HIT Standards Committee
Final Transcript
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Presentation

Operator
All lines are bridged with the public.

Michelle Consolazio, MPH – FACA Lead/Policy Analyst – Office of the National Coordinator for Health Information Technology
Thank you. Good morning everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Standards Committee. This is a public meeting and there will be time for public comment before lunch and at the end of today's meeting. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. If you are tweeting today, the hashtag for today's meeting is #HITSC. And with that, we'll just go around the room to take roll and we'll start with Andy.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Hi, Andy Wiesenthal.

Wes Rishel – Independent Consultant
Wes Rishel.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.
Kim Nolen.

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

Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina
Anne Castro.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
John Halamka.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Jon White.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Steve Posnack.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Lisa Gallagher.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC
Floyd Eisenberg.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Leslie Kelly Hall.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
David McCallie.

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
Anne LeMaistre.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Eric Rose.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And on the phone we have Becky Kush?

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
Yes, I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Becky. Keith Figlioli?

Elizabeth
Hi, this is Elizabeth for Keith Figlioli. He's coming off another call, will be here shortly.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you. Jeremy Delinsky?

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.
I'm here.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Jeremy. Kevin Brady for Charles Romine? Anyone else on the line?

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare
This is Stan Huff, I'm here as well.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Hi, Stan. Okay, with that we'll turn it over to you Jon. Does mine work?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, yours is working.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Come sit with me, Jon.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Ah ha, ha, okay, that's better. So thank you. Normally I am more than contents…to have my comments be unheard, but I do want to share some news with you and I want to make sure that, you know, both you here in the room as well as the folks on the outside have heard. So, welcome to Washington, lovely spring day, no Cherry Blossoms this time, but it actually is one of the best times to be here in DC; so thank you for coming.

Been, of course, busy over the months, aside from our colleagues going to represent us in Latvia at the meeting of the EU and the US, thank you; I hope we hear more about that at some point. And an HL7 meeting of significance that also took place in the past week. There have been some things that have evolved here in Washington as well; some of them I am not going to talk about, for example active legislation, right? You all are well aware this is the kind of thing that we as public servants really don't comment on an active basis. I cannot stop the rest of you citizens from doing so, but I'm not going to offer a lot of thoughts and neither will Steve.

I do want to say though that, you know, regardless of what happens in terms of law and things that happen in Congress that the work here continues and until it's the law, as those of you who are fans of Schoolhouse Rock know, while it's a bill, it's still just a bill and until it's the law, it's not a law. So we will continue apace with our work and our focus and moving us ahead as a country in terms of the use of standards and Health IT.

To that end, we posted a blog post on HealthIT.gov this morning talking about how the Standards Committee gets its work done. We've had an ongoing discussion here as a committee for several months, longer sometimes in some cases, about how we generate the recommendations that get discussed here at the committee and get then forwarded to HHS and the Secretary in terms of the standards that are adopted. And historically we've been doing that work with standing workgroups and many of you have devoted heart, soul and body to these workgroups and have produced amazing work and we're grateful for it.

Recently we've also had some significant experience with task forces, time-limited focused task forces trying to take a look at particular topics of interest and trying to come up with rapid cycle recommendations for the committee to consider and to be able to feedback. And we've had good success with those and frankly, from you all, we've had good feedback as well. So what we like to do to

improve our operational efficiency and to a improve handoffs from the Policy Committee and a couple other things, we'd like to work on sunsetting the existing workgroups, the standing workgroups, probably by the end of June and we would like to move towards this task force focused approach to things.

You know, really it's, as Jamie and I were actually discussing before the meeting started, you know, it came…became more clear to us, especially in dealing with the NPRMs, okay, that are out there for your consideration. You know, a lot of meaty substance, hard to figure out how to divide it up amongst the existing workgroups in some cases, and being able to take a focused approach to things like the NPRMs I think is going to of benefit for everybody. It's hopefully going to be more efficient with your time as a committee, rather than having a meeting every other day try to be able to do our work in a focused way.

Also for public participation it's, you know, it's really hard for folks in the public to be able to engage in something that's, you know, literally there's something happening here and something happening there when they want to engage in the focused way. We've also heard that we need some better focus in terms of handoff from the Policy Committee. When the Policy Committee says, look there's some standards work that needs to be done here in a focused way; that it's challenging to do that in the workgroup kind of approach.

So with that, I'll stop and I'll say that, you know, we're looking forward to discussion with you about how we do this and some of the merits of what's in the existing workgroups that we can try to incorporate it in other ways. Whether it's the work here that we do on a monthly basis in the committee or in other ways, but that we look forward to this change and we think that renewal's going to be a good thing for us all as we move ahead. So with that, thank you very much for the comments and turn it over to my distinguished Co-Chair.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well thanks very much. Can you hear me now?

Multiple speakers
Yes.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, so as Jon had said, it's time of great change. He may not be able to comment on active legislation, but I can and so at 5:30 this morning I posted a complete review of all of the active legislation calling it flawed, dangerous and harmful. And what you have is some well-meaning people, and we all recognize there have been challenges to interoperability where interoperability means an outcome of coordinated care, quality measurement and achieving efficiencies. But, those well-meaning people are writing some of the pieces of active legislation don't really understand the issues.

Some of the things I pointed out in the blog are such things as information blocking; it's like the Loch Ness monster, often talked about but seldom seen. As it is understood by some these people writing the active legislation that if we have a hammer that says we are going to decertify vendors that engage in information blocking. My view is you're going to have a free-for-all of vendors making claims against other vendors through FTC, OIG and other means every time they lose a deal in a region. It's going to be a mess.

They've also suggested that we create standards to measure interoperability. Well I would love to know from all of you, what is a standard that measures interoperability, because I don't know. And such things as, gee, if we had a process measure of interoperability, I know, we'll send C-CDAs and count the number you send; that will achieve a good result. Well look at Meaningful Use Stage 2 and the number of folks who sent C-CDAs to themselves or to what I'm going to call electronic garbage cans as opposed to, let's measure care coordination, close loop referrals or some other positive outcome.

So as you read through that blog, you'll see I do enumerate some of the things in the active legislation that you can only hope that through whatever influence we can offer, that we try to explain to those who are writing it, our colleagues in Congress and anyone who will listen, there are some things that are true enablers for interoperability that we would require; policies that could be standardized across states, some reconsideration of barriers like 42 CFR Part 2 and the challenges that creates in sharing data, the SAMHSA restrictions.

Enabling infrastructure, what if, I'm making this up, CMS decided to host a provider directory for the country that was FHIR-enabled and queryable by any EHR; would that help us? Or a record locator service with a voluntary opt-in national identifier? Again, controversial points, some of them, but these are the kinds of things that would truly increase our capacity to exchange data in a meaningful way and not decertification, penalties for information blocking or the blunt instrument of legislation.

So I know that was controversial, but you know, somebody had to say it. If we find that there is legislation for which the Emperor has no clothes, somebody has to say that. Well that, with one kind of turmoil being legislation, whether it's the 21st century Cures Bill, the Burgess Bill, etcetera; we also have the change of 10 people in this group that are going to be moving off this committee. We also have these NPRMs with their 731 pages, and I know that was the raw original document…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Thank you...

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…needing to be pared back and so you've just heard from Jon this proposal to move to task forces and, you know, task forces can be used in very effective ways in some fashions, but, you know, would of course look forward to discussions in the committee and of cour…we'll have to think about how we fit this in the agenda as to how you think we should be best organized, especially after 10 of our members leave, to deal with the onslaught of well-meaning but misguided legislation, paring back the NPRMs and trying to ensure that we do no harm as we move forward with health care IT and interoperability. I think, we respect the blog you just posted, but there may be some dissenting opinions that we should hear about.

So today's meeting, of course we will hear from our existent workgroups and their reviews of the NPRMs where we'll hear about APIs, we'll hear about content standards, we'll hear about semantic interoperability and vocabularies, transport and security standards and from the implementation workgroup as to where there is burden and where we might be able to simplify and some of the NPRM language. Unfortunately, Liz could not be here because of a medical issue, but Cris will be joining us by phone.

So that was a long preamble…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
I was going to say…more exciting comments than you usually…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…but, you know, people say, I'm a pretty unemotional guy, but when you start to see things maybe going in a direction that is not going to be as helpful as it could be, you know, I think it's time to get emotional. So, maybe Michelle, before we actually dive into John Feikema's presentation, might we get some reaction from the committee to a reorganization of our workgroups or other statements that aren't on the agenda?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Yes, and we have a break, so we can take away the break if we have to.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Arien?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
Can I just…want to say one…I'm sorry, am I on. Okay. I just want to comment that as you're saying about 10 folks that are cycling off the committee because their terms have expired, we are looking to put…to replace folks and bring new experts, new perspectives on to the committee. So it's not like there will be a gutting of the membership, there will be a refresh and while we'll lose some of that expertise of folks that have been working collaboratively on this group, we will be bringing on new folks that have applied and that are interested in participating in this process.

So, I just want to make sure folks understand that we're not reducing the size of the committee, it's just that term limits are expiring and we will be bringing on new folks aligned with our FACA nomination process and approval process.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And of course, completely understand and respect that but it…two thoughts; pretty hard to switch out 10 people who have been here for 5 years and replace…

W
Six.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…or 6…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
But who's counting?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, you know, people like Dixie Baker, Dave McCallie, etcetera with equivalents because, you know when I was chatting with Politico yesterday and they said well, I am sure the Charter Organization that's stipulated in 21st Century Cures will bring new experts together in novel ways that will be agile. And I'm thinking, how many experts of the caliber of Dave McCallie and Dixie Baker do we have in this country; oh, that would be none. So yeah, completely agree with you, but their loss will be felt. So, Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, so thank you and I guess have two thoughts; I'm one of these people who's got a foot, I guess in both camps. I've been here long enough to have had a little bit of institutional memory, but I'm bridging over into the next class, if you will.

The last time we did a reorganization of committee structures, which I'd remind everybody wasn't that long ago, we had, I think, a relatively good process for articulating a set of mission issues and then soliciting the committee's feedback for how to address those mission issues. And we had relatively good participation and relatively good buy-in to that reorganization. That reorganization, I think was telegraphed well in advance, was discussed with members of the committee and members of the committee had, as I said, enough time to participate in that process to make useful and helpful comments that, you know, that led to the organizational structure that we have.

I'm not sure that we have enough experience in this organizational structure to say that there's a problem or there isn't a problem. I've got a significant concern about process; I don't feel it's, as I said one of the members who going to be continuing on, I don't feel it's terribly respectful to announce a reorganization via blog post that's of the nature that it is. I think it would have been a more appropriate and the past is the past, I think it would have been more appropriate to say…to have ONC come to the committee and say, here's a set of problems that we're struggling with, do you have…here's some suggestions that we have for how to affect that reorganization. Do you have any feedback or participation?

Some thoughts are that an organization by task force can be successful; I've participated in a number of task forces that have been successful in the past. An organization that is by subject area can be successful; I've participated in a number of those in the past. What tends to be successful, frankly, is the composition of the workgroup, the dedication the members have to the workgroup and some of the institutional memory that folks build up as they gain the experience that involves institutional memory about how the…what the role of the FACAs is relative to ONC. What the constraints are of legislation versus regulation? What are the constraints of the regulatory process? And it's hard for me to believe that we are going to have ad hoc task forces that are going to form with new blood every so often and build up that level of institutional knowledge.

I don't have a particular attachment to the existing workgroup structure; I think we've done good work in that workgroup structure. I think we've done good work in the past and I more am not happy with the means and way that this proposed reorganization has been announced and would respectfully suggest to my friends and colleagues at the ONC that there's a better process to follow; a process that first

addresses the substantive challenges that you may be facing and allows maybe more of a thoughtful discussion about what those challenges are and how best to address them.

I guess the final point that I'd have is that we do have a structure in the Steering Committee that was intended to address potentially some of the cross-cutting concerns that you've raised. And I'd suggest that we might want to use that Steering Committee more effectively to make sure that the interface between ONC and the Standards Committee is the most efficient for both parties. The work at the end of the day is going to be the work at the end of the day and you can't magically make that work go away by a change in the committee structure. You can't magically have fewer meetings by changing the committee structure.

So it might be that a more appropriate interface between ONC and the Standards Committee that enables us to get a better outcome would be more useful. But again, my ask back to my friends and colleagues would be, rather than announce by fiat a reorganization, rather announce or talk to us about a set of mission issues that you have and let us work collaboratively through that process.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Before we go to the next, may I…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes, please.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…sorry, I normally don't mean to jump ahead, but I thought there were a couple points, excellent points that you raised that I do want to address. So in the first, and for everybody else that comes after, genuinely, no disrespect is intended, okay? It's ahh, you know, I think that…I'm sorry if we…this was conveyed to you in a way that shows disrespect, genuinely not meant. It's…some of you I've worked with literally for a decade and many of you I've worked with for several years, you know, close to that and everybody here is excellent and does amazing work. And then going out further, the folks in the workgroup also do excellent and amazing work. So I'm genuinely sorry if there's been disrespect that's been conveyed.

You know, I think the perspective that we came at it with was the folks on this committee are just top-notch and do great work and we're looking…the committee is, we're not saying that the committee should go away, we're not saying that work outside of the committee should go away either. I think that looking back over our past year or more of experience with task forces, which include, you know, Arien and David and colleagues, you know, we've gotten really good results from those and I think it's helped move us forward in a really substantive way.

I think that there's merit to some of what happens in the workgroup in the…some of it the focused way and some of it in the institutional memory way, right, that you pointed out Arien. I think that we're open to that conversation, I think that I'm not necessarily saying, this is it, we don't want any more input from you about that. I think we want to hear that input from you about how we preserve some of the good stuff. I think that, you know, in terms of you all show up to these regular meetings on a regular basis, we

do too, you know, and not just Steve and Michelle and me, but a slew of folks at ONC and, you know, the experience that we've had with the task force has been really positive in terms of moving things out.

So, bottom line, number one, no respect…disrespect intended; number two, we are certainly open to that discussion and we look forward to having it here and then again in subsequent days and weeks to come. But number three, I think we do obviously clearly feel that need for substantive change so, and I think we can achieve it together. So thank you for the comments, they are well received and look forward to the discussion.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
David?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics- Cerner Corporation
I have just a jumble of thoughts, so they may not be all that coherent; but just to take advantage of this chance to comment. First, since I'm rotating off, some of this will be relatively unimportant to me in terms of personal activity, since I won't be in the committee. I'll miss that excitement of seeing what happens, but otherwise, you guys are on your own. Hope it works out.

But what I think has been striking or stunning in some ways to me through the six years that we've been doing this is to learn how incredibly difficult it is to get standards in place. And what I think you have to come away from it with is this realization that it's a really subtly complex problem that can't be fixed with brute force approaches and it can't be fixed with process-driven approaches. It's got to be fac…based on some kind of outcome driven model. So you will get what you ask for if you ask for good things and the markets and the processes that we have with the SDOs and the way things get figured out in the real world in an iterative fashion will work much better if there's a clear target that everybody agrees we need to get to.

If you take the other approach, which I'd say we've tried for the last 20 years in the standards world of essentially appointing a standards organization to produce a standard that you think solves a problem that you think needs to be solved, you will end up with the same mess that we've had with HL7 V3, for example, of 15 years of essentially not much progress, not much usefulness. And it's just a natural side effect of what happens when you try to make a standard in an open process where anybody who has an edge case can show up and put it on the table and get it on the ballot and get it nominated and pushed all the way through to the final standard.

That's just not how the real world works. And if we…if this new legislation changes back to that kind of a model, they'll have the same effect that we've had for the last 15 years of interoperability which is to say, a lot of pain and not much to show for it.

The…one of the most important meetings we had way back at the beginning was, a gentleman and I don't remember his name, who came from the insurance industry, the casualty insurance industry come and talk about that industry's experience with trying to do top-down standardization for the entire industry and what a dismal failure it was as compared to a bottom-up approach where a group of agents essentially got together and started creating solutions to real problems that they had, which then grew slowly over time to in fact encompass almost all of the capabilities that the insurance industry needed. And that iterative bottom-up approach, driven by real market needs worked; the top down approach cost them tens if not hundreds of millions of dollars and was a complete failure. And you can just see

that coming, if that's where this heads with deeming and of a charter organization to go and solve this problem. And if there's anything that you can do in the interim while that legislation is being figured out, to prevent that outcome, you will save yourself a lot of hair and…yeah, well…it needs to be focused on an outcome, it needs to be market enabled and market-driven. And it needs to be iterative and it needs to be proven before it's blessed as a standard and if there's anything we've learned from these 6 years, that's what we've learned.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well said. Eric?

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
So, I second Arien's comments in their entirety, so I won't…I'll try not to repeat any of them, but just ditto. The…I'm at a loss to understand why the current workgroup structure needs to be dissolved; I think it is a bit too early, it was just about six months ago when it was put in place. A bit too early to tell for sure how well it will work, but from the perspective of the Semantic Standards Workgroup, on which I serve, it does have the virtue of putting people who know about a particular area of standards in EHRs together and putting them to work on the questions that pertain to those areas of knowledge.

I would be out at sea trying to deal with the kinds of questions that Dixie is an expert on in the areas of security and she might not be as facile as I am on questions like whether NDC codes or CVX codes are better for representing immunizations. As…and so what I have seen in the six months that the Semantic Standards Workgroup has been in place is a lot of benefit from getting those folks together, focusing on those questions related to that area, and you're going to see and hear some of the output of that. It allowed us to be highly productive in a very short amount of time in analyzing the nitty-gritty details of the 2016 certification NPRM.

And so there seems to be a lot of benefit. I don't understand what the problem is that you're trying to solve by dispensing with this structure that has been put into place with a lot of work and effort. So it's perplexing.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Sure, this is Steve Posnack. So, you know one thing to note is that this was discussed earlier in November that we'd be moving to a task force model in the future. The presentation that I gave to let folks know, so, I mean, this has been on the committee's radar in general as an approach that we were looking to consider and pursue. And there's…we've had a period of additional reflection in terms of the operational efficiency.

We have 10 years of managing Federal Advisory Committees, this being the third including the American Health Information Community, the Health IT Policy Committee and the Standards Committee. We have a lot of experience in terms of how the back-end staff support to make this committee work, in addition to the workgroups, need to be done. And I think the experience that we have thus far has been that having…to continue to get your point Eric, I…focusing on particular issues and having to right people at the table is the problem that we'd like to have a firm solution to every time and by having standing workgroups, we may not have the finding the may not be finding the best fit talent for the particular problem that the workgroup needs to address.

So by having task forces where we can dynamically address the particular need with the right fit of talent on an ad hoc basis is something that we've, based on our experience for the past decade, found to contribute much more value to the type of recommendations that we're getting and the ability to get additional expertise. The committee as a whole remains and is the standing committee and is the institutional knowledge and experience by which those of you that are on the committee can participate as chairs of those task forces or members of the task forces.

