HEALTH INFORMATION TECHNOLOGY ADVISORY COMMITTEE (HITAC) INTEROPERABILITY STANDARDS WORKGROUP MEETING

April 26, 2022, 10:30 a.m. – 12:00 p.m. ET

VIRTUAL

Speakers

Name	Organization	Role
Steven Lane	**Sutter Health**	**Co-Chair**
Arien Malec	**Change Healthcare**	**Co-Chair**
Kelly Aldrich	Vanderbilt University School of Nursing	Member
Hans Buitendijk	Cerner	Member
Thomas Cantilina	Department of Defense	Member
Christina Caraballo	HIMSS	Member
Grace Cordovano	Enlightening Results	Member
Steven Eichner	Texas Department of State Health Services	Member
Rajesh Godavarthi	MCG Health, part of the Hearst Health network	Member
Adi Gundlapalli	Centers for Disease Control and Prevention	Member
Jim Jirjis	HCA Healthcare	Member
Kensaku Kawamoto	University of Utah Health	Member
Leslie Lenert	Medical University of South Carolina	Member
Hung S. Luu	Children's Health	Member
David McCallie	Individual	Member
Clem McDonald	National Library of Medicine	Member
Mark Savage	Savage & Savage LLC	Member
Michelle Schreiber	Centers for Medicare and Medicaid Services	Member
Abby Sears	OCHIN	Member
Ram Sriram	National Institute of Standards and Technology	Member
Michael Berry	Office of the National Coordinator for Health Information Technology	Designated Federal Officer
Al Taylor	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Denise Joseph	Office of the National Coordinator for Health Information Technology	ONC Staff Lead
Evelyn Gallego	EMI Advisors LLC	Presenter
Asha Immanuelle	Center for Black Women's Wellness	Presenter
Riki Merrick	Association of Public Health Laboratories	Discussant

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

Michael Berry
And, good morning, everyone, and thank you for joining the Interoperability Standards Workgroup. I am Mike Berry with ONC, and we are glad that you could be with us today, and we also have a few guest presenters, and we are happy that they can be with us as well. Our cochairs will introduce them shortly. As a reminder, your feedback is always welcomed, which can be typed in the chat feature throughout the meeting or can be made verbally during the public comment period that is scheduled from around 11:55 Eastern Time this morning. I am going to begin roll call of our workgroup members, so when I call your name, please indicate that you are here. I will start with our cochairs. Steven Lane?

Steven Lane
Good morning.

Michael Berry
Arien Malec?

Arien Malec
Good morning.

Michael Berry
Kelly Aldrich is not able to be with us today. Hans Buitendijk? Thomas Cantilina or Jeff Ford? Christina Caraballo?

Christina Caraballo
Good morning.

Michael Berry
Grace Cordovano? Steven Eichner?

Steven Eichner
Good morning.

Michael Berry
Sanjeev Tandon?

Sanjeev Tandon
Good morning.

Michael Berry
Raj Godavarthi? Jim Jirjis? Ken Kawamoto? Leslie Lenert? Hung Luu?

Hung S. Luu
Good morning.

Michael Berry
David McCallie?

David McCallie
Good morning.

Michael Berry
Clem McDonald? Mark Savage?

Mark Savage
Good morning.

Michael Berry
Michelle Schreiber? Abby Sears? And, Ram Sriram?

Ram Sriram
Good morning.

Michael Berry
Good morning. And, I see several other workgroup members joining us, and I appreciate that, and I would now like to turn it over to Steven and Arien for their opening remarks.

Co-Chair Remarks (00:02:05)

Steven Lane
Thank you so much, Mike, and thank you, everyone, for joining us this morning. We are very excited to have an updated presentation from representatives of the Gravity Project today talking about their ongoing work to standardize the data surrounding social determinants of health in support of interoperability of that data. You will recall our preceding taskforce did a lot of work in this space in past years and got some initial inclusion of SDOH data elements into the USCDI Version 2. This was not a focus for USCDI Version 3, but we knew that the team at Gravity was going to be doing a lot of work over the course of the intervening year to move forward a number of the domains within the scope of the Gravity Project, and we are excited to hear how that work has gone and to see how, if at all, there may be advancements within the ISA to support that work, presumably in anticipation of future discussion of inclusion in the USCDI.

So, after the Gravity presentation, we will be coming back to the modified lab recommendations that a number of our group has worked on, as we recommended, looking back to the prior recommendations of the taskforce, and to bring those forward, incorporating some of the changes that we discussed at our prior meeting. And then, as Mike said, we are going to have public comment before we close out before noon. As always, members of the public are invited to participate in the public chat, as well as to take the mic if they have something they would like to share verbally toward the end of the meeting. So, with that, Arien?

Arien Malec
Thank you. I just want to first of all be very thankful of the panelists for their flexibility. Scheduling sometimes is more entertaining than it deserves to be. Secondly, I just want to call out a number of folks who have been doing work in the spreadsheet, and I wanted to make the distinction again between the prioritization

framework that we are using, which is really about prioritizing where we are going to go deep, and provide recommendations in a particular topic area that require panel sessions and require significant thought through various policy levers, and where we can make recommendations to include or track a use case in the ISA or include or track a standard or implementation specification in the ISA.

David McCallie, for example, has been doing fantastic work in surveying the landscape and putting in topic areas, so I know a number of taskforce members have already done this, but I just want to encourage you to go into the spreadsheet. If there is a topic that is worthwhile making sure that we can make a recommendation on, I think it will be relatively simple to make recommendations on the order of "We recommend that the ISA track Use Case X and recommend that the ISA track Standard Implementation Guidance Y." So, with that, let's dive into the Gravity Project presentations. Mark, why don't we lean on you as our lead-off just to set up this panel session?

Gravity Project Presentation (00:05:58)

Mark Savage

Perfect. So, we are so fortunate today to have presentations from Evelyn Gallego, who is CEO of EMI Advisors and Senior Advisor at the Gravity Project, and Asha Immanuelle, Maternal Health Equity Program Manager at the Center for Black Women's Wellness and Population Health Advisor and Community Liaison for the Gravity Project. Ms. Gallego will present recommendations on adding the Gravity Project SDOH standards to the Interoperability Standards Advisory, and Ms. Immanuelle will summarize a high-priority use case, maternal health equity, to illustrate how those standards and ISA use cases can advance health equity, which is definitely a priority for all of us.

Just a brief introduction of both them, and then I will turn it over to them. Evelyn, as I said, is the CEO of EMI Advisors, which she founded in order to deliver value-driven health data management advisory services to her government and commercial clients. Many of you on this call probably know her work and leadership well. She provides specialized expertise in digital health interoperability and health and human services policy, with a focus on alignment of regulatory, technical, and process improvement requirements. She leads and leans in especially in the areas of care coordination, social determinants of health, health IT policy, analysis, and development, health information exchange, interoperability, and health IT standards development, and is the project manager and subject matter expert for a number of governmental clients, including HHS's Administration for Community Living, NIH, and CDC, among so many other things, but we are so fortunate to have her today.

