online access viewed their record within the past year. This is up from 42% in

2014. Eight in ten individuals who viewed their information rated their online medical records as both easy to understand and useful for monitoring their health. We developed this Guide with the broadest audience in mind under current HIPAA rule of access (Health Information Portability and Accountability Act). Today we are working on further post-launch consumer testing. Based on that information, we will build in another round of updates by the end of May.

HITAC members, please walk through the site and offer us feedback. You can share it with your contacts at health systems and health organizations to help spread the word about this new resource.

Moriarty then walked the HITAC through the Guide.
For more information, go to HealthIT.gov and click on the April 4, 2018, news release.

HITAC Member Discussion Presentations 1 & 2

Cynthia Fisher: You might consider creating a video and posting it on YouTube. Often that's the first internet resource people of all ages turn to for answers to questions.

Raj Ratwani: I would be a bit careful with the eight in ten individuals finding. If you look at broader research in the space, that is generally not true. Putting a good gloss on things can reduce the amount of energy and effort put into making needed improvements.

Moriarty: Those are very good points. We are trying to encourage more plain language and more user-friendly websites to help people understand their health information. I appreciate your points.

Sheryl Turney: In your 'Use It' quiz on the site, you might call out secondary uses of the data by third parties. Payers are getting more requests from patients to release data to third parties, but patients often are unaware of the uses of secondary data. If we are attempting to educate them, working with them to view that more broadly is important.

Steven Lane: Yes, it is very important that we educate consumers about the potential risks of releasing their data. So, while getting it to use for themselves is very important, as they share that data with apps, what might happen when it goes outside the control of HIPAA? Taking this opportunity to highlight those risks is important.

Fisher: I have a question about Sync for Science. Do we have any data or evidence that those individuals who would be willing to contribute their data for science are similar to those who would not? Otherwise, we could end up in a situation where we have some confounders that we are not anticipating.

Moriarty: The NIH has been tracking all of this—both the folks who have enrolled and those who did not. NIH wants to do follow up to try to understand, for those who didn't enroll, why didn't they?

Ken Kawamoto: Thank you. Around that question about security, could you comment on education needed for pulling down data for these third-party apps, specifically given the FHIR standard?

Cabán: For individuals in the All of Us research program, there is a comprehensive protocol that explains exactly what individuals are consenting to and how the data is stored. For Sync for Science specifically, individuals are walked through what they are donating and get a confirmation screen and an email back listing that information.

Moriarty: Education for consumers around apps was one of the reasons we wanted to update the model HIPAA privacy notice, which we did several months ago. When consumers engage with an app, they need to know what happens next. We are trying to educate and inform consumers to know how their data is used, shared, stored, sold.

Leslie Lenert: How is work with Sync for Science informing TEFCA? And what specific areas do you think TEFCA needs to be strengthened to support this research? Where do you think TEFCA needs to be strengthened to advance the agenda of using the healthcare system for science?

Cabán: Sync for Science will be leveraging standards work that's already being done, which includes certification requirements, anything coming out of the Cures Act regarding APIs to get better technology, so data can better be shared. Beyond that, it is not necessarily about a point-to-point exchange, but more about enabling the technology to do so. All the interoperability work that ONC will be undertaking under the Cures Act will make Sync for Science possible and help move the program forward.

Sweeney Anthony: In the Draft Trusted Exchange Framework we released in January, we did not include research as one of the permitted purposes. We did receive comments around that. We are in the process of reviewing all those comments and making updates to the TEF.

McDonald: There is a queryable observation ID. You could subset it.

Kawamoto: By permission, you can query for it. When you give the app authority, the base FHIR standards right now require allowing you to query for anything.

Fisher: This question goes to both speakers. What is the approach you are taking now with respect to the general data protection regulation (GDPR) that the EU has put forth, as we look to not only U.S. records but healthcare on a global basis?

Cabán: Specific to Sync for Science, GDPR is not something that directly applies. We have been focusing on HIPAA. I have been involved in a recent effort of international cohorts looking at how to collaborate across cohorts, how to standardize tools such as consent forms and enrollment protocols, and how to potentially begin querying across cohorts.

Moriarty: I have a similar answer. And working with OCR, we have focused on the HIPAA right to access as well. Looking at privacy and security, that is a good question and I would take that back to OCR. As we move forward we are working closely on the 21st Century Cures Act Section 4006, around patient access.