The other experience that we've had with the current workgroups as they exist is that often you need to deal with an issue in its full context and just simply focusing on semantics questions op…absent the full context, and I know there's been some difficulty in terms of the challenges between how the semantics fit in with the content standards that the content workgroup has been addressing? And that's a staff and a group intersection challenge that could otherwise be resolved if the entire context of the issue were addressed by one group. And with standing workgroups, that's not necessarily something that can be addressed in a more dynamic or full way.

So we're looking to have an approach that allows an outcome, to David's point, or a problem be addressed in full by a set of experts together, having the privacy and security experts together with the group that's also dealing with the technical, potential clinical issues that other folks have the expertise. So that would be more of an interdisciplinary approach to the output as opposed to having issues being swimlaned and missing context for those particular groups taking it on. That's experience that we've found, in terms of the, I think, the depth and the breath and the body and fullness of recommendations that we've gotten out of the task forces that have been richer than in other cases where the standing workgroup has had a long agenda of particular items.

The other aspect, you know, to be quite frank is the longer out a current workgroup is looking, the less connected it is potentially to advice that ONC will be seeking. And so there's a little bit of an impedance mismatch, to use our usual lingo, of something that a workgroup may put on…a standing workgroup may put on its roadmap for 6-12 months out that doesn't necessarily align with something that ONC is going to be seeking advice on.

And the committee's job is to provide advice to ONC, so, our operational efficiency approach is to look for areas where we can be more nimble, we can support you in being more nimble, and to provide the right expertise from an ONC staffing perspective with right expertise assembled for a task force in order to address particular issues at the time that they're warranted and by which ONC is seeking advice. I think many of you have been part of either this committee or other committees where you put in a lot of time and effort and you don't feel like the recommendations have been fully address.

And at times that happens because the recipient of the recommendations is not prepared to receive them and has no process necessarily to fully intake and process them and execute on them because there…it wasn't lined up from a timing and input perspective; and so all of those things are little things that pile up from an operational administration of an Advisory Committee that we are trying to reconcile in real-time.

In addition to the points made earlier, we're going to have a membership change, too and that's not anything necessarily to shrug off. There will be a lot of members that will be transitioning off, we will be getting new expertise and people with other experiences in the industry and blending those together and I think creating an on-ramp by which we can create a dynamic approach to get people engaged with…paired with members that have experience from the committee, is something we're looking to

pursuing. If there's a need for a longer standing workgroup or for particular focus, then I think, you know, that's…if there is a word cloud being generated from this meeting, you probably heard us iterate the word focus more than any other word. That is what we want, discrete focus, on particular issues and in a finite amount of time where an output and a recommendation can be made.

And we feel that that can be best achieved through the task force model and that's really why the standing workgroups as they currently exist may be sunset, but that doesn't mean necessarily that semantics issues in particular, if we have a specific question there couldn't be a group stood up to take that on and we'd then, as I think Jon mentioned as well, there's a lot of talent that we've already assembled in the current workgroups that we'll continue to pull from because we know those folks exist, we know they have that experience and we know they've been through this process before. And so I think we've got teams of expertise that can be pulled from and I feel like I've kind of gotten into the point of opening monologue, so I'll shut up now.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So let me summarize everyone's comments on both sides of this issue, and I'll of course get to Wes and Dixie, don't worry; but just to do a checkpoint so far. I think what we've heard is strategy will dictate a structure as a structure could dictate our staffing and so in fact, focus; we all agree, focus really, really important.

Let's say, and I'll make this up, that the focus we believe is important to enhance interoperability is lack of a patient identifier, lack of enabling infrastructure like provider directories, lack of economic alignment, policy variation In states, 42 CFR Part 2; I mean, you enumerate some things that you say strategically are barriers. And therefore the focus is, we will streamline the NPRMs, we will accelerate APIs, we will create enabling infrastructure, we will move to value-based purchasing and we will simplify privacy policy in the states. I recognize that's more than standards, but let's just say those are the things you want. Then, oh okay, well then what are the structures we need to support those areas of focus and who should be in them.

And I think what you're hearing is sometimes those are going to be very tactical and you're going to have to have a multidisciplinary group come for a short time and give you a recommendation, but sometimes they're more longitudinal. And so I think what Arien was saying is form follows function and that is, if you gave us a set of requirements and then that clearly explained to us where a task force is useful or where a workgroup would be useful, then everyone would be happier. But let's…Wes and then Dixie.

Wes Rishel – Independent Consultant

Thanks. I'd like to believe that as one of the 10, I could position myself as someone as disinterested as a Jew at a Notre Dame versus SMU game; but I guess I have some institutional memory of my own. The…just a couple points; one, the futility of commenting on legislation, whether it's a law or whether it's a bill; if there's one thing I learned in six years here, it is what are the challenges that ONC staff works under? And part of it is working under existing legislation, knowing when there is one of those key points in time when you might be able to influence a bill and knowing when it's just a waste of energy.

Now how did I learn that? Why did it take so long? I learned it the hard way because staff isn't allowed to talk to committee members about the way the government works. So we never…we're always trying to read some level of context behind the specific questions that are being asked and recommendations

that that go forward and that takes time. And as you look at the turnover of 10 people and the necessity of taking them through storming, forming and norming, remember that part that some are going to come in saying, my God, all we have to do is say it'll be this way and put enough moxie behind it and meaningful use penalties and by God it'll happen. And other people will come and say nothing will ever work, you know, the government has no role…you might screen those out before they get here.

And I saw a flurry of activity and the card go up over here, so I want to make sure that I don't mean that staff can't tell us what's going on from the government's point of view that happens all the time and it's part of our education. What I mean is sort of the real context, the…even…there's just not even time to talk to us about the complexity of what it means to send a recommendation to some organization that doesn't have…that isn't in a position to accept that and things like that.

I…if I were to talk about one other thing that we learned the hard way, we learned through dialogue and would this work, would that not work with staff, it's the concept of levers. What is a governmental lever and what isn't? You don't come into a committee like this understanding that. And it's, in fact, a very shadowy thing, I mean, it's not even well-defined in written out law, it's a pract…it's the practice in terms of government.

I was fortunate enough to be a member of the Privacy Tiger Team, which had been formed after…the name Tiger Team implied there had been a lack of tigerosity in a previous effort, and we did some work and a particular stage was passed. And then we did some other work and then another issue came up and it took the committee chairs to remind the rest of…the workgroup chairs to remind the rest of the workgroup about the work we had done before. That is to say our own institutional memory at the workgroup level significantly changed how we addressed the second challenge, just to be consistent with how we had worked two years ago.

And if I have an overriding concern about losing institutional memory, it is at the sub-task level rather than at the level of the entire committee. I think that, and I haven't been one so I can…don't have to blush to say, we've had some great working group leaders in this committee and we have had some that have had the hard job of speaking truth to power or speaking truth to ONC, if you don't equate ONC with power. And particularly in the area of what is practical about certification, what is practicable about rollout, I mean ONC staff seems to, as a person, believe that a…to a person believe that a meaningful use set of revised criteria could come out and be adopted across the country in a year.

And it was the staff…it was the committee educating the staff and actually having the advantage to point out what actually happened when they did it that caused a better awareness of the non-governmental processes on staff side. And I don't…I fear that this focus buzzword will lead to a loss of the ability to reciprocate the exchange of information as you go forward. I seriously doubt that there's any point to this debate in terms of changing a decision, but I urge you to consider the institutional memory that you have at fairly detailed levels and not throw that away. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. Dixie?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Thank you. I was reading the blog from today and I noticed that this one sentence really jumped out at me, in light of recent experiences, we believe that a Standards Committee with targeted, time-limited

task forces will be a better way to get the expert and public feedback we need. And I would agree with Arien that it might have been better for you to bring these recent experiences to us because I really don't really know what they might be.

In looking back over my tenure here, and I too am one of them who is being transitioned off, you know, I think that the Security Workgroup, our contributions, I'm very proud of what we've done and I think what exists in law today would not exist in law had it not been for the subject matter experts in the Security Workgroup. Subject matter experts tend to be subject specific, they're not task specific and in fact, for any given task, ONC may not even realize they have security implications or privacy implications and need security experts to make a statement on them.

So I think that the value of the…and the same thing is true with, as Eric mentioned, with vocabulary; you may not even realize that you need a vocabulary expert on a given task. I further, speaking to Steve's comment, I think it will be more difficult for ONC to assign staffing support to task groups than it will be to subject ma…to subject-based working groups. So like Wes, you know, I'm leaving, I don't have really a vested interest in whether the Security Workgroup exists, continues to exist at all moving forward, but I think it's a serious mistake to abandon the subject matter focus for a task specific focus.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And I think we had Stan Huff and then Arien, did you have a follow up?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
I did, yes.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, so Stan and then Arien.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare
Thank you. This is Stan. Another aspect of this, I think, is a frustration I guess that I've felt that in fact the…a lot of the committee work seems like sort of a game of 20 questions; that is, we're presented with a series of sort of focused questions that say, you know, when should we use SNOMED versus when should we use LOINC? And should we use, you know, when should…what's the best role for FHIR versus CDA or, you know, each of you could come up with the right set of questions around security or privacy or confidentiality.

And one of the things that I've longed for is to get this brilliant group of people together for two days and say, what is the overall…what would we like the world to look like five years from now? Starting from the premise that we want to exchange data in a much better way, you know, I've just never seen a diagram that said the way this is going to work is that, you know, I'm working at my workstation and I want to see data that integrates across different institutions that are part of an Accountable Care Organization and this is how I initiate the transactions, this is how the security works as part of that, this is how the terminology focuses. What do the transactions look like? How do I know the address on the network for the people that I'm going to talk to?

It's, you know…what I'm I guess trying to say is that whether you have committee or subject…task focused or subject focused or other things, one of the things that I think is lacking is the ability, you

know, an opportunity for this group, brilliant group, to get together and lay out a vision of what it should be. I don't think it's covered or adequately addressed by the roadmaps that we've seen and other things because those have sort of been again created by committee and there, you know, the coherent vision at a level of detail that would allow you to pursue a truly new kind of architecture and a new kind of information flow that would be enabling for the country.

It…I long for that kind of discussion, you know, where we could have a two or three day retreat of the group rather than just essentially dealing with the issues that appear in a semi-magical form on our agenda and we tackle each one and I think we do it in the best way we know how, but I don't feel like it's attached to an integrated and shared vision of where we are trying to get to. And so I would just throw that on the table as another sort of perspective about what I think might be lacking in some of our deliberations.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thanks very much, Stan. And Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
There's a theme here, I mean, there's obviously a theme of institutional knowledge, there's also a theme of focus. And I think John said it very well, Stan underscored it, you can achieve focus through time and task limited activity; that will get you a very narrow and very tactical perspective. Or you can achieve focus through a tieback to a vision of the future, and elicitation and articulation of the steps required over time to get to that vision of the future.

And I very much worry that the proposed structure will get us into a very tactical and reactive mode and I suggest that over time, we haven't had nearly enough of the strategic input and nearly enough of the pre-work towards the necessary end stages. And if the workgroups haven't been functioning well with ONC in providing the strategic advice, I'd say that's the point that ONC should be thoughtful and respectful…reflectful about, which is how can ONC do a better job thinking through and tying back some of the long-term planning work that it has done, for example in the roadmap to understand some of the long-running activities that need to get done in order to be successful in the more tactical work.

So I would suggest back to ONC that if there was a focus area for reorganization it would be to better tie the work of this committee back to the long-running activities to make sure that we've established and thought through the prerequisites so that the tactical works actually significantly easier in practice.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Cent
And David, I think last comment and sorry Michelle, but this is pretty valuable discussion.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well thanks for that and running a little bit on Stan and Arien's thread; I think maybe the big flaw, if you look back from 10,000 feet at the approach that the FACAs as a whole have fallen prey to is the notion that you can separate the policy stuff, which is where theoretically the strategy is happening, from the technology stuff, which is what we're worrying about being overly tactical. And the reason I think that Wes had a good experience on the Tiger Team and I was on that as well and Dixie was as well, was because there was a 50:50 mix on that particular workgroup of folks from the policy side and folks from the technology side. And we were able to address thorny questions that are mix of policy and

technology capabilities in a rational way and make what are probably going to be in the long run, some of the most long-standingly useful contributions of any workgroup.

Those…so if there is to be a reorganization around focused things, I wonder if it applies also to the Policy Committee? And then I know that you may not have that authority and I don't understand all the details, but the degree to which you can mix the strategy that's driven by policy considerations with the technology concerns that constrain you as to what's doable and not doable in the context of given systems, the better you'll have useful outcome. So if there's to be a reorganization maybe it needs to be much more aggressive than the one that you've proposed; it should affect both FACAs.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

So let me try to summarize all of that and then, of course we'll seek the counsel of Jon and Steve, which is John Kotter, who I'm sure you've all read, our friend from Harvard Business School who tells us about how to affect change, tells us in order to have an effective change we needed an urgency to change. We need a guiding coalition of people. We need to empower people. We need a strategic vision. It's not that any of us are averse to change, and I don't think we made our comments about pending legislation just because they suggest eliminating this group.

We simply ask, what is the outcome you'd like to achieve and therefore, as I said, what is the strategy structure and staffing that will support that? So without creating too much burden on staff, I mean because again, that's the last thing any of us want to do, I mean might it be possible for you to enumerate a few focus areas so that then we can see, as David just said, the wisdom of reorganizing ourselves to address those strategic areas in a most agile way and that will lead us to an outcome.

And it could be that we have some focused task forces, but we still maintain some workgroups; like as Dixie said, security, maybe that's not the project, it's a process, that one needs, or Liz and Cris aren't here, but Cris, are you on the phone? He isn't, but implementation isn't exactly a project, it's again, it's a conscience, right? That's what they've always been, you know, taking that higher-level view of the impact of what we suggest.

And we hear you and that you want to be efficient, you have limited resources, you have limited time; we want alignment, we don't want an impedance mismatch. And I think if we see that goal, that set of strategies you want, that collectively we will all support change where change will improve the status quo.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology

So, I have three quick things to say; it's been great discussion. The first is to thank you for your excellent comments, I expected nothing less in terms of, you know trenchant, thoughtful and heartfelt, but genuinely heartfelt comments. So that's the first thing. The second thing I will say is that I feel the need to defend my colleagues at ONC a little bit. I've heard, you know I've heard everything you said and I think the intent is right. I think that, you know, as happens when people take positions that there is a subsequent discounting of the experience and thought that my very talented colleagues have put into this, you know, considered position that we've put forward. So, I won't say more than that. I just, you know, I think that to say that we don't know necessarily appreciate everything and that we don't think that things are necessarily connected in the way that they should be, I think discounts my experience over the past 10 years, but in a very focused way in the past six months with the folks at ONC.

And then the third thing I'd say is that I don't think we're actually that far apart, you know, in terms of, you know, I think that what I'm hearing you all say and what we've discussed at ONC, I don't think is far apart as we…the rhetoric is sounding like. So I will look forward to a good focused series of, huh, there's that word again, series of discussions off, you know, off of the public, you know, domain but then to bring it back at the next full committee meeting in June. So, I thank you very much for everything.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well great. Jodi, did you have a comment?

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
Yeah, I just want to make a comment. I've been listening to the comments that have come forward. I think Steve articulated sort of the thoughtful process and background and backdrop and history that we've had in thinking this through. And we do appreciate the concerns and I'd like to…and as Jon said, I think we're probably not as far apart, so let's think about, we'll take this feedback back as we're thinking through the task forces and how we want to organize them; we will take this feedback. I'd like us to, you know, we're going to try this approach, we will continue to evaluate.

We would like your feedback; if at some point it seems like we're really missing something, then we can always stand up a standing workgroup, this isn't, you know, we can…we're managing this as best we can, we're trying something that we've seen working and working well, both from a management and a recommendation standpoint. And we would like to, you know, we'd ask your patience as we try to do this and your support in what we think makes sense and with the understanding that we are…understand your concerns and we will think about that as we are trying to roll this forward and we can reevaluate at any point in time.

So, you know, thank you for this conversation. We do, you know, you all have wisdom and experience that…to bring to the table both in terms of the content as well as in how to organize and get us feedback that we need. And we appreciate that and we'll have our conversations as we're rolling this out and making sure that we're reflecting those concerns.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Very good. Well thank you for your patience.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And remember as we always say, when we make comments to you, they are purely out of affection.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
I feel the love.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
With that Michelle, here we are 45 minutes behind schedule and so two questions, you know, it may very well be that the presentations from our workgroups will be shorter than allocated, but I also would ask, and this is again call of ONC folks, is DAF presentation today something that is time sensitive? I just look at the themes of the rest of the stuff.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
I'll defer to Steve. I did ask John to shorten his presentation and he said that he could, but…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
I don't think so, they might be able do it brief; it was really more like the evolution of this initiative has reached its next stage where it's looking at the federated/distributed query work associated with DAF and wanted to give everyone a heads up per our prior comments about having more engagement with S&I activities and the Standards Committee. So, I mean, you know, we could give…we could do a 2-minute drill if you want or we can just go…move on.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well what I might suggest again, certainly defer to you folks is that we have a series of NPRM-related agenda items. We go through those; hopefully we make up some time and then put the DAF at the end. Now I again don't want to…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Why don't we see if we can do that?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, cuz I don't want to wreck John's day.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yeah, and the only thing that I would add is that DAF has significance for Precision Medicine Initiatives, which are moving rapidly, as you all know, because a lot of you have been contacted about them, so, ultimately it would be good to actually to have that…but I have no problems with the agenda change if John Feikema's available.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And so we know if John can change?

John Feikema – Coordinator, Standards & Interoperability Framework – Office of the National Coordinator for Health Information Technology
John's on the call. There are…I'm sure we can accommodate that. There are a couple of other standing meetings, DAF-related this afternoon with ONC folks, so we'll just have to be flexible with those.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
We'll do everything we can to make up time, it's just I thought that since I had heard that there might be a few comments regarding the reorganization that we get that discussion out of the way.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
(Indiscernible)

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Very well; okay, well, let us proceed then with David and Arien on their NPRM comments on APIs.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
All right. So we had a very focused organization around our workgroup where some of the long-running strategy work that we did was incredibly helpful in preparing our workgroup findings. So David and I are going to split our comments; I'll take the first section and David will take the second section. This is the membership of the workgroup. We had a really great and engaged set of members who provided a lot of the meat that's going into the comments.

So we first took on comment on the API proper section of the workgroup's charter and of the NPRM. A little sort of funny aside was that the first tasking that I saw, that was the one section that was missing, so we thought it would be, I think, appropriate for the API workgroup to take on some of the API activities. So we have a lot of very detailed comment in a transmittal letter and I'd encourage folks to look at the detailed comment. The summary comment here is sort of an abstraction of that transmittal.

