Health Information Technology Advisory Committee

Transcript
April 18, 2018
Virtual Meeting

Operator
All lines are now bridged.

Lauren Richie – Office of the Na btional Coordinator for Health Information Technology - Designated Federal Officer
Good morning, everyone. Welcome to the spring edition of the Health Information Technology Advisory Committee. I'm glad to see everyone made it here safely. We don't have a full day agenda, but we do have some very important recommendations to discuss. I will officially call the meeting to order, starting with a roll call. Carolyn Petersen?

Carolyn Petersen – Mayo Clinic Global Business Solutions – HITAC Committee Member
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Robert Wah is going to be late. Christina Caraballo?

Christina Caraballo, Get Real Health
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Tina Esposito?

Tina Esposito, Advocate Health Care
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Brad Gescheider?

Brad Gescheider, PatientsLikeMe
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Valerie Grey?

Valerie Grey, New York eHealth Collaborative
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Anil Jain?

Anil K. Jain, IBM Watson Health
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
John Kanksy?

John Kansky, Indiana Health Information Exchange
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken Kawamoto?

Kensaku Kawamoto, University of Utah Health
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steven Lane?

Steven Lane, Sutter Health
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Leslie Lenert?

Leslie Lenert, Medical University of South Carolina
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Arien Malec? I believe he's going to join us on the phone a little bit later. Denni McColm?

Denni McColm, Citizens Memorial Healthcare
Present.

Lauren Richie, Designated Federal Officer (ONC
Aaron Miri?

Aaron Miri, Imprivata
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Brett Oliver? I believe he's going to be a few minutes late as well. Terry O'Malley?

Terrence O'Malley, Massachusetts General Hospital
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Raj Ratwani?

Raj Ratwani, MedStar Health
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Steve Ready?

Steve L. Ready, Norton Healthcare
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sasha TerMaat?

Sasha TerMaat, Epic

Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Sheryl Turney?

Sheryl Turney, Anthem Blue Cross Blue Shield
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Denise Webb?

Denise Webb, Marshfield Clinic Health System
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Cynthia Fisher?

Cynthia A. Fisher, WaterRev LLC
Present.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And our federal representative, Lauren Thompson?

Lauren Thompson, Federal Representative
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Rom Sharom? Kate Goodrich?

Kate Goodrich, Center for Clinical Standards and Quality
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
And Chesley Richards.

Chesley Richard
Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Just a few other housekeeping items – just a quick press of the button will turn on the microphone. As a reminder, we will turn our name cards vertically when we have a question or comment. This is a public meeting.

Clem McDonald, National Library of Medicine

Excuse me. Should I not be here? McDonald?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Oh, I'm sorry. Did I miss you? I am sorry.

Clem McDonald, National Library of Medicine

Well, you didn't call me out or I just didn't hear it. I don't know.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

I'm sorry. I did.

Clem McDonald, National Library of Medicine

Okay. Maybe I should leave.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Clem McDonald is present. We have Patrick on the phone.

Patrick Soon-Shiong, NantHealth

Yes.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Michael Adcock? Not yet. And Andy Truscott?

Andrew Truscott, Accenture

Here.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Alright. Did I miss anyone? Apologies. Restrooms are out in the hallway, one you exit this door, to your right. We do have a few members on the phone. We promise we will pull you into the conversation and we won't forget about you. With that, I will turn it over to our National

Coordinator, Dr. Rucker.

Dr. Don Rucker, National Coordinator for Health Information Technology

Thank you very much. I appreciate everybody making the effort to get here. We especially appreciate the task force work. I've had the chance to look at the TEFCA, and I guess we're still working on the USCDI. There are lot of good thoughts in there, so I appreciate the large amount of work and thinking that went into that.

Obviously, these are extraordinarily complicated issues. I think the HITAC is in a very good position to give advice and thought on those issues. I think it is part of a larger national debate. I will say that, when I am out on the speaking circuit, the issues around how to hook up the various networks, how to share information, and what information to share are absolute top of mind.

I was at the Community Information Exchange Event in San Diego, where San Diego Health Connect and 2-1-1 San Diego had a big event. 350 people were out there from throughout the United States and even a little bit of Canada. They were working on what data to share, how to share data, and how to get information out on folks who have any number of social welfare issues, substance issues, and behavioral health issues. That is probably one of the hardest populations to actually address. I think, as we look at the U.S. Core Data set, it is critical to understand that. I want to thank folks for that.

I want to give a little information. I think we talked about this at the last meeting, but I want to reiterate that, from CMS's point of view, there is a deep interest in the interoperability. Administrator Verma has made that a passion in her group. I don't know if Kate wants to say word about that as well, but I know you and your colleagues are working on that. I think that was just something I wanted to make sure everybody in HITAC knows about.

Kate Goodrich, Center for Clinical Standards and Quality

This is definitely a top priority for the administrator, and the White House as well. So, in collaboration with Don, as well as the VA, there is lots of ongoing work around interoperability. We are looking very broadly at all of the levers that we have within CMS around how we can promote interoperability. There were a number of roundtables held at the White House around this topic. Some of you may have participated in some of those. It actually gave us a lot of really terrific ideas that we are actively exploring.

So, you will see some provisions intended to enhance the ability for folks to have access to their data from a patient centric point of view. I do want to emphasize that. I think that is really important. The frame that we are using around interoperability is really primarily around getting patients access to their data in a very secure way, timely, and in a manner in which they can actually use it. You will start to see more from us, as well as from ONC, in the coming months around this. Thank you for highlighting that, Don.

Dr. Don Rucker, National Coordinator for Health Information Technology

Great. I just wanted to make sure everybody was aware that. That is effectively the lever for much of what HITAC does. I want to have John Fleming give a couple of words. John is one of the political appointees in the Office of the National Coordinator, as are Genevieve and myself. I'll let John say a little bit about what he is working on and involved in. John has a long career as a family practice doctor in northern Louisiana. He always tells me he's on his third, or was on his third electronic medical record. I don't know what that says, but I think anyone who has

switched records has a pretty good idea of what that is. John is a Deputy Assistant for Health Technology Reform. Maybe, most interestingly, in terms of policy, John was in the U.S. Congress for four terms. So, John Fleming.

John Fleming, Deputy Assistant for Health Technology Reform

Thank you, Don. You just gave my speech.

Dr. Don Rucker, National Coordinator for Health Information Technology

No, no. It was a warmup.

John Fleming, Deputy Assistant for Health Technology Reform

Don and I kid a lot with each other. I just want to welcome everybody here. Thank you, Don. My background – I'm a family physician with six years as a Navy medical officer. I then went into private practice in 1982. Those were the dinosaur days, where we actually wrote our notes out by hand. But actually, I dictated my notes from day one, when I opened up my private practice in 1982.

I also got my foot in the door into franchising, fast food, and that sort of thing, and began to appreciate the value of technology in delivering services cost effectively, and more effectively, to customers. Also in the supply chain – I got involved in the businesses that way. I really developed a huge appreciation for technology. But, I asked that rhetorical question, "Why don't we see it in healthcare?"

Well, I decided in 1997 to buy an off-the-shelf system and implemented it. By 1999, we were fully paperless and happy. We were interoperable in a sort. We did have e-prescribing at some point, and we had faxes, so we felt like we were pretty interoperable at that time. But, as time has moved forward, we found a lot of that is insecure and there's a lot of problems with data matching, individual matching, and so forth. But, somehow – I got off my medication or something – and I ended up running for Congress and actually got elected. So, I spent eight years there. I was deeply embedded in the healthcare debate. I was very involved in the whole discussion about healthcare policy.

How does that apply to us? I think the one place, whether you feel like government has a larger role in healthcare or a lesser role, we all agree that we need to lower the cost of delivery of healthcare. That is where we come in, All of Us here in the room. How do we enhance data liquidity, access to data, and better control of data by the patient so the patient can shop for cheaper, more valued, care? Your work here today is very fundamental in applying that. One of the caveats to keep in mind is the increasing cognitive and time burden placed on the people who actually put the information in the system. That is primarily physicians, mid-levels, nurses, and other allied health.

There are articles coming out today saying that 50 percent or more of a provider's time is spent in non-direct care of the patient. That is a huge loss of productivity, which again gets back to the cost of care. Also, our burnout rates, the shrinkage of the independent medical practice, which is the theater that I come from – which, I think, again has a huge negative effect on productivity and the lowering of cost of care.

So, what I will leave you with today is to think about the decisions you make and how they apply to the independent practitioner out there. If you can fix it for him or her, then everybody else will be fine as well. Thank you, and I look forward to talking with you today.

Dr. Don Rucker, National Coordinator for Health Information Technology

Thanks, John. I think that perspective is very important because I think that is actually where a lot of the competition and innovation comes in, in those smaller practices. We do try to be mindful of that. Carolyn? The stage is yours.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Carolyn, I want to do a quick audio check. Arian, Are you on the line? Can you hear us? Okay, we'll circle back to Arian. I also just wanted to briefly introduce my folks. We are joined by Principal Deputy National Coordinator Genevieve Morris; Dr. Jon White, our Deputy National Coordinator, should be joining us shortly; Director of Policy, Elise Anthony, next to me; and Steve Posnack, Director of Technology at ONC. Now, we will turn it over to Carolyn.

Carolyn Petersen – Mayo Clinic Global Business Solutions – HITAC Committee Member

Thanks, Lauren. Before we get started, I will review the agenda we will be going through today. We will also take a vote of the minutes from the previous meeting. This morning, we start with two updates from ONC. First, an update of the Precision Medicine Initiative, the All of Us research program, and Sync for Science. That will be handled by Teresa Zayas Cabán, Chief Scientist at ONC. We will also have Lana Moriarty, Director of Consumer eHealth and Engagement at ONC, presenting on the ONC Guide to Getting and Using Your Health Record.

We will then go into the meat of our meeting this morning. This will be a presentation of recommendations by the U.S. Core Data for Interoperability Task Force. We will have a discussion and a vote today. Christina Carabello and Terry O'Malley, the co-chairs of that task force, will present for us. We will also have a period for public commentary and some closing remarks by Lauren. We will adjourn the meeting at 12:30.

The first order of business is to approve the March meeting minutes. Those were put on the website and distributed to you previously. May I have a motion, please? Thank you. We have a motion to approve the March meeting minutes. May I have a second? Thank you. We have a motion and a second. Can we take a voice vote to approve those minutes? All in favor, please say yes.

Multiple Speakers

Yes.

Carolyn Petersen – Mayo Clinic Global Business Solutions – HITAC Committee Member

All opposed, please say no. All who wish to abstain, please acknowledge that now. We have approval of the March meeting minutes, Lauren.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you, Carolyn. At this point I would like to invite Lana and Teresa to the presenter's table. Just as a quick process note, we love both of them present first, and then we will open it up for free questions afterwards.

Teresa Zayas Cabán, Chief Scientist at ONC

Good morning, everyone. My name is Teresa Zayas Cabán. I am Chief Scientist at ONC. Lauren, thank you for the introduction and the opportunity to be here. I lead the Office of the Chief Scientist, and the role of our office is to direct projects that leverage the health IT infrastructure and the health IT investment that this country has already made to support the biomedical and health services research enterprise. We do not fund research, but are involved in projects in collaboration with those who do – NIH, FDA, the Agency for Healthcare Research and Quality. Some of those projects fall under the Precision Medicine Initiative. We also have a portfolio of patient centered outcomes research projects. My office also leads ONC's international portfolio.

So, today, I will be providing a brief update of some of our activities under the Precision Medicine Initiative. The Precision Medicine Initiative was launched in 2015 with the goal of enabling a new way to deliver care that is tailored to you as an individual based on your lifestyle, your preferences, and your genome. When initially launched, it included the National Institute of Health, the Food and Drug Administration, the National Cancer Institute – specifically within NIH – as well as ONC. It was later expanded to include Office for Civil Rights, the Veterans Administration, DOD, and, most recently, the Department of Energy and NIST have also joined the initiative.

The cornerstone of the PMI is the All of Us research program. This is an ambitious project to enroll a million more people and get them to donate their health data for science. NIH is leading that. They have made a number of awards to healthcare provider organizations that will be recruiting these individuals. Participants will be responding to survey data. We will have some bio specimens and their health records will also be included as part of the data. The data are being collected and stored by what is called a data and research center. That award was made to Vanderbilt, with Verily and a few other institutions as the subaward.

The idea is to then curate the data and make them available to individuals to do research, and that process is being worked out. There will be a researcher portal that individuals can log into and access data and conduct studies. The goal is also to share the data back with the participants. That is something that NIH is very much committed to, to ensure that individuals are engaged throughout the lifetime of the project and they get value out of it. In addition, they are hoping to make sure that people get results from the research for which their data were used.

As I said, ONC has been involved with the PMI before it was launched. We have been a very active participant, collaborating both with FDA and the NIH. I actually sat as an ex officio member of their advisory panel for the All of Us research program. Our role has been to focus on standards, development, and pilot testing to enable sharing in using of data for the cohort, as well as looking at issues around privacy and security.

Today, I will highlight the ongoing and most recent projects listed on the slide. So, Sync for Science, the pilot project focused on privacy and security, and Sync for Genes. Sync for Science is a cutting-edge way of sharing data with applications. All of Us is being used as a use case, but the idea is the technology will make it easy for individuals to share their health data from their provider's EHR with the app of their choice. The work is being led out Harvard Medical School's Department of Biomedical Informatics, by Josh Mandel and David Kreda. It leverages the 2015 edition criteria around developers having published APIs, is also very much relevant to language in the Cures Act regarding the use of APIs to make it easy to access and share health information without special effort.

It also leverages existing standards for authentication, so it uses All of Us too. If you go to the website, you can see demo of how the system will work as well as the testing tool that Josh

and David put together for the developer's participating in the pilot to use to test their API to make sure it was meeting all of the requirements of the project. It really is a groundbreaking project. We have been proud to be engaged with it from the beginning. It has implications, both for research and for clinical care.

Going back to the All of Us research program, NIH hopes to recruit the majority of the cohort participants through what they refer to as healthcare provider organizations. They may award to different medical systems across U.S. They expect to bring in 700,000 of the one million participants through that way. Those organizations have been working very closely together in terms of how EHR data will be shared and submitted to the data and research center.

