



Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) MEETING

April 13, 2022, 9:30 a.m. – 11:00 a.m. ET

VIRTUAL



Speakers

Name	Organization	Role
Aaron Miri	Baptist Health	Co-Chair
Denise Webb	Individual	Co-Chair
Medell Briggs-Malonson	UCLA Health	Member
Hans Buitendijk	Cerner	Member
Steven Eichner	Texas Department of State Health Services	Member
Cynthia A. Fisher	PatientRightsAdvocate.org	Member
Lisa Frey	St. Elizabeth Healthcare	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Valerie Grey	New York eHealth Collaborative	Member
Steven Hester	Norton Healthcare	Member
Jim Jirjis	HCA Healthcare	Member
John Kansky	Indiana Health Information Exchange	Member
Kensaku Kawamoto	University of Utah Health	Member
Steven Lane	Sutter Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
Arien Malec	Change Healthcare	Member
Clem McDonald	National Library of Medicine	Member
Aaron Neinstein	UCSF Health	Member
Eliel Oliveira	Dell Medical School, University of Texas at Austin	Member
Brett Oliver	Baptist Health	Member
James Pantelas	Individual	Member
Raj Ratwani	MedStar Health	Member
Abby Sears	OCHIN	Member
Alexis Snyder	Individual	Member
Fillipe Southerland	Yardi Systems, Inc.	Member
Sheryl Turney	Anthem, Inc.	Member
Thomas Cantilina	Department of Defense	Federal Representative
Adi V. Gundlapalli	Centers for Disease Control and Prevention	Federal Representative
Ram Iyer	Food and Drug Administration	Federal Representative





Jonathan Nebeker	Department of Veterans Health Affairs	Federal Representative
Michelle Schreiber	Centers for Medicare and Medicaid Services	Federal Representative
Ram Sriram	National Institute of Standards and Technology	Federal Representative
Micky Tripathi	Office of the National Coordinator for Health Information Technology	National Coordinator
Steve Posnack	Office of the National Coordinator for Health Information Technology	Deputy National Coordinator
Elise Sweeney Anthony	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Policy
Avinash Shanbhag	Office of the National Coordinator for Health Information Technology	Executive Director, Office of Technology
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer





Call to Order/Roll Call (00:00:00)

Michael Berry

And, good morning, everyone. I am Mike Berry with ONC, and I would like to welcome and thank you for joining the April 2022 HITAC meeting. We are always very excited that you could be with us. As a reminder, your feedback is welcomed, which can be typed in the chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled at about 10:50 Eastern Time this morning. So, let's get started with our meeting, and first, I would like to welcome ONC's executive leadership team to the meeting. With us today is our National Coordinator, Micky Tripathi, Steve Posnack, the Deputy National Coordinator, and Avinash Shanbhag, the Executive Director of the Office of Technology. I am going to call our meeting to order and begin roll call of our HITAC members along with the federal agency representatives of the HITAC, so when I call your name, please indicate that you are with us. And, I will start with our cochairs. Aaron Miri?

Aaron Miri

Good morning.

Michael Berry

Denise Webb?

Denise Webb

Good morning.

Michael Berry

Medell Briggs-Malonson? Hans Buitendijk? Thomas Cantilina or Jeff Ford? Steven Eichner?

Steven Eichner

Present.

Michael Berry

Cynthia Fisher? Lisa Frey?

Lisa Frey

Good morning. I am here.

Michael Berry

Raj Godavarthi? Valerie Grey?

Valerie Grey

Good morning.

Michael Berry

Adi Gundlapalli or Sanjeev Tandon?

Sanjeev Tandon





Yes, Sanjeev Tandon is here. Good morning.

Michael Berry

Steven Hester?

Steven Hester

Good morning, I am present.

Michael Berry

Ram Iyer? Jim Jirjis?

Jim Jirjis

Present.

Michael Berry

John Kansky?

John Kansky

Good morning.

Michael Berry

Ken Kawamoto?

Kensaku Kawamoto

Good morning.

Michael Berry

Steven Lane?

Steven Lane

Good morning.

Michael Berry

Leslie Lenert? Hung Luu?

Hung S. Luu

Good morning.

Michael Berry

Arien Malec? Clem McDonald will be joining us a little bit later this morning. Jonathan Nebeker? Aaron Neinstein?

Aaron Neinstein

Good morning.





Michael Berry

Eliel Oliveira?

Eliel Oliveira

I am here. Good morning.

Michael Berry

Brett Oliver?

Brett Oliver

Good morning.

Michael Berry

James Pantelas?

James Pantelas

Good morning.

Michael Berry

I believe Raj Ratwani is absent today. Michelle Schreiber or Alex Mugge? Abby Sears? Alexis Snyder? Fil Southerland?

Fillipe Southerland

Good morning.

Michael Berry

Ram Sriram? And, Sheryl Turney?

Sheryl Turney

Good morning.

Michael Berry

Good morning, everyone. Nice to hear your voices this morning. And now, please join me in welcoming Micky Tripathi for his opening remarks. Micky?

Welcome Remarks (00:03:05)

Micky Tripathi

Great. Thanks so much, Mike, and thanks, everyone, for joining. I am going to be really brief and really just wanted to say hello because I know we have a packed agenda today, and then, we hope all of you are able to join us in the annual meeting that follows immediately after this. So, first off, I just want to express our really sincere appreciation to the HITAC members and the guest presenters for what we thought was a really successful Health Equity By Design hearing last month. We are really grateful for all the expertise, passion, and insights that were shared, and right now we are compiling themes and potential actions that we heard during the hearing to help inform our strategy as it relates to Health Equity By Design, and we





really look forward to the ongoing engagement with the HITAC as we dig more and more into this really important area.

