



**HIT Standards Committee  
Standards & Interoperability Task Force  
Virtual Hearing  
Final Transcript  
February 27, 2015**

**Presentation**

**Operator**

All lines bridged with the public.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you. Good afternoon everyone this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standard's Committee's S&I Task Force. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I will now take roll. Arien Malec?

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

I'm here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Arien. Stan Huff?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Stan. David Tao?

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, David. Holly Miller?

**Holly Miller, MD, MBA, FHIMMS – Chief Medical Officer – MedAllies, Inc.**

Present.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Holly. Jamie Ferguson? Josh Mandel?

**Joshua C. Mandel, MD, SB – Research Scientist – Boston Children’s Hospital**

I’m here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Josh. Joyce Sensmeier?

**Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Health Information Management Systems Society**

I’m here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Joyce. Ken McCaslin?

**Ken McCaslin – Director, Healthcare Standards – Quest Diagnostics**

Ken McCaslin is here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Mark Segal?

**Mark Segal – Vice President, Government & Industry Affairs, GE Healthcare IT – GE Healthcare**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

And from ONC do we have Mera Choi?

**Mera Choi – Acting Standards & Interoperability Coordinator, Office of Science & Technology – Office of the National Coordinator for Health Information Technology – Department of Health & Human Services**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Mera. And Mazen Yacoub?

**Mazen Yacoub, MBA – Healthcare Management Consultant**

Hi, here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Mazen. Okay with that I'm going to turn it over to Stan and Arien to kick off our virtual hearing.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

All right, so this is actually a really exciting part of our process just to remind people that we were asked to evaluate the role, historic and future, of the Standards Interoperability Task Force to make recommendations as to whether it or something like it should continue and if it should to suggest changes in both strategy and operations.

We've had a number of upfront meetings to clarify, at least from the perspective of the members of the Task Force the unique jobs that the Standards and Interoperability Framework or something like it can do as well as some key operating principles relative to prioritization and relative to how to structure initiatives for success not just from a process perspective but also from an outcomes perspective.

This is the part in our process where we're hearing from the community of interest and I think we've got a pretty exciting lineup, folks who represent standards development and standards implementation both in horizontal technology as well as in healthcare specifically including people who have a deep experience in S&I Initiatives, people who have experience at SDOs and some folks who have been on both sides of the fence who have advocated for and driven standards development activities both in S&I and outside and then implemented the resulting standards and implementation guides.

And I think we're going to learn a lot about success patterns, failure modes and get some really useful insights that will guide our deliberations and recommendations going forward. Stan any other preparatory comments?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

No, I think that's a great introduction, thank you.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Yeah, with the agenda, this is where we are, we're in the virtual hearing, but we're lining up to make recommendations for the upcoming Standards Committee meeting and this information that we're hearing in this hearing will be absolutely critical for those recommendations.

Let's go onto the next slide. We're in the public hearing period. Next slide. I think this is the set, actually Michelle do you want to tee some of this stuff up relative to what we asked the panelists to do?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sure, I might go over a few administrative items too if that's okay. So, before we even kick it off I just want to remind the Task Force members how today's meeting will go and also for the panelists. So, for the Task Force members hopefully you're logged into the web conference. We're going to use the hand raising feature today which will put you in the queue to ask questions.

So, what we will do is, we have three panels today, for each panel we'll have all of the panelists go limiting their testimony to five minutes. I will let you all know when it's getting close to your time being up if it doesn't sound like you're getting close to wrapping up and I will have to cut you off if you go a little bit too long. Those of you who have participated before know how this works.

So, we'll let each panelist go and then we'll open to questions from the Task Force members. Task Force members will use the hand raising feature to ask those questions and then we...once it seems like all questions are exhausted or if we hit the time limit that we've designated to that panel we'll move onto the next panel.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Can I just ask a question?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yeah.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

As a panelist were we supposed to answer these questions exactly, because I hadn't been aware of them?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So, the questions were shared when we invited you but I'm sorry if that wasn't communicated. To the Task Force members if you want to look at the questions throughout the hearing they are also on the agenda that we sent around but we were hoping that the panelists could touch upon these questions or a variation of these questions within their testimony. We know that there is a lot there so that...and you only have five minutes, so you may not be able to get to everything but some of that may come out when the Task Force asks questions of you anyway. So, we're really just looking at your five minutes to give a brief summary and then usually we can really get into some good rich discussion once we open up to questions.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

But I would...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So, hopefully...

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

But I would say, Clem, I mean, we're...you know, the goal is for us to come to good understanding and to come to good recommendations so we're not trying to muzzle anyone or try and force you to only talk about the things we want to talk about. So, it's just a way of sort of organizing it so that...

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Yeah, I wish I had...I mean, it's my fault, right.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Well, we didn't give you all much notice either, so, anyway hopefully Clem we'll get to the right questions.

So, the goal for today's hearing is for us to better understand the role of S&I and its job and that basically is the question that we asked all of you to help us answer and we shared these questions with you all hopefully, as we just discussed, we'll get to most of them throughout the discussion if not touched upon within your testimony. Next slide.

Okay, so before we kick off the first panel any questions from the panelists or Task Force members about logistics or administrative items?

Okay, all right, so you all should have received a Bio-Sketch which just gives a brief summary of each participants Bio, so panelists shouldn't feel the need to provide any background of who they are and who they work for or past experience as it relates to a lot of you, so please just feel free to get into your testimony within the five minutes allotted. So, if you're ready Bob, go ahead and get started.

**Robert Dieterle – esMD Initiative Coordinator – Centers for Medicare & Medicaid Services**

Okay, thank you very much. I'd like to thank the Co-Chairs and members of the Standards and Interoperability Task Force for the opportunity to present a few brief remarks today regarding the role of the S&I Framework in advancing standards and implementation specification development.

As bit of background, my name is Robert Dieterle and I have held executive management roles in multiple domestic and international companies in the healthcare sector. For the past 2 years I've been CEO of Enable Care which is engaging, consulting with and providing services to public and private sector healthcare clients including working with CMS as the Initiative Coordinator for the Electronic Submission of Medical Documentation or esMD.

I have participated in or led S&I and ONC/FHA Initiatives for the last four years including esMD, laboratory initiatives, provenance, structure data capture, healthcare directories and Direct.

I've participated in the following standards organizations and industry Workgroups, HL7 including attachments, structure documents, orders and observations, EHR functional models, security, record management and evidentiary support, community-based collaborative care and FHIR Workgroups, and for X12 attachments, prior authorization acknowledgements. And I'm a member of WEDI and I've participated in operating rules development with CAQH CORE.

You've asked for input on any changes we'd propose in S&I roles. Response is the following; we strongly support the role of the S&I Framework as a national convener to identify priority use cases for interoperability, define specific requirements and evaluate existing standards for the utility and addressing the identified requirements.

Specially S&I supports national priorities and production use of standards through the creation of highly constrained implementation guides that can be reliably implemented on a national scale. We agree that S&I needs to increase its focus on the production use of the S&I Initiative and constrained SDO work products or implementation guides.

S&I needs to support not only pilots that validate the implement ability of the standards but more importantly lead rapidly to broad production use.

As far as facilitating federal participation in SDOs, there are no other SDO independent venues that encourage clearly identifying national interoperability problems and then look across all SDOs for standards-based solutions. S&I needs to continue to encourage SDO participation in S&I Initiatives and federal agency and S&I Initiative participation in the SDO process.

You've asked for comments on proposed criteria and their impact on S&I Initiatives. As far as balanced participation every initiative I've had the privilege to work with has actively solicited participation from all interested sectors of the healthcare industry.

Unfortunately, like all volunteer standards efforts active ongoing participation is mostly from individuals and organizations directly and immediately impacted by the specific use case.

All S&I Initiatives normally have between 10 and 50 participants on each call which is about the same as most SDO Workgroups. Asking for balanced participation is appropriate, requiring it is too restrictive. If the same requirement were applied to the SDO Workgroups than most of them would be unable to continue.

We need popular initiatives that attract broad participation and necessary initiatives that attract those that are willing to work to solve important but not necessarily exciting interoperability problems. As far as meaningful and measurable real world results this would not have impacted any effort in which I've been engaged, all of them were focused on providing measurable meaningful real world results including Direct, laboratory initiatives, provider directories, esMD, etcetera.

As far as a reasonable implementation path this may be the most difficult of all of the issues to address. We've always tried to provide for reasonable implementation paths but the definition of reasonable differs depending on the specific initiative.

When something is new and additive to the existing interoperability landscape the issues are quite different than when the solution is intended to replace existing methods of information exchange, both have reasonable implementation paths but require different participants, infrastructure and timeline expectations.

As far as interim and long-term goals and outcomes, as in reasonable implementation paths the ability to find interim and long-term goals depends on the specific initiative and work products. Many require the establishment of infrastructure to enable adoption such as X12 support for X12-based standards, CDA support for incorporation of structured documents, authorization and security infrastructure for RESTful applications. As long as the criteria is flexible there should be no impact on any well planned initiative.

As far as rapid cycle implementation, again, this is dependent on the initiative and the interpretation of rapid cycle. As an example, esMD pilots are all considered to be pre or limited production pilots. The expectation is they will all progress through actual production. However, rapid is certainly dependent on having support for both sending and receiving organizations for implementing any of the standards.

In summary, the S&I Framework is the only open forum for discussing SDO independent solutions to national interoperability problems. Participation in the SDOs in the S&I Initiatives and participation of the federal agencies in SDO activities is a necessary prerequisite to effectively address the national interoperability issues.

Applying specific criteria to S&I Initiatives only works if they are flexible enough to accommodate the specific nature of the initiative and currently deployed standards that may need to be updated or replaced.

I'd like to thank the Co-Chairs and the members of the Task Force for the opportunity to present these brief remarks.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you. We're going to move onto our next panelist who is Jitin Asnaani from athenahealth. Jitin?

**Jitin Asnaani, MBA – Director, Product Innovation – athenahealth**

Thank you. Thank you very much to all for the opportunity to participate in this event and to provide testimony. I'm on a mission to commoditize health information exchange. In 2010 I was appointed by ONC to help launch the S&I Framework leading the program and some of the first initiatives for the duration of my appointment.

Since 2012 I have been driving interoperability initiatives in the private sector through my work at athenahealth where I have guided the evolution of our own cloud-based interoperability platform while furthering the achievements of community-driven activities such as the CommonWell Health Alliance and Argonaut Project.

In my view, the primary job that S&I Framework was initially designed to fulfill was the support of national priorities and production use. Indeed when we launched the framework there were only two...I'm sorry there were two key glaring gaps in interoperability that we were trying to address.

Number one, the standards chosen for Meaningful Use Stage 1 were perceived as chosen by exclusive bodies of participants.

And number two, standards were being developed by stakeholders who had no skin in the game so to speak in terms of implementation. We sought to address this by creating a duocracy where initiatives were considered successful only if implementers used the work products. To that end before the first initiative was even launched ONC published a list of potential use cases and sought public input into them with again an explicit bias towards implementation.

Thus, the first two initiatives introduced by the S&I Framework the transitions of care and lab results interfaces initiatives were not the brain children of any one federal agency or special interests, but were jointly owned and prioritized by the community of people who wanted to use them. Alas, if we had really just stuck to that paradigm we might be having a very different discussion today.

In terms of the proposed criteria for the S&I Framework I'll just focus on those for which I think I can provide a unique perspective. Let me start with balanced representation which seems like an obvious criterion but it's actually devilishly tricky and even misleading. To start with we could ask the question, what's the value that balance actually provides. As a counterpoint one could say that a successful initiative does not need to be balanced at all as long as the imbalance leans in the way of people who implement it and the stakeholders who depend on that implementation.

That aside, the second thought around this is, does balance really mean equal numbers or equal fervor of participation. Here's the reality, the most ostensibly balanced community-driven efforts, the overwhelming load of thinking and hard work is driven by a small handful of people. Indeed defining "balance" as a check list of stakeholders like providers, SDOs and so on is just a method to optically cover your bases in front of potential critics.

Take the S&I Framework lab results interfaces, the LRI initiative for example, which had a highly balanced membership consisting of SDOs, government agencies, medical practitioners, software implementers and other interested bodies, of that 90 person initiative perhaps just five deeply vested individuals accounted for 90% of all the work products created. Moreover, those five individuals were typically paid for by deep pocketed organizations who in reality represent a minority, a large minority, but a minority nonetheless, of our highly fragmented healthcare landscape.

At the end of the day then the sausage was made by skilled alignment of the most active 5-10% of the participating community with the capabilities and needs of the small under-represented organizations that truly represent the mass market of everyday healthcare. That suggests that the secret sauce to an effective S&I Initiative is leadership, is getting the right leadership by a small group of unbiased, entrepreneurial individuals who have nothing to lose and preferably everything to gain by the mass proliferation of implementations of the targeted standard.