First section, we tried to organize our comments in terms of findings and recommendations. So first in terms of findings, one is a general finding that underscores a lot of comments that ONC has received over time that APIs should be based on consensus-based standards that have sufficient production usage to be adequately tested and certified.

Functional API requirements accompanied by clear regulatory intent signals industry towards standards-based approaches; so again, just as reminder for folks, the API section, API access to a common clinical data set both for providers for certification and for patients both for certification and for meaningful use attestation takes a functional-based approach. That functional-based approach is…was actually recommended by a number of the workgroups precisely because we were in this odd time where many folks looked at HL7 FHIR and some of the SMART work as being really the target end state for certification; but where the certification timeline was not lining up neatly with the standards development adoption and production utilization timeline.

And so accordingly, a number of folks made recommendations that ONC adopt a functional approach to certification with clear signaling that there is a well-understood end state. So the workgroup was concerned that without adequate signaling and adequate regulatory intent that some HIT developers might take a shortcut and that it's important that those HIT, those health IT developers actually engage in the HL7 FHIR, the SMART and the Argonaut work, as well as the DAF work, in order to make sure that we end up with an interoperable standards-based approach for APIs.

So that's really the intent of the first two findings is, it's an appropriate step at this time because we don't have maturity, but that step needs to be accompanied by some clear interpretive guidance. The second or the third finding here is that we've seen a success pattern at public-private organizations such as HL7 and the Argonaut work, and believe that those organizations are the best places for doing development documentation and testing in the time frames.

So with regard to that, we recommend on the next slide, which I guess I need to click; we recommend that…so we endorse the functional requirement approach with appropriate interpretive comment and guidance from ONC that essentially puts health IT developers on notice and warning that future regulatory cycles will tie this requirement more closely or more precisely to certification approaches based on standards-based APIs.

There's been a little bit of a discussion and regulatory jujitsu set of comments about are there other ways to achieve the outcome that we're seeking to achieve? I think in terms of the regulatory jujitsu, this is indeed the best way to achieve the outcome, but that outcome will be best achieved if ONC in effect double underlines and triple exclamation points some of the interpretive comment that go behind the functional requirement.

The second major theme, and we've seen this come out in a number of HIT standards or Health IT Standards Committee…I'm trying to re…myself to say Health IT, Standards Committee meetings that sub-regulatory flexibility in a deeming-based approach might be a very appropriate measure for this…or a very appropriate target for this…for the certification approach. Such that if there are functional public-private organizations such as something more institutional out of the Argonaut project or other public-private organizations that provide appropriate governance and certification, it would be helpful for ONC to provide sub-regulatory guidance that allows those organizations to fulfill the terms of certification.

And again, just for memory and for comment, the notion here is that there are organizations like Surescripts for electronic prescribing, like DirectTrust for directed exchange; that perform very thorough certification that is…and provide a level of governance relative to that certification that is highly rigorous and is, in fact, more impactful in terms of the ability to deliver true interoperability in the field and in the wild than the respective certification approaches that are tied…that are more formally tied to edition 2014 or 2015 certification. We think that's a useful framework and think that should be applied. Jon, I see you have comments.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Point of…not working? Okay, thank you. Just a point of clarification, you use the word sub-regulatory; I just want to make sure I understand; do you mean sub-regulatory or non-regulatory because they're o…does that make sense? They're often used interchangeably.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, so just to be precise, I think the regulatory approach that allows for a wider range of certification-based approaches that is inclusive of public-private organizations data sharing arrangements and the like. I think sub-regulatory in that case is the right term, but I defer to the regulatory ninjas to set me straight.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Cool, thank you.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Can I…Arien, can I make a comment?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Arien has a way of packing incredibly important concepts into a sentence that's hard to parse because it's so complicated. So, I'm a much more simple and probably overly emotional way of speaking, I want to restate what Arien said so that nobody misses it. I think this experiment that is proposed essentially in a 2015 edition around the API functional requirement with the declaration of intent for the future, but essentially inviting the industry to respond and get its act together to meet that with a standard that can be tested evolved in the field before it becomes the regulatory handcuff is an astonishingly good experiment to go do.

And I commend ONC for attempting it and I think it'll be the most interesting thing to watch in next few years because is its successful; this is just such a much better way to do this than to pick standards off-the-shelf that have never been used or have been used in limited settings and then expect everybody to figure out how to make that work on the one hand; we know that doesn't work. Or on the other hand, to go create S&I Framework projects populated by consultants and limited interest stakeholders who go put something together that nobody's particularly interested in because it's not important to them.

Neither of those two approaches work; this, I think, has some real potential because it declares where you want to go, it declares what you think is the right answer and it invites the market to go figure out and prove that it's right or wrong. And by the time you get to the point of where you have to actually make it a regulatory requirement, you'll know whether they got it right or not because the market will already either be doing it successfully or will have thrown up its hands and said, this just doesn't work. So I really commend this approach and I think it bears copying. Let's watch it carefully but I like what you've done here.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Thanks for the interpretation; sometimes I definitely need the sub-interpretation. So the next slide goes through a number of more focused comments on the certification requirements themselves. We found in general that the certification requirements were relatively right on, but there were some areas where they were overly precise and overly prescriptive, in ways that could limit flexibility and attainment.

So the first is that there is a call out for "by category" API; so again as reminder, the certification requirement states that the common…the common clinical data be retrieved as a whole, formatted as a consolidated CDA and individually and that individual access is further constrained to be "by category," with the intent that I could retrieve the…all the medications for a patient. We believed in comment and discussion that that might be too limiting; we don't know if "by category" is the appropriate way. It could be that active med list is a more useful scenario. It could be that access to discrete medications is an appropriate scenario. And we believe that the regulatory intent is to allow each of the individual

discrete items that are available in the common clinical data set to be retrievable and that that should be the focus of certification. So we recommend that that work…that language be generalized.

We recommend that the XML or JSON requirement be removed. The intent here, I believe, was to clearly signal that FHIR might be a really good way to achieve that because it gets to the XML or JSON requirement by default. There are some transitional approaches that might be useful in practice, for example, a PIX query that allows for patient identity to be looked up via HL7 ADT V2 messages that may be useful transitional constructs as we get to full FHIR-based replacements for PIX. Likewise, if you look at where industry's going in general, things like protocol buffers and those other kinds of serialization formats have been useful in practice and wouldn't be achievable through in XML or JSON requirement.

Third, the as a whole common clinical data set specifies the consolidated CDA as the package; the workgroup believed, we understan…we understood the tie back to the other areas where the consolidated CDA is explicitly called out as a package. We believe that there's other approaches for pulling out the full record including FHIR-based documents, FHIR-based bundles of the like, that might prove more valuable than a consolidated CDA. So our…would recommend that ONC make clear that there are alternative mechanisms for achieving that outcome.

Fourth, the functional requirements for patient look up I think appropriately stated. We had a worry that certification bodies when they looked at that would only look at a demographic-based query approach. We believe that there are multiple means, we enumerate some of those in our requirements and suggest that ONC in its interpretive guidance and in comment note some of those means, not as an exhaustive list, but as a suggestive list to better guide certification bodies in constructing certification requirements.

Okay, on to the next page; here we, I guess pop back up a level into the…out of the very detailed requirements. Our first comment looks at the tieback between certification and meaningful use; properly speaking, we're going outside of our mandate, so providing hopefully helpful comment with regard to your colleagues at CMS. But it's our understanding that the way that the meaningful use requirements or attestation requirements are written with respect to patient access, you can meet the requirements either through a VDT portal or through an API.

We believe that in order to create the right incentive and right regulatory structure that the outcome of patients accessing their information should be the thing measured and that either of those activities should be enabling for achieving that outcome. That is, I should be able to deploy either or both or get credit for any if the patient access that gets achieved.

And last on the API requirements, the intent of the certification requirement is to certify the entire package as a whole with the intent that the developer experience be streamlined, that each of the co…the subcomponents of the functional requirement work as a whole. That's a laudable goal. We believe in practice that there may be configurations where the patient lookup can be achieved through data sharing arrangement, health information organization or what have you. The document lookup could be through a document registry and the API is discrete data access could be directly to the EHR.

And it's been our experience in past certification rounds that when certification criteria are bundled, it often creates strange alignment whereby if all I do is, so as an example, a selfish example but an example nonetheless, if all we do in CommonWell is enable look up of the patient and provide means to go directly to the EHR to get the document-based and individual discrete databased access,

CommonWell, in order to be a certified health IT module would have to go mock out some fake document and patient data lookup in order to get certified without the intent to ever use it.

We think that other organizations such as state-based health information organizations and the like would be placed in a similar position with respect to this bundling and we'd therefore recommend to ONC to unbundle, but make sure in terms of its certification approach and its regulatory intent that the intent is that that unbundling itself is modular. In most cases, the unbundling that's the most relevant is getting a patient identifier and using that patient identifier to either lookup a document or lookup discrete information and we believe that that approach can lead to meaningful modularity. Steve?

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Steve Posnack, just a quick clarification, maybe if I can be the David translator for you as well.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Perfect.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
So unpacking this a little bit in terms of practical reality an streamlineification, what you're suggesting is three certification criteria.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's correct.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
So for those that count pages and count criteria relative to the, you know, effect of the regulation, you know, it…this is a splitting and lumping is, you know, always something on which feedback is really appreciated. We obviously have experience with other criteria where we've split and lumped them before. And so in this case, the, you know, if we finalize that today, then there would be three criteria in a final rule as opposed to the one criterion that exists right now.

I'd have to think about the other implication, because it's…there's the kind of "API certification criterion" itself as…today and then it's basically replicated in the VDT certification criterion. So, there'd be ways in which we'd have to accommodate that kind of split. But the bottom line would be, you're suggesting a split for certification of, you know, a response…an API response to a patient identifier, an API response to, you know, a full document-ish thing…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's right and I'm…I guess I'm also suggesting that if it is lumped, you'll get the kind of strange behavior that we saw with…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Right, right.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…receive and incorporate or transm…send and trans…yeah, receive and incorporate was the odd one.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Does the flexibility of allowing different technical approaches to meet that kind of…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Correct.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology- Office of the National Coordinator for Health Information Technology
…response, but with the overall policy overlay that you can't deliver a product or solution that can't supply those three capabilities; even though they may be separately certified, they'll need to be added together cumulatively at some point.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
This is David's comment here. That was entirely our concern; it was not that these are unreasonable functions…

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics- Cerner Corporation
…it's just the different ways that one could imagine certifying them if you had to do them all in a single process was bewildering and was just going to create friction where no friction was needed. So, find a way to make the functional requirement meetable without overly complex certification testing, particularly given that you're not actually testing to a particular standard. In other words, you just want to say, prove that you can look up a patient, access detailed data by the API and get a summary by the API.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And then just in terms of aligning our comments, if the sub-regulatory approach is chosen whereby certification could be achieved by meaningful participation in a data sharing arrangement, that kind of stuff would come by default because you'd be able to certify the working practice of the health IT system in context of use.

So now we're going to move on to…oh, sorry, last one. I apologize. I do have more on the common…on the API set. So this was related to, we had a lot of comments on a very small line in the certification requirement that suggested that the document…the documentation for the API be available, for example, via…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Go...

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…I'm going to advance…via hyperlink. And the discussion that was enabled out of that was frankly policy oriented, so have the right caveats here relative to a Standards Committee Workgroup commenting on policy. But, we believe that the intent of the certification requirement is again very laudable. That a developer, whether that be, you know, the stereotypical developer in her garage creating the next innovative patient engagement application or frankly a developer aligned with a competitor to the health IT system in question, should be able to have unencumbered access or appropriate access to the API set.

We used the term FRAND in its fair, reasonable and non-discriminatory intent as the overall means. And we commented that access to documentation is but one of the means by which the API could be limited. There's also pricing, the use of terms of use and the like that can also be limited. And we also noted that those limitations can be placed both by the health IT developer or by the provider-based organization. In some cases, the means of limiting would be through the developer, in other cases the means of limiting would be through the provider with whom the technology is used. We also noted that API documentation could well be available by means of follow the respective standard as opposed to go to my specific documentation.

So we recommended on the next page that ONC look at existing developer ecosystem best practices. We commented on, for example, the App stores that are available that sometimes make their documentation for early access stuff behind a developer registration, but have been able to achieve FRANDish access, generally over time. So look at the existing ecosystem for best practices and collaborate with some of your sister agencies with respect to voluntary policy and governance practices that are sufficient to meet the policy outcomes. Again commenting that just access to documentation isn't likely to achieve the outcome that you're looking for.

Second is, and again referring back to our comments on data sharing arrangements, the best way to achieve the policy goals is through participation in open governance-based approaches that are working networks. And those working networks may well provide all of the safety and policy attainment you're looking for; so it would be useful to give again, sub-regulatory guidance to allow somebody to achieve the…this particular certification criteria through participation in one of those data sharing arrangements.

And last point, make sure that we allow…sometimes certification bodies can overly interpret and they may require that the health IT vendor scrupulously write every single word relative to the API specification, even if that is just a repeat of information that's already available through, for example, the FHIR-based API site. So make sure that there's again interpretive guidance that allows for this requirement to be met by pointing to the standard as opposed to rewriting all of the certification criteria and implementation guidance.

So I guess with that, now we conclude our application access to the common clinical data set comments and go onto the other items that we're tasked with.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, the clicker…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Which button is it though?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Oh, yeah, it's right there.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Good, on the right. Are we showing the right…there we go; okay, data portability. This will go a little bit faster I think. So we found that the criteria as written were a little bit overly prescriptive in the ways to achieve so-called data portability that added some complexity without just simply addressing the policy goals. And we felt that some of the functionality specified was not really tied to the goal of data portability and data availability.

So we sifted through that and came up with this list of specific recommendations. We thought that number one; it wasn't clear who could do the data portability, so we thought it would be worth cautioning that it be limited in some way to only those with appropriate authority to actually dump the data out on a patient. It's not open-ended for anyone who happens to login, but only with certain users with privileges to do that. We appreciated the focus on data summary documents that were listed; however, the breadth of every single CDA template available seemed to us to be overly complex and extremely difficult to certify because you wouldn't know in advance what templates were in fact required for proof that you could do it.

So we suggest given that the goal is to, in fact, port a summary of the record, the CCD would be the targeted certifiable document. Obviously someone could go above and beyond that if they wanted to enable additional templates, but as a certification test, the ability to dump out a CCD would be what we recommend as the target. We also noted that there were some places where the certification specifications suggested data value sets that differed in subtle ways, particularly around things like administrative gender from the data sets used in the core common clinical data set and that just struck us as unnecessary complexity. So we suggest cohering or sticking to the common clinical data set in all of these contexts when data is to be generated and exported from the record.

And then finally we were really quite confused about the listing of all the triggers that could cause data to be exported and didn't understand how that had to do with data portability. And then we had the helpful suggestion from one of our members that if there is in fact an API that the API could be used to address more complex triggering scenarios for data export and that the certifiable test be limited to something where a user could, in fact, without vendor assistance, export the CCD. And I believe that's on the next…hang on a second here…there we go.

So our recommendations would boil down then to notion that an authorized user should be able to export data without vendor intervention. At a minimum the export should be limited to the CCD, available on demand, even if that is a manual process and it should allow for some flexibility in the data. And the patients exported, it could be one patient, a subset of patients or the entire set of patients for that setting of care. And limit the focus to that set of constraints.

The next slide, we were asked to comment on the create and patient matching data quality mandate. We found these generally to be reasonable but had some specific suggestions regarding the specificity and applicability of the certification criteria. So our recommendations include that number one, it was possible to read this that you should only send a complete date of birth. We have found in the real

world that sometimes you don't know the complete date of birth and that we would encourage it to be clear that you should send what you have, even if it's not complete. Someone may know the year of birth, but not the actual month and day or they may know the month and year, but not the day; all of that information is potentially useful and shouldn't be discarded.

I think you'll see this as the general notion that we have here that I might call preservation of granularity; don't discard stuff that you know about the patient to simplify the matching process. For administrative gender we recommend the certification criteria should point to applicable sections of the C-CDA rather than to create enhancements and additions to that list; let's do it one way consistently across the board is essentially the recommendation there.

And then on the name normalization, we struggled with this a little bit. It was our experience with real-world patient matching systems that a good patient matching algorithm will tease apart the components of the putative name of the patient and look at all those components as adding potential matching power and that if you throw away knowledge you have about how the dat…how the patient's name was captured before you submit it to the matching service, you may, in fact, be discarding essential information.

So our recommendation is to basically don't throw anything away that you could possibly use to help facilitate matching. So this notion of pre-normalizing the data to the CAQH standards before sending it struck us as something better focused on as an implementation guide on the matching side rather than on the sending side. So on the matching side, you may in fact find it useful to transform to the CAQH subset of flex…of formatting, but don't send it…don't require senders to send it that way because they may throwing away information that they actually have that's relevant to the match.

So it was a little puzzling because what really was going on here was a specification…an attempt at a lightweight specification on how to best do patient matching and for that the CAQH experience may, in fact, be relevant but there are matching algorithms that are more powerful than that and you shouldn't preclude the use of them simply because you force the senders to match to the CAQH subset.

So, we also wanted to be clear that you shouldn't take the CAQH subset as a definition of what gets persisted in the actual legal record; that that should, in fact, be the full name that you may have captured in whatever way you capture it. So a distinction between the subset that might be used as part of a matching process from what's actually stored in the record; I don't know that I explained that very carefully. Arien, do you want to qualify my explanations there?

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

No, no, that's right on and then I guess the last piece is that the part of the CAQH core processing rules have a specific algorithm for splitting out a suffix, when it's included in the last name. It is a best practice and probably an appropriate practice for certification that if I enter it separately, it be sent separately and that I should be able to enter it separately, but…without constraining what goes on at the database level or what have you. But we also should remember that, as the saying goes, you can work really hard to make something foolproof but at the end of the day some fool will come in and prove you wrong that often what happens is the suffix is added to the last name field, even though there's a perfectly good suffix field. So, we believe the intent of certification should be to store the suffix separately, allow it to be entered separately but not to pre-split out the suffix; again, make that a receiver side activity.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, anyone who is a junior, as I am, who has to deal with the airline reservation naming systems and the TSA requirements around exact match of names will run into that problem when I'm McCallie Jr. is my last name to most of the frequent flier mile sites because they can't accommodate a suffix. And that causes all sorts of trouble when the TSA says your last name doesn't match your actual last name. So, preserve granularity, don't force people to concatenate fields together.

Moving on to the next topic, XDM package processing. We agreed with the spirit of this criteria that XDM packages should be certifiable to be processed correctly. Our problem was that the certification language points to the entirety of the IHE document, which includes many details which are probably irrelevant but which wasn't clear by pointing to the whole document. So we specifically recommend…we recommend specifically narrowing it down to the section that's noted here, 3.32.4.1.4 whatever it says which basically focuses on verifying the integrity of the components of the data captured in the zip file and ignores the rest of the surround material, which may not be relevant.

