Transcript

HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS PRIORITIES TASK FORCE MEETING

March 11, 2021, 2:00 p.m. – 3:30 p.m. ET
VIRTUAL
## Speakers

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

Operator
All lines are now bridged.

Michael Berry
All right, thank you very much. Hello, everyone. Welcome and thank you for joining the Interoperability Standards Priorities Task Force. My name is Mike Berry, I am with ONC, and I am the Designated Federal Officer of the HITAC and this Task Force. I see that many of you are returning members, and on behalf of ONC, I would like to thank each of you for your time. I especially want to thank Arien Malec and David McCallie for serving as co-chairs for the Task Force. We are really very pleased and fortunate to have them leave the charge.

Just for everyone’s information, all these Task Force meetings will be held publicly, and members of the public are welcome to share their comments and feedback through the chat feature, or they can also do so during the formal public comment portion of our meeting, which will be held about 3:25 p.m. Eastern Time, which is about five minutes before I close out the meeting. Also, I will be taking roll call at the top of each of these calls, so when I call your name, please indicate your presence. Let us start with our co-chairs. Arien Malec?

Arien Malec
Hello.

Michael Berry
David McCallie?

David McCallie
Present.

Michael Berry

Jim Jirjis
Present. Can you hear me?

Michael Berry
Yes, thank you. Edward Juhn?

Edward Juhn
Present.

Michael Berry
Ken Kawamoto indicated he is going to be out today, but he should be joining us next week. Victor Lee? Les Lenert? Clem McDonald? Jack Po? Raj Ratwani? Ram Sriram?
Ram Sriram
Present.

Michael Berry
Sasha TerMaat? Andy Truscott?

Andrew Truscott
Present.

Michael Berry
And, Scott Weingarten?

Arien Malec
We have a couple of people who were having audio issues, so Victor Lee, Jack Po, and Raj are all saying they are having trouble connecting to audio.

Michael Berry
Okay, we will capture them as we go along, then. Thank you.

Arien Malec
Cool. If folks can hear me, as you join and connect to audio, just tag yourself in the chat and we will make sure to acknowledge your presence.

Michael Berry
Thank you, Arien. Thank you all. I would now like to turn it over to Arien and David for their opening remarks.

Introductions (00:02:42)

Arien Malec
Howdy! We are excited. I think we are super pleased to kick off another round of the ISP Task Force. We are going to go over our charter in just a bit so we do not belabor it, but I think that the work that we are doing here sets the foundation for the next generation of the U.S. health care system and standards interoperability related to national priorities, so we are excited to be able to put some useful advice in front of the national coordinator and help set the agenda for where the nation goes in the future. David?

David McCallie
Thanks, Arien, and hello, colleagues, former friends, and new friends. I would not have guessed that it was the ISP Task Force that would drag me out of retirement, but here I am, and I am looking forward to how we can make a contribution.

Arien Malec
All right. I am going to cover the first administrative bit and cover the history of the last ISP Task Force since I have this shared history, and then we are going to turn it over to David to lead us through a discussion of potential priorities for the ISP Task Force to take on. I think we are going to take an approach that goes broad first and then narrows, understanding that we cannot take on every possible charge, so we are going to intentionally go wide first, and then narrow in second. Go to the next slide.
Here is the membership. I think we are really pleased that we have a good group of members, both from the HITAC and from the general HIT community, and also that we got representatives who represent payers, providers large and small, consumer organizations, and patient advocates. We are really representing a broad swath of the U.S. health care system, both the people who are data holders in many cases as well as people who desperately need access to data and are probably underrepresented, pretty obviously in public health, but I suspect we are going to get into the public health weeds and pull in folks on the public health side.

So, I think we have a great group, and we will spare each other from going around the room and doing introductions. I think most of us have worked together in the past, and we are going to be able to work together very comfortably in the future. Go on to the next slide.

Priority Uses of Health IT (00:05:46)

Arien Malec

So, where does the ISP Task Force come from? This is actually enshrined in the CURES Act with the notion that the national coordinator shall convene the HIT advisory committee to identify priority uses of health information technology and associated standards and implementation specifications, publish a report, and make appropriate recommendations that in association with NIST, HITAC will annually review priorities for health information technology, standards, and implementation specifications. So, at least one reason for why we are all together is that Congress told us to be, and we have to produce a report.

I think a lot of us are in this for the interests of the nation, and just producing a report with a check box would not be a terribly satisfying thing to do, so the real reasons we are here is that the standards and technology evolution for the U.S. health care system is a journey, and we identify unmet needs and then need to continually fill the pipeline of projects for ONC, stakeholders, and industry to work on in order to address the end stage of where the U.S. health care system is going. If we do our job well, we help digest a lot of potential things that ONC and other stakeholders could work on and get to a narrower set that is easier to action.

I would also point out that the list of things that ONC and the U.S. health care system could take on is potentially infinite, so a useful thing we can do is prioritize, which is in our name. We can prioritize and also think about the timeframe of standards interoperability evolution so that we are thoughtful about dependencies, past dependencies, and timeframe dependencies, and are setting an appropriate and thoughtful roadmap or helping the ONC set an appropriate and thoughtful roadmap in our recommendations. So, I am just going to pause there and see if there are any questions on the reason that we are all here. Otherwise, we will go to the charter. Let us go to the charter. Sorry, that is our charter.

David McCallie

It is the next. Actually, Arien, there is one more slide, so go one slide forward.

ISP Task Force Specific Charge (00:08:27)

Arien Malec
Thank you. Narrowly constituted, our charter is to identify opportunities to update interoperability needs within the ISA section. So, if you think about the ISA, it is a really well-organized list of standards interoperability components for the nation. Part of the way to frame our charter is to ask what items in the ISA are missing or have additional needs in order to advance standards interoperability for the nation. Thinking of our mission a little more broadly, we should feel free to publish additional recommendations that may not fit this particular narrow charter, but we need to make sure we address this narrow charter of additional or modified interoperability needs for consideration of updates to the ISA, including related standards implementation specifications. Okay, now we go one back.

David McCallie
Arien?

Arien Malec
Go ahead.