I am also really looking forward to hearing from the cochairs of the Interoperability Standards Workgroup, Steven Lane and Arien Malec, who I know have been working very hard, as they always do, with all the other workgroup members to develop recommendations on the draft USCDI Version 3. The HITAC will be voting on the workgroup's recommendations today, but the public feedback period is open until April 30th, so everyone should know that and is welcome to add additional feedback by searching "USCDI" on HealthIT.gov, and you can enter your comments in the ONDEC system, the ONC New Data Element and Class submission system. And, I very much encourage the HITAC to finalize your recommendations today so they can be transmitted to me at ONC within the public comment period.

The work for the Interoperability Standards Workgroup is going to continue after today. The workgroup is going to transition into the next phase of their charge, which is to provide recommendations on the 2022 Interoperability Standards Advisory Reference Edition that was published in January, so let me just thank you for all the work that you have done to date and for all of the work that you are going to do in the next phase of this.

On another note, the Department of HHS has recently released our updated strategic plan for FY '22-26, and that reflects the department's strategies, actions, and progress toward its goals. The plan aligns very much with the 2025 Federal Health IT Strategic Plan, which many of you may be more familiar with, and certainly includes a strong focus on supporting patients' access to their data.

Let me just give a brief shoutout for the annual meeting that is going to follow immediately after this. We have an abbreviated meeting agenda today so that all of you can join us. We plan to host panel sessions to discuss health IT, health equity, public health, patient access and advocacy, health information exchange, and we are going to be kicking off with a live short talk from Secretary Becerra, so hopefully, all of you can join us for that, and let me again just thank all of you for joining today, and let me turn it over now to Aaron and Denise for their opening remarks and the rest of the meeting.

Opening Remarks, Review of Agenda and Approval of March 10, 2022 Meeting Minutes (00:06:03)

Aaron Miri

Wonderful. Thank you, Micky, we appreciate it, and yes, welcome, everybody, to the April HITAC meeting. It is going to be a fun agenda today, really quick, but we are going to get right into it and also allow everybody to transition to the larger meeting, which should be just as exciting, as Dr. Tripathi was just saying. Denise?

Denise Webb

Good morning. Thank you, everyone, for joining us today, and hopefully you all can make some time for some of the sessions this afternoon. I think we will just go ahead and get started so we can stay on schedule.

Aaron Miri

Great. So, let's get into it, and let's get a vote for the prior minutes, if I could get a motion to approve.





Unknown Speaker

Motion to approve.

Aaron Miri

Wonderful. Can I get a second?

Unknown Speaker

Second.

Aaron Miri

All right. All those in favor, please signify by saying aye.

Several Speakers

Aye.

Aaron Miri

Any opposed, please say nay. Any abstentions? Okay, let's go through today's agenda now so we know what is on deck for the rest of the day. So, obviously, we just had our opening remarks. Next will be the Interoperability Standards Workgroup recommendations. As Dr. Tripathi was just mentioning, HITAC will vote on the draft USCDI Version 3, then we will go to public comment, and then final remarks and adjourn. That way, we can all get to the bigger party and join the rest of the crew. So, with that, I am going to transition over to you, Denise, to lead us through the first workgroup.

Denise Webb

All right. So, I would like to welcome Steven Lane and Arien Malec to present on their workgroup's recommendations to the HITAC, and we will have some discussion and questions and answers, and then hopefully we can move to a vote to move the recommendations forward from the HITAC to the Office of the National Coordinator. So, Steven and Arien, you are up.

**Interoperability Standards Workgroup Recommendations on Draft USCDI v3 – HITAC
Vote (00:08:01)**

Steven Lane

Terrific. Thank you very much. Is my sound coming through okay, I hope?

Denise Webb

Yes, you sound great.

Steven Lane

Marvelous. Well, I feel great.

Denise Webb

Yeah, but early morning there.

Steven Lane





You know, it is oh dark thirty here in California, which may represent why Arien is having trouble connecting, but we are very excited to be here to present the hard work of our Interoperability Standards Workgroup that has been meeting for the past few months to focus in on recommendations regarding the draft USCDI Version 3, so let's go on through the slides. Next one. So, we are going to talk about who is in the group, what the background is of the work we have been doing, what we were asked to do by the ONC and the HITAC, and how we approached that. We are going to present a full set of recommendations related to the tasks that we were given, and then also, some additional recommendations for future work that ONC could focus on and that we would actually like to ask you to have us focus on.

As Micky mentioned, we are transitioning or have transitioned to move towards making recommendations around the ISA, and that is going to occupy us for the next couple of months, and we will be back here then to present those suggestions as well. Next slide. So, this is who has been involved. It has been a wonderful group to work with, a lot of really engaged membership. I want to remind people that this is probably the fourth iteration or so of a taskforce or workgroup that the ONC has chartered to focus on the annual update process of USCDI. Each time, we have had a broad range of stakeholders represented and engaged in making these recommendations, and this year is no different, so I really want to thank the hard work of all these members, a number of whom are here today at the HITAC. Frankly, I think those who are not HITAC members are probably listening on the phone, so we are here representing the work of all these folks. Next slide.

So, this was the draft USCDI Version 3 that was published earlier this year. I want to remind everyone that this is an annual process of advancement. Each year, there is a thoughtful look at the existing USCDI version and what has been included therein, and then, of all the recommendations that are presented by the public, the ONC looks at those and decides which should be added each year of items that are ready for exchange, they have proven themselves ready through connectathons, etc., and that are felt to meet the priority topics and approaches that the ONC is looking at.

So, you can see here in the draft Version 3, with the stars, all of the new data elements that were proposed in draft Version 3. You can see also there are some new data classes, like health status, for example, which was there with one item of health concerns, but they brought over a couple of other items and added a number of additional ones. So, we are going to be going through these, not every one, but looking at the recommendations about these. And, has Arien joined yet? All right, well, we will go right ahead. He and I are brothers from another mother, and I am happy to just continue on, and when Arien shows up, maybe someone could just flag me so I know.