Okay, let me switch gears. I think a truly catalytic opportunity for cooperation between implementers and informaticists is in the definition of the right goals and outcomes. Together they can define work products that appear adequately sound, practically usable and ultimately sustainable.

Again, using the LRI Project as an example, consider that we achieved broad-based agreement that a new LRI implementation guide, while being less easy to implement than an existing guide such as for example the ELINCS guide, best enabled the long-term goals of ever increasing and ever richer laboratory results exchange. Not only did that approach achieve greater buy in by the informaticists community it also drove more usage because of the implementation focus of the initiative while also securing a future home in HL7. This should remind all of us that an approach to products sustainability should be built into every S&I Initiative. I'll leave it at that for now. Thank you again for inviting me to this testimony. I look forward to the discussion.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you Jitin that was perfect timing we appreciate that. Larry Garber from Reliant Medial Group.

**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

Thank you Michelle and thank you to the group for having me and giving me this opportunity to provide testimony. I'm one of the Co-Chairs of the...I was one of the Co-Chairs of the S&I Framework Longitudinal Coordination of Care Workgroup which did a lot of the foundational work that fed into HL7's development of updates to the Consolidated CDA that were published this past December.

Right now we have the Standards Committee that identifies the needs for standards and SDOs that codify those standards and the question is, you know, do we really need the S&I Framework and I strongly believe that we do, that we need the S&I Framework to ensure that our standards are clinically useful and usable.

Now the SDOs have, you know, members that are brilliant and hardworking and dedicated but they do tend to be heavily weighted toward technologists and academicians with a posity of people who are working in the front end of clinical settings around the country and I don't think it's reasonable to expect the SDOs to actually be able to do all of the foundational work that's necessary to obtain consensus and define the models for the standards that are going to be built, you know, for instance you can look at the care plan, the initial care plan that the CCD represented was very primitive and really not very useful, even the first FHIR care plan resource was similarly deficient.

Instead you really need to have a forum that's no cost, easy to join where clinicians and vendors and academicians and technologists, and SDOs, and the public sector can all convene to rapidly develop consensus and work on the foundational elements that are necessary for new standards which of course sounds a lot like the S&I Framework.

So, the S&I Framework bridges that gap between the Standards Committee and the SDOs it's the convener, it's the consensus builder, it's the accelerator. I think it also absolutely needs to act as a representative on the SDOs to carry the vision and understanding that was developed during the S&I Framework consensus building to make sure that the final standards actually truly represent and reflect the work that was developed during the S&I Framework building.

And then the S&I Framework needs to be responsible for piloting the new standards. As was mentioned before basically if you know you're going to have to eat the food you're going to make it a lot better. So, I think that those are really the three things convening and building the vision, carrying that through to the SDO and finally piloting the new standards.

So, you asked a few specific questions, I agreed with most of the things that you would be asking us to do in the S&I Framework and I wanted to focus on two of them.

First is the balanced representation, the fact is it's a wonderful idea. We had...there were 100 people who were following or participating in our Workgroup some of them are on the phone here and I appreciate their dedication, and as was brought out, you know, it was a small subset of those 100 people that did the vast majority of the work.

Realistically, I would have wanted more people to be actively involved, you know, broader roles, different care settings beyond what we even had in inner most active people and the problem is that all of these people have day jobs and they have employers that expect them to do, you know, these day jobs and so I think what's really missing is that the S&I Framework was entirely voluntary except for our great facilitators and I think that we really need to add some sort of financial incentives to those who are actively participating in order to broaden the participation and those incentives need to not just be to the participants but they also need to be to their employers so that they can justify freeing up the time of these valuable employees.

The other thing that I noticed is that after we had our face-to-face meetings where we actually got to meet with these co-workers it was incredibly valuable and increased our ability to work over the phone. So, I think the S&I Framework needs to fund some face-to-face gatherings.

And then rapid cycle implementation, I think it's a great idea but that really means that you're asking people to do pilots early on and feedback iteratively and to improve the standards that's very expensive to do and I think the S&I Framework needs to find ways to fund these pilots through grant programs right from the start to make sure that they are done and effective, because the poor people that are doing these pilots will then be giving the software for free to their competitors and it's an unfair disadvantage. So, thank you and I hope you accept my testimony.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Larry and the last panelist for this panel Margaret Donahue from the VA, whenever you're ready Margaret.

**Margaret Donahue, MD – Director of VLER Health (Veterans HIE), Co-Director of the Office of Interoperability – Veterans Health Administration**

I'm ready. Good afternoon. The Department of Veterans Affairs, Veteran Health Administration greatly appreciates this opportunity to provide input into the proposed changes in the S&I process with respect to federal partners particularly.

As you know the VA believes in the concept of ubiquitous interoperability of health of electronic health records as a means to assure that veterans receive high value care from any delivery network public or private.

Seven out of 10 veterans receive some portion of their healthcare from private sector providers. Veterans live and work in every healthcare delivery market in the country and as such veterans represent one of the nation's strongest business cases for interoperability.

VA has a long and successful history of leadership in the healthcare standards development process. We have strongly supported the S&I Framework and have participated in its Workgroups and panels. We do think it is time to re-evaluate the criteria for defining federal priorities and support the criteria as proposed with really the following areas of emphasis.

First of all, and I think this is very similar to what others are saying, is that federal partners participation leadership in the standards development process needs to continue and any facilitation by S&I to enable that participation is welcomed.

Too often our departmental priorities and available resources limit participation by our subject matter experts and these standards development organizations are really “participate to play” organizations. They are often internationally based and VA experts must be able to travel as needed to participate. So, clear statements and demonstrations of support for standards experts from the federal ranks would go a long way in helping to justify their involvement.

Next, there needs to be an emphasis on measuring the value proposition of interoperability both from the veteran’s perspective and from the federal partner perspective. VA would support and participate in national initiatives to derive the monetary value and all the improvement gains of health record availability through interoperability. Present quantitative data are slim and we too often rely on anecdotal accounts of value of sharing information beyond network boundaries.

Next, the VA supports the development of robust uniform semantically computable non-ambivalent standards but optionality and innovation can occur in the application of those standards for interoperability. VA believes that the various interoperability methodologies support valid use cases, that they constitute a portfolio of potential solutions and that one methodology should not be regarded as superior to another at this time.

In order to promote real world implementation of interoperability we really need tools and reference implementations such as the CONNECT model or the MDHT, the Model Driven Health Tools, for CDA model.

An implementer’s user group to share notes and lessons learned is helpful. Once data sharing is implemented we need automated testing tools for data quality and surveillance. Good data enhances adoption which can result in benefits.

The final point is that we have to make is that interim and long-term goals within the federal space have long been departmental specific. There are some instances of interagency collaboration which include the open source connect gateway, VA-DoD interoperability projects and the VA-DoD SSA collaboration on disability claims. VA supports strengthening inter-departmental collaborations such as these.

For example, the federal partners should have a thorough understanding of various roles and impacts of the conversion to value-based reimbursements by CMS.

So, I want to thank you for this opportunity to speak on the behalf of Veterans and the Department of Veterans Affairs on this very important topic.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you Margaret and thank you to all of our panelists. We’ll now turn to our Task Force members to ask any additional questions that may have come up. So, first in the queue is David Tao.

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Just a point of order, our goal is to ask questions of the panelists right not to give our own opinions at this point is that correct?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Correct, so we...

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So, members can give their opinion when we follow-up next meeting.

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Okay, great. I do have a question to any of the panelists. A lot was said about, you know, balance, several mentioned the concept of balance and how tricky it is. What do you think...the alternative is like get balance through an open initiative like S&I Framework which is free and open to all versus doing more efforts within SDOs to ensure the, you know, end user clinician type participation maybe more so than it is today.

Could any of you comment on, you know, there are...if we agree on the objective of wanting the, you know, the people who really are implementing and using these standards to be involved including especially, you know, clinical users is S&I...do you feel like S&I is the best way to do that versus other approaches to recruit them into...more of them into SDOs.

**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

Michelle, do you want us to raise our hands or how do you want to do that?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

For the panelists if you can just go ahead and answer that would be great so since you're the first to speak Larry go for it.

**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

Okay, thank you and David thank you your help in our S&I Framework. I think that there is a free for all when you're first building the true requirements and definitions that are part of the standard. There is a lot of chaos, there is a lot of inefficiency and I would hate to waste the time of an SDO going through that process, you know, we clearly felt this as we were, you know, trying to understand the care plan and building the definitions for that and getting consensus and understanding, and it's an ugly process building the consensus and getting broad input and it just seems like it's a...from my experience with, you know, HL7 as an SDO there is a lot of very focused work done at a very technical level and I wouldn't want to waste their time going through the kind of stuff that we had to do on the S&I Framework. So, that's just my perspective.

**Jitin Asnaani, MBA – Director, Product Innovation – athenahealth**

This is Jitin I'm also happy to answer that question or at least give my perspective on it. My view is that the best work products are created in the context that evaluates itself on the work products created.

So, I wonder...well, I more than wonder, I'm fairly certain that some of the outcomes that we would have achieved outside of SDOs could not have been achieved within SDOs not because you don't have the great people within those context but because, at least historically, SDOs have not been...one of their work products and measures of success has not been working code, real world exchange, etcetera. They have not necessarily measured themselves against those criteria.

So, in fact the best place for getting a balance is probably not in S&I Framework but an actual private sector initiative and I'd say S&I Framework is somewhere in between those two, between the SDO and a private sector initiative. Not that the SDOs should not be fully engaged that's actually I think...they're a critical part of the balance that enables you to create the best work products.

But if the ultimate goal is the actual usage of the standards or implementation guides, or other artifacts of the initiative then it needs to be created within an implementation focused body preferably an actual implementation body or network. That's just my perspective.

**Robert Dieterle – esMD Initiative Coordinator – Centers for Medicare & Medicaid Services**

Yeah, this is Bob Dieterle I'd like to make one comment. I don't see the two venues as mutually exclusive; I think they play very different roles.

I think the role of a standards organization is to develop, maintain and support the standard.

I think the role of S&I is to convene a national set of interested individuals and organizations to discuss national priorities to look at the problem and pick the best SDO and the best standard to work with to solve it.

And I think both needs to encourage broad participation in particular in the clinical sector.

**Margaret Donahue, MD – Director of VLER Health (Veterans HIE), Co-Director of the Office of Interoperability – Veterans Health Administration**

This is Margaret Donahue and just to reinforce that I do think as a clinician and as one who has implemented many of the standards that I think that the concept of clinical usability and the ability for the standards to really improve patient care and healthcare in general must always be on the forefront of development and the more that we can engage frontline users and clinicians in these processes the better.

I agree with not, you know, wanting to get them wrapped up in a lot of the technical details but I really think that real world view and that frontline view is always needed for validation of the standards.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Margaret. I'm going to move onto our next question from Joyce.

**Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Health Information Management Systems Society**

Thank you, Michelle. My question was piqued by Margaret's testimony and the comment on measuring the value proposition of interoperability. I think that's an excellent point and would just like to hear a little bit more from your perspective Margaret, and of course the other panelists, on how the S&I Framework efforts could move that forward.

**Margaret Donahue, MD – Director of VLER Health (Veterans HIE), Co-Director of the Office of Interoperability – Veterans Health Administration**

This is Margaret; well I would say that it would really need to be a collaborative effort. I think that there are certainly efforts out there in the community and elsewhere in the government to try to really measure the benefit of interoperability and it's just very challenging at this time. I think that more of a framework around that evaluation for consolidating efforts and interoperability results would be needed to really start to see where we're moving with quality both on a monetary and a clinical level. So, I think some framework around evaluation is needed.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Any others want to respond to that?

**Jitin Asnaani, MBA – Director, Product Innovation – athenahealth**

This is Jitin, I guess I'll sort of chip in. At the time when we launched S&I Framework we at least had a group of measures to measure the impact of the initiative, we had measures that took into account just how much work we were doing, so how many meetings did we have a week, how many meetings did we have a month, the course of initiative, etcetera.

There were measures on...I would call those process measures. There were measures on results in terms of the work products that group members were creating as well, so what are the number of artifacts, how was the quality artifacts to the extent you can measure them, how many votes were yay and nay when standards were put up for a balloting for example in HL7.

So we kept track of those things but we also kept track of the implementation metrics. How many pilots did we have out there for the particular initiative, how many participants, how many different types of companies, how many in each kind of bucket, small, medium, large kind of companies were able to pilot the standards.

We should have gone even further than that in retrospect and started measuring production but in some sense as well we just ran into the Meaningful Use wall during those initiatives where, at least the few that I was leading, became part of Meaningful Use Stage 2 and then it certainly became sort of a moot point since everybody had to implement them.

But I feel like those sorts of measures kind of get at the key drivers of different types of stakeholders involved in each initiative including the final end result itself which should be to just enable exchange of data.

**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

This is Larry; I'd like to add one more thing. You know this is sort of an interesting concept because we've been thinking about the S&I Framework as its role in standards development but if you look at it as a role for creating a pool of diverse and dedicated, and interesting people across the healthcare system it's possible that it wouldn't just be a resource for the Standards Committee but maybe even for the Policy Committee to bounce ideas off of if you're looking for sort of a broad rapid input this maybe a group of people that you could tap in for that.