And, Asha Immanuelle serves as the Maternal Health Equity Program Manager at the Center for Black Women's Wellness in Atlanta, Georgia, which has a 30-year legacy of protecting and promoting the health of individuals in communities, focusing on Black women and families, especially those who are underserved. She is a community-based, participatory researcher, a birth equity advocate, and a community clinical integration champion. Fortunately for all of us, she believes there is no reason to accept the current status quo in maternal and infant health outcomes in our nation.

She is doing a lot of leadership to try to improve that. Besides her leadership at the Center for Black Women's Wellness, she also serves on the Georgia Maternal Mortality Review Committee and the ECHO Core team, organized for the Georgia Department of Health to improve maternal health outcomes within the state, as well as the National Diversity, Equity, and Inclusion Committee of the Association of Women's

Health, Obstetric, and Neonatal Nurses. And, as I said before, she is the Population Health Advisor and Community Liaison on the Terminology Team at the Gravity Project. Like Evelyn, Asha is among so many other areas of health expertise and experience. We are grateful to both of you. Thank you so much. I turn it over to you, Evelyn, and I understand that the two of you will be tag-teaming over the course of the presentation.

Evelyn Gallego
Yes. Thank you so much, Mark. Can you hear me?

Mark Savage
Yes.

Evelyn Gallego
Okay, perfect. Well, good morning, first of all, and thank you to Mark and the Interoperability Standards Workgroup for the invitation today to provide an update on the Gravity Project and our thoughts on next steps beyond USCDI Version 2. I am delighted to be joined by Asha, who will speak to what I like to say how the Gravity standards can be applied now to maternal health equity, and of course, we all appreciate the intersection between social determinants of health data, health equity data, and maternal health. Move on to the next slide.

So, here is our quick agenda for today. I will recap the Gravity Project activities and approach, and then hand over to Asha to speak to the practicality and the use of the standards for maternal health. I will then take it back and present on our collective Gravity Project team recommendations for the ISA. I do want to thank our project team across terminology, technical, and policy, where, of course, Mark plays a key role as our SDOH policy advisor, and they have done tremendous work and due diligence to help us come up with these recommendations to present today. Next slide.

All right. So, before I jump in, I want to ground us on definitions. Beginning with the SDOH lexicon that builds on the global definition for SDOH, to recap for everyone, what we mean by SDOH is the conditions in which people are born, grow, live, work, and age, which are shaped by the distribution of money, power, and resources. SDOH can offer both positive and negative forces. Positive forces are defined as protective factors and negative forces as social risks. What do we mean by protective factors? You will hear us talk through this in some of our upcoming presentations in how we work with our Public Collaborative and Governance Committee.

Protective factors, as defined by the Center for the Study of Social Policy, with a reference there at the bottom, are defined as the characteristics of strengths of individuals, families, communities, or societies that act to mitigate risks and promote positive wellbeing and healthy development. When we talk about social determinants of health, we also differentiate between social risks, which are the adverse social conditions associated with poor health, and social needs, patient-prioritized social risks. This is important as we define the data concepts because as we go through, and I will walk you through the social conceptual framework, we talk about capturing data that is social risk data and then capturing the data as a social need. Next slide.

So, again, for those who are not familiar with the Gravity Project, I will recap the overall scope of our work. So, foremost, we work collaboratively to develop data standards to represent and exchange patient- or individual-level SDOH data documented across the four clinical activities of screening, assessment, diagnosis, goal-setting, treatment, and interventions. Second, we test and validate this data for use not only in patient care, but also to support care coordination between health and human services sectors, population health management, public health, value-based payment, and clinical research. Since we initiated in May of 2019, we have defined coded data concepts for 14 SDOH domains. You see them there on the right-hand side. I will speak more to these in the coming slides. Just as a reminder, these domains are grounded by the domains reference in the National Academy of Science and Engineering in Medicine, or NASEM, 2014 report on capturing social and behavioral domains in electronic health records. Our new domains are also being informed by the domains referenced in Healthy People 2030. Next slide.

So, we use this conceptual framework to illustrate the capture or documentation of SDOH data across those four activities I mentioned of screening, diagnosis, goal-setting, and interventions. For each activity, there are specific code sets used to represent the data. Again, I will walk through this in the forthcoming slide with this code set. What is important here is the visual illustrates how these three overarching use cases support the data around those four activities. Our first use case is gathering this data in conjunction with a patient encounter. This is within a clinical setting; it is also acknowledging that our work initiated with the integration of social care and clinical care, so our use cases are grounded by that in our current FHIR implementation guide.

So, that first activity incorporates that data collection, but as we talk about standards, it is also the ability to exchange that data that is captured as part of that patient encounter. The second use case is documenting and tracking the SDOH-related interventions to completion. This includes the referrals or the closed-loop referral, the ability to document once the individual or patient acknowledges they have a social need they would like the health system to work with them on or identify treatment or interventions for. Use Case 2 really speaks to those transactions needed for data exchange. And then, our last use cases is the ability to gather and aggregate this data for uses beyond point of care.

So, our current FHIR ID stops at just the ability to document individual-level data, but when we talk about other uses, we talk about upstream uses, for example, population health, public health, research, and downstream activities that conclude quality reporting. So, it helps bring it through together, but again, our work is grounded with the ability to capture this data or use it initially within a clinical setting of exchange outside of a clinical setting. Next slide.

We do all our work by convening a very large public collaborative. We stopped counting, but it is over 2,000 participants from across the health and human services ecosystem. What is important is that this not only includes the clinical providers, the certified technologies, or the platform vendors, it includes person and patient advocates, community-based organizations, many that continue to join us and have never even heard of HL7 or coded terminology, but they wanted to be part of our process. It includes standard development organizations, federal/state governments, and payers.

Our ability to engage and collaborate with these diverse stakeholder groups, which I think is important, is what truly sets us apart as a standards-based project. We are recognized for our open, consensus-based approach, something that our current federal partners recognize, as it is important to replicate in other
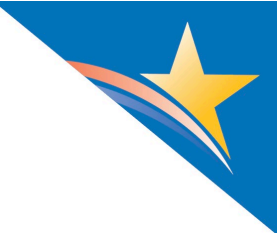
standards-based projects or multi-stakeholder engagements. And, of course, we meet every other Thursday from 4:00 to 5:30 p.m. Everyone is welcome to join. You do not have to be a specific HL7 member. Next slide.

Okay, so, I assume some of you, if not all of you, have already seen this video that walks through our current list of domains and coded terminologies, respective activities, and SDOH FHIR implementation guide. The text you see in black is what has already been incorporated in USCDI Version 2. You see the specific code systems. So, I talked about the coded terminologies, reference for the activities. These are all listed in the far-right column. So, you see LOINC, SNOMED CT, ICD-10, CPT, HCPCS. Again, these are very specific to activities or data elements. Then, the next column, as I move from right to left, you see in black the 14 domains we have completed to date. What you see in blue, then, are the new ones that we have proposed to work on. Some are already in our pipeline for this year: So, health literacy, health insurance coverage status, and medical cost burden are what we are working on right now. What we propose for the fall and beyond are those you see listed there, including digital and equity, neighborhood food access, and neighborhood safety.