All right, on the next slide, we break down the new items that were added for the new data classes and elements you can see here. Each of these is categorized based on why it was added, what specific goal it addresses in terms of the goals that have been identified by the ONC and by the HITAC as being high priority. You can see those that support equity, those that address the needs of underserved populations, those related to supporting public health data exchange, additional USCDI needs that have been identified by the HITAC, and those that relate specifically to or are pointed to by ONC certification. So, let's go to the next slide.

And, as I said, this is an annual process. Once a draft version is published by the ONC early in the year, there are opportunities for public feedback, including feedback from the HITAC. The feedback is meant to





be both general and specific, and looking at what is in the draft, looking at opportunities for improvement in the names and definitions of new data classes and elements, looking for suggestions regarding value sets that can be used to help define the scope of those data elements, and then looking at other data elements that perhaps should be included in the next version, recalling that within the ISA, there is a leveling process where any new suggested data element is looked at by the ONC and its readiness is determined for inclusion, so those that are considered to be at Level 2 are felt to be technically and socially, if you will, mature enough to add, so we look at all the Level 2 elements to see if there are additional ones that might be added, whether there are any barriers to the implementation of any of the elements that have been proposed that perhaps would suggest they should not be included in the next version.

And then, in this year's round, there were very specific questions that were asked by ONC regarding work by other groups that perhaps could be incorporated into the USCDI, so in this case, we and the public were asked to look at the work of the Gender Harmony Project, looking at whether their suggestions around recorded sex or gender might be used to further elucidate the current sex assigned at birth data element. Similarly, the Gender Harmony Project has done a lot of work on gender identity, and the question was raised as to whether that should be incorporated into the definitions within USCDI. And then, a lot of work has been done by the ONC team and others on the Project US@ work around defining specifications for address data, and the question was raised as to whether that should also be included into the USCDI. So, our group addressed all of these questions and more, as you might imagine.

On the next slide are the specific charges that we were given for our workgroup. We have been focusing on the first of these two charges, but in general, we are looking at USCDI, as well as other interoperability standards. Our first charge was to evaluate the draft USCDI and to provide input on the data elements that were suggested, as well as others that might be included, and as we have noted, we are moving on now to focus on recommendations for the ISA. We will be back in June to discuss those. So, another check to see if Arien has joined us. All right, we will carry on.

On the next slide, additional areas, as I said, that we were focusing on, and I will not reiterate these in detail, but we looked at work from Gender Harmony and Project US@. We also held hearings on disability issues, as the health status data class includes disability status and other issues, so we invited in a number of experts to speak to those topics. We also had somebody come in from the physical therapy community to discuss disability, and functioning, and functional status, and then, Dr. Terry O'Malley and Holly Miller also came to provide input regarding functional assessment. So, a lot of great information came to support the recommendations that you are about to hear. Onto the next slide.

So, we came up with quite a number of recommendations, and we will go through those one by one. We can linger on those that generate questions. I do not know, Denise and Aaron, whether you want us to grab questions as we go or come back to them at the end. Given the volume of recommendations, I think it might be best to go through them top to bottom, and then take questions at the end, if that is all right with you. I want to be sensitive to the time.

Denise Webb

Right, that was our plan, for you to go through all the recommendations, and then we will open it up for discussion and questions.





Steven Lane

Perfect.

Denise Webb

And, Arien is not on yet. We are looking for him.

Steven Lane

That is fine, all right. It is all good. He does have unique expertise in some of these areas, and I am going to do the best I can as a one-legged stool here. So, the recommendations break down into, first, those new data classes and elements that were included in the draft, next, those that were not included in the draft and which we felt might be worth consideration for inclusion in Version 3, we made comments related to data elements that were already included in prior versions of USCDI, and then some areas of future focus, so let's just dive right in with the first group relating to items that were included in draft USCDI.

So, the first thing we do want to say is that we really were very impressed by the work done by the ONC team to put together the draft USCDI V.3. We really supported the addition of all of the new data elements that were recommended, as well as the new data classes, so you can assume as I go through that we support each of these as they were presented, with some changes in wording, definitions, etc. that we will be commenting on, and a little bit about the arrangement of them.

So, on to the first recommendation, which is that the health status data class, which is really one of the key new data classes that was included, we felt should be named "health status and assessments" because really, to document and quantify the health status or the status of an individual, that is typically done using standardized assessments. There is a long list of assessments that have been standardized and have been coded within the LOINC hierarchy, and our thought was that for this data class, we should include the fact that it involves assessments, that we should bring existing assessments into that class so that they are all in one place within the USCDI structure, and that each of those should be specified using a LOINC code. Onto the next slide.

The second recommendation is that the health concerns data element, which ONC did recommend putting into this health status data class, is really a different sort of a thing. It is more of an open-ended item. It is a legacy data element that we have had in the USCDI from before its conception, from its earlier life as the core clinical data set. It does not have the kind of structure of these other assessments, so we felt that health concerns should be maintained in their own data class, where they are currently in the USCDI Version 2, leading the health status and assessments class to hold these more formalized assessments. Next recommendation.

This is that we really do feel that it is important to have a robust set of LOINC codes, which is to say assessments that are representative of each of these areas within the health status and assessments data class, specifically those that focus on functional status, those that focus on disability status, and those that focus on mental and cognitive status, and you will note a little bit of a change in wording here in that data element of mental and cognitive status. We thought that was more specific to how that data element is going to be functioning.





