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

April 1, 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
Okay. Thank you, and hello, everyone. My name is Mike Berry and I am with ONC. Thank you for joining the Interoperability Standards Priorities Task Force with us today. We really appreciate everyone's attendance and joining us – and especially the task force and our cochairs for all their hard work and putting together their thoughts for this important program. We do have some special guests with us today from Audacious Inquiry that the cochairs will introduce shortly. I will start our meeting with roll call. So, when I call your name, if you could indicate your presence that would be great. I will start with the cochairs. Arien Malec.

Arien Malec
Good morning in my time.

Michael Berry
David McCallie.

David McCallie
Good afternoon in Central Time.

Michael Berry

Cynthia Fisher
Present.

Michael Berry
Valerie Grey. Jim Jirjis.

Jim Jirjis
Present.

Michael Berry
Edward Juhn. Ken Kawamoto.

Ken Kawamoto
Hello.

Michael Berry
Victor Lee.

Victor Lee
Present.
Michael Berry

Andy Truscott
Present.

Michael Berry
And Scott Weingarten. Okay. If I missed your name, then I will keep track of the attendance and that you were here and that [inaudible - crosstalk] [00:01:48] –

[Crosstalk]

Arien Malec
I see a lot of people who are listed as participants in the meeting. So, I'm wondering whether we're having folks with connectivity issues.

Michael Berry
Right. All right. Arien, David, I'll turn it over to you. Thank you.

Audacious Inquiry SANER Framework Presentation (00:02:00)

Arien Malec
All right. Well, I think we will start with bang, with a SANER presentation, which is better than the reverse. I think Keith looked at the FHIR pubs and discovered that we just didn't have enough puns in the HIT community. So, he really wanted to double down on additional puns. But we're going to hear from Keith, and Lauren Knieser, and Scott Afzal as well, from Audacious Inquiry, who are the program leaders, enterprise architect, and head of AI somewhat respectively. They are here to talk to us about SANER and situational awareness, which is one of the proposed priority areas. At the conclusion of that presentation, we will run through the output of our priority process voting and do a group discussion about where we end up with priority process. And then, if we are ambitious enough we will pick up and discuss homework. But with that, I will turn it over to David to introduce our SANER participants.

David McCallie
Thank you. You have done a great job of setting the stage, so I will just turn it over to Lauren. You will lead the presentation and Keith will be color commentary. But you guys feel free to do it however you want. So, hopefully, you are all set. There are your slides, so take it away.

Lauren Knieser
Great. Thanks. And this is Lauren Knieser. I will have Keith introduce himself first and then maybe turn it to me.

Keith Boone
So, hi, guys – and especially some of you old friends. This is Keith Boone. I am an enterprise architect at Audacious Inquiry, and I have been involved in interoperability standards throughout the past 15 years, starting with CDA and CCDA, and then, over the last five years working in HL7 FHIR, where I am presently working on three different FHIR implementation guides, including the SANER IG. I have been involved in
past development and FHIR. Its and the core FHIR standard itself. And I'd say it is also Lauren Knieser. I apologize [inaudible - crosstalk] [00:04:33] –

[Crosstalk]

Lauren Knieser
You're not the first to mess it up. Thank you. So, great. Thanks. As Keith said, my name is Lauren Knieser. I am the Director of Emergency Preparedness and Response at Audacious Inquiry. Before coming to the company a little more than a year ago, I was a federal employee, like perhaps many of you on this call. I worked for HHS at the Office of the Assistant Secretary for Preparedness and Response. One of my roles in Operational Response was as the Information Management Section Chief in the Secretary's Operations Center. In that role I really had a front row seat to a lot of the challenges at the local, state and federal level with regard to healthcare situational awareness. This topic is something I am very passionate about. I have had a great time working with Keith this year on the SANER project and we are excited to present our progress today to you today. Next slide, please?

Great. Thank you. Before we get into the technical detail, which I will leave to Keith, I would like to give a big picture operational context since I think operations and the technology need to go hand-in-hand to be successful. As most of America knows now, during COVID-19, hospitals and public health authorities have a limited visibility on healthcare capacity, supply, and staffing across facilities. This is particularly true when we're looking at a regional level or outside of one's own network or hospital system.

The challenge here is that it complicates patient transfers, evacuations, and the ability to take care of a patient surge while also maintaining essential routine healthcare services. Today, the responsibility to load balance, or to move patients from one system to another, really falls on the healthcare facility. There is not a trusted central entity that has visibility of capacity at a regional level. The challenge is exacerbated by the fact that technical infrastructure that the facilities rely on for load balancing is very fragmented and often very specific to a hospital or healthcare system. While we have state-level systems today, as you have likely all seen in the news over the last year, these systems tend to be manually populated and can be very burdensome for hospitals and healthcare facilities to populate with any regular frequency. Furthermore, there is no national or federal standard for the exchange of healthcare situational awareness information during disasters and public health emergencies. And this is true both for essential elements of information we call EEIs in the response community, as well as for the underlying technical infrastructure that you all on this call think about much more frequently than I do. Next slide, please?

Okay, great. So, my next three slides I'm actually going to just tick through really quickly. You have the content and can review it on your own time. But I really wanted to drive home the point here that this is not a COVID-19 specific problem. This is a problem that we in the response community have experienced for certainly my entire career, and well before that. This is just an example from an after-action report from 9/11, and the attack on the Pentagon, specifically. Next slide.

A second example here from Hurricane Katrina, where there was a big challenge in evacuating patients before, during, and after the incident. Next slide. Yet another example from H1N1. I will pause here for a moment just to highlight a finding from Dr. Eric Toner from Johns Hopkins University, that highlights the fact that obviously situational awareness is very important for direct patient care decision-making. But it is also critically important for the way that we make policy decisions. And having been in that seat in the
Secretary's Operations Center, I can tell you some firsthand knowledge it is extremely difficult to make data-informed decisions when you do not know what is happening on the ground. It is difficult to know where to send limited resources, when to execute policy waivers, and went to implement other program flexibilities that you might have to alleviate pressure on the healthcare system. Next slide.