David McCallie
I just have a couple of comments on the previous slide if we can go back. I sometimes struggle to read bureaucratic language, and I have to parse it into chunks that make sense to me. I see two somewhat different goals here. Adding new standards or updating existing standards that are already in a priority use case that is documented in the ISA is one thing that we can do, but we can put new things into the ISA in terms of these interoperability needs. So, if it is a category that does not cover something we think is important, it is in our charter to identify those priority needs, not just to add standards to existing categories. I think about those two quite differently, and I think the skills that may be required to be knowledgeable are different as well, so I just want to make that point. Arien, it is all yours.

Selected and Future Focus Areas (00:10:37)

Arien Malec
Okay. So, if we go up, let us just do a little history review. So, the last time this band of superheroes met, we identified a set of focus areas in 2019, and then we lined up a set of future focus areas. I am going to note that something very obvious happened in 2020 that means that the future focus areas that we outlined may be in need of some revision, and that is going to be a tee-up for David to lead us through the next section. But, just as a reminder for the group, particularly for those who were either part of the group and have forgotten what happened two years ago because of the intervening year or people who are new to the group and are interested in what the group worked on, we identified a big focus on orders and results.

We actually went really deep on orders and results and followed the workflow from order to result all the way through back and forth, followed that pathway, and then thought about standards interoperability levers and policy levers associated with improving workflows for orders and results. We went on to closed-loop referrals and care coordination. It was the same kind of thing. We asked what it would take to transfer information from primary care to specialty or proceduralist and get back the report. And then, we also did a deep dive into medication and pharmacy data, really from the perspective of how we get a complete summary of medications taken and medications dispensed relative to assembling a complete medication list, and then we also thought about cross-domain activities associated with code sets terminology and other kinds of foundational activities that we would take on.
And then, we thought that in the future, we would take on chronic care management, SDOH, and cost transparency as future areas, and I think if we look at those areas, they are pretty high-priority areas, but we also note that in the intervening time, we had a pandemic, and we noted the areas where our U.S. health care system worked and did not work from the perspective of data flows and interoperability to respond to a public health crisis, and I think that also exposes some larger-scale interoperability needs that are independent of public health. So, there is an obvious set of future focus areas addressed in, first of all, just closing out the journey that we had relative to public health and COVID, but also to look at that as a good learning experience for what kind of system we can build toward in the medium term and the future to ensure that we do not have the same kinds of issues. I am going to pause and see if there are questions on the previous work of the ISP before I turn it over to David, who will lead us through a discussion on future ISP activities.

**Andrew Truscott**
I have my hand up.

**Arien Malec**
Sorry, Andy, go ahead.

**Andrew Truscott**
I was just wondering how you were going to handle it, Arien. I just have a quickie. It would be very easy for us to say, “Hell, we have had a global pandemic, we need to go and do something really specific over COVID testing, et cetera.” I would urge that we have a little bit of caution on doing too hard a knee jerk, although it has been a year, and actually look at how we could finesse orders and results and maybe do specific use cases in there around both active infection and antigen-type testing and just explain how that services it. Obviously, the glaring area in here that we did not look at and have not considered would be around immunization histories and immunization administrations. I think given the current climate, it would be an unsatisfactory overlook if we did not look at that. What do you think?

**Arien Malec**
I agree, and that is part of what David is going to lead us through.

**Andrew Truscott**
Oh, perfect.

**Arien Malec**
Andy, I really like the notion that we should think about following the data through. Actually, one of my takes was that when we looked at the work we did in orders results, if all that work had magically gotten done between 2019 and 2020, we would be in a much better position with respect to be able to flow order information into labs with demographic and contact information, and from there to public health, so it is worthwhile to relook at these areas from the lens of how our system fared in response to a pandemic, but that is definitely part of the work that David is going to lead us through.

And then, I agree with you all that we should not over-rotate and over-fixate, but I guess the lens that I am advocating is to look at the experience of the past year as exposing some gaping holes in the U.S. health care system as a system and acknowledge that there is some work to be done there. Other examples in
that light are things like the work the U.K. did in recovery trials that I think the U.S. was objectively not as advanced in being able to use and marshal the data that we had flowing in order to inform real-world evidence and emergent evidence trials. If other folks have questions or comments, please raise your hands. Otherwise, we will turn it over to David to facilitate through a discussion on future priority areas for the Task Force.

David McCallie
Thanks, Arien and Andy. Your suggestion is exactly what we are going to dive into here over most of the rest of our time together this afternoon. I do not have a predefined plan for exactly how to coordinate the conversation when we are at this highly zoomed-out level, but I think the process might go something like this: In today’s session and perhaps in our next session, we surface some broad ideas without a lot of detail other than the detail of why you think it is an important idea for us to consider, and we will try to build a list of the ideas that resonate with the group, and then maybe prioritize amongst those before we dive into the details of the best ideas or into the categories that we choose in the near term and long term. We might break it up in different ways. But, I would look at today’s session as a harvesting of ideas, not to go deep, but to go broad. We may come up with some things that we review with our other colleagues and ONC, and they may say, “That was well covered, so we can have you guys skip that one,” or we may come up with things that we had never thought about. So, let us open it up to that discussion.

Just for the sake of keeping us from bouncing all over the map, maybe we could start with things that are related to the 2020 experience. That does not mean we will not touch on non-COVID-related or non-public-health-related topics later on, but just to avoid whiplash, Andy, do you want to take the lead and reiterate what you just said to give us a kickoff for the discussion?

Arien Malec
Before we do this, can we just confirm attendance? I saw that Ricky said he is here, Raj was trying to join, Jack was trying to join, and Victor was trying to join. Do we have audio from all these folks who were eagerly trying to join the conversation, just to make sure we are taking their input?

Andrew Truscott
Or is it just the three of us?

Raj Ratwani
This is Raj.

Arien Malec
Okay, Raj is on. Ricky, are you on?

Ricky Bloomfield
Yes, I am on.

Arien Malec
Okay, Ricky. Jack, are you on? I think Jack is still having issues. If people are trying to get on and having issues, please tag folks, and the Accel group will try to address your audio issues. Sorry, David. Back over to you.
Victor Lee
This is Victor. I am on.

Arien Malec
Thanks, Victor. Sorry, I apologize.

Victor Lee
My bad. I do need to drop in a few minutes. Would it be okay if I shared a quick thought to answer that question around priority areas vis a vis COVID?

David McCallie
Yes, please, Victor. I am glad you brought up that your time is limited. Go first, please.

