# Transcript

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

April 8, 2021, 2:00 p.m. – 3:30 p.m. ET

VIRTUAL

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# Speakers

| Name | Organization | Role |
|------|-------------|------|
| **Arien Malec** | **Change Healthcare** | **Co-Chair** |
| **David McCallie** | **Individual** | **Co-Chair** |
| Ricky Bloomfield | Apple | Member |
| Cynthia Fisher | PatientRightsAdvocate.org | Member |
| Valerie Grey | New York eHealth Collaborative | Member |
| Jim Jirjis | HCA Healthcare | Member |
| Edward Juhn | Blue Shield of California | Member |
| Ken Kawamoto | University of Utah Health | Member |
| Victor Lee | Clinical Architecture | Member |
| Leslie Lenert | Medical University of South Carolina | Member |
| Clement McDonald | National Library of Medicine | Member |
| Ming Jack Po | Ansible Health | Member |
| Raj Ratwani | MedStar Health | Member |
| Ram Sriram | National Institute of Standards and Technology | Member |
| Sasha TerMaat | Epic | Member |
| Andrew Truscott | Accenture | Member |
| Michael Berry | Office of the National Coordinator for Health Information Technology | Designated Federal Officer |
| Wanda Govan-Jenkins | Office of the National Coordinator for Health Information Technology | Staff Lead |
| Denise Joseph | Office of the National Coordinator for Health Information Technology | Staff Lead |
| Robert Dieterle | EnableCare LLC | Presenter |

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

**Operator**
All lines are now bridged.

**Michael Berry**
All right, thank you, and welcome, everyone. Thank you for joining the Interoperability Standards Priorities task force. My name is Mike Berry, I am with ONC, and we sincerely appreciate your participation and your input along the way. I just want to note that our meeting next week is moved to Friday, April 16th because the HITAC meeting meets next Thursday, so we had to move it just for next week, so make sure you check your calendars for that. I am going to start with roll call, so when I call your name, please indicate your presence, and I want to note that Arien Malec, one of our co-chairs, is out today, but he should be returning next week. David McCallie is here with us today. David?

**David McCallie**
Present.

**Michael Berry**
Ricky Bloomfield?

**Ricky Bloomfield**
I am here.

**Michael Berry**
Cynthia Fisher?

**Cynthia Fisher**
Present.

**Michael Berry**
Valerie Grey? Jim Jirjis?

**Jim Jirjis**
Present.

**Michael Berry**
Edward Juhn?

**Edward Juhn**
Present.

**Michael Berry**
Ken Kawamoto? Victor Lee?

**Victor Lee**

Present.

**Michael Berry**
Leslie Lenert?

**Leslie Lenert**
Good afternoon.

**Michael Berry**
Clem McDonald?

**Clement McDonald**
I am here.

**Michael Berry**
Jack Po? Raj Ratwani? Ram Sriram? He indicated he might be out today, but Ram, are you with us?

**Ram Sriram**
I am kind of listening a little **[inaudible – crosstalk] [00:01:34]**.

**Michael Berry**
Okay. Thank you. Sasha TerMaat? And, Andy Truscott indicated that he is not available to join us today, but he should be back next week as well. All right, thank you, everyone. Welcome again, and I would like to turn it over to David for his opening remarks. David?

## Introductions (00:01:56)

**David McCallie**
Thanks, Mike. Welcome, everybody. As you know, Arien is out today, so I am going to run this solo. As you might expect, if something can go wrong, it will go wrong, and our guest speaker has not yet logged into the session, so we have to do a little bit of a tap dance.

**Robert Dieterle**
I am here, David.

**David McCallie**
Oh, Bob. Good, great, you are here! You are not on the list, or I did not see you on the list, so I was assuming you were not here. Excellent. Okay, let me give the group our agenda for today, and then we will hand it over to you in a second. So, we are going to first hear from Bob Dieterle, the executive technical director for the HL7 Project Gravity, which is part of our investigation into how standards priorities can affect health equity issues. Bob is going to cover a ton of material for us today.

When Bob is done, we will have some discussion, and then, at the close of the meeting, I have a few corrections to our priority spreadsheet voting. We found a few errors in the Excel formulas. The good news is it did not change any of our rankings or decisions. And then, as usual, after our discussion, we will close with public comment. But, the main focus of today's meeting is to hear from Bob and to think through how

we might make priority recommendations back to ONC to address some of the issues of health equity, which was our No. 1 priority in our voting. So, Bob, I am going to turn it over to you and let you introduce yourself and give all the details about Project Gravity. Thanks.

## Project GRAVITY Presentation (00:03:37)

### Robert Dieterle

I am more than happy to do so. I am Bob Dieterle. Many of you know me. I have been around the standards work for a while. Broadly, my background is that at one point, I was a general manager at the Cerner Corporation. In the last 10 years, I have focused almost entirely on standards, working with CMS, ONC, the FHA, HL7, WEDI, and X12. I am one of the founders of the Da Vinci Project, I am one of the founders of the FAST task force under ONC, and I also have the privilege of being the technical director of the Gravity Project. So, we are focused almost entirely on social determinants of health and health equity.