Great. Thanks. This is a report from the University of North Carolina that I thought summarized really well a lot of the challenges in the healthcare system as it pertains to hospital capacity reporting. We, with the SANER project, are aiming to address many, if not all, of these challenges. So, I'm just going to tick through them very quickly. The first is that the systems that exist today are variable in scope and they were not built to communicate with each other. The second is we do not have a common language or parsing system for reporting data from across these different IT infrastructures. The third is we often lack human resources or people who know how to analyze and aggregate data as it is coming in and turn it into information that is operationally useful for decision-making. And finally, we have inconsistent and perhaps nonexistent standards for health information exchange during disasters. Next slide, pleas?

Okay, so one more disaster example for you. There are plenty of them to draw from. I included this one after Hurricane Harvey for a specific reason. As you can see here, Texas, during Harvey, was hit. The entire Gulf Coast was affected. Many of you probably remember the stories coming out of Houston. In this incident, patients were evacuated and many of them went quite a long distance. They went into Louisiana. They went up north into the state. This report shows there was a healthcare surge as far away as Dallas, which is several hundred miles away, several hours driving distance from Houston and the coast. I like to put this in here just to highlight the fact that when we think about health IT systems for situational awareness we need to think about systems that can scale up or scale down depending on the magnitude of the incident we are talking about. It does not show it on the map; it cuts Louisiana off here. But I think it's also critically important to remember that we need to be able to share data across state lines. Often when we fund programs for systems like this we funnel the money down to a state level and the funding has to stay within the state borders. So, that's just simply not the way that people access healthcare in America. Next slide.

All right. So, I am going to shift gears here and talk a little bit about policy. I think it is important, if you are not aware of this legislation, to be aware of it. There is enabling legislation that authorizes the Secretary of HHS, in collaboration with state, local, and tribal public health officials, to establish a near real-time, electronic, nationwide public health situational awareness capability. This language was first authorized in 2006. It was reauthorized in 2013. And it was re-reauthorized in 2019. It still remains in effect today. Importantly, there is a funding line, a budget line, also authorized with the legislation, although, to my knowledge, I do not believe it has been appropriated. Next slide.

All right. You can see the GAO has been very direct with their feedback as to the progress that HHS has made toward the system. Their 2017 report is called – HHS has made little progress toward implementing enhanced situational awareness network capabilities. They say it better than I can, so I am just going to read a quote from one of the reports on the screen here. It reads, "HHS developed an implementation plan; however, the actions identified in the plan did not address all of the required activities, such as defining data elements and standards. Until the department addresses the required activities it will lack an effective tool for ensuring that public health situational awareness network capabilities have been established in accordance with the law." Next slide.
All right. Great. And so, that brings us pretty much to the beginning of next year and the beginning of the COVID-19 response. At that time, I had just joined AI, I think, about six weeks prior. I was still very new. In early March 2020, we learned that ADT networks were being considered as a mechanism for potential healthcare situational awareness systems. ADT is the core business of what AI does, and so that should have been exciting for us. But actually, we found it unsettling. The reason for that is several years before, AI actually wrote an analysis commissioned by ASPR. I was not involved at the time and did not actually even know this report existed until then. The main finding of that report was that FHIR was very likely a superior methodology to ADT for hospital capacity reporting. At the time, we did bring this up to the COVID-19 taskforce but there was not a formal mechanism for a public private partnership or to continue the work in any way. And so, we began to work with collaborating with industry partners in a much more grassroots way as the SANER project. Keith has been at the helm of the initiative all year, so I will turn it to him from here to give you more details on where we are.

Keith Boone
Thank you, Lauren. So, if we can go to the next slide? I first started talking to people in industry about this a little bit more than a year ago. Actually, Arien was one of the people that I had reached out to about this particular challenge. When we started the SANER project, we called it Situational Awareness for Novel Epidemic Response. And then, Arien's right. I didn't look into what the acronym was, but it was a very happy accident. We were looking at the crazy that was being reported by our customers, our customer's customers, about having to staff up or take staff time to be able to manually report on all of the situational awareness. In fact, in one case I spoke to somebody at a hospital who was having to manually handle a lot of this reporting. Went down in the basement, and some of the previous standards that I will talk about when we get to the history, were still in use but were not actually being used to support the COVID reporting. So, we go to the next slide.

For those of you who lived through this, HITAC's grandfather was AHIC, the American Health Information Community, who was a federal advisory committee that preceded this by at least one ancestor. Their job was to create use cases which would be the focus of standardization efforts in anti-HITSP. They had, in 2005, issued an emergency responder use case. They added and addended to it in 2006 to really address situational awareness reporting. And as a result, those of us who were working on this use case in HITSP, we called this the Katrina Use Case. Yes, we had other use cases. We have bird flu use case and the anthrax use case, as well.

What we were trying to address was what was the problem of the last year where standardization could help? HITSP put together a publication called the Resource Utilization Component, which was supposed to be a standard to report on bed availability in emergency departments on diversion. To support that, we used the OASIS Open EDXL and have standards in that publication. That was informed by and then later fed back into some of the HAVE bed specifications that have been developed by AHRQ and ASPR and were in use from 2005 to about 2016 in the Hospital Preparedness Program. And then, that program stopped requiring hospitals to report, I think, around 2016 or 2017. Subsequently, HL7 and OASIS Open collaborated together on HAVE 2.0 to improve the HAVE standard to address some of the shortcomings that have been discovered in the implementation of HAVE bed and HAVE previously. We go to the next slide.

Where that falls down in the COVID-19 epidemic, is that we realized we needed to know not just about beds but about ventilators, or in other disasters, other kinds of things you would need to treat patients that
might be in short supply. We also wanted to understand how that was impacting deaths due to the emergency. How many patients were actually catching the disease in the hospital versus out? How much of that capacity in the hospital as related to COVID versus other things going on? What was going on with lab testing results? How often were tests being performed on a daily basis? And then, what were the outcomes? Also looking at, do you have enough staff to the work? Do you have enough supplies to be able to do the work? These were rolling out. They started rolling out in March, and by April and May there were four different modules that had been rolled out. And the first one, the Patient Impact and Hospital Capacity, needed to be refined to further clarify for people, "Well, what did we mean by the patient died?" This is one of the first emergencies in, I would say, a very, very long time where the issue at hand was actually resulting from an emergency that was impacting at a national scale and a global scale. We go to the next slide.