Victor Lee
My apologies to the whole group. One of the things I had an opportunity to work on, which is still in progress so there are a lot of details that I do not understand, is this whole notion of understanding early detection of novel infections that could be of pandemic proportions, as well as just other notifiable conditions, and it is really the first time I have jumped into this world, so there is probably a lot of the ecosystem that I do not understand, but there appears to be a lot of siloing with laboratory information. While there are meaningful use requirements for the ability to electronically report labs of notifiable conditions, it is my impression that there is a disconnect between what is happening at local laboratories and health care delivery systems, across providers within a delivery system, and how that information can be shared among those actors as well as health information exchanges and state health departments, and also having that information seamlessly roll up to federal agencies like the CDC.

And so, what I have witnessed is a fragmentation of the flow of that information, who has access, and how easy it is to do electronic laboratory reporting, and this has ties with electronic case reporting. Anyway, I just wanted to comment on that. That has been my experience working with some projects within HIE, and that is just the observation that I wanted to share. I think some of it may have to do with policy, but I also noticed issues with current interoperability standards and variability in how you construct, for example, HL7 V.2 lab messages syntactically as well as semantically. So, I know I have said a mouthful, but basically, I wished everything would seamlessly flow together, and it was my observation that it did not, so I will leave it at that.

David McCallie
So, Victor, I would suggest that there be a broad category here that you started with called syndromic surveillance, which is the ability to detect some of these things earlier, and that the specific gap in syndromic surveillance that you are identifying is low-level flows of information between systems that could contribute to better situational awareness for emerging syndromes. Is that a fair statement, or is that too narrow?

Victor Lee
I think you summed it up beautifully.

Arien Malec
David, just editorially and as the voice of the past ISP Task Force, one of the issues that we discovered when we looked at orders and results in the last ISP Task Force is that unsurprisingly, all the standards we would ever need or want were already there and actually pretty well vetted and done with narrow guidelines, but because the electronic reporting CMS measure was topped out, it was removed as a CMS measure, and then it was dropped as a certification measure, and then there were no policy ties to do an orders standard.

And so, even though we had all the standards we could possibly use, including LOINC subsets and the LRO orders and results standard that had gone all the way through the HL7, was vetted and validated, and in some cases, incorporated into EHRs, they were not universally or even broadly adopted because we basically grandfathered everybody to have their own legacy lab reporting standards, and that is a little bit of the issue that Victor is pointing out.

**David McCallie**
One of the bricks that we adopted in the last incarnation of this group was where Ken and Steven Lane managed a spreadsheet where we tried to categorize policy issues, policy lever arms, regulatory constraints, and/or opportunities for each of the priority use cases that we tried to surface, and I think it is probably going to be valuable to follow that model beforehand. So, as Arien just discussed there, there was a regulatory opportunity that got dropped that might or might not be something we would want to surface back as saying, “Hey, this is an important lever arm for improving syndromic surveillance, et cetera.” So, we should try to keep track in our heads the difference between where there is a gap in the standards, a gap in policy, a gap in incentives, a gap in regulatory pressures, et cetera.

**Jim Jirjis**
David, it is Jim Jirjis here.

**David McCallie**
I do not know how the hand-raising mechanism works. Let us just try to respect each other’s airspace and speak up because I do not see the hand-raising.

**Arien Malec**
I can help you with the hand-raising. We have done the hand-raising in the past, and I think it has been really useful, and we need to call on people who cannot use the hand-raising because they are not connected to the thingy at the end, but if we can use the hand-raising, I will help you out.

**David McCallie**
Great, I appreciate it.

**Jim Jirjis**
May I make a quick comment?

**David McCallie**
Absolutely, Jim. Go ahead.
I want to strongly support what was just said about this because from our perch and our experience with 19 states, it was not that the standards were lacking. For example, with public health departments, it was not that the policies that would have caused people to actually implement or put something in place, it was that you were showing good faith that you were on your way toward having discussions toward building something. So, we found that there were several states that had never actually done it, and so, even though we were ready with the data thanks to standards, the biggest barrier to actual reporting was the lack of progress in having ready interfaces.

And so, if there is some way to support going beyond that white touch with preparedness of public health technologies and interfaces to receive it, and I would advocate for that. The other thing was I was just curious about people’s notion around the fact that is many-to-many. Just because you have standards does not mean you do not have to go through contracting, data use agreements, surveys, and testing of each of these interfaces, and I am curious if there is a better model, kind of like where TEFCA is headed, to have some sort of one-way onramp intermediary that de-complicates the many-to-many.

For example, we are in 19 states with 190 hospitals. We had to interact with every single public health department and they had to interact with every hospital, and so, is there an opportunity, for example, to use the HIEs so that providers are interacting with someone who has that skillset and that skillset is interacting with the public health department, creating more of a many-to-one/many-to-one with a highly capable person in the middle? We think that would have simplified things. I do not know if those are appropriate for the scope of this committee, but those would be further comments in support.

David McCallie
I think at this stage of our discussion, anything is appropriate. We may get feedback or make a mutual decision to exclude some if it feels too far off, but at the moment, that seems exactly what we are looking for. Jim, maybe not at this moment if you are not ready, but I would be curious to know what the data was that you wanted to be able to move when you tried to move it around and were unable to? In other words, what was the low-level data?

Jim Jirjis
I can tell you briefly. What worked well was federal reporting of the White House Task Force because it was clear and teletracking. Sometimes there was not enough notice, but it worked. What did not work well was when we had to report to each state’s public health department all the requirements around the vaccinations, et cetera, and not just vaccinations. Many of the states wanted the same data that the federal government wanted. We were ready, willing, and able. They were neither ready nor able, though they were willing. So, I think that is where we ran into problems, and then there is this whole other category. Forget the vaccines and stuff that HHS wants that the states also want. Some states had an enormous number of additional data elements that were never part of any standard. I am ignoring that as a problem that would be hard for us to solve. Maybe USCDI would solve it one day.

Andrew Truscott
Jim, can you give some specific examples of which states and which additional data elements in what context?

Jim Jirjis
I am trying to remember the states. I think Florida was the one that proliferated its additional data elements way beyond what HHS wanted. I am thinking of states like Kentucky and Tennessee early on. I am trying to remember if it was New Hampshire. I can get you the list. There were about five states, and Texas was one of them, where they just could not do it, so we were trying to figure out how to be compliant. We were faxing them PDFs that they never used.