So, as we move on to the next column, these are the activities in black. The blue ones are new ones. Again, these are ones where we have been thinking through and recommend that we work on next. So, I will start with the ones with the asterisk because these still have to be approved, but we want to look at outcomes, data aggregation, accounting for care, and health insurance. Consent does not have an asterisk because there is ongoing work. I think you all can recognize there are many activities, many initiatives that cross around consent management. We want to be part of that, but we have to acknowledge we have some work within our IG, but there are broader national initiatives. And then, we move on to our IG and use cases. So, we currently only have one FHIR implementation guide, which I will talk through, published as a standard for trial use Version 1, and we are working on Version 2, and clinical care focus based on that conceptual framework.

What we are looking at as next steps are what you see in blue. So, we have been looking at a social care use case. This is really where we are looking at data exchange outside of the clinical setting. We are asked by our community often what we are doing to define how data is exchanged between one community-based organization and another community-based organization. We also have lots of discussions along quality measurement, so, looking at a proposing of quality measurement use case. Then, we have a population health IG as well as a research IG. Again, these have not been started. And then, we do have a public health use case that we have started with sponsorship from the CDC that we kicked off last week, so that one is no longer under consideration, but it is in active works, but we just started, so therefore, it is in blue.

So, what I will emphasize here again is what you see in blue are things that we have proposed or we have been thinking through, but we have not yet started. The Gravity Project is a project, and so, we are governed by an executive committee that reviews all our activities and approves them, and with funding available, then we act on. So, I do want to emphasize that these are things that we have proposed to our executive committee. They have not been approved, but they are things we think very much fall under our scope of work and could be future activities for us and for consideration for Version 3. Next slide.

And, for those who have not seen our visual of transactions for our FHIR Implementation Guide Version 2, our STU2, this is currently in ballot reconciliation. We have balloted through the HL7 process. Our target

has been to have a publication date for June of this year, but what we would like to highlight here is the STU2 incorporates data transactions between FHIR endpoints that exist, so those are the blue lines here, but what is nice about it is that it incorporates data transactions with non-FHIR endpoints that include smartphone/web-based apps. A community-based organization may not be connected or have another way to receive the data, so we want to incorporate all the different ways. We always say we want to meet entities where they are at from a data exchange perspective, and so, the FHIR IG incorporates that they may not be using certified technology or be connected to an HIE, but there is a way to be able to connect to them using smartphone technology or web-based platforms. Next slide.

And, I think some of you have seen this. What I want to walk through here is as we talk about use cases, this slide really emphasizes the unique way both USCDI and the SDOH data conserve the myriad needs simultaneously. They are really cross-cutting and can be incorporated across various areas, both SDOH and USCDI, so we talk about patient access, value-based care, shared care planning, PDHD, COVID-19, of course, precision medicine, and research. So, again, thinking through of them hand in hand that they are cross cutting and can support multiple use cases. Next slide.

So, we will just do a preliminary summary of what is in ISA now. So, when we talk about SDOH, we know this is what exists right now. ISA has two components. Under vocabulary code set terminology, there is social, psychological, and behavioral data, and it represents several domains that we have already worked on. We also have an area under specialty care and settings that has, again, reference to social determinants of health under vocabulary and content structures. So, this is what exists right now. Next slide.

So, what is missing? And, I will speak more of this in the coming slides, but just to initially point out that of course, what is missing first are the domains. We have completed 14 domains since the initial inclusion, so there is an opportunity to address those missing domains there. There are also the value sets for the Gravity domains. There is missing specification around the core screening tools as well as what is in VSAC. So, this is really important. As of this last week, we have 100 value sets for Gravity, Gravity being the steward under the Value Set Authority Standard. These are only for diagnosis, goals, and intervention, but they can be used now, and they are missing from ISA. Also, under services and exchange, there is no reference to our current implementation guides, both Version 1 and Version 2, as well as our reference implementation. So, with that, if we move on to the next slide, I am happy to hand over to Asha to do a deeper dive on the applicability to maternal health equity. Asha?

Asha Immanuelle

Wonderful. Thank you, Evelyn, and thank you, Mark, for a warm introduction, and I am excited to be here today to talk about all the ways that I think the Gravity standards could be applied to the maternal health population. Next slide, please. So, going back just a bit, I am a community health nurse specialist who is passionate about advancing maternal health equity in my own community and beyond. And, a couple of weeks ago, we celebrated Black Maternal Health Week. The Center for Black Women's Wellness is a kindred partner for BMMA. And, this year marked the fifth anniversary of the Black Maternal Health Week campaign. It was founded by BMMA, and it is a week of awareness, activism, and community-building intended to deepen the national conversation about Black maternal health in the United States as well as to amplify community-driven research and care solutions.

So, last year, the White House officially recognized April 11th through 17th as Black Maternal Health Week, and I say all that to say this: We are in a maternal health crisis. This country is in a maternal health crisis because a woman giving birth today is 50% more likely to die of childbirth-related causes than her own mother, and Black mothers are bearing the brunt of that crisis because we are three to four times more likely than our white counterparts, regardless of income and education level, to experience a perinatal death related to childbirth. In fact, a Black woman with a graduate degree is more likely than a white woman with less than a high school education to die.

And so, we know that a part of the problem is bias, racism, and discrimination. There is no other course for that. And, I can tell you my own personal experiences. I have been a perinatal nurse since the mid-'90s, and I have been the object of racism and discrimination, but I have also witness and observed countless instances of bias and discrimination from my Black patients that went on to cause harm, either through a care delay or a care denial. So, I want to be frank about where I am coming from and tie it back to the title. What maternal health equity problems can SDOH data solve? They can solve us getting to the underlying drivers of maternal health equity and to begin to talk more about the transformational impact of applying the Gravity standards to the maternal population. In my estimation, it would lead to better care, lower costs over time, and increased quality. Next slide, please.

So, just to give you some background about the Center for Black Women's Wellness, we are a premier community-based organization with a mission to improve the health and wellbeing of underserved Black women and their families. We have been around for 33 years, and we commit ourselves to accessible, free, and low-cost healthcare, to home visitation to improve health outcomes for mothers and babies in Atlanta through our Atlanta Healthy Start initiative, and also to build financial literacy and microbusiness training to improve women's economic self-sufficiency.

So, we believe that with these three levels of programming, these really are the keys to health, and in the maternal health equity program, there are three main categories in our portfolio for maternal health equity. The first is community-based participatory research. We are always attempting to amplify the voices of those with lived experience into the continuous quality improvement effort, policy and advocacy training, because we want to increase civic engagement and elevate community voices to decision makers, and then, finally, the AIM CCI effort, which I am going to share more with you about that in future slides, but essentially, AIM CCI is a community-oriented approach to standardize perinatal care and care services in a community. Next slide, please.

So, I talked a little bit about the research that we do at the Center for Black Women's Wellness. IHI came to Atlanta and worked with us for several years in a birth equity lab, and it was called Better Maternal Outcomes, and the goal here really was to strategically influence leadership within the care delivery system to develop a better understanding of and a deeper commitment to addressing systemic racism as a root cause of morbidity and mortality for Black mothers in Georgia.

And so, we found that there are three main drivers to improve maternal health, and those are supporting women across siloes, having more peer support for systems, but also more seamless patient handoffs between clinical and community resources. This is the notion of community clinical integration. Also, respectful care and shred leadership. Next slide, please.