Now, it is not to say that we feel that USCDI needs to name every single potential assessment instrument or LOINC code that might be applicable here, but that it is very helpful for the industry to have a minimum set of assessments that go into each of these data elements with their associated LOINC codes. It can be used to support testing and exchange, but the thought is that any structured assessment that is so coded could be exchanged within this data class, so we did a fair bit of work, both last year in our taskforce and this year in the workgroup, putting together some recommendations about specifically which elements are useful in assessing each of these areas of function.

And, as I mentioned, we felt that “mental cognitive status” was a more appropriate label than “mental function” for that particular data element, but we do feel that there is a need to do ongoing work with stakeholder groups to identify additional terms, which is to say formalized assessments, to support these data elements that could go into additional areas such as learning disability and mental disability, autism, and caregiver’s disability status. So, there is much to do in this area, but having it together in this new data class with these elements is a great start. Next slide.

All right, continuing, there are specific data assessments, I should say, that have been developed and widely used to support the documentation of disability status, and we called these out in particular. A couple of groups here, the American Community Survey and the Washington Group on Disability Statistics, have developed and extensively utilized these seven questions identified by the bullets, and we specifically recommend identifying these as a data set that can be used to support the documentation of disability status, thinking that eventually, all certified health IT might have the ability to capture and exchange these particular data elements. Next slide. Going on, this is a short list, and again, they are all in an appendix to the document we have sent you, of specific instruments used to document mental and cognitive status.

On the next slide is a specific set of instruments and assessments that are standardized and coded that are used to document functional status, and then, on the next slide, we have the next recommendation, which really, as I said, we did have a representative from the physical therapy domain who educated us about the international classification of functioning, disability, and health, the ICF model, a little different than the international classification of diseases, the ICD model that many of us clinicians are aware of. It was very interesting to learn about this value set, which has a hierarchy looking at function, structure, activities, and environmental factors that impact health, and we felt that it was worthwhile for the ONC to consider referencing this ICF model as a potential value set that would be also applicable in this health status assessments data class. We did not go so far as to say that it was ready for primetime in this next version, but it is definitely worth consideration for inclusion, potentially, in Version 3 or in a future version. Next slide.

With Recommendation 5, there was a lot of discussion in our workgroup about the importance of patient- and caregiver-generated health data and the importance of identifying which data did come from the patient as opposed to from a professional clinician, so we felt especially in this area of health status assessments that these assessments could be populated either by the patient, their representative, or a clinician, and we felt that it was important as this data class came online that we were able to identify the source of the data, that we could accommodate self-assessments, either by using the specified LOINC codes that would point to self-assessment instruments, and/or utilizing the author data element within the provenance data class to indicate that the source of the assessment was the individual, and I think we will touch additionally on this author data element in the next recommendation. So, go ahead.





So, Recommendation 6 speaks to the additional data element on related person and related person's relationship. These were newly suggested data elements, and we felt it was important that in the final Version 3, it be clarified that these are identifying the relationships of these individuals for such purposes as medical record linkage, patient matching, and demographic purposes, and that these are different than care team membership, which is already existing within the current USCDI and has a different role in the exchange of information, but the idea of having related persons that can be used for a number of additional use cases is important, but needs to be differentiated. Next slide.

All right. There is a new data element, called pregnancy status, in the draft USCDI Version 3, which we applaud and appreciate its value, but we did feel that there was an additional pregnancy status beyond those that were presented. It was recommended that this data element could be populated with "pregnant," "not pregnant," and "unknown." We felt that the intent to become pregnant was an important pregnancy status which should be considered for inclusion in Version 3 that has a lot of critical uses in terms of planning medical care and looking at medication use, etc. Next slide.

All right, Recommendation 8. There is a new data element, called reason for referral, within the procedures data class. We felt that it needed to be clarified that this could be used whether or not it was required to be used by all certified health IT because it is not necessarily the case that every certified system needs to give its users the chance to document this particular data, and this ends up being a motif that we have considered, really, across multiple discussions. That is to say that whether or not an element being in the USCDI means that every system needs to have the ability to collect that data element as opposed to whether it needs to be able to receive and store that data element when it is collected by others, there is a real sensitivity to the burdens that additional data collection requirements could place on clinicians, and we felt that with this one in particular, reason for referral, not every system is going to need to collect that, but again, if they receive it, they should have a place to store it. Next slide.

All right, the reason for referral data element, again, within the procedures data class, we felt that it would increase clarity if it were named the reason or indication for the referral or procedure because it can be really used in these multiple ways, and we felt that this was clearer as questions were coming up from stakeholders as to what this meant. Next slide.

All right. We felt that the SNOMED CT was the applicable vocabulary standard for the specimen type data element within the laboratory data class. Remember that one of our tasks was to look for applicable vocabulary standards where those were not specified, and we felt that this was worth including and that ONC should also consider specifying the value sets defined by HL7 for specimen type as well as in their FHIR V.2 specimen type specification, that identifying these value sets would be helpful. Next slide.

Recommendation 11 is to specify the applicable vocabulary standard for laboratory values and results data element, which is SNOMED CT for qualitative lab results and UCUM for numerical results, and again, these are well-established standards that are in used today, extensively exchanged, and another opportunity for the Version 3 to add additional clarity. Next slide.

The 12th recommendation for these new data elements that were included in draft Version 3 has to do with the health insurance information data class. It has a number of component data elements that were





suggested, and we thought that those were all quite valuable, but we felt that it should be specified that these refer to the patient's primary and secondary coverage, and they may not be at the individual encounter level. Sometimes there are encounters, for example, in the case of workers' comp or auto insurance cases, etc., where you have an encounter-specific insurance, that we felt that that was too much to ask for this first round out and that the health insurance information should be at the individual level. Also, a recommendation that ONC should continue to work with appropriate stakeholders to align the minimum vocabulary and value set for coverage type and to improve that over time within the USCDI specification. Next slide.