Andrew Truscott
Jim, what was it that they could not do?

Jim Jirjis
Oh, I am sorry. Some of the requirements were vaccination status of your employees or patients where you were submitting. Hospital utilization data was one of them, and when we got into vaccinations, there were specifics around who was vaccinated and how many of your employees were vaccinated. Those were requirements to report to the public health department.

Andrew Truscott
Got it, thank you.

Jim Jirjis
I have a list.

Ming Jack Po
I am not sure if anyone can hear me. I can actually add a little bit of color because I was also dealing with some of those issues. I think states like Connecticut also started asking for adverse event reporting, when and where they got first or second shots, and whether the family also got vaccinated, so there were a lot of other fields that got asked by the state, or sometimes public health at the county level, that got extremely confusing, and there were no standards on any of those.

Arien Malec
That is super helpful. There was overlap with VAERS. Does VAERS have electronic standards associated with it, or is it all paper-based or form-based?

Andrew Truscott
VAERS is form-based.

David McCallie
I do not know what that is.

Arien Malec
VAERS is the FDA Vaccine Adverse Event Reporting System. That sounds like a “go get” in terms of identification. We want to know whether there are actually standards for vaccine adverse event reporting.

Andrew Truscott
Would that not just be AAR reporting, with a use case around AARs from vaccines?
Arien Malec
Right, exactly. So, it would be SAE or AE reporting, but FDA has split theirs versus the other one, which I cannot remember but will come to me at some point, but we actually have split medical device reporting, vaccine reporting, and direct reporting. I think we also have biological adverse event reporting that is split off from vaccine adverse event reporting.

Ming Jack Po
I would say that is not just that. Basically, states are trying to deal with equity issues, adverse event issues, and long-term tracking issues, so they are looking at social demographic issues, ZIP code, who else is in your family, what your job is, why you are currently qualifying, and what your health status complications might be. Frankly, even in some states that were asking for it, some providers just decided to ignore the requests because they did not want to collect the data, whereas, as you guys know, some private contractors got hired to go give shots and they were going berserk, implementing their own systems, and collecting a lot of data. It got extremely confusing at both the state and national level on a lot of vaccination data, and that is before we even get into the logistics. I guess there were a lot of people asking for who has what shot, [inaudible] [00:34:27] for which category. All of that was complete chaos, and it continues to be quite chaotic.

Jim Jirjis
Just to clarify, it was not the lack of whether there was a standard available or not, it was more remedial. They had no interface built, and three of the five were months away from having a live interface because they had never gotten that far with public health reporting data, and that is where people were piggybacking.

Ming Jack Po
I totally agree. I think this was similar to previous conversations we have had. In some cases, there were no standards, in some cases, there was no implementation, and in other cases, too many people did not know about the fact that there were apps and things built. I think in some cases, there was public lack of knowledge because in the states I was advising, to your point, so many states switched to PDF or just asked for an Excel sheet. They said, “Give us some columns and some data, and we will figure it out on the back end.” And then, even more problematically, there were perhaps three dozen startups that started to fill this gap. All of them were growing internal systems and basically made up their own standards that they pushed to the other people in the state, so there is actually quite a lot of confusion right now on what the standard is.

Arien Malec
Just to repeat back what I am hearing, what I heard was that there is a number of issues. In some cases, there are standards that are not implemented or no readiness to adopt standards. Standards would have been perfectly fine, but there was no readiness on the part of implementers, especially states, to adopt the standards. Second, there were cases where there were well-established standards, but then there were additional state requirements above and beyond the standards that made the standards unusable in practice, and that overlapped with the first issue. Third, in areas like adverse event reporting and some of the other information we were trying to collect, there were no applicable standards, or they were dealing with a system that was almost inherently paper-based and the concept of electronic interface was somewhat foreign.
Clearly, all three of those are going to require slightly different policy responses, but I think it is useful to bucket these by saying we saw a bunch of issues, some of them were lack of standards adoption, some of them were people not adopting the standards consistently, and in some of them, there just was no standard, and we exposed a gap of a complete lack of standards. David, I see that Andy has his hand up.

**David McCallie**

Andy, I will queue you up. I just have one last little comment on that. It is obviously well known that the power to set public health policies devolves to the bottom levels, such as the state and even the county levels, and the ability to do something about it federally is somewhat limited, but I might look to our group to identify and clarify what the ideal standards are. I assume that is already clear in many cases, but we could endorse the clarity if we find it, knowing that ONC and its sibling agencies have some limits as to what they can do, but at least gaining clarity about the preferred way to do it can help in the long run. Public health policy is obviously frustrating, and then, the funding deficit is obviously well understood as well. Andy, go ahead. I think you were next.

**Andrew Truscott**

Thanks. I think it would be a good piece of helpful input to the discussions going on if this Task Force were to just draw together and say that in these use cases, these are the standards that this Task Force would suggest are extant and usable, and this is how you should use them. Elsewhere right now, there is legislation being drafted around data standards for public health, so it would be great if we could actually inform that so that similarly to the 21st Century CURES Act, that legislation actually points at something tangible. Now, I think that could be useful.

**David McCallie**

That is very well said. That is what I was stumbling my way through. Perhaps they get attached to financial incentives and grants in the future so that even if there is not a regulatory incentive, there can be a financial incentive to push states forward.

**Arien Malec**

David, Raj and Jack are in the queue for comments.

**David McCallie**


**Raj Ratwani**

Great, thanks, everybody. I wanted to switch directions a little bit and just bring up something we have been struggling with. I have been out of the loop with a lot of this Task Force and the deep policy pieces, so please feel free to tell me that this issue has been addressed and is not relevant. So, for the last month, MedStar Health has been focused on vaccine distribution like everybody else, but targeted outreach to try and combat some of the disparities that we are all plagued with, and as part of that process, we are having a really big challenge understanding who has already been vaccinated, and in particular, as we try and work with our HIE to learn whether folks have been vaccinated or not, there is no API process, and so, currently, it is a very manual process of looking within each patient’s record and connecting to the HIE to see whether they have been vaccinated. The HIE is kind of building a capability for us to do a batch process
to match patients, but it is not there yet, so I am wondering if that is a space that we should be looking at and whether others have faced similar challenges.