We also wanted to note that it was unclear that it might require that everything that got wrapped be presented to the clinician, whereas some systems do things such as virus screening and decide to not expand or extract certain things that might have been inadvertently packaged in the XDM. So we recommended in the language you see here that the certification criteria not inadvertently require that all documents, regardless of type or security risk be extracted, but leave that to the judgment of the implementer as to whether the contained material was inappropriate for extraction. So we basically are just fine tuning the certification criteria there otherwise thought that was a reasonable goal.

And then finally, healthcare provider directory; our finding was that with regard to the use of HPD as a standard for provider directories to work with has not observed sufficient adoption and production utilization that would be sufficient to understand what the criteria…certification criteria should be. So we found that this is premature at this time and recommended that ONC not include these HPD requirements of the final rule.

What we don't suggest here, but we discussed extensively in our conversations was that we believe provider directories is a good use case for the emergence of FHIR-based approaches rather than the senescence of the SOAP, SAML-based approaches. So to that end, we did a little experiment on our own to show that a practitioner record in FHIR, which is what defines providers, has sufficient query flexibility to in fact cover the essential requirements that would be covered by HPD and could be implemented quite trivially in code.

And to that end I implemented a little demo of a FHIR-based provider query against the NPPES database and showed that I could meet those requirements with literally under 100 lines of code, without any of the overhead and complexity of HPD Plus. So we recommend HPD is not an appropriate standard.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, I'll provide also some comment here. In our deliberation with respect to the roadmap into the framework that we presented and was endorsed by the Standards Committee, this is one of the areas that we discussed as being on the border. That is, we provided a roadmap framework for thinking about standards that are not aligned with core composables and orchestration patterns. And we commented that standards that are in wide use but not aligned with the long-term architecture should, in fact, be continued to be used with appropriate certification, that new standards be aligned with the core

composables and the orchestration patterns. And we acknowledged to that point that there is a cut-off point and sometimes a fuzzy boundary of that cutoff point.

With regard to the workgroup, the cutoff point that we're proposing is, if it's not already in enough production use that you would know what's…where the issues are and where you need to focus certification, it should not be included as a certification criteria. And I'd also note that this criteria that we're proposing for delimiting what should be and shouldn't be in certification is aligned with the S&I Task Force recommendations, which were also adopted by the HIT Standards Committee and presented to the National Coordinator as sort of the official deliberation of the FACA.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And if anyone is interested, I have a demo of what the FHIR…a FHIR-based practitioner query looks like running and I'd be happy to show it to anyone after the meeting.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well thank you very much for an excellent presentation. So just two quick comments; so David, the advantage of having the same last name as your father, when I was 18 my credit score was 850.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well I got, when I first asked for my credit report years and years ago when that law was passed that allowed you to get a free copy of your credit report, there was a big bold warning across the top that says, warning this person had an established credit rating before they were born. Okay? Fortunately my father's credit rating was better than mine, so that was a good thing for me.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So with your permission, I have sent the URL of your FHIR-based NPI scheme to Michelle that we might record for the members of the committee to take a look at. Just look me up, you will find that within 10 milliseconds, you will get the fact that my NPI 1497860456, emergency physician, gives you my Direct address implemented in one hour on a server in his basement using FHIR. And this is the kind of thing that CMS now needs to issue for the country. This is a real enabling, interoperability infrastructure.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yes, but does it have your genome?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well no. It also has my incorrect home address, by the way, and I need to fix that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah, that's the real challenge is keeping the NPPES database up-to-date, right? That's much harder than the…query.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, let's go through the comments and I know we need to catch up on a little time; so I believe Jeremy Delinsky was first.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.
Thank you. Guys, that was a tremendous presentation and I think you did a really great job parsing all of this. I'm compelled to make a couple of comments, and it might just be for intellectual tidiness, but I feel compelled to point out a couple of things.

One is that I think this whole API discussion kind of got started by the JASON report and I think that there is something very important that report said that we need to remember which is that APIs by their nature are propriety to the platform owner. And I think that we've identified really a really good public good here around the use case, but we previously also talked about things being a floor and not a ceiling. And I think it's critical that we continue to encourage deeper API exploration among EHR vendors rather than kind of end the journey here.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, very good point; thank you. Kim, I believe you were second.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.
Okay, thanks. Thank you all. I wanted to make a comment about the public-private certification process. I think it's important that this process be transparent and sometimes private entities have vested interest in other healthcare organizations that may push their personal business interest through the certification process and create a market dynamic that puts the standard, or in this case, the API in a bias platform. So the certification process should not be the place to put the name standard or API on a bias platform.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Any comments?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
This is David. I wanted to comment on Jeremy's point, I was just thinking about it and we moved past; so Kim, let me just jump back and comment on Jeremy's stuff. The JASON Task Force wrestled with the notion of proprietary API versus "public API." And I think we had a pretty good compromise in our recommendation which was that the public API, and by public we're talking about basically what's being proposed here in the certification rule, something that we required of the vendors to implement.

That it should include a core set of services that were, in fact, standards-based and applicable to everyone. And those core services would include the…basically what's in this certification requirement here; the problems, meds, allergies, etcetera, the essential data about the patient. But that a vendor not be precluded from going beyond that, preferably by using a built-in extension mechanism of the standard itself, but not precluded from doing additional services and offering additional proprietary services that would, in fact, differentiate one vendor from the other for market-based reasons.

So the compromise that we settled on was everybody does the core services using a core standard and then is allowed to add on top of that in a proprietary way if they see fit. And I think that covers both sets of needs, allowing for innovation and flexibility to do unanticipated new things; whereas…while at the same time ensuring that everybody can exchange the essential data about a patient using a standards-based API.

Jeremy Delinsky, MBA – Senior Vice President, Chief Technical Officer – athenahealth, Inc.
Yeah and I think that that threads it very well. I just think what we don't want to have out there as a conclusion is that proprietary APIs are bad. And I also think that we maybe should build on some thoughts that were raised earlier in the meeting; we've really identified a core national priority around the ability to exchange the core clinical data set and do interesting things with it. That…and it's a rather extraordinary length to go, I think, to regulate an API given the proprietary nature under which many of these started.

But I also think it means that it's not licensed, that we should be very careful when we go beyond this particular use. So for instance, while I'm incredibly supportive of this particular case and I think it's very, very important, you know, further defining and regulating of APIs to say make the administrative burden of CMS lower, not necessarily that's something I'm in favor of putting on the EHR vendors. And so I just think, appreciating the continued nuance of what opening up APIs to this kind of regulation means is important for everybody. But, I very much appreciate your point.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, with regard to Kim's comments; I think the proposal back to ONC is to provide a sub-regulatory mechanism. I'd anticipate that sub-regulatory flex…mechanism would have some requirements for who is and isn't able to be deemed for purposes of certification and I'd anticipate that some of those requirements might include the ability to be open to all participants, the balance of interest that's reflected. And I'd assume there has to be some process for creating that mechanism.

Really this recommendation comes out of, I think, some practical observation that if I go through the DirectTrust mechanism and get certified for Direct and I'm able to get green checkmarks all along the row in terms of my ability to interoperate with other HISPs that are out there in the wild. That's actually improved my ability to interoperate in practice whereas my experience going through the certification process was that it was a compliance-oriented check the box and didn't practically improve interoperability in the wild. I had very similar experience with respect to certification requirements for electronic prescribing.

And I think we found in the work that we've been doing in Argonaut and the work that some of us have been doing with respect to CommonWell, that it's that interoperability in practice and in use that drives to broader interoperability. Definitely understand Kim the point that you're making that it would be the wrong policy to let any public-private organization certify for anything. There needs to be some respective balance of interest, some respect for ability for that organization to be open to all players who are relevant.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
It's Jon White; I have a quick point of procedure. Please keep the comments coming, please try to make them focused; we're at 11:20 a.m. and we…you know. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes, we're going to do our very best to manage getting us to lunch eventually. So Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
So first of all, I thank you very much; it's clear that you had both the current ecosystem in mind and the patient being added to this as you made your comments. I think the single most important thing that you've said that will help with market innovation and with patient participation is the…an authorized user should be able to export data without vendor intervention; that so important to both existing health IT ecosystem and inclusion of the patient. However, I would add that the ongoing changes, as changes happen could considered in your recommendations on the export functionality. You indicated it's available on demand, but even if a manual process. I think there is opportunity to be able to say, when changes occur that that would also provide update rather than requiring new manual processes to be considered.

And then I had a question on, if you thought through the new players that would come to the market who may or may not be a current certified EHR because they're not in the data collection business at that EHR level, but will be in the data collection level from the patient in the future that would want to participate. So I think the Apps will often be not certified coming from the world that is just free market and consumer driven, but their ability to import data into that next use case, which is bi-directional coming from perhaps that new world. How do you see that playing out with regard to your recommendations? Or do you think that's a future need not yet to be addressed?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I'll comment on the trigger question. I mean, our concern was that the requirements as written were so open-ended and vague that it would be untestable.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Okay.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I mean, which triggers? What subset of the data? What differential data determined by what rubrics sent to where? Measured by whom? I mean, it was just so vanilla open-ended that we couldn't envision a way to certify it and suggested that if people want to develop approaches that do provide publish and subscribe kinds of updates to a record that the API would be the way to do that and would be built out by people who could, in fact, address all those thorny questions. It's just not a certification.

Leslie Kelly Hall – Senior Vic President of Policy – Healthwise
On the Apps side, but not on the API side; okay.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right, it's just not something that you're going to do with certification test; it's just too open-ended.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And Wes, you're the last comment on this topic.

Wes Rishel – Independent Consultant
Thanks. We had one of those ah ha moments where we on the committee got to see issues that staff deals with in writing regulations where Steve asked, well how many criteria is that when David said we want to separately regulate…separately certify three steps in the process of doing a query. I just want to emphasize the full extent of the bilateral exchange on that information which is that the principle behind what was suggested here about independently testing those three portions of the API rather than constructing a single or a set of dozens of complicated scenarios is really critical to the whole direction that FHIR is going.

It's not just a matter of convenience. Borrowing Arien's term of regulatory jujitsu, there must be some way to write a regulation that requires that independent testing while calling it one criterion. And I wanted to emphasize that this is…the importance of this particular principle and the worthiness of a black belt jujitsu artist on the regulatory site is supported.

Whenever we care…whenever we talk about interoperability with regulations that come out of another FACA, we get into another set of interesting issues. And the issue about CAQH which by its…which just comes out of the HIPAA FACA and by itself does have a balanced process but nonetheless has focused over the years on the administrative transactions that CAQH might require some things that are convenient for payer systems but limit the opportunity, such as the ability to get the full information through the data format to do a better query in another clinical system. That's a very hard balance to achieve and people tend to look at data formats and say…and imply a bunch of functionality for it.

So I'm sure there will be discussions about, should the data format be exactly the same as what payers require? I think it's really important to recognize that the data format does not imply process that it's possible to have a data format that has more information than the receiver's able to deal with and that's a normal and acceptable way of writing standards. So again, even though it sounded like a…it could have sounded like a minor thing, I want to emphasize the importance of that statement.

Finally, we had discussions about private versus public APIs and the particularly very well…very strongly endorsed, and I agree; process in these regulations in terms of letting 1000 private APIs bloom to some extent before producing a public APIs. Just want to emphasize that probably the most successful in terms of adoption specification in healthcare IT formats is probably HL7 Version 2 ADT. And that was exactly the process that HL7 went through. It had a bunch of sites and vendors that implemented ADT interfaces, got together and shared their experience and created a union of the data elements they were interested in and that went forward. So, when you get down to the wisdom of the current approach in the draft regulations, there's evidence to point to that that approach really works. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. So Michelle, I believe we have a transmittal letter that incorporates all of the suggestions and listening to the comments, I did not hear a need for substantial revision of any of the aspects of that transmittal letter. So let me just ask the group, based on everything that you've heard, are we okay with sending the transmittal letter; any objections to that? Well thank you very much, excellent presentation.

We now need to catch up some time and we do have, here's my proposal Michelle and it depends a little bit on the blood glucose level of the people around the table, that we allot no more than 40 minutes for each of the two next discussions. We then have a 40 minute lunch followed by two 40 minute afternoon presentations and we defer John Feikema to the next meeting. Okay, so it's a balance of your blood glucose and getting these things sent to ONC in a timely manner because we want to be at your side and well-aligned.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
But if somebody took less than 40 minutes, that would be okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Oh that would…yes, indeed. So before Rich and Andrew began, one last thing I forgot to ask for approval of the minutes at the beginning of the meeting. Were there any edits, revisions or comments on the minutes? Okay, none being heard, Michelle, your minutes are approved. So let us go forward and Andrew and Rich.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
So we're going to save a lot of time, okay? We've made an executive decision amongst ourselves that it's not really important for us to go to the detail; you've all got the detail. What we're going to discuss are some overarching themes. I just want to thank the diligence of everybody on the workgroup. We divided into three…committees of three to do this work and they were very…those three groups were very diligent about moving forward.

So we don't have any showstoppers that we found in any of this, so there's nothing to be seriously worried about, but a great deal of very detail commentary that you can see and some themes that we want to elucidate for you. So Rich is going to start with the next slide which gets at the thematic approach that we're taking. And that's who participated.

Richard Elmore – President, Strategic Initiatives – Allscripts
Okay, great. Thanks Andy. And I also just wanted to recognize Michelle, Matt and Mazen who…from ONC supported this workgroup and really did all the hard work of taking the expertise from the teams and making it transparent to the Standards Committee. So wanted to start by reinforcing the idea of focus; the workgroup felt strongly that having a singular focus on consolidated CDA, which is already has some traction through the work that's been done in preparing systems for Meaningful Use Stage 2 is important to being able to get interoperability at scale reasonably quickly.

And so the recommendation of the workgroup is to focus exclusively on that, not to complicate it with 1.1 to 2.0 exchange, not to try and cover every template that's out there, but to try and create the grounds for success through simplification and deliberate actions that move us toward being able to have document exchange that will work. We're recommending that a limited set of templates, those for CDA, those for referrals and for inpatient discharges be the templates that are focused on.

We recommend that the complexity of the asymmetric bilateral exchange, if I got the terminology correct, Wes, is probably impeded by some of the problems of vocabulary change between versions.

And there's also a limited time of overlap recommended the rule which is sensible, as opposed to letting it go longer; our recommendation would be not to try and do it at all. So that's really the first point. And then of course, to ensure that we have a consistent set of transport standards, Direct project, to accomplish that.
So number one, we think that's important. Secondly in reinforcing a lot of the work that came out of the API group, which we're very supportive…the workgroup is very supportive of, we also felt that it was very important to specify FHIR as the API standard. We went so far as to say to specify if it's successfully balloted, I mean, there was some nuanced discussion earlier which we would say we are supportive of going as far as ONC is able to go in terms of making…encouraging consistency amongst health IT developers moving forward.

And we thought it was right the way the rule was put together to have a lower bar for the certification around basically requesting information to be read-out from a system rather than getting into some of the more complicated areas. And as a result of that, we think that there are several standards that were in the rule that should be rethought in light of the API and FHIR evolution or revolution, which includes our approach to clinical decision support and also to care planning.

We saw…the workgroup saw many standards requirements that are going to have really significant beneficial impact on the health care system, so we just wanted to call those out and just say that clinical quality measures, common clinical data sets, updated SNOMED, quality reporting and API all important, endorsed by the workgroup.

A consistent theme was that for those which are evolutionary standards, it's important to move to the latest versions, which where we benefit from the learnings from earlier versions and while there could be debate about relative maturity of those latest versions. We viewed those as evolutionary rather than new and immature and worth ONC trying to get us to a point where we have the most…the latest version available.

There's also some comment that it would be helpful to think about what is the process for as corrections or improvements are made to those standards? How can we be nimble and flexible in adapting to that change? This kind of goes in the face of some of the constraints of regulation but nevertheless if we can find a way to encourage the community to stay current with reasonable updates to standards that have been adopted, that will be helpful.

There were also standards that were identified where it was thought that the requirement would be quite impactful and very important, but there was refinement needed including the identification of food substance reactions and intolerances, also lab and med order entry, some of the details are in the supporting documentation for workgroup and I won't go into them here.

And then I believe we've been asked as a workgroup to come back to you on June 11, I don't know whether that's a call or a meeting, but to come back to you with a list of standards where the workgroup believed that the level of maturity of the standard was not yet ready for prime time. We wanted to signal to you now what we've learned from the feedback from the workgroup so far. And those included clinical decision support, data segmentation for privacy, electronic sending of medical document requests, virtual medical record, quality improvement and clinical knowledge data model, which is otherwise known as QICK and electronic delivery of service, which is also called eDOS.

There were also a couple that were recommended both formulary and benefit standard where there may be an alternative…preferred alternative of real-time prescription benefit. And then there was also a consolidated CDA care plan template where the recommendation was to consider, and take a step back and consider a model, and HL7 model which would support more dynamic care planning rather than more of a static document approach. And we thought that that in the long run was important and more beneficial if the industry would take some additional time beyond the rulemaking cycle we're in now.

And then finally there were a number of places in the rule where there were discussions of testing requirements, gold standards and so on which we are very supported of; the greater clarity that can be given to a health IT developer about what is going to be successful and is going to pass certification we're all in favor of. The problem is one of timing. So if it comes before or with the rule, it's great, it gives the developers time to react to it; when it comes later, it causes rework and additional consternation, I would say, from the developers. So we just encourage, as much as possible, to the extent that ONC can get us to that place where we have that up front, I think it will help the industry rather than create any rework.

And I would just say in general that the workgroup felt…that work that was done in the proposed rule was excellent. That the generalization to health IT from EHR focus was appropriate. There was a cautionary note that some cases requirements really still were more EHR-to-EHR versus…but when you generalized health IT, there may be some that don't apply in the same way; so you need to think about use cases in certain cases. And again, that's in the detail of our notes. Andy…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
And again we were going to spend more time going through the detail, but in the interest of everybody's sanity and glucose levels we will stop here.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
That was focused ninja jujitsu. Well done.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So, a couple of comments; some people have asked me on the Argonaut Initiative, is there an ongoing body of work because the Argonaut Initiative time-limited activity designed and focused on a single deliverable. The answer is that you have told us today that there is going to be an advantage of using FHIR-based constructs to replace some of these other kinds of standards that either are not ready for prime time or architecturally don't make sense…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Right.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…in a world that's Web services oriented. And so, on May 28, there will be a vote of the Argonaut group regarding funding and continuing its activities for a second round of such thing as, CDS support, write

back support, care plan support; all the things you enumerated. I think it's highly likely that that will go forward, so yes, there will be additional focused work to fill some of those gaps.