So, let me go ahead and walk you through the Gravity Project for those of you who may not be familiar with it. Next slide, please. Broadly, social determinants of health are important because they contribute a significant portion of what becomes health-related outcomes, whether it is food insecurity, the ability to get food, and its impact on diabetes, hypertension, or heart failure, or housing instability and the inability to go and adhere to treatment protocols, or it is transportation barriers that prevent someone from getting to an appointment, or being able to go to the store, or being able to go to work. Those are all the things that affect your ability to go and have healthy behaviors and healthy outcomes. So, basically, roughly 40-50% of the entire health picture is focused on socioeconomic or health-related issues. Next slide, please.

The Gravity Project is a spinoff from some work that was done by SIREN, Social Intervention Research Evaluation Network, at UCSF. It started in May of 2019, focused on developing standards to document and exchange social-determinant-of-health data. Next slide, please. In August of 2019, the Gravity Project became an HL7 FHIR accelerator program to take advantage of the support that HL7 gives in working with and particularly creating FHIR implementation guides to solve unique exchange problems. We are a FHIR accelerator along with many of the others, such as the Argonaut Project, the CARIN Alliance, CodeX, Da Vinci, and Gravity, and I believe we also have Vulcan now. Next slide, please.

The Gravity Project has a very broad collaboration environment. The public collaborative has over 1,800 participants that have been involved with various aspects of the Gravity Project, from every domain, from every stakeholder group, such as clinical provider groups, community-based organizations, and standards development organizations, federal and state government, who are regular participants, payers, who are becoming much more involved, and technology vendors. We have on this slide a couple of the public calls that we hold. There is one general call every Thursday afternoon with the full collaborative, and then we have a call on Wednesday afternoon, working on the FHIR implementation guide. Next slide, please.

The Gravity Project requires support to be able to do what we do, and we have been very lucky in having some significant organizations be willing to become sponsors of the Gravity Project and provide the funding necessary, both in-kind grant and direct funding, to accomplish the goals of the Gravity Project. Next slide, please. The program management team for the Gravity Project consists of Evelyn Gallego from EMI Advisors, Carrie Lousberg, who is the project manager, also from EMI Advisors, Mark Savage, who is the policy lead, from UCSF SIREN, Sarah DeSilvey, who is the clinical informatics director and is focused on

the terminology work in the Gravity Project, from the University of Vermont, and myself as the technical director, and I am the CEO of EnableCare. Next slide, please.

There are two broad work streams within the Gravity Project. One is focused on creating terminologies and filling gaps that exist, but having terminologies that are consensus-based and evidence-based that define any of the aspects of social determinants of health, from assessment and surveys to defining health concerns and problems, establishing goals, establishing interventions or referrals, and tracking those to completion. The technical side is focused on creating the FHIR implementation guide to support the exchange of those semantics that we just talked about on the terminology side. Next slide, please.

On the terminology workstream, we have 18 different domains that we are focused on. We have completed food insecurity, we have completed most of the housing-related items, we have completed most of transportation, and by "completed," I mean taken it all the way through to the point where these value sets are created and either submitted to or published by the terminology authorities. We have a number of other ones we are working on right now, and we will give a graphic of where we are in the process in a minute. Next slide, please.

The terminology team has a very formal process they use, much like we do on the technology side, where they have subject matter experts that work with informatics experts and the community to establish appropriate terminologies and value sets for each of the specific SDOH domains. Next slide, please. This is the slide of where we are in the process for each of the domains that we have worked on. So, as you can see, food insecurity, housing instability and homelessness, and adequate housing are well along the process of being submitted to the particular terminology authorities for publication. Transportation is almost at that stage, and then we have others that we are currently working on right now, such as financial strain, demographics, material hardship stress, inter-partner violence, and social isolation. Next slide, please.

This is where you can find the published Gravity data sets. They are available on Confluence under the Gravity portion of the HL7 Confluence environment. Next slide, please. One item of note is that the Gravity Project submitted a number of new codes for ICD-10 CM. That submission was done in December, and it was defended on March 10th, presented formally. We believe that these have been accepted for publication. The question is if they will be published the September release this year or the following year, and that is something we are in the process of trying to influence to make sure that they get published as soon as possible. Next slide, please.

This is the timeline for all of the projects that are under way right now. You see the various ones. You have inter-partner violence that is going on, social isolation, stress, material hardship. We are working on new use case development with the intent that after a bit of a break for our community group, meaning not the people that are working on the Gravity Project itself, but food and neighborhood safety are ones that we plan on picking up in the fall after the break. We will talk about the timeline on the technology side in just a second. Next slide, please.

So, broadly, this works by defining terminologies and value sets for each of the various SDOH domains, using those to define the specific set of clinical activities, assessments, problem identification, goal-setting, and the ability to define appropriate referrals and interventions, and ultimately tying it back into the FHIR implementation guide. Next slide, please. We created a FHIR implementation guide that went to ballot in

the January ballot cycle for HL7. It had started out roughly a year ago as an implementation guide focused solely on food insecurity. We expanded that to be a framework guide to support any of the domains that we have talked about. So, it went to ballot as a framework implementation guide supporting multiple domains. It supports the processes of assessment or survey, establishing health concerns or problems, goal-setting, referrals, and interventions. It supports consent and aggregation for reporting. There is a link here to the implementation guide that was balloted. Next slide, please.