But, they also want to recruit people off the street, if you will, through what they call direct volunteers. Approximately 300,000 individuals will be recruited that way across the country. They are setting up enrollment centers at places like CVS, for example, where people will walk in, learn about the study, be consented, and begin the enrollment process. As you can imagine, it poses a bit of a challenge if the individuals are not being recruited a provider organization to get their health record data. That's where technology like Sync for Science comes in. If the pilot is successful, we hope it can be scaled to other provider organizations as well as other developers and make it easy to obtain their health record data for research and for their own personal care.

We have 13 sites that are clients of four leading U.S. vendors. Something I wanted to highlight is that there is some overlap between the healthcare provider organizations that NIH has made awards to and those that will be participating in Sync for Science. It will give us an opportunity to compared what comes out at the other site through both enrollment processes, in terms of what health record data makes it to the data and research center. NIH has also engaged federally qualified health centers. They've partnered with HRSA on this. One of the pilot sites is an FQHC that is also participating in the All of Us research program as a provider site.

So, how will this work? Vibrant Health, a local company who is also an NIH awardee and is responsible for developing the All of Us research app and portal, has been working with the Sync for Science team to have a Sync for Science enabled version of the app for those who are recruited to participate in the pilot. Once they enroll, they will be directed to the app, and then they will be taken to a separate process through which they will consent to participate in Sync for Science. They will be given a list of the information that will be shared, and for how long. The original sharing period is one year, after which sharing will be revocated. Then, they will receive confirmation of what exactly is being shared through the research app and the All of Us research program. Individuals can choose to withdraw it they would like. If that doesn't happen, then data will be pulled quarterly for the study.

Moving on to the privacy and security project. As you can imagine, it is very important that the API and the data is shared in a private and secure manner. We engaged some of the pilot sites and vendors who voluntarily wanted to participate in testing of the API being developed under Sync for Science. We came away with were considerations that we think would be of value, of folks who want to develop APIs in this space. It will be more relevant as more APIs are developed for healthcare. The link to the resource is available on the slide, and I encourage you to take a look. It is a useful document with some key recommendations.

Last, but not least, I wanted to talk about Sync for Genes. This is our attempt to make it easy to share standardized genomic information at the point of care, and also with patients. Also, HL7 FHIR, the genomic resource, we concluded Phase I of the project last summer and published a final report, available on our website, engaged five different pilots looking at different data

types and use cases to really further develop the FHIR genomic resource. We recently launched Page II, I'm very happy to say. That work is being led by Bob Freimuth with Mayo Clinic. The goal is to move into some implement projects and demonstration projects that will have useful lessons learned for those who are interested in adopting this standard, and for us to see how easily genomic data can be incorporated into an HER as well as shared with individuals. Some of these highlights will be sharing genomic testing results with patients through a portal or other means. With that, I will turn it over to Lana.

Unidentified Speaker

I want to add one editorial comment. Some of this may sound like a lot of deep science, but we think this is actually the exact same interoperability that will be used for American healthcare. So, think of this as sort of a cutting-edge experiment on doing this. But these APIs and these transmission modes will form the basis for modern medical care going forward.

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC

Thank you. My name is Lana Moriarty. I am the Director of Consumer eHealth and Engagement at ONC. I'm delighted to be here today to show you one of our newest resources we launched. On April 4th, we launched ONC's Guide to Getting and Using Your Health Information. We also launched a data brief on the latest trends for patient access. I'm going to talk a little bit about that today. Individuals' ability to access their electronic health information is a measure of interoperability and truly a cornerstone of ONC's work toward patient engagement, improving health outcomes, and advancing patient centered care.

We have seen great progress in access and having folks access their health information. I will show you a little bit of our recent data. In 2017, ONC partnered with the National Cancer Institute, as well of the National Partnership for Women and Families for the HINTS survey. We will continue to do that through 2020. This is the first of the data that we got out of the results from that survey. As you can see here, one half of Americans in 2017 reported that they were offered access to an online medical record by either their provider or an insurer. Of that, those reporting, over half of individuals offered online access viewed their record within the past year.

We still have a way to go, but this is up from 42% in 2014. We have made progress. Eight in ten of the individuals who viewed their information rated their online medical records as both easy to understand and useful for monitoring their health. I think that is a good statistic to look at, especially when we know that people don't want to just have data and numbers. They want to have knowledge to better inform their healthcare choices and to help their family members.

However, we know that a lot of challenges remain. Almost half of Americans in 2017 who were offered access to their online medical record did not access their record took, frequently citing a perceived lack of need as one of the reasons for not accessing their record. The other top reason was the ability to speak to a healthcare provider. I think that is also telling, because this is not meaning to have clinicians out of the picture, but rather to build that patient/provider communication and relationship.

I also wanted to give you a little bit of background. In 2016, you will remember that we launched the Patient Engagement Playbook at our annual meeting. That was the online resource that we created for providers and care teams with tips and advice. It is an evolving document called a playbook because it is meant to not be static, but to evolve with the market

and with what people needed. That was to help people leverage health IT and engage their patients.

That was our beta prototype. That fall of 2016, we launched the Health IT Playbook and got very good feedback from stakeholders. But, one of the key pieces that we got from a lot of our stakeholders is, "What about patients? What are we doing to help them? This is created for the care teams, but a lot of teams are confused about their access rights. They go in and are told no. There's a lot of myths and misconceptions. What are we really doing to help patients?"

We also did a lot of consumer research at ONC in early 2017 to look at both the patient/consumer side as well of the health system side, because we know there are challenges on both. We interviewed a lot of patients. Then, we look at 50 healthcare systems and the way that they had release of information and their process for getting patients their health information. Along those lines, we found there was such a need for plain language and content that would give actionable tips for patients and help them along their journey of getting their health information.

In other words, many people felt lost and they felt confused. They didn't really have a lot of resources to turn to. I would also encourage you to look at the recent report that we published last July, called Improving the Health Record Request Process for Patients. Some of our personas in the healthcare journey of the patients we interviewed are illustrated in that report.

Taking all of this information into account, we set out to create an online resource for patients and families that would provide them with clear actionable steps, easy to follow information, and an educational tool to get, check, and use their health information. We are excited to show you this today. I also want to mention that this supports the 21st Century Cures Act, which has the goal of empowering patients and improving patient access to their electronic health information as well as supporting the My Healthy Data Initiative, which we all saw launched at HINS, and is led by the White House Office of the American Innovation Initiative to empower patients by giving them control of their healthcare information. With that, I will show you a little bit about this resource.

As you see at the top, this is split into three sections. I will mention, we developed a prototype, and then we actually did pretesting before launch with a group of patients. We were able to go in and iterate and have two more versions of that before the launch in April. This is a single webpage, but the split into three sections was to make it as easy as possible. We wanted the guide to be very user friendly and engaging. I mentioned the plain language, the layout.

But, not only that, we used fun graphics and an FAQ section to educate people when they are looking for things and troubleshooting.

I will just show you here, we have an introduction. This is to guide people through what this resource is, showing them their right, showing them why they should get their health information and the benefits of this. Then, you can jump right in. We made it both navigation at the bottom – but then, here at the top, if you wanted to get quickly back to where you were. So, in Get It, it's, "How do I get started? What am I looking for? What should I ask for?" And then walking them through even a quiz – I will show you a bit about this. In the interest of time, I will not go through all the quizzes.

You can see frequently asked questions. Here we say, "I care for my child, a family member, or another adult. Can I access their health record?" All this information was developed with our colleagues at the Office of Civil Rights. We've developed this very closely with them, and looked at developing this with the broadest audience in mind under the current HIPAA Rule of

Access.

Then, you go into the troubleshooting tips. Know your rights. Then, we give information on what people are asking for. Are they needing their full record? Are they needing a partial record? Again, we're always trying to encourage electronic means, trying to encourage people to use patient portals, and being able to access information when and where they need it, which is truly the definition of interoperability when people need to get that information.

Then, we even call out the Blue Button Initiative here. We are updating this constantly with the launch of CMS's Blue Button 2.0. We worked with our federal partners here to be mindful of our active duty and veterans who might be accessing your health information through those sites.

And then, going into Check It. When I have my health information, what do I need to look for here? What does Check It mean? We wanted to define why it might be important, what you should be looking for, and if this information is incorrect, how can you get it corrected. So, we're encouraging people to look at their personal information and their health information and figure out how to find this information, and also how to get this corrected if there is missing or incorrect information within their record.

We give steps on this. Again, the resource was reviewed by clinicians as well. We would really encourage anyone here – your feedback and sharing with your networks to make this a better resource for patients. Troubleshooting tips. Frequently asked questions. Trying to anticipate what people would need to know. What would they want to know when they're checking their information?

Finally, what happens next? What do I do with my provider does not agree with my request? Then, we wanted to also encourage people in using this. We have quizzes in here for people to learn things. There's Share Your Health Records, Stay on Top of Your Healthcare, and How Do I Manage My Health Information? Also, just talking about apps. People want to know about what health apps are out there. How can they best vet an app to protect their privacy and focus on their health data and protecting that. We give a few tips on this. Then, we have Some statistics. About four in ten people with a smartphone or tablet have a health or wellness app.

We will be constantly updating this information, similar to the patient engagement and the health IT playbooks, to make this a living document where, when people ask us for information that's not on here, we can respond to them.

Where can you find some of the health apps? Do I have to pay for a health app? The upside of downloading. All of this was meant to be encouraging and making it easier and more streamlined to get access to your healthcare information. I think our next steps – we will go through another period of patient testing. We are undergoing another round post launch of consumer testing with individuals to see if we got it right or if there are still issues that we need to address. Then, we will undergo another round of updates by the end of May. So again, working with health systems and organizations to help spread the word on this new resource.

I think, additionally, we decided to create a resource that we are calling a web badge. This is something we are doing a dissemination of through our own networks, through our partners in the private sector, to really get this embedded on people's websites, on patient portals, in order to make sure that we can reach the greater swath of individuals and do a greater outreach. I think that is all I have. I would just encourage you to share this with your networks and any feedback you have back with ONC. Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology -

Designated Federal Officer

Thanks so much, Teresa and Lana. We will open it up for a few comments or questions for our presenters.

Unidentified Speaker

Lana, thank you very much for that in-depth presentation on making it easier for access for consumers and patients. May I make a make a suggestion, that state-of-the-art go-to training and learning how to do something oftentimes in today's world is using YouTube video? If you were to interview someone who is six to in their mid-80s, and different professions across the board, they would oftentimes go to YouTube as their first search. So, may I suggest that ONC consider the same for your important work?

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC

Thank you. Absolutely.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Clem?

Clem McDonald, National Library of Medicine

I could not find the document you described that reported the data. Could you provide the URL to that? I did a quick search on the web and it didn't pop up.

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC

Sure. And it should be on our healthit.gov. I don't have the URL with me, but I'll be happy to send that to Lauren and share it with the counsel.

Carolyn Petersen, Mayo Clinic

We can send that to the full committee.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Okay. Any other questions or reactions? Raj?

Raj Ratwani, MedStar Health

Lana, thank you. I have more of a general comment thank a question. Thanks for the presentation. The resources that you put out I think are fantastic. I think they're very powerful patients. But, I do want to be a little bit careful with the third bullet point which is that you have on your first content slide, which is that eight in ten of the individuals who viewed their information rated their online medical records both is easy to understand and useful for monitoring their health. If you look at the broader research in this space, and I think what patients and many clinicians are saying today, that is generally not the case. There are a lot of usability challenges with patient portals and other ways that patients access their data. Sometimes it's inaccurate and it's oftentimes not in a format that helps inform decision-

making. I understand that's probably a very valid data point from what you have in your trend, but I think we have to be very careful when you make these claims. It can reduce the amount of energy and effort that is put in making those improvements. I think there is a lot of work that needs to be done in that space. I just want to be very careful with that kind of content.

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC

Thank you. I think those are very good points. In fact, that is exactly what we are doing in trying to encourage more plain language and more user-friendly websites to help people understand their health information. I appreciate your points.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Sheryl?

Sheryl Turney, Anthem Blue Cross Blue Shield

One point that I thought could be brought out in your Use It quiz would be to call out secondary uses of the data by third parties that people provide access to. From a payer perspective, we are getting increasingly more requests from patients to release data to third parties, but they're completely unaware of those third parties' secondary uses of data and have never even heard of it. If we are attempting to educate them, working together to do that more broadly, I think, that is very important.

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC

Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Steven?

Steven Lane, Sutter Health

I just want to second that. I think it is very important that we educate consumers about the potential risks related to releasing their data. So, getting it, using it for themselves, is very important. But, as they share that with apps, the challenges that could provide when it goes outside the control of HIPAA – I think taking this opportunity to highlight those risks is important.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Any others? Yes.

Unidentified Speaker

I have a question about the Sync for Science. Do we have any data or evidence that those individuals that 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.

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC
Yeah, that's a great question. NIH has been tracking for the broader All of Us research program, of the folks who are being approached to participate in the study, who have agreed to and enrolled, and who has not.. They want to do follow-up to try to understand, for those who didn't, why they didn't. It will be part of the overall study.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer
Ken?

Kensaku Kawamoto, University of Utah Health
Thank you. Great stuff. Around that question about security, could you comment a little bit about education that is needed for pulling down data for these third-party apps, specifically given that the FIHR standard now – as I understand it, if you wanted to just share your height and weight with a fitness app, the only way to pull that down is to pull down your entire list of observations, or at least five access to it. That might mean pulling every data point or observation. Can you comment on the education needed and what you think should be done to educate folks on the lack of granular data polls that a lot of these mechanisms currently support?

Teresa Zayas Cabán, Chief Scientist at ONC
I can talk a little bit about what we are doing for Sync for Science and then Lana can maybe talk a little bit about broader education that may be needed. One thing I will mention is some of the developers are using an all or nothing approach. Either you share your entire record, or you don't. Others are making it easy for individuals to share data types. It will be granular as to one medication versus another, but you could select your medication list and not your problem list, for example. For individuals, there are a couple of different things. They will be consented into the All of Us research program. It is a very comprehensive enrollment and consent protocol that explains exactly what they are consenting to, how their data are being stored, and all of that information. For Sync for Science specifically, we leveraged network's education and consent resources, and their expertise, to develop a set of screenshots that the developers use as guidance for what to implement in each of their portals, where individuals are walked through what it is they donating and what that includes. Then, they get a confirmation screen and an email back listing what they are donating.