So, it is always good to level-set so we all have a mental model of how deep the crisis is. This is a fact sheet from the Georgia Department of Public Health, which Mark mentioned that I serve on the Georgia Maternal Mortality Review Committee in my state, and there are three takeaways that I want you to see on this document. These numbers are between 2015 and 2017, but the one that jumps out to me and wakes me up in the middle of the night is this fact, that 87% of pregnancy-related deaths are preventable. Eighty-seven percent. Some of the leading causes of pregnancy-related death are cardiovascular, cardiomyopathy, hemorrhage, infection, cerebral vascular accidents, and also, Black women in my state are two to three times more likely to die than white mothers.

The other thing I want you to take note of is the timing of these deaths. It is very hard to see in the middle there, but only about 19% of the deaths occurred either during pregnancy or birth. The balance occurred in the postpartum period. So, this is the opportunity to really impact our maternal health crisis, to standardize how we care for that population, and we will talk more about that coming up. Next slide. Just one more compelling piece of data that I want you to see, because this illustrates why this work is necessary. So, this is the maternal mortality rate in the United States compared with the maternal mortality rate in other countries, and what you see here in the richest nation in the developed world are rates that, if you compared with other countries, would be embarrassing.

For instance, in my state of Georgia, our maternal mortality rate is on par with that of Syria. Syria. Syria, that has been in a civil war for 10 years. So, about two women die in childbirth-related deaths every day. That is about 700 souls that impact 700 communities. But, there are about 50,000 women every year who suffer severe complications or life-threatening injuries. We call those the near misses, and this slide just really illustrates the crisis that we are in. Next slide, please.

So, I wanted to have a discussion on how health affects everything else, how the social determinants of health connect to health equity. So, health equity means that everyone has a fair and just opportunity to be as healthy as possible, and so, the social determinants of health, such as poverty, unequal access to healthcare, and housing instability all contribute to health inequalities. So, to achieve health equity, we need to eliminate health disparities and address the social determinants of health. So, the path to achieving health equity looks like this. There are social and economic factors that really have to be addressed, and the one I want to start with on the top is the discrimination and minority stressors. We know that chronic exposures to discrimination and minority stressors can lead to increased cortisol levels, which have all sorts of health implications.

Food security and access to healthy foods are critical to being healthy. Stable income and job security and environmental quality. I live in a historically Black neighborhood. In my neighborhood, we cannot grow food in the ground. The ground is contaminated, so we have to have raised beds in there. Neighborhood conditions: How walkable is your neighborhood? Is it safe to walk in the neighborhood? Are there any green spaces available for you to look at on your walk? Obviously, quality, affordable healthcare is critical, educational opportunities are critical, and housing. Housing is healthcare. If you are unhoused, your priority is not going to be managing your blood pressure. So, it is all of these that affect health, and health equity aims to ensure that all people have a full and equal access to opportunities to be their best selves. Next slide, please.

So, here come the solutions! So, AIM CCI stands for the Alliance for Innovation on Maternal Health Community Care, and this is a National Healthy Start grantee with a five-year cooperative agreement with HRSA, and the goal of this program is to address preventable maternal mortality and severe maternal morbidity among pregnant and postpartum women outside of hospital and birthing facility settings. So, this is a community-oriented model of care. And, there are about six pilot sites across the country, and their role is to complete a test of feasibility on community-oriented post-partum interventions, a few of which I am going to show you momentarily, and to also convene a local maternity safety workgroup to guide program activities with an equity lens.

And, I want to pause right here just to explain to you what I mean by it. So, the equity framework is used to inculcate equity into the continuous quality improvement journey, to discover and address the systemic structural and racial inequities that are at the root cause of negative maternal health outcomes for Black women. So, this is the work that we are doing, and I would say that there are a few elements that I want to share with you about what it is that we do. So, some of the hallmarks of it are we have non-hospital-focused maternal safety bundles or interventions, we have the maternal safety workgroup, and we do a lot of quality improvement, and really, this effort is about advancing community clinical integration by connecting, coordinating, and collaborating centered around the birthing person. We are moving towards whole-person care. Next slide, please.

So, I am not going to spend a whole lot of time on this slide because it is confusing, but this is the AIM CCI approach to stakeholder management. So, this theoretical model really helps to emphasize everyone that is on the team because this is a community-wide effort, and what you will see here down in this middle circle, if you can see my thing moving, is the maternal safety bundle. That is just the intervention, and we want to use partners such as outpatient providers, Early Head Start, WIC, Healthy Start, community healthcare organizations, and other FQHCs, and we have left this one open because essentially, we want anyone who has frequent touchpoints with pregnant and postpartum people, and we would like for them to begin to implement these maternal safety bundles in their location. So, that is what I will say about that, and of course, equity is embedded all throughout the effort here. Next slide.

Okay, so, let's jump into a few of the use cases and the ways I think we can apply the Gravity standards right now. So, we want to document chronic stress and/or weathering assessment for Black birthing people, and the goal here is to predict and intervene in preterm birth risk factors for Black birthing people because we are 50% more likely than women of other races to experience preterm labor. So, the intervention from the AIM CCI effort is here in the star, and it says, "To develop and implement a risk assessment strategy inclusive of stress and its connections to birthing persons' experiences of racism and sexism." And so, essentially, this would be another domain that the Gravity Project would take on, and just a few of the screeners that have been developed, that have been validated for use in documenting chronic stress are things like the JHP contextualized stress measure, the PREM-OB, which is the Patient-Reported Experience Measure of Obstetric Racism, and then, of course, ACES. Next slide, please.

So, this next use case is about documenting and tracking SDOH-related interventions to completion. I think I shared initially that the main drivers of poor perinatal health outcomes are social determinants of health, so we want to ensure a closed-loop referral process for nonclinical health-related social needs. I cannot tell you how many times I have handed a paper referral to someone, not knowing that when the person goes to the other community-based organization to get that information, sometimes the organization was out,

and so, the need still went unmet. So, ensuring that we have a closed-loop referral system with visibility into the lifecycle of the referral is transformational for this population.

So, the AIM CCI intervention is this: "To implement systemic processes to assist women and birthing persons in completing timely referral and follow-up for all identified medical behavioral health, reproductive health, and social determinants by working collaboratively with community partners." This getting to a point of holistic care. And then, the other AIM CCI intervention is this: "To implement communication pathways between inpatient, outpatient, and community-based providers to facilitate and ensure continuity of care." And, what this does is it enhances how essential health-related social needs are identified in community. It also ensures residents are connected to vital resources that meet basic need with confidentiality and safety protocols in place. And then, finally, it fosters partnerships across the service spectrum to enhance access to services and begins to build those cross-sector partnerships. Next slide, please.

Okay. So, to gather and aggregate SDOH data for uses beyond the point of care. And here, we want to identify and reduce birth disparities by using SDOH data to detect inequities across systems, and remember all of those systems that I pointed out when we talked about achieving health equity. And, the AIM CCI interventions are this: "To assess current systems for unequal treatment and its impact, to stratify maternal health outcomes data by race and ethnicity, and connect with SDOH data." And, this is what I am really, really excited about as a population health practitioner because what it will do is promote community awareness, build population health accountability, and also mitigate those social and environmental risks that can cause up to 80% of a health outcome.