So, as we said, this is linking back to clinical activities with various terminologies. We focus the assessments and surveys on LOINC-coding both the questions and answers. The health concerns and problems are coded as SNOMED CT and ICD-10. Goal-setting is both LOINC and SNOMED CT. Establishing interventions or referrals is based on SNOMED CT, CPT, and HCPCS. And then, recording the interventions were completed, again, is SNOMED CT, CPT, and HCPCS. And then, we are working with NCQA and NQS to establish appropriate quality metrics. We will probably using the Da Vinci/DEQM guide for that. We are just showing it here as one of the additional activities. On the right, you will see consent. We will talk about how we are working with consent in a second. On the left is aggregation for reporting. Next slide, please.

We have defined a process using both Regenstreif's LOINC survey definitions and some National Library of Medicine open-source tooling to be able to take a defined LOINC survey, convert it into an SDC questionnaire, administer the questionnaire, and create a consistent set of FHIR resources, a questionnaire response, observations, which include the question and answer to each of the questions, and then, ultimately, the outcome of that questionnaire as health concerns, which, based on the conversation between the provider and the individual, a patient can be promoted onto the problem list, goals can be established, and interventions can be defined. Next slide, please.

This is where we started, and we will modify this in a second as far as expectations and scope of implementation guide. We started with the idea that this would be primarily a clinical exchange between provider organizations and community-based platforms, exchanging the things that we had defined, meaning referrals, goals, problems, or health concerns, and then recording the outcome of the interventions. So, the initial implementation guide was focused on the blue lines, which are the exchanges related to the assessment between provider organizations and community-based referral platforms, as well as between provider organizations and community-based organizations that actually deliver the services, such as food pantries, for example. We had identified a set of interactions here with payers and other interested parties, but we had left them out of specific workflows at the time we started the work on the implementation guide. Next slide, please.

I am going to touch on consent, and then I am going to go back to the overall workflow. What we have defined within the implementation guide is a way to both define and exchange a consent resource where the exchange of information goes out of the HIPAA-controlled environment to a community-based environment. That would be maintained within the EHR, for example, when the exchange is directly to a non-HIPAA-covered entity, such as a food pantry, which does not have a business associate relationship with the provider organization. What we have also done is defined a consent resource that can be exchanged between a provider organization, which is a HIPAA-covered entity, and a business associate, such as a referral platform in the community, that establishes a patient's consent to share that information outside of the HIPAA environment with a non-HIPAA-covered entity such as a food pantry or someone who

is going to work on getting housing or transportation. Next slide, please. By the way, we presented this as part of the ONC annual meeting in the panel on data-taking and consent.

Based on feedback from our executive committee, from the strategic advisory committee, and some of the general stakeholders worried about health equity, we have expanded the workflows supported by these implementation guides. It did not require changes to the underlying FHIR resources, profiles, extensions, value sets, et cetera, but what we have done is defined an additional set of supported exchanges that we are in the process of including in the implementation guide and including in the reference implementation that we are developing.

So, this would account for surveys that are delivered by payers and community-based organizations exchanging the outcome of those surveys or assessments, being able to exchange referrals between payers and community-based organizations, and being able to exchange referrals between community-based platforms, for example. So, all of the blue lines will be in the final implementation guide as the supported exchanges using the resources that we had already developed and validated in January. Next slide, please.

This is kind of a simplified diagram to show all of the players that we are supporting as part of the exchanges without showing each one of the exchange arrows, if you will, other than to show that they would be between a FHIR API and between two organizations. We are assuming there are both patients and community-based organizations that will not have technology platforms. We are looking at developing reference implementations that include applications for smartphones so that they can participate in the FHIR-based exchanges. Next slide, please.

This is where we stand on the implementation guide. It was valid in January. It met the 60% approval threshold so it could be published as an ST1 once we finished ballot reconciliation. We had 227 comments. Seventy-two were negative and 155 were affirmatives of various types. We started ballot reconciliation on February 7th. As of yesterday, 161 of those ballot comments had proposed dispositions, and we are working through the dispositions on the remaining 66. We are on track to have that work completed by the end of April. We plan on taking it and the updated reference implementation to the connectathon in May, testing most of the interactions, and then using any learning coming out of the connectathon to go and provide additional update to the implementation guide prior to publication, and our target is to have it published by the end of June. That would be in time for pilots that we are in the process of establishing that would basically be starting in July for the summer of this calendar year and extending a little into next year. Next slide, please.