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC
I will speak a little bit to education for consumers around apps. I think that was one of the reasons that we really wanted to update the model privacy notice that we did several months ago. I think that we understood at the time that the notice came out, it was really about PHRs. When you look at the changing landscape, we have moved so much to apps and mobile devices, and having data flowing back and forth. I think that, for consumers, one of the most important things is understanding when you engage with that app what is it doing with your data. We are trying to build more education around that, to have more informed consumers and people that are really looking at how their data is used, shared, stored, and sold. I think

that is something we need to probably do more of. I appreciate the comments about incorporating educational aspects of that into this guide.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thanks. One last comment from Les?

Leslie Lenert, Medical University of South Carolina

How is work with Sync for Science informing TEFCA? What specific areas do you think TEFCA needs to be strengthened to support the research in the United States?

Teresa Zayas Cabán, Chief Scientist at ONC

Sync for Science will be leveraging standards work that is already being done, certification requirements, as well as potentially anything coming out of Cures around APIs, to make the technology possible for data to be shared. Beyond that, it is not necessarily about point-to-point exchange. It's more enabling the technology to do so. All the interoperability work that ONC will be undertaking under Cures will make things like Sync for Science possible. It's a little bit of the reverse. So, some of the TEFCA work will enable things like Sync for Science to move forward.

Leslie Lenert, Medical University of South Carolina

Then where do you think TEFCA needs to be strengthened to advance the agenda of using the healthcare system for science?

Teresa Zayas Cabán, Chief Scientist at ONC

Honestly, I'm not sure that it does. I think the pieces are there to make this work, not just for care delivery, but also for science and for research.

Leslie Lenert, Medical University of South Carolina

That leads that there's only just a statement that it's available for that, but there's no specific policy. Again, do you think that TEFCA needs to be strengthened in this area, or do you think that a general statement that it one day might potentially be useful to science is enough?

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC

I'll take that. As folks know, in the draft test that we released in January, we did not include research as one of the permitted purposes, that you can use it the trust exchange framework for exchange of data. We did receive some comments around that, and we are in the process of reviewing all those comments and making updates to the Trusted Exchange Framework.

Leslie Lenert, Medical University of South Carolina

Certainly, work with Sync for Science could inform that framework as it goes forward.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

We do have to move along, but I'm going to take the last two comments from this side. Clem and then Cynthia?

Clem McDonald, National Library of Medicine

This may be as much to Ken as to the main speaker. There is a queryable observation ID. So, you could subset it. Maybe that's not in the earliest version. I didn't think you had to load everything down.

Kensaku Kawamoto, University of Utah Health

I think the issue is that, by permission, you can query for it. But, when you give the app, for example, authority, the base FIHR standards right now require you to allow it to query for anything. The app could decide it will only query for certain things, but it will be given the authority to query for anything it wants.

Cynthia A. Fisher, WaterRev LLC

This question goes both for Teresa and Lana. To look at your respective areas, both Sync for Science and then for the patient consumer, what is the approach that you are taking now with respect to GDPR, or the General Data Protection Regulation, that the EU has put forth as we look to, not only U.S. records but care on a global basis, for healthcare?

Teresa Zayas Cabán, Chief Scientist at ONC

Specific to Sync for Science, GDPR is not something that directly applies. We have been focusing on HIPAA and, frankly, leveraging individuals' right of access to enable data sharing. There are some privacy and security trust principles under the PMI that are being adhered to. Of course, a host of other federal regulations with regards to security and things like that, that the data and research center, and all of the parties involved, have to adhere to.

Separately, the department is participating on a global digital health partnership. We are meeting next week. There are issues around cyber security that will be discussed, and how to potentially harmonize across the globe, or how to leverage that work across the globe. I have also been involved in a recently launched effort of international cohorts that is looking at how to collaborate across cohorts, how to maybe standardize things like consent forms and enrollment protocols, and how to potentially begin to start querying across cohorts to do research. So, all of that will come into play.

Lana Moriarty, Director of Consumer eHealth and Engagement at ONC

I think I have a similar answer. In working with OCR, we have focused around the HIPAA right to access as well in looking at privacy and security. I think that is a good question, and I would take that back to them. As we move forward, we are working closely on Cures section 4006 around patient access. This will be part of the conversation as we move forward, both internally with our federal partners, but more importantly, with private sector stakeholders as well – and individuals.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

I would like to thank Teresa and Lana for their time. Maybe they can hang around for a little

bit, if others have questions after the meeting. If not, you can email them to me and we will provide their email addresses. We are going to move to the core of our meeting, no pun intended. Before we get started, I'll turn it over to our cochairs to walk through a couple of process points before we dive into the recommendations. I'll also ask terry and Christina. Thank you.

Robert Wah, DXC Technology

Great, Lauren. Good morning, everyone. Thank you for your patience while I got here. It is great to be with you all. I realize this is our first chance to be face-to-face again after we had our initial meeting in January. I think we had a good successful on-the-phone couple of meetings, but we're now back together. I think it is worth recognizing that we are making progress here, and we are moving very rapidly. Before we move too fast, I want to take a step back and maybe have a quick review of how we work as a committee and make sure we are working optimally.

I think we all recognize we have a very rich source of expertise and experience around the table. We want to make sure we are leveraging all that in our work as a committee. As chairs, we have tried to make sure we get the information out with Lauren and the team to you in a timely fashion, recognizing that there's a tension between how long it takes to prepare the materials to get them out to you and get them to you in a timely fashion for you to review. We know that that is never enough time to review. At the same time, we've asked the task forces to prepare the materials as quickly as possible and get their work completed before the materials get distributed to you.

I hope you all recognize that there is a little bit of a tension there between getting the task force work completed and in a format that can be distributed and getting it to you in a timely fashion to review. We will continue to work on that. We are open to suggestions and comments about that as we go forward.

Also, it is important to think that, by creating two task forces, we've given a large charge of work for them to take a deep dive into a topic and help the committee work through the very high detail it takes to create these things. As you saw with the last task force that we reviewed their work, it was a lot of work in a very short period of time. Many of you were already involved in that, so there is a lot of crossover between the task force and the entire committee.

I think the job of the committee is to review the task force work and contribute to it, but not repeat the task force work. So, we don't have time as a committee to redo all of the detail that the task force does. We do want to make sure that we access that expertise and experience around the table to contribute and enrich and strengthen the work of the task force.

In that context, what we plan to do with this next task force with Terry and Christina leading the discussion – as you've seen, we've distributed the work of the task force. I believe there are nine recommendations. We thought we would go through each recommendation and have a discussion about it. Some naturally group together, so we will probably vote on them as a block. We'll go through how we plan to do that as we go through this.

But some, like the first four, naturally fit together. We will probably vote on those as a group. If you only vote two and not three and four, it might not hang together right. We are trying to be mindful of that. The other ones, five through nine, we will probably vote on individually. We thought it would be useful to have the cochairs of the task force lead the discussion and give background information. You have all had the materials distributed to you. Then, we will open it up for discussion and make sure we have a good understanding as a committee and we

have the appropriate contributions to the work of the task force. And then, we will move on to the next recommendation. For voting purposes, we will group one and four together. Then, we will go through five and nine individually.

At the end, I think we will hopefully have the work of the task force fully discussed and voted upon. Those recommendations will then go to the National Coordinator for their use. I think that is a good use of our time and how we can be most useful to the National Coordinator.

We wanted to spend a couple of minutes talking about that again. And I would say, this is not in any way trying to limit or stifle discussion. If anything, I want to make sure we have a very rich discussion of these materials. But we don't want anyone to feel like the train is moving so fast that you can't get on and can't say anything. At the same time, we have that natural tension of trying to get a lot of work done in a very short period of time.

If you are feeling rushed or you feel like you're not getting in, just let us know. We certainly don't want that to be the sense that anybody has. At the same time, we don't want to redo or re-create or re-discuss every element of the task force work. We don't have the time to do that. That is why we break into the task force and have them take the deeper dive into the issue.

I'm happy to have comments about that initially. If anybody has a question about that or wants to have discussion about that, we will do that as well. We just thought it was important, before we go into this discussion of our task force recommendations, to again review where we are and make sure it is clear to everybody. I'm not seeing anything from that. Why don't we turn it over to Terry and Christina to start the discussion of their task force recommendation?

Christina Caraballo, Get Real Health

Great. Thanks, Robert. Everybody is getting excited about core data. I know you guys all read this Saturday morning when you got it, so jumping right in. We are very thankful to be here today. Terry and I have had quite an adventure putting these recommendations together. It has been a really great experience. It has been a privilege working with our task force.

Before we get started, we did want to say at the very beginning of this, that there were a couple of items that the task force did not have clear consensus on. And, there were a variety of views. Through this presentation, we will try to call out those differences. And, we did make some editorial decisions to best present our recommendations to the committee as a whole.

This is just an overview of our presentation and a list of our members. We were pretty evenly divided between HITAC and non-HITAC members. We try to include the different perspectives that we thought were important to make our recommendations even more valuable. We have a bunch of big hospitals and organizations, really great thought leaders in health IT and interoperability, as well as patient advocates and advocates for groups such as nursing. We were happy to work with this remarkable and talented group of people. We can't thank them enough for what they did, especially in such a short time period.

Today, we are going to broadly review the structure and process of the USCDI and specifically comment on how to get stakeholder feedback regarding priorities. Three categories that were proposed in the original draft of the USCDI, which were the emerging candidate and actually USCDI – and specific promotion around them and how to expand the USCDI on a timetable, as in the original draft or in some other process. And then, how and when to publish the USCDI. We added a few more things to our charge that will also go through at the end.

Before we get started, we wanted to define data classes and content with a specific disclaimer.

This is an area for the task force did not reach consensus on the details. There were a couple schools of thought, and we arbitrarily picked one, not because it was better, but because it was a way for us to go through our recommendations to make it clear with our meaning. So, we are not focusing on the definitions themselves, but just to give clarity and content as a reference for what our recommendations mean.

The point of these definitions that you see here were to establish a common vocabulary and describe the relationship depicted in the diagram on class objects and attributes. The definition on here is that a data class is a high-level group of data types related to a common subject. An example is demographics. Within the data class, there are objects related to the subject – in this case, something like an address. And finally, an address has attributes in the case of a street number and ZIP code.

Going on to define a couple more of our terms, a stakeholder is anyone with interest in sharing interoperable data, either as an originator or a user. The data class workgroup is a new term to encompass the responsibilities involved in creating a new data class or preparing an established data class for testing. As we'll get to later, the testing is going to be a critical role. The data class workgroup we have identified as a very key element to the success of our whole process. A data class biography is a history of the data class as it moves through the process. Effectively, it is the data class's provenance.

The net value is a concept we came up with for assessing the amount of support in the stakeholder community for advancement in a data class. And then, the USCDI process itself encompasses all of the stages for receiving recommendations for data classes or components to demonstrate a wide rate of adoption and deployment.

In our draft recommendations, we talk about four main components. Number one, a public forum to enable data classes to emerge from proposed data items. The second is the workgroup structure, or the data class workgroup, which assumes the role of a steward and defines the data class and prepares it for testing. The third is, the cycles of testing or refinement in pilot and production settings. Fourth, the application of regulatory authority of HHS to promote adoption of items in the USCDI.

Our next slide, Terry will walk us through some of the key things blocking interoperability.

Terrence O'Malley, Massachusetts General Hospital

Thank you, Christina. Good morning, everyone. This is the intro to the intro. Thanks to Dr. McDonald, we have this hierarchy of reasons why interoperability has been so difficult to achieve. I will walk you through it. Our attempt was to create, in this USCDI process, a way to address each of these issues – some of them in one stage and some in several stages.

The first reason is that there is no data. No one is collecting it. No one realizes they need it. We need a process to identify things that are important that we are not even collecting, that we're not even sure about. This is the most difficult data class. You don't know what it is. You have no standards attached to it. You have to consent someone to get it. You have to convince some standards development organizations to create the standards. Then, you have to convince industry to collect them, refine them, test them, and get them out. This is a heavy, steep lift. But, there may be data classes that emerge that we haven't thought about yet.

The next class is that there is data out there. It exists, but it is not being collected all or in part. In many ways, this is like the first data class. It is one step easier. At least it's out there. The question is, is there value in collecting it, and is it worth the effort to get it? We needed a way to somehow reflect the value of the data.

The third group is that the data are collected, but there are no semantic standards around them. So, they are collected in a non-standardized way, but at least they are collected. This is a group that requires the standard development organization to create the necessary semantic standards, first and foremost, and then the process of how you get the standards adopted, how do they get applied, how is it collected, and so on down the line. Each one of these levels is a little less complex than the level before it, but they all end up going on the same common pathway.

The fourth group is that it is collected and there are standards, but they are not being broadly applied. This is one of the major roadblocks. There are standards out there, but for reasons that are known only to the developers and the creators of the large systems that are collecting the data, it is not consistent. So, you end up collecting a lot of data, but you are not able to share with everyone because you can't understand it. There is no shared vocabulary. That is a huge problem. That is, I think, going to be more of a regulatory response to that. Someone has to have a reason to do it.

The next group is again similar. It is collected. There are standards. It is being collected with the standards. Then, something happens. There is a set of local codes or non-widely adopted standards that are in play. There, within the system, you have sort of interoperability, but you don't have interoperability because you can't get those local codes outside to have any meaning to anyone else. That's again a regulatory issue. There is going to be a carrot, which might be, "Let's demonstrate how this might work," and show them a process that's effective. And it might be a stick that says, "Well, the regulations say you have to do this." Those are probably going to be the two approaches.

Finally, once you've done all of this, there were very few good examples of the workflow outside of your own organization. How do you get the information around to the other folks that need it? It needs to demonstrate the pathway.

That is the framework, the thinking, that went behind the recommendations that we will go through next. We will go through and tell you what the stages are, as we've reworked from the three to six stages in the process, and the rationale behind that. We will take you through the details.