Richie: I would like to thank Teresa and Lana for their time. We will provide their email addresses if you have additional questions. Now we will move to the core of our meeting, the USCDI Task Force presentation.

Presentation 3: U.S. Core Data for Interoperability (USCDI) Task Force Draft Recommendations

Christina Caraballo, Task Force Co Chair
Terrence O'Malley, Task Force Co Chair

USCDI Task Force Draft Recommendations: Overview

Overview and Charge

Christina Caraballo: We want to point out there were a couple of items here that the Task Force did not have a clear consensus on, and members had a variety of views. We did make some editorial decisions in our recommendations to the committee as a whole. We were asked to review and provide feedback on the structure and process of the USCDI and on how to get stakeholder feedback regarding priorities. We also were asked to provide recommendations on specific promotion of data classes, how to expand the USCDI, and how and when to publish it. We added a few more recommendations to our charge, more things for ONC to think about throughout this process.

Definitions

This is an area where the Task Force did not reach consensus on the detail. The point of these definitions was to establish a common vocabulary and describe the relationship depicted in the diagram on objects and attributes. A data class is a high-level group of data on a common subject. An example is demographics. Within the data class, there are objects related to the subject. In this case, an address. And finally, an attribute. Examples here are street number and ZIP Code.

USCDI Task Force Draft Recommendation 1: Six Stage Maturation Process

Terrence O'Malley: Interoperability has been extremely difficult to achieve. To frame our Maturation Process, we created a list of reasons why, and this hierarchy provided a platform for the process. The Draft USCDI had three Stages. We kept three of them and added two more. We asked why we needed each Stage and how should the USCDI be expanded? It should be expanded if the data classes make it through the process.

Stage 1: Proposed

O'Malley: We have three Stages from the earlier Draft USCDI. Emerging, Candidate, and USCDI. In Step 1, there are no barriers to electing a data class. Any stakeholder, individual practitioner, home or community-based services, public health, whoever could propose a set of data objects or data classes for consideration. In this Stage, submissions are sorted, data objects aggregated, and net value to stakeholders is estimated. You get out of Stage 1 when you have created a sufficiently large amount of value.

Stage 2: In Preparation

Preparing a data class is the job of Stage 2. At the end of Stage 1, we have a valuable commodity. Now we need to make it a data class with appropriate semantic standards that apply to the data elements, and if they don't exist, development them. Development can take a long time—years in fact. Meanwhile, to harmonize the data objects with CMS and other providers, a shared common vocabulary should be found.

Structured or Unstructured Data

O'Malley: A data class may emerge out of Stage 2 in two forms: structured or unstructured. It may emerge in a highly specified machine-readable, computable form—structured. Unstructured data could be wrapped in enough standards to know who the individual is, what the data is in this particular data class, and who it is going to. It must have a minimum set of standards to direct the traffic and identify what is there. But the payload could be unstructured. It could be an image or text or radiology report, for example. The data class must have standards, so it can be passed on to Stage 3.

Stage 3: Emerging

The point of this Stage is to have something that can be tested. We'd want to clarify the cost and resources required for pilot testing, whether a Data Class Work Group (DCWG) can perform the work assigned to it in this stage and whether the criteria for moving to Step 4 are too great a barrier to advancement. To get out of Stage 3, a data class must have sufficient technical specificity to be tested in production settings.

Stage 4: Candidate

Candidate is an important Stage. The data class undergoes testing at scale in a commercial venture, and it will likely need modifications, revision, and retesting. It is hard to know how

long it will take a data class to get through the Candidate Stage. Once you have made it through Candidate status, you are pretty much assured that you are going through to the end. This gives industry a long heads up.

Stage 5: USCDI
Once you are in the USCDI, you are now tightly specified and ready to go. Anyone can put this data class into effect if they have the will, energy and resources. The endpoint would be getting out of USCDI by being widely adopted and deployed.

Stage 6: Widespread Deployment
All that gets you to Stage 6. Now deployment and monitoring how much traffic the data class gets are important. The RCE might be able to track the extent of deployment by monitoring the traffic of the data classes. Actual measurement rather than surveys would be best, to actually see what is going through the pipe. Before we go to discussion, I'll touch on a few other items linked to the Stages.