So, what is next? We are continuing to work with NLM and Regenstreif on the survey process. We are working with the community to establish clinical content required for the multiple SDOH domains. We showed you the domains we are working on at the beginning of the presentation. We are advancing the development of a reference implementation to include the additional exchanges that we will be supporting as part of the guide, we are incorporating dispositions from the ballot comments into the implementation guide, and we are in the middle of doing preparation for the May connectathon. We do have a track, which is the SDOH exchange track, that we will be running as part of the May connectathon. And then, for those of you who wish to join us in working on the implementation guide, please feel free. It is an open public call,

and it is every Wednesday afternoon from 3:00 to 4:00 Eastern. It is available on the HL7 calendar. Next slide, please.

And, this is information for those of you that wish to join the Gravity Project either as a sponsor, an in-kind contributor, or just to participate in the public collaborative. Next slide, please. I believe that is the end of the presentation.

**David McCallie**
Thanks, Bob. That is impressive scope and an impressive amount of participation from community organizations. Having worked with the early Argonaut work when we had 10 groups, most of them did not show up. Getting to something of the size that you are dealing with now is kind of hard to imagine. Let me start some questions, and then invite our task force members to raise their hands and ask some other ones, but let me lead off with what may be a completely naïve initial question, which is grouped broadly into the health equities umbrella are questions and concerns about capturing race, ethnicity, gender, and related stuff, which I suppose are technically different from social determinants of health. Does Gravity address any of the race/ethnicity/gender nomenclature and interchange, or is it strictly focused on the stuff you described?

**Robert Dieterle**
Well, it is focused on that. The way we are focused on it is by adopting the US Core profiles, and to the extent the US Core profiles basically represent the SOGI work, we would adopt that uniformly across both provider, payer, and community-based organizations.

**David McCallie**
Okay. So, that makes sense. You just essentially take that as your starting point and you do not need to refine those. They are built into the US Core process.

**Robert Dieterle**
I do not think we want to do something different than the rest of the industry is doing.

**David McCallie**
No, I would not. I would think that would be a problem if you were. I just wondered if maybe you had been asked to to refine some of those things, but it sounds like it is outside your scope. Okay, I have lots of other questions, but let's start with the group. Ricky, I see you have your hand up.

**Ricky Bloomfield**
Sure, thanks, David. First of all, I want to echo the comment that this is just fantastic work. The scope is large, and you have taken on a lot, and it seems like you have made great progress, so it is great to hear that. I have a question. So, when you have been thinking about this, is the assumption that the workflows within the care team, providers, and care management already exist to enter this information into their software, whether it is the EHR or any other software they are using, or is part of this work to help define those workflows and for the EHR vendors as part of the connectathon to produce those workflows if they do not yet exist?

**Robert Dieterle**

That is a really good question. We do have EHR participants in this. Some of the workflows exist depending upon the particular EHR, such as the ability to go and conduct surveys. The major EHR vendors have already adopted some of the standards, whether it is a **[inaudible] [00:27:44]** care community survey, PREPARE, or some of the work that we are doing around hunger vital signs, they have adopted those survey processes to collect information inside of the EHR. What we are doing here is defining how to represent them in FHIR and exchange them.

Goal-setting depends upon – sorry, I should say problem definition and health concerns. Basically, everybody has a problem list of some form or another. Whether they are able to support the concept of a health concern that is not yet a problem is variable. It depends upon which EHR vendor you are talking about. Goal-setting is pretty much universal. There is support for it, but it varies as far as its depth, and so, we are probably going to define only a very high level of exchange of goals related to social determinants of health, not trying to go and preempt the work that is being done, for example, by the multiple chronic conditions work that is going on, defining goals in a broader community-based care setting.

As far as interventions and referrals, that is really an interesting problem. There is work that is being done by a number of EHRs. In fact, they are participating in some other work that I am involved with around post-acute orders, which is an electronic exchange of referrals and interventions using service requests, paths to coordinate it, and procedures to document it. So, this is really an emerging environment. Most of that work is currently done, as you all know, by telephone and fax, not by any kind of electronic exchange, so we are defining FHIR-based standards for that exchange with the assumption that at least a certain group of organizations will be able to support them. We do have one or more referral platforms that have already indicated they are in the process of implementing the ability support task and service requests for referrals, so I think we are skating to where the puck is going, but the puck is getting there pretty quickly.

**Ricky Bloomfield**
Yeah, that is really helpful. There is definitely an element of "if you build it, they will come" here, and it is a catch-22 because you need the infrastructure there to exchange it before entities will spend a lot of time investing in the user-facing data entry part. One of the things that I think back to – I know David mentioned Argonaut – is thinking through the original Argonaut, then US Core, around data types like care plan, for example, where clearly, there is a need there, and it is a highly requested data type, but every EHR vendor implements that differently, and even if the EHR supports it and the health system supports it, getting clinicians and care teams to actually spend the time to enter that and to create that data in a structured way has been a significant challenge, so it is great that you are thinking about some of those things and how to avoid the data entry clerk problem and try to make it as seamless as possible.

**Robert Dieterle**
Let me make one comment. One of the early drivers in health equity and exchange of information is probably going to be the payers that have an interest in this space, and particularly because they do not have complex platforms already associated, like EHRs, for example, where they have to change workflow. They have something that they can adopt pretty quickly. So, we think that they are going to be one of the early adopters of it, perhaps in advance of some of the work that is being done by the EHR vendors.