Leslie Lenert
May I comment? This is Les Lenert. We have been focused on this as a huge issue. I have a paper that I can share with you on this. It is a great area for flat FHIR. If you are interested, we have a REDCap program that speaks flat FHIR that you could use this with, but what is really needed is for the states to replicate their data in an interoperable platform like an IIS that takes it out of the IIS and moves it into something like a FHIR clinical data repository or something that can speak flat FHIR. Is that what you want?

Raj Ratwani
Exactly.

Leslie Lenert
You want to send a list of patients every day to the public health department and get back the ones that have been vaccinated so that you can stop calling them.

Raj Ratwani
That is exactly right. Les, I just dropped my email in the chat, so if you could share that, that would be great. And so, from a policy perspective and our use cases, we would love to see that added if others think that it is relevant to be here.

David McCallie
Raj, this is David. I just have one clarification. The data are being captured on the vaccine administration electronically at some point, but it is just very hard for you to get to it. Is that the problem?

Raj Ratwani
Correct, it is captured at some point. The challenge is within MedStar Health’s 10-hospital system, we can see our patients that have been vaccinated if they have been vaccinated at MedStar Health, but if that patient happened to have been vaccinated at Hopkins or anywhere else, we keep reaching out to them saying, “Hey, do you want the vaccine?”, and we are going through this manual cold-call process, and it turns out about 20% have been vaccinated already. It is a super simple HIE problem that could save us a lot of resources and time.

Arien Malec
It turns out that there is a query/response HL7 interface where you can do it on a one-by-one basis. There are no standards to do it on a batch basis, but I do not even think the query/response standard is well adopted by states.

Raj Ratwani
It is designed from a web-based interface that is often provider-specific or vendor-specific. So, the vendor says, “Okay, you can check the vaccine status on your EHR if you work with me on this.”

Arien Malec
We just want to acknowledge who is in the queue…
Andrew Truscott
We are querying set immunization registries across the country using HL7 2.5.1 for immunization status both to supply administration information and to retrieve an individual’s vaccination history, not just their single status, and then we are aggregating it into JSON and passing it up as a FHIR resource.

Leslie Lenert
That is right, and the only thing that would be better than that is to have the registry there, ready to respond with a FHIR-enabled database that could respond to a flat FHIR query.

Andrew Truscott
Maybe, but I must admit that feels like putting a gold Cadillac into something that is working right now where we have bigger gaps.

Leslie Lenert
I totally disagree. This is not a gold Cadillac.

Arien Malec
Let us save the details for a second pass through this because I think we will have to be a lot more specific if we want to recommend specific standards or specific implementations around the standard. So, I will register that this is a hot topic. I also register that I believe Raj said the phrase “super simple HIE problem,” and I wanted to point out that that is an oxymoron. I have never met a super simple HIE problem in my life.

Raj Ratwani
Fair point.

Arien Malec
We will register this as a broad category of vaccination status tracking across regions at a minimum, and maybe even nationally. Jack, I think you had your hand up, and it may be on the same topic or not.

Ming Jack Po
Can you guys hear me?

Arien Malec
Yeah.

Ming Jack Po
Okay, great. I wanted to talk about three things. I wanted to quickly also add a plus one on the vaccination status part. I do not think [inaudible] because honestly, it is now an international issue that there are multiple entities doing vaccination passports. I think we have a very unique opportunity to make a standard with the potential to be global if we do it quickly and well, or we could basically have this entire thing fragment globally into every county.

There are other two things I wanted to quickly mention about priorities that I would love to talk about. The first is price transparency. The executive order has started on that side, but as you guys probably saw, it is
a mix of RAM, Excel sheets, and web pages, so it is basically nonsensical. Having a way to deal with that will be very important. The other thing is also COVID-related. Because of COVID, there is a lot of health equity and socioeconomic demographic data that a lot of people want to access, and that standard is complete chaos. It would also be really good to implement something there before that whole field fragments.

David McCallie
Okay, Jack. You were a little bit broken up there, but I want to reiterate what I heard, and you or others can correct me if I missed something in the choppiness. The first one is vaccination status might be communicated in a passport or certificate with which you can prove you have been vaccinated with, so I will just lump that into a broad category called “vaccination passports,” not necessarily limited to literal passports.

Arien Malec
We should call it “vaccine credentialing passport” for the obvious reasons.

David McCallie
“Credentials,” yes. So, that is a broad category. For the second one, you said to pick up where we left off with price transparency in the past due to the lack of standards there and the fact that there is policy, but not very much in the way of standards. The third was health equity, where you said the standards are in chaos, and I wondered if you could clarify which standard you were referring to.

Ming Jack Po
Sorry, what I [inaudible] [00:48:05] current data collection is in chaos. I do not think people really know what the standards are or if there are any. Because of COVID and because of the current administration, there is an incredible focus right now on collecting this data and simply doing better on disparities, and we have an opportunity to make the right standards in this space right now.

Arien Malec
Sorry, let me pick up on two of those comments just to underscore what I think the request is. So, on the price transparency, CMS put out a rule that requires letting out the price transparency on a patient-specific basis or a plan-specific basis from the hospital, but the standard was basically PDF, text file, or other structured document, and there is no computability of the data that is being put out, so publishing a standard there would be a useful addition to the information that is already being shared.

And then, I understood your point on the demographic and other equity issues. I remember from the standards committee that we actually have pretty well-thought-through demographic standards that are very thoughtful in terms of capturing granularity on a person-specific basis for social determinants of health or racial and ethnic underrepresented status, et cetera, but maybe you are pointing out that on the ground, we do not have any policy levers that make sure that information is actually faithfully collected, so although we may have the standards, we have chaos on the ground in terms of whether it is collected, how it is collected, and whether it is collected in a way that aligns to the standard. Is that the key point?

Ming Jack Po
Yeah, and I think you said it much better than I could. Thank you.
Arien Malec
That is my superpower. I just repeat what people say and clean it up on the fly.

David McCallie
The advantage of taking a second shot at something is always a big advantage. On that topic of selecting the health equity information and social determinants of health, I would look forward to at least a little bit of discussion about the barriers to collecting that in the context of our desire to become blind to those issues. I think there is a tension there that by collecting that information and obsessively focusing on it for good reasons, we are also creating an awareness of it that we are trying to move past as a society, so how to frame that is an interesting discussion. Maybe we can defer that until later. Maybe someone can even come and talk to us about how to think through that topic. I suspect the current administration will be very sensitive to that. Okay, is there anybody with their hand up right now?