**Margaret Donahue, MD – Director of VLER Health (Veterans HIE), Co-Director of the Office of Interoperability – Veterans Health Administration**

This is Margaret again, and one thing that I think we find is a challenge now in interoperability is that we really are measuring transactions as our metrics. Certainly at the VA we look at transactions as how we evaluate how well we're doing but, you know, in general we need to move beyond transactions and really try to start figuring out if this is helping patient care and healthcare in general.

You know I use the example of transitions of care in Meaningful Use and I'm hearing that a lot of people have just automated the process of sending a C-CDA at the end of a visit but is anybody actually looking at that on the other end, is it actually improving, you know, the transition of care from the hospital to the office and how...I think we need to step our measurements up to the next level to figure out how care is actually being improved and not just looking at transactions.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Margaret. I'm going to move onto the next question from Ken.

**Ken McCaslin – Director, Healthcare Standards – Quest Diagnostics**

Hi, everybody. I heard a lot of people talking about pilot and I think it's a great idea to pilot something particularly as new as a lot of the stuff that we've been doing, but it seemed to me that a lot of people were reticent about getting engaged in the pilot and incentive money might make that happen but it felt like some of the people were afraid to fail and fail in a public way.

Does anybody have any feedback about why it was so difficult to get some pilots particularly in the MU 2 piece and do you have any sense of how we can make sure that pilots are successful?

**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

This is Larry; I'll take a stab at that. So, we've been piloting or working on piloting the new Consolidated CDA release 2.0 standards and part of the problem is that, you know, we were...it takes a while to develop the software support for new standards and so we kind of were building the boat while we had set sail and were building the software, the C-Tool in our case, before the standards had actually been finalized and as a result of that we're actually piloting an earlier draft and not the final standard, at least at this point and, you know, we'll be updating that now that the standard is published.

But it is a laborious process, you know, to do all the software development and give it a try knowing that you're going to have to do more software development when you're done because you need to bring it up to the final standard so that's been a problem.

The second thing is that, you know, until we can show that this new standard meets our needs in real world use we need to continue the old process. So, the current paper transitions of care forms are still being used in parallel with this extra process so it's redundant work until you know that it's sufficient and then you can stop the old process but you can't just, you know, jump off the cliff and hope that this new process is going to meet all your needs. So, it's inefficient for our organizations to participate in these pilots and that's also a barrier which is why I was suggesting that, you know, there be grants to help take some of the pain off of that.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Can I contribute? I'm not a panelist but can I answer that question?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Well, is this Clem?

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Yes.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

You're on another panel, go ahead.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Okay, well, I think, you know there are a number of problems one of them is that you really can't test network things until a lot of people are using them you can't get the reality of it that applies a little bit to measuring the benefit of interchange, you know, until it's really working any measure will be a negative.

And then the other part is that some of the pilots are toys and they don't really give you the answer. I know of one where they ran it but no clinicians used it, you know, so you don't know if it worked or not.

So, I think there is a combination of to do a serious one is just a huge amount of work and it can't maybe work until lots of people in the neighborhood are using it and the other one is that we do these pilots and then give credence to sort of really knowing something when we may not when the hard part wasn't tested. On the other hand it would be nice if we could do them.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Anyone else from the panel have any additional comments?

**Jitin Asnaani, MBA – Director, Product Innovation – athenahealth**

This is Jitin I'll add a couple of things, actually I like the direction Clem took us there. Two thoughts, one is, you know, as I look back at the pilots that we did manage to run for C-CDA and for LRI every discussion with a potential pilot participant, not every discussion but almost every discussion, was an ROI discussion. At the end of the day before companies put in, you know, any serious investment, which they have to, they have to put in one of the most valuable resources which are R&D resources into doing a pilot, they asked for the ROI up front and if they don't see it then they kind of huff and haw, and have a pilot that moves at glacial pace even if they cannot, you know, outright tell the government we're not doing it and that was sort of an interesting experience.

And in fact, some of our pilots were conducted by companies which were extremely small, had small user bases and their ROI was the marketing they would get, the PR they would get from being involved in an ONC initiative and that was sort of one learning I got from that process.

And in terms of, geez, and I've forgotten my second thought, but anyway so that's...so it did become a challenge to get pilots in the face of that sort of thinking which is actually perfectly rational obviously from a private sector point-of-view.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

This is Arien, I'm going to take a Chair's privilege and ask a follow-up to that whole line of inquiry. I think many of you have focused on the notion of not just benefit, production benefit in terms of people using the transactions in the real world but also clinical and, you know, end customer and patient benefit as well as ROI benefit as was just mentioned.

And I think many of you have pointed to situations where the folks who are involved whether it's in the SDO or the S&I Framework fervently believe in the clinical and end user benefit and yet nobody who is in a position to implement that whether from a vendor perspective or a provide perspective actually steps up and says, that problem is so important that I'm willing to take the time, energy, cost, effort to solve that problem.

And I just want to throw that back to the panel, (a) did I hear that right and (b) does anybody have suggestions for what to do if you run into that problem, you believe there is clinical benefit, you believe there is economic benefit but people are showing up for marketing reasons, they're showing up because it's their hobby horse but nobody who would implement in the real world and make a difference bothers to show up or bothers to commit to implement. This seems like it's the nugget, it's the nut of the problem that we face. So, I want to throw that question back to the panel.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Well, this is Clem and if no one else will speak I will.

**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

This is Larry I'll give the floor to Clem.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Well, there are two parts of it. Some of the stuff that the world outside of care in the industry comes up with really is not a good idea in my opinion. And what it really does is create more work and we don't have any way to sort through those differences. There are some things that are just killing physicians now and it's because non...people who haven't walked in these shoes have these ideas, seem like a great idea but it really isn't a great idea but yet the process marches on and it all gets implemented. It does get implemented at least as regulation. So, that's the one side of it.

The other side of it is that, you know, the vendors want to do this stuff which they know will have to happen, so and this is a totally different side, so when it's still in the early smoky phase and which way it's going to go and there are all the arguments over this and that they probably want to hold back until it's settled and then they'll make their investment.

**Lawrence Garber, MD – Internist/Medical Director for Informatics – Reliant Medical Group**

So, this is Larry, I'd like to also say something which is, you know, there really is precedent for solving this problem and it's in the research community, you know, that's what, you know, the ARC grants and PCORI grants, you know, that are out there are basically to fund...at least from my experience as a 500 physician group practice, we take these grants and we try things that may or may not work.

We implement processes that are, you know, do require some burden on our medical assistants who are rooming patients or our patients who might be filling out questionnaires or our doctors, but, you know, we do them because number one there is a possibility that they might work, you know, and number two that we're receiving funding to allow me to justify this to my bosses saying that we really should give this a try and there is an ROI at least in the sense that we won't lose money by trying this out.

So, it works in research, I think that's how a lot of, you know, new processes and new tools are developed is through grants and really that's what we need in S&I is that we go into each of these standards with the knowledge that there is going to be a certain number of grants and that we identify those people who are going to pilot right up front and, you know, get that worked out even before you start working on the project.

**Margaret Donahue, MD – Director of VLER Health (Veterans HIE), Co-Director of the Office of Interoperability – Veterans Health Administration**

This is Margaret, is there opportunity to engage provider organizations more up front in the standards definition and I'm thinking of like the American Academy of Family Practice and the AMA, and the American Health Association, and the organizations that often react to the standards after they've been implemented but maybe should be actually driving some of the standards at that level. That's just a thought. You know is there a way to get provider organizations more engaged up front and driving the standards.

**Jitin Asnaani, MBA – Director, Product Innovation – athenahealth**

So, this is Jitin, I'll add in that, you know, from looking at the...and again I learned this really while I was on the initiative although it's bearing out fruit even beyond that. When I look at the providers and I look at vendors, you know, there is probably good agreement on some of those problems in healthcare, some of those opportunities to use health information exchange for betterment in healthcare, but when you start thinking about these things as just opportunities to do better things for healthcare it is charity, it's down the line of charity and so for a vendor thinking about this as charity is not an effective means of developing or putting the right resources towards it or any resources towards it until you have to.

And even for a provider, like it or not providers get paid to do the job they do, and for them it's not an easy thing to start adopting a new workflow or a new method of doing work, or, you know, a ton of different kind of new sort of nice to have features in their minds until you get to the point where it actually makes sense for them as running a business or a practice and not to mention of course that it's even worse for providers because they are dealing with vendors who may have not implemented it with the best resources or the most iterative lifecycle that could actually get them a great product out the door.

These things first come out in really poor versions, you know, there was a Windows 3.0, you know, once upon a time and it was terrible and it took a while before we got to, you know, 95 XP and the like which are actually not too bad. And in the meantime the user has to suffer through all of that and if the user doesn't see that value and certainly doesn't see the value economically then they don't necessarily want to go through that sort of pain of evolution without seeing it at the end.

I'll also say that one thing I did realize particularly as I left ONC and joined the private sector is that the continuous change or the perception of continuous change and rotation of standards coming from programs like Meaningful Use is disenchanting. In the first place it puts providers in the mindset that, well not just providers but people in general, in the mindset that, you know, let's just get it done now because it's going to change shortly and of course now that there is, you know, accountable care and real economic motives for exchanging information a lot of that skepticism disappears because at the end of the day that's going to be a fundamental way, a fundamental leader into a provider and the vendor getting paid and actually getting revenue. So, that's a business model change and obviously the incentive for participation changes.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

This is Clem, could I just comment, you know, we talk about exchange but the truth is there is relatively little exchange that has been produced by all this activity and if you look at the individual requirements at least 70% of our different workflows and different additional work in the practice, you know, there is not a single mention about EKGs in any transmission standard we've talked about for the last four years and so we really are...we talk of exchange but we haven't focused on it to get it done. I think providers would be pretty happy if they could get all the data they wanted.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

So, this is Arien, I think we're at the top of the hour. Michelle, how are we doing in terms of our agenda?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

We're doing perfect because there is no one in the queue and I think it's a perfect time to transition to the next panel.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Excellent.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So, our next panel is just made up of two people, so we'll start with Brian Behlendorf and...

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Hey...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Go ahead.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Yeah, Michelle before we tee up this panel I just wanted to give context, you know, we first heard from a lot of people who have been involved in S&I Initiatives, we wanted to get a perspective from more of the broad technology sector, folks who have been involved in IETF and other kinds of standards development and just as one kind of a “hmm” moment is that IETF just recently finalized HTTP version 2 and within I believe two weeks of the finalized version of it there was vendor support for the upgraded standard, now clearly different operating environments, but I think that kind of lag time between a standard and implementation in the real world that leads to material and quantifiable benefit would be pretty much unimaginable in the healthcare sector. And so, part of the intent here was to see is there anything we can learn as takeaways from the way standards development is done more broadly.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

And I guess that’s my cue. This is Brian Behlendorf, can you all hear me?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

We can hear you.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

Great, okay. So, thanks for that intro Arien and I have to say for those who might not have my context Arien and I worked on the Direct Project in 2010 and that was just a really terrific experience and seeing some of these principles applied.

And so, you know, it’s been actually a while since I’ve been involved in Health IT and so my conversations are probably much more from the outside than all the other panelists here today so I appreciate the willingness to kind of explore this outsider view even though I’ve had kind of dip into the pool so to speak.

But I did want to speak from a couple of different perspectives, one is as one of the Founders of the Apache Project which became the Apache Software Foundation and having worked on the Apache HTTPD and I’m actually not sure yet if we support the 2.0 protocol. It’s interesting that it’s been about 20 years between 1.1 and 2.0 which is also a testament to something about the pace of standards development.

But I was involved in defining the HTTP 1.1 specification and I’ve kept my feet in somewhat of a standards pool just kind of as an observer these days in addition to working as a venture capitalist at a growth agency called Mithril.

I also sit on the board of the Mozilla Foundation which puts out the Firefox browser and is very passionate about pushing out open code not just that meets the standards as defined by the W3C and IETF and others, but also fights for the user rights.

And I stay involved with Apache here and there and involved in other non-profits and open source projects, but, so I wear a bunch of different hats and wanted to really speak to a principle that guided...that I fought for during the Direct Project and I think bore some fruit through doing that, but just for the sake of others wanted to talk about the importance of the existence of open source implementations of the standards that get defined in any of the standards processes.

The most successful Internet standards have tended to have at least one if not multiple open source implementations developed concurrently to the standards process. Vendors have typically been free to integrate this into their commercial even proprietary solutions thanks to the liberal open source licenses that typically have been used, in Apache's case it was something called the Apache license which had, you know, very little...placed very few requirements upon any other software that incorporated it meaning it could be embed inside of any vendor, you know, web server stack, it could even have been chipped by Microsoft if they had wanted to, it was chipped by IBM and by Oracle and all these other vendors out there and that was great, that was actually seen as a wonderful thing by the Apache community.