We had the following recommendations based directly on our charge. There are four of them. One is the maturation process. How many stages do we need in the USCDI process and why do we need them? We will go through that. And then, how should the USCDI be expanded? The bottom line on that is it really should be expanded as the data classes make it through the process. It is hard to put a timeline on anything, just given the variability. How long does it take to develop standards? How long does it take to apply them? How long does it take to reprogram everything? It is very hard to predict what data classes will be ready when.

The third recommendation was that we establish or suggest a process for publishing the USCDI. We will tell you it will be annual with periodic bulletins. We will go over that at the end. Finally, how do we incorporate public feedback? We have wrapped the public around the term stakeholder. It is really how do you get stakeholder feedback through all this, including the public as a key stakeholder. We have some recommendations on that.

So, let's dive into the six stages. Here they are. We have the three old stages – emerging, candidate, and USCDI. They emerged unscathed in our process, so congratulations to ONC. They did fine. We did not tinker with them very much at all. But, we thought we needed some sort of bookends. That is where stages one and two came in. How do we build data classes? How do we figure out that some group of data elements has meaning to some set of people? How do we identify that value?

And then, once we identify that, how do we make a data class out of it? Once you do that, getting it into emerging, candidate, and USCDI is relatively straightforward. And finally, we added a sixth stage, and that is the goal of this whole process, to identify data classes that have been widely deployed, widely adopted, and widely in use. The goal wasn't to get into the USCDI. The goal was to get out of the USCDI, and you'd essentially be retired because you have now succeeded.

I'm going to go through each stage, one at a time. Each of the slides for these stages is constructed the same way. We tell you what the purpose of the stage is, how you get into it, what happens while you are in the middle of it, and how you get out of it. A then, there's a final section on the recommendation of what issues do we need to nail down before we can put this process into play. This is Christina's point about testing this process in pilots – the whole USCDI process – and some of the issues that we need to clarify in that testing process.

Stage one we called Proposed. The goal here was to create a process that was wide open. There are no barriers for anyone to propose anything. Any stakeholder, individual, practitioner, home- and community-based services, public health, CMS, or whoever could propose a set of data objects or data classes for consideration and propose them into just some sort of shared public resource that allowed people to go look at what is being proposed, see if they could identify communities of interest around particular data elements and items. And, from that development of the communities of interest, create enough of a constituency that sees value in those particular data elements or classes, and will help move it forward.

That is really the purpose of Stage I, is to really widely seek out nominations for data of value and then to package it in a way that you can identify who might be the group that will help push it along. So, you get out of this Stage I when you have created a sufficiently large amount of value. One of the issues we will want to test is, "How do we measure value anyway?" Is it time? Is it money? Is it reputation?

Almost any metric of value is probably worthwhile. It is the same set of metrics for cost as well. It will be a combination of how you achieve net value – what is the value you will gain, and what is it going to cost you to get it – that will be a tension that goes throughout the whole process. It is not unique to Stage I.

The things that we thought we might want to test in this is, does this even work. Can you ask the public to suggest data items, find communities of interest, package them together, and move them on? I think you can, but I don't know. We probably want to look at that. Then, we don't really have a good idea what this will cost. There will be costs in setting it up and maintaining it. That is probably an ONC cost, I would think. The question is, can you really identify these communities? If you can, how well and clearly? And then, how do you measure value? If that's a criterion for leaving this stage, then we need to have some sort of objective measure of value. But, I have a feeling it will be like beauty. We will know it when we see it, but we are not exactly sure how to put it down on paper.

So, now we have found sort of a proto-data class. We've found a bunch of data elements that seem to be related to something that has value to some people. Now, we will kick it into what we call Stage II - In Preparation. This is preparing a data class. That is the job of Stage II. We have figured out we have the valuable commodity, we think, and now we have to actually make it a data class. This is a lot of work. It is not only just creating a data class, which means you will define what is in the data class. You will be clear about what is in it and what is not in it. You are going to have to find the appropriate semantic standards that apply to these data elements. And, if they don't exist, get someone on the development pathway. Get a standards development organization picking this up and working with it. We know the cycle time on that

is pretty long.

And then, in the meantime, you will want this group to try to harmonize these data objects so that, if CMS is asking for one thing that is similar to what public health wants and is similar to what home- and community-based services want, is there a shared common vocabulary that we can apply? This process of harmonization is really critical and very difficult. We shouldn't underestimate how hard this is. It will take time and effort to do this well. That will be one of the challenges of this group.

And then, finally, once you have done all of this, you really just want to create enough of a data class, with standards wrapped around it, so that it can be passed on to the next stage and be tested. It is really the point of this stage, to get something that can be tested. There are already lots of data classes out there that are well-defined, that we will have no problem getting through Stages I and II. They will fly through. They will be rubberstamped and off and gone. There are some, however, that need a lot of work, particularly the attachment of standards. That is hard work. It is necessary work if we want to have interoperable data.

That is Stage II. How do you get out of Stage II? You get out when you are defined well enough that you can be tested. There is probably a technical set of definitions that we can apply to that. We did not dive deeply into what those might be, but I am confident we will find some.

It occurred to us at this point that we are likely to see one data class, or one set of data objects, but it may emerge out of this In Preparation stage in two forms. It may emerge in a highly specified, machine-readable, computable form, which may take longer to get to and get out. The value there being the ultimate value of machine-readable data. But, it may get out in a different form. That is a form that is wrapped in enough standards to know who the individual is, what the data is in this particular data class, and who it's going to.

You will have to have a minimum set of standards to direct the traffic and identify what is there. But the payload, what is in the data that gets sent, can be unstructured. It could be an image, text, radiology report, clinical notes, advanced directives, immunization records, or a medication list. This may not so much advance interoperability because you are just getting a text blob, but it will certainly advance patient care because it will move information that is available, collected, and ready to move. We just need to get moving.

So again, two ways of getting out of Stage II. One is a text blob and one is a highly structured standardized set of interoperable machine-readable data. But, those paths are likely to diverge. But again, there are some data classes that meet both standards already and they're going to fly through.

The issues we thought we might want to test in this are, how hard is it to stand up a data class work group. The concept of the data class workgroup is that it is a voluntary group of stakeholders with an interest in this information, who have to work to do all of the tasks at hand. So, can you find volunteers who are willing to do this? Because it is a lot of work. The other thing is, how much support will it take for them to do it? The model in the back of our minds was something like the S&I framework, where ONC stands up a process and a platform and gives support, but the data class workgroup does the work. But, they need guidance and help and so on. The question is, what does that mean for ONC in terms of resources?

And then, the question is, will it work? You have a bunch of interested, committed volunteers. What is the skillset? Are they able to make the decisions that need to be made? Does there need to be more of a structure around this? We felt that it was important that the data class really has to have a steward. It has to have an interested party that will want to see it all the way through the end of the process. That won't happen spontaneously. I don't see a lot of volunteers stepping forward to say, "I am going to take this data class, and we are going to get

it to the end." If there are, let's get them in and get them working. It is likely to take a fair amount of effort and structure to get that done.

So, can this data class workgroup do the work we are expecting it to do, or is it going to need more help? One of the other issues that was raised was, "It sounds like it is really hard to get out of Stage II." It is real hard to get out of Stage II. So, maybe we move some of this work into Stage III, particularly around the standards and how they are applied and whether we sort of merge it into finding draft standards and testing at that level. There is some tweaking to be done. But, the general principle, whether it is Stage II or Stage III, is less important than the fact that this is work that has to be done in order to get a data class ready to advance interoperability.

Now we get to the easy part. This is the part that was well thought out before we got to mess around with it. Once you get into Emerging, you have a data class that is sufficiently defined that you can actually test. Someone can say, "Okay, I will try this in pilot." You have standards available for testing. You know what you're doing. You can get this out into pilot and tested, and it will likely require a series of revisions, modifications, retesting, and on and on until it is tight enough to get out of the pilot phase and some brave company will say, "okay, I'm going to deploy this at scale and see how it works in a commercial venture."

That is the goal of Stage III, getting this ready for someone to pick up and really push. That is how you get out of this stage. The things you want to ask about while you are in Stage III is again, what are the resources that we will need for pilot testing? Who will do that? Who will step up? Will that be voluntary? Will that need support? We don't know.

And then, the data class workgroup – can they do the work of redefining and revising the data class at that stage? Is there enough technical know-how? Once you get out of Stage II, which is really about value and starting to get the technical specifications, and into Stages III and IV, you're really talking about technical stuff. Is the workgroup the right workgroup? What level of testing do we need to be satisfied? How many pilots – one, three, ten? How often do you have to do it? How many revisions can you take? It is really going to be a question of – you get out of Stage III when you have something that somebody of commercial scale is willing to work with. That is a fuzzy definition, but again, we may be able to have some very technical specs wrapped around that. But, we did not dive into the technical specs. This is one of the things that we want to figure out in testing the process.

Then, you get to Candidate. Candidate is a really important stage. It's hard to know how long it will take a data class to get through the candidate stage. But, once you are there, this is a flag to industry that says, "Heads up, guys. It is coming your way. We don't know when it will get there, but it will get there." 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. It may take a year or more to get through the Candidate stage for some data classes. But, once you are there, this is the heads up to everybody that here's what's coming, so pay attention because you are going to be asked to do this sometime in the near future – TBD.

Again, this is testing at scale in a commercial venture, and there will probably be more modifications and revisions and some retesting that has to be done. The whole process of just making this a not quite cookbook but almost. You should be able to take this data class off the shelf. The specs should be there, and you should be able to put it into your system with all the work that is required in doing that. But, you should not be in the press of having to retest everything, or redevelop, or redesign, or re-specify. It should be ready to go.

What we need to do in this stage is the same as Stage III. How much testing is enough? How much is too much? If it is too much of a barrier or not enough of a barrier, we have to see how

it works. Can a data class workgroup do this work? It is even more technical. Or does that job of retesting and defining fall to some other group, particularly the organization that's actually driving at scale?

Finally, almost to the goal line – USCDI. Once you are in the USCDI, once you've gone through the Candidate stage, you are now tightly specified and ready to go. Anyone can put this into effect if they have the will, energy, and resources to do it. The challenge on this stage is how do we encourage that will and energy and resources. So, what are the levers that exist to move this data class to wide deployment and contribute to interoperability? So, what are the policy levers more than anything else at this point? How can we leverage TEFCA in this process? How do we work together on this?

Once you get to USCDI, that is not the endpoint. The endpoint is getting out of USCDI and being designated that you're widely adopted and deployed. That gets you to Stage VI. We are thinking that the RCE might be able to track the extent of deployment by just monitoring traffic, and monitoring the traffic that has to do with the data classes. We will see how that works. It would be nice if we could do it with big data instead of having surveys. Are you doing this? I don't really care what they answer, we want to see what is going through the pipe.

So, those are the stages. Do we want to talk about those now or should we – yeah. Let's pause.

Robert Wah, DXC Technology

I think it is worthwhile. That is a lot of material, and it is important. I think it is a good summary of how your task force look at this. It is worth having a discussion now and have input on that. Why don't we start with Clem?

Clem McDonald, National Library of Medicine

I have some differences with the committee about the number of levels. But, I think, the key question is, are we trying to measure the reality or are we trying to change it? If we are trying to measure the reality – how far have we gotten, just to put it up in the newspaper – then, I think all six are good. If we are trying to change reality, I will be dead before anything else happens with the six levels. So, there is guidance on what's the primary goal of this thing. Is it trying to get to a point where there would be a push to change the reality, or are we trying to just keep track of it and keep score?

Genevieve Morris, Office of the National Coordinator

This is Genevieve. I'll just jump in. The goal is to change the reality and get to, over time, all data as required by 21st Century Cures. So, while measuring, I'm sure, is an important component of this, that is not the end goal of the whole process.

Clem McDonald, National Library of Medicine

Well, then, I think we should squish the levels considerably.

Robert Wah, DXC Technology

I'm trying to see who puts their sign up and in what order. It's a little challenging. If I get you out of order, I apologize in advance. I think Denise is next.

Denise Webb, Marshfield Clinic Health System

Thank you. I want to commend the USCDI task force for their work. I think the work on this

part really resulted in a thoughtful, logical approach and processes. I realize that it's six stages, but quite quickly, without repeatable, ubiquitous, well-established processes, we won't have the predictability that we need. I think it provides the ability to manage expectations and address immediate needs by permitting sharing of non-structured data while a data class is being addressed.

I really appreciated how what is proposed will ensure the need for harmonization that need be more easily identified, and then ensure harmonization is addressed through a central repository of data class information for the life cycle of the data class. The processes, I also think assign roles, responsibilities, and accountabilities. Obviously, the details have to be worked out.

I think it creates a broader work flow and pathway at a national level and provides some data governance process nuggets that I personally would consider in my own health system – present effort to formally establish data governance, policies, and processes. There are multiple actors in this that want data for different reasons.

I really like the proposed Stage I process because I can give you a specific example. When I joined Marshfield Clinic Health System, I joined as their CEO over their health IT company that was developing their next generation EHR. We have stopped doing that since, and we're going to go to a commercial EHR. But, our researchers at our research institute came to me and said, "Can you collect information on veteran status? Can we have that added to our existing legacy EHR and put it in the new HER?"

Being a veteran, right away I had lots of questions. What do you want to collect? What objects do you want to collect in that data class? Do you want to know whether they were just a veteran, or what branch of service? What is their status? Are they active duty retired? What different periods of time did they serve when they might have been exposed to certain agents that affect their healthcare? On and on and on, I had all these questions. Is there already a standard around collecting this? What about our HER vendor that we use in our hospitals? How are they collecting it? Do they even make that available?

So, just in our own health system, trying to vet whether you will establish a particular data class was challenging. I really like this. I think you did a nice job.

Robert Wah, DXC Technology

Ken is next and then Anil.

Anil K. Jain, IBM Watson Health

I agree. Great job on this. I think on slide seven you did a nice job of outlining some of the challenges of sharing data. But, that is missing that might be important to include in the discussions around the different stages, would be those that might have a perceived competitive value to organizations versus those who are holding on to the data and how that gets folded into the various stages, especially around the value proposition.