Arien Malec
I do not see anybody with their hand up. Leslie put his hand up.

Leslie Lenert
I will put my hand up just because I think the point about what the performance capacity of existing IIS systems is and whether we need to create an infrastructure around bulk FHIR for immunizations is a really important once. There are two use cases. There is obviously the COVID-19 use case, but we have also had a whole year of children and adults who have missed vaccinations, so I think that the outbound message from the vaccine registry needs to be standardized. That is the link. We have a V.2x message going in, but we do not have an outbound message, and while I think flat FHIR might help with that, even that is not really terribly specific in detail. But, I will let Andy argue back with me that he has the outbound message HL7 V.2x specified, but I would love to hear how he did that and what that means.

Andrew Truscott
I put my hand up already, Les. We have a 2.1 response, so we can get that, but I agree with you on the modernization to at least a FHIR façade, and if not, we have also got the creation of the performant underlying IIS because at the end of the day, there is not that much variability between the underlying IISes. Now, as we started incubating with them, they were not that different. I am not sure it is the scope of this Task Force to start proposing IIS changes. I think we can absolutely talk about the standards that are used to interface to them, but I am not sure we can talk about things like performance latency and all those good things. Les, we absolutely should be talking about it, and I think it is something that HITAC should be talking about, but not necessarily this Task Force. I will share with you the 2.5.1 work we are doing.

Leslie Lenert
That is a fantastic advance.

Arien Malec
Andy, one point there is in the real world, there are about 40 of the IISes that are all done by the same vendor, and one of the reasons many states are very similar is not because states have broadly adopted standards, but that many states have broadly adopted literally the same IIS, but anybody who says that states are relatively well-modernized and are easy to work with has never been to California, where I think
we have seven regional IISes, and then some shims and hack-arounds to implement standards. So, just because 40 of the states are literally on the same common platform, at least from the code-based perspective, it does not mean that we have universally addressed this problem, it just means that you have probably done a lot of work that has happened to hit those 40 states that are on a common systems.

Andrew Truscott
I agree with you entirely, Arien. It is a standardization by accident as opposed to a standardization that is being deliberately well managed from public health, and I get that. We have things like New York City and the city of Philadelphia, which have their own immunization registries. San Antonio has its own, as well as San Joaquin, San Diego, and the other ones in California. I agree with you guys entirely, and I would like nothing more for my life’s work now to be to fix immunizations for exactly the reason that Les was highlighting. Look, we will work through COVID, we will work through boosters, and we will work through variant doses. We will get through that. But, there is an entire group in the pediatric space where vaccinations have gone to one side, and that needs to be traced, tracked, and Remediated, but I do not know if we can do that in this Task Force.

Leslie Lenert
I totally agree that that would be necessary, and I think there is this necessary thing about an outbound message from a public health registry to an EHR, so we can talk about this as being with an opiate overdose registry or the opiate prescription registries, it can be the vaccine registries, or maybe it can be notifiable diseases. The afferent loop away from public health is what is underspecified. The input loop is pretty well done by meaningful use.

Ming Jack Po
I want to be careful about some of the conversations that everyone seems to be having because we have a unique opportunity right now because of COVID for some potentially global standards in this case, but keep in mind that we are using pharmacies, we are using stadiums, and federal sites are thinking about asking churches to give shots. We are not talking about HIEs, and we are talking about places that frankly have no access to an EHR, so we have to be a little bit careful about [inaudible] [00:56:46].

Arien Malec
I think we lost you at the end there, but I think we captured that comment.

Leslie Lenert
You are correct that there is a very good issue here about whether a site that is administering vaccines without an EHR or without a lightweight substitute that can generate an HL7 V.2x message to the registry should be in business, but I do not know whether that is a standards issue or a policy issue because somebody is deciding to give them vaccines.

Arien Malec
Can I move that we move off this topic? I feel like we are going deep on one area as opposed to sticking to David’s approach of going broad, collecting broadly, and then going deep. I worry a little bit that we are going down to solve this particular issue rather than collect hypotheses to work on for later workgroup meetings.
David McCallie
I think we can come back to this. It is certainly a high priority for several of us, so we are not going to abandon it, but we should cycle back when we have had a chance to organize our thoughts a little bit.

Arien Malec
David, who have we not heard from yet? Maybe we can do the thing of calling people out who have not been raising their hand. Ricky? I think you are on, but I do not think we heard from you.

Andrew Truscott
Ricky just had to drop.

Arien Malec
Oh, he just dropped? That is awesome.

David McCallie
Smart move.

Arien Malec
I think Denise was on for a while. I do not see her here again. Who has not gotten a chance to speak? Let me just put it that way.

Edward Juhn
This is Ed. I can jump in right now. I agree with what all the folks have mentioned here. I do think one of the things we can do as a committee is maybe spend a little bit of time unpacking all the complexities within the social-determinants-of-health conversation because I do think there is an opportunity to get a little bit crisper on the hypothesis and how the implementation, standards, or the opportunity to change the space may or may not look, so it might warrant maybe a separate, more focused discussion because there is a lot of great input.

Arien Malec
And then, I am going to raise my hand as a Task Force member. I think I alluded to this before, but we are a country that, at least on the acute care side, has 96% penetration of electronic health records in this country, yet, though this is not a national fight or national contest, I think relative to the U.K. and the work that they did in the set of recovery trials, our ability to use the electronic information that we have to inform things like relative COVID risk or course of history for administration of hydroxychloroquine, or mAbs, or other kinds of therapeutics, use of steroids, use of corticosteroids, or use of anticoagulant therapy, our ability to take real-world evidence and apply it to clinical practice was objectively lacking relative to the U.K. despite what I think we could argue is an equal or potentially greater deployment of EHRs.

The way I summarized this in a Twitter comment was that when it comes to sponsored clinical trials, we have got a great PRO infrastructure, a great PI infrastructure, and we can investigationally trial the hell out of anything we want, and I think we saw this with the trials for mAbs and certainly the trials for vaccines, but when it comes to real-world evidence, when it comes to natural histories, when it comes to non-sponsored clinical trials or comparative effectiveness research, we are just objectively not there.
David McCallie
Arien, let me piggyback on that one because I have a similar concern or a similar thought that I think overlaps with yours a little bit. What struck me as an outside observer watching mostly via Twitter at the beginning of the pandemic when it became clear that we needed to aggregate data better to generate hypotheses about what might work, what was going on, and which patients were at highest risk, there seemed to be a gigantic absence of the ability to quickly do that. So, I am going to get detailed here, but I will just take it as a “for instance.”