The existence of these implementations are essential during standards processes to really see where the standards break down, the implementations that don't stand up to hostile and non-conformant actors in the ecosystem or the gaps between standards that hinder true interoperability, you know, when it's clear that there is a missing piece, you know, as it was sometimes during Direct or trying to understand the role of say certificate authorities it really helped to have the implementations going on to help us see, you know, really how those played out in the real world.

The existence of these implementations also result in a shorter path from standardization and final standards agreement to production implementation. Arien gave that great example of HTTP 2.0 followed by, you know, official support for that in some of the other servers and browsers out there and that's really been due to the fact that interim, you know, tests, implementations have been ongoing for years.

To make this work these must be both reference implementations of the vast majority of the standard, you know, any of the "shoulds" or optional pieces may be missing although it should implement all the "shoulds" but it must also be production quality.

There was a lot of focus during the Direct Project in making sure that the two reference implementations were implementations that people would actually run they weren't just demonstrations, they weren't just demos, they were code that, you know, could sit underneath Microsoft HealthVault if they wanted to run it, it could run underneath, you know, any production instance.

This dual focus helped during the process, and by the way these can be separated, the IETF and Apache are separate organizations, they were separate teams they just had a lot of overlap between individuals. On Direct we did kind of unify it although even there we allowed for separate conversations amongst the implementers, one focused on the implementation versus the standards process, but this kind of dual focus helps separate the participants who were there just for marketing or hobby horse reasons from those who are there to solve actual problems and I think that really speaks to Arien's last question which is, how do you try to filter some of this out.

Now certainly people showed up on the Direct Project list with their own kind of views of how things should be done but because we kind of inherited this principle of duocracy from Apache and rough consensus and running code from the IETF it only really matter when we sat down and wrote code, you know, and yet there were some people who didn't write code who had thoughtful things to say who usefully participated in defining the use cases or the architecture and still had an impact. So, I guess I should say code is broadly defined there its anything that's useful during that software process.

Another point that I want to make is that low cost participation is essential to this. It's important that both the standards projects and effective open source projects provide an opportunity for casual low cost participation and by that I mean sitting on a mailing list, being able to browse an archive, you know, on line of those conversations, being able to see a Wiki, not having to qualify oneself as, you know, an employee of a vendor in the space or as somebody who is an expert, a noted expert, you really want this long tail of followers and developers and those who at the very least can act as bridges to other projects and other standards communities. And this also helps ensure that the use cases and the architectures are broadly representative of the eventual user pool and vendor community. And the right way to do this is to be public, digital and transparent from day one.

You know while we had our phone calls to coordinate activities we tended to do the majority of our work over EML, over the Wiki, in the source code and that set us up for the greatest amount of participation.

I think there are a bunch of other points I can make during the conversation, I think one of the other final things I'd like to add that I think is somewhat responsive to the questions that were originally posed is, you know, I feel like it's important for the standards and particularly in the health data space to focus on the role of the individuals patients and data sovereignty.

You know, I've been really struck by, you know, some of the structural challenges in this space coming down to the fact that patients themselves are seen as having very little role themselves in facilitating health information exchange and some may say that's because they care, they don't want to be involved in their health data, but I think the majority, not the majority but a substantial number of people that I know who have to take their paper records from doctor to doctor who change jobs and have to fill out tremendous numbers of forms they feel unempowered and the focus typically, because that's where the resources have been, have been on vendors who are building solutions, you know, at the institution level, at the hospital level, at the organizational level and, you know, we're lucky if it scales down to the individual doctors and small clinics, and the personal health databank kind of concept has certainly struggled.

Yet we should try to make sure that in the standards that get defined we keep an eye towards how possible is it, and this is something we did during Direct and how possible is it for an individual to set up their own Direct note or for somebody who acts as their proxy, you know, for 100 different accounts, right, is it as easy to set up as it is getting to the server.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Brian can you please wrap up?

**Brian Behlendorf – Managing Director – Mithril Capital Management**

So, that's all I wanted to throw in and happy to elaborate and go into other points during the conversation, thanks.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Brian. There are only two of you on this panel so I let you go quite a while, sorry. Justin?

**Justin Richer, MS – Independent Consultant**

Hi, everybody my name is Justin Richer and I'm actually formally of the MITRE Corporation as of a couple of weeks ago and am now independent and I've actually got slides to talk to which I believe if you go...oh, there we go, fantastic.

So, what I wanted to do is kind of even follow along from what Brian was just saying and give some concrete information about how things are run in two standards body organizations that I have a lot of experience in which is the IETF and OIDF. Next slide, please.

The IETF is the Internet Engineering Task Force and they define things like things you may have heard of like HTTP, TCP/IP, DNS stuff like that. A whole lot of these RFC standards so many of them come out of the IETF. The others, the OpenID Foundation...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hey, Justin, this is Michelle, I'm sorry; I know you mentioned you're on a new headset you're going in and out. Is there any way for you to...

**Justin Richer, MS – Independent Consultant**

Yes, sorry, I can stop pacing around my room that will probably help immensely. My apologies.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you.

**Justin Richer, MS – Independent Consultant**

All right, no problem. So, and there is the OpenID Foundation which is focused more on the digital identity aspects of the Internet. Next slide, please.

And in particular my experience with these are on a handful of standards that have come out of these namely OAuth 2.0 and OpenID Connect both of these organizations are responsible for a number of different standards the IETF very, very many, but these are the two groups that I've got the most experience with. Next slide, please.

They do have similar goals and one is that they both produce completely open standards and this is something that is very, very important to the charters in both organizations and these are things that you don't have to license, you don't have to ask permission to use they are available and you can use that is a truly open document that anybody can implement and that's very, very important in order for that to drive adoption, but even more important is that the development of these standards is also in the open and this draws some very broad participation from lots of different people sometimes people coming from very big companies, sometimes people coming from particular interests or their own selves. Next slide, please.

But even though these share a lot of very similar goals they really run on two very different models which is very interesting to see given that they are in many ways fairly similar organizations. So, we're going to compare and contrast them for just a couple of minutes. Next slide, please.

The IETF has been described as a bit of anarchy with lots of hierarchy to make sure the anarchy doesn't completely explode. There is absolutely no formal membership in the IETF itself. To join a working group you join a mailing list that is literally it. There is nothing sign. There is nothing to do you join the mailing list and start posting. It is one of the lowest barriers to participation that I've ever seen in a standards organization and they really, really mean this.

Now we do meet in the IETF three times a year in person at various places around the world but as we'll see in a little bit the meetings are really there to facilitate the mailing list discussion. Now in order to combat the chaos that could come out of this completely wide open to the public process there is a lot of hierarchy, a lot of checks and balances as documents go through. There are working groups that have editors and chairs, and area directories, and steering groups and everything goes up through the RFC editor at the end of the day before a finalized IETF document actually emerges out the far side. Next slide, please.

The OpenID organization on the other hand does have formal membership to the organization and that does require a fee. The IETF membership no fees it cost money to go the in person meeting but you can also attend remotely for free if you like. And all of the decisions are really made on the mailing list.

For the OpenID Foundation if you want to join the actual foundation you do have to pay a fee and there are different fee schedules for different kinds of groups, but anybody can join a working group for free and this is very important, and this goes to Brian's point of open participation, you don't actually have to join the foundation to join a working group, however, there is a formal intellectual property rights assignment, there is a document that you have to sign in order to contribute to the OpenID Foundation. Next slide, please.

In the IETF on the other hand there is this thing called the "Note Well" which all you literally have to do is read the note well, note it well and continue on with your day there is nothing to sign, your participation implies your consent. This is a very, very powerful mechanism of getting that long tail of getting people actually involved. There is no voting and all of the discussion, all of the canonical discussion happens on the mailing lists themselves.

The standard is rough consensus and running code which again echoes Brian's point, I swear we didn't coordinate this, where the most successful standards are actually those that have implementations that are built as the standard is being developed. You don't know if something is actually going to work until you try it is really what it comes down to and the IETF process has codified this explicitly with this notion of rough consensus and running code.

And artifacts as they're produced go through that hierarchy and I'm speaking as somebody who has been in various positions in that hierarchy over the years I'm now actually an editor in one of the working groups in there. Next slide, please.

On the OpenID Foundation side there are different working groups but they kind of define their own processes it's a little bit looser but it's also a much smaller organization. There are mailing list phone conferences, there is no sort of single canonical communication channel and there is a mixed consensus model. Unlike the IETF where it really is rough consensus there is no voting, nobody gets a veto, nobody...there is no majority rule, there is nothing like that.

In OpenID Foundation the consensus model is actually that same way within the working group but once it's out of the working group the actual paying members of the OpenID Foundation vote whether or not to accept the final products of the working groups themselves in order to produce the final standard and it's a really interesting way to balance the two different interaction mechanisms with the foundation itself. Next slide, please.

So, in other words IETF is kind of a benevolent dictatorship of the elders of the Internet and I say that with love. It has a very, very large membership base and because of the extraordinarily low bar of participation bad leadership can absolutely destroy it. It's susceptible to people stalling, it's susceptible to people injecting in sort of bad conversation and sending people down garden paths and rabbit holes or chasing squirrels, pick the metaphor that you like, but if you have really good leadership there are ways to move it forward that's why the hierarchy is in place to kind of contain that chaos a little bit.

There are lots of heated arguments in the IETF to figure out whether we should paint the bike jet blue or green. This happens in any standards body and in a lot of places the strong personalities do still tend to win but because there is such wide participation there is a very good chance of lots of different opinions and perspective being actually heard.

Unfortunately because of this non-voting structure you can't vote around somebody who just wants to give you a bad day. You need to have strong leaders within the working group and area directors and things like that in order to move past stumbling blocks. Next slide, please.

In the OpenID Foundation it's a little bit looser because it's a much smaller community so there is slightly more friction for contribution, you actually have to sign something, there is a legal agreement that you explicitly enter into so you tend to get people that are a little bit more directly engaged but again there are heated arguments and strong personalities tend to win, but again, good leadership can actually move things forward and move things around the argument.

Because of the smaller size and the fact that things can happen in phone calls and stuff an organization like this can be a little bit more susceptible to clicks, you get a couple of people that go off into a corner and decide to inject something into the standards process and try to kind of move that through.

And in OpenID Foundation, and again, organizations like this, you tend to have a lot more of "oh, it would be a really good idea if we added this feature because we might want it some day" that does still happen in the IETF as well, but in my personal experience, limited to a handful of groups I would say, not as often because...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Justin, can you work on wrapping up, I'm sorry.

**Justin Richer, MS – Independent Consultant**

Yeah, I'm done.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay.

**Justin Richer, MS – Independent Consultant**

So...a really hard thing on running code, last slide, I just wanted to say that there is a big commitment to open standards in both of these and no system is going to be perfect but there is a lot that S&I can learn from both of these organizations in what works and what doesn't work they both have pros and cons. Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Justin and thank you Brian. Actually we don't have any questions in the queue yet. I'm not sure if...

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

This is Arien; again I'll take my Chair prerogative.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yes, I was going to ask you anyway. Thank you.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Yeah, so, you know, I'm interested in the kind of inter-standard implementation time, that is the time between when a standard is published and there is a working implementation of it and I guess maybe the difference between a working implementation in open source software and a working implementation that's in production.

Brian I know that during the time that HTTP errata for 1.0 and for 1.1 were published you were writing C so I wonder if you've got a perspective on the interplay between standards development and implementation in that period.

And then Justin, to you, I know that OAuth 2 went through literally 31 drafts before it was published as a proposed standard and yet people wrote working implementations on that. I just wonder if you can give your perspective on the pros and cons of that process.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

So, to address your first question, so standards processes are typically not good places to invent things, right, you know, they tend to fail when you've got architects of your own saying "would this be good, would that be good." What they've tended to be good for...and the other extreme, right, is when a vendor brings a sophisticated completed solution to something and says, you know, please adopt this as a fait accompli, right?

What tended to be a successful pattern was for, in the HTTP working group, one of the implementers to, you know, propose something and quickly followed up with code, right?

In the case of the cookie header for example there were some discussions about, you know, how might we maintain states in HTTP which was designed to be a stateless protocol so that we could keep track of things that users had read or interesting information about the end user or about the browser.

And Lou Montulli who was working on the Netscape browser, you know, implemented cookie and wrote a very brief spec on how it worked and then we could all look at that and see what we liked and didn't like about it, right, and after some hammering through on that it became the HTTP cookie header extension draft, I forget the number that was assigned to it, and it was a little more generalized, a little more sophisticated introduced expiration that sort of thing, but it was...Lou Montulli's proposal was followed within hours by somebody implementing it as mod cookie in the Apache web server and then, you know, progressively, you know, as we'd make modifications and conversations on the list about, on the IETF list about how things should be and how it should work it was pretty easy to make those changes into the code.