So, that concludes my presentation, but I hope you have a sense now of how the Gravity standards could be applied to the maternal population and really begin to improve outcomes. I will also just say one last plug. I have worked in a variety of care settings with data siloes, information siloes, and all of those, and I am tired of faxing this sort of information. In 2022, we should not be faxing documents anymore, and so, that was my final plug here. I will give it to you, Evelyn. Thank you.

Evelyn Gallego
Thank you so much, Asha, and that is incredible. Every time I hear you speak, it is just overwhelming, and the message here is that this is preventable, we have the technology, we have the standards, we have the wealth, and here is the opportunity. We can move forward collectively as a nation. So, I am going to move forward with recommendations. Move on to the next slide. So, again, to recap where I left off, acknowledging what is in the current ISA under the vocabulary code set terminology component, we have limited domains, incomplete value sets, and restrictive scope statements. So, our recommendation as Gravity Project is to revisit this and update with the completed Gravity domains and the Gravity domain-level assessment tools, as well as the value sets as published in VSAC specific for diagnosis, goals, and interventions. We also want to amend limitations, dependencies, and preconditions, so those are a recommendation for this component. Next slide.

Under services and exchange, we recommend referencing both our standard for trial use Version 1 of our IG as well as the current one, STU2, that should be published this summer. We also recommend adding the reference implementation. So, we currently have a reference implementation both for STU1, and it is being updated for STU2. That is available and can be referenced in this section. Next slide.

Okay, so, let's talk about race and ethnicity standards that are very important for all our discussions. Move on to the next slide. So, I will start by acknowledging that the current 2015 edition as well as ISA requires a list that both CDC and OMB value sets for race and ethnicity be used. The federal standards prioritize self-reported values, as listed here in the comment. However, the current state is that most or major electronic health record platforms do not exchange the source or method of collection of race and ethnicity data, so therefore the value may not be a patient self-reported race and ethnicity, as is best practice and as federal standards prioritize. So, as a result, the Gravity Project is testing the exchange of source and method of collecting race and ethnicity values as a draft specification in our current SDOH clinical care IG Version 2, STU2. Go on to the next slide.

So therefore, our recommendation is to build on what we are working on right now, so, under the vocabulary code sets terminology section in ISA, under race and ethnicity, you have CDC and OMB value sets. We recommend that you add to this section "Amend limitations, dependencies, and preconditions to include recommendations for source and method of collecting value for race and source and method of collective value for ethnicity." We do want to note, as here in the last bullet, this recommendation could have equal merit for other self-reported personal characteristics, such as gender identity, sexual orientation, and personal pronouns. Move on to the next slide. I think that leaves it. Okay, so, we will pause. I think we are a little early, but we will open it up for questions.

Steven Lane

Well, thank you so much, Evelyn and Asha. That was a marvelous presentation. You were both broad and deep, which is ideal for a group like this. I invite people to raise their hands so that we can take questions as they come in. I had a question early on, Evelyn. In one of your early slides, you were talking about your model and the identification of goals, and you identified that they were self-identified or self-prioritized goals, and I was just curious as to whether that was an absolute, whether others could identify a goal for an individual or whether it was always based on the individual's self-prioritization of that goal.

Evelyn Gallego

Oh no, thank you, Steve, absolutely. It includes both patient- or person-identified goals and provider-identified goals. So, building off the HL7 FHIR goal resource, it has the opportunity to incorporate both.

Steven Lane

Very good. And, I really, really appreciated the way you were just very crisp with the specific recommendations for how the ISA could be advanced to support this. A lot of those recommendations are very much in line with recommendations that we have already sent up to ONC related to USCDI in our first phase of work, so I think that alignment is excellent. Hans, your hand is up.

Hans Buitendijk

That is correct. Thank you, Steven, and thank you for the presentation. It was very helpful in trying to focus a little bit on the ISA part of the recommendations, where in the services exchange, you are providing direction of services and exchange, and in the discussion, it was also further emphasized that that opportunity to have referrals not on paper or fax would be quite helpful. In that space, though, there is currently the BSeR guide, and there is the SDOH guide. Both are attempting to address referrals, but not exactly the same.

So, from your perspective, what kind of efforts are ongoing and what could be represented in the ISA to get a better understanding of when to use one or the other, or whether we should really align them and have a recommendation that work is being progressed to achieve that alignment so we have a consistent way across social services/community services as well, perhaps others, but particularly in that space, where BSeR and SDOH have been looking at to have a consistent common approach? Unless there are good reasons that they need to be different, and that would be great, then, to understand as well. Any thoughts on that? And, I have a second question after that.

Evelyn Gallego
Sure, yes. We get asked that a lot, Hans. I want to acknowledge that the FHIR IG is built off BSeR. It initially looks at the transactions and how you acknowledge the referral types of referral responses. It also looks at IHE. I see Holly has also the 360 work, so it builds off existing standards. So, how we differentiate them is really looking at the use cases themselves. So, when we looked at BSeR, again, this is where I rely on our technical team that has been really clear that the constraints specified in the BSeR FHIR IG are very specific to the public health use cases, which is distinct, and ours is clinically care-focused and broader. So, we have worked closely with the CDC BSeR team, and of course, the CDC is also sponsoring the public health use case that we just kicked off last week. They are also part of the BSeR team. So, we definitely want to do alignment.

When we think of IHE 360, again, this acknowledges that we always talk about the analogy between the different roads. We really have been working closely with the IHE team to look at how our coded terminology… When we talk about Gravity, we have the coded terminology work that works in parallel with our terminology workstream, which has been working on the FHIR specification, so the coded terminologies can be used in other content standards, like C-CDA. They can also be exchanged using the direct protocol. So, we want to acknowledge that there are different standards we can use the same way to move data or expose data, but build off each other as well.

So, definitely, I do think the community on the whole… We have had presentations with both the BSeR team and the IHE team to acknowledge that there are specific us cases we are working on, but definitely, I think overall, what I would always emphasize is we do need more testing, and we need to ask when it is best to use one or the other or if we can set up a glide path for the nation so you use this when you are working on this specific use case or you have this existing data infrastructure you are working across.

Hans Buitendijk
I appreciate that because the source or the initiation of these referrals typically start to happen in the same place. From that perspective, whoever interacts, but particularly whoever initiates, we potentially have to deal with two or three different variants. Depending on where you are trying to go or what you are trying to do, it might just complicate things, so it would be great to have some focus on that. The second question, if I may, Steven and Arien, is related to SDOH and FHIR US CORE. What we are finding with USCDI, too, is that in order to be able to progress some of the standards under certification, the content of the guide has to be copied, adjusted, moved, etc. into FHIR US CORE. Any thoughts on how that process can be streamlined so that the work that is done in these individual, more focused implementation guides need not have to be copied as much, and therefore create additional variations? Any insight from your experience on how we had to support USCDI Version 2 and the standards that we used to get that in play? Any thoughts there?

Evelyn Gallego

Sure. So, ONC has funded pilots, so we have pilot sites that have been identified to test the FHIR IG, and part of it is how they align, so we will work very closely with the US CORE team as well in ensuring there is alignment and reference, so we actually have created, I would say, a requirements traceability matrix for those that are implementing the Gravity FHIR IG, how it aligns with US CORE, how they implement the US CORE requirements, as well as those that are distinct within the FHIR IG because we align very much, but there are some areas that are specific for our SDOH work, and we have a traceability matrix that we have developed with funding from IHE to support the implementation.