**David McCallie**
Victor, I see you have your hand up. I think you were next in line.

**Victor Lee**

Thanks, Dave. This kind of builds upon Ricky's comment, which I think relates to the capability to enter this information into EHRs, and I wanted to build on that by addressing a potential gap in the authority to enter these codes. I am an expert here by no means, but this is what I heard in a webinar, and I am referring to the slides from that webinar, and this might be from CMS, but it sounds like it is around who has the authority to enter these social-determinant codes, and there is the concept of a "clinician," the definition around that, and who is able to officially enter these codes. I am wondering if it might be within the purview of this task force to seek clarification around that and also to educate clinicians or other people who have the authority to officially enter these codes and be a permanent part of the record. This may be outdated. The slide deck that I am looking at is from 2019, so it is admittedly two years old, and progress may have been made on that. So, that was really the comment, around the authority to do that in addition to the capability, because I think if people do not enter the data, then your data set is only good as what is there.

**Robert Dieterle**

Let me make a comment. I am not aware of any formal authority requirement. There is some question as to what information can be exchanged without patient consent outside of a HIPAA-controlled environment. There is also some concern related to specific types of social-determinants-of-health documentation and the sensitivity of the individual to having that information exchanged. I think that we can clearly understand where they do not want inter-partner violence data to be exchanged with most organizations. There are other things that may wind up being more of a concern to some individuals than others, such as lack of income or lack of housing, where they believe it might affect their ability to get a job, so there is sensitivity around this. It is not so much in the entering it as in the use of it, from what I understand.

**David McCallie**

Let me jump in. Clem, I see your hand. I am going to come to you in a second, but just to follow directly on the consent question because I think it fits with what Bob just said, Bob, does the IG make some assumptions around the process of capturing the consent? Is there some assumption that it has been captured before any of this survey is put up on the screen or engaged with? How is the consent workflow envisioned to flow?

**Robert Dieterle**

That is a good question, David. The only consent that we are dealing with in this version of the implementation guide is the consent given by the patient to the provider to share information with a community-based organization. So, share the information requesting a referral to a food pantry, requesting a referral to someone that could deal with housing, and the associated documentation to go with it, which, in general, is not specifically on the clinical side of documentation, and it is more along the problem or goal that may be associated with it, but the intent is to have that documented somewhere in the EHR, and all we are doing is providing the definition and profile on the consent resource to exchange it, assuming it will more than likely be something that is an attachment, not something that is computable, so we are trying to live with where the industry is today.

**David McCallie**

Yeah, that was going to be my follow-on question. Are you going to stretch for computable consent? Because you could theoretically mask off some of these data types that you mentioned were maybe more sensitive than others, but I agree with you that the industry is not there today.

### Robert Dieterle

Well, there is work going on at HL7 and a number of work groups around the fine-grained consent and data tagging. There is work going on at ONC trying to define what makes sense for standardized consent across the industry or across portions of the industry. At this point, we have decided not to take on that task. We will let that process mature as it is going to, and then we will adopt it in the next round of the implementation guide. The only thing we wanted to do is make sure that we had a way to exchange patient consent with business associates allowing the release of information that the provider and the patient have agreed to or that the payer and the patient have agreed to. It will provide consent in both those spaces. Does that make sense?

### David McCallie

Yeah. From my perspective, it is reasonable to start with something that covers most of your use cases rather than trying to start with something that is really hard to achieve and fails to cover any use cases. Start small and scale up. Clem, I think you had your hand up next.

### Clement McDonald

Yeah, I have a couple questions related to the burden. So, it is a very large spec. Is the survey instrument the one that was used widely? I forget if it was called PROVIDE or PREPARE.

### Robert Dieterle

PREPARE.

### Clement McDonald

Is that the core survey instrument? That is pretty straightforward, and it would not be hard to complete, but all the other stuff looks like a lot of work, and the things that would apply to clinicians could keep them busy all day, so I just wonder if people thought about that. Secondly, what percentage of people do you estimate would require these data to be entered? Would it be everybody, even if they were not subject to these risks?

### Robert Dieterle

It is a great question. I think that is going to be dependent on a couple of things. It would be dependent on decisions made by provider organizations as to what surveys they want to do related to social determinants of health, it is going to be related to quality measures, it is going to be related to decisions that are made by payers on what they want to have their members assess for, and it will be based on decisions that are made by HHS, CMS, ONC, the SSA, et cetera. We are not making those decisions. What we are doing is trying to go and automate as much of the process as possible, and you and I talked about that in the fall.

What we are doing is trying to take the open-source tooling that you have developed that can take a LOINC-coded survey, convert it to a FHIR questionnaire, administer it to an individual, and ultimately record those outputs as FHIR resources, observations, condition resource, and questionnaire response that could potentially be incorporated into an EHR, trying to take that entire survey evaluation process off the plate of

the provider, and rather, using it as input for them to review and coordinate appropriate interventions by talking to the patient.