So that iteration was very tight and maybe even a little crazy and it's not something that, you know, is necessarily recommended for everybody and maybe the cookie header isn't the best example of a well thought out standard at this point, but that kind of agility, you know, is really important because you don't see the impact sometimes of a design and until it's running in the real world and it's being used on production data.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Could I ask him a question? This is Clem again.

**Justin Richer, MS – Independent Consultant**

Okay, I was going to...

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Oh, go ahead; someone else has got it, go ahead.

**Justin Richer, MS – Independent Consultant**

All right, I was just going to give my answer before the next question came.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Yeah, go ahead.

**Justin Richer, MS – Independent Consultant**

Okay, so I was going to, you know, I heartedly agree with everything that Brian was saying and so for OAuth it's actually kind of an interesting case that OAuth 2 is like, you know, 80-90% of OAuth 2 is actually something called OAuth wrap which predates the IETF proposal, it was dreamed up and proposed at a little conference on the West Coast called IIW, and much of the actual functional mechanics of OAuth 2 are from the OAuth WRAP document, they're nearly even wire compatible.

And what was a little bit different about OAuth 2 is that we actually had very, very large Internet implementers Facebook, Google, AOL, Yahoo, GitHub others that were implementing OAuth 2 to the draft specification long before it was actually published and for me this told me that, you know, one we had definitely kind of hit on the right architecture and people who needed a solution for this problem and so they were going to kind of take it, and it was very, very helpful for us within the standards group to get the feedback of the people who were running this not only just in kind of a test implementation, which we still have lots of, I've written some, and not just them but also people that are saying "like, yeah, you know, we're running this against a billion users a day, we, you know, see performance issues when we do it this way and, you know, we solved it doing this" but that breaks the specification as it currently stands. That tells us that there is something that the specification probably isn't doing.

And at the end of the day a specification with no implementation it's just academic exercise, it doesn't actually mean anything and you really need to have the two side-by-side. The biggest problem with this is that they do run at very, very different time scales and getting things back in sync after those initial trial implementations can be difficult, you know, Facebook was non-compliant in some pretty egregious ways with OAuth 2 for a number of years actually during the process because they didn't want to break backwards compatibility for their developers even though the standard had moved on and, in many opinions, improved on what the initial draft actually said.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Could I ask both of you the question I was going to ask? So, you've both emphasized the importance of building an implementation and at least one of you said that you don't deal with things you might want in the future you just deal with what you need and that's not the case in our standards area. I mean, everybody piles on and of course we don't have to have an implementation and how can we solve that problem or is it a problem?

**Justin Richer, MS – Independent Consultant**

It is absolutely a problem and you solve it by telling people that this sounds like a great idea and show me your implementation once you have that then we'll include it, because you're going to get...

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

...

**Justin Richer, MS – Independent Consultant**

You're going to get that attitude with any standards building body whatsoever, it happens absolutely everywhere; it is not unique to the healthcare space by any stretch. You just need to be able to push back at it and push back at it in a reasonable and measured fashion.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Well, we don't have the requirement to build an implementation so we're screwed I think.

**Justin Richer, MS – Independent Consultant**

No you make one to implement and when people are bringing things to the standards body you say, that's cute now build it, once you've built it then we're all set.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

...okay...

**Justin Richer, MS – Independent Consultant**

I mean if you were building a spec you don't include it until you know that it actually runs.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

I like that idea.

**Justin Richer, MS – Independent Consultant**

I didn't come up with...

**Brian Behlendorf – Managing Director – Mithril Capital Management**

I think it also does boil down to effective leadership of the process you know...

**Justin Richer, MS – Independent Consultant**

Yes.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

It's as communitarian and as hippie as it sounds...a lot of this sounds sometimes admittedly, you know, every...one of these communities tends to have its Roy Fielding who played the role in HTTP 1.0 and 1.1 of the specification author meaning it was kind of...an editor, sorry it was his kind of job to corral things down and in an open source you have, you know, many projects, you have somebody like Linus Torvalds and the role he plays in the kernel which is to kind of be the final air traffic controller, arbitrator of priorities, you know, that sort of thing and the degree of muzzle and control that they exercise, you know, varies but, you know, that's an essential hedge against chaos, right, and I think good leaders know that if they don't effectively, you know, make sure the people who are bright and motivated, you know, can see their changes get implemented lose that talent and lose that energy that it dissipates and so they run a balancing act.

And I think that leadership style is teachable. I think we taught quite a few people how to do that in Direct and I think given a quantity of leadership talent I think a standards process that has a reference code, implementation that corresponds produces a better outcome.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Where do you sign up for that school?

**Brian Behlendorf – Managing Director – Mithril Capital Management**

So, that's a good question and there are a number of different conferences that I could point you to, there are a number of different books that I could point you and I'd be happy to follow-up to the panel with a list of resources. There might even be tutorials out there for that sort of thing, but generally, you know, this is something that is learned kind of by seeing how the well run open source communities work.

Probably the one best book, I'd point people to, is something called "Producing Open Source Software" written by Karl Fogel. I may be biased because I wrote the forward for it, he gave me the privilege of that, but he has really done a good job of capturing kind of the leadership techniques, sometimes it gets a little geeky but the essential kind of rhythms kind of come out of that.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Brian, this is Arien, if you have other recommendations we can make sure they get into an appendix of a recommendations letter that I think we'll be producing.

**Justin Richer, MS – Independent Consultant**

And to add to that I'll actually just say one of the best places to learn how to do this is to join standards organizations that enforce this, you know, with something as large as the IETF there are good groups and there are bad groups and I will refrain from commenting which is which but observe the good groups, observe the ones that actually are producing things that people are using and see how they work, you know, the archives are public, the same with open source communities, there are successful very large scale open source projects that do really well with taking in outside contributors and making things that are actually functional and all that other stuff. Find those and join them and learn in the shadow of those who are already doing it. That will teach you more than a book any day. It is a good book, I will say that, it is a very good book but nothing beats experience.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

David has a question.

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Yeah, thanks, in contrast to what Brian and Justin have been talking about it seems like an HIT nationally we're pretty anxious to get results soon and create standards where there weren't any and as a result there have been, you know, DSTUs or even things that are not draft standards for trial use, you know, recommended, you know, for, you know, rapid adoption and it seems like, you know, when you talk about HTTP 1.1 to 2.0 being many, many years it's so different.

Do you guys think that we just need more patience to sort of go back to the pre-Meaningful Use, pre-ONC days where there was sort of a forcing function to get the standards out and just let them evolve until they were mature and have implementations then and use them or is there something different about the healthcare world that sort of forces us to have to leap into the fray sooner with standards that are not quite as widely proven.

**Justin Richer, MS – Independent Consultant**

So, I think that it's more that the healthcare world, in general, tends to have things a little bit backwards in assuming that the standard has to exist before the implementation and it really should be the other way around by getting a quick turnaround and lots of very rapid, you know, development and adoption and then you standardize that once you see what works.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

I mean, I'll add to that and say there is definitely room for innovation within a standards process and there is...it's definitely a successful pattern of collaboration is one where vendors approach and say, here's what we've done with our point-to-point integrations, here's what we've done internally when we've needed to connect two nodes to a network or share data between two systems, and here's, you know, a prototype standard or a draft standard and obviously you want to make sure the IEP comes along with that as well, but, you know, it shouldn't be presented as a take it or leave it as a fait accompli, it should be presented as here's an arrow in the right direction.

**Justin Richer, MS – Independent Consultant**

Right.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

And here's, you know, something that, you know, other vendors should be able to come to and say, well, we solved it a little differently and, you know, we had a different set of requirements and through conversation kind of converge on something that meets an 80<sup>th</sup> percentile of the needs or more, right, but I think there is an essential humility to that act as well not just ratifying kind of a single vendor's pre-existing standards no matter how well it's worked for them.

**Justin Richer, MS – Independent Consultant**

Yeah, I agree and to give an anecdotal example from personal experience I'm the draft editor for something called OAuth token introspection in the IETF and the introspection draft started by me looking at a handful of proprietary but well-documented implementations of this kind of action which is I have an OAuth token what is it good for and trying to...me sitting down and actually just trying to distill those along with a pre-existing standard from user managed access doing something very similar and tried to pull those together and I brought that to the OAuth working group basically saying like, look people are already building something that does this we really should be paying attention to this and we should define a good way that works for as many people as we can and as we were doing that, you know, my team built an implementation of it as well, and we actually put that into production, you know, a pre-draft, a pre-IETF draft version of that with the mindset that once it...if it were ever picked up and finalized we would be able to roll and switch to that directly.

So, you know, we didn't show up and say, this is the answer, you know, because this is what we've implemented and we're not willing to change it now. There are people that tried to do that in the standards bodies and it really doesn't work, it doesn't go over well.

But nor did we come in and say, we think that maybe it might be a good idea if we do something kind of like this. We ended up with something, you know, right down the middle of those two and know that it's going to change. I agree with Brian's sentiment on the humility of the presentation both in the idea of what you think you need to accomplish and also in the codification of existing work.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

It looks like we don't have any other questions in the queue so...

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

So...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

I'll defer to Arien and Stan.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, I had a question, this is Stan, or maybe it's a comment that might provoke some further discussion. I mean, this has been fascinating, so, you know, as the Chair of HL7 I'm thinking of, you know, things that we want to do maybe better or different, you know, the whole idea of, you know, maybe we've got it backwards that we do implementation and then we write a standard when we have working implementations that's a fascinating concept.

But the...in this discussion we started out talking about S&I Framework and what it's role was and, you know, going back to the first panel, you know, there was the idea of sort of a division of labor where S&I Framework would be about understanding what the important problems were and prioritizing, and then sort of triaging the work to an SDO, and then the SDOs would be the ones who would actually develop the standards and so, you know, I'm trying to understand whether all of the very interesting concepts that have come forth are things that you're saying the S&I Framework would do or is that advice that the S&I Framework maybe needs to work with SDOs to try and implement.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

Well I think...

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

And then I've got maybe a follow-on question to that, but...

**Brian Behlendorf – Managing Director – Mithril Capital Management**

So, I think it was very useful during Apache's existence to be explicitly not a standards body that we were able to write the code that we felt was meeting the needs of our...our own needs and needs that we felt our users might have without having to worry about proportional representation, without having to worry about building a big tent, you know, if we pissed a vendor off we had the freedom to do that, if we felt...not that we would do it wantonly but like, you know, we didn't have the political concerns about trying to make sure that this was a broadly accepted standard which we really did want, we wanted HTTP to be everywhere but we didn't want to have to be nice to everyone in order to do it.

Whereas the IETF, they also can have a bit of that kind of focus on high quality code and meeting the needs, but necessarily it should be about the extent of broad representation that sort of thing. So, I think there still is a useful role for standards bodies out there to be these Switzerland's these neutral zones where ideas can be shared but I do have to say I think widespread interoperability, if that is your number one objective, widespread interoperability to maximize the value of interconnections so that you get the biggest shot at significant health outcome, I would look at two other communities as examples, the Bitcoin technical community and the Big Data community.

Both those communities right now don't really have what you might call, you know, standards bodies, right, what they do have are these giant libraries of code of reference implementations, if you do anything in Bitcoin you want to be using the libraries that the core of the coin engineers have been building and maintaining because they're bullet proof, they are accurate, they're correct and they've had millions of dollars thrown at them and you'd be crazy to build your own because it's likely to have security holes at best and just not work, right.

Likewise with Big Data there are, you know, hundreds of these new Big Data startups and a lot of them are building on top of Hadoop and Apache's work and these other underlying open source databases and libraries and adding a little bit of IT on top and a little bit of, you know, customer specific sector specific functionality on top but at their core they're common data.

And in essence those common libraries and the common code have, you know, generated ad hoc standards that have none of the downsides of traditional proprietary ad hoc standards, right? At some point it may be useful and I know the Bitcoin Foundation has emerged and they tried to do some standardization and, you know, certainly see some proto things in Big Data especially as it gets more sector specific but by and large if your goal ultimately is widespread, standardized interoperability at the most possible price, highest possible outcome large quantities of high quality production quality code ultimately maybe more important than the biggest most successful standards body would be.

**Justin Richer, MS – Independent Consultant**

Right and not just code but code that, I think this is very important, that can be used and incorporated freely. So, code for license isn't really going to get you very far especially if people aren't sure it's going to work yet but if it's something that you can pull down and try, and try to make it work, try to make it interoperate that's going to go much farther.

At the end of the day it really does go hand and glove, you standardize the implementations and you implement the standards and, you know, it's an ouroboros it kind, you know, feeds back into itself.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Can I just present the situation that we have in healthcare there are two parts to it, one of them is, and we are open and very democratic and anyone can propose anything and there is no...there is no question about marketability, no question about charges, no mention of how hard it is to do and then on top of that then we can standardize it and then the government can require it. It doesn't seem like the usual business model.