The second comment is, I don't see any discussion here about when data classes could be either retired, because they are no longer necessary and might need to even be deprecated from the requirements, or when they get superseded by something that replaces it as we get enhanced attributes or things in healthcare change. Just those two thoughts.

Terrence O'Malley, Massachusetts General Hospital

If I can just respond. Great. Thank you very much. We are going to come around to the

question of retirement. We didn't have a good solution for it. We just flagged it as something somebody ought to think about. Thank you.

Robert Wah, DXC Technology

Ken?

Kensaku Kawamoto, University of Utah Health

This was already alluded to in the notion of what kind of sponsorship or coordination there will be from ONC. Having been engaged in these kinds of things, this does take a lot of effort. I think the challenge is, this is a classic public good, where the best-case scenario is you don't lift a finger and other people work hard in volunteering to get everything done. And then, magically, everything is how you want it.

I think the challenge is, everyone will be in that situation where you are waiting for someone else to just go ahead and do it. Any given individual or institution, your best-case scenario is someone else does all the work and you get the benefit from it. I think it is just a reality, even when you look at current, barely mature FIHR specs, for example, you see things like value sets in there where you're like, "How come nobody thought of this?" or, "How come they didn't think about the difference between a facility and a professional bill who anybody who has actually used that data would be like, 'I can't believe they haven't thought of this?'" There are so many things like that that will come what. Just a general question, for a public good, how do you make it happen?

Robert Wah, DXC Technology

Great. Thanks. I'm reminded that we are doing this on audio for some people. It would be helpful if you will identify yourself before you speak. I'm probably not doing a good job of identifying you when I name you. So, you can just say, "This is blank," and go ahead and say it. Thanks. Aaron, I think you're next.

Aaron Miri, Imprivata

Yep. This is Aaron. Great job. You guys did an excellent job with this. I think it's very helpful to have it. I think the stages are necessary gates and checkpoints to make sure we sanity check the whole process throughout. A question you may want to consider is, and I take this from personal experience – I happened to be a CTO of a very large health system in Dallas, Texas during the Ebola situation. As we were trying to figure out everything that was going on at that time, we worked very closely with our EMR vendor, CDC, and others to figure out what we should be asking for from the patients presenting to make sure we could stratify and qualify if it was a larger issue than what it ended up being. At the time, you can imagine the chaos.

So, is there a need for, upfront, to put a fast track process in and for situations of epidemiology, and other issues that come up like that, to say, "Oh, shoot. We have an issue. How do we get this out there so that everybody can be leveraging a qualified class or whatnot?"

Terrence O'Malley, Massachusetts General Hospital

Great comment. The committee considered that briefly and said, "I think this is beyond our scope, but let's call it out." So, actually, recommendation eight or nine or seven is precisely that. There needs to be some sort of process for fast tracking. But, we were unable to come up

with one.

Robert Wah, DXC Technology

Steve.

Steven Lane, Sutter Health

Stephen Lane. I just wanted to echo what Aaron was saying. I think the importance of keeping a focus on urgency – it is not just for emerging data items or classes, but really this entire effort warrants a sense of urgency. It was published in draft form. I think we have made it richer in the task force. But, this should not slow down the process. The intention of the multiple classes, Clem, is not to make this last until after you finally retire, but rather, I think, to provide some structure.

As you say, one of the recommendations is that there is no minimum time that anything needs to be in a given stage. The stages are descriptive. I think they are helpful in terms of saying what work needs to be done. But, if it can all be done in a season or a quarter, that is great. I think we need to keep the pressure on so that the USCDI continues to advance.

Terry, I will take a little exception with the way you are characterizing the final stage, the idea that a data class retires out of USCDI. I think it is more that it just becomes fully baked into this core data for interoperability. Retirement, in that sense, doesn't mean we stop interoperating. There's another sense of retirement in that a data class is no longer useful. But, I think the way we describe the final stage is just to say that it is fully mature and interoperating on a daily basis.

Terrence O'Malley, Massachusetts General Hospital

Yeah. Thank you.

Robert Wah, DXC Technology

We also have a comment on the phone from Arien. This is the Arien that I meant to say before that one down there.

Arien Malec, RelayHealth

Thank you. I really appreciate the multiple stage approach. With respect to the definition of terms, or the introduction, I really like the six-stage classification of common causes to prevent data from being shared. One of the things I didn't see in your early stages of the USCDI evolution is addressing the blocking factors where data does not exist or exists sporadically. It sounds like, once you have data that is collected, there are no semantic standards for normalizing it. You have a well-established process for catching that and leading it through preparation, development of standards, promotion to candidate, et cetera.

In cases where there is a high priority need, but there is not collection on the ground, I don't see any place where you have addressed that in your recommendation. I wonder whether you would comment. And, as a meta comment to that question, I note in the area of clinical quality measurement in other kinds of data collection we've done on meaningful use, the cognitive burden and time burden of collection on clinicians has been a frequent critique. I am also interested in how you would assess the business drivers for collection, as well as the cognitive burden for clinicians on requiring additional collection of data in order to improve interoperability. Thanks in advance.

Terrence O'Malley, Massachusetts General Hospital

Thank you, Arien. Those are easy. Much to the delight of the clinicians in this group, there are lots of efforts underway to simplify and reduce the number of quality measures and tie the quality measures more closely to actual clinical processes. So, we can all applaud those because, I think as we moved in that direction, you will find the data collection for quality measures becomes a systems process rather than a clinician process.

To the extent that that occurs, wonderful. To the extent that it doesn't occur, and all the other adverse consequences that you mentioned continue, yes, there will be a lot of burden and a lot of cost while this rolls out. Having been on quality measurement and development – they are developed with the best of intentions. There is not one quality measure out there that is not being put forward because somebody thinks it will improve care and improve outcome. But it is one more straw.

Every quality measure that appears, good as it may be, just adds one more small incremental burden. It is hard to know what balance point is. So, to answer your question, we didn't have a good answer. 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 data sets and putting them through this process. The idea would be to combine the quality metrics, the data required that, with the data required for clinical care. To the extent that those can by synced, we are one step closer to getting quality measures that are driven by clinical process. I hope that answers your question.

Christina Caraballo, Get Real Health

You also mentioned the barrier of information blocking. I think that is where we have a lot of crossover, and the importance of mapping the USCDI with the work that TEFCA is doing and the RCE. Our goal is to make it where there are no questions. By the time you get to Stage V of USCDI, the data is ready. It can be exchanged. There are no issues with the data class. Then, I think it will be up to the task force to make sure that different organizations are exchanging it.

Robert Wah, DXC Technology

I think the next person is Denni.

Denni McColm, Citizens Memorial Healthcare

I just have a quick comment. Good work. On Stage VI, when we get around to measuring that widespread adoption, I hope it will be more than just moving data. Because today, we are moving a lot of data that is not being actually used by clinicians on the other end. Hopefully, that will be the ultimate measure.

Terrence O'Malley, Massachusetts General Hospital

That would be a wonderful measure, but I don't know how we are going to measure that. It would be great to have a way for the user to vote on the usability, the appropriateness, and the timeliness of the data. It would be nice to get that feedback. I am not sure quite how we could do that. I think it is a great idea.

Denni McColm, Citizens Memorial Healthcare

Even access to the data. I know our clinicians will access data a time or two, and if they don't

find it of value, they won't access it anymore. I think there are some measures out there.

Robert Wah, DXC Technology
I agree. Clem, I think you had another comment?

Clem McDonald, National Library of Medicine
I wanted to touch on the burden issue a little bit. I think, if we had in one of the classes the question of who is asking for it and who has to do it. Because a lot of people want someone else to do it. If we expose that – I hear researchers say, "Well, the clinician should've collected this better." But, it's for them and not for clinical care. Across the board, if we kept track of who wants it and who has to do it, it might clean up some of this.

Terrence O'Malley, Massachusetts General Hospital
Clem, I could not agree more. The benefits and the costs of interoperability are not evenly distributed. I think that is just the fact of life.

Clem McDonald, National Library of Medicine
Well, it's not the interoperability. It's the initial collection where the issue is. You can't do it, if you don't collect it. We get a lot of stuff. I would love to have this, and physicians are not doing it. They only have a finite amount of time, and it is getting tiny nowadays.

Terrence O'Malley, Massachusetts General Hospital
Good point. Thank you.

Robert Wah, DXC Technology
Sasha?

Sasha TerMaat, Epic
I just had a question about how a data class progresses through the stages when it's objects and attributes are at varying levels and would be classified in the stages differently. One of the examples in your recommendation was social determinants of health. I could imagine how certain social determinants of health would reach levels of adoptions or levels of specifications and standards at different points in time. So then, I was trying to follow in my head, when would the class of social determinants of health move stages if it might consist of 40 different objects that were each at varying points?

Terrence O'Malley, Massachusetts General Hospital
That is a great question. We did not really delve into that. That is certainly an issue that will have to be clarified. Does the whole data class lag until the final object is specified? Maybe. Or, maybe that final object gets kicked off the bus and the data class moves ahead. The question is, if that final object is kicked out of the data class, is there still enough value for it to move forward? I think it is a balance between value and maintaining value through the process against the technical specifications. I think that will be a tension that exists at every stage. You are right to call it out. It will be an issue.

Robert Wah, DXC Technology
Steven?

Steven Lane, Sutter Health
Steven Lane. I just wanted to follow-up on the comment, Denni, about measuring the utility and the use of exchanged data. I think this is a very important area, and one that we need to do more work on. I know that ONC did publish and receive public comment on how to measure interoperability. I think that, as that work advances, we should be drilling down into this. As we share provenance data, and as that data stays with the elements that we receive into our systems, we should be able to ask that question. What is the data I received from Brett's system actually looked at? This also becomes very important as we define the legal health record, which is based on what data was accessed and utilized in supporting medical decision making. I would hope that we could leverage the HITAC, perhaps, and put it in our parking lot as something that we might be able to contribute to in terms of some of these metrics and how to standardize those so that we can get all the vendors collecting that data in a similar way to actually be able to compare it.

Robert Wah, DXC Technology
John?

John Fleming, Deputy Assistant for Health Technology Reform
Just responding to the issue that Sasha called out, which is very real and, admittedly, I had not thought of it before you said it. Not to make this sound easier than it would be, but it seems like it would be manageable – social determinants of health being a perfect example – to chunk that up into social determinants of health stuff that is ready Phase I, and social determinants of health stuff that isn't ready yet Phase II.

Robert Wah, DXC Technology
Cynthia?

Cynthia A. Fisher, WaterRev LLC
Following up on John's comment, I think the committee has done a great job to lay out the various stages of addressing interoperability. The concern is the timeline and the timeframe to deliver that to the marketplace. One would think that the empowerment of the patient is first and foremost. So, a patient can navigate their own care needs, their films, the radiology report, their prescriptions, their allergies, and their physician summary of notes. In order to have this in hand in their mobile device, one could say we could really solve interoperability if we made, whether it is the first phase, available say within a year, and make it a condition of payment.

If it were a condition of payment, that no one got paid for their medical services unless the digital record was provided to the patient in whatever mobile form it could be, it may not be perfect, but in Stage I done is better than perfect. I would beg us to look at the approach of delivering Phase I in a human readable form that could be shared with the patient as soon as it is digitally available. The patient could then share it to whomever the patient desires – the physician, etc. – and at least start with a human readable form, digitally available, as a condition of payment. And CMS and HHS has financial leverage to be able to start that domino

to fall into place. Secondly, we could move toward the standardization to have machine readable, machine analyzable, and well-organized data sharing. Again, I encourage us to keep the patient, their family members, and their family members in mind, for done is better than perfect.

Robert Wah, DXC Technology

Seeing no other comments, do you want to move on to the next recommendation?

Terrence O'Malley, Massachusetts General Hospital

Christina, you're up.

Christina Caraballo, Get Real Health

Sure. Yeah.

Robert Wah, DXC Technology

Clem, did you want to comment on this?

Clem McDonald, National Library of Medicine

Some early stuff. I think this may not be anything the group wants to get into. The definitions of object and class and all of that are not lined with what technical people think of them. Classes have attributes and the object and classes are one. I think it's the same thing, and we need another layer in there. This is a boring subject, but I think we'll mislead people who are already technically oriented to what we're talking about if we don't clean that up a little bit.

Christina Caraballo, Get Real Health

Clem, I think that is an excellent point. We had to move past this area in our task force discussions because we didn't have the time for it. One of our recommendations, that we haven't formalized, and Terry and I have discussed, is we were surprised that we didn't have these definitions. It is something that ONC could possibly do to help us out. This is something that is a fundamental thing for us to understand what we are talking about.

With that, I am going to move on to the next three recommendations, which are two through four, starting with our expansion process. For the expansion, we want to reiterate that we think this is going to be very organic and things are going to move as they are ready. We wanted to establish a process for any stakeholder to propose a data class without restriction. This was an important piece of our Stage I, to be able to get anything that has a need to someone or a value to someone looked at.

We wanted to add the data classes to the USCDI after they successfully went through stages one through four. Once they have met all the criteria through these stages, then they would become part of the USCDI regardless of the timeline that they've taken or the amounts that are in there. We don't want to put a number of how many we would add each year. We want them to come in as they are ready.

And we want to establish a process to review the progress of the data classes through Stage V, including the timeline for advancement. We want to be able to look at some of the gaps and understand where a data class is getting stuck in the process so that way we can better identify how to progress it forward or take it out. Another thing we've discussed of the task

force, is that a data class could go up and down in the process.

And then, the last point that the task force had on this was, when the data class advances to Stage VI, that's when the RCE has determined and let us know that there is widespread adoption. We are going to go through these three recommendations and then open it for comments.

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 did discuss this with the ONC team, what worked with their timelines as well, before just proposing the annual and the calendar year. We thought the reference edition should be similar to the interoperability standards advisory reference edition. But, while there would be an annual publication or reference edition for public comment, we thought it was important that we have the ability to make recommendations and have dialogue throughout the course of the year.

So, we wanted to also incorporate the use of public bulletins, that would let the industry know on a quarterly basis what was coming, what the major changes are more regularly. We thought at a minimum, we should have this available as a PDF, but we would really like to move to having a more interactive document where people can comment on the different data classes, have open collaboration, and even discuss some of the barriers.