Data Class Work Group
O'Malley: We have recommended that ONC create a Data Class Work Group (DCWG)—a voluntary group of stakeholders with an interest in this information who need to direct and accomplish all the tasks at hand. We would recommend modeling the DCWG on the ONC's Standards and Interoperability (S&I) Framework, a model of health information exchange. ONC would offer a platform and support with the Task Force, the work group does that work. One question here is whether ONC would have the resources to organize this and offer ONC staff resources.

Discussion of Recommendation 1: Six Stages
McDonald: I have some differences with the committee about the number of levels. Is ONC trying to measure reality or is it attempting to change reality? If measuring, the six Stages are fine. If changing reality, it could take decades, so we should squish the levels considerably.

Sweeney Anthony: The goal is to change the reality and get to, over time, all data as required by 21st Century Cures. While I'm sure measurement is an important component of this, that is not the end goal of the process.

Denise Webb: These recommendations offer a thoughtful, logical approach and process. It provides the ability to manage expectations, address immediate needs by permitting sharing of non-structured data while the data class is being addressed. I appreciate the need to ensure harmonization. And a central repository data class information on the life cycle of the data class—the process, assigned roles, responsibilities and accountabilities—is needed. I like the Stages, especially Stage 1. Trying to vet whether you are going to establish a particular data set is challenging. So, I like this. You all did a nice job.

Anil Jain: I think on slide 7, you did a nice job of outlining some of the challenges of sharing data. One item you might include would be those that could have a perceived competitive value to organizations versus those who are holding onto the data, and how that gets pulled into the various Stages especially around the value proposition. Also, I don't see any discussion about when data classes could be retired.

O'Malley: Thank you very much. We are going to come around to the question of retirement. We don't have a good solution for it. We just flagged it as something we need to think about. Thank you.

Kawamoto: What sponsorship coordination will there be from ONC? This is a classic public good, and people who benefit from a project don't always put much work into it. That's a reality with open systems—everyone is waiting for someone else to do the hard work. How do you make it so that people do pull their weight?

Aaron Miri: This is helpful, and the Stages are necessary. You may want to consider emergency situations, like the recent Ebola situation in Texas. We need a fast-track process to deal with rising epidemics and pandemics that may require changes or new data classes to address such situations.

O'Malley: The committee considered that briefly and decided this is beyond our scope. So, there is a Recommendation saying there needs to be some sort of process for fast-tracking.

Steven Lane: It's important to focus on urgency, not just for emerging data items or classes, but the entire effort. The intention of the multiple Stages is to describe the steps to maturation. They are helpful in terms of saying what work needs to be done. If it could all be done in a season or a quarter, that would be great.

Arien Malec: I like the classification of things that prevent data from being shared. One I did not see in the early Stages of the USCDI evolution is when data does not exist or exists sporadically. It sounds like once you have data collected but no semantic standards for normalizing it, you have a well-established process for catching that and leading it through the rest of the steps. Also, I don't see where the group addressed cases where there is a high-priority need, but not collection on the ground. In the area of clinical quality measurements where we've done a Meaningful Use, clinicians' cognitive and time burden of collection has been a frequent critique. And, how you would assess the business drivers for collection, and the cognitive burden for clinicians on requiring additional collection of data to improve interoperability. Thanks in advance.

O'Malley: Those are easy. [Laughter] To answer your question, we didn't have a good answer to your question. I think, again, to the extent that we can match our quality measures to our clinical processes, we will simplify this and make it better for everyone. In the meantime, we will be creating new data classes and new data sets and putting them through this process. Data collection for quality measures becomes a systems process

rather than a clinical process. Quality measurement and development work are done with the best of intentions. But every additional quality measure that appears, good as it may be, just adds one more small incremental burden.

Caraballo: You also mentioned the barrier of information blocking. That is where we have a lot of crossover and the importance of mapping the USCDI with the work that TEFCA and the RCE are doing. Our goal is to make it so there are no questions when you get to Stage 5. Then it is up to the RCE and TEFCA to make sure that the different organizations are exchanging it.

Denni McColm: In Stage 6, measuring that widespread adoption, it should be more than just moving data. Today, we are moving a lot of data that is not being accessed or used by clinicians. We need to measure this.

O'Malley: It would be great to have a way for the user to vote on the usability, the appropriateness, and the timeliness of the data. I am not sure quite how we could do that.

McDonald: Considering the burden issue. A lot of people want someone else to do it. If we kept track of who wants it and who has to do it, that may help.