I think that June 11 meeting, which is a call, is also going to be very important to signal that there are a series of standards that are too early to prescribe at this time. And I think Dave McCallie said it very well that if you are at a point in history when you're seeing rapid evolution of technology, do you really want to put in concrete the use of EDI when the Apple watch has just been delivered; umm, probably not. In fact yesterday my developers demonstrated to me telemetry gathered from patient homes on the Apple watch being sent into our electronic health record, and of course, that uses set of APIs, SDKs, OAuth, FHIR-like stuff and not any of the standards that you have enumerated here which aren't quite ready for prime time.

So we want to be really careful and probably as David has said, in some of these areas where there's immaturity, let's actually be less prescriptive and more functional and more outcomes based and when the industry has demonstrated its stuff things works pretty well, then we can put it in regulation. So I look forward to that discussion. Well a number of cards went up; I believe Floyd, you were the first.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC
So thanks…thank you. Just, in our sub-workgroup, well, just to reiterate, we didn't want to indicate that just stop moving forward with decision support and quality, but more continue to let the industry evolve and the standards evolve and to continue to support that evolution. It's just that the standards that are there are still in development, as Rich said, even the QICK, which is the data model is still not even balloted, and that's what these others are based on. So, it would be real…and the FHIR quality profile is only partially balloted; so it's really premature to think that these should be incorporated in a rule at this time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And so I think one of the great challenges, and this is again the affection for ONC, is they of many federal agency customers that would like to see these highly prescriptive, not quite ready for prime time standards used because it will make their lives easier…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…your customers.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, I know, but I mean so you have this really impossible task which is on the one hand, we tell you in some areas be prescriptive, but in others don't and you're going to alienate some stakeholders because of such a statement, but that's the balance we have to strike, so well said, Floyd. David.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Uh yes, thanks. I agree with your recommendations and the list of things that are considered immature. I want to just add the note of caution that just because a standard is listed and is currently immature doesn't meant that there's a guarantee that it will ever, in fact, become mature.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Um hmm.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Some of these standards, I think, may in fact be replaced by better approaches that leverage this orchestration model that we presented last meeting around weaving together the APIs to achieve things where you don't and need to invent something new, you just really need to script what you can already do with the core APIs.

So in particular, the clinical decision support as a service, Josh Mandel and I are working on a project to surface some models to extend the current pluggable App model to accommodate clinical decision support as the service and it's very premature work. We've talked to half-dozen content service providers who want to integrate with EHR vendors and have challenged them to restructure the way they expect to do their interoperability with the vendor community using FHIR and OAuth and the SMART App as a way to inject a conversation, if you need the conversation.

And so far it's been extremely positive and actually sort of eye-opening when confronted with this different approach, they are excited about the fact that it actually opens up new opportunities rather than limits them to some specific set of VMR-defined data migrations and things like that. So, I totally agree that these are not ready for prime time; some of them may not even be ready to be finished, ever.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
In relation to your comment on CDS, my own opinion is that the specialty societies are the real place where the game is going to be played if they ever get their act together. And if they have a way to do it along the lines of what you just described it will be a lot more straightforward for them to continue to update guidelines…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
…and decision tools that their specialists can use. And by the way, I looked myself up and my address is also out of date, so…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, you better go fix that.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
I better go fix that.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
No, and I think that's exactly the point, I mean, if we have a common orchestration like the pluggable App orchestration, there's no reason not to assume that there will be hundreds if not thousands of Apps

that could emerge over time because the common capabilities are so powerful you allow the innovation to just plug-in and use it.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Um hmm.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And the same could be said for the clinical decision support orchestration; it could be made simple enough and robust enough because it has the access to the FHIR services for when it needs additional data and it has ability to push a conversation in front of the clinician with a SMART App when it needs to talk to the clinician that you could achieve essentially an unlimited number of decision support capabilities with a very simple footprint on the vendor's side. Very simple, it's a separation of concern if you push the data that you need definitions over to the requester side rather than to the sender side, it really simplifies and opens the door to that exact kind of capability where a society could quickly put together guidance and deliver it to the vendors and the vendors wouldn't have to do anything, other than add them to the white list of acceptable sources.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. Leslie.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I would echo David's comments. The Info Button, that little teeny App or standard has been used a gazillion times to get a common query and I think I applaud that that was part of the recommendations on clinical decision support. But I do think the emphasis should be on using a common query approach and using a way to get it back into the record. The actual decision-making tool itself doesn't…is content, it's updated constantly and the ability to have standards that define the artifacts inside of a clinical decision support tool seems very premature and not necessarily useful.

However, potentially certifying developers so that we have the knowledge that things aren't biased by commercial interests, that there is some sort of process that assures that the creation of those decision support tools are done in a mindful, responsible way that serves the public is one area that could be considered. And I wasn't sure whether your group talked about that at all as a way to somewhat mitigate the concerns of having decision support tools be willy-nilly.

So, I'd like to hear if you discussed that at all or your thoughts about that; but definitely support David's approach. We also…I'd also like to just comment on your specificity that not including the patient in the design of decision support is very limited and narrow minded and so thank you for that.

Richard Elmore – President, Strategic Initiatives – Allscripts
If I may, Floyd led the group that was responsible for looking at that. Would you want to comment?

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC
Yeah, so two things; one is, the group did make sure to indicate the patient has to be part of this and they were strong on the comment that this seems very provider-centric and it's not just providers who need decision support. As far as the prematurity and perhaps standards that may not go forward, we didn't actually address that specifically, but that certainly is something to consider.

Within the standard development at HL7 around decision support and quality, there is a metadata section that all quality related and decision support related standards is best to address and that does have some of what you're looking for, but it doesn't have the grading. In a sense a grading mechanism for which is a higher level or lower level, but it does have some concept of where did it come from, when it was last updated, what is the supporting evidence and that is in the metadata that's already been balloted at HL7.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
But I think Leslie you're talking about some kind of curating of the actual developer and that's a very…

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Right.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
…we didn't talk about…I don't think we talked about that and it's a very good idea.

Leslie Kelly Hall – Senior Vice President of Policy - Healthwise
Because otherwise you just cannot predetermine content…

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Right.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
…it changes too frequently.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Right.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So thank you for the summary. There's actually a lot of gold in the comments and I would encourage people to read them. I actually would bias more towards more detailed readings than more summary readings because I feel it's sometimes important to get down to the details, particularly with regard to certification criteria.

I have a question on Consolidated CDA Version 2. It was the sense of a number of members of our workgroup, although we clearly explained that was turfed to you guys that consolidated CDA version 2 there's a work that's required to upgrade every health IT system to be able to send and receive consolidated CDA version 2.

That work is because there are all new templates and all new template IDs. That work is not a matter of just updating the template ID, it's…and everything else works; it's pretty substantive. I think there's a question as to whether the work that's required is accompanied by a meaningful enough upgrade to specificity in the implementation guidance that we're going to get significantly improved interoperability on the basis of the work that is being taken on.

The folks in my team who have extensive knowledge of parsing and processing gazillions of consolidated CDAs and have been through the CCD to 1 dot to consolidated CDA 1.1, work where we effectively had to redo the whole thing all over again without a lot of leverage leans more towards the lots of work, not much benefit side of the equation. And I think I've heard comment that's been split in this group as to whether the balance is lots of work, enough benefit or lots of work, not enough benefit.

And I wonder whether your group explicitly examined that question of work to benefit or not. And I guess the context for the question is that to my understanding the HL7 work that got balloted was based on the need to internationalize 1.1, make sure the template IDs were configured appropriately for openness in the future. And I don't believe that some of the work that Josh Mandel and others did to look at real world interoperability issues with consolidated CDA was explicitly addressed in the Consolidated CDA version 2 work. So again, it's just a question; did your group look at the cost to achieve versus benefit in terms of improved interoperability for that question?

Richard Elmore – President, Strategic Initiatives – Allscripts
So no, there was not an explicit cost-benefit trade-off discussion in the workgroup; there was discussion of an improvement in the expectations of what was going to be sent in consolidated CDA creation based on additional constraints that are part of 2.0. And that was based on…and that was built into the 2.0 based on the learnings of the 1.0, the version 1 ex…release 1 experience.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Wes.

Wes Rishel – Independent Consultant
Thank you. Question, you talked about preferring the future of FHIR in terms of the API over the C-CDA to some extent. Did you mean FHIR as a way of exchanging C-CDAs or did you mean FHIR as a way of basically restructuring the data?

Richard Elmore – President, Strategic Initiatives – Allscripts
So, no we do not mean that; as a matter of fact, the workgroup is very explicit, we didn't call it out in our overarching themes but we agreed with the API Workgroup that it made more sense to, if you wanted to retrieve all of a common clinical data set, you probably wanted to do that in terms of FHIR resources rather than mixing and matching with Consolidated CDA.

Wes Rishel – Independent Consultant
Yeah, that's kind of what I thought, but I just wanted to…

Richard Elmore – President, Strategic Initiatives – Allscripts
Was there part 2 to your question or was that...

Wes Rishel – Independent Consultant
No, I have some comments, but that was the end of the question. As far as, since I'm the titular owner of asynchronous bilateral cut over, and it was called out by name in the presentation, I feel like I have to comment a little bit here. You really will hardly ever make that easy unless, the old standard was designed for this process of cut over; we don't have that situation between 1.1 and 2.0 and my experience as I, when I was working for Gartner, when I would go to hear about a vendor or a user that claimed they had a lot of interoperability based on the CCD or the CDA, so I had the opportunity to drill down; I would find one of two cases.

Either the receiver was essentially using the incoming document to create a text display using fairly standard rules so that most of the…didn't really matter or they had a lot of vendor specific rules in there based on the source, in order to get to a common representation of data in order to be able to trend it or do something else. To me that limits the need for this bilateral cut over and not requiring a vendor to receive a 1.1 in certification doesn't mean that they're necessarily going to decide to throw away that capability, having already certified it in a prior. So just the fact that you might need a different interface or something like that is not a failure of bilateral…of…it's not going to be that devastating not to have asynchronous blah, blah, blah this time.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
(Indiscernible)

Wes Rishel – Independent Consultant
I just want to make a prediction that 50% of the current vision we have for FHIR…things that'll get done in FHIR will never come about in a recognizable form, whether it's CDS or whether it's something else, at least half won't. And we will have set a new track record for the amount of things that do come through a standards process in recognizable form; that is very few things come out. So this tentative, let's do a few things now and let's let other things develop, including our idea of what's the right relationship in CDS, you know, are examples of doing it right, not rushing to a process that's not there. So it was no disrespect whatsoever to say less than 50% for FHIR, it, in fact, would be very respectful if they got anywhere near 50%.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well again, all friendly comments. So we…Michelle, I presume although these guys haven't written their transmittal letter yet, have the same issue with this presentation as the last that we are going to look for support of the committee that these concepts as enumerated will be forwarded to ONC as part of a formal transmission process. Any objections to that? Okay, well very time efficient; you put us back on track and so, yes Michelle.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
But we have an agenda dilemma. So we have two presentations after lunch and not everyone is available for those presentations until after lunch. It's 12 o'clock; those who ordered lunch, the lunch probably won't be here until 12:30 but I think Dixie and Lisa's presentation might go a little bit longer than 40 minutes. So I'm asking if people can sustain themselves for a little longer before lunch.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And that is what I had proposed, that it was 40 minutes, 40 minutes, 40 minutes, 40 minutes.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
But they need longer than 40…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…what?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
They need longer than 40.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well, so here's a question for you Dixie. Can you go from 12 to 12:40, give people a glucose break and if need be, get a little bit of time after lunch?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
I don't think it'll take more than 40, but...

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
See.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…but I thought it would take at least about 40.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Do you agree?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Michelle does that sound okay.

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

W
Is it too late to order?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Go talk. So let's move forward then with Dixie's presentation and Lisa's presentation. We will be time efficient and then we will break for lunch and we should be able to, I think, complete our agenda today except the DAF presentation; my apologies again to John Feikema.

…bar if anyone is starting to fade we can pass that around.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
I've got a Slim Jim in my back…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
…set up.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Maybe get through it a little faster.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay are we set?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yes.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Go for it.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Okay; we are reporting back the conclusions of the Transport and Security Standards Workgroup. Those are…our people that we thank for all of the contributions that they've made and time that they've given us. Today we're going to address four things; the first is that the NPRM proposes a change in the…cer, in the method that electronic health records submitted for certification are certified against the security and privacy criteria.

So the first thing we're going to do is to comment on that. The second is the…oh, first thing we're going to do is to talk about readiness, the second is the method. Third and fourth are relating to questions that were specifically asked the security workgroup; first, those that directly address the privacy and security criteria and then there were other questions that aren't directly related to the privacy and security criteria.

So first the readiness; you've seen this before, this is the diagram from the…that the Standards Committee uses to determine whether a technology specification is ready to become a national standard for the certification of electronic health record technology. The "Y" axis is maturity, how mature the specification and technology are. The "X" axis is adoptability, how…the ease of implementation and operations basically.

We looked at the standards that were assigned to us and going down the list, this is a summary; some of these we'll go into more detail later, but this is our summary that we're giving up front. The SHA-2 is a specification for hash functions and it's been used and we judged that it is ready. Data Segmentation for Privacy and the HL7 implementation guide for provenance; we judge as not ready for…to become national standards for certification. The eSMD we judged not ready for…to become a standard and finally the…a specification that we are recommending to be Incorporated is NIST 800-92 and I'll describe this; it is clearly ready.

This is a summary, going back to that initial table, this is where that initial graphic that shows it…where we think each of these fit into the scheme of things. We think the least mature is eSMD and you can see the others how they fall out in the diagram.

So moving on to the revised approach for certifying security and privacy criteria…certifying technology against the security and privacy criteria. The NPRM proposes an approach that is very, very similar to the approach that the Transport and Security working group actually recommended. So again, we want to thank ONC for listening to us. And we…and basically this is that health information technology modules that are presented for certification are certified against all of and only those criteria…privacy and security criteria that are relevant to the functionality provided. And the functionality provided being determined by the section of the criteria that that module is addressing.

And this is a slight difference from what we recommended, but actually we are quite supportive of it, is that they need to…they have the option to comply with…demonstrate compliance with the criterion by either technically demonstrating their capability are through their system documentation. So, we agree with the new approach but we did…we do have a couple of recommendations that are…for slight changes in the applicability table that's provided in the NPRM.

First a clinical module is required to be certified against all of the security and privacy criteria except data integrity. And I brought this up at the last Standards Committee meeting and Steve responded that that's because the integrity criteria really addresses just transmissions and the clinical criteria don't address transmissions.

So we went back and we looked at the clinical criteria that are included in the clinical modules set of criteria and there are criteria that explicitly require transmissions, lab order compendium exchange, as well as formulary benefit file exchange. But in addition, depending on the architecture that's used in module, it's conceivable that all, you know, that all of them require transmissions where the data integrity criterion would be applicable. So we do recommend that that be included for the clinical…that integrity be included for the clinical modules as well. In the care coordination module, amendments was excluded and we recommend that this should support patient-requested amendments for care coordination as well.

And then finally there, as was mentioned earlier, this…the data and performance module is a section of the NPRM that includes this API that has been discussed earlier. So we suggest that in that API area that there be two additions. One is that authentication access control and authorization, which is section 1 of the privacy and security criteria, be added. Secondly that auditable events and tamper resistance be included and finally that the integrity requirement be included. And that goes for both places where the API criterion exists; both in design and performance and in the patient…in patient view, download and transmit.

Okay, questions regarding the privacy and security criteria; there are a couple of these that are, you know, yes we agree and so we'll try to go through those as quickly as we can. The NPRM proposes making a change to user privileges auditable; this is in the auditable events and tamper resistance. So the NPRM proposes they…a change in…proposes making a change in user privileges auditable and they ask us, should certain critical events be enabled at all times?

We've been asked questions about what should be made auditable a number of times. And first of all, I do want to make the…make it explicit that there is a difference between auditability and audited. So HIT that are submitted for certification should be certified for their ability to record audit…an audit trail record for certain events. But that says nothing about an end organization actually turning that on all the time. So we want to make it clear we're not imposing policy here, we're saying what this technology should be certified to be capable of recording an audit trail for. So basically our…all security relevant events should be auditable; so a change in user privileges is security relevant and therefore should be auditable.

And so we should add a certification criteria stating that; so, let me back up a bit. So as we looked at the NPRM, we suddenly, you know, lightbulb going off, we realized that the NPRM never says that all security relevant events should be auditable. The NPRM cites ASTM E2147, which says that all accesses to health information technology database should be auditable; but that's just one type of security relevant event. So the NPRM never says that certified EHR technology should be capable of auditing a recording a record in an audit trail for all security relevant events.

This is an oversight on our part and so we…our proposal here is to help remedy that, Steve. So what we're recommending is that we add a security criterion that just states that certified HIT should be capable of recording an audit trail of all security relevant events. And we also propose that we add NIST special publication 800-92 sections 2.1.2 and 2.1.3 as the standard for the specification of what auditable events are, in addition to the ASTM E2147.

As I mentioned, the ASTM is already in the NP…in the certification criteria for 2014, but it only addresses when you open an EHR record, for example or when you write EHR record. It doesn't address events like creating a user on the system or adding a privilege to a specific account. And so we really need to close that gap and specify that all security relevant events should be auditable and so adding this 800-92 we feel will do that. We…and what exactly what to, this addresses my comment earlier, exactly what an organization actually audits is a risk management decision; but the auditability should be a certification capability.

And as…regarding the second question, should certain critical events be enabled at all times? We actually were asked this previously. And at the time we responded that we recommended no change and we said that the ability to disable the audit log should be an administrative decision. In most organizations, they have an audit administrator and as probably most people know, an audit trail can get quite voluminous and sometimes can affect storage. And ultimately the question about whether we need, in an emergency situation, for example, to be able to shut down audit, it's a…it is an organizational risk management decision, it's not a certification decision. So our recommendation stands, we think it should be left as an organizational decision and that there should not be a certification criterion that says that the audit trail can never be shut down. Okay, next slide.

This has to do with the automated access timeout. The NPRM proposes to require a module to just automatically stop user access to health information after a predetermined period of inactivity and to

require user authentication in order to resume or regain access that was stopped. We're just suggesting a language change that the…it be capable of automatically terminating access to protected health information after a configurable period of inactivity, that should be organization specific based on a risk management profile and to be able to reinitiate the session upon re-authentication of the user.

The end-user device encryption is just a change in the FIPS and they propose to update it and we agree, it should be updated; but, in addition we suggest adding, FIPS 140-2, Annex A, which is already in the certification criteria now includes an additional specification which is a guideline for transport layer security or TLS. TLS is what's used to authenticate the server that you're attaching to and to encrypt and integrity protects the channel that's set up between them. So we suggest that this…that a reference to this FIPS 140-2, Annex A and specifically the guideline for transport layer security be added for both the patient…for the API criteria that appear in both the patient engagement and common clinical data set. Next slide.