With this, we went through each of the stages and gave some general ideas of what would be published, or could be published, as an example. Stage I could include the data objects and classes that are being proposed for transparency of what's out there. And, the stakeholders and use cases – identifying the different stakeholders and use cases we thought was a very key part so we could understand, as we transition to that overall net value, where we're not just looking at the technical requirements but looking at the overall value of a data class to move.

In Stage II, we were recommend publishing the status of the data class work group, whether it's active or inactive, along with the status of the data class itself. In Stage II, we think it would be important to reference the technical issues identified by testing, that have both been resolved and may still be outstanding. For Stage IV, we recommend publishing the testing status, technical issues, both resolved and outstanding, and the scope and requirements for beta implementation, which could also be a reference to where to find materials.

We thought it would be important that anything that is available to help guide and educate stakeholders through the process, there would be links to it. An example of this would be a link to the interoperability standards advisory where it was relevant. For Stage V, for the USCDI, we would recommend publishing a detailed scope of requirements for production or implementation, and again, with reference to where to find the implementation materials. This is also another way to, with Stage IV and Stage V, alert industry that this is coming and is soon going to be most likely requirements.

And then Stage VI, measurement of adoption levels – we wanted to reiterate the importance of this. Stage VI is going to allow us to see what is being used and what is not by the industry. So, the purpose of the whole publication is to be very informative to multiple stakeholders and encourage and recruit people to participate in the data class work groups.

With that, we will move on to our final recommendation that's not part of our bonus recommendations. This is to get stakeholder feedback. For this, we have recommended that public and stakeholder feedback is supported by two parts of the process that involves all the stages. The first, is the annual USCDI reference edition with public comments, which I just discussed in the last recommendation. And the second, is ongoing reporting and an opportunity for comment within the public resource as progress is reported through Stages II-

IV, and as the data object is actually assembled in Stage I.

So, specifically, the task force has recommended a two-month public comment period following the release of the USCDI reference edition with an open public forum to promote the collaboration and information sharing in Stage I as well as report progress in a public resource under each data class to solicit public comment through the course of the year and as the data class becomes more mature. And then, report in Stage III and IV as well. So, that concludes our recommendations two through four, unless Terry wants to add anything.

Terrence O'Malley, Massachusetts General Hospital

Nope. Thank you.

Robert Wah, DXC Technology

Great. I think Carolyn had a comment about IV.

Carolyn Petersen – Mayo Clinic Global Business Solutions – HITAC Committee Member

This is Carolyn Peterson. I'm speaking personally, and not as a reflection of Mayo Clinic position or policy. I want to thank you for these comprehensive guidelines and for all of the thought process and work that went in, particularly with regard to the expansion and clarity of the steps that classes go through, and the guidance for helping people get them through that. I did want to ask a question related to this consideration of the open public platform for promoting collaboration and information sharing in the first stage. I'm wondering if you thought at all about how to engage patients and consumers in that process? I think there are some strong patient and consumer advocates who are on the committee and, of course, some people who follow our meetings very closely. However, for the average patient and consumer, the infrastructure of ONC and knowing where to go and how to do that is somewhat far removed. I'm wondering if any consideration has been given to getting that patient and consumer involvement outside of the intra-agency situation?

Christina Caraballo, Get Real Health

Yes, that is definitely an excellent point. Two things. We had thought it could be a very similar platform to the S&I framework, but specifically to the patient. We think it is very important, and one of the things that was discussed is to have educational material and make this not a scary standards document. But, through the use cases and business cases, present to people what is being looked at and why.

So, presenting the use cases with the interested stakeholders and lists of those interested stakeholders, we are hoping to steer industry dialogue and identify larger groups by looking at specific things, down to that principle data element. This is what I need. Being able to put that in, so the different groups within the whole ecosystem can start looking and seeing where we have overlap and similarities to help push things forward collectively. It has that overall really important net value and not just the technical value. Terry, did you want to add to that?

Terrence O'Malley, Massachusetts General Hospital

In our bonus recommendations, we touch on that. I think it's a critical issue. We were fortunate on the task force to have a lot of patient advocates.

Carolyn Petersen, Mayo Clinic

That's true. Thank you for recognizing the challenges associated with the scary standards document, both for consumers and patients, and likely for some other stakeholders in the process. It sounds like we are going down a path that can be more inclusive than things have been sometimes in the past.

Robert Wah, DXC Technology

Is there someone on the phone that had a comment? Alright. Next to Cynthia.

Cynthia A. Fisher, WaterRev LLC

Thank you, Robert. I'd like to make a suggestion following up on Carolyn's point, that perhaps ONC, Lana's group, and Terry and Christina's subcommittee work together to perhaps identify the best way to address a diverse population of consumer participants in the stages of development of the standards, from teens to octogenarians, plus. If we could also think about how the future generations digitally receive their information today with that opening of an emphasis to the younger generations as we look towards the future. And then, finally, to look at those best in class, that have this direct-to-consumer digital experience, whether it be the Apples of the world, the Samsungs of the world, Google, Yelp, or Amazon, that may also look to participate from a consumer point of view, a social media type of view, to connect to this population and this engagement. So, perhaps it's a subcommittee of the subcommittee to identify how we can best address consumer input along the process.

Robert Wah, DXC Technology

Clem?

Clem McDonald, National Library of Medicine

I want to speak in defense of the scary standards documents. And, also, to distinguish that there are scary standards documents that are really ugly and should not have happened. And there are scary standards documents that are really pretty beautiful, like a mathematical proof. The defense is that the scary standards document is what made Apple Health possible and things like that. So, they're our air underneath, so we want to encourage people to work on them.

Robert Wah, DXC Technology

Other comments on this group of two through four recommendations? Okay. Then, as Terry continues to refer, I guess, we are into the bonus round at this point. So, we can move on to recommendation number five. I will also point out, for those on the phone, we have public comment period scheduled at 12:15. Because we publicized that as the public commentary period and people have made plans around that, we will try to be careful to adhere to allowing the public to comment at that time. If the committee is at a place where we are not quite done, we can probably resume after that. But, I want to make sure we are mindful of the fact that we have given the public a notice that that is the time to comment. We want to respect that notice. Terry?

Terrence O'Malley, Massachusetts General Hospital

Thank you. At no additional cost, we are bringing you five more unsolicited recommendations. Here they are. One, we wanted to test the whole process. Much as we trust in it and believe in

it as a task force, there are some members of the task force who believe more strongly than others. So, we thought testing would be important.

And then, recommendation six is, how do we guarantee the voice of the patient or the individual. Again, calling these out. Another shout out to harmonization and why it is important. And then, some issues around data class management where we raise the fast track and retirement issues. And finally, one that we didn't really tackle a whole lot but want to call out. That is the need for a good governance structure for this.

So, here they go. Unsolicited. Our testing recommendation was actually the mashup of two pretty well agreed upon issues. One is that this process should be tested, and the other is that we should support TEFCA. What was not reviewed with the committee was meshing them together and saying, "Well, let's test this process by developing and testing the data classes that TEFCA needs to get off the ground and get working."

In particular, the data classes would be a unique patient identifier. Can we specify a data class? Get it through this process? See how it works? Let TEFCA kick the tires and get it working. The other was patient authorization for the permitted uses, and the use cases to go with them. That would allow us, as the overseers of the USCDI process, to sort of test it out with two data classes that have tremendous value for the whole enterprise. And, the advantage of doing it with ourselves, is when we find failure modes we haven't taken private partners, on whom we are relying heavily for their volunteerism. We take them out of the loop the first time around. If we inflict any damage, it will be on ourselves rather than the public. This is our proposal, that we test and test it with things that TEFCA could use. That's recommendation five.

Recommendation six was the voice of the patient. This came out loud and clear. What did not come out loud and clear was exactly how we were going to do it.

Robert Wah, DXC Technology

Terry?

Terrence O'Malley, Massachusetts General Hospital

Are we going to stop between?

Robert Wah, DXC Technology

I think it might be useful. These don't all fall together, so it might be easiest for the group to discuss each one of the recommendations individually. I think it might work a little better.

Terrence O'Malley, Massachusetts General Hospital

Yes. Thank you. Sorry.

Robert Wah, DXC Technology

I know you were on a roll, but now that I've said that I now see – anyway, great. Thanks for that first recommendation. I have no idea the order in which these came up. I think I'm going to start over here just because I think I saw these come up later. Denise, why don't you start. I apologize if I don't get the order exactly right.

Denise Webb, Marshfield Clinic Health System

Could you clarify who you are referring to in, "we would only be inflicting damage on

ourselves?" Who is the ourselves since you excluded the volunteer private stakeholders?

Terrence O'Malley, Massachusetts General Hospital

Of course, 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 will include a fair number of other volunteers. You are right, the damage won't be contained necessarily within house.

Robert Wah, DXC Technology

It would be the workload or burden rather than damage, might be preferable terminology. I'm going to come this way. Aaron, why don't you start that way?

Aaron Miri, Imprivata

Sure. Aaron Miri. I love this recommendation, this optional bonus recommendation. I think it's excellent. I think testing it is important. Specific to the UPI, I think it's also an opportunity to tackle some of the very challenging items that have been sitting out there and lingering, that the healthcare community knows needs to be solved, and we can try some things very safely amongst private stakeholders. I think you can use the Apple initiative recently as an example of private companies getting together with advanced EMR vendors to make things work. I think, in the case of the UP, I fully support. It's needed in healthcare. I think you have the full support from a lot of folks. Just things like that to go tackle.

Terrence O'Malley, Massachusetts General Hospital

Thank you.

Robert Wah, DXC Technology

Sheryl?

Sheryl Turney, Anthem Blue Cross Blue Shield

Thank you. Sheryl Turney. I also think this is a great recommendation and appreciate you putting it on the table. But, I have a couple things to throw out. Relative to improving data matching and unique patient identifiers, there has been a lot of work in the PAIR claim data space with how to do patient matching for public health. One of the difficulties that they're dealing with today has to do with some of the work. I think it's actually CMS that's coming out with a new identifier, and they want to be able to retain longitudinal patient records and now don't know how to match up this new identifier with all the data that they currently have. So, has there been any discussion from this group relative to how you would handle things of that nature?

Terrence O'Malley, Massachusetts General Hospital

No.

Sheryl Turney, Anthem Blue Cross Blue Shield

That something we probably need to –

Christina Caraballo, Get Real Health

Yes and no. Not all of it, but we will get into a recommendation later, where we have the harmonization. That will be looking at the different data classes that are being formed by different groups and organizations and how do we collectively do things, and not in pockets. We will get to that recommendation.

Sheryl Turney, Anthem Blue Cross Blue Shield

Okay. Thank you.

Robert Wah, DXC Technology

Clem?

Clem McDonald, National Library of Medicine

This business about linking patients is essential. For statistical work, you can get by with a five percent error rate or so, but if we are taking care of patients we could do bad things. In certain subpopulations, it's very hard to match on the available ones – like Hispanic and Asian names are often very similar. I think it is a tough reach, although I was glad to hear maybe it's happening, to be able to get a new identifier. Because I think it's banned by law, but maybe CMS can get past that. That would be great. I don't know why we don't at least allow the last four of the Social Security Number, because that will cut our errors down by thousands. And everything uses it. It's in commercial use all the time. I would at least plead for allowing that to be collected, or encouraging that to be collected, for the purpose of helping in matching.

Robert Wah, DXC Technology

Great. Yeah. Go ahead.

Tina Esposito, Advocate Health Care

Tina Esposito. I agree. This is a very difficult pilot, if you will, or test. But I also think it will stretch the framework appropriately, in that some of the newer approaches to identifying patients include referential matching – looking at addresses, and not just most recent, but five-15 years back – as well as having the patient identify whether these two records meet. If we think through it, it's tough. Yes. But, I think also there are different and innovative ways to approach this problem.

Robert Wah, DXC Technology

Thanks. Terry, do you want to go on to six? If you could, take your signs down after you spoken.

Terrence O'Malley, Massachusetts General Hospital

Okay. Moving on. The voice of the patient. Loud and clear. We have to figure out a way to get this representative, the patient, in the process. I think Leslie Kelly Hall pointed out that there is no natural constituency for the patient. There is no national organization that is going to come to the table, like the American Medical Association, to say, "We want the following things." So, our challenge is at what levels and how, do we assure that there is a voice? The RCE, I believe

its charter says it will include patient representatives in the process, in the governance structure, which is probably a good start.

But thinking about Stage II and this recommendation, how do we guarantee that there will be patients on the workgroups, particularly workgroups that have relevance or information that the patient may be contributing or benefiting directly from. That is a challenge. And, I don't know how that will happen. Most of the professional members of the workgroups are going to be on salaried leave from their organizations to participate. It's hard to get patients who are on salaried leave because no one is paying their salaries. We may have to figure that one out. And the final point here, the move to person centered care at all levels – and Kate pointed that out in the beginning – is really critical. What used to be nice to have – the patient's voice – is now critical. It is a must. We must include it. Period. The end. That is our recommendation number six.

Elise Anthony, Directory of Policy (ONC)

One clarification is that the RCE charter doesn't exist as yet. We are in the process of working on a cooperative agreement and funding instrument for that. But, there is not one as yet. That said, the recommendation, should it come to ONC, could be considered as part of our ongoing work.

Terrence O'Malley, Massachusetts General Hospital

Thank you.

Robert Wah, DXC Technology

Great. Carolyn?

Carolyn Petersen – Mayo Clinic Global Business Solutions – HITAC Committee Member

Thanks, but I think Elise just covered it so I'll put my sign down. But, I do appreciate that this wasn't a part of what the task force was asked to accomplish. I am grateful to see that it was not left out of this work because it's critical. I encourage ONC to keep pushing the pedal toward the metal on this. As you have often stated, patient engagement is at the core of what you want to do and it's very valuable.

Robert Wah, DXC Technology

Don?

Dr. Don Rucker, National Coordinator for Health Information Technology

Thinking about the patient engagement, because it is a huge issue, I was just making a sidebar comment. The way patient engagement works, or consumer engagement works, in a market economy, is entrepreneurs get in and provide new products. I'm wondering whether folks, as part of this number six recommendation, could come up with a way of getting some sort of competitors who might be in the business of providing new products to be part of this. Because they would potentially get paid to show up and have an economic interest that would be aligned with the consumer. I'm just wondering if folks have some ideas of who and how we might get in an interesting class of consumer proxies.