O'Malley: I could not agree more. The benefits and the costs of interoperability are not evenly distributed. That is just a fact of life.

McDonald: It's not the interoperability, but the initial collection is where the issue is.

Sasha TerMaat: I just had a question about how a data class progresses through the Stages when its objects and attributes are at varying levels and would be classified in the Stages differently?

O'Malley: We did not delve into that. That will have to be clarified. Does the whole data class lag until the final object is specified? Sub-Stages could help, such as Stage 2.1. Maybe the final object gets kicked off the bus and the data class moves ahead. It is a balance between value and maintaining value through the process against the technical specifications.

Steven Lane: Measuring utility and use of exchanged data is very important and needs more work. ONC did publish and receive public comment on how to measure interoperability. Provenance also will be important as we define the legal health record, based on what data was accessed and used to support medical decision making.

John Kansky: It seems that we could break a data class into chunks that could be moved through the system at different times.

Fisher: If we linked more rapid development to payment, we could solve interoperability. We need to look at an approach to delivering Stage 1 in a human-readable form that could be shared with the patient as soon as it is digitally available. HHS has the financial leverage to tip that domino to fall into place. I encourage us to keep the patient and family members and our caregivers in mind because done is better than perfect.

McDonald: The definition of object and class are not aligned with what technical people think of them. Classes have attributes. we need another layer in there. Technically oriented people will be confused if we don't clean that up a little bit.

Caraballo: That is an excellent point. We had to move past this in our Task Force discussions because we just didn't have the time for it. This is something that ONC could possibly do to help us out.

USCDI Task Force Draft Recommendations 2 through 4

Caraballo: Here are Recommendations 2 through 4, starting with our expansion process. Data classes are added to the USCDI after Stage 4 with no limit on the number added. Once enough data classes have moved through the process, we would review the progress of data classes and establish a timeline for advancement. Our next charge was to look at the frequency of publication. We decided as a Task Force that we thought it should be published annually as a Reference Edition. This would be at the end of the calendar year. We also wanted to incorporate the use of public bulletins to let industry know quarterly what was coming, what major changes have been made. more regularly. Task Force recommended a two-month public comment period following the release of the USCDI reference edition.

Discussion of Recommendations 2 through 4
Carolyn Petersen: My comments do not reflect those of Mayo Clinic. Thank you for these comprehensive guidelines and processes, particularly regarding the expansion and clarity of the steps. I did want to ask how you intend to engage patients and consumers in the process? This committee has some strong patient and consumer advocates.

Caraballo: Good point. We had thought it could be a similar platform to the S&I Framework. But specifically, for the patient. Presenting the use cases with the interested stakeholders we are hoping to start a dialogue, so different groups could see overlap and similarities to help push things forward collectively, so it has that overall important net value and not just the technical value.

O'Malley: In our bonus Recommendations we touch on that. It's a critical issue.

Fisher: Thank you, Robert. I'd like to make a suggestion following up on Carolyn's point. Perhaps ONC, the USCDI Task Force and Lana Moriarty's group, ONC Consumer eHealth

and Engagement, could work together to identify the best way to address a diverse population of consumer participants in the Stages of development of the standards. We could look at those best-in-class businesses that have direct-to-consumer digital experience. That could be the Apples of the world, the Samsung's, Google, Dell, Amazon, that may also look to participate from a consumer point of view, a social media view, to connect to this population and this engagement.

Wah: Any other comments on Recommendations 2 through 4? Okay. Recommendation number five.

USCDI Task Force Draft Recommendation 5: Test USCDI, Address TEFCA

O'Malley: We wanted to test the whole process and do that with an eye on how it will interrelate with TEFCA, one helping the other and vice-versa.

Discussion of Recommendation 5
Webb: Could you clarify who you are referring to when you say we would only be inflicting damage on ourselves? Who is ourselves?

O'Malley: We would be inflicting damage on some of us. It depends on who is volunteering to move these forward. Who is going to be the stakeholder group that sees value in this that wants to move forward? It may just be a bunch of ONC people sitting around the table or more likely it would include a fair number of other volunteers. You are right, the damage won't be contained necessarily within-house.

Wah: It would be the workload burden rather than damage.

Aaron Miri: I love this optional bonus recommendation. Testing is important. It's also an opportunity to tackle some of the very challenging items that have been lingering and the healthcare community knows they need to be resolved. We can try things safely among private stakeholders. You can use the Apple initiative of private companies getting together to make things work. In the case of USCDI you have the full support from a lot of people.