**Brian Behlendorf – Managing Director – Mithril Capital Management**

So, this is Brian, I...when we were working on Direct we certainly had Meaningful Use level one kind of on our mind but I'd say the more persuasive mandate was replace the fax machine as the primary method of health information exchange, right, and, you know, the government mandate, at least the context that we operated in, didn't come from the, you're going to have to shut off your systems if you're not interoperable, it came from the perspective of you don't get reimbursements if you don't meet these requirements, right, and that felt like a useful carrot rather than a stick it's a useful carrot, right, but we knew that this would be moot and it would be completely unacceptable if the standards we came up with were not practical, you know, implementable, inexpensive, you know, standards, right?

So, you know, there are all these policy questions about, you know, requirements for things, but I think as long as the requirements and the government mandates stay focused on outcomes, stay focused on, you know, achieving certain percentages of outcomes and metrics that sort of thing rather than saying you must implement RFC blah or this specific technology then that's the right thing.

**Justin Richer, MS – Independent Consultant**

Yeah, I mean, at the end of the day an organization, a standards body organization like IETF, OIIF, HL7 all these others you can write standards as much as you want but you can't force people to actually use them and we've actually seen that a lot in the OAuth community, especially in the early days of OAuth 1 I couldn't tell you how many vendors heard about OAuth and they had some...they had a plucky engineer who thought they could do OAuth better and so I heard the phrase, oh, we have an OAuth-like security mechanism on our API, it's not actually OAuth but it's OAuth-like and, you know, that's pretty close.

And so, you know, the problem with that is of course that, you know, we as the OAuth community wanted people to use OAuth but we couldn't mandate that they do that and even if we were mandating it or providing other incentives they might just choose not to anyway and the same is going to be true in the healthcare space, you know, people are going to find ways to do things and find ways to get their jobs done no matter what the, you know, recommendations are at the end of the day.

So, it really needs to be easy for people to do the right thing. So, there needs to be stuff that they can easily adopt, that they can easily pull in. So, a great example of this is with the SMART Project, I know Josh is on the call here, they're doing some great work to have a FHIR-enabled system that you can just kind of plop into something and it goes and it does FHIR and you kind of don't have to worry about it. It goes and it does its FHIR thing and it works. And the availability of stuff like that is vitally important to people actually doing anything with it.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

So, I mean, to be even more pointed about this...I mean there are two things there is sort of the creation of the standard and then our standard operating sort of procedure is that, you know, starting with Meaningful Use 1 and 2 is actually government, you know, mandating and regulation or strongly incentivizing the use of those standards by...I mean is that...what are your thoughts, is that completely wrong?

We shouldn't...you know, we can create standards but mandating them in some sense may be counterproductive to what we're really trying to achieve, especially if things aren't efficient or, you know, have unexpected consequences because we haven't implemented all of the things that we've written standards for. Is it counterproductive to mandate standards in regulation?

**Brian Behlendorf – Managing Director – Mithril Capital Management**

So, I feel unqualified only because I'm not familiar with the last, you know, few years of where S&I has been on this and how specific those mandates have become. I would say the best outcomes tend to come from intrinsic motivators rather than extrinsic motivators, right, extrinsic means, you know, I have to do this or I lose my job or I lose my contract or whatever. Intrinsic means I'm doing this because I know I get better outcomes from doing this, I know that, you know, I'm more productive or I'm able to achieve higher metrics and so my...and I don't know quite where Meaningful Use 2 went after I stopped working on Direct as well.

My sense from Meaningful Use level 1 was that it was about, you know, achieving certain demonstrable outcomes, right, you know, you can send a patient record from one system to another that sort of thing and that felt appropriate. If it's mandating other sorts of outcomes, other use cases that continues to feel not inappropriate to me if it boils down to here is a specific spec...you know, I guess there is...I'd have to judge it case by case but it could be that to get your government compensation for something, to get Medicare reimbursement for something, you know, I can see that as being a reasonable thing to say, you must implement this API because that's the API we implement and we want to talk to you, right, when it came to incentive payments though I felt like outcomes was the best way. Yeah, I feel torn on this.

**Justin Richer, MS – Independent Consultant**

So, I think that it can be useful and it can also go horribly, horribly, horribly wrong. But one thing I think the healthcare...one example that the healthcare community can look to is...as a good example of how to structure incentives is the adoption of the Chip and PIN credit card system here in the US.

Now we are of course years behind Europe in having even remotely reasonable credit card security, but where this is actually...where the rollout is actually being pushed down to the edges, all the vendors and everybody like that, is in terms of the liabilities that are a part of all of the credit card acceptance contracts and it's basically boiling down to if you take a swipe and signature you're more liable for fraud than if you take Chip and PIN. And I'm completely glossing over the details and, you know, it's not an exact map for healthcare data, you know, you can't be reimbursed the disclosure of your sensitive health information for example like you can a fraudulent credit card transaction.

But there is still a lot to be learned from the motivation that's going in there. There are vendors that will say "you know what it's not worth it for me to upgrade all my systems I'll take on the extra risk at least for now until it becomes easier for me to go and do this." And there will be lots of things that are going there that will make it easier for them and they will probably switch eventually.

And I think we need to see similar things like that in the healthcare space in terms of the top down regulation type of thing. It needs to be thought of really in terms of kind of a game design mode, what are the motivations, what are driving people to make these decisions and how can you use those to get people to do what you actually want them to do.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

This is Michelle, I'm just looking that the time we're a little over for this panel, but I want to make sure that Stan and Arien you have all of your questions answered before we move on.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

I'm done.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

I think this panel has been fabulous.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yes.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

I want to thank them.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, let's move.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

All right, thank you both.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

All right thank you, again.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So...

**Thomas Sparkman, JD, MPP, BSPHarm – Vice President, Government Relations – American Clinical Laboratory Association**

Great.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Sorry...go ahead Thomas.

**Thomas Sparkman, JD, MPP, BSPHarm – Vice President, Government Relations – American Clinical Laboratory Association**

Thanks, Michelle, thank you for the opportunity to testify today, thank you to ONC and the Task Force. I'm here on behalf of ACLA and we wish to express our continued support for the Meaningful Use rules and the ONC EHR Meaningful Use Certification program.

ACLA, as you know, is an association representing clinical laboratories throughout the country including local, regional and national laboratories, in addition to esoteric labs, hospital labs, and nursing home labs. As providers of millions of clinical laboratory testing services each year ACLA member companies are actively engaged in the secure and standards-based electronic exchange of health information and are supportive of appropriate efforts to accelerate the advancement of interoperable health information exchange such Meaningful Use.

Given labs central role in providing laboratory diagnostic testing, ACLA members are on the front lines of these work efforts to ultimately increase the quality of care of patients and if you just think about it conceptually laboratories...the actual laboratory that might be performing the test is not in the same geographic locus as perhaps the ordering physician or the patient so the value of electronic health records being able to transmit that information is very apparent.

Going forward, as you're well aware, clinical laboratory results impact a majority of the diagnostic and therapeutic decisions that are made and our laboratories continue to work closely with standards development organizations and with vendors providing systems to our physician clients and that sort.

We've seen a lot of great success through the S&I Framework Initiative as an early leader in the area. For the first time we have a single laboratory results interface such as the laboratory results interface implementation guide to support interoperability across all laboratories and EHRs. This was done as a draft standard for trial use and it's a significant advancement in the US market since it's a decentralized market it should not be overlooked.

But, skipping ahead of my testimony a little bit, we're still seeing some challenges as we're looking to model consistent behaviors through the LRI IG effort. So, far the lab experience is that we've several vendors who are struggling and have asked the labs to alter the LRI IG and we believe that these alterations could put ordering providers at a risk of attestation failure and we're not going to know until a few of these interfaces are validated.

Going to the seven bullets that speakers were asked to present on, looking at national priorities these should drive improved patient care across different healthcare providers through the successful exchange of data through highly interoperable systems and as we've discussed a little bit today this should be done and really can only be done with deliberate piloting of DSTU implementation guides that drive the interoperability. Such an effort will require additional initiatives to help facilitate expanded implementation guidance.

There is the concern, again that's been discussed, that there is no incentive to pilot these programs but the piloting is important to make sure that we can avoid any, you know, barriers in the future.

As an example, you know, laboratories have an additional burden, our own burdens as many providers do, that our interfaces have to be verified by the College of American Pathologists as part of our compliance with the clinical laboratory improvement amendments and we very much need the support from other government agencies to reduce penalties and burdens and that sort.

I think it's useful to think about this as, you know, the initiative or the project as a giant ship that's trying to be brought to port successfully by a number of tug boats. If all the boats and the ship captain don't talk to each other than ultimately the initiative is going to run aground or sink so thus necessitating the communication between everyone.

In terms of facilitating federal participation in SDOs it's not as critical as the support to community to facilitate for SDOs to resolve issues encountered during the pilot of DSTUs. ONC's support through the S&I Framework has been successful in engaging broader participation through participants like ONC and NIST.

We've talked about the issue today about balanced representation; we want to reiterate this is absolutely critical. We'd also suggest perhaps considering weighting, putting in weighted votes essentially amongst provider types as opposed to just each organization having a single vote it might be useful to have weighting the votes across provider types not to say that someone still can't lose but the weighting might better represent the various industries and stakeholders that are involved.

For measurable meaningful real world results we think it's important for the KISS principle to keep it simple to resolve longstanding problems, some examples of things to look for, defining additional universal order codes for lab tests and standardizing short and long names, producing a single national implementation guide for clearly defined use with minimal deviations and that would reduce implementation costs.

A reasonable implementation path, ONC's roadmap defines a guiding principle to "build upon the existing Health IT infrastructure." We strongly endorse this guiding principle, especially for laboratories.

Looking towards interim and long-term goals and outcomes, this should be driven by a community of subject matter experts with knowledge of the critical patient care issues that need to be addressed short and long-term.

For example, incremental, scaled adoption of result level LOINC codes starting with voluntary usage in the early adoption phase followed by expansion to a target adoption rate for Meaningful Use Stage 1 and ultimately being required for Stage 2 that is a reasonable approach.

Rapid cycle implementation we don't think is as critical perhaps it is more critical to reduce the scope of the initiatives, again, thinking about the ship example, it's much easier to steer a smaller ship than a bigger ship to get past obstacles and icebergs, and that sort.

For, example, the major initiative to clarify usage and harmonize value sets across the four S&I Framework sponsored laboratory implementation guides, this is an example of an initiative that could potentially be restructured as a separate mini-initiative subject to rapid definition and implementation to pilot a new rapid cycle approach.

And that brings me to the end of my remarks. I look forward to the discussion and while I'm one of the newest on this hearing to many of these issues I'm happy to work with individuals to follow-up on questions or discussion with my...and coordinate with my membership to find examples in granularity that might be useful to the Task Force. Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you. Walter Suarez.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Yes, can you hear me okay?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

We can hear you.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Great, thank you. Good afternoon Co-Chairs and members of the Task Force, my name is Walter Suarez, I'm the Executive Director of Health IT Strategy and Policy at Kaiser Permanente. I'm also an active member of standards development organizations including HL7 and serve as the Co-Chair of the Sub-Committee on Standards of the National Committee on Vital and Health Statistics.

I have been involved with the S&I Framework in various capacities, including standards development advisor, initiative co-lead and technical liaison, and I thank you for inviting me to provide testimony on the role of the Standards and Interoperability Framework and its initiatives. My remarks will reflect the cumulative experience with the S&I Framework process and with selected initiatives over the past 5 years.

First, let me say that I believe the S&I Framework has served as a valuable forum for bringing together stakeholders to discuss specific use cases that represent important challenges in the journey towards interoperability. The work done within the various initiatives has helped advance the industry's understanding of these challenges, identify gaps in standards and develop tools and products to help address them.

I will focus my remarks on the following three areas and address the questions posed by the Task Force as I move along. First, refreshing the purpose of the S&I Framework the "why" and the role and relationship of the Framework to standards development organizations.

Second, reframing the process components of the framework including the process for identifying priorities for the framework itself and that will be the "how."

And then lastly, redefining the products coming out of the framework the "what."

With respect to the purpose of the S&I Framework there is still some degree of confusion, fragmentation, redundancy and overlapping parallel work between the work done by the various S&I initiatives and the work done by the standards development organizations on the same topics.

The S&I Framework Wiki states that the primary objective of the Framework is to "create explicit, unambiguous documentation of use cases, functional requirements and interoperability specifications of real world issues" and in other parts of the Wiki it is described as "developing user stories and use cases, harmonizing interoperability specifications and implementation guidance, offering opportunities to pilot and test implementations, providing tools and services that facilitate productivity and identifying and documenting best practices."

All these statements together with the work products completed thus far by the various S&I Initiatives raise a question, is the S&I Framework developing standards or even becoming a standards development organization?

Many of the products developed by the S&I Framework Initiative end up having to be introduced, vetted, balloted and voted within standards development organizations before they are adopted by the industry either through regulations or industry consensus, given this I believe the role of the S&I Framework should really focus on, if it were to continue, it should really be reframed to more appropriately align with the actual standards development process rather than attempting to replicate it in a parallel manner.