All right, so, that brought us to the end of the first 12 recommendations that had to do with what was included in draft USCDI Version 3, and then we turned our attention to our next subtask, which had to do with those data elements that were in Level 2, but were not initially suggested for inclusion in Version 3. I will add an aside here that we did work with a number of representatives from HL7. We have said in our prior work around USCDI that it is important that as we add new data elements to the USCDI that they are supported not only by data standards, but also by the relevant implementation guides that are required so that users and vendors can really put these data to use, and we appreciate that a lot of work needs to be done by the HL7 community to get those standards out the door, especially for some of these newer data elements, that there is a certain amount of throughput that that system can support, and that there may be data elements in this ask that are really too much for that system to come forward with over the relevant period of time to be able to support.

So, while these are all things that we felt were supported by the community and were important and worthwhile including in Version 3, we appreciate that perhaps HL7 will say that one or more of these is just more than they can support in a single year's cycle. So, with that, let's go ahead.

The first recommendation in this, and our 13th recommendation overall, as I mentioned earlier, was to add the author data element to the provenance data class. Those of you who have been around a while will recall that this was proposed for the very first version of USCDI, and we held it back because we thought it was too much to ask.

There are clearly some technical challenges defining and capturing the author for every single data element, but as mentioned earlier, it is particularly important when we are looking at patient-generated health data and the need to identify that data that is generated by the patient or a caregiver, for example, a family member, as opposed to those that are generated by professional clinicians and caregivers, so we felt that it was important for specific data elements within USCDI that we could make this differentiation, and we have discussed race and ethnicity, gender identity, sexual orientation, as well as the new disability and pregnancy status data elements, as those can be particularly important to identify which data is generated by the author, so I think it is important for ONC to think through this carefully, that requiring the author for every data element might be challenging for some systems. I think there do need to be some definitions going on, but at least for this set, we think it is particularly important. All right, I hear a rumor that Arien may be joining us. Are you here yet, Arien? Not quite? He is on his way. That is great. We will keep going.

Onto the next recommendation, 14, we felt that the following data elements that are leveled at Level 2 should be included in the USCDI Version 3: Family health history, problem date of onset, two sub-elements under allergies, which is to say non-medication and food allergies, as well as travel information. Obviously,





travel information was important early on in the pandemic, and clearly has an impact on a number of health conditions. These are all elements that the ONC has felt were ready technically and socially for exchange, and we felt that it made sense to consider them for inclusion in Version 3, and here, again, all of these might be clinical observations and/or patient-reported data. Next slide.

I am just going to get us through this section, and then Arien can pick it up as we transition to the next. Our 15th recommendation has to do with average blood pressure. This is an element that we have had a lot of opportunity to discuss because at three of our meetings now, we have had public comment from the American Medical Association and American Hospital Association about how important they feel this is. Certainly, average blood pressure is often utilized to monitor hypertension, especially in the outpatient setting.

There are a number of groups that have worked on defining this, and we felt that it was worthwhile for the ONC to work with those groups to determine what this definition needs to be. To just say “average blood pressure” is a little vague. It needs to be defined as average, perhaps, over how many readings, over what period of time, or if they are all within the same setting or a different setting. This is important to differentiate this from the mean arterial pressure, which is really an average of the systolic and the diastolic pressure. So, we felt that there was an opportunity to advance this data element from Level 2 into either the next or a future version of USCDI, and that it was important for ONC to put some focus on this given the importance of this for stakeholders. Next slide. There we go.

We recommend that V.3 also include an organizational identifier. This was of particular importance to CMS, the idea of being able to identify the organization in which care took place, and for this identifier, you need to have the number as well as the assigning authority, which is to say what this number is a part of. This is true for a number of elements of USCDI where you need to have, for example, if a physician has a medical license number or a nurse has an identifier, you need to be able to say, “Here is the alphanumeric string and here is the assigning authority with the meaning of that.” So, we felt that organizational identifier was ready for primetime, very important to the community, and worth adding.

As part of this, we also felt that there should be a defined set of assigning authorities that would include and be able to accommodate a number of different numbering systems, including NPI, CCN, and PTN, and that this data element be able to support multiple identifiers, as sometimes there is more than one that is applicable in a given setting, and we felt that this organizational identifier should be associated with the encounter as opposed to with the patient, which seems sort of self-evident, and as we said, this does not mean that every system must collect this data, but that it should be required to exchange this data if it is known. Next slide. All right, and then, that brings us to the next stash of these, the data elements that were already included in prior versions of USCDI, where we wanted to provide some commentary on those. Arien, are you on audio?

Arien Malec

I am here. Let's go.

Steven Lane

Terrific. Why don't you take it from here?





Arien Malec

All right, great. So, we had a good amount of discussion, as Steven already covered, about the notes information, and we want to make sure that discharge summary data element, which is already a data element in USCDI, refers to the unstructured narrative. We have a fair amount of discussion about how to handle narrative notes. There is some ambiguity here between handling the narrative section of a discharge summary and what is often called the discharge summary in health IT land, which is a fully structured either consolidated CDA or FHIR document. So, go on to the next recommendation.

And so, going along with that recommendation, we want to make sure that USCDI includes all note types parameterized by a LOINC code. If that is a bridge too far, then at least we should be adding the surgical op note and the tumor board note. So, just a little bit of background clarification: We have been adding note types one by one, and at this point, we have quite a number of note types, and we are trying to add them in terms of clinical utility, but what is clinical utility for one specialty may be too much for another, and what is not included may have the most vital or critical information, so we felt it was a better approach just to make sure that notes are coded via LOINC codes, are made available for purposes of interoperability, and again, we can go through the clarifications here. So, No. 1 is we want to make sure that this recommendation is for the narrative note, the clinical document textual summary, as opposed to a CDA- or FHIR-structured document. Go on to the next page.