Turney: There has been a lot of work in the all payer claims data space to improving data matching and unique patient identifiers for public health. CMS is coming out with a new identifier, and they want to be able to retain longitudinal patient records but don't know how to match up this new identifier with the extant data. Has there been any discussion from this group about how you would handle that?

Caraballo: Yes and no, but we will get into a Recommendation later for harmonization.

McDonald: This business about linking patients is essential, but difficult. A unique patient identifier is banned by law but maybe we can get past that. We should allow the use of the last four digits of the SSN to help with matching.

Tina Esposito: I agree this is difficult. But it will stretch the framework appropriately. Some of the newer approaches to identifying patients include referential matching—looking at addresses, not just most recent but maybe five, 10, even 15 years back, as well as having the patient identify whether these records match.

USCDI Task Force Draft Recommendation 6: Voice of the Patient

O'Malley: Recommendation 6 came out loud and clear. Keep the voice of the patient in mind. It was pointed out that there is no natural constituency for the patient. There is no national organization that is going to come to the table. The RCE I believe in its charter says it will include patient representatives in the governance structure, which is probably a good start. But how do we guarantee there will be patients in the work groups?

Sweeney Anthony: One clarification about the RCE charter; that doesn't exist yet. We are in the process of working on cooperative agreements, funding instruments. There is not one yet. The recommendation should come to ONC as part of our ongoing work.

Petersen: I do appreciate what the Task Force was asked to accomplish, and I am grateful to see that it was not left out. It is critical. I encourage ONC to keep pushing with the pedal to the metal on this because as you often stated, patient engagement is at the core of what you want to do and it's valuable.

Rucker: This would be a good area to get some product development specialists to work because customer engagement is a large part of product development in a market economy.

John Fleming: We could rely more on people who are active in fighting for specific diseases, especially genetic and chronic and rare diseases and disorders. My grandson has cystic fibrosis. My daughter is an activist in the Cystic Fibrosis Foundation, so I know there is a whole pool of candidates who may be very excited to engage in such a project.

Fisher: There are many vehicles we could use from the entrepreneurial world, in product testing and consumer markets—from focus groups to user groups to market research.

Brett Oliver: We do have to make sure we're representing the larger population, too.

Caraballo: I wanted to make a comment on the question about how we recruit patients. Right now, we are starting to see an uptick in industry trade groups like HIMSS and the health alliance are building consortiums of patients. Right now, the group WEGO Health has

a big bundling of patient leaders across the country. They offer services to different vendors to look at their products and offer opinions from the patient point of view. We are starting to see those things built and I'm sure that Lana Moriarty and her team are familiar with a lot of them. There are more resources than we think exist, that we can tap into.

Petersen: I want to speak to John's point about chronic disease communities. We also should be considering how we might do outreach to rare disease groups. Rare disease folks are real innovators in figuring out what can work for them, how they can work with the system to get the special unaddressed needs met. I would be happy to work on such a Task Force within HITAC.

USCDI Task Force Draft Recommendation 7: Data Harmonization

O'Malley: Data harmonization is hard. There are no two ways about it. It is difficult, but an essential piece of normalizing the data. Rather than have a similar data object that is called out in several different work groups sail through the different definitions in each work group, at a minimum we need to make sure that what comes out of this process is a single set of understood, mutually shared, clear specifications telling us just what the data object is all about and how it is described.

There were no questions or comments on Recommendation 7.

USCDI Task Force Draft Recommendation 8: Data Class Management

O'Malley: We recognized but did not think much about data class management. There should be a process for data class modification and for emergencies such as the Zika virus and Ebola. With Zika, for example, we needed to know pregnancy status down to about 12 levels, which no one was collecting.

There were no questions or comments on Recommendation 8.

USCDI Task Force Draft Recommendation 9: Governance for USCDI

O'Malley: We recommend a special panel, or Task Force, on governance for the USCDI.

Discussion:
McDonald: The ideal to reuse something if you could. We have the S&I Framework.

Rucker: We have a number of standards organizations and should always consider the standards work that is going on, making sure we leverage that and have the USCDI Recommendations work off the prior work.