In developing the specifications, one of the insights we came up with was that what we are actually doing is process control. These essential elements of information that emergency preparedness and response agencies are asking for are measurements of capacity or utilization events that are occurring. [inaudible] of queues. How many people are waiting for service? How many people are waiting to get into a bed? How many people are waiting to be discharged? Average service times. So, if you looked at – as testing proceeded and the pace of testing got faster and faster, how long it actually took to get results was indicative of stress on the system because you could do the test but you could not result faster than you had people to do the evaluation results or the other resources. So, being able to look at average service times. And then, also needing to be able to put facilities into different groups to address status. In a local emergency, I am accepting patients that are on diversion when this national emergency – are you in a red, yellow, or green status with respect to available staff to treat patients? Or your PPE supplies. We get to the next slide.

In looking at this, we looked at the whole workflow and what would need to happen to support this. The first thing was, making sure the public health and emergency response agencies were defining those measures at a level of detail, right down to what are the LOINC codes that tell me what tests you're interested in? Or what are SNO MED CT codes that tell me what symptoms you are interested in reviewing for suspected COVID patients? In the definition of the measure, that then enables the hospitals and other healthcare provider organizations to be able to collect and compute that data automatically from the relevant information systems – and I put the accent on the "S" there – because your EHR does not have PPE data. That is going to be in inventory management.

It may not know what is going on with your work force. That might be in your work force management. And your ICU central monitoring solution is going to have much more real-time access to who is on a vent than might happen if you do not have that system integrated into your EHR. And so, those observations are not necessarily flowing automatically in and you have to wait until the shift end when somebody enters an order for ventilation in order to find out that you have a patient on a ventilator. So, we needed the ability to collect all of that data in the hospital, and then aggregate and publish that data to local public health and emergency response officials through what we call the Local Public Health Network. But you could think of that as your health information exchange or some state- or federal-level public health networking system. For example, NHSN. And then, be able to share that data at the local level and do it in such a way that you might also be able to have the local share with the state, the state share with the feds, and have them have the capacity to, as necessary, may be able to reduce what is needed locally to what the state is asking for, or what is needed at the state level to what the feds are asking for.
Because another complaint we heard from some of our hospital customers and some other folks I have been talking to was we have to report this out, and we have to report this in New York City, we have to report it to HERDS in the state, and then it also has to go to HHS. And then, there is a separate report that has to go to FEMA. So, a pretty significant challenge for hospitals to have to handle that multiple reporting – wouldn't it be nice if the locals could report to the state what's needed, the state could report to the federal government, and at the policy level we could have federal and maybe state standards to say, these are the essential elements of information that we want to be able to collect and have them build on each other. Let's go to the next slide.

What we tried to build in SANER IG was a way to have a complete reporting approach where you could take your non-API enabled systems, such as your bed management solution or ICU central monitoring, and be able to query its database, produce a CSV file, and push that to a restable end point and have that data be recorded in a measured report. Or where you have API enabled solutions to be able to read that definition, do the right queries using standards such as those based on USCDI and FHIR R4, automate the computation by building some consistent data centered around how you compute different kinds of measures, looking at different kinds of process control measures, and then, store that in a report and have that aggregated up by that server in the hospital, push it off to local or state public health agencies. And then, also be able to be used by the hospitals for local command and control so they can see that broader picture. We go to the next slide.

In the process of developing this implementation guide, which was supported very early on by ONC, we saw there was an opportunity through the STAR HIE grants and work with Texas Health Service authorities to apply for one of these STAR HIE grants to pilot test this because, not only do you need the standard but you actually have to prove out that it works. So, we are supporting THSA, and HASA, another other HIE in Texas working together with THSA, to do a pilot of the SANER IG. Just recently, THSA issued an RFP to support open-source development of Smart on Flyer app and a SANER servicer to support that automated data exchange.

That particular project has both a technical and policy advisory group that includes membership, not just at the state level in Texas, but also local agencies, vendors, and federal agencies. We have routine participation weekly from people from CDC and US Digital Service, where we are able to talk about the different kinds of things we are thinking about and learning about the kinds of experiences that others have had at that national level. And then, also being able to provide that feedback to those federal agencies. We go to the next slide.

So, just to recap, we have a way to automate computation of measures through FHIR, be able to pull data in from non-FHIR based systems through simple CSV integrations, aggregate the data from multiple sources because there is not a single hospital information system that has it all in a lot of cases. Looking at applying process control science and measurement to what folks in the emergency response field think of as their essential elements of information. We identified early that we needed to be able to stratify by social determinants of health, such as age, gender, race, ethnicity, and geography, but also understood that there were other ways to stratify and look at the data with respect to outcomes and health risk factors and comorbidity. That would allow us to better understand what was going on with the COVID disease process and see who is impacted. One of the pieces about feedback that we received was, "Well, measures are great but we want to see line level data as well," because you might have two hospitals that are at 85% capacity and similarly sized, but one of them could be dealing with a variant of COVID where their patients
in the ICU are much more severe cases and are going to be there longer, so you need potentially to risk adjust the measures based on that line level data. And then, building out open-source implementations and making sure that those are tested over various connected on and testing events. Get to the next slide.

I was heartened to see very early on in the development of the work of the SANER project that it was actually identified in the ISA, the Interoperability Standards Advisory, last year and I wanted to give you my thoughts on where it is going to be at soon with respect to that advisory. So, we are looking to have the Standard for Trial Use published by HL7, and that's estimated to be sometime in May 2021. So, that would be a balloted draft. We talked about the THSA STAR HIE pilot, which is currently a pilot in progress. But I have also been working with IHE, and others in the IHE, who are working on development of an IHE profile that looks to use the SANER IG in IHE profile development. And the lead of that effort is Keith Parker from Health Current in Arizona, who is another STAR HIE participant. So, I am expecting to see other pilot activity from yet another star HIE participant as well. I have to say adoption is low because we do not even have the published STU. How can you have adoption if you do not have the final standard? But we have seen some promising efforts and I'll talk about those on the next slide.

I laugh at this next one. Sorry, if you could go back to the previous slide. I was not quite done there. I laugh at this next one because it says to be federally required it has to be called out in a federal regulation or a grant. It is specifically called out in a grant. Realistically, it is not federally required. It's required for that specific grant. The work that is happening, both in IHE and HL7 is going to be a free standard, and there will all be open-source implementations. And we also spent some time with MITRE in the first two connective funds working a lot on testing. And so, test tool availability is available through the MITRE developed Inferno Community edition. Now, if we go to the next slide.