Activities that the S&I Framework should consider focusing on include in the front end first developing user stories and use case documentation.

Secondly, identify functional requirements.

Thirdly, identifying current standards applicable to the use cases and any possible gaps.

And fourth, recommending specific needs for SDO products.

Once these items are completed the information can be then provided to the appropriate SDOs for the standards development work to take place. During this time the S&I Framework can help coordinate federal participation on the SDO process.

In the back end, working, once the standards have been developed, working with the SDO, the S&I Framework can support pilot testing the artifacts developed by these SDOs. The S&I Framework can also take a leading role in developing and implementing a systematic evaluation process of standards, post implementation. And then the S&I Framework should also continue to offer its resources Wiki, educational tools and others to support the initiative

To your question would you add or change any of the proposed S&I Initiatives, looking at the current list of staff assigned and community assigned initiatives I believe there are a number of foundational initiatives such as the data governance, data access framework, structure data capture, the need to reach really a point of completion soon in order to create value to the industry.

Other initiatives seem to focus more on a narrow specific set of needs of a single or limited number of stakeholders and other initiatives which have been going on for years, such as the EU/US eHealth Cooperative Initiative need to be revisited to determine their current status, value, deliverables and timeframe for completion.

Moving on to the process components of the framework “the how” one of the S&I Framework process steps that have been difficult to understand is the way in which new initiatives get identified, prioritized, and selected to be part of the Framework.

In the future making the identification and selection of initiatives an open and transparent process will be critical. This process should include defined governance and parameters for evaluating and selection. For example, creating an open process for submission of proposed initiatives via perhaps a Wiki and having them reviewed and prioritized by a governance board or governance group of balanced stakeholders could help establish a representative set of initiatives for the Framework to take on. Another important concern about the process of implementing initiatives is the role that staff and consultants play. While it always is valuable to have devoted staff resources to support and facilitate the implementation of an initiative having them lead staff and also provide product content plays against the active involvement and participation of key stakeholders. In some cases, the majority of the work, discussion, and ultimately decisions are made within a limited number of participation throughout the wide cast of stakeholders. Equally important will be to ensure that initiatives have a defined, time limited span, and not struggle indefinitely.

You asked “how would the proposed criteria developed by the Task Force have affected the S&I initiatives had the criteria been in place at the time?” I would only say that using consistently and systematically these proposed criteria would have meant that some of the initiatives would probably have not made it into the S&I Framework in the first place.

Along with my comments above regarding the need to refresh the purpose of the S&I Framework I believe and I would suggest considering redefining the framework process to streamline and simplify the steps and align better with the role and responsibilities of standards development organizations.

And then finally, with respect to products of the S&I Framework there have been many products, tools, services, resources, use cases, functional requirements, pilots and other documents completed and released by the various S&I Framework, some of them, as I mentioned earlier, have been moving to standards development organization processes and have to be reintroduced, vetted and balloted in some cases by the same people that helped develop them in the first place. Other items clearly reside in the S&I Framework repository or on the Wiki pages of each initiative.

Given the number of S&I Framework initiatives already completed and/or closed it would be helpful to conduct a more formal evaluation of those products and artifacts to identify the current status in terms of industry use and learn about possible areas for change and improvement. This also points to the questions about ongoing sustainability models...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Walter, can you wrap up, sorry.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Yes, I'm in my last statement. For the entire S&I Framework as well as the need for ongoing maintenance of framework artifacts and products already completed.

So, in conclusion I believe the S&I Framework has the potential to offer specific opportunities to advance development of the next generation of standards that support interoperability to ensure better understanding of its role avoiding duplication and redundancy and ensuring more efficient use of federal and industry resources and expertise the S&I Framework should refresh its purpose, redefine its process and make the identification and selection of initiatives an open and transparent process.

I would also like to make a final comment regarding some related work that the National Committee on Vital and Health Statistics is beginning to do. Under the Affordable Care Act Provision the Secretary designated the National Committee to perform a periodic systematic review of the standards and the operating rules being adopted and implemented for administrative simplification. I believe there is an opportunity to look and implement a similar formal review and evaluation function for standards being adopted under Meaningful Use and for Health IT purposes.

I thank you again for the opportunity to participate in the hearing and look forward to discussing some of these points during the hearing. Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Walter. And last but certainly not least, Clem McDonald. Clem if you're speaking you're muted.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

I am muted, okay, I lost minutes there. I agree with an awful lot of what Walter just said and I have sort of a lot of rambling thoughts and I may be the most sour person on this call. So, I've spent time in about four S&I Framework projects and the ones that worked best were the active community led ones and the ones that worked really well, the ones that already had sort of a model of something that existed they were tuning and that's the two laboratory standards and they based it really on what existed and they were tweaking it. So, I think starting from scratch and whole cloth they didn't work as well.

There are two kinds of problems with the other and one was indecisiveness, relative lack of work between meetings and the continuous recycling of the same issues and tediously processes. I've heard some painful stories about what people would rather do then spend time on this committee sometimes.

The big general problem is they last forever, participant interest lags, savvy industry participants is meager or absent possibly because of the time and the lag, people drop out and groups can be rapidly dominated by a few patient people with very special interests.

Further the designs never consider a burden of extra data input they may require nor the size of the development. The effort, cost and market demand seems to be ignored. And they ignore all the balanced requirements but I won't get into that.

Further, how the set of projects happen to be chosen and who and by what group initiating them and how they fit in the broader standards world and sometimes what they're even talking about can be difficult to understand.

Some have seemed to be stimulated federally but there is no labeling of this to know where they really came from and it's to the point of having some open process.

And then I looked at all the current standards and I can't really...that I didn't...I mean, the current initiatives, I can't really criticize them except it was so hard to figure out what was going on. So, the Blue Button Plus looked like it could be very interesting but it seemed very much like a CDA with some transport mechanism added and it seemed simpler in CDA so it might be better but there is no explanation or rationale or comparison, or sort of the environmental comparison, I think you really need that and with some specific examples.

The clinical quality framework confesses to do the same thing in a different way from its cousin another framework and I think somewhere it should be faced up that why are we doing both or which is...what's the advantage or why are we doing two.

The data access framework I couldn't tell whether it was related to SMART or how it related to the HL7 attachment query solution or whether they even thought about those things, they might have, it might be great, because I wasn't on them.

So, all these projects should be required to give a concrete example of what they are intending to be. I mean, a real example and show some awareness of other similar functions and why this is better or worse, why are you doing both.

There is already a requirement...I mean, for example the provenance is a really tough one to sort out, I know roughly what it is. There is already a requirement or a CLIA in present fields in HL7 carry where it came from so what's this difference, how is it different.

These abstract proposals that Doug Fridsma said yesterday, an abstract proposed for a standard is impossible, you know, that building a regular standard with concrete proposals is hard enough.

And then, I think I won't get into many of these other things. The US interoperability thing like a third order need compared to some other things and then I'm still totally confused as to why we are doing this medical record thing and interoperability and we mostly only looked at labs, I mean, there is not a little interest in imaging reports. What's going on? No one realizes it ain't a medical record if you don't have all those diagnostic studies in it.

The thing about structure data capture didn't look at existing simple widely used form generated such as REDCap which has lots of capabilities but requires only eight fields per question, I mean, it just started out to build a new thing and why shouldn't the alpha versions start out simple and build up from it.

So, I can't tell you more about these because I really don't know about many of them on the inside and I agree with the answers that Walter gave to most of the questions.

I think it gets to be...it's more work trying to get the S&I Framework...standards meetings and I would rather go to the standards meeting if I had a choice, I mean, I think it's almost squeezing out that time. So, we've got to worry about how much time it takes and how much overlap there is. That's all I've got.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you Clem and thank you to all our panelists. The first question in the queue is from Joyce but before we go to Joyce I just want to see if Stan and Arien have any questions or any comments before we get started?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

No, I'll wait my turn.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, all right, Joyce go ahead.

**Joyce Sensmeier, MS, RN-BC, CPHIMS, FHIMSS, FAAN – Vice President, Informatics – Health Information Management Systems Society**

Thank you. I have two questions specifically related to Walter's testimony but of course welcome any responses from the other panelists. And it's a two part or two kinds of connected questions. First of all, Walter, thank you for that great framework. I think laying the questions out in terms of the purpose or the why and the process as the how, and the products as the what was really refreshing and helped me to kind of frame it in my head in a different way that was productive to me. So, thank you for that. My first question to you is around your comments about using the S&I Framework to better align with the standards development organizations so the role and responsibilities of those groups and how this effort can work more in sync with that. I would love to hear if you have any thoughts about how that alignment might be able to take place more clearly and, you know, linking up the processes so that's my first part of my question.

And then really a similar question related to connecting the dots with NCVHS and the subcommittee on standards. I know there are a lot of parallel and in some cases duplicate efforts that occur within that body that I think you pointed to some synergies that would be there. So, those are the two parts of my questions and starting with Walter and open to others certainly.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Thank you, thanks for the question. With respect to the first I think there are really concrete ways that the S&I Framework can better align with the standards development process. The very first one is really avoid producing the type of work that is really the scope of the SDO itself. In other words, I think the S&I Framework it's the best part that it plays in the way I see it is sort of the investigative process, the pre-development process of the standard developing and understanding the use cases and examples of use cases, the functional requirements, all the elements that can help then the SDO actually perform its job.

And I think where it becomes confusing is when the S&I Framework actually develops a product that is referred to and known and becomes sort of a standards itself, an implementation specification, a document that looks and feels like is a standard in the hands of others and then that document has to be put in a process of the standards development organization so that it can be vetted and processed and so there has to be a lot of rehashing and reopening, and it goes back and forth in some cases the document is still being developed by the S&I Framework and at the same time is being developed or refined in the standards development process and you don't know what calls, as Clem was saying, you don't know what it calls to attend or to listen to try to address issues with this document.

So, it's a matter of aligning really the type of work that is done by the S&I Framework in the front end, as I explained, and defining and limiting the work to that type of work and then passing that information to the SDO so that the SDO can actually do the work that the SDO is best doing in developing the actual standards.

And then in the backend, at the end after the process really the S&I Framework could support the piloting and the testing of the standards. So, that would be my way of really thinking of a better alignment.

And then with respect to your second question about the NCVHS, funny I just came out of a hearing I was chairing yesterday a full day hearing on the review committee evaluation criteria, the evaluation criteria that we as a national committee will be using to evaluate standards that have been adopted just looking back and seeing we've been doing this for 10 years or more, actually more like 15 years, in the administrative world how are those standards working, are they meeting the purpose for which they were created and being used, what are the issues in the industry about those standards and so that kind of a process and those kinds of evaluation criteria can be used to do a similar job with respect to the standard being adopted for clinical messaging.

And I think, you know, we need to really better converge both the clinical world in terms of the standards that are being used in that world and the administrative world and not continue to pursue this sort of parallel work and so I'm very much in line with trying to bring together those two worlds and using both the National Committee as well as the Health IT Standards Committee working together to try to align better those two worlds.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hearing silence, do any others want to comment?

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Well, just, I agree with him.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, Mark Segal has a question.

**Mark Segal – Vice President, Government & Industry Affairs, GE Healthcare IT – GE Healthcare**

Yeah, hi, this is for Walter and, you know, others as appropriate and sort of builds on Joyce's great question and Walter's statement. You know you talk Walter about sometimes there is maybe perhaps a bit of a confusing overlap between the roles of a particular S&I Framework project and what an SDO does and I'm wondering if you might care to elaborate a little on how you would see those roles more sharply and productively delineated, thank you.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Thank you, yeah, I mean, I have tried to describe those in the statements and the way I framed them were basically...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

I'm not sure what just happened, did we lose Walter?

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Yeah, I don't hear him.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, it sounds like yeah we might have just lost him.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Well, hopefully, he'll call back in. In the meantime David Tao had a question.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Hopefully not for Walter.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Right.

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Could have been, sort of was but it was more like stimulated by one of his comments. So, I'll pose it to anybody and then I think it may just be something for us to tee up as a Task Force.

Walter raised the intriguing concept of S&I taking a leading role and evaluating standards post implementation sort of like, you know, how practical was this, you know, particular standard that was developed not by it but by the SDO and so it sounded like almost like an accountability or oversight, or at least evaluation separate from the group that produced the standard and I think we can understand the separation of concerns and the benefit of having someone not the developer evaluate the work.

He also mentioned though a formal evaluation of like the Meaningful Use Program of S&I. So, we as a Task Force...

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

I'm here.

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Want to evaluate S&I but I just wonder whether others...what do others think about some outside organization such as S&I or anybody else being sort of a formal evaluator of the effectiveness of standards.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Did we hear you come back Walter?

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

I'm sorry, yeah, I don't know what happened to my line, can you hear me okay?

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Now we can.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

I'm so sorry about that. And I don't know where you are in the discussion I was trying to answer the question but...