Hans Buitendijk

Thank you.

Steven Lane

Thanks, Evelyn. David, your hand is up next.

David McCallie

Yes, thanks, and thank you, both presenters, for the breadth and depth that Steven mentioned before. That was an impressive run-through of the problem. I think my question got a little bit asked and answered in Hans's interchange with you, but I will say it again or say it slightly differently. When I was looking at one of your early slides, Evelyn, of the data flows, it struck me that you have a bunch of point-to-point exchanges, but you also had what I think you called a coordinating entity or something like that that looked like it could centralize the exchange.

I have a couple of reactions to that. One is although I am a big believer in FHIR and the value of structured APIs, when you are talking about point-to-point interchange, there is a lot that can be done to replace the facts by using direct, and I would hate to see the perfect be the enemy of good enough, where the attempt to build point-to-point FHIR interchanges, which is challenging given the lack of endpoint directories and the lack of workflow tools to address inbound messages that show up unsolicited on your FHIR API that you do not lose sight of the fact that direct can accomplish much of the interchange of structured data. So, that is Comment No. 1, just an observation, and I think you addressed it a little bit in your response to Hans.

The second is a more subtle concern, which is that I wonder if a focus on these point-to-point interchanges and maybe standalone coordinating entities could have the undesired consequence of actually separating the social determinants data from the rest of the health data. So, if you want social determinants data to be a part of the health record of the patient, you should couple it to the interchange-of-health record data, I would argue, rather than create separate pathways and new pathways because I think you will run the risk of isolating the data even more. Anyway, I will stop there.

Evelyn Gallego

Sure, I am happy to answer. I will start with the first one to acknowledge yes, absolutely. Even in our piloted approaches, we have a tiered approach where we are saying we meet everyone where they are at, they are going to have different ways to exchange the data, and like we always say, even though we have Teslas or electric cars on the market, it does not mean people are going to stop using engines, so it is just acknowledging the infrastructure overall.

To the second point, part of this is to incorporate the data in the person's electronic health record, so that is what the FHIR IG does. It becomes part of their overall record. The screening data is added, the diagnoses, the goals that then can inform the overall care plan that is exchanged across different entities, so our current use case in the FHIR IG is for the integration within social care, but as we look beyond, as we look at the new use cases, particularly the ones where you are going to have data, and correct me if I am wrong, if you are interpreting if we are going to create a use case where there is community-based-organization-to-community-based-organization data exchange, how do we incorporate that or align it to the overall record?

I know that is a bigger scope for us, but it is just like when you have information about a person everywhere, and I have heard Judy Faulkner talk about a person record that incorporates not only clinical data, but other data about the individual. We are not there yet, but I think this is something where as we look at creating data standards, eventually, we get to a point where we truly have whole-person information that encompasses not only health-related data, but social services data that may never touch the health system or be incorporated, but may be of interest to the overall care team.

David McCallie

Thanks. So, I think you understand the concern I was raising, and I have just been thinking about it more in listening to your answer. The success or failure of information flow usually depends more on the workflow at the endpoint than it does on the interchange between the endpoints. Electronic health records, for better or worse, accommodate fairly complicated and hard-won workflows in a given institutions. I would be leery of creating new workflows by defining new flows that do not fit into the current workflows because the chance of success just goes down the more new workflows you have to depend on above and beyond your API endpoint conversations.

So, some of this data obviously is connected to the health record, but when it is processed, it does not actually need to be tied so tightly that the health data is exposed to people who do not need to see what I will call the clinical data distinction from the health data. On the other hand, you do not want to completely cleave those workflows because then your clinicians will not actually be seeing the social determinants data because they come in through some different channel. Anyway, maybe it is a theoretical concern only, but thanks for your reply.

Evelyn Gallego

Absolutely, you are on point, David, and I think this is the conundrum within the Gravity Project. You can develop the data standards, but more work definitely needs to happen on workflow. This is really a new way of incorporating and using data, so, again, these are recommendations we have also given our overall federal partners as well, that there is an opportunity to better define this in the field, and the standards are really what we say is the floor, but we need more work on workflow.

David McCallie
Thank you.

Evelyn Gallego
Thank you.

Steven Lane

Arien?

Arien Malec

Hey! So, maybe two questions. I think we already have a callout for Holly to clarify 360X versus BSeR. I think I have maybe the same comment as David, that ideally, the EHR workflow would be one of a referral, and sometimes we refer for specialist care, sometimes we refer for social services, but it would be useful to have the concept in ways that do not have a hard conflict between different types of referrals, and again, I am just going down all the threads and trying to figure out where 360X plays versus BSeR plays. I get confused, so it would be useful, maybe for Hans, or for Holly later on, or for Evelyn to maybe help us make some recommendations relative to consolidating and aligning the underlying operational workflows, of which the more specific SDOH referrals for maternal services can be seen as a part.

And then, a question on race and ethnicity. I think this was already part of our charge. I need to retrack back where we are slotting this in our overall agenda and where this showed up in our overall prioritization, but the current state is that the CDC code set is the underlying code set, but only the OMB 5 codes for race and two codes for ethnicity are required for collection. I think we are contemplating the use of a slightly expanded subset of the CDC list because the CDC list itself is incredibly comprehensive, but a little overwhelming, so I wonder whether you have recommendations or can point us to recommendations for better subsets that better reflect the lived experience of individuals, but are not so overwhelming as the full CDC code set.

Steven Eichner

Arien, this is Steven Eichner. A friendly amendment: Also in the context of public health reporting so that we are looking at consistency between the clinical use of race/ethnicity data and public health use.

Arien Malec

No doubt. I am constantly reminded that at least in the Bay Area, and I am sure this experience was the same nationally, when we had increases in case counts, those increases very consistently followed social determinants and geolocation, and were tied to specific groups that had specific needs, where the broad-scale lumping that we do administratively just was not helping us in being able to track the spread. So, a lot of questions at you, but No. 1, I really welcome your thoughts in terms of streamlining the notion of a referral, and in particular, helping us triangulate between 360X, BSeR, and the Gravity implementation guides, and, second question, on appropriate code set subsets on race and ethnicity coding.

Evelyn Gallego

Thank you, Arien. So, I will just highlight again that we do work closely with the BSeR and the IHE team. In several discussions, I think the need to communicate has come up. We have had initial brainstorming on how best to do that, so I think that could be a recommendation, that all of us have limited resources, so we work within our specific swim lanes, but know there is a need to better communicate this. So, it is definitely an opportunity. It has been brought up more than once. I think we just need dedicated resource to do it. So, I think that helps answer Question 1.

For Question 2, this is where I will acknowledge that we keep within our Gravity scope of work that the data sets are specific to the domains I mentioned. When we talk about race and ethnicity, those are the CDC and OMB data sets. We have not been doing a deep dive on streamlining it. I think with our IG and upcoming pilots, there is an opportunity to actually test this within the context of the Gravity STU2 FHIR IG on really determining a part of it is if there is an opportunity, even within workflow, to better define how we capture and use this type of data. I would see that as an opportunity, but it is not something we are doing a deep dive in right now, but I know, Asha, you are doing pilots as well. They could be paper-based. I do not know if you have anything you want to add around race and ethnicity data sets.