We will talk a little bit about the industry support for the efforts. We have been involved now in this project in three different HL7 connected funds as well as the IAG North American connected fund. Had very, very strong support in HL7. This project was initiated March 23rd of last year as a project proposal in HL7. And within two weeks we had approvals from six different governing bodies within HL7. Probably the fastest project scope statement approval in HL7 history. Strong support in all of the connected funds, not just the IAG connected fund, but also the HL7 connected funds from IAG USA. And as I said, the first two connected funds we worked closely with MITRE to make sure that there was testing support. And about mid-April of last year, the HIMSS EHRA sent out a letter of support for SANER to 12 different federal agencies, including ONC, which we would be happy to send you a copy of as well if you don't already have that with our other materials, strongly supporting the work of the HL7 SANER Implementation Guide. We look to the next slide.

So, to wrap up, I think some things that would be very helpful for dealing with COVID-19, and for other disasters, is if the work that is happening with the SANER IG continues to get support for development and piloting by federal agencies, by ONC, for example, as through the STAR HIE grant or by CDC, through other states, or ASPR, other agencies. I want to make sure there is greater collaboration among those of us who are in the health IT interoperability space, but also those who are working in the disaster response communities, to make sure we are better aligning the subject matter experts on essential elements of information for healthcare and making sure they fit well into the technical standards and the information infrastructure that's available for hospitals, making sure that is really lined up. Recognizing, as I think both Lauren and I have said a couple of different times, that this is not about just COVID-19. Hurricanes in Texas, forest fires, or rolling blackouts in California – everybody can benefit from being able to support greater situational awareness.
We heard from a healthcare agency where we are working with in Boston about some of the very real challenges making sure that STUH data is included in that reporting. And you will actually find, in some of the work that's done in CARES Act, requirements for states to be reporting, and federal agencies to be reporting to HHS data that's broken down by age, and gender, and race, and ethnicity, and geography to address that ongoing need for STUH data to understand about healthcare disparities. And lastly, we have done a lot of work on SANER IG working with EHR vendors, and infrastructure vendors, and interface engine vendors, and organizations like CDC and HSN to make sure we get a lot of the clinical data. We would love to see more done to foster engagement with healthcare supply chain and work force vendors. And so, we have started some outreach on those sides. But any available assistance we can get would be appreciated. And so, at this point, I think we have reached an opportunity for you to ask questions.

Arien Malec  
Thank you so much. This has been a fantastic presentation. We really appreciate the history in this space. Maybe a question for – I'll tell you what went through my head as we were thinking through this presentation, which is, Keith, I have no doubt with the work that you have done that we can land a standard that solves the capability needs for situational awareness in emergency response. And I have no doubt, from, I think, Lauren's up-front presentation, that whether it is wildfires here in California, or hurricanes on the Gulf Coast, or earthquakes here in California, or tornadoes in David's neck of the woods, that emergency response is an ever-present need independent of COVID-19. I think David could provide you the best attestation for why a multistate approach is necessary, that just lining up in state boundaries is not that helpful when you have a major city that straddles two state boundaries.

Where my head was going was maybe to Lauren, to think through the policy levers that are in play. And again, if you just think through Keith's history of standards development – and this is not unusual. This is not a critique of public health readiness or emergency disaster readiness. It is a endemic problem in the U.S. healthcare system. The question that comes to my mind is policy alignment and incentive alignment. And what policy levers are needed to make sure that the ecosystem of standards adopters – to case in point, it is not just the EHRs, and so you can't just pull on the EHR certification program. You have HR IS systems. You have supply chain management systems. What are the policy levers that are required? How do those policy levers distribute nationally versus state? And where are both the funding mechanisms and economic incentive mechanisms that will be required to have standards adoption deploy at the level of scale that would be required to have a future emergency fully informed with dashboards that allow for emergency response?

Lauren Knieser  
Thanks. This is Lauren. Luckily, I have spent a fair amount of time thinking about that question, and actually have been involved in several initiatives out of ASPR with the National Academies of Medicine, asking somewhat similar questions. So, I am going to start with the easy levers because that is a nice place to start. I think, first and foremost. if we are accepting the state boundary restriction, which is where – it's the environment we are in today, the way that funding is flowing from the federal government to state governments. There are some things that we could do to move us in the right direction. For example, the grants and cooperative agreements that states are currently leveraging to be more prepared, the HPP program, the FET program, the Homeland Security Grant program under DHS, all of those programs allow for funding to be used for situational awareness systems. And most, if not all, of the states and territories actually are spending some of those dollars for their statewide systems.
But there is not currently very many, if any, parameters around what those systems need to do. And so, I think a very proximal solution to at least start with would be to use those grant programs to implement some of these standards, or require some of these standards, if they are going to expend funding on situational awareness systems. So, that is recognizing the restrictions that we currently have and trying to work within the current rules. Obviously, like you said, the challenge of policy that is expansive enough to allow for national adoption of some sort of standard that crosses state lines is super challenging. I do think we could start from a policy perspective back with the PAHPA, the PAHPRA, and the PAHPIA legislation. That legislation requires the funding to go to state health departments. But if funding were able to go to other entities that have a stake in this challenge – for example, hospital associations, or even directly to healthcare systems – we might be able to get around the state boundary challenge.

And then, the other suggestion I would have is we are thinking very much top down here. If we think bottom up, and think about the fact that these systems that we are proposing and the standards that we are proposing, might actually be useful on a daily basis for healthcare systems to do their more routine load balancing. For example, in urban areas, where you have traffic incidents, or large structure fires, or even for seasonal flu where there's a surge every single year and start getting these health systems to use a standard for those more routine use cases, we might be able to expand into the nonroutine.

**Arien Malec**
Awesome. And then, that last one proposes the perpetual problem of how you compete against people picking up phones and faxing people that they know how to do and get them to adopt and use more electronic dashboarding methods. So, I think I sort of parsed the first part of your question as there are existing grant programs, and at least a pretty obvious thing to do would be to tie those granting programs to a condition of participation for granting programs to a standards of adoption would be – if you think about top-down levers that would be the most obvious top-down lever. Okay, I see – David, I do not know if you want to jump in with questions, using chairs prerogative. I see that Les has a hand up.