For instance, with the ability that EHRs are now required to support bulk FHIR exports, would it be possible to create a standard with OMAP or something like that where, in an urgent situation, across vendors and communities, people could export enough data to build databases for hypothesis generation? This is done knowing that it is not robust clinical trial data, et cetera, but it might let you ask questions about who is most at risk from this virus and which drugs have been either purposefully or accidentally used in the virus that might warrant deeper investigation. So, I would call it urgent hypothesis generation as one use case. Is that similar to what you are talking about, Arien?

Arien Malec
Yeah, I think that overlaps with real-world evidence, that we want to know the time course of disease and see if there are correlates from an exploratory perspective on the time course of the disease, and then, more from a real-world-evidence trials perspective, see if we can look at a cohort of patients who were on X or Y all the way up to the more recovery-related formal comparative effectiveness trials where you actually look and compare a drug or a therapy against control, but it is not a sponsored drug, and where the public health community and the medical community are effectively the sponsor. Both Ram and Leslie have their hands up, so I just want to acknowledge that.

David McCallie
Okay, I will just go with Ram.

Ram Sriram
Can you hear me? This is Ram.

David McCallie
Yes.

Ram Sriram
So, there was a recent act, which I presume is called the American Rescue Plan of 2021. I believe President Biden signed this act recently regarding the pandemic support. Is there anything in there that we are required to look into in terms of the coronavirus? Most of it has to do with coronavirus, but some of the things we just mentioned now are related to that, like the vaccination and syndromic side of surveillance. So, are there any specific recommendations to ONC on that? Did the Congress ask ONC to do something on that?

Arien Malec
This is going to get into the deep legislative weeds, but I think structurally, what you can do for reconciliation is only appropriation, not authorization or legislation, so basically, I think the way that act was structured, it
was almost entirely around earmarking sources of funding for existing programs as opposed to creating new legislative asks, but I think it is probably a good callout back to ONC staff to see whether there are any specific callouts we need to do with regard to that bill. Again, I would acknowledge that at least some members of the health committee have proposed legislation that would put in additional funding for state public health and tie that funding for standards adoption in ways that align with some of the conversations we have talked about.

**Ram Sriram**
Thank you. The things that were mentioned about syndromic surveillance and vaccine credentialing all fit into that same box, so that is what I was wondering.

**Arien Malec**
So, maybe the other way of framing this is there is funding that the U.S. federal government has to spend, and it might be worthwhile for us to make some recommendations with regard to how the programmatics for that spending work.

**Ram Sriram**
Thank you.

**Leslie Lenert**
I guess it is my turn now.

**Arien Malec**
Go ahead, Les.

**Leslie Lenert**
Thanks. The thing I would like to raise is that we need development of standards for talking about facilities’ readiness and ability to respond to pandemic-like challenges or other disasters. I know that there is a CDC form that is a de facto request that the government is making there, and we are migrating back to the CDC approach, which was to have a platform at the hospital that had manual data entry into it largely to talk about readiness, but is there a way for us to look at this surge capacity in a hospital and the availability of critical resources like CT scanners, operating rooms, or other things like that in a more systematic way or an EHR to publish in a systematic way the status of the facility as a whole?

It might even come down to things as crazy as allowing patients in a systematic way to know how long the wait is in the ED or, on average today, how long they would be waiting in the clinic or waiting for a pharmacy prescription versus from a more emergency response, how many beds in the ED are occupied, how many ICU beds are availability, or what the nursing status is versus availability of beds. There is a lot of detail about the status of any one given facility that needs to be surfaced in an appropriate way, and there is a lot of manual data entry in this area currently, and there are some CDC virtual standards by dictating what they have to do, but I am not sure all of those are rational.

**David McCallie**
I do not know much about an implementation guide called SANER, but I think it is based on FHIR and it may try to address some of those concerns. Is anybody aware of what is in SANER and whether that is close to what Les was describing?

**Arien Malec**
I have the same impression that you do, but I have not followed the work closely. We could easily pull in Scott or Keith to comment on it.

**Andrew Truscott**
Keith is driving SANER, but it is around COVID, bed utilization, ventilators, and that space.

**David McCallie**
Maybe we could get a presentation on that if it looks like that is a topic we want to pursue. It is technically already listed in the ISA, but just in bare-bones form and without much clarification of exactly what it does.

**Arien Malec**
I believe it is generalized to an all-hazards approach from COVID.

**David McCallie**
I know it is based on FHIR. I think it is a query/response kind of thing based on FHIR.

**Andrew Truscott**
Yeah, I think it was specifically crafted for COVID, but it was all done by Audacious Inquiry.

**David McCallie**
Maybe we could get somebody to talk about it.

**Andrew Truscott**
Keith is our guy.

**Arien Malec**
I think either Keith or Scott could speak to it. Keith is probably the person who can give us all the details.

**David McCallie**
Yeah, he can give us the pep talk. Let me purposefully shift away from COVID and pandemic thoughts. We have about 15 minutes left, of which we need to take five minutes for public input. I think Jack may have mentioned price transparency as something worth following up, and we have named the equity discussion as worth more attention. Are there other broad areas that come to people’s minds?

**Arien Malec**
Equity and SDOH probably map pretty well together, so that allows us to capture health equity, social determinants, underrepresented groups, and underrepresented geographies as a category, and we can potentially follow the data flows, capturing the point that in many cases, even when there are standards, the data are not captured in conjunction with those standards. Back in the COVID public health line, we should also talk about contact information. I think we saw real gaps in getting contact information all the
way to labs, and then from labs to public health, even in cases where it was collected in hospitals and in the EHR.

**David McCallie**
I will add a second bullet to the contact tracing. Just for our consideration, there were a number of attempts at deploying app-based contact tracing tools to allow you to detect if you had been exposed to someone. I do not think any of them had a huge amount of uptake, but that is something that could bear investigation in terms of maybe standards around privacy constraints that we felt should be developed to govern those tools and so forth, so I guess “exposure tracing” is a better way to say “contact tracing.” I will put that on. And then, on the equity thing, maybe you mentioned it, Arien, but I would also add a bullet point to that one about access to data. This came up in the HITAC meeting, that it is one thing to put something out on a smartphone, but if you do not have a smartphone, you cannot get it. Should there be minimum standards for access, such as saying browser-based access must be provided?