Anil K. Jain, IBM Watson Health

One thing to keep in mind – I have a grandson who has cystic fibrosis. My daughter, his mom, has been very involved as an activist in the cystic fibrosis foundation and so forth. A lot of good developments have come over the years. I think there is a whole pool of candidates out there among the chronic disease disorders – Rheumatoid Foundation – and I think they would be very excited to be engaged in those things and without renumeration.

Robert Wah, DXC Technology

Cynthia?

Cynthia A. Fisher, WaterRev LLC

Likewise, in the entrepreneurial world, and also in product testing and consumer markets, there are all sorts of vehicles we could utilize – from focus groups to user groups to market research. Survey Monkey is out there. All along the thread of the process, we can bring in a wide range of patients, family members, and caregivers through the threading of the process. I think it may warrant for us to think through, and perhaps in a subcommittee or small quick acting task force, to vet some of these ideas on how to best engage the end user customers.

Robert Wah, DXC Technology

Brett?

Brett Oliver, Baptist Health

I agree with all of the comments, and this is an additive to what was Dr. Rucker mentioned, Carolyn mentioned, and then Anil. I think the real challenge is that there are certainly committed stakeholder groups in the chronic disease space that are very interested in this. I think the challenge always is there are two filters. The first is, are you sick. We're leaving out a large portion of the population that would be motivated to have these discussions, who are well. The second piece is those individuals who are more highly engaged broadly in the process and in their care. That's another subgroup. To Anil's point at the very beginning, I want to make sure we are representative of a larger population. That is a challenge, but one we should note.

Robert Wah, DXC Technology

Christina?

Christina Caraballo, Get Real Health

I wanted to make a comment to Dr. Rucker's question about how we recruit patients. I think right now we are actually starting to see an uptick in the industry, where groups like HIMSS and the Personal Connected Health Alliance are actually building consortiums of patients. There's a group we go help that has a big bundling of patients across the country that they can offer services to different vendors to come in and look at their products. We are starting to see those being built, and I'm sure that Lana and her team are familiar with a lot of them. I think there are more resources then we are thinking exist that we can tap into. Thank you.

Robert Wah, DXC Technology

Carolyn?

Carolyn Petersen, Mayo Clinic

Just to follow-up on the previous discussion, and particularly to speak to Dr. Fleming's point about chronic disease communities. I think we should also be considering how we might do outreach among rare disease communities as well. In many cases, these are families and individuals who don't get the resources for treatment and research that we see with some of the more common chronic conditions. Those folks are real innovators in figuring out what can work for them and how they can work with the system to get the special unaddressed needs met. I also want to mention that, if you are interested in putting together some sort of task force on patient engagement, as has been suggested by Cynthia, I would be more than happy to volunteer to work on that or function as a liaison between this group or others to help further that work.

Robert Wah, DXC Technology

Great. I see no others. Terry, are you want to continue?

Terrence O'Malley, Massachusetts General Hospital

Data class harmonization. A fun subject for everyone. This is really hard. There are no two ways about it. It is difficult, but I think it is an essential piece of normalizing the data. Rather than have a similar data object that is called out in several different workgroups sail through the different definitions in each work group, I think, 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 of just what the data object is all about and how it is described.

Again, this is not an easy process, but it has to be done somewhere. The question is, where in this proposed process does it get done and how much support is it going to take to get done?

Robert Wah, DXC Technology

Questions or comments about this recommendation? None? Do you want to proceed, Terry?

Terrence O'Malley, Massachusetts General Hospital

Some of these are more mom and apple pie than others. Data class management. As it says, we recognized, but did not think much about, a couple of issues that need to be thought about. Once you have an established data class, is there a process to modify it? And, if you modify it, where does it go back? Does it go back to Stage II? Does it just get an FYI that we're just adding these six things? There needs to be a process about modification.

One thing that is certain, no data class is going to remain unmodified over time. There will always be changes, all the time. Part of those changes may be retirement, and part of them may be additions. But that is one. And that goes to the next one. How do we retire, put aside, or replace data classes whose benefit is no longer widely shared? That's another process we didn't have any suggestions for.

Then, and I can't remember who raised the point about what do we do in the case of an urgent situation where we need to get a data class up and running, whether it's Ebola or the next great thing is going to happen? Part of the discussion with some folks was that a lot of that will be done just by cobbling together what's currently available. But, there will be things that need to be specified. And again, the Zika case that was presented to the Policy and

Standards Committee about a year ago is a perfect example of needing to know pregnancy status down to about 12 levels, which no one was collecting – thinking about being pregnant, may be pregnant, unsure, tested positive, tested negative. So, that sort of work we need a process to tackle. That is an emergency SWAT team. I don't know where that will come from.

Robert Wah, DXC Technology

Additional comments or questions about this recommendation? Alright.

Terrence O'Malley, Massachusetts General Hospital

Now, we are on a roll. Finally, governance. This is a process that doesn't currently exist, and it's not going to exist unless there are rules of the road to make it exist and ways to make sure the pieces fall into place, that the pieces work, and that the ones that don't work get replaced. There needs to be another group that works on governance. Where will it live? Who will be in it? What is the purpose? Our plea is, "Let's get a governance group together to figure that one out."

Robert Wah, DXC Technology

Great. Other comments or questions about this recommendation?

Clem McDonald, National Library of Medicine

We have a history in ONC of the S&I framework and stuff. I don't know if we have to start a new invention. I think it would be ideal to reuse something, if you could.

Unidentified Speaker

I was basically going to make the same comment, which is, to Terry and Christina's points eight and nine, we have a number of standards organizations that are doing, and have done, tons of work. I think the trick is to make sure that these broader ideas are coordinated with what is out there, with some of the work that Steve's group is doing. I think we need to be mindful of the standards work that has gone on and make sure we leverage that and have the USCDI recommendations work off of the prior work.

I think that is very important. Obviously it's very helpful to have this framework for prioritizing. To me, when I look at USCDI, it's where are we as a country going to spend money on standardizing data? Who are we going to incent or force to collect and structure data? That is what USCDI is ultimately about. Terry, as you mentioned, microscopic things and burden are adding up. We have to be extremely careful about it. I appreciate all of this thinking on that, but I think we do want to hook it up with what we have as best we can.

Robert Wah, DXC Technology

Great. Other comments about this recommendation? Ken?

Kensaku Kawamoto, University of Utah Health

I completely agree with not reinventing the wheel. I think, if we do that – and S&I framework has been brought up a few times – we should look at what were the things that didn't work so well with those processes. Personally, having been involved in a number of those initiatives, I think the one that sticks out to me is a lot of these initiatives were focused on one thing. And there were a lot of related things. But, as those things came about, there was really a, "No, we

really need to focus on this and we are not going to harmonize and work together and collaborate because that's not part of this initiative." As we talked about harmonization, I think the biggest challenge is that ONC needs to figure out a process where, if we are going to reuse something like S&Is, that crosstalk between the different data workgroups is something that is thought out and, if it is going to be contracted out, it's in the contract.

Robert Wah, DXC Technology

Thanks. Any other comments? So, what we have now has gone through all nine recommendations. We've had a fairly extensive discussion. Again, we are trying to strike a balance, making sure we have a full discussion and be time efficient. I hope you recognize the balance there. We talked about taking recommendations one through four. If we could display slide eight for that? Clem.

Clem McDonald, National Library of Medicine

There was a recommendation that didn't get written down, but there was support for it. That is to encourage federal agencies that have very specific local standards, but they are not interrelated at all with the general standards – I don't know. Terry was interested in this, but he may not be now. I can't get his attention. About the use of existing governmental, very specific, standards. So, they work but they are not tied in at all to the general health standards in terms of transport, etc. Whether there would be some way to make that a recommendation, too. You might want to speak to that, Terry. It was your idea.

Terrence O'Malley, Massachusetts General Hospital

Thank you, Clem. It was our idea. I think there is a great opportunity with CMS, as being the greatest data standardizer, that unfortunately doesn't standardize much outside of CMS, with widely shared standards. There is a huge opportunity to bring them into the process of creating this standardized data set. The Data Element Library that they are working on in CMS, for example, is a great prototype, and it is an ideal model for probably what we might want to think about building within the USCDI structure. Certainly, a related effort. But, to the extent that we can bring government agencies, particularly ones with huge throw weight behind these recommendations and this process, the better it's going to be.

Robert Wah, DXC Technology

I want to understand what we are talking about here. If I may, let's deal with the nine that are on the table. And, if we want to construct another recommendation at some point, let's do that. I want to get through that process first. I understand what you are trying to do, but I think we can be more time efficient. Before you are recommendations one through four. They are described here. I will let one last round of comments or suggestions before we vote on this, just to make sure we've completed that. I see none. Cynthia.

Cynthia A. Fisher, WaterRev LLC

I would just encourage us, as a group, to put together goals and objectives on a timeline as we go through these. Perhaps that's the next step, but at least to keep in mind what are realistic goals and objectives to implement in a timeline.

Robert Wah, DXC Technology

Alright. Other comments? Seeing none, all of those in favor of this group of recommendations, one through four, that you see displayed on the screen here, signify by saying aye.

Multiple Speakers
Aye.

Robert Wah, DXC Technology
All those opposed, say no. Any abstentions? Okay. I'd say we passed that. So, if we could go to the slide – yes. We initially thought we would go through these individually. But, I think, even though they're not related to each other – unless anybody has one they want to pull out of this group and discuss or vote separately, let's just do them as a group. So, we discussed them individually, but I think we can vote them as a group. Does anyone want to take any one of these out to vote separately? Not seeing anything like that – sorry, Clem.

Clem McDonald, National Library of Medicine
I don't know what I want to do, but I think these are much broader and many times vaguer than what we had before. I'm a little more cautious in getting blanket support.

Robert Wah, DXC Technology
Alright, that's fine. Let's go through them one at a time. It's not a problem. Let's go through each one. First, any comments additional that we haven't already heard on any of these remaining recommendations? Yeah.

Unidentified Speaker
I have a question about what recommendation eight actually is. It's worded a bit funny in the explanation. I understand that you're calling out that data class management is important. But, what is the actual core recommendation there? Just the recommendation that it is important?

Terrence O'Malley, Massachusetts General Hospital
Yes. And that we need to think about processes to execute on them.

Robert Wah, DXC Technology
Other comments or questions about any of them?

Clem McDonald, National Library of Medicine
I come back to these – these shouldn't have the same force as the other ones. Some of them are somewhat afterthoughts. They haven't had as much specificity or clarity. I think I would call these things to think about, but not necessarily – you won't go to jail if you fail. I'm also not sure what some of them really are. They're all – yes. Motherhood. But, I'm not sure what they really mean, all of them.

Robert Wah, DXC Technology
Well, some of the recommendations, the way I read it, is that this is an issue that needs to be considered without any specifics about how that consideration goes.

Clem McDonald, National Library of Medicine
Okay. If that's how we take it, yeah.

Robert Wah, DXC Technology
I think the task force tried to begin what you are calling softness. If it's not right, let's talk about it.

Clem McDonald, National Library of Medicine
If you take it that way, I'm fine.

Robert Wah, DXC Technology
Okay. Alright. We can go through these individually and vote on them, unless people have a different way to go. So, for recommendation number five, you see the verbiage here and you've seen the recommendation and we discussed it. All those in favor of recommendation five, signify by saying aye.

Multiple Speakers
Aye.

Robert Wah, DXC Technology
All those opposed, say no. All those abstaining. Okay. Recommendation six. All those in favor say aye.

Multiple Speakers
Aye.

Robert Wah, DXC Technology
All those opposed, say no. Okay. Recommendation seven. All those in favor say aye.

Multiple Speakers
Aye.

Robert Wah, DXC Technology
All those opposed, say no. Alright. Recommendation eight. All those in favor say aye.

Multiple Speakers
Aye.

Robert Wah, DXC Technology
All those opposed, say no. Alright. Recommendation nine. All those in favor say aye.

Multiple Speakers
Aye.

Robert Wah, DXC Technology

All those opposed, say no. Okay. I broke my own rule, and we're now past the 12:15 time. I thought I was going to just make it under the wire, but I guessed wrong again. At this point, thank you all, first of all. I hope you don't feel rushed. I'm sorry?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Just a clarification. Were there any abstentions for five through nine?

Robert Wah, DXC Technology

Oh, that's right. I skipped that part. Okay. Again, I am a couple minute short of where we said we were going to be for the public, and I apologize for that to the public. And again, to the committee, I hope you did not feel rushed through that. We can still have a conversation after the public comments, so there's nothing breaking that part. Why don't we go to the public commentary part? Lauren, are you going to run that part?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Sure. For those members who are seated in the room with us today, we will start here first. If you would like to make a public comment, please come to the table and we will remind everyone that you have three minutes to provide your remarks.

Leslie Kelly Hall

Thank you. Leslie Kelly Hall, member of the task force and former member of Standards Committee and committed patient advocate. I would just like to amplify some of the great work that was done in the committee. In particular, I'd like to reflect on the earlier recommendations last year to the Standards and Policy Committee, about asking of that the 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 organizations or patient proxies and patients themselves.

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 requests 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 of 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, adding budget and resources to seek out some of these 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.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you. Any other public comments in the room? If not, operator, can you please open the public line on the phone?

Operator

Certainly. Ladies and gentlemen, if you would like to make a public comment, please press star-one on your telephone keypad. a confirmation tone will indicate that your line is in the question queue, and you may press star-two if you would like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys. Again, that is star-one on your telephone keypad to make a comment at this time. Our first comment comes from the line of Shelly Spiro with Pharmacy HIT Collaborative. Please go ahead.

Shelly Spiro, Pharmacy HIT Collaborative

Good morning. May name is Shelly Spiro. I am the Executive Director of the Pharmacy HIT Collaborative, representing over 25,000 members of the Majority National Pharmacy Association, including pharmacy education and accreditation. Our members include key pharmacy organizations involved in health IT, including the National Council for Prescription Drug Programs, NCPDP, and ten associate members representing e-prescribing, health information networks, transactions, processing companies, system vendors, pharmaceutical manufacturers, and other organizations that support pharmacist services.