**David McCallie**
Yeah. Let me ask one quick question of Keith. I hope it is a simple question. Keith, it was not clear to me what the work output of SANER will be in terms of is just a spec for the transactions or is it the system code that would do the aggregation and dashboarding? What's the scope of the work technically?

**Keith Boone**
So, there's a couple of different scopes that we need to look at. There is the implementation guide effort that is being developed through HL7. That is going to be the technical specification and framework for the standard that is used. Then there is the broader SANER project that AI is sort of sponsored that is driving forward that work in HL7 and devoting resources and time to put together the ballots, and do the editorial work, and convene the meetings through HL7. But also, then, build out open-source tools. So, we have already released an open-source tool that has been picked up now and expanded on by Leidos, with NHSN, to demonstrate their capacity to receive the situation.

And that's built on HAPI, on FHIR open source FHIR server, to be able to essentially receive the reports. And further in the star HIE pilots we are working closely with THSA to get more open source to be able to support these pilots. And so, that is part of the broader – what we are trying to do from our perspective to enhance and advance situational awareness, is actually to be able to deliver tools that can make this stuff work. Because it is one thing to deliver the standard and expect everybody to implement it but you also
need the infrastructure and technology to go along with that. And then, build up around that organizations who are familiar with it, who know how to deploy it, manage it, etc. And so, trying to build out that infrastructure.

**Arien Malec**
Right. And so just to follow-up –

[Crosstalk]

**David McCallie**
Yeah, that's great. That's great.

**Arien Malec**
Sorry. Just to follow-up on that, Keith, my understanding of the architecture for SANER is that it at least contemplates that there are networks that are associated with this so it is not just a clinic at a hospital level and everything works. There might be a state HIE in the mix, or there might be an aggregator in the mix, who serves as a destination point and a routing point into both state and federal areas for situational awareness and might also, to Lauren's previous point, provide a regional dashboard.

**Keith Boone**
Yes. Absolutely. I think there is a huge role in here, for example, for health information exchanges, which already many have very close relationships with state public health. And then, as we heard, for example, in a presentation from OCHIN two days ago, where they were supporting ECR across multiple states. Another network like that would be able to support something like situational awareness in multiple places.

**David McCallie**
Okay, let's go to the longsuffering Les.

**Leslie Lenert**
Hi. Nice to talk to you again, Keith. It has been a few years. Back when I was at the CDC and running BioSense and other things, we spent a lot of time thinking about situational awareness and all hazards preparedness. Since then, there has been a lot of work in this area about how to get ready for a wide variety of things. I go to the most practical aspect. When the hurricane you were referencing blew into Texas, or wherever it was, the first thing you can find out about infrastructure is which hospitals stopped reporting data. That is actually a very practical issue because the Internet goes down, or they do not have enough bandwidth to use systems that are very high data volume and have to go to a satellite backup. We have been very fortunate in the COVID-19 experience to have a slow-moving disaster that does not disrupt our infrastructure too much. In fact, it has allowed us to make more investments in infrastructure.

I think the second point I would make is that I think architecture and mapping onto what has worked previously is very important. In meaningful use, under that at least, we were able to make substantial advances in situational awareness by requiring or incentivizing the creation of a syndromic surveillance message. And that wound up bringing up thousands of hospitals into the BioSense program while it was running. And then, budget cuts and other things like that set that back. But that was based on a single, one-standard, outbound messages, going to a cloud-based resource that was segmented by state. I'd point out that that architecture is working really well.
Now, what can I say did not work so well? The original BioSense infrastructure, which is very similar to what you were proposing, put a server at each hospital, and then standardized data mapping into that server to then aggregate it up to the supply chain. It had some errors in it. It did not include state and local resources specifically in their mapping. It routed directly to the feds and then we tried to route down from the feds. But that was a problem. The data mapping was not consistent. And as a result, the data were often uninterpretable. Now, I think we have made a lot of strides in the research community in particular in standardized repositories that are behind institutional firewalls, that can be queried in federated ways. I think that is a very exciting architecture. But if you want to get a big bang for the buck on something that can matter right now, it might be better to focus on outbound V2X-style HL7 communications to a central authority, whatever that is – either cloud or whatever. And let's not the perfect be the enemy of the good. Let's build from what we learned with syndromic observance and the wide existing capacity for that. Because, if you could emulate that in some small way you would be doing better than what you are doing now. Now, [inaudible - crosstalk] [00:51:22] –

[Crosstalk]

Keith Boone
So, that's a fair commentary, Les. And I would note that BioSense and some of the other HL7 V2-based are really good at being able to get at some of that clinical data. I think you probably saw Farzad Mostashari's alerts about what was going on in New York on the basis of some of what he was seeing based on very similar solutions. What we are learning from this, though, is that it is not just the clinical data about what is going on. It is very hard to get at what's your bed capacity from ADT messages. You know about admits but you do not necessarily know what is being done to expand the bed capacity. What HL7 Version 2 message is actually going to tell you anything about PPE or ventilator utilizations. It's not there.

Leslie Lenert
I completely agree with you. Just, let's not let the perfect be the enemy of the good. Let's [inaudible - crosstalk] [00:52:30] –

Keith Boone
Oh. Not going there at all. There's a lot that we can learn from what has been done.

Leslie Lenert
Well, and let's do what we can do immediately. Let's not wait for that. But then, secondly, I agree with you that the idea of a FHIR server at each institution for public health would be a great idea. In fact, we have written about this already with the CDC in the context of replacing a lot of notifiable conditions with the idea of a searchable FHIR server. And I think it is a great idea to do that. And it parallels [inaudible - crosstalk] [00:53:08] –

[Crosstalk]

Keith Boone
We call that the SANER server, Les. And, yes, we are using a FHIR server to support that capacity.

Leslie Lenert
Okay.
Keith Boone
But it has really one function. It is not designed to be an all-purpose FHIR server for the hospital. A hospital could certainly take, if they had an all-purpose FHIR server, to accomplish that. But that could also be, quite honestly, a network appliance that is really just to support that public health reporting need and the ability to aggregate and collect the data and send it forward. Or it could be something that exists as we have seen from several of the interface engine vendors, an interface that is supported to accomplish that.