Asha Immanuelle

The one thing that I will add about it is that that is a really big push here locally to standardize how we document race and ethnicity because what we are after is really trying to understand the disparities that exist in outcomes. So, in order to know who is having a first-time C-section, we want to know a breakdown by race and ethnicity so that we can begin to understand if there are system problems there, if there are practitioner problems, but why are we seeing disparity? So, building a way to standardize how we capture and exchange race and ethnicity is critical to the development of disparity dashboards, which we are advocating for each health system to have one on the ground.

Arien Malec

Thank you very much.

Steven Lane

Ike, your hand is up.

Steven Eichner

Yes, thank you. I have questions in three distinct areas. One, looking at making a recommendation regarding the provenance of information that is collected so that downstream users can understand not just what the data is, but what the source of the data might be. Secondly, looking at segregating out or maintaining information either consistent with a medical record or distinct from a medical record can be challenging, looking at ensuring that any disclosure occurs in the appropriate legal context with respect to HIPAA, so, any guidance you might provide in that space would also, I think, be appreciated. I think I will leave it at that.

Evelyn Gallego

Ike, are you asking about provenance? Sorry, I am just making sure.

Steven Eichner

Looking at the provenance of data and support for provenance of information because some information may be self-reported, some information might come from other sources, and second question, looking at managing information in the context of constraints such as HIPAA about what information may be shared. I guess the third piece is looking at individual control of data exchange. So, the eyes, the patient, or the individual affected. What rules do I have in controlling with whom data may be shared?

Evelyn Gallego

So, the FHIR IG builds off other FHIR resources and profiles, so it incorporates provenance data collection, so it does align there. Consent, similarly, builds off the current consent specifications, but I know consent is a much broader discussion. We always say that is bigger than our scope of work because there are lots of efforts going on around how to share data and consent for data sharing between HIPAA- and non-HIPPA-covered entities, which very much also is applicable to our work in particular as we exchange data from a HIPAA-covered health system to a non-HIPAA-covered community-based organization.

So, the FHIR IG does acknowledge that it has an overall consent use case that does specify for the implementer how they collect that consent. For individual control, again, I think, aligning with consent, the specification really just outlines how that data can be captured, but I think the individual control builds on the workflow piece as well as how the individual consents to what data about themselves they want to share with their care team or with other entities, so, again, I would align it to the consent piece, and knowing, again, full disclosure, I am not a consent expert, so I am really relying on what is specified in the current IG build.

Steven Lane

Thank you so much, Evelyn and Asha, for that great presentation and taking us through the Q&A. We really appreciate it. You are welcome to stay or go as you prefer, but we need to turn our attention to our modified laboratory recommendations, so again, thank you so much for your time.

Arien Malec

Thanks indeed. We appreciate the thoughtful presentation.

Lab Recommendations and ISA Priority Topics Discussion (01:13:04)

Steven Lane

And crisp recommendations. We appreciate that more than anything. So, as advertised, Hung, Hans, and some others have gone in and made some modifications to the laboratory recommendations to incorporate some of the information that we heard about the SHIELD LIVD project, and we wanted to go through those and see how those will translate into potentially a set of recommendations from our workgroup with regard to the ISA. We also have this tremendous list here of the topics that have been submitted. I am not sure this one includes everything that was submitted at the last moment, but we have had a number of submissions already on the topics worksheet that you all have access to.

I think Clem added the last tranche, and we are up to 27 recommendations that have a lot of meat on them. You will recall that we have gone through a ranking process for the first dozen that were mostly carryovers from the prior work of this group and the preceding taskforce. We are still waiting for prioritizations from Tom Cantilina, Michelle Schreiber, and Ram Sriram, so we would love to get everybody to submit their priorities on that first dozen, and then we anticipate going through a second prioritization process once we have collected everybody's input. So, we are just orienting you there. Arien, do you want to add to that before we turn back to the lab recommendations?

Arien Malec

No, just a recall that again, the purpose for prioritization is to allow us to focus on areas where we want to go deep and get very thoughtful presentations and more nuanced recommendations, but I definitely want to be encouraging. This is a broad workgroup that has a fair amount of experience across the board. If

there are areas where the ISA can better track items, do not let the prioritization work get in the way of making those recommendations. I think you already see some pretty fantastic work from the workgroup.

Steven Lane

I see that Riki is with us again today and is providing some comment. Thank you very much. Riki was also involved in the updating and editing of the lab recommendations. So, Hans or Hung, I want to ask the Excel team to pull that document over from the Google docs. Do you guys want to walk us through that and how you approached the edits?

Hans Buitendijk

Sure. Would it be easiest if we go top to bottom, and then, as we see comments, we go back and forth?

Steven Lane

Sounds good. We have nine minutes, so, take as much of that as you can. Not that document, but the one that has the lab recommendations on it. There we go, that is the one we want.

Hans Buitendijk

Can you help with putting… I can find the link. Never mind.

Steven Lane

I do not think we are supposed to put it in public.

Hans Buitendijk

No, in the panelists. Hung, do you want to start? Is Riki going to be able to comment?

Arien Malec

Maybe just as a reference for everybody else who has not been as deeply into this, there was a previous incarnation of this workgroup where we made very detailed recommendations for improving electronic ordering and resulting. Since the time that we have made those recommendations there has been a tremendous amount of progress with both SHIELD and LIVD in areas that are right in line with the recommendations that we made in, I believe, 2018, even though we revised them in 2019, and then, we have clearly had some experience with electronic lab reporting for reportable conditions and reportable labs in the pandemic, and so, the request was just given all the experience that we have, can we take the recommendations that we did four years ago and recast and revise them, given the work that is on the ground, to make them a little more focused for ONC for prioritization?

Steven Lane

And, whoever is running the display, if you could just close that panel on the left so that we can see the comments as well as the text, that would be ideal. Perfect. That is great. All right. Hans, I sent you the link in private chat.

Hans Buitendijk

I can jump around and see the comments. So, the first one, communication: To include that, when it comes to interoperability, it is really about what I need on the wire, if you will, what we agree to as a common language there, and the information model at times can be a little bit more abstract and a little bit higher

level that may imply other things as well. I added communication to really make clear that in the end, that is what we are trying to communicate and that is where we need to agree. However we do it on the respective sides and the respective systems, an information model may address some of that, but that is up to the individual systems. It is about how we communicate, how we can be unambiguous about what goes across the wire. That is the reason why I put it in there, whether or not it helps clarify your question.

Steven Lane
No, that is great, thank you.

Hung S. Luu
My suggestion is to include SNOMED CT and UDI as examples for the codes to emphasize the ecosystem approach that SHIELD is taking, that we recognize that no single ontology is able to fulfill the needs that are required for robust interoperability, and that we really need to lean on what existing codes are available to fully flesh out the meaning of the test so that it is apparent to everyone what test it is, and also for downstream secondary uses.

Arien Malec
We should include UCUM as well.

Riki Merrick
Agreed.

Arien Malec
What is a little funny about this is this obviously parallels the work we did with USCDI, and I think we are making basically the same recommendations back a bit.

Steven Eichner
This is Steve. From a pure edit perspective, in the second line, it should probably be "utilize" rather than "include." We are talking about using the standard, so you are using a standard, not including a standard.