**Clement McDonald**
That is a limited-size questionnaire. It is all the other stuff, like having to do care plans and all, which are not part of the average provider's day. I think they are getting between 8 and 15 minutes per patient now in some of these plans, so I hope the system, not you, will be sensitive to that. And, I guess that that should not apply to the average person who comes in the door who has a good insurance policy, et cetera, and a good income, but anyway, just keep that in mind, or at least when it comes up, to try to keep the physicians from having to shut down and spend their whole day filling in things instead of seeing the patient.

**Robert Dieterle**
Agreed. Just to be clear, we are not covering care planning in this implementation guide at all. We are only covering the ability to exchange goals if they have been set. That is out of scope for what we are doing.

**Clement McDonald**
All right. You are always sensible. I do not know why I even asked.

**Robert Dieterle**
We try as much as we can to not burden the provider with things that either can be automated or are not ready for, say, public consumption.

**Clement McDonald**
Thank you.

**David McCallie**
To that end, Bob, I understand the technical focus of Project Gravity, but I may be thinking back a little bit to Ricky's first question. Is anybody working, maybe in conjunction with your group, on model workflows for a physician office to incorporate the capture and use of this kind of information, such as the AMA or the AAFP here in Kansas City? Is somebody saying, "In parallel to the development of these questionnaires, here is a model workflow of how to use that"? Is that something anybody has talked about?

**Robert Dieterle**
Yeah. Interestingly enough, my primary partners in developing this implementation guide are two people from the AMA, Corey Smith and Monique van Berkum, and one of their consultants, so they have been working with me on this from the beginning, so they are reasonably sensitive to the provider-related issues. AAFP was actually the very early-on sponsor for helping the Gravity Project to become a FHIR accelerator and a permanent member of the executive committee. So, we do have at least provider-facing associations or organizations that are participating on a regular basis.

**David McCallie**
Good. As with all these things that start out as a well-done technology piece, getting the adoption in the community will be as much of a challenge as the work of defining the technology, if not more so, so, taking that into your workflow early on is a smart thing.

**Robert Dieterle**

I absolutely agree with you, David. We are concerned about adoptability with everything we do. In fact, it is the first thing we ask when we try to define something, is whether it would inhibit or accelerate adoption.

**David McCallie**

Yeah. I have a technical question, but does anyone else have their hand up? I do not see it on my list. Is there anybody that I missed? Okay, let me ask my technical question, and if it inspires you to ask more questions, please weigh in. This is really nerdy, Bob, but that is my job. Your internet bubble diagram where you had entities on the left-hand and right-hand sides and internet in the middle sort of implies point-to-point FHIR communications, and I am just wondering how you think that would work. I totally understand the nomenclature work, the FHIR questionnaire work, and the consent capture and conveyance work, but are you envisioning that a food pantry will be firing off FHIR queries to all the EHRs in town to see if they have something about one of their customers, or whatever food pantries call their patrons? Does that make sense?

**Robert Dieterle**

That is a really good question. We are actually looking at two different workflows, one for those that are FHIR-enabled and ones that are only FHIR-capable. In the case of those that have permanent relationships, we are assuming that the directory work we are doing will provide the endpoint resolution and the trust framework, which is work being done in FAST, will wind up providing the common authorization authentication environment, if you will.

So, really, it is a question at that point of connecting and exchanging. We are not eliminating the concept that there could be somebody in the middle, such as an HIE, a clearinghouse, a particular service provider that goes and basically assembles all of the pieces and provides for the exchanges, and in fact, the AMA is working with Onyx to create such a platform. What we are doing is designing in the implementation guide everything that is point to point because we believe that will be part of the exchange ecosystem, if you will, with the assumption that there can always be somebody in the middle who is value-added. What we do not want to do is design it for an intermediary to be there and have it not work point to point. Does that make sense?

**David McCallie**

Yeah. Designing it so that an intermediary is not required sounds very smart to me, but let's just say you have the directory information accessed, permissions granted, and everything is legit. Would you query for specific observation codes? What would you query for to get the process started? It is on a screen in front of a human, you see it in a whole block of text and you can read it, but if you do not know what is out there, do you fire off a query for everything?

**Robert Dieterle**

Good question. The things we are focused on in this implementation guide are primarily related to referrals, the referral process, closed-loop referrals in particular, but also to be able to share information that is associated with an individual that has labeled social determinants of health and permitted by the organization or the individual to be exchanged. So, let's talk about the referral process. We have defined basically two referral processes, one that assumes you have a FHIR-enabled organization such as a community-based referral platform. I will just name a couple names for the sake of creating concept: Aunt

Bertha, Unitas, NOFO, 211. It would be one of those platforms that is out there that provides a lot of the referral infrastructure.

So, there is one path that says we know that we work with that referral platform as a provider. The first step in the process for referral is to push a task to that particular referral platform, post it, and have the referral platform come and get the associated service request, associated information, patient resource, goal, et cetera, and then decide whether or not they can perform the request that has been made. If they can, then there is a defined exchange of status related to the task to show where it is. It has been accepted, in process, on hold, or completed. So, this is basically FHIR RESTful peers exchanging information.