Integrity; they propose…they ask us when they should move from SHA-1 to SHA-2. The preamble talks about how industry is moving to SHA-2 and we agreed that we should, for the 2015 edition, it should move to SHA-2 for integrity…data integrity. We also changed, this is interesting; in the last Arien and David's presentation reminded me of this is that the integrity criterion requires that both the sender and the receiver be able to support the integrity specification, SHA-1 for integrity. But it's really hard to test whether the sender is actually, you know, applying the hash to the data. Where it's actually, you know detectable is that the end if you're able to show that the hash that comes through agrees with the data that came through. And so the proposal is to just change the testing approach so that it's only tested at the receiver end and not the sender end, which we agree with makes sense.

Finally, the other questions that were asked that don't relate to…just to the privacy and security criteria. Data segmentation for privacy, the NPRM proposes two new certification criteria that would focus on the capability to separately exchange and track or segment sensitive health information. So the two criteria are to be able to send this information in accordance with the DS4P and be able to receive it…the information with…consistent with DSP.

The data segmentation for privacy specification is beyond the pilot stage and large vendors are now experimenting with DS4P, but…and they're reporting needs for further refinement that they will be reporting to ONC in their own responses to the NPRM. DS4P is important because it enables an exchange of data that currently, in many cases, are not being exchanged at all, so it is important. And it's important that piloting continue and that implementations continue along these lines. So we recommend that ONC continue to support and encourage the trial implementations of DS4P in EHR technology to help accelerate both the specification and refinement and its adoption. But we do not believe that DS4P is ready to be included as a standard for certification of HIT.

ESMD is electronic submission of medical documentation. You recall CMS presented the eSMD specification to this group over a year ago, August of 2013 I believe it was and this group brought up a number of issues having to do with digital signatures and whether the digital signature standard was consistent with the DEA digital signature standard. There were issues about workflow that were inherent in the specification. There were lots of questions and subsequently the Clinical Workgroup and the Security Workgroup met…separately met with CMS and heard the eSMD and made recommendations. So this has come back around and now eSMD is being proposed as a standard for certifying HIT in the 2015 timeframe.

So…and the NPRM includes both the creation of a C-CDA document for the purposes of electronic submittal of medical documentation to CMS. It proposes the use of the World Wide Web consortium XML Advanced Electronic Signature standard to digitally sign content for both segments of a C-CDA and for the overall C-CDA that bundles the segment…separately signed segments. So that covers that…those other two bullets.

So we, actually the CMS…again Bob Dieterle met with our group and we heard that significant progress has been made since August 2013 when that was presented…when he presented eSMD to this group. The digital signature standard is consistent with the DEA standard at this point; it's compatible, it's not identical but it certainly is compatible. The capability can be provided either…for certification…can be provided either natively by the module itself or through the use of an external interface.

The eSMD is tied to C-CDA Release 2, which itself lacks wide adoption. And eSMD is a new standard, it hasn't been piloted and it certainly hasn't been widely adopted. So we recommend that ONC support pilots to advance it's refinement and adoption, but it certainly is not ready to become a national standard. So.

The C-CDA data provenance; ONC was seeking comment on the following, the maturity and appropriateness of the HL7 implementation guide for the tagging of health information with provenance metadata in connection with C-CDA. And secondly, the usefulness HL7 implementation guide in connection with certification criteria such as transitions of care. Now the usefulness was really addressed by the task force that Lisa led in January so we did…this workgroup didn't really address the usefulness, we really focused on the maturity and appropriateness of the HL7 implementation guide for data provenance.

The…we discovered that HL7 is currently working collaboratively on two different provenance specifications; one being the provenance implementation guide and secondly the FHIR provenance content specification. And the two workgroups, we understand, are working together but fact is, there are two standards coming out of HL7 regarding data provenance. Neither of these standards is ready to be adopted as a national standard for certification of HIT; but data provenance is a significant component of data integrity, so it's very important. So we encourage the ONC to follow and support the development of both of these specifications and ultimately to adopt one or possibly both as standards for certification. Okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Wow, that was time efficient.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
We're ready.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
I thank you. So let me just summarize the last three things that you said which is, we all recognize DS4P is a very important concept, there is no one, I mean especially Leslie who would say, giving patients granular choice as to what we share, when we share it, how we share it; very important, it's just alas, it's not really in the wild and so we need more experimentation before putting…

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Not in the wild, just in FHIR testing right now, so work that the VA's done and ONC's done…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
…which has been quite profound.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes, and so we need, you know, testing and experience with that one. ESMD, really immature in its lifecycle at this point…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Right.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…and provenance, again, very important but there are multiple competing approaches, not clear which will succeed; more testing, more experimentation required. So, per the Dixie Baker paper on standards maturity and the David McCallie rule about where do you get prescriptive versus functional versus outcome based. I mean, the challenge for, I know Steve, you don't write this stuff anymore, but for the staff of ONC to take our guidance and say, hmm, you know, where can you say this is directionally correct and let's signal it, but allow some industry experimentation versus measure based on an outcome versus be prescriptive. And I think you've heard some important guide as in that continuum, DS4P is kind of middle of the road, eSMD very early, provenance still a work in process. So let's open up for questions. I know Jon, you had a comment.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yup, two; one, thank you again for the excellent and thoughtful consideration of the issues that were laid out, as always, I mean, shouldn't expect less, but I appreciate it. So I will actually extend what John just said little bit further. So as I was listening to your recommendations, it's lovely to have the nice clear yes, no, yes, you know, right? So, but let me harken back to David's earlier comments about, you know, some of the approaches that we've taken in the NPRM are hey, we…functionally we want you to be in this direction, we're not going to be prescriptive, but you need to get your act together, right, to paraphrase you, sorry if you want to add more…you're welcome to. And I didn't quite hear that in your recommendations, you know, your recommendations were, you know, a little more pilot testing is needed, we support that, we think that's a good idea, you know, this is important. So may…could you address that a little bit further? Do you think that, you know that David's kind of described approach might be applicable to some of these?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
The prescribed approach be...

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
The approach of saying…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…having

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…you know functionally we want to get here and industry we need you to, you know, collaborate and work to get us there in a quick period of time otherwise, dun, dun, dun.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Well I think that that's what we said when we strongly encouraged ONC to continue to support these efforts. We aren't saying ONC is really wasting its time on any of these.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Got it.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
So I think that by, I mean, first of all you've included in the NPRM, that pretty much, you know, communicates to everybody that you're paying attention to it. But I think that if ONC continues to seriously support these efforts, not just give them lip service, but seriously support them and follow them, it will communicate to the industry that it's important and that that's the direction you're going and that that's the direction they should head. That's not to say that you make law that says you must implement a premature standard. There's a huge difference between those two…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yeah.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…and that's what we're saying that really, it's our responsibility not to put in…to codify into law something that's not ready to become a standard.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Yeah, and I guess that's a little…there's a different nuance. And again David, I'm going to throw it back to you at some point, just that, you know, there's a difference between, you should continue to pilot and work on these things and industry please help us take get to a point where we can achieve this particular type of functionality or this characteristic of a system, because if you can't we're going to do "X." And I'll stop there and I'll let you issue further comment, if you want.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well let me just try to give you guys an analogy; this is an imperfect analogy but, what if we see that for the home entertainment industry there's this thing called videotape. And we think videotape is going to

catch on, but we're not sure whether VHS or Beta is the right format for videotape. Well then to declare prematurely that it's Beta would have been a mistake because the market has to decide. So you just say, we think videotape should be used and the market decides. Versus, you know, there's this thing called a DVD; it's not quite ready yet, but it's pretty clear that videotape is no longer going to be useful so let's not even mention the words videotape and say directionally, let's get to DVD.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Right.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And I think this is the challenge you have because, you know, let's take the HPD plus thing. I think we can all agree, HPD plus just don't even go there, right? Provider directories are important and it's going to be a FHIR-based approach, as David has put on his home computer that's going to win, so don't even mention HPD plus. With DS4P, I think the pilots are going pretty well, looks like there's pretty much indication that's going to be ready, just not quite yet. And on the provenance stuff, we're going to absolutely need it, but boy is the jury out as to which of the implementation guides is going to win.

And so I wonder, you know Dixie because you've written about this so well, if we can come up for Jon with a classification scheme, you know, and ranks this, where can we totally be prescriptive? VHS. Where do we have to be a little bit wishy-washy? Videotape. And where can we say, we know where the future's going to be, it's going to be at DVDs, but boy, it's too early to say that in regulation.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, I see where, you know, David mentioned functional specification of things versus use of a standard; these are not functional specifications, these are, this is what you shall do.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Right…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
There's a huge difference between the two; there's a huge difference between the two so, that's what we're saying is that these specifications are not ready for prime time. We're not really making a statement about functionally whether EH…certified EHR are capable of doing any of this, although I think, you know, it may be that…yeah, maybe that's what you're calling for, there may be a way to really determine…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…offering.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, yeah and I wonder Michelle, if for June 11, and I know we can't do this for everything that's in the NPRMs, but for those things that are kind of obvious, you know, because I think we heard from Andrew and from Richard same sort of thing, you know, it's like, here are things that are really clearly not ready.

Here are things that might be ready and oh, here are the things that are definitively ready and we, you know, sort of group things into those three buckets.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Well I think Jon is also asking whether there might be, in some cases, an opportunity to just specify it functionally versus…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
No…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…because I know, for example, at least one of those DS4P, I know that there are vendors who already provide that functional capability, just not DS4P. So, it might be.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So, I mean, you know architecture is hard and it's not going to always be obvious what's the right way to get to a good architecture, but the requirement for API access to discrete data elements is an architectural level requirement that can be stated fairly…in fairly high-level functional terms. Vendors understand roughly what that means and can go and figure out ways to get there and can do it in collaborative fashion, particularly if there's a good target like FHIR that looks like a right way to solve it.

The DS4P and the provenance things, I think, are not quite the same because they are highly specific things targeted to very specific external pressures, the DS4P tied to SAMSHA and things like that. Where I think what we realize now, maybe if we think about it a bit is that those are, in fact, instances of a much higher and much more challenging architectural question which is basically, EHR repositories now need to track additional information about the data elements than they've ever had to track before.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
It's a metadata problem that will include all sorts of secondary requirements on use and reuse of those data elements that no vendor has ever thought about before, because we all grew up in an era when that wasn't a requirement. So address the problem at the level of, what is the metadata and additional usage requirements that should be trackable at discrete data elements, figure that out and then work backwards to say, can we accommodate some of the inconsistent and conflicting SAMHSA rules by some subset of these new metadata capabilities.

And recognizing that it's a fundamental metadata problem that touches every data element in the vendor's database heightens the fact that this is a really big problem. This is not merely adding headers to a CDA file that you then discover you can't handle because your system doesn't know how to deal with the metadata that those headers just imputed to the CDA data. So zoom back out, approach this as an architectural metadata problem, recognize that this is a multiyear, complex issue to go figure out, then come back and address DS4P, and provenance tracking and things like that. Because othe…we won't have a clean solution otherwise, it'll be too messy.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Arien and then Leslie and then lunch.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Well, all right. So, with regards to this notion of a functional requirement so…was the original intent to my comment. But the justifications for functional requirements in the API space were by and large that the work was already getting done in the EHRs; there were already a bunch of EHRs that had APIs. Number two is that there was a pretty clear direction to go in, we all knew it was going to be DVDs. Number three, we were already working together to get the work done. That seems like a really great case for a there's a body of practice for doing it, we know what the destination is and there's already work on the ground to get there; seems like a good case for a functional-based approach.

In DS4P or in the general area of data segmentation for behavioral health, there's not…we're still working out the body of practice. There are fundamental questions about, what do I get to do with the packet of data that I receive? What do I get to not do? What does it mean to look at a privacy metadata header? Do I treat it the same way that I would have treated a paper document that I got and put a stamp on it that says do not redisclose and put it in…the one I copy if they don't do it?

So, there's a body of practice that we don't know how to do, doesn't meet test number one. Doesn't meet test number two in that I don't…or test three, I don't believe that we know what…that we're going towards DVD and I don't believe that we've got the mass…the already mass adoption, just not quite ready for prime time. So in terms of the test that I propose, I don't believe that DS4P would be appropriate for a functional test.

I wanted to ask a number of questions related to your comments, which as always were super helpful and very well organized. With regard to integrity, I want to make sure that I understand that you're proposing integrity previous to the Steve Posnack rule only in cases where there's transport. And the reason I'm asking that is this is an odd translation to certification requirements and I want to make sure that certify…certification organizations or testing organizations aren't improperly ascribing that…they're doing it in the right context.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Right. And that's already in the certification criteria is that they...

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So what…I guess what you're proposing is with respect to those modules, to the extent that…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
That they…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
…they do transmissions, yeah. Right.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah and so I propose that potentially as an amendment to your transmittal. Two comments on configurability and certification; you mentioned auditable events and you also mentioned configuration on timeout and there is a range of health IT developer responses to these areas. So, just taking time out, I could choose to define a timeout period that's reasonable and that's my timeout period and providers could adopt it or, you know could purchase my technology or not purchase my technology. Or I could make it configurable.

I think on your test, if I chose a reasonable certification, you know, a reasonable timeout based approach, it would fail certification and I want to make sure that I understand that. I also want to make sure that I understand relative to auditable events, would I fail certification if every event that was auditable wasn't also configurable. That is, how do I translate your I think appropriate policy-based guidance to certification criteria and do you intend for health IT systems that don't meet that task, in fact to fail certification?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Well with respect to the automated timeout, the…I think most vendors would default it to something reasonable, but the idea is that if an organization had a need for there never to be a timeout, emergency room, you don't want ever to, and I'm just making this up.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
You know, you have an environment where you don't want to ever to have a timeout; you want that always to be ready to be…you should be able to configure it that way.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So again, just to ask the question, would…if I have a system that has a reasonable timeout, I'm thinking Cloud-based or SAS-based system, right? I've got a reasonable timeout enforced, I enforced it at the system level, but I don't allow providers to extend it to infinity, I'd fail certification. Or are you suggesting that it should be appropriate to certi…it should be certifiable, even if I do have a configuration that allows me to extend the time?

Do you understand the difference between those two? So in one I would fail certification because I've got a default timeout period.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
In the other, I am allowed to extend the timeframe, so…if it's not configurable, I'd fail certification…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…scenario one. Or I would pass certification even if the timeout period is user defined. Do you understand the difference between those two?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
He's asking, Dixie, is are you interested in certifying the configurability of the timeout or just that there's a timeout?

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And I would…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
I would say this…I think you need the configur…I think you need; two things. I think you need the configurability, but in truth, you know, you could look at it as a market question, too.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Yeah, that's right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
You know, the market would say, I'm not going to buy it if I can't…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's right, yeah.

W
You make a great point.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, it all comes back to risk; HIPAAs all about risk.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And so my concern in these cases is we're making product management decisions on behalf of HIT developers; sometimes that's appropriate because there's value that it always gets done one way. Sometimes it really is a market question and I should just fail the market test if I don't have it configurable, but I do have it timed at a reasonable…a reasonable timeout…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm, yeah, I see, yeah.

Arien Malec – Vice President, Strategy & Product Marketing – RelayHealth Corporation
And it's the same question relating to configurability of audit and auditable events; I worry that with that drives to is a certifica…set of certification criteria where somebody's in effect playing product manager for my product that may or may not be appropriate.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Well, we haven't discussed those explicitly with the workgroup. But I think in both cases you're really talking about a trade-off between…you could be talking about a trade-off between security and safety as well. So I think both of them need to be configurable for certification because that's important to patient safety as well.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Right.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
But that's my opinion.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President Technology Solutions – Healthcare Information & Management Systems Society
And on the auditability requirement, we've heard from a number of folks in industry that they expect that that would be configurable; the audit log could be turned off at their discretion, that's common practice in most industries. And so that's kind of where, you know, as both a system management and safety issue as well.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So, I've got a SAS-based product…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Yeah…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…and it audits what it audits.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
Um hmm.

Arien Malec – Vice President, Strategy & Product Marketing – RelayHealth Corporation
And it, you know, it writes to an effectively infinite storage and there's no sense in turning something on or off as a configurable change because it's not installed software that's logging to somebody's local hard drive.

Anne Castro – Vice President, Chief Design Architect – BlueCross BlueShield of South Carolina
But that…risk; it's a…risk, not the individual.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Right, so but this is a certification criteria, does this SAS product, is by definition non-certifiable unless it has the ability for users to configure or not configure an audit trail, in which case…

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
…be non-certifiable.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…we're already auditing everything. I mean, does that…that by definition already auditing everything would fail certification.

Lisa Gallagher, BSEE, CISM, CPHIMS – Vice President, Technology Solutions – Healthcare Information & Management Systems Society
I would say that we did not look at those two questions that ONC posed us in that light. And so the questions become difficult…the questions they asked us become difficult, but, I mean, do you suggest that we revisit with the workgroup? I mean, that's the thing that we can do.

John Halamka, MD, MS – Chief Informatics Office – Harvard Medical School/Beth Israel Deaconess Medical Center
What I propose in the interest of time, because I know people's glucose levels are getting sub-100, and Leslie, I mean, is there a material addition to this discussion?

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
I just wanted to make sure that the tamper resistance comment being added to the API was…even though it might not meet the criteria for maturity that it is still putting fo…you're putting forward those things as recommendations to the existing API criterion.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Tamper resistance.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
You have it on page 11.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Uh huh.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Because that's fundamental for patient-generated data to be trusted or for patient movement of data created by others to be trusted.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Oh, the auditable events, yeah.

Leslie Kelly Hall – Senior Vice President of Policy – Healthwise
Yeah. Yeah, yeah, yeah.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
What I see then is it sounds like good discussion, that Dixie and Lisa, there was a point that Arien made that sounds valid that you may want to do a little bit of wordsmithing. But, you know, in the spirit of forwarding your recommendations to ONC, as long as there is some wordsmithing that accounts for his edge case, which is, you know Cloud-hosted provider for which goodness is provided and risk reduction for everyone, allowing every Cloud user to have a different audit trail configuration seems like a peculiar certification criteria; maybe you can wordsmith a bit.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Um hmm.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
But, objections to forwarding otherwise their report to ONC? Okay, well hey, let us open it up for public comment and then do lunch and then we can return at 1:30.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Okay. If there's anybody in the room that would like to make a public comment, please come up to the table. As a reminder, public comment is limited to 3 minutes and I'll turn it to Alan to open the lines.

Alan Merritt – Interactive Specialist – Altarum Institute
If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
While we wait for callers to call in, we do have a public comment box that people use and we've decided to start to share those during the meeting. So we have a comment from Thomas Boyd, from Hahnemann University Hospital in Philadelphia and this goes back to our initial discussion at the very beginning of the meeting. But he agreed with Dr. David McCallie, wanted to have outcomes…have an outcomes construct rather than process construct; in this manner we can all point to that goal and know that we arrived.

He made another point, the Data Provenance Task Force in January 2014 was among the most efficient and most productive; scope as very well managed, the subject matter is key to stakeholder adoption and trust. The work produced from this task force served as the basis for a number of comments to both the ONC and CMS NPRM. And we have no public comments.