Kawamoto: I completely agree with not reinventing the wheel. If we go with an approach like the S&I Framework, we should look at processes that didn't work so well there. One is they were too prescriptive. Crosstalk among the different workgroups is something that should be thought out and if it is contracted out, then it should be in the contract.

McDonald: We discussed but did not include another Recommendation, to encourage federal agencies that have very specific local standards, but they are not interrelated at all with the general standards.

O'Malley: Yes, CMS is great at standardizing. Unfortunately, it doesn't standardize much outside of CMS. There is a huge opportunity to bring them into the process of creating the standardized data set. The data element library that they are working on is a great prototype. And it is an ideal model for what we want to build or might want to think about building within the USCDI structure.

Wah: Let's deal with the nine Recommendations on the table. And if we want to construct another at some point, let's do that.

Fisher: I would encourage us as a group to put together goals and objectives on a timeline as we go through these. Perhaps that's a next step but to keep in mind what our realistic goals and objectives are.

VOTE ON USCDI RECOMMENDATIONS
The HITAC approved Recommendations 1-4 by voice vote. No member opposed. None abstained.

Wah: Any additional comments before we vote on Recommendations 5-9?

Wah: Some of the Recommendations, the way I read them, basically say, "These are items to be considered." If it's not right, let's talk about it.

McDonald: If you take it that way, I'm fine.

By voice vote, the HITAC approved Recommendations 5 through 9. No members opposed. None abstained.

Wah: Again, I am a couple minute short and I apologize to the public. I hope committee members did not feel rushed or that there was not enough time for dialogue. We can still have a conversation after the public comments.

USCDI Task Force Draft Recommendations: Discussion of Changes to the Recommendations

Caraballo: More of an administrative question. With USCDI, I know we voted on it, but can any changes be made without bringing them up today before it goes off to the National Coordinator?

Morris: A member of the committee would have to make a suggestion and text edit to the letter in the public forum. Then the committee would vote on those edits, whether they want to accept or reject them. Then they will be incorporated in the final version that goes to the National Coordinator.

Caraballo: There is one area in the letter that we didn't update a section. It was under the publishing. But it is in the presentation slides.

Sweeney Anthony: They were presented to the HITAC today and they were aware of them. That would be fine but usually what we do is what is used in the presentation materials is what is considered, and we format that into a transmittal letter that we run by the chairs to make sure we captured everything correctly. That is then shipped over to our wonderful National Coordinator.

McDonald: Are we going to change the definitions? Someone mentioned that earlier.

Wah: The definition of terms is a background piece. Going forward, we can redefine them without changing the numbered Recommendations.

Rucker: We can work on it in the letter.

Webb: I also saw this as background material to the Recommendations in giving context.

Final Comments and Next Steps

Wah: On to next steps. I get a sense that some wish to discuss what is next. Any comments? Anything we didn't get through in the Recommendations? Perhaps suggestions for additional areas to look at.

McDonald: Thank you for the job you did. I was wondering what other jobs do we have? Are we done?

Sweeney Anthony: The next upcoming issue is one that will be in Steve Posnack's shop around standard use cases, which is a requirement in the HITAC section of the Cures Act. Also, the proposed rule on TEFCA will be out shortly. We will discuss that in this committee.

I know It appears that we are moving pretty fast, particularly in testing the USCDI. Also, since the USCDI is done, we will delve into the standard use cases.

Wah: Unlike prior federal advisory committees, ours had legislation set some of the agenda. But there is still latitude for us to have our own agenda. We all recognize that this has been a slightly different kickoff of this federal advisory committee.

Sweeney Anthony: And to that point, there is a section in the HITAC provision of the Cures Act that talks about the priorities, target areas to look at. We at ONC, as we choose the charges that we want to bring for consideration, look very closely at the Cures Act language. Of course, this discussion also will be helpful to us in writing those charges.

Wah: I want to make sure we capture this in our discussion. There was a great discussion today.

Turney: Now that you have Recommendations for the TEFCA and USCDI, what happens next? Do they get republished? Do they go back for public comment?

Wah: We create a letter that goes out under our signatures as the Co-chairs of this committee, representing the HITAC. We forward the letter and recommendations to the National Coordinator.

Morris: For TEFCA, we have reviewed the HITAC Recommendations along with all the other public comments and we will incorporate both in the updates to the Framework. Under USCDI, we will take the Recommendations in as well and talk internally about putting it in motion.