Leslie Lenert
It is not just a SANER appliance because – I don't think it should be because there are many needs for public health for this type of data. And there does need to be some governance around that. And I refer you to the work we published work with Georgia Tech on this, and Jon Duke there. But going forward from the idea of an appliance – and again, this is close to what the original BioSense implementation was – I think it is a good idea. Now, when you are looking at the right architectural models for this, I think you would learn a lot by looking at research networks like Trinetics, or i2b2, or other instances where people have successfully set up large federated networks that can do dynamic queries of databases securely with the idea that you are distributing the queries across the network. Now, the standard then become a little bit of a different type of an issue for that. But I think that [inaudible - crosstalk] [00:55:03] –

[Crosstalk]

Keith Boone
So, don't mistake the notion there is a server sitting inside the hospital and that image, as if that is denoting a physical software deployment architecture. i2b2 did some work with Query Health. In fact, some of what we are doing with SANER is derived from some of the Query Health work. And the notion is that there might be a cloud-based connection to that server that the hospital has to be able to communicate that data. That might be a –

[Crosstalk]

Leslie Lenert
It might be hybrid cloud solution.

Keith Boone
It might be a segmented repository where each hospital has its own virtual review of its data but it could all be cloud-based.

Leslie Lenert
Well, that's –

[Crosstalk]

David McCallie
Let's see if there any other questions. Les, let's see if there are other questions from the group. And if not, I have one. Because we are going to run out of time here in a couple of minutes. Well, I do not see any other hands so, Keith, let me give you a quick one. Given that there are multiple paths that this data might reach an aggregator, it might have gotten aggregated locally, then at state level, then at national level. And there might be a different path where it goes straight to national. Does the standard contemplate a way to
deduplicate the data so that you can say, "I've already seen that data. I'm not going to sum it up inappropriately." Does that make sense?

**Keith Boone**

So, that gets into – yes, that does make sense. It is a challenge that we often see, for example, in trying to reconcile problems that mention allergies when you have data coming in from multiple CCDA documents from across multiple sources and from inside the EHR as well. And plenty of duplication. There is a couple of keys to that. One of them is being able to have provenance information, to be able to tell you who the data source was and potentially be able to trace that back. And then, the other aspect of that is, the ability to incorporate line level information so that you can potentially just record say record identifiers associated with the accounts and be able to use that to trace back and be able to support that deduplication.

Honestly, that sort of topic is a really deep topic in terms of how you potentially, for example, take data from the state of New York and be able to factor out data from the city of New York because maybe you already received that from the city of New York and there could potentially be overlaps in that. It is a pretty deep topic. I'll rely on Les Lenert's we are not ready to boil that ocean yet.

**Leslie Lenert**

I am always ready to boil the ocean. I just want a nuclear weapon when I do it.

**David McCallie**

Yeah, just be thinking about it when you define your data elements. As much provenance as possible, because it could lead to a catastrophic mistake if an assumption about bed availability turns out to be the same bed got counted three times, obviously. How about other questions from the group? Maybe we will go for another few minutes here and then we will pick back up with our task force agenda. Any other questions from folks who have not had a chance yet? Do not be shy.

**Arien Malec**

All right.

**David McCallie**

While other people are thinking, I have one other question for you, Keith. Who is the competition for successful adoption of this? Is it just the fax machine or are there other – I mean, Les has put a quasi-competitor on the table, if you would, in the sense of leveraging existing HL7 V2 feeds. Are there proprietary approaches that are moving into the space that will be likely successful or not successful? What's going to stop this from succeeding?

**Keith Boone**

So, what we are seeing right now is that there are a number of states that are currently supporting reporting, say through Juvare or through other deployments where there are not emergency operation centers, where that is the connectivity that exists today for this. And they all have their own way of communicating. As a matter of fact, Juvare has two different products and two different protocols to support that capability. And not really to pick on any one organization, either. It is just what I know. So, that is one part of it, is that there is this sort of break between what happens in emergency operations and that channel of communication and what happens elsewhere in health IT.
We have also previously mentioned HAVE, which maybe has more adoption at the international level. I know there is a feed still running in New York, from one New York hospital to HERDS. But that data is not being used for COVID-19 reporting. It is sad that they do not turn that one off. That has the challenge that it is not getting at the other data that's needed – the ventilators, the deaths, and the hundred or so different questions that are being asked at the state and/or federal level for this.

Les mentioned ADT. ADT has its own set of challenges and, as we said, we did not report for ASPR that identified one of them. But one of those is just within an ADT stream. You have to get and deal with the deduplication challenge because you get the same admit several times because maybe it did not get sent or you did not receive an acknowledgment. And so, it got sent again. Then you have to look at all of the transitions of a patient got admitted, they got moved, this thing happened, that thing happened, they changed class from being outpatient to observation to inpatient, to finally getting discharged. And does that all line up to give you what you need to actually be able to count occupied beds? Which says nothing about your capacity because you just converted OR3 to an ICU that supports six patients. And now, you have additional capacity that never shows up in that ADT feed until it starts to get used.

David McCallie
Yeah. Okay, thanks for that. Arien, back to you. Do you want to wrap this up and we can move to our priority agenda?

Arien Malec
Yeah. First of all, that was a really beautiful presentation. I see Clem has a question. Clem, is it a quick question? Because we do have to wrap up and go to prioritization.

Clement McDonald
No, it was not a question. It was just a comment that for deduplication, FHIR does have a unique key that's supposed to be persistent wherever it goes. And it should solve the problem. But I do not know if it is really implemented well or if anybody is using it. But just be aware of that. And one other thing is I did not get the name of the new product that was competing with ADT – or the new standard. What is the name?

Keith Boone
It is called SANER, Clem.

Clement McDonald
Spell –

[Crosstalk]

David McCallie
No, the other one.