John Halamka, MD, MS – Chef Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, with that, thank you so much for a very productive morning and here we are only five minutes behind schedule or so and so we will see you at 1:30 pm and have a good afternoon.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And for those who ordered lunch, lunch is in the Lincoln room.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you very much.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Have no Jon White, but, you know, because we are running short on time, I mean, it's…I will defer to our legal colleagues if we can begin without Dr. White.

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
(Indiscernible)

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Oh, okay.

M
All you need is yourself.

Multiple speakers
(Indiscernible)

Jodi G. Daniel, JD, MPH – Director, Office of Policy – Office of the National Coordinator for Health Information Technology
As long as we have a quorum, you're good, I think. Well, at least for voting purposes. You can get started.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yeah, I mean, it looks like a quorum to me. Shall we begin? Are the lines bridged?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
You don't have to open.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, very good. Well Cris Ross, are you on the line?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
I am on the line, John.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Very good. So we have reconvened. Thanks everybody for all of your hard work this morning. We are now going to move forward with Cris Ross presenting the work of the Implementation, Certification and Testing Workgroup. So take it away, Cris.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Thank you John. I'm sorry I'm not there in person, one of the joys of being a Co-Chair is you can double up; unfortunately, our colleague Liz had a minor medical emergency on the way there. She's fine, but I know that your best wishes for her will be much appreciated.

I'm in Minnesota because I had a meeting of 200 managers today and yesterday that I needed to be present at, but I will be there in person, the next time. John just quickly, how much time do I have for this presentation, just so we can stay on time?

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Right, so 40 minutes would be ideal, if possible.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Okay, I'll keep to less than 40 minutes, if possible.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So if you can go to 2:10 PM.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Okay, will do. Can we go to the first slide, please? This is a list of our membership. Let's go to the next one. This is a list of membership applied against the particular groups that we assigned people to lead. Special thanks go to David Kates, John Travis, Sarah Corley in particular and all of the others who participated in some of the sub-teams that we had around the NPRM. You can see the topics assigned to each of these groups. There was a little bit of bleed over from one group to another and they did very nice work which we're about to walk through. Next slide, please. We can go to the next slide, please.

Thank you. So we did want to apply a couple of overarching comments, and I hope that these are in tune with some of the feedback that may have been received earlier today. The first around the intent and spirit of the changes, noting some unintended consequences; some of them will be called out later in our recommendations that have to do with both process kinds of issues, of how the ACBs, vendors work together. And also unintended consequences from the standpoint of a burden put on both vendors and practice.

Second, we wanted to call out the need for balance between the benefits that we may get from all of the things that have been proposed in the rule compared to the time and cost commitments. A number of times our workgroup as we worked through the issues noted that there's not a single bad idea,

actually there's a couple that we may want to call out to say that we thought that they perhaps should be removed or modified, but in general across all the ideas that were included in the NPRM, there is nothing in here that one would say would not make a marginal contribution to healthcare in the US. But in aggregate, the question really was, can we effectively move forward with the breadth of the agenda as proposed. And we were looking for opportunities in which ONC might introduce more a concept of balance that would emphasize more around the reasonability as opposed to the aspiration.

The third is to be cognizant of time and bandwidth required by the developers and we note that some of the criteria was not directly related as we could trace it anyway to Meaningful Use. Argue that ONC and ANS should assure that the ACBs and the ATLs behave consistently. We observe variability in the market and that that has some consequences, depending on which route developers take towards certification. Next slide, please.

Specifically with regard to costs and benefits; particularly our vendor participants on the workgroup noted that the estimated costs associated with each of the items in the NPRM were significantly low and there were a number of instances where we have included in various detailed comments, places where we believe that the estimates are simply inaccurate. But that in aggregate, those costs that are estimated are too low. In particular it doesn't include the direct and indirect costs incurred by providers and vendors to prepare for regulatory requirements.

So whereas the estimates might include development time or analysis time, they don't include the effort required to go through the development and training process. We also urge that we get additional feedback from the industry in order to get realistic evaluation of the time and effort required for development. We can go to the next slide, please.

With respect to applicability; we wanted to notice the positive things around applying to other care settings. Long-term care has been something that has long been on the agenda and the Standards Committee has noted it on a number of occasions and has put workgroups around it. A number of workgroup members, including John Derr, have been very good about noting the importance of the connection between other care settings and long-term care.

But the real issue is that when those other care settings have tools, techniques, methods, processes applied from other areas of certified health IT, we need to assure the appropriateness based on the current baseline and feasibility for implementation. So a good idea from acute or outpatient care setting, for example, may not be appropriate in long-term care. We also wanted to urge caution that the changes that are proposed are specific to the needs of that specific domain, so that we don't apply requirements from other care settings. If we go to the next slide, please.

At this point forward, we're going to get into more specific detail. So the gap certification eligibility table; regardless of how a product is certified, we're arguing that end users should have the same level of confidence in all the certified products that they receive. Again, we made the note around minimization of variability across ACBs and ATLs that were in…higher in our recommendations. And we thought that ONC should consider some form of standardization or defined set of criteria for how the ACBs assess vendor products for gap certification. Next slide, please.

With respect to the CCDS, we were generally supportive of the semantic change to the CCDS. We had a fair amount of conversation on two topics; one was around unique device identifier, particularly in ambulatory practices and immunizations mapped to NDC codes, since providers usually don't include

those NDC codes when they're documenting immunizations therefore we wouldn't have them in historic data. And because immunizations can be received outside of a practice setting, for example immunizations that are delivered by a pharmacist, for example, or other venues. So UDI and NDC have great value, the question is, how do we target them appropriately? Next, please.

With respect to the consolidated CDA, we continue to believe that constraint of optionality is needed before additional testing at certification. And that's going to provide some assurance of what th…around in-field C-CDA mapping appropriately. Made note around the gold standard C-CDA, good concept, more clarity is required about who exactly is going to develop and maintain it.

Our workgroup had been engaged earlier in evaluating C-CDA constraint and the step from version 1 to version 2 was a step forward. We believe that there were additional steps that should and can be made. We wanted to urge consideration of some kind of ongoing non-mandatory test frames to allow ongoing interoperability assurance. The model here is HIPAA X12 for lessons learned; we described that in last month's Standards Committee meeting as well. That recommendation still applies to the NPRM. And we believed that the ONC should provide further details to the ACBs about specific aspects around C-CDA testing. Next slide, please.

Around CHPL, we were generally supportive of proposals here and did not have additional detailed feedback. I just lost the web presentation version, my screen just went blank. So, I'm hoping that you can all still hear me and that I haven't fallen off completely.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
We can hear you fine.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Beautiful. Well then I'm going to jump to my manual version and go to slide 11, the removal of Meaningful Use measurement certification requirements, and I'm hoping we can keep up with the slide. We were supportive of this proposal providing useful additional optionality for industry.

We can go to the next slide on ONC Health IT Certification Program and health IT module. We felt that ONC needed to provide additional articulation around what the phrase, field surveillance of a deployed system would entail. In particular, what components? By what method? For what purpose?

The workgroup supported the recognition around deployed versions of a lab tested systems that they may vary in performance from site to site and those variations often times require…excuse me, sometimes those variations are because of site-specific user training, configuration or usage issues. That the idea of homogenization makes sense, but at least in today's world, many care settings are not homogeneous they are more heterogeneous.

We noted that alterations to the "standard" or "lab tested" implementation should only require documentation if those alterations affected the achievement of meaningful use and not look at those variations just in general. Understand why there's sometimes some challenge to that, but we wanted to make sure that the focus was really on achievement of meaningful use. That ONC…we had a fair amount of conversation about audit and that ONC should limit with specificity what is meant by the audit and/or the requirement to document and report changes to the standard deployment. We note the possibility and the actuality of undue burden on both developers and sites because of it. So in general, the idea of a

certification program in health IT module makes sense; these had to do specifically with implementation kinds of issues.

Go into slide 13 on base EHR definitions; here we had some very specific recommendations. I'm not going to read through them in detail as I have so far, but this dealt with noting some redundant criteria with respect to the full C-CDAs. We recommended explicitly including security criteria. Earlier we had noted the implantable device and UDI issue and believed that it was premature to be in the base EHR definition, in large part because of ambulatory considerations. We wanted to support the inclusion of this application access to CDS for the provider-to-provider use case. Note around the consumer access to CCDS arguing that it ought to be optional. And then some additional specific recommendations around these two sections in §170.315(a) and (h) around drug-drug, drug allergy and around alternative means.

We can go to slide 14 around retesting and certification; we supported the proposal. We believe that ONC should adopt guidance for ONCs ACBs to use in evaluating is user interface changes have been made in an apparently significant change. There's some art to the language of "apparently significant." This recommendation might apply to the ongoing test frame that we recommended should be in place around usability and interoperability may apply here as well. We suggested that ONC should not fix a monthly update cycle but to match it to vendor typical release cycles. And normalization about how major and minor updates appear on the ONC CHPL for purposes of getting clarity to vendors.

We can go to 15 on safety enhanced design. This is one of these areas that we believed had clear clinical and patient merit; the question is at what level of specificity and thoroughness did it make sense to implement in this version of the NPRM. So the recommendation was to not require recruitment of clinical end users for testing of those administrative criteria. Ways to reduce test burdens to focus on summary descriptor information that demonstrates that the participants have relevant perspective rather than descriptive factors. It was not clear how those would be evidence of correct use of user-centered design procedures.

We recommended using industry standard and literature recognized satisfaction measures rather than the proposed user satisfaction rating. We believe that industry has a significant number of ways that this is already reported and could be applied. And urge that ACBs include the full usability test report in the public test report. If part of the goal is to improve usability and patient safety, providing some transparency in that public test report would make sense.

Sixteen around web content accessibility guidelines; we recommend that ONC propose, excuse me, postpone raising the web content accessibility guidelines to 2.0 level AA because there's a lack of quality compliance test tools and a need for clearer guidance. We believe that ONC should support improvement in tools, provide…help develop guidance for mobile accessibility and then revisit the decision on moving to 2.0 level AA. We believe that this is something that is simply not mature enough to be applied in this context.

Slide 17 around design and performance; again generally supportive of the proposal with a couple of recommendations that we recommend. A pattern require…that the requirement be patterned after the 2014 edition of the quality system management that includes the clauses as applied. We recommended the requirement related to identification of user-design standards for accessibility that were applied.

Slide 18 around the requested comment on summative testing. So, on this issue the team working on these issues recommended that formative testing should not be a required form of testing, but at most an alternative and an option to summative testing. Some of the specific issues related to formative testing in certification are that it occurs during the product development lifecycle and therefore might not correctly represent the product which is actually being certified. And that it's difficult to achieve this…achieve standardization because approaches are simply too variable that they're context-specific and that the results may be deployment specific as products are modified for implementation in any particular setting.

Slide 19 on encounter diagnosis; we recommend that ONC should clarify that this is meant to be a billing diagnosis and whether it's necessary to include all billing diagnoses for encounters or simply the primary one. If it is a signal one, ask ONC to clarify how exactly the primary billing diagnosis should be determined. There are…we observe that there might be a great degree of variability about this in the field without more specificity on what that process should be. And we discour…encouraged having a discussion about solutions to the problem of requiring double coding and making sure that we get all stakeholders around the table on the issue of encounter coding.

Slide 20, we're coming near the end, some very specific things around non-metric units and about the requirement should be applied for structured fields, but the vendors need to continue to provide support for free text fields and other kinds of things that didn't have…where end users use non-metric measures. Those are more technical feedback.

Slide 21 with respect to the implantable device list; this is again topic that came up in several instances. We believe that the full functionality of this requirement should not be required for all products and domains of care, in particular calling out the ambulatory environment. We believe it's reasonable to require the fields to store and display device identifier and description, but it was not reasonable to expect the software would support retrieval of the device description from a global UDI. The reasons for this is that it would increase complexity of products significantly and that many vendors would be forced to use some form of third-party provider because the data changes frequently. So most of our focus here was again, making sure that this good idea was applied as appropriately by domain and with regard to how the data is displayed.

Next slide 22 on pharmacogenomic data, there was a request for comment. Our overall comments were that the current standards for representation of pharmacogenomic data are not yet mature and that the evidence for improved outcomes associated with widespread use of that genomic data is not yet available and the costs are high. And that before mandating that all developers implement or support this functionality, will there be ROI associated with it? Obviously not requiring that it be implemented will not foreclose vendors from including that data…excuse me, that data, the question here was the mandatory nature of it.

Our second major recommendation was to note the promise of personalized precision medicine, but is it ready for incorporation in EHRs as structured data with additional consensus needed in the representation of genetic variations. We'd note that during the conversation on this, there is a number of ways in which that genetic data is being collected today in an adjunctive way to the EHR and that a potential solution is not necessarily to include this requirement in the EHR itself. We also noted that while there's movement towards the use of reference SNP ID numbers, this has not yet been standardized, more work remains to better understand the relationship of SNP to specific individuals' health.

Slide 23, data portability; the workgroup believed that a better title for this is bulk export of C-CDAs since more data is needed for transfer and conversion to new systems. We did not believe that the requirement as written met the expectation of broad users of HIT systems who expect data portability of everything and not just a subset. This has a number of usages, not the sort of classic ones around individual treatment of individual patients, but broader treatments as well.

We noted that adding additional data elements that may be required by a few specialties would increase cost, development effort and complexity so again, urging that there be a business case with respect to any da…to additional data elements that would be added. We thought that that could be distinguished from a base certification, vendor certification requirements that would be limited to that specific domain. We noted that vital signs are not part of the base EHR definition or part of meaningful use requirements, but they are listed as part of the CCDS and we thought that there ought to be clarity around either including them or removing them.

Next slide continues data portability; we urge a provision of realistic use cases for the new timeline and event requirements for a variety of reasons and noted that the timeframe and event requirements for generation are overly prescriptive. And the question is, you know, will they meet the data portability functional requirements which may be more likely for an HIE or for transition of care than for moving to some new practice or product as a product is upgraded.

Last two; slide 25, automated numerator recording; we believe that there should be no requirement for automated numerator recording for any measure where doing so would require additional clinical documentation that's not necessary for patient care. So the idea of automated numerator recording obviously has significant appeal because if it's done once by the vendors, it can be applied across multiple care settings, but the requirement that adds additional clinical documentation, we noted was one of the biggest factors creating inefficiency in EHR use. And I think all of us who are close to point of care on the eligible hospital or eligible provider care would note that this is true.

We recommended that the measures for §170.315 two sub-clauses that are unchanged from Stage 2 should be eligible for gap certification when the measure definition is the same. And as an overall sort of observation, unless there's a proven business need to document numerator performance and that it can be done without requiring additional development work or data entry, it should be eliminated from this requirement. And finally, measures that require complicated setup in order to do accurately should be eliminated. So there may be some places where there may be a universal use of some sort of data and that it would have even some business value associated with it, we argue parsimony to eliminate those where a complicated set up gets in the way.

And then the second slide and final slide on automated numerator calculation; we note some similar issues with regard to automated numerator calculation. The complex conversation here was around the need to calculate measures has required vendors to add a number of buttons and checkboxes and other methods that are only used to calculate numerators and to calculate measure performance, but do not have clinical value. So can we look for those instances where we are doing something to ease some sort of back end administrative capability when it gets in the way of care; we urge that we should back off that requirement?

We recommended that there should be no requirement for automated measure calculations for any measure where doing so would require additional documentation. That may be a bit redundant to our

earlier comments. And again, unless there's a solid, proven business case it should be eliminated from this requirement. I think we may have some redundant comments on slide 25 and 26; apologies. That's the end of our comments; John if you would like to do so, I'm sure we can go to discussion.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well wonderful, thanks so much and we are right on time and we have two comments; Andy Wiesenthal and Arien Malec. Andy.

Andrew M. Wiesenthal, MD, SM – Director, Deloitte Consulting, LLP – International Health Terminology Standards Development (SNOMED)
Thanks John. And Cris, thank you very much, that was wonderful detail. I have just a couple of brief comments. First to the points you made about implantable devices. I can speak as a member of the Management Board of IHTSDO that we're rapidly drawing to a close negotiations with the Global Medical Device Nomenclature people so that that hierarchy will be incorporated into the SNOMED hierarchy for therefore part and parcel of what every developer and end user in the United States gets for free, since the United States is a member nation and it will be a single standard. So…and that's going to happen within the next few months actually. So that…with subsequent releases of SNOMED CT, at least that will be available to everybody.

And the second comment I would make is related to your request that the encounter diagnosis be essentially defined as the billing diagnosis. I think that's great for now in an environment, and I guess I'm just speaking as a former Permanente physician who came from a different world, but an environment that's moving to a…toward a world in which there will not billing for encounters, that would be a mistake, actually in the future, there would be an encounter diagnosis and not a billing diagnosis for a particular encounter.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah good…very good point.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Thank you and thanks Cris to you and Liz and whole workgroup, really excellent commentary. One comment I think directed at ONC, I really endorse your workgroup's comment on better constraining optionality of Consolidated CDA and I guess a request back to ONC would be to put together with HL7 a work plan to better constrain consolidated CDA version 2 with respect to creation standards and gold standards; that kind of work would help tilt Consolidated CDA version 2 from the lots of work and not much benefit to the lots of work and lots of benefit category.

One is an overall process question, did anybody address in a workgroup parceling out the quality management system changes?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
It was done on the policy side in the Implementation, Usability and Safety Workgroup.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Ah, okay. I wonder if those groups have the experience in implementing quality management systems to be able to understand the difference between, for example ISO-9001 and the variety of medical device certification requirements. So, I'll just comment as proposed, the requirements are maybe too restrictive. They call for only standards…only quality management systems that have been endorsed by a standards development organization. There are quality management systems like the CMMI that are established by Carnegie Mellon that are often widely used and often widely tied to government contracting, but would not meet the definitional requirements.

And there's an odd mapping between for example ISO-9001 and CMMI Level 2 or Level 3 so you've got to jump through a bunch of artificial hoops even if you have an existing quality management system in order to meet the requirements as they're stated. So, looking at other kinds of quality management system that have wide industry applicability and adoption might be helpful in order to address less hoop jumping.

And then the last question is related to summative versus formative testing. My general comment is that of the two, I would rather do…I would rather work with a piece of software that had been through formative testing than summative testing. Formative testing informs design in the early stages where you actually have a chance to do something with the findings that you have. Summative testing is kind of uh, umm, as a check at the end. So Cris I'm wondering when I read your comments I had a hard time understanding whether you're making a recommendation or making some observations. I think if I were to frame it as a recommendation, I would recommend that either formative or summative testing be applicable for this criterion; but I wonder what the sense of the workgroup was.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Well, I hope that I can represent the viewpoint accurately. I think part of it was to try to get a clear line of sight between formative testing and what is actually put in production in a particular location might be a hard line of sight to draw. And it would be the second bullet point under the second note that the idea of how do we get standardization since approaches are varying widely and that they're context specific? So your point is a good one, I'm trying to get formative testing early in a process is going to have more value in terms of what actually gets produced as a general principle. I guess the question is just given how heterogeneous the actual production environment is, is it practical? Can't argue with your general proposition, I think the question literally is, can it be made real?