And, any time where you recommend that any be available, it is important to clarify that for purposes of some future certification or testing, we are not intending just to say that every EHR be able to produce every possible class of document or note type. It would be a little illogical for a pediatric EHR to produce a surgical op note, but we want to make sure that when a note is produced, it is labeled with the correct LOINC code, and that when a note is received, it is also labeled with the correct LOINC code, and that the receiver can at least display it as a note. It would be useful for conformance purposes or testing purposes for there to be a core value set. Oftentimes, when we have a possibly infinite value set, it is useful to constrain to a core value set for purposes of conformance testing. And then, because we have a large number of notes that are currently uncoded, we suggest to ONC that they work with LOINC to create a new code to address legacy notes that are not especially coded, so, maybe a generalized note code. This one spans pages, so, go on to the next page.

So, No. 19: We want to make sure that the smoking status data element is not a thing, but something that can be represented using a number of assessment instruments or assessment methodologies, and I believe we have some sample LOINC codes associated with this. Go on to the next recommendation. So, here, we have a number of classes in USCDI where we make a reference to a single element or, in some cases, a range of elements, but the actual class includes much more.

So, here, we are recommending in USCDI that we include a fully scoped medication data class, and here, we seek to constrain that fully fleshed-out data class using data elements that are already required for a variety of interoperability specifications and associated certification. That could be in NCPDP script, FHIR, and consolidated CDA, and we list here a number of the data elements that are associated with that fully scoped-out data class. So, just for the HITAC's reference, the medication data class currently requires medication and RxNorm code. Clinically, that is not really interpretable without, for example, some of the other data elements that we are listing here. Go on to the next recommendation.





So, we already have an address specification. The address specification has a number of fields associated with it. In conjunction with a number of other federal stakeholders, ONC put together a wonderful set of specifications with an accompanying companion guide called Project US@, and it puts together a set of formalizations and requirements for address, including current address and previous address. Those data content recommendations help and facilitate data matching, and the Project US@ spec also has accompanied with it an API for test. In the future, we would like that API to be available for broader use and normalization. Normalizing that address information consistently would help with patient matching.

The Project US@ spec has an address metadata spec. That is used for labeling an address, and as a particular type of label, we feel it is very important that the metadata specs that speak to homeless status, temporary addresses, multi-stakeholder dwellings, etc. be included. So, basically, we would like the Project US@ metadata schema to be added to the current address and previous address. Again, that is going to help with matching by allowing us to distinguish whether an address that is in use is one that is persistent over time or one that may be temporary or associated with an unhoused status.

Because, again, we are adding content and structure to a field that previously did not exist, we are going to have the issue of legacy data sitting in EHRs, and so, we feel it is appropriate in our last sub-portion of this recommendation to include a content specifier in the same way that we often have content specifiers or value set specifiers. Go on to the next slide.

All right. So, we had a fantastic presentation, as Steven already noted, by the Gender Harmony Workgroup, and there is a set of data associated here, and in USCDI V.3, we would like Gender Harmony's five data elements and their associated value sets to be included for gender identity, sex for clinical use, recorded sex or gender, name to use, and pronouns. We would like to make sure that the gender identify value set combines values from both Gender Harmony and ONC, so the Gender Harmony value set was male, female, nonbinary, and unknown, and we have added two more to stay current to the current ONC value set. Go on to the next one.

All right. We have an existing field, called sex assigned at birth, and to be principled, we would like sex assigned at birth to be one part of what Gender Harmony calls recorded sex or gender. The notion of a recorded sex or gender allows for observations or legal status documentation to be captured at any point in time, and we believe sex assigned at birth should be a recorded sex or gender assigned at the time of birth. That puts it at a much more principled status. There is a lot of sometimes murky legal definition or jurisdictional definition around sex assigned at birth, and all we are looking for is for that field to stand for the sex that was either legally observed or legally assigned at the date of birth.

We believe that gender identity should be in the patient demographic class, and name to use and pronouns should also be included in that class. As we have already discussed with metadata, gender identity, name to use, and pronouns should be specified as typically being self-reported or coming from self-report from the individual, and we note the recorded sex or gender may be a clinical value, or it may be a legal documentary status, so we are not making any particular clinical judgments when we think about a recorded sex or gender. Go on to the next one.

So, sex for clinical use. As I think many people know, in our understanding of sex and gender, we contemplate usually that sex is the biological fact and gender is the culturally determined or self-reported





identity, and in some situations, both either associated with a person who is transitioning or a person whose basic biology does not fit to a neat binary schematic, there may well be some context-dependent aspects to the biological fact that may have clinical interpretation, and so, because of that, the Gender Harmony group, backed by other stakeholder groups that have delved deeply into this topic, believes that we should have a clinically context-specific and context-dependent identifier or observations, which is sex for clinical use, and you can imagine a number of situations where, for example, the sex for clinical use for lab ranges may be different from the sex for clinical use for physical imaging. So, we give the example of an image study versus a laboratory assessment.

And then, for both of these values, recorded sex or gender and sex for clinical use, we recommend that we have the associated metadata that goes along with it that identifies whether this is an observation or a self-assessment. So, there is a lot there, and again, we had a fantastic presentation from the Gender Harmony group. They have already done a lot of pre-thought there. Go on to the next set of recommendations.

All right, as we discussed under medications, the current USCDI spec for lab says that it is a lab that has an accompanying LOINC code, and a well-structured lab observation/lab result has quite a bit more to be clinically interpretable, and so, there is a set of data elements that are already included in Level 2 currently, but already functionally included in every EHR or in most systems that are associated with certification, and are already required by, for example, CMS under CLIA with a specific regulation associated with the transmittal of lab results, and these are mapped to existing certification requirements using FHIR, consolidated CDA, and the ELR spec, and these include the unit of measure, laboratory result date and time stamp, when the test was performed, the specimen source, and test kit unique identifier.