Keith Boone
Oh, the other one. Oh. That was –

David McCallie
You mentioned Juvare, and that's what I thought Clem was asking about. But maybe he was after SANER.
[Crosstalk]

**Clement McDonald**
SANER is the HL7 standard you started, right?

**Keith Boone**
Yes. Juvare is one of many vendors in the emergency operations space.

**Clement McDonald**
Okay. Thank you.

**Keith Boone**
Juvare. I gave you the spelling in chat.

**Clement McDonald**
I got it.

**David McCallie:**
I got it. Thank you.

**Arien Malec**
All right. Well, Lauren and Keith, thank you very much for a very well done and very insightful presentation. And thanks for the two of you, and for Scott, for jumping on in short notice and giving us a situational awareness as to the situational awareness project. So, we're going to go to –

[Crosstalk]

**Keith Boone**
I would be happy to stay on if you think there are going to be any public questions I might need to –

[Crosstalk]

**Results of Prioritization Voting (01:04:36)**

**Arien Malec**
You are obviously welcome and it is a public meeting. So, we are going to transition now to primarily talking about some of the voting that we did in prioritization. We did this a little bit out of order, but that is fine. So, a number of people submitted their – let's go to the next slide and just review the prioritization process. So, as noted, we put together a variety of major areas coming out of our previous conversation. You can see them here. I will not go through all of them. We have deferred the vaccine credentials project because ONC's already picked that project up. So, the remainder of the 11 or 12 projects are under prioritization scope, if we go on to the next slide.

We put together a prioritization approach, where we looked at overall priority, potential impact, existence of policy levers, and the current burden of existing pressures. And an overall scoring system for high, medium, low that over weights highs relative to mediums relative to lows. And we submitted a scoring email. And then, I went through and picked up – I believe I captured everybody's input, as well as mine and David's
input. I think there were some people who were not able to provide their input. But we rolled up to a broader scoring presentation. So, if we go to the next – here is how the current weights roll out.

So, you can see the distribution of highs, mediums, and lows for each of the areas. And then, we did a simple even weighted sum across the average of each of the priorities. So, again, we weighted the priorities according to the weighting mechanism we saw previously, which was an exponential weighting mechanism and high counts for a nine, a medium counts for a three, and low counts for a one. We weighted those together and put together a weighted average for each of these areas. It is not quite a weighted average, but it is a weighted sum across this. And then, we summed that up to a summation column in which you can see is that – and we did this prior to scheduling any of these reviews. But, just for discussion purposes, what we saw was that there were two very clear top priorities, which are health equity standards and the EHR data use Flat FHIR real-world evidence compared with effectiveness recovery type uses for data that scored in the 40s. Health equity clearly scores at the top.

And then, there is a cluster in the middle, in the mid-30s to mid-20s. [Inaudible] [01:08:04] chronic care plans, immunization registry reporting, data sharing to federal commercial clinical administrative data standards, and harmonization burden reduction, and syndromic surveillance. And then, a cluster below 20 for contact and exposure notification, situational awareness, adverse event reporting, and patient advice. And so, we are going to have a discussion here about whether this emergent ranking based on individual voting passes a sniff test and whether we should contemplate running forward with these as our priorities. And I’d also note that there are some people who did not have an opportunity to vote. I think we’re more than happy to take those in.

What we noticed was that, if you think about sensitivity analysis, so far the top two results have been relatively robust. And then, rank order in the next five has been relatively non-robust. So, the rank order bounces up and down but that group of five seems to be relatively robust, and a group of four at the bottom seems to be relatively robust. That obviously could change because we have low in so far. That obviously could change if we get more votes. So, I think we are more than willing to get more votes in.

But I just wanted to throw out whether the priority ranking here passes the sniff test and how we would contemplate moving forward. So, if we just took this as handed from on high guidance we would say, we should go all guns blazing for the first two. We should do appropriate work for the next five. And then, we should get around to the bottom four when we have time to get around to them, if we think about prioritization order. So, I am just going to pause. And I see Clem has his hand up – but really look for folks to raise their hands and chip in in terms of overall prioritization. This is not the avenue for arguing that your priority that you thought was high ranked low and that's bad. More, just from the aggregate perspective, do we feel like we ended up in a place that seems sensible. So, Clem, go ahead.

**Clement McDonald**

Well, I am just not clear on what our technical equity health standard is. I can see the attraction to having health be equally distributed. But where does it fit in technical standards? And it's maybe one of the ones I asked the other day. When I heard it, I got it. But I didn't get [inaudible - crosstalk] [01:10:54] –

[Crosstalk]

**Arien Malec**
Yeah. I think I appropriately, in the email that we sent out for voting, I think I appropriately glossed it. So, if you go back to that email and refer back to it, we did, I think, appropriately gloss. The email that we are really talking about, both FDLH – so, the output of the Gravity Project. So, again [inaudible - crosstalk] [01:11:26] –

[Crosstalk]

**Clement McDonald**
Yeah, yeah. Okay. I get it. I get it.

**Arien Malec**
And then, basic demographic information attached to various flows, looking at race, ethnicity, gender, and basic demographic information like geolocation ZIP Code or census tract information.

**Clement McDonald**
Okay. Thank you.

**David McCallie**
And, Clem, I believe next week’s session we will hear from the Gravity Project and they can expand on some of those details. That's our current plan for…

**Clement McDonald**
Yeah.

**Arien Malec**
Yeah. And I also, as I was explaining the averages, I think I understand what I did that makes these [inaudible] [01:12:07]. So, I'm more than happy to go back and clean up the math and see if that changes the rankings. I doubt it will, but the average really should be below nine. So, let me go back and do another pass at doing the Excel to make all these things count up appropriately. I averaged across the sum of the high, medium, and low as opposed to averaging across all the values. We will work it through.

**David McCallie**
From my perspective, one of the things here was to get sort of a driving sense of where we should put effort on learning more about these categories. But that, as we learn more, we may revisit some of what we thought was important or not important based on discovery. So, I think at this stage of the game, the way I'm looking at this is it is a prioritization for our discovery work, which may get revisited in terms of final priorities presented as recommendations from the task force to ONC. Hopefully, those align closely but there is potential – like, I do not think we knew a whole lot about SANER before today's presentation. Now that we know more, that may affect the way people would prioritize that work. So, that is probably going to change with others of these domains once we get more input.