There is another process where we assume you do not really have much capability at the other end, so what we are doing is assuming an out-of-band exchange, possibly just using email, that says, "Hi, click on the link here," and then you can authenticate to either the payer or service provider EHR and pull down the information related to what you are being requested to do, but the updates are all made within the context of the FHIR platform, the EHR, the referral organization, or the payer. There is not going to be a lot of capability in a food pantry, for example.

We are going to use the same approach to do something with the individual. We would like to do closed-loop referrals with the person, so we have an app on the smartphone that can say, "Hi," we send them an email saying, "You have been referred," and they can go online and pull down where the referral is, it shows this food pantry, and they can feed back and say, "Yeah, I went there, and I was able to wind up getting food that is ethnically appropriate. We have not had any problems in communication." So, our goal is to closed-loop refer with both the organizations and the individual by the time we get done. It will not all happen right up front, but it is within the plan of the next year or so. Does that make sense?

**David McCallie**
Yeah, I think so. You could imagine a care coordination entity taking responsibility for distributing these tasks and capturing data from the patient or consumer to see what outcome was obtained and so forth.

**Robert Dieterle**
Correct.

**David McCallie**
That makes good sense. Not that you need my advice, but I would make sure that it is easy to get readable information from a screen before you have developed the ability to do point-to-point FHIR with all of the complicated authentication stuff that is not even fully baked yet, much less well implemented. It would be valuable information if you could just read it and a human could say, "I see what I need to do."

**Robert Dieterle**
So, we are developing a reference implementation right now that actually shows a clinical workflow, a payer workflow, and a community-based organization workflow, which is actually a set of UIs that go and instantiate the workflow, and then, behind the scenes, create the FHIR resources and do the exchange. So, we have a way to go and demonstrate how this could work, and it is going to be open-source and available to anyone to either take and extend or just use the reference on how to potentially create their own environment.

**David McCallie**

So, we are closing in on the top of the hour. We can certainly keep going, and if there are more questions you guys think of in the next couple of minutes, get your hands raised, but I want to give you a softball, Bob, which may be the last question, depending on whether anybody else thinks of one. If you could wave your magic wand and make something happen, what would that list look like? You know how the government works. You kind of know how lever arms work and all that. If you could influence a recommendation back to ONC, what would you put in it?

**Robert Dieterle**

The first thing I would do is make sure that the submission we made for USCDI for a social-determinants-of-health class and the associated elements within it were part of USCDI 2.0. My understanding from the task force is that that is being carried forward, but ultimately, it needs to wind up getting into USCDI. I would make sure that the implementation guide gets into the ISA so it can be cited. I would consider, at some point where it is appropriate, **[inaudible] [00:53:16]** the requirement to use this implementation guide for payers and providers to be implemented over some period of time. I think requirements for the community-based organizations would be difficult at best, but at least we could require it around coverage into these that typically wind up having regulation provided to them by ONC, CMS, HHS, et cetera.

**David McCallie**

Good. Good list. You are doing our work for us. Are there other questions from the group? You guys have been unusually quiet. Is that because Arien is not here to stir things up, or is it because Bob just did such an excellent job of covering stuff, or is everybody burnt out from their week? I am looking back through my notes here while you guys think as well.

**Robert Dieterle**

So, David, there is one other thing I would add to this. As a society, we need to define ways that we can have interventions associated with health equity and social need become part of the coverage that individuals have. So, part of what we are doing is working with payers to say if somebody needs food, we have a way to go and have the food pantry compensated for making that available. If they need transportation, we have a way to do the same thing. So, as we start to deal with these social problems that affect health in particular, but probably are broader than just health, we have a way to go and bake that into the fabric we currently have for dealing with covering costs of care delivery.

**David McCallie**

And, CMS obviously is a big player in that opportunity. To see something like that happen, CMS could drive that.

**Robert Dieterle**

And, they could drive that. We are seeing payers that have an interest in it too. The national payers are all very interested in making this happen. The problem is we just do not have the vehicles for it today, and we do not have a way to verify that something has been ordered, delivered, and the patient has been served properly, which is why we are trying to do the closed-loop referrals because we think that will become a big part of the ability for payers to say, "Yup, that got delivered, therefore I am going to pay for it."

**David McCallie**

Okay, excellent. All right, I do not see any other questions, so, Bob, thank you for excellent work and for an excellent presentation about the good work. If we have questions that come up afterwards, I know how to get in touch with you if we need clarification or follow-up, but thank you for joining us. We really appreciate it.

**Robert Dieterle**

You are more than welcome. If you have an urge, come join Gravity. I am always available to answer questions. Thank you, David, for the opportunity.

## Correction to Results from Prioritization Voting & Obtaining Additional Expert Input (00:56:39)

**David McCallie**

Great, thank you. So, let's see what our next slide is. It has a few things to cover as a task force agenda, and if we are lucky, we may finish a little early. Let's go to the next slide. So, as you guys remember, we identified these top-level areas. We do not need to linger on this because you all have seen this slide many times, so let's go to the next one. And, we came up with a simplified scoring mechanism for an initial rating of what we thought was important.