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

You didn't finish I think we wanted to hear it.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Yeah, so what I was mentioning is in many ways the process for, you know, for addressing a specific issue that has been identified through the S&I Framework there are a lot of steps and at the frontend there is a number of investigative steps that are the key parts that the S&I Framework can take the definition of user stories, the use case, the documentation, the identification of functional requirements even identifying what kind of standards exist to address the issue that is being asked about. All that investigative work, all that research work, if you will, can be performed through functions like the S&I Framework.

But when it comes to actually developing the standard, which is where the confusion in many cases come, I think that's where all that information in the frontend can be passed to the standards development organizations identified actually through that investigative process and have them be the ones that perform the development of the products because like I was saying, I mean, there are cases where the same product is being vetted in two different processes at the same time.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Hey, Walter, this is Arien, I'm going to maybe ask you to follow-up on that, because I'm wondering if I'm hearing a divergence between the last panel and this one and I just wanted to ask that question explicitly.

One of the hypotheses has been that S&I can be a place where more iterative implementation oriented work can get done in conjunction with an SDO or SDOs to standardize the working implementations. And it sounds like your...I'm just wondering how you reconcile the workflow that you just proposed where the S&I Framework might come up with a use case and the SDO develops the standard with the need identified in the previous panel for tighter feedback between implementation use and standards development.

And maybe you've got...maybe you believe that should get done in the SDO or maybe that's not an activity that you prioritized, but it seems like a very big contrast and I wanted to see if you had an explicit reaction to that.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Well, I would argue that when it comes to implementation there is probably a couple of aspects, one is you are implementing something that has been already developed and that implementation could be an implementation for the purpose of testing and piloting to see how the artifact that has been developed, in this case a standard for example, how would that work in a pilot environment. So, that's one part of implementation.

And then there is the actual, you know, production implementation once a standard gets adopted. So, I think, you know, my thinking is more about the role that a group or an activity like an S&I could play, it's more in the pilot of the artifacts that are developed by an S&I, excuse me by a standards development organization.

The implementation per se in terms of actual operational and production implementation will happen once some standard gets adopted whether it's voluntarily by the industry or through regulation. But, I see implementation in those two ways, really a pilot implementation or piloting really an artifact and that's separate from down the stream implementation in a production form.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

It sounds like you, just to summarize, it sounds like you do not agree with the approach that IETF and the OpenID Foundation work as presented by the last panel that you develop a standard in the context of implementation, you don't feel that's an appropriate role in standards development?

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Could I qualify a little bit. I didn't hear what you heard exactly from the other group, what I heard was you build the standard as a piece of software...

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Correct.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

That's separate from actually installing it and running it and testing it, which is what I thought Walter was talking about.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Yeah, exactly.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

So, another question and that would certainly control the excesses that people might wish to have if you had to build it first, but I think that they're separate, but Walter you ought to really respond.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Well, and I think the other question, this is Stan, I think you could agree with that strategy but not assign that as a responsibility of S&I.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Of S&I that's the other perspective that I heard...

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Correct, right, right.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

That's right. Did we lose Walter again?

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Yes that is correct, no, no that is correct, I was...I mean that is part of what the strategy would be in defining the steps and then who would be in the best position to take on those steps.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

So, then, let me...if I understand both Stan and your comment then you don't...you think it's appropriate to develop a standard in conjunction with rapid implementation, you would advocate for SDO processes that allow that rapid iteration maybe in close conjunction with an S&I Framework to tee up use cases and outcomes?

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Yes, I would say, yes, so long as we understand that the word implementation in that context is used within this aspect of, what are we implementing, are we implementing an artifact just to pilot test it or are implementing it as it's being developed to be a production type mode implementation, because I'm worried about, you know, moving standards that are not even piloted into some production environment.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

You know in that comment you used the word "rapid" and I know that's the new way to do it, you know, move fast, but I think it's a little bit of an oxymoron, you know, standards really don't happen that fast...

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Yeah.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

And I think that's been highlighted by the 20 year delay and some of the advantage, you know, IP4 was 30 years before...it still isn't replaced and I think some of the reason it works well is because it didn't change every two weeks. So, that's just an aside.

But I think it would be great if we could actually implement the "things" that we describe, it's a little tricky to install them, you need a bunch of places to install them and that's the real implementation. But I don't know how we do it. I mean, I think it would have a really leavening effect and everybody gets smarter if you had to build what you declared it had to be.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Thank you.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Anybody want to comment?

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Hi, this is David, could I...are we done with that question about the roles? I was going to try to reframe and narrow down my question. This was triggered by Walter's comment, but he was talking about S&I taking a leading role in evaluating standards post implementation and I wonder whether Walter or others felt does that mean sort of narrowly like, okay, S&I does some pilots and they do reports after the pilots about how well the standards did in those pilots and that would be their evaluation, but, you know, that could be very limited versus a much broader thing like, okay, not just the pilots but let's take any standard that comes out of, you know, S&I and goes through an SDO, etcetera, and then when it gets put into like MU 2 in a much wider scale and then they do some evaluation.

So, is it...did you have in mind, Walter and others, just limited to the pilot, evaluation post pilot or much broader evaluations when it's really in production?

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

I was...for the S&I Framework purpose I was just talking more about the pilot part. I was thinking that the activity of evaluating standards post implementation is an activity that is at a much higher level like at a Health IT committee level just like...and the reason I was bringing in NCVHS is because that is one of the functions that we are taking on this year for the first time stopping to look at the standards that have been adopted for administrative transactions how are they doing.

Now the Health IT Standards Committee, for example, could ask the S&I Framework to perform some post implementation, you know, let's say two years after implementing the Meaningful Use Stage 1 or the 2013 edition or whatever the 2012 edition standards let's look two years down the road how those standards are doing. That role, you know, could be the Health IT Standards Committee asking the S&I Framework to perform some evaluation steps of it.

But my primary suggestion was really about the S&I Framework taking more on the role of the pilot evaluation and then leaving it at a much higher level for a more formal post implementation evaluation down the road.

**David Tao, MS, DSc – Technical Advisor – ICSA Labs**

Okay, thank you for clarifying.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Could I just...Walter I like sort of that idea but I have a little bit of concern because the...is just a bunch of volunteers mostly and how do you get a reliable...I mean how would it work? You know where there is no expertise in evaluation necessarily residing in it.

**Walter Suarez, MD, MPH – Director, Health IT Strategy & Policy – Kaiser Permanente**

Yeah, no that's...yes, I agree, I think that function of post implementation evaluation, you know, has to take a different approach. The National Committee for example is looking at using various mechanisms to access the standards that have been adopted and are evaluating... are activities that evaluate different aspects of the standards.

Yes, I would agree that the S&I Framework in that role might not have the appropriate type of expertise and they might need...if that was one of the functions that they were to play then a different type of expertise would be required.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Well, it doesn't look like there are any more questions in the queue so I want to first thank all of the panelists and I will then turn it over to Arien and Stan for any closing remarks or comments.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Okay, so this is Stan, I would just thank everyone too. I've learned a lot and thought some new thoughts so it was time well spent today.

I guess if I were to summarize, you know, what I've heard the themes that sort of came back again and again is that the S&I Framework activities need to be clearly defined relative to what happens in the SDOs. And what people have proposed and really emphasized is that S&I could focus on requirements, use cases, identifying candidate standards that sort of activity followed by support for pilots and then evaluation, you know, of those pilots and other kinds of testing and activities, and that it really is...an important part of that work would be the prioritization of the work and I think emphasize that this needs to be a truly transparent process so that people understand why given projects were chosen whether it came as, if you will, because there was a need and funding from another government agency or whether in fact there was a groundswell from the user community that said this was something that was needed and so real transparency in that activity.

Also, you know, the thought that...I felt a lot of support and consensus around the ideas that were presented in terms of following a process closer to an IETF sort of strategy where standards are developed, implementation first if you will, and there seems to be...that resonated at least with me and so I don't know if I could say that's a consensus, I think...and I'm biasing it with my own opinion some here, but I think I really agree with that process. I would like to see that probably happen as an improvement in the current SDOs rather than have that be an activity of S&I.

And a key part of what I heard I think that also has value if we're trying to really get these things implemented is that implementation first coupled with, if you will, open source reference implementations is that gives a software base to people who want to be first adopters and actually try these things out in their institutions or in their organizations and so that...one way or the other whether it became some part of S&I's responsibility or part of the SDO's responsibilities that idea of rapid development and implementation first and sort of the standard following after successful implementation I think really has some potential value.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Stan, could I just...I think, you know, what IETF did was you had to have two reference implementations before you could have a standard, but I think in reality they kind were in parallel in a lot of cases, it wasn't necessarily first and I think that's...it's intrinsic to the SDO process it's not separable. So, I think if you're going to do it it's got to be in the SDO.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

But that's probably my quick summary of where we thought we were at and I'll let Arien give your thoughts Arien and then we can talk about next steps.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Right.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

I think where we're headed to is toward some recommendations.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

I absolutely endorse Stan your comments. The big theme that I heard today was struggling with tying standards development activity to implementation and also to clinical benefit.

We heard a really strong passion/plea from the first panel for how we tie not just standards development into working software but how we tie that working software into clinical and operational benefit to clinicians, provider organizations informed by or implemented by software developers that enable that kind of workflow and in many ways what this panel did was...and, you know, I think Walter's comments were illustrative to this, helped us situate the S&I Framework as a part of an end-to-end process and we need to be mindful of that end-to-end process by which the work that we do generates not just a standard but also working implementations that drive clinical benefit.

And I think with that maybe Michelle we should open up for public comment.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Well, do you want to say anything...

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

This is Michelle, I'd actually like to open up to public comment and then we'll come back and talk about a few other items for the group.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Oh, okay.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Is that okay?

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Sure.

**Public Comment**

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, operator or Lonnie, can we please open the line?

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

If you are listening via your computer speakers you may dial 1-877-705-6006 and press \*1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press \*1 at this time.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So, while we wait to see if there is any public comment I do want to note that we did include...there were a lot of materials for today's meeting so I just want to make sure that everyone saw everything. In addition to some of the testimony from the panelists and the Bio-Sketches we also included some background material from Gary Dickinson and we also included a summary of our previous meeting which I know a few of you were looking for.

And we do have a public comment so let me go to our commenter. Shelly Spiro. Just a reminder Shelly you have 3 minutes for public comment and if you could please state your name and your organization it would be appreciated and please go ahead.

**Shelly Spiro, RPh, FASCP – Executive Director – Pharmacy Health Information Technology Collaborative**

Thank you, my name is Shelly Spiro, I'm the Executive Director of the Pharmacy HIT Collaborative representing over 250,000 members of the majority National Pharmacy Associations and key pharmacy organizations involved in Health IT including the ANSI accredited SDO of the National Council for Prescription Drug Programs.

I've been involved in many of the S&I Framework Initiatives as a committed member representing the Pharmacy HIT Collaborative and its members. NCPDP's mission, the National Council for Prescription Drug Programs, is to provide a forum where they're diverse membership can develop business solutions including ANSI accredited standards and guidance for promoting information exchanges related to medication supplies and services within healthcare systems. This is mainly seen through, especially in the ePrescribing standards, through a consensus building process in collaboration with other industry organizations NCPDP members develop these solutions to improve safety, privacy, healthcare outcomes for patients and healthcare consumers while reducing cost in systems.

NCPDP provides a model forum for...especially with standards and interoperability initiatives related to the pharmacy industry and patient care related to medications. NCPDP played a significant role, a leadership role in the prescription drug monitoring program S&I Initiative.

As a member and an active leader in NCPDP it's important to recognize the successful NCPDP consensus operational and SDO processes in using this model as an example where SDOs can successfully lead S&I Initiatives including bringing in industry leaders to participate and implement pilots. Thank you very much for allowing me to comment at this time.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thanks, Shelly, and it looks like we have no other public commenters. So, just to conclude with the Workgroup, a summary of the past recommendations that were discussed has been included in today's materials, you might have to dig through, I think there were three batches sent but it's in a PowerPoint version and so hopefully you can find that and look through that and let us know if you have any concerns.

And then we are going to work on drafting a draft version of the transmittal letter and then we'll also need to discuss today's hearing during the next call and see how that can get integrated into the draft recommendations. Anything else from you Stan and Arien?

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Nothing for me.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

No nothing for me I'm good, thanks.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Okay, well, thank you everyone, especially this is a Friday afternoon virtual hearing, we took up a lot of your time, we greatly appreciate all of our panelists who took the time out of your busy schedules to share your insights with us and want to thank the Task Force members as well, every one of the members was on the call today, so thank you for that on a Friday afternoon and hopefully everyone has a wonderful weekend. Thank you so much.

**Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation**

Thank you.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yeah, thank you.

**Clement J. McDonald, MD, FACMI – Director, Lister Hill National Center for Biomedical Communications – National Library of Medicine**

Thank you.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Goodbye.

**Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare**

Yes.

#### **Public Comment Received During the Meeting**

1. Producing Open Source Software - by Karl Fogel, <http://producingoss.com/>