**Obtaining Additional Expert Input (01:13:30)**

**Arien Malec**
That is exactly right. All right. Other questions on the ranking? And as I said, I think, we are more than happy to get additional votes and rerun this and see how robust they are to additional data. When you have low ends, you sometimes get wacky results. So, the more people who vote, the better off – the more robust
the priority ranking will be. All right. So, hearing no other questions, I think the conclusion that we would have is that our next priorities for hearing from the community would be primarily around health equity standards. And as David mentioned, we are already lined up with the Gravity Project. And then, the cluster of EHR data use relative to real-world evidence, or compared to effectiveness, or recovery, like comparative effectiveness trial, or emergent trial design work. This is the long mythical learning health system that we've all wanted to get to. David, remind me where we are with that one. I think there are folks we reached out to who we would like to get additional –

David McCallie
Yeah. I think the next slide has our current status on that. Can we go to the next one? Yeah. Here we go. So, in the black font are the ones we have already lined up. We have heard, obviously, from SANER just a few minutes ago. Health Equity is queued up for next week. We have conversations underway in these other four areas. I've got a call tomorrow with one of the key players in the Flat FHIR standards and profiling space to get suggestions for that category in the third position there, that learning health system leverage EHR data. I am hoping that that after the call I have tomorrow we will have some specific names for people that we could invite either on the 8th or the subsequent week. We have conversations underway in the other three areas as well with requested feedback from folks.

But we have not slotted them into a session. We are certainly open for suggestions. I can tell you on the federal/nonfederal boundary question, I had a long question conversation with Scott Stuewe from DirecTrust and now I have a better understanding of what the status of that problem is and advances that have been made that we might not have been aware of. But I think we will still probably get some expert opinion about what is yet to be solved for that space. Arien, do you have other comments? You were going to – I think the administrative and clinical data standards was your space?

Arien Malec
Yeah. I did reach out and I think we got a favorable response and we just need to line up better. I've been remiss and slack on that. So, we will work through that. But I do think we should prioritize health equity and real-world comparative effectiveness to make sure we get at least good presentations there.

David McCallie
Yeah. We are well underway on that one – on those two.

Arien Malec
Any other comments from the group in terms of other folks you would like to hear from, just hearing that overall prioritization process? Other folks you would like to hear from? Other input we would like to be able to do?

Leslie Lenert
Yeah, I mean, I think it is important to hear from OHDSI. You were going to bring down one of the leaders from that for the real-world effectiveness data But also from PCORnet. So, I would urge you to think about both of those as potential standards for real-world effectiveness data. And then, focusing on how we produce those from other standardized data sets like FHIR, for example.

David McCallie
Les, if you want to send me some suggestions for PCORnet, we would appreciate that. Just email them to me or speak them out loud if you have them right on the top of my head. I have an OHDSI thought but we have not made contact yet. I have names. Obviously, George Hripcsak.

**Leslie Lenert**
Yeah, I know George pretty well. So, if you want me to reach out to him – I think it is an interesting question who to reach out to about PCORnet. But now it has been taken back inside the – not the agency but something close to that. Probably, someone in PCORI would be the right person to talk about it. So, I can poke around that. If nothing else, we can also get you a STAR or 1Florida, or somebody like that, to talk about their PCORnet installation.

**David McCallie**
Okay. All right. You hand is up. Is Clem's hand up a leftover?

**Arien Malec**
No. I think Clem has officially got his hand up.

**Clement McDonald**
Yeah. I just want to bring up about the PCORnet. We are working with some of the data and I just want to compliment it. But I thought that Duke was the organizing center. There is a guy named Keith – I've lost his name – who would know all about it. But I do not know if it is still true, that I thought Duke was the coordinating center. There's a guy there who runs it.

**Leslie Lenert**
Yeah, Duke is the coordinating center but sometimes the – yeah, we could go to the coordinating center but the coordinating center really does mainly coordinate in that. But that is fine. Whoever –

**Clement McDonald**
Well, just – they know a lot about it in case you just wanted overview. I'm not trying to push anyone.

**Leslie Lenert**
I am pretty neutral. As I said, the number of direct as of – I am the institutional lead for PCORnet at NUSC. And so, I – yeah, whatever data. Duke could be great, too. They will tell us all about the global nature of it and those things there. I think the data quality assessment is really the – both of those, which DSI and PCORnet really distinguish themselves by having systematic testing of the data for quality. And that might be an important part of any standard, would be to define what those measures are.

**David McCallie**
Interesting.

**Clement McDonald**
And they're both pretty well standardized with code. So, PCORnet has over nine billion test results. It's striking there's that many.

**Leslie Lenert**
Yeah, PCORnet has about 100 million people –
Arien Malec
So, this has been good just in terms of thinking about who we want to speak to. Let's wait a little while before we go super deep into the weeds. Keith, I see you have your hand up. We have one minute before public comment. So, if you have a one-minute comment, go for it, as a guest.

Keith Boone
Well, it was really for public comment, looking back at your rating slide. And I was not really able to tell whether people could give out an unlimited number of high, medium, lows or not. I find that if you have ranking like high, medium, and low and people can just mark that on specific things, it is best if you make them make decisions and say, "Well, you can award three of these, and five of these, and the rest fit into this bucket," just in terms of getting them to make decisions about where things fit, putting everybody on the same scale so that you do not necessarily have one person ranking a bunch of things high. I do not know if that is something that you applied to that or not.

Arien Malec
We did, so thank you for the comment. We definitely did. We were not super heavy-handed about it, but we saw some separation. And I assume that separation is going to survive some of the redoing that we do. Clearly, the next stage after, if you do not get separation, is to force people to rank order as well. There are definitely tricks we can do to force separation. Why don't we go to public comment?

Public Comment (01:22:45)

Michael Berry
All right. Operator, can we please open the line for public comment?

Operator
Yes. 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 the star keys. One moment while we poll for comments. There are no comments at this time.

Arien Malec
Thank you. So, we can go to additional discussion or we can give each other back four whole minutes to check email and use the facilities. Okay. It sounds like people have voted for the four whole minutes. So, thank you very much. I will not be able to attend the next meeting. David is going to ably lead us through the Gravity presentation. If you have not voted, please do vote and we will make sure that your priorities get represented and we get to a final version of prioritization, or an interim version of prioritization as David said, contingent on or prior to hearing all the presentations. Thank you.

David McCallie
Thanks, Keith and Lauren.

Arien Malec
Absolutely.
Keith Boone
Thank you.

Lauren Knieser
Thank you so much for having us.

David McCallie
Very good.

Arien Malec
Bye-bye.

Adjourn (01:24:39)