Again, I think all of you who have been on our recent calls know this process that we went through. And, we put that in a spreadsheet, Arien automated it with a few glitches, we figured out the glitches, and the next slide shows our corrected voting priorities, and surprisingly, perhaps, given that there were a couple of mistakes in the formulas, the numbers changed, but the actual rankings did not. So, the ranking is the same as the original spreadsheet, but the numbers are a little closer together. I think that is sort of a testimony to the robustness of the data that we captured. It is not highly sensitive to math errors.

As we went over last week and Arien pointed out, you can see that there are two or three items that got the high priorities, there is a group of about four items in the middle, and then a group of four items that were clearly lower than the others, so none of that has changed. I tried to make a clarification last week that this ranking should be taken as our preliminary cut at this because at the time we voted on these things, we were not up to speed on what all of the content and choices actually meant, so I think we will almost certainly go through a reprioritization after we have learned more and have had some discussion in our future meetings. Any questions about the corrected rankings? The fact that it did not change dramatically makes me a little bit more comfortable. If it had radically swiveled things around, then we would have a bit of a problem, but it did not.

Okay, next slide. For your entertainment and to verify that I am not making it up, these are the old number from the previous meeting. We do not need to dwell on this one, but there they are if you are curious. And, in the next slide, this is where we stand in recruiting expert testimony for the group. We have heard from SANER about the situational awareness category, and obviously, today, we just heard from Project Gravity about health equity. Next week, we are shifted to Friday, so do not forget that, and we have two speakers invited at the moment, George Hripcsak, who is leading the Odyssey work and can talk to us about their project to coordinate FHIR and OMOP, and on the PCORI side, I have asked Russ Waitman from University of Missouri, who is a longstanding implementer of PCORnet, to come join the program with George to talk

about PCORnet and the work that they have been doing at University of Missouri over quite a few years now. So, Russ and George will walk us through two of the current large-scale efforts at extracting EHR data and putting it to these aggregated uses rather than for direct patient care.

And, in the future, we have Paula Braun from CDC scheduled on our April 29th meeting to talk broadly about CDC modernization. We are still working through the other items on the list that are in blue to see if we can find the right person and define an appropriately focused topic, so that is work to be done, but it is under way. Are there questions from the group? We are a little ahead of schedule, but everybody is being pretty quiet today. Any questions about the process and where we are? Mike, I am not hearing any things that are pressing on people. Do we want to do the public comment early? Does it break the rule if we do it early? Is that okay?

**Michael Berry**
Les has his hand up if you want to call on him.

**David McCallie**
Oh, okay. Yes, Les, I did not see you there.

**Leslie Lenert**
Can you hear me?

**David McCallie**
Yeah.

**Leslie Lenert**
Okay, good. I just wanted to mention that I had reached out to the organization of PCORI to try to find the best expert, having been part of PCORnet for seven or eight years now, and I think Russ is a great expert to talk about what PCORnet looks like. Ken Marcelo is the data architect in charge of the development of the data model at the Duke Coordinating Center, and he is willing to come also if you want to do that. I understand if there are time limitations. Next time, I guess I will be more aggressive at making my efforts to help you choose the right person.

**David McCallie**
I appreciate that. I think Arien and I are both feeling kind of pressed because the meeting is not flexible as to when it is, and finding people who have open schedules at the time of our meeting has not always been easy, so we did not wait for you. Let that be a lesson. Speak quickly. You say Ken's focus is on the data modeling details.

**Leslie Lenert**
Well, yeah. He runs the whole network. Basically, there is a whole quality improvement process that comes from taking the data, mapping it to the PCORnet model, assessing it, and advancing the PCORnet networks, the subnets, of which Russ the leader of one, to create this integrated system with 100 million patients in it for research for this. I think the other group you could be talking to is CD2H and bring in Chris Chute to talk about what is going on with that, which is the network that NIH has put together for COVID

response, which has some of its newest technology in there. So, those would be my recommendations to you in this area.

**David McCallie**

Okay, that is great. Would you email me the email address of Ken? My email for Chris is probably out of date, so if you have an up-to-date one for Chris Chute…

**Leslie Lenert**

I will get you both.

**David McCallie**

Okay. I may contact them and see if it makes sense. I do not want to have too crowded a discussion, but I certainly do not want to leave out important perspectives. Are there other questions or reactions? Okay, Mike, can we do the comment ahead of schedule?

## Public Comment (01:05:36)

**Michael Berry**

Sure, and if anyone thinks of anything they want to ask, we can go back to that when we finish public comment. 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 *. One moment while we poll for comments. There are no comments at this time.

**Michael Berry**

Okay, thank you. David?

**David McCallie**

Thanks, Mike, and thank you, operator. Well, everybody likes to get a little bit of time back, and I think we will give you 15-20 minutes of your time back, barring any other questions. Going once, twice…okay. All right, thanks, everyone. Thanks for your questions, and we will see you next week on Friday.

**Michael Berry**

Thank you.

## Adjourn (01:07:04)