Test kit unique identifier is a new addition. It is very important to be able to track in test kits that have some level of disposability associated with them, tracking back to the original observation. But, the first four are really pull-ups from things that I think people have already assumed are implied to be in the laboratory data class, and just making it clear that they really are in the laboratory data class. All of these data elements are to be sent if available, and inclusion in USCDI does not imply a requirement for collection, only a requirement to transmit and use when the data is available. This actually is pretty consistent with the documentation in CLIA. Go on to the next page.

Steven Lane

That comes back to me.

Arien Malec

All right.

Steven Lane

Great. Thank you, Arien, for taking us through those, and just a reminder/reorientation for everybody, first we presented recommendations regarding the data elements and new elements and classes included in the draft V.3. We then went through recommendations related to Level 2 data elements that we felt were deserving and warranted to also include in Version 3, knowing that that might be a lot to ask, but we felt that it made sense to try to include those in this phase, and then we did a little bit of out-of-scope work, as we so often do in our workgroups and taskforces, so these next few recommendations are





recommendations that do not directly address those two questions that we were asked, but we felt were important to bring forward, so we present them to you here. Next slide.

We do request and recommend that ONC charge our workgroup with some additional work. Specifically, Arien just talked about the data elements from Level 2 that should be added to the medication data class to make that more robust and functional, but even with all of those, we do not have the data required to be able to construct specific medication lists, which is to say, what is the current medication list, or what is the discharge medication list? This requires some additional data in addition to what has already been suggested, and really, some additional thought with the input of vendors and other experts, and we feel that this would be an appropriate area of focus for the workgroup, and if you all see fit to ask us to do that work, we would be happy to do it this year after we are done with our ISA work, but of course, that would require some additional support from ONC, and I think our workgroup is willing to do that, to stay on and focus on these.

The next, Recommendation B, is that similarly, we request to be charged with the development of recommendations around the data models necessary to support the interoperability of discrete laboratory test results. Again, this is a very important and complex area, where a lot of work has been done by different groups and a lot of efforts have been made. In the context of the pandemic, I think we actually saw substantial success in the ability to exchange discrete laboratory data related to COVID-19, but that was really bespoke development that was done by a number of vendors and organizations to make that possible, and that is really needed for all discrete laboratory data. It is a big bunch of work, and one that we feel that the ONC should be continuing to advance, and our workgroup would be happy to participate in that work in trying to move that forward and develop specific recommendations. Next slide.

The workgroup also wants to encourage the ONC to explore qualifiers regarding the collection and measurement of vital signs. We talked about multiple vital signs, average blood pressures, but there is more to it than that. It is important to be able to qualify vital signs, when, where, and how they are collected. There are existing LOINC codes to support this work, and while these were not data elements that were not at Level 2, so we could not suggest their inclusion in this next version, we do feel that ONC should support them and see what is needed to get them up to snuff for Level 2 so that they can be added into a future version of USCDI. Next slide.

The workgroup also encourages ONC to work on the development of a new data element, called accommodations. We had, as we noted, a lot of discussion about documenting disability status and other health statuses, but accommodations has not been submitted as a data element for inclusion in USCDI. This comes up a lot in our discussions. People say, "Oh, we should also include this," and we say, "Well, we cannot do that because nobody has bothered to submit it into the system, so we cannot approve the addition of something that has not been submitted, leveled, and evaluated. Accommodations is one of those things, and we feel that ONC can work with stakeholders to help bring that forward into the mix for future inclusion. Next slide.

Similarly, laboratory reference range is down at Level 1, so we were not in a position to recommend its inclusion in USCDI Version 3. I think a lot of people are surprised to see this down at Level 1 because, of course, we exchange laboratory reference ranges all the time, so again, we are encouraging ONC to work with stakeholders to see what is really needed to bring that up from Level 1 to Level 2 so that it can be





included in a future version of USCDI as such an important data element. Next slide. And those, my friends, are our recommendations. So, as you can see, our workgroup has been working as a group and has brought forward these recommendations for your consideration. I think we have plenty of time here to entertain questions. So, Denise, why don't you take us through that?

Denise Webb

Yes. Thank you, Steven and Arien. So, let me see if we have anybody in the queue. It looks like Eliel made a comment in the chat. I do not see any hands up.

Steven Lane

I did respond to that. He made the good point that we have previous address, but it would be nice to have previous phone numbers and previous emails to support patient-matching efforts. I could not agree more. That is a great example of one of those data elements that nobody has bothered to suggest. We cannot bring it forward if it has not been suggested and leveled, so any member of the public has the opportunity to go into the website to create an account and to suggest new data elements and/or classes, and I will say I have done that personally, it is very satisfying, and it has been great working with the ONC team. They work closely with submitters. Anybody can put that in for suggestion.

Denise Webb

All right, thank you. Michelle Schreiber has her hand up.

Michelle Schreiber

Hi, thank you. First of all, thank you for a great presentation, Steven and Arien. On behalf of CMS, we are really very excited to see the recommendations coming forward. CMS was also collaborative with CDC in bringing forward some of these as well, and we are really pleased to see this. We really particularly want to support ONC moving forward with support for this committee, especially around medication classes, because we think having a standardized medication list is so important clinically, as well as the other recommendations for further support, but particularly that one.

The other areas for support that were not quite captured, but I think maybe we should talk about in the future, would be end-of-life issues as well as detailing out encounter and encounter history, but I am fully supportive of the recommendations and really want to thank the committee and our cochairs.

Denise Webb

Thank you, Michelle.

Arien Malec

Yes, the medication list is one we believe we would like to be tasked with more specifically. Again, as a reminder to the committee, we used to have the functional requirement that EHRs be able to capture medication lists. That was removed, but we feel it would be important to have the interoperability specifications for medication lists when they exist, and again, we feel that would be a good part of a future work plan.