**Arien Malec**
I think it also lines up. The thought I had when we were having that conversation at HITAC was how I take the same API-based access that we provide directly to individuals through their smartphones and allow that to also be used for delegates and extenders. So, for example, in the case of a call center where somebody wants to schedule on behalf of a person, how do we enable delegated access so we can take the same information in multiple modalities and in ways that are more easily consumable by a wider range of patients and are not just hardwired into portals that have some inherent access issues?

**David McCallie**
That is another bullet point. Are there other broad suggestions?

**Leslie Lenert**
I just wanted to comment on the EN things. I think it is a great idea. It goes with the digital passports or the verification for the vaccination. That verification of exposure or non-exposure using this is the opposite side of that, along with combining it with test results.

**David McCallie**
You used a phrase at the beginning of your sentence there that I and the transcriptionist missed. Did you say EM?

**Arien Malec**
EN, electronic notification.

**Jim Jirjis**
This is Jim Jirjis. I rejoined. I have a quick question. Again, I am not familiar with whether this would be in scope or not, but if we are talking about where to focus, I know that in part, at public health, the issue of promoting interoperability not really yielding progress we want to [inaudible] [01:15:07].

**David McCallie**
Jim, you are breaking up. Try again. Jim?
Arien Malec
Well, we can collect Jim’s commentary either via email or on the next meeting.

David McCallie
Yeah, and that is obviously true for any of you. Please email either or both of us if you have thoughts that occur after the meeting, and we will bring them forward in the next meeting to discuss.

Arien Malec
If you can hear us and you are having trouble connecting, just hold off a little bit and we will try to get your information later. David, it occurs to me that if we look at our future focus areas, we have addressed SDOH and cost transparency, at least in what it would look like to clean up the existing requirements for hospitals. We have not addressed chronic care management, and I wonder whether chronic care management, burden of disease, and ongoing case management is an area that this group would want to potentially add in the context of going wide.

A topic that has typically gone to this area are how we expose a plan of care in a computable way that is multi-stakeholder-accessible, and the other category that tends to go into this area is other data that needs to be standardized, such as dietary recommendation, and then, the category of patient-reported outcomes, and I forget the acronym here, but basically, patient-reported data, particularly standards for [inaudible] for blood pressure monitoring, and other kinds of remote patient monitoring and remote patient data collection that is easily computable and sent to caregivers, nurses, and other folks who are helping the patient manage the plan of care.

David McCallie
Those are important areas.

Arien Malec
Les had his hand up, dropped it, and put it back up.

Leslie Lenert
Sorry, I am just having trouble with the interface. I say that again, this is an interesting issue, where there is one standard for how you identify a person to a device and another for how a device gets identified back to whatever authentication structure is accepting the data from it. A lot of this is very poorly specified right now and is definitely a Wild West type of arena, where you have people standardizing based on a proprietary stack in and out of the ED EHR, rather than being able to allow any device to work back with any EHR.

David McCallie
Is this the space of OAUTHs and standards like that? Is that the kind of handshaking you are talking about between devices?

Leslie Lenert
No, in my world, it has been issuing a unique encrypted ID to a smartphone so the smartphone can send back medical data that it collected from a device to an electronic health record and have it integrated automatically.
David McCallie
You could certainly use a lot for that, but there may be better standards.

Leslie Lenert
There might be better or easier-to-use standards for that. There should probably be a standard way to do this. It can be any standard you want.

David McCallie
Agreed.

Arien Malec
[Inaudible] [01:19:38] UDI, which has been an ongoing topic for the standards committee for about the last 10 years. You are talking about different devices, but for example, when we talk about a continuous glucometer, how do we actually identify that device and track that device information? We have had a UDI standard since forever, but that data is not currently flowing.

Leslie Lenert
Then, there is the linkage between the device and the person, even though the device might be technically used by several people.

David McCallie
That is very hard. Should we open for public comment, Arien? We may need one minute at the end.

Arien Malec
I think we are supposed to do that in two minutes, so we could stall and tap-dance for two minutes and then open for public comment and close the call. I think we did our job of going broad. It might be worthwhile for the next meeting to start to consolidate some of this, come up with a punch list of items that we discussed, survey the group to see if there is anything obvious that we missed, and then start the work for the next meeting.

After we go broad, we should start to go narrow, and also, David, I think you and I might want to put together a framework for how we think about recommendations based on the conversation we had prior to this meeting about how we think about the time course of recommendations, how we think about the centrality or leverageability of certain recommendations, how we think about policy coordination that requires ONC to publish more recommendations, versus requiring administrative agreement, versus requiring literal acts of Congress, versus requiring literal acts of Congress and states to coordinate. Each of those have different policy requirements. So, we might want to put together a framework for how we think about recommendations in this area as a potential next step, so I just want to see from the group whether that approach makes sense before we go to public comment.

David McCallie
No other comment.

Arien Malec
I think we have successfully stalled for time and are now available to open for public comment.

Public Comment (01:22:30)

**Operator**
Thank you. If you would like to make a comment, please press *1 on your telephone keypad. A confirmation tone will indicate your line is in the queue. You may press *2 if you would like to remove your line from the queue, and for participants using speaker equipment, it may be necessary to pick up your handset before pressing *. One moment while we poll for comments.

**Michael Berry**
Thanks, operator, and while we are waiting, I just wanted to mention while we had a few seconds that the next call for the Task Force will be next Thursday on March 18th, from 2:00 to 3:30 p.m. Eastern Time. Anyways, thank you for joining us today. Operator, do we have any comments?

**Operator**
There are no comments at this time.

**Michael Berry**
Thank you.

**Arien Malec**
Should we give people back four additional minutes in their day?

**Leslie Lenert**
How generous of you.

**David McCallie**
It is our gift to you.

**Arien Malec**
I am seeing people vote with their feet already, just looking at the chat.

**David McCallie**
Thanks, everybody, for the great suggestions. We will try to pull them into some sort of an organization and go at it again. Bye-bye.

**Arien Malec**
Bye-bye. Thanks, all.

**Adjourn (01:23:46)**