Arien Malec
Yeah, that is good. I would say for this pass, let's focus on content and then go back and clean up the editing language, but clearly, if we see things where we can clean up right now, that is useful.

Steven Eichner
Gladly.

Hans Buitendijk
On Grace's comment, I believe that the intent is to include pathology. I would be surprised if somebody wants to exclude it, but we need to figure out a way to make that more clear.

Riki Merrick
I don't know. "Labs" covers that. Clinical labs and pathology labs, if you wanted to highlight it. Clinical and pathology, or all.

Arien Malec

Great. Thank you, Hans.

Hans Buitendijk

I will keep the note on refreshing. I do not think that 2019 is the latest guidance there any more. I think there is the current one, but that is just the URL. I think the bigger ones are going to be Riki, next, and then me. So, Riki? You had "When result observations are quantitative," etc.

Riki Merrick

Oh, yeah. So, we are just saying for quantitative, we probably should add units of measure. I think we say that further down, but we need to identify that result observations can be in different formats. They can be free text, which is not as great, they can be codified, and in those cases, they should be using standard codes, or they could be quantitative, and then they should be using units.

Hans Buitendijk

Scroll down on the screen just a little bit more below.

Arien Malec

I see that Clem has a question or a comment related to this section. Clem, is it related to this section, or is it something that is more general?

Clem McDonald

It is related to this section and the changes because for going on 20 years, the only code for lab test has been LOINC. I think if we break that, we are going to break standardization. As to the idea that it does not cover everything, everybody can submit to ask for additional codes, but I think it will just create confusion and distraction if we now add multiple codes.

Riki Merrick

But Clem, we are not talking about identifying the test with anything besides LOINC, but we are talking about the result values here.

Clem McDonald

No, I know that, but I think the specific thing they crossed out, the codes to identify clinical test… I understand that distinction, but I do not think that is what this now says.

Arien Malec

It says, "Resulting organizations should provide LOINC and other necessary standardized codes," so I think the intent here is LOINC for the test and standardized codes for the result when necessary.

Clem McDonald

Well, that is a separate sentence further down, so I do not think this is going to create anything but confusion, and I think there is a specific request…

Arien Malec

Maybe your comment is for all test orders and resulted tests. That is the nut of your issue here. We should be using LOINC as the ordering vocabulary and as the resulting test identification vocabulary. Again, I think we are in an area where everybody agrees we just need to make sure the words match what I think everybody agrees here.

Clem McDonald
Adding the other necessary standardization codes breaks it because there is another sentence that talks about…

Hung S. Luu
LOINC does not include…

Arien Malec
Again, I do not think this is an area where there is fundamental disagreement about what we want to say. This is in the area of making sure what we say when you parse it appropriately acknowledges the reality because I am pretty sure everybody on this call is saying that our orderables should be LOINC, and CPT where appropriate relative to mapping to administrative coding, that the result should come back with a LOINC code to identify the test and that the actual result should be either numeric with a UCUM code or qualitative with a SNOMED description, and then, UDI relative to device identification for the IPD.

Steven Eichner
I just have a follow-up. Not local, obviously.

Steven Lane
All right. Steve, did you have a comment for this spot, or can Hans proceed?

Steven Eichner
Just that it is a national code, not a local code, just to put everyone on exactly the same platform.

Steven Lane
Okay. Hans, do you want to keep going? Did we lose you, Hans? There you are.

Hans Buitendijk
So, I just want to make sure, Riki, you covered everything with the one result observations.

Riki Merrick
Yes.

Hans Buitendijk
Okay. I think next is Hung, with specimen code. Anything to add there?

Hung S. Luu
I am just adding a paragraph to explain why we are proposing the UDI.

Hans Buitendijk

And, the next comment that starts with LOINC **[inaudible] [01:25:50]**, I think the intent there is to clarify that upstream discussion that we had, do that as soon as possible in the flow, and is trying to provide some context behind that. That is what we are trying to do. That is where LIVD fits in as part of SHIELD to bring it to the fore as well. That seemed to not have been as fully fleshed out, so that is the intent.

Clem McDonald

I would like to weigh in on the specimen thing once again because 90% of all tests… Back to reality, it is very important, but it is not crucial. For 50 years, everybody calls it serum glucose and there is not much confusion about it, and if we are going to add that extra burden of an extra segment or an extra resource to be sent with everything, it will be disruptive to labs and to medical record systems that do not have a place to put it, so I think this should be qualified to say for certain kinds of tests, it is very important, but it is not when they already have the name of the specimen built into the test name for the vast majority of testing, which are the chemistry tests and the hematology tests. Blood hemoglobin is what it is.

Riki Merrick

And, that is what the sentence says. Some lab tests are performed on different sorts of specimens, and so, in that case, that is when we need it. That is what that paragraph says.

Clem McDonald

We agree.

Hung S. Luu

Yeah. But, Clem, one of the reasons you developed LOINC was because you recognized the fact that we cannot rely on the local lab to name their laboratory code the same way, and so, that is why we could never rely on local codes and we could never rely on the local lab name because they just were **[inaudible – crosstalk] [01:27:47]** change it all. That is why you developed LOINC.

Clem McDonald

You are right on that. Probably the local labs are not doing it as much as they should. I had another comment on that. That whole thing in 2015 about how they topped out was wrong. They had not topped out.

Arien Malec

It was wrong. I think we need to move to public comment. There is obviously a lot of GC work to get into.

Steven Lane

And, we will come back to this. Thank you.

Arien Malec

We will get back to it.

Public Comment (01:28:18)

Michael Berry

All right, thank you. We are going to open up our call for public comment. If you are on Zoom and would like to make a comment, please use the hand raise function, which is located on the Zoom toolbar at the bottom of your screen. If you happen to be on the phone only, press *9 to raise your hand, and once called

upon, press *6 to mute and unmute your line. So, let's pause for a moment to see if we have any public comments.

Steven Lane

I do not see any hands up in the public attendee list, so it is a lucky thing. Ah, there we go. Holly, your hand is up.

Michael Berry

Holly, you have three minutes.

Holly Miller

I actually have to drop for another meeting. I just wanted to mention that Steve put a URL into the chat with some excellent link to the 360X project regarding social-determinants-of-health referrals. At this time, 360X is only contemplating clinical referrals, so, from a clinical environment to a community-based organization, to get those social-determinant-of-health needs met. The same general workflow that is throughout 360X applies, meaning that there is a distinct referral and patient ID that persists throughout the referral process. The steps of the referral are tracked at all points. The difference is that for the SDOH use case, we have anticipated that there will be community-based organization hubs that will manage some of these referrals, but some community-based organizations will have their own software. For example, Feeding America is planning to build their own software and to include 360X processes in their software, and they are very actively engaged in the 360X social determinants of health use case definitions. So, for information, please go to the website that Steve listed. Thank you.

Arien Malec

Right, so, thank you for that. This has been a fantastic presentation. Again, we are really appreciative both of the Gravity presentation for their thoughtful and very detailed recommendations as well as for the deep dive on lab that we got into. We will continue the adventure in next week's session. As a reminder, we are closing in June to make final recommendations back to the full HITAC. Again, thanks, everybody, and we will close out today.

Adjourn (01:31:08)