The pharmacy HIT Collaborative's vision is to assure US health IT infrastructure will better enable pharmacists to help optimize person centered care. Our mission, as a leading authority of pharmacy health IT, the collaborative advances and supports the use, usability, and interoperability of health IT by pharmacists to help optimize person centered care.

A major focus of the Pharmacy HIT Collaborative is to assure pharmacists in all practice settings, community, health systems, hospitals, managed care, behavioral health, long-term and post-acute care, are integrated into the national HIT infrastructure.

On behalf of the pharmacy profession, the collaborative, over the last eight years, has dedicated our efforts to define and promote the use of standardized terminology within clinical documentation systems used by pharmacists. Through help from an ONC high impact pilot ending September 2017, the 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 NCPDPD and HL-7, using a consolidated CDA and FIHR standards. The collaborative is a steward of over 500 SNOMED CT codes and over 100 value sets within to National Library of Medicine's Value Set Authority Center to standardize the collection, documentation, and sharing of medication related pharmacist provided patient care services within standards such as the pharmacist electronic care plan. The collaborative supports the recommendations of the USCDI task force. Thank you.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Thank you for your comments. Operator, do we have any other commenters in the queue at this time?

Operator

Not at this time.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Okay. Thank you. I will turn it back over to Robert.

Robert Wah, DXC Technology

Alright. Again, I want to make a few summary comments. First, just to recognize the tremendous amount of work the task force has done for this committee, and particularly the chairs, Terry and Christina – but also last time, Denise and Arien. There is so much work that has to be done in these task forces. Every member does a lot of work, but I think the chairs do just that little extra work that goes on top of that. We want to recognize and appreciate that as a committee, and thank them for their efforts on that regard.

Again, thank you all for your participation, both on the task force as well as on the committee. Again, I hope you appreciate the art of how to balance this tension that we have between trying to get it all done and do it right. We are struggling with that all the time. My other comment is, we have to think about how we are going to do these signs. It's getting a little hard to see way down at the very end of the table. My apologies to those who get seated at the end. We don't quite see you. We are trying, but we may have to figure out something electronic to recognize people before they speak.

I can tell you, from the American Medical Association board, this was the ongoing challenge we had with 21 members, to make sure we recognized the people and people got their name in the queue and all that kind of stuff. We will talk about that over some drinks some another time.

Finally, I think we need to think about next steps. I think there were a number of comments about, now that we have this work – what I'm hearing is there is a sense that we want to have another bit of discussion about what the next steps would look like. We have a few minutes here and I'll elicit some of those comments to do that, to think about what next steps are.

And, I think I heard perhaps there were things that were missing from the recommendations that we didn't get all the way through, if there are some suggestions for additional areas to look at. Again, they won't come out as a formal recommendation in this particular discussion, but maybe there are additional areas we need to continue to look into. We can at least enunciate that and put it on the list of things we want to do.

Does that sound reasonable to you all? I'm looking at Clem because I know he's got –

Clem McDonald, National Library of Medicine

I don't have a card.

Robert Wah, DXC Technology

Yeah, he's lost his card. He has to look at me and get my attention that way.

Clem McDonald, National Library of Medicine

I think you did a great job. I don't think you should be apologizing. Thank you for the job you did. But, I also was wondering what other jobs do we have? Are we done? Do we have another two years? What else is up for us?

Elise Anthony, Directory of Policy (ONC)

I can comment a little bit on the next areas to examine. Obviously, depending on what's going on with ONC and what we are working on, that will depend what charges we bring to the HITAC for consideration. The next upcoming one is going to be in Steve's shop. It is around the standard use cases. It's one of the requirements in the HITAC section of the Cures Act. Also, once we are at a stage where the rule is release in the proposed format, then we would share it with the committee as well for their consideration.

Those are some of the upcoming pieces. I think we are very cognizant. It appears, and is the case, that we are moving pretty fast, particularly in the TEFCA and the USCDI. That's so we can build your feedback back into the work that we are doing on those pieces. At the same time, we try to be cognizant of not having too many pieces rolling at the same time, which is why we structured it so that the standard use cases come after the USCDI.

Unidentified Speaker

What Elise outlined really covers – pretty much gave a to-do list here.

Robert Wah, DXC Technology

Yeah. Unlike prior Federal Advisory Committees, they had a little more latitude to what their work was going to be, the 21st Century Cures was much more proscriptive on what they wanted to see out of this particular advisory committee. That has set a little bit of the agenda, but I think there is still latitude for us to have our own agenda. But, I think we all recognize that this has been a slightly different kickoff of a Federal Advisory Committee than is often seen.

Elise Anthony, Directory of Policy (ONC)

Yeah. And to that point, there are, as folks know from our first meeting and your review of Cures, which I'm sure you all have read page by page, there is a section in the HITAC section that talks about the priority target areas for the FACA to look at. As we at ONC think through what the charges are we went to bring to the FACA for consideration, we look very closely at that language. Of course, as you are talking about now, what are the areas that you think are helpful as we move forward, that will be helpful to us as we think about future charges, whether it's this year or in coming years.

Robert Wah, DXC Technology

Great. Again, I want to make sure we capture this in our discussion. It was a great discussion today and at the last meeting. I think these people have their signs up to talk about this. Sheryl, do you want to --

Sheryl Turney, Anthem Blue Cross Blue Shield

Thank you, Robert. Sheryl Turney. I did have a little question regarding the process. As you said, for next steps, we have provided these recommendations for TEFCA and USCDI. What happens next in that process? Do they get republished? Do they go back for public comment? Do we get to see them again? I'm not familiar with how that works.

Robert Wah, DXC Technology

I'll give you mine and then these guys can chime in, too. What we did with the last set of

recommendations that we all voted on, Carolyn and I then had a letter that went under our signatures at chairs of this committee, representing you, saying, "These are the recommendations that the committee has now voted upon and wish to forward to the National Coordinator." Our recommendations, as a committee, went over to the National Coordinator under our signature. That answers part of your question?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

I will take specifically the TEFCA recommendations you guys made. We have been reviewing those, along with all the other public comments we received. Review of those comments goes into updates that we will make to the Trusted Exchange Framework. On the USCDI, we will take these recommendations in as well and talk internally about setting up all the different process things we need to set up on the USCDI front. Does what go back? The Trusted Exchange Framework – the timeline that we are working on right now -- the funding opportunity announcement for the recognized coordinating entity will be out this spring. That will be out shortly.

While that process is going on, we are working on updating the Trusted Exchange Framework, which is part A and Part B. Once the RCE is on board, which we are hoping is around the August timeframe, we will at that juncture have a good portion of the Trusted Exchange Framework done. The pieces that aren't done, we intend to work collaboratively with the RAC and stakeholders on putting together.

We will also, at that point, have the RCE working with their stakeholder groups and us on the full common agreement. All of that, which then becomes the TEFCA – so the framework and the agreement together -- will be published, we are hoping, towards the end of the year, in both the Federal Register and on our website for public comment, with a "final" version one being sometime second or third quarter of next year. Again, every timeline I laid out is somewhat dependent on internal clearance processes and how fast we can review those.

Robert Wah, DXC Technology

Christina?

Christina Caraballo, Get Real Health

More of an administration question with the USCDI letter. 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?

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

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

Christina Caraballo, Get Real Health

Perfect. Then, there is one area in the letter. In our haste to get it out, we didn't update a section. It was under the publishing. The Stage I-VI examples, we have different examples that

are reflected in the slides but were not updated in the letter. I have seen how it's hard to get things edited, so I want it to be correct.

Robert Wah, DXC Technology

Let me understand. You are saying that the ones you presented today are the most up-to-date?

Christina Caraballo, Get Real Health

That is correct. And the letter just doesn't reflect it.

Robert Wah, DXC Technology

But, the one you submitted as preliminary materials for the committee was a different version?

Christina Caraballo, Get Real Health

The one we submitted -- in that area in the transmittal letter, they weren't updated to reflect what was presented in the slides. I wanted the letter to reflect exactly what was presented in the slides.

Robert Wah, DXC Technology

Okay. Some people cannot get their microphone working. We have to work on that. Some of these times, if too many people have their microphones on, we can't turn additional ones on. If you're not speaking, please turn yours off.

Elise Anthony, Directory of Policy (ONC)

They were presented to the FACA today, and the FACA was aware of them. I think that would be fine. Usually, what we do is, what is used in the presentation materials is what is considered, and then we format that into a transmittal letter that we then run by the chairs to make sure we captured everything correctly. Then, that is shipped over to our wonderful National Coordinator. Lauren can correct me if I – no? Alright.

Robert Wah, DXC Technology

Clem?

Clem McDonald, National Library of Medicine

Well, the issue about the model and the introduction, I thought that was going to be open to change. I don't know where that stands. If it gets locked into the letter as it is now, I'm not sure that's good. Whether we should try to propose some alternatives and get an email vote, or you guys can take care of it.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Can you clarify which model?

Clem McDonald, National Library of Medicine

It is the class, and that's fine. But then, you go to object. But, I think these are synonymous. Classes have attributes – you don't talk about attributes until you get down to the object. And then, you describe an example that's really a datatype and wouldn't be considered an object – although it is. Everything's an object. I think it could really lead to a lot of wasted cycles in people responding and thinking about it. We should clean that up again. I don't have an immediate solution, but I think they need slightly different names.

Elise Anthony, Directory of Policy (ONC)

Clem, if this in reference to the definitions, that is something we can possibly address as we think forward to the final version, pending a potential --

Clem McDonald, National Library of Medicine

I think it would be a good thing for ONC to take care of, but some of us would be happy to make suggestions. I'm just worried, if it's locked down now forever. That's the only problem I worry about. It sounded like it was.

Robert Wah, DXC Technology

Again, this is a little bit of on-the-fly thinking and speaking at the same time, which makes me nervous. The definition of terms, I'm not sure that was going to go in the letter. That was background material for the discussion. One could submit that that is not the actual transmittal. You know what I'm saying? We had a background to the discussion today, which is definitions. That is sort of like a footnote at the bottom. It's not the actual letter.

The letter will go with some recommendations that will verbalize what we all saw on the proposed recommendations that we voted on. Again, this is a little on-the-fly thinking and talking. But, it seems to me the definition of terms is a background piece and not the recommendations that we are forwarding. So, if the definition of terms needs to be refined, then I think we can do that without changing the recommendations.

Unidentified Speaker

Yeah, I think we can work on it in the letter. I think there's an understanding of that. Certainly, we are not going to rewrite that part of computer science here in this committee. Those things and datatypes all have some pretty well constrained meanings that have been around since, in part, I believe since Simula 67, which was the first object-oriented programming language. We are mindful of the history of that.

Robert Wah, DXC Technology

Denise.

Denise Webb, Marshfield Clinic Health System

I just want to reinforce what you said. I read the draft letter, and I saw that as all background in giving context for the recommendations. I did not see anything in the draft letter that was recommending the ONC redefine those computer science definitions, being a computer scientist myself. It helped to understand the recommendations. They had to set some sort of framework, although not everyone agreed on the definitions.

Robert Wah, DXC Technology

Sheryl, do you have another comment?

Sheryl Turney, Anthem Blue Cross Blue Shield

Yes, I had a follow-up too. Genevieve, did I hear you correctly that there's going to be a stakeholder group working on the common agreement?

Genevieve Morris, Office of the National Coordinator

One of the requirements for the recognized coordinated entity is that they have appropriate governance structures in place, which include committees, workgroups, and things like that. The RCE, under that structure and working with us, is responsible for putting together the full common agreement. Just to jog everyone's memory, in Part B of the Trusted Exchange Framework, it is not the totality of all the legal terms and conditions you need in a full participation agreement. Those other important things are things we didn't think we needed to weigh in on to set a minimum requirement. Those are the pieces of the common agreement where the RCE would be responsible for working with us and their appropriate committee structures to put that together.

Sheryl Turney, Anthem Blue Cross Blue Shield

Okay, great. Thank you.

Terrence O'Malley, Massachusetts General Hospital

To add to the record, we forgot to, on behalf of the task force and co-chairs, thank our ONC support. So, Stacy Perchum and Adam Wong were great. We appreciate everything they did to help this move along.

Robert Wah, DXC Technology

Are there other discussions about the next steps and potential future areas to look at that we want to have a discussion on? I heard some energy about that.

Kensaku Kawamoto, University of Utah Health

Just a suggestion. It would be awesome if this committee could at some point tackle the orderable catalog issue of every HER having different orderable catalogs. If we want to tackle that, I think it has been an acknowledged need that hasn't yet been tackled.

Robert Wah, DXC Technology

Thank you. Other comments in this area?

Steven Lane, Sutter Health

The comment I was going to share earlier is I think 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.

Robert Wah, DXC Technology

Other comments? Again, I will make the observation from this end of the table. I like the way we are coming together as a group. I think we are working together pretty well. I thank you for all of the work you are doing in that regard. It is good when we can joke with each other a little bit and it's not all formal and that kind of stuff. It's a good sign for me when I see that kind of change in the committee. I think that's a good thing for us. Again, I don't know that there are other wrap-up comments we need to make.

Carolyn Petersen – Mayo Clinic Global Business Solutions – HITAC Committee Member

I would just like to express my appreciation to the chairs and all the members of the task forces that are put in so much time and energy in bringing forward some really strong documents that provoke good discussion and help give us to move forward. Of course, thanks to the ONC staff who have helped all of us in keeping the train on the tracks going forward.

Robert Wah, DXC Technology

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 am a strong believer in the more input we have to our decisions, the stronger and better those decisions are. Please do not hesitate to provide that input in the decision-making process. I hope you all feel empowered to do that. If you don't, please let me know how we can make that better for you. I don't want to delay this any longer.

Lauren Richie – Office of the National Coordinator for Health Information Technology - Designated Federal Officer

Just one more quick reminder, especially for the public. Our next HITAC meeting will be May 16th. That will be a virtual meeting. You can also find all of the meeting information on our website at healthit.gov.

Robert Wah, DXC Technology

If nothing else, we stand adjourned. Thank you all.