The funding opportunity announcement for the core RCE entity will be out this spring. That is, shortly. We're hoping the RCE is on board around August. While that process is going on, we are working to update the TEF Part A and Part B. And I'm saying hoping because of contracts and other complex items. At that juncture, we will have a good portion of the TEF done and the pieces that aren't done we will work collaboratively with the RCE and the stakeholders. We also will have the RCE working with the stakeholders group and ONC on the full Common Agreement. All of that will then become the TEFCA framework and that agreement would be published, we hope, towards the end of 2018, in the Federal Register and on our website for public comment. We could have a final, and I say "Final" because it's a legal agreement, in the second or third quarter of 2019. Every timeline I laid out is dependent on internal clearance processes and how fast we can move on those.

Turney: Will there be a stakeholder group working on the Common Agreement?

Sweeney Anthony: The RCE is responsible for putting together the final Common Agreement and it will be required to have appropriate governance structures in place—committees, work groups, etc. Part B does not have all the legal terms and conditions you

need in a full participation agreement. ONC didn't think we needed to weigh in on those, just set a minimum requirement.

Public Comment

In the Meeting Room:

Leslie Kelly Hall: I would like to amplify some of the great work that was done in the committee. In particular, reflect on the earlier recommendation to the Standards and Policy Committee about asking of that they can ISA-- include a consumer-friendly section. This could be harmonized and aligned also with our recommendations today to see a way to encourage participation in standards by patient orgs and patient proxies or pt as well. I would also like to remind us all that as we include the patient as a stakeholder, which we did very aggressively in these recommendations throughout, we should consider that today's idea of burden changes when the provider does not have to be the intermediary of data. But the data request can go directly, it can go directly to the patients themselves. So, researchers can have access, public health can have access, so let's rethink our ideas about burden and go directly to the source as this Task Force recommendation would encourage. Also, the great comments of this committee on patient inclusion and stakeholders. Also, it is great to hear all the sources that we can seek out and participate in. But the actual process has to be deliberately driven to include the patient voice whether that's participation in governance or adding budget and resources to seek out some of the specialty groups that we talked about. All of that is important. I am honored to have been part of the workgroup and I thank you for allowing comment.

Comment on the Phone:

Shelly Funro, Pharmacy HIT Collaborative: Good morning. I am the executive director of the collaborative representing over 25,000 members of the majority National Pharmacy Association. It includes pharmacy education accreditation. Our members include organizations involved in health I.T. and the national prescription drug program and 10 associate members representing e-prescribing, health information networks, transactions, processing, system vendors and pharmaceutical manufacturers and other organizations that support pharmacist services. The pharmacy HIT collaborative is to ensure U.S. health I.T. infrastructure better enable pharmacists to help optimize care. Our mission is -- as a leading authority, the collaborative advances and supports the use, usability and interoperability of health I.T. by pharmacists to help optimize person-centered care a major focus of the collaborative is to a short pharmacist are integrated into the national infrastructure. On behalf of the pharmacy profession, the collaborative over the last eight years have dedicated our efforts to define and promote the use of standardized terminology within clinical documentation system used by pharmacists. National adoption of the use of the pharmacist electronic care plan by hundreds of community pharmacies is underway. The pharmacist electronic care plan effort is a joint project between NCPDP and HL-7. Using a consolidated CDA and FHIR Standards. The collaborative is a steward of over 500 codes and over 100 value sets within to standardize the collection, documentation and

sharing of medication-related pharmacist-provided patient care services. The collaborative supports the recommendations of the USCDI Task Force. Thank you.

Public comments received via the online chat:

Gary Dickinson, CentriHealth: How does the Precision Medicine Initiative assess/ensure data quality: fidelity to source (of truth), accuracy, completeness, consistency, comparability, full clinical context, uniformity, the purpose of capture?

How might it be assessed/ensured that data transformation (in the course of a single exchange) does not result in data loss, alterations or unresolved errors? Data is often transformed twice during exchange – from its source representation to the exchange artifact (e.g., HL7 message, CDA document or FHIR resource) and then to the receiver representation.

Metric for cost/value of capturing and maintaining data classes/objects/attributes must include the challenge of reducing vs. increasing clinician documentation burden.

Need to consider whether objects/attributes within a data class are captured together (e.g., at the same time, the same point of care/service) or captured in separate instances over time.

Are the full set of clinical quality measures intended for inclusion in the USCDI?