Steven Lane





And, with regard to the end-of-life issues, there are a number of advanced directive data elements that are sitting down at Level 1, and so, were not available to us to recommend bringing forward. Certainly, workgroups that have looked at USCDI over time have enthusiastically discussed the potential value of exchanging information about advance directives, pulsed, etc., and our understanding is that ONC has looked at that work, has determined that it is not yet ready for inclusion in USCDI, and hence the Level 1 work. So, I think anybody who is working in that space who wants to see those standards advance has an opportunity to comment within the website, to engage with ONC, and to prove that those elements are ready for exchange.

Denise Webb

Okay. Our next question is from Hans Buitendijk.

Hans Buitendijk

Good morning, and thank you. First of all, thank you, Steven and Arien, for doing a great summary of all the work that was done in the workgroup. It really reflects well what happened and what to focus on. There is one that I would like to underscore a little bit more, and that is not necessarily directed at USCDI, but some of the impacts of USCDI expanding that perhaps, at some point in time, could become a discussion of HITAC as well, or at least an awareness, and that is around the motif that Steven started with. Arien has repeated a couple of times that as USCDI grows, it starts to include data that is very appropriate to include in USCDI, which needs a lot more in it, that not necessarily all HIT, and I am not saying EHRs, but HIT in general, including EHRs, need not support for their particular focus in their role in supporting the respective stakeholders.

But, at this point in time, which has been called out that we do not have to be careful about, while there is optionality on the provider side to support or not, on the HIT, to be certified to capabilities, and particularly assumed that everything is adopted in USCDI Version 3, then for somebody with HIT who would like to certify using the SVAP approach, they would have to certify against everything, not necessarily just what they need. So, I think the comments are being made that are already in USCDI, but which need to be looked at generally, that we have to be very cautious and considerate that not all in USCDI need to be supported by all HIT. So, somehow, we need to figure out how that works as to not encumber and effectively create special effort on the side of HIT to create capabilities that they actually do not need. So, that is something to consider for future discussions. It does not impact what is being proposed in the USCDI right now because all that data is relevant, and we need to grow it to ultimately count for all of EHI. It is a consideration of how we manage it downstream.

Denise Webb

Thank you, Hans. That is a really good point, and I know that has been a concern for me as well as a number of other folks who have raised that issue, and it would probably encourage vendors to get their health IT certified if there was some optionality there that was appropriate for the particular product that they would like to get certified in. I know from a provider organization perspective, there is some assurance to acquiring a certified product versus a noncertified. Any other hands? I do not see any.

Steven Lane

Denise, I will introduce a comment to simply say what a pleasure it has been to work with the ONC team in this effort. They have really been providing tremendous support in terms of putting together the group,





helping us with meetings, bringing experts to the table, and really all of the background work they do to evaluate the submissions that come into the website, to do the leveling, etc. Certainly, our workgroup could not have accomplished this without the tremendous support of ONC, and we thank them for that.

Arien Malec

As usual, at that last moment, when a bunch of workgroup discussion gets turned into a thoughtful, readable, and coherent recommendations letter, we are really appreciative of ONC and AI especially for all that work.

Denise Webb

I could not agree more. It is a great collaboration, and we could not do the work we are doing without their help. And, of course, they need all of the subject matter expertise. All right, any other final comments or questions from the committee before we go to a vote on the recommendations that this workgroup has offered to our committee to vote on? Well, Steven and Arien, it looks like we are ready to move to a vote. Could I have a motion to approve the recommendations that the workgroup has brought forth to the HITAC to deliver to the National Coordinator?

Aaron Miri

So moved.

Michelle Schreiber

Second.

Denise Webb

All right, let's see. Who did we have motion?

Aaron Miri

That was Aaron.

Denise Webb

Okay. And, second was Hans?

Hans Buitendijk

Hi, I am happy to, but I did not get a chance. There were others ahead of me.

Michelle Schreiber

It was actually Michelle, Denise.

Denise Webb

Oh, okay, Michelle. Thank you. All those in favor, say aye.

Several Speakers

Aye.

Denise Webb





Okay. Any noes? Any abstentions? All right, so moved and voted. It is unanimous. Thank you very much, Steven and Arien, for leading this group and for all the work that the workgroup did, as well as ONC. We really appreciate it.

Steven Lane

Well, wait until you see what we bring you in June.

Denise Webb

Oh boy. Right, that is coming up next, or in a couple months. All right, so, Mike, are we ready to move to public comment? Let's see. How are we doing on our time?

Michael Berry

We are doing great, and we are ready to move to public comment if you are.

Denise Webb

All right. We are a little ahead of time, but that is good. Certainly, let's do that.

Public Comment (01:10:30)

Michael Berry

Great. So, we are going to open up our meeting today for public comment, so if you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be just on the phone only, press *9 to raise your hand, and once called upon, press *6 to mute and unmute your line. So, let's pause for a moment and see if we have any public comments. I am not seeing any, but we will give it another minute, and I just want to remind everyone while we are waiting that the next HITAC meeting will be held on May 18th, and that all the materials from today's meeting can always be found on the HITAC page on HealthIT.gov. I am still not seeing any hands raised, Denise and Aaron, so I will turn it back to you to close us up.

Aaron Miri

Denise, you first. You are on mute.

Denise Webb

Thank you, everyone, for joining today, and thank you again, Steven and Arien, for your excellent job presenting your recommendations, and I wish you all a great day, and I hope you all get to enjoy some of the sessions that ONC is sponsoring at their annual meeting today and tomorrow.

Aaron Miri

Absolutely. So, thank you, everybody, and welcome to the new ONC meeting after this. Enjoy it, and we will talk to you next month. Have a good one.

Denise Webb

Thanks, everyone.

Final Remarks and Adjourn (01:11:55)