[Building on Clem's suggestion regarding the collection of specific data objects/attributes...] For value/cost assessment, need to know who collects it (at what frequency), who uses it? Also, is it needed in the form of discrete elements (instances) or as aggregations (averages, summaries)? Is it broadly applicable (or useful) or only to a select few (e.g., specific services/specialties, specific researchers studies)?

Meryl Bloomrosen: Are you able to clarify what data elements patients were offered access to via these online records?

To what extent did the TF review the proposed USCDI v1? And what were the TF's thoughts? Did the TF discuss harmonization of the USCDI with any current/planned CMS/ONC requirements (such as for certified EHRs and/or CMS reporting)?

r: If patients identify errors in their records, it would be better to enable them to change that in real-time. Waiting for providers to amend anything, which might take weeks, is not a good way to promote engagement as well more complete and accurate records.

Would it be more appropriate, in certain cases, to mature standards around data attributes rather than classes?

Does "data matching" mean "patient matching" here?

Robert Gergely, MD: What happened to the idea of a single unified longitudinal medical record?

We are all patients at some point in our lives. A lot of talk. No action. Sad!

Thompson Boyd: USCDI TF Comments: Slide 27 Common Causes that Prevent Data from Being Shared: consider adding - how well the outside data is Integrated into the Provider's EMR. How well has Usability been maintained?

Please consider aligning the efforts of the USCDI (especially the annual updates) with the ONC's Interoperability Standards Advisory (the ISA). www.healthit.gov/isa

Patient Matching: Consider using a Patient Matching Score, which points to the quality or the probability of the Patient Match. HIEs (HINs) use such techniques to match patients, being cared for in different health systems.

Steve Wagner: The criteria for getting into and out of a step need to be as specific and clearly defined as possible. There need to be specific, clear, measurable evaluation criteria for each to eliminate the feelings/biases of the individual evaluators and ensure reasonable consistency across evaluators.

Catherine: I wasn't aware that TEFCA call for a unique patient identifier. Could you please clarify this?

Micheal Smith: I appreciate the USCDI Task Force identifying the individual, caregivers and Home and Community Based Service providers as a stakeholder in 2.1 Recommendations Related to Charge. I also appreciate the overall focus on the individual in all aspects of this work. In Stage 3E merging section on testing data classes, the SDOH example was also appreciated as it is important to remember the broader home and community-based services and supports needs to be able to share information using TEFCA. For your testing of the unique identifier, it might be good to consider the ONC work with CMS n eL TSS planning elements. On recommendation 6, I would recommend that the Task Force take the leap from the “Voice of the "patient" to "person". Thank you.

Lindsey Hoggle: Have you identified specific domains for the data classes?

Thank you for this meeting. The Academy of Nutrition and Dietetics has been participating in advocacy for nutrition inclusion in health IT standards, policy and regulations. We have extensive work at HL7 and remain committed to promoting nutrition data interoperability. I look forward to participating in this initiative.

Closing Remarks

O’Malley: To add to the record, on behalf of the Task Force and co-chairs, we’d like to thank our ONC support. Stacy and Adam were great. We appreciate everything they did to help us move along.

Kawamoto: Just a suggestion. It would be awesome if this committee could at some point tackle the issue of EHRs having different catalogs.

Steve Posnack: The USCDI Task Force ended up dealing with a very narrow piece of a large process. And we acknowledged repeatedly that there was so much more work to be done. I certainly look forward to hearing from ONC what the plans are to help move that

forward. I can see this Task Force being repurposed to work on the next piece or another Task Force being Launched for that.

Wah: I like the way we are coming together as a group. we are working together well. I thank you for all the work you are doing. It is good when we can joke with each other and it's not all formal.

Petersen: I would just like to express my appreciation to the Co-chairs, members of the Task Force and ONC staff that have put in so much time and energy and bringing forward some strong documents that provoked good discussion and helped get us to move forward.

Wah: As Co-chairs, we are trying to make this meeting run well and be productive and effective. Any comments, suggestions on ways to do that, please let us know. I hope you all feel empowered to do that. If not, please let me know how we can make that better for you.

ADJOURNMENT

Richie: One more quick reminder, especially for the public. Our next meeting will be May 16, 2018. That will be a virtual meeting. You can find all the meeting information on our website at Health IT.gov.

Lauren Richie adjourned the meeting at 12:44 pm ET.