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And Cris, maybe if I can understand then your comment; if I do summative testing of the product as certified but it's changed through configuration in a particular setting of care, wouldn't that also be an issue relative to that concern?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Sure. Absolutely; I think the question is which form of testing would be more proximate to what actually exists in the hands of a clinician, I think was the gist of the conversation. Hard to argue again with the general principle, the question is which of the two, not in an idealized way but in a practical way, is going to have the most impact on putting an appropriately well-designed, well-formed, compliant product in the hand of clinicians. So there was some different viewpoints about this within the workgroup for sure. I think this is merely an observation of what was practical as opposed to what's

aspirational. Your argument is a good one, I think it…we…you could come down on either side of this question. I think the consensus of the workgroup was that requiring formative testing was too difficult.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
So I guess I'd agree with that, I'm just wondering whether you underscore your alternative to as opposed to that you could meet your….meet this criteria in either through documenting your formative testing plan or your three-year summative testing plan.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Sure, if in a particular context a vendor thought that that was an appropriate approach being able to have that as an alternative or an option might make sense, probably at the discretion of the vendor.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Dixie.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Ah yeah. Cris this is a lot of content here so I probably missed about half of it but I did want to comment on the slide 22 about pharmacogenetics data.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Yeah.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
I wanted to comment there certainly is evidence of improved outcomes for certain genetic markers such as the marker for warfarin sensitivity; so there are some genetic markers that are well known and well documented. But I also want to agree with your recommendation and note for ONC that the Institute of Medicine currently has a workgroup, the EHR Action Collaborative that is developing standards for integrating genomic data with the EHR and is initially focusing on pharmacogenomic data. So I think that it would be well, maybe Cris even add that the recommendation that the ONC follow that work because I think that that's what's going to lead to some standards in this area.

Cris Ross, MBA – Chief Information Officer – May Clinic
Dixie that's a really welcome addition, thank you. I mean I would just note that in the standard of…in the care setting in which I work, we're doing substantial work in this area and want to find the right ways to represent it. I think this is an area that's got a lot of progress and a lot of activity. I think we noted in general is a mandated standard required in order to advance the art or is it happening at its own pace without this requirement? And I think we would look at this against the maturity of standard criteria Dixie that you brought to this committee what, two years ago and I know it's published. I think this falls into a standard of one that needs more time to emerge.

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Totally agree.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Jon White.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Just two quick comments; Dixie, you'll be happy to know if we finish it 3:00 I'll be calling into the Institute of Medicine's workgroup call, have been paying attention to that…

Dixie Baker, MS, PhD – Senior Partner, Martin, Blanck & Associates
Yeah, yeah.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…and especially in the context of precision medicine, so thank you for bringing it up it's definitely something that we're paying attention to.

The broader comment, Cris, for the presentation which of course was excellent, a lot of really good stuff in here; I'm going to have to parse it out afterwards. And I'm not suggesting that you change the recommendations, but what I'm going to say is that I think my observation is that there are several recommendations that you are presenting here that are linked back to requirements of the Incentive Program, and in particular that means the Meaningful Use NPRM. And those cascade down, right?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
Right.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
The certification downstream is downstream from that so, they're well observed points. I'm going to have to kind…my folks and I are going to have to kind of consider how that relates to the CEHRT Rule versus the other one. So, I appreciate it but I just wanted to call that out as we kind of take it back and process through it.

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
It makes total sense that, you know, the world of the regulatory requirement and traceability that you and Steve Posnack and others have to deal with is substantial. We were looking at this purely from the standpoint of burden from an implementation/certification testing perspective for sure.

John Halamka, MD, MS – Chief Informatics Officer Harvard Medical School/Beth Israel Deaconess Medical Center
And I realize of course, we don't control our own fate here, but if CMS says we could solve our commuting problems with flying cars and Cris Ross says, flying cars don't exist; well CMS should probably know that. Floyd.

M
So noted.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC
So, thank you. So first of all, thank you for a comprehensive review and I just have three comments. I share Arien's concern about the formative and summative testing and I'm not entirely convinced that a showing evidence of formative and summative testing in development of the product would be…should be cumbersome, in effect it should improve usability, so I'm little concerned about that.

The second item I wanted to comment, the Content Workgroup basically agreed with every point you made on the numerator automated calculation and the data within quality measures, so that was good to hear that there's concordance. I didn't see, and maybe you weren't looking at that, any comments on decision support from your group and implementation, did you look at that at all?

Cris Ross, MBA – Chief Information Officer – Mayo Clinic
It wasn't within our scope; if you go back to slide three lists out what we were asked to look at. I think there was a number of places where we wish we could have slightly broader scope, if we had more time. Can't disagree, we thought that ONC staff did a really great job of focusing on us…focusing us on the vital few, but we did not include that. I would note to I think Arien's earlier comment, we also would have made recommendations with resp…I think, we would have made recommendations with respect to the methods for quality reporting from an implementation and certification standpoint, but it was not included in our scope and frankly we had enough to handle as it was.

Floyd Eisenberg, MD, MPH, FACP – President – iParsimony, LLC
Okay.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay; any other comments? Ah, yes.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.
Hey, this is Kim. The Content Standards also reviewed the pharmacogenomics data and we came up with the same conclusion that the standards were not mature. But we did think there was a consensus among the group that we felt the marketplace was going to move faster than the standards and that we should take some considerations into a subset of pharmacogenomic data that is highly used and has a lot of information. Dixie had mentioned the warfarin sensitivity, but also the Cytochrome P450 enzymes are another pharmacogenomic marker that is very influential in medication metabolism. So I just wanted to point out we had two slides of recommendations in that section from ours if people want to review that.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. Sorry for missing you, your card is exactly at the angle where it is just a single line in space.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Wes' gravity is limiting our ability…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay, well again, as in previous presentations, sounds like the amendments were all quite friendly. Is there any objection to moving forward with submitting these recommendations to ONC? Okay, none being heard, Michelle, we have another set of recommendations for you. And Cris beautifully right on time so we now have 40 minutes to the finish line. Jamie, are you going to be joined by Eric?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
(Indiscernible)

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Okay, very good. Well, let us go forward with the final presentation of the day on the Semantic Standards Workgroup.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
And I don't…do we have Becky on the phone? I guess not.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
Yes, I'm on the phone, I was just on mute.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute or Health Policy
Okay.

John Halamka, MD, MS –Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Sorry Becky, I of course would have recognized you, I didn't know you were on the phone.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Great, thanks. So thank you everybody. I think first of all before we go through our recommendations, I want to recognize the leadership of the workgroup members, specifically Eric and Mitra who are here, co-presenting with us. As we divided up the work into a couple of subgroups, Becky and I found that we were unable to attend several of the calls and so these folks really stepped up and along with others really led the charge and so I want to thank them and recognize them for the hard work.

That's another nice…it's a nice way of saying Becky and I were AWOL to some extent because of our day jobs in the last couple of weeks. So I'm going to walk through these general themes and then the sub-group leads will present the detail in several different areas were assigned to our workgroup. Also, I'm going to take these a little bit out of order in order to do so…to make some connections and logical groupings of these themes.

And I'll start out with the next to the last one; the common clinical data set needs more vetting. This is something that is a recurring comment that we've made before about this. These items should not all have the same priority and then tying the…that general theme up to the first one on the page here, there needs to be a balance between the requirements for learning health system and the impact of these additional requirements on implementers and implementations.

But the requirements of systems that support research, in particular, are not well represented in this set in terms of the coding and terminologies. And so we think that achieving learning health system objectives may require more interagency coordination, you'll hear more about that, particularly on the

coding and terminology standards. For example, the FDA core common data set is one that should be harmonized with this ONC common data set.

I think next I'll go to the last point on this page which really has to do with specifying. There are several areas where pending LOINC codes were specified, such as in demographics and behavioral health data and so we think that that's inappropriate and should not be there. And then linking back up to the second bullet on the page, generally it's desirable to avoid enumerating specific codes in the regulatory text. For example, codes are regularly maintained, in fact we had some examples recently where the meaning of existing LOINC codes was changed by LOINC and so the codes weren't changed, but their semantics, the meaning behind them, was changed.

Or, you know, codes regularly are maintained and deprecated in SNOMED, for example. And so we feel the regulation should refer to the coding system as the standard as well as a source of guidance for the particular codes to be used for that purpose, such as the Value Set Authority Center.

And then lastly, in terms of our general themes, we wanted to come back and reiterate on the…I guess it's the third bullet on this page that generally LOINC should be used for the question and SNOMED should be used for the answer, unless there is a good reason not to do that. And there can be a good reason and that can be documented, but the agreement between SNOMED and LOINC, the essence of it is that SNOMED will be used to code the parts of the LOINC code. And so…but I think the overriding recommendation that we would have is that LOINC should be the question and SNOMED should be the answer, unless there's a good reason to do it otherwise.

So what I'd like to do is all of my…all the points that I've just gone over in these general themes are expanded in the detailed comments. So I'd like to turn it over I think Mitra first to go through and then Eric and then we'll have the discussion on these.

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration

Okay. Next slide, please. Okay, so I was assigned to workgroup 1 and you see the standards that we were reviewing as a group. Next slide, please. So the first one was pharmacogenomic data and a question in NPRM was, are there existing or developing standards applicable to the capture, storage, display and exchange of potentially clinically relevant genomic data including the pharmacogenomic subset?

So our workgroup came up with the recommendation that within CDISC SDTM there is actually a domain, pharmacogenomic domain that has been added recently. Then also CDISC and NCI have been collaborating on life sciences domain analysis model and FDA as well. Then we see more and more pharmacogenomic data as part of the HL7 SPL, or Structure Product Labeling. So our workgroup thought that we should have a natural area of focus for needed standard development and including more pharmacogenomic data into HL7 SPL the future releases of SPL.

The next topic that we were working on was the common clinical data set definition focusing on vocabulary standards. This is, for example, the HL7 version 3 administrative gender code or LOINC version 2.5 or SNOMED CT or UCUM. So our workgroup thought also that, as Jamie mentioned, that the common clinical data set needs further readying and harmonization, especially among federal government agencies. And we should also look CDASH, which is Clinical Data Acquisition Standard Harmonization. CDASH is one of the foundational standards from CDISC and it's used for data collection,

especially focusing on clinical research. And then specific versions of vocabulary standards specified may become obsolete or superseded and systems that are able to use later versions should be allowed to do so.

Then the workgroup members would like to see source of truth on each item in the common clinical data set and its associated vocabulary; for example, a table. And then as Jamie mentioned, there has been an effort to align the common clinical data set. Actually, we should have an effort to align the common clinical data set with the core common data set from FDA and those are also the CDASH standards. And CDASH is a collaboration between NCI, FDA and CDISC and Clinical Path Institute. Next slide, please.

So on national drug code for administrate vaccinations; this is actually the view from the workgroup and not from FDA. So our recommendation is that we disagree with replacing CVX with NDC because CVX codes exist to support documentation of immunization when manufacturer packaging and lot number are not known or needed. What…however, we also recommended supporting the use of NDC to augment CVX in specific…for specific use cases.

And then the next area was transmission to public health agencies, syndromic surveillance and the question on NPRM was technology must be able to create syndrome-based public health surveillance information for electronic transmission. And the only recommendation from our workgroup was to…we assume that UCUM it is not precluded based on our reading of the implementation guide. The next standard was the transmission to public health agency reportable lab tests the value results. And here our only recommendation was, as long as the UCUM is not precluded.

Then the last one assigned to our workgroup was immunization history and forecast and here is focusing on maturity of bi-directional immunization data exchange activities. And the question in NPRM was should we include immunization data exchange in certification? And our recommendation, as Jamie also mentioned in the general comment area that CVX codes exist to support documentation of immunization where manufacturer package and lot number are not known or needed, such as in a shot record. So we disagree with replacing CVX with NDC, but we also would like to augment CVX with NDC codes as appropriate or for specific use cases. That is it, so I will hand it now to Eric.

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Thank you. Do we have a controller to advance of slides or do we just say move on?

W
(Indiscernible)

Eric Rose, MD, FAAFP – Director of Clinical Terminology – Intelligent Medical Objects
Okay. Oh, thanks. Well, I'll just holler across the table. So, these are the members of our sub-workgroup; if you can go to the next slide, please. So we have I think seven slides to get through, but I'll try to go as quickly as possible. So for the area family health history we had two bits of feedback that really apply across the NPRM; one is, simple point of clarification. It is the case that the US edition of SNOMED CT constitutes the union of SNOMED CT International and SNOMED CT US Extension; that was something that we felt wouldn't be necessarily clear to everyone so we encourage that to be clarified at some point in the reg, at least in the preamble.

Secondly, there's this phrase, "in accordance with," which is used liberally throughout the NPRM and we felt it would be helpful to have some clarification of that. And in particular, even though that's actually been used in prior CEHRT re…final rules, we felt it would be helpful to clarify the use of an interface terminology to capture data at the point of care with a mapping on the backend not necessarily visible to the end-user; it is…constitutes functionality in accordance with a standard.

So as far as the second item on this slide, we simply agree that yes, it's a good idea to…we agree with the NPRM's frequent stipulation that subsequent versions of standards…versions of standards subsequent to the ones specified are acceptable. So, we're in agreement there. Next slide, please. Also, nothing…no issues with the OIDs for code systems.

So moving on to demographics, we did have some feedback. There's a req…the NPRM proposes to require replacement of the OMB, Office of Management and Budget codes for race, of which there are I think five or six, with the CDC 's list for codes for race, which number over 900. And we felt that that…we understood the reasoning behind that that more granular capture of any demographic data helps to further the societal goal of identifying disparities in health status and health care and that this list of codes really could be quite problematic to implement. And furthermore, that it might be taken to require recapturing of data from all patients who already exist in a system.

So we thought that that really deserved a second look and was potentially problematic. A little nuance to that in the last bullet there is, one of the requirements in the NPRM is that the…so, as background, the CDC…the 900 CDC race codes are actually mapped to the five or six OMB race codes. And the NPRM proposes to require that EHR systems be able to essentially do that mapping and output the OMB race codes if needed and we felt that if that kind of data transformation or manipulation is needed, it really belongs in the downstream analytical systems, it doesn't belong in the transactional EHR system that is intended to be there for…to facilitate patient care. So next slide, please.

There were, apologize, there's so much on this slide, but I'll try to make it clear. There were some new requirements regarding capture of vital signs, most of which seemed perfectly sensible and we had no objection. There were a few areas where we thought clarification might help avoid a reg that doesn't…whose impact has unintended consequences.

So one of them is that there are requirements around…that might be taken to indicate that vital signs that are calculated, like BMI, which is the ratio between your weight in kilograms and the square of your height in meters, to require that calculated vital signs be…that the system allow users to enter them. And we thought it was important to clearly that if system can calculate a calculable vital sign like BMI, body surface area, etcetera, it is not required that it allow a user to hand enter them, in fact, that might actually be detrimental to data quality.

We…Jamie already talked about the stipulation of specific LOINCs, but I want to just touch on that a little bit because I think it really is quite important. So the section on vital signs lists a number of LOINCs, like a LOINC that generically refers to body temperature and by implication, a system that captured body temperature but used a different LOINC, for instance one of the LOINCs that indicate body temperature and specify the mode of measurement, like whether the temperature was recorded tympanically or by axillary measurement, would not be acceptable.

And there is a reference in the preamble to maintaining the semantic synonymy of data between when it's captured and when it's exported and used in another system. And in fact, we feel that it's actually

very important to be able to capture all of those details to the degree they're supported in the semantic standard lifeline. And so what we propose is that yes, require a LOINC for coding of vital signs but don't list the specific LOINCs and certainly don't forbid systems from capturing LOINC at…LOINC codes that represent vital signs at whatever level of granularity they do. So hopefully that's clear.

The next item in vital signs that we had some comments on was regarding the recording of date of birth and sex. And this is one where we think that the verbiage of the proposed rule may not quite reflect its intent, but we felt that it could be read to require that the date of birth and sex of the patient be entered every time a piece of vital signs data is captured. And since those are generally entered once when the patient's registered and not at every time that vital signs is measured, we felt that that ought to be clarified. And then I won't take time to read the last two bullets which were very minor comments but that I think may have reflected some typographical errors in the NPRM.

Moving on to smoking status, we were very pleased to see that the NPRM now will allow use of any SNOMED code that describes smoking status to be used for smoking status; however, the common clinical data set still requires use of the infamous eight codes that up until this proposed rule have been required. And those eight codes are awkward and aren't sufficient to represent all possible situations regarding a patient's smoking habits. And in fact, there are some SNOMED codes that represent smoking behavior that don't roll up; so it's not the case that those eight codes are high-level groupers, if you will; there are some orphans.

And so our proposal is simply to require that smoking status be represented with SNOMED period and any valid SNOMED code that represents smoking status ought to be allowable. The other point is…that we'd like to make is that there are things you can smoke other than tobacco and the intent of this, we believe is to represent tobacco smoking behavior and we think that that ought to be clarified.

So moving on to the next slide; so regarding social, psychological and behavioral data there are lots of new requirements and we feel that most of them are quite sound, we…and represent important steps forward in capturing data that is quite relevant to health and health care. The…Jamie already alluded to the fact that in general, where there is a need to encode both a question like, how much do you drink or how stressed are you or how often do you exercise; and an answer like, you know more than five drinks a week or never or what have you, in general it makes sense to use LOINC for the question and SNOMED for the answer, in particular the SNOMED qualifier hierarchy is kind of designed for that.

The NPRM does propose to use LOINC answer codes for some of those answers and they happen to be answer codes that were developed specifically by LOINC to go with certain questions. So there's some logic there, but our concern was that it may pose an extra implementation burden on EPs and EHs; so we thought that that ought to be, perhaps, reconsidered.

And the third bullet there, we advise against requiring use of any code that's pending, anything that's not…anything that is not directly under the control of ONC and might not happen shouldn't be required to happen in order for EPs and EHs to comply with the rule. We applaud the proposal to record gender identity separate from biological sex, because that's important and valid. Regarding sexual orientation, we did not think that the three specific SNOMED codes that were proposed were sufficient; there are actually 18 SNOMED codes today for sexual orientation and we believe that anything in SNOMED that describes sexual orientation ought to be allowed because the three codes that were mentioned may not be sufficient.

And there were some items there that we felt may be a little bit superfluous or may really not be critical in all cases. There were quite a few highly detailed items that were proposed to be captured as discrete data, like how many times a week do you talk on the phone with your family, friends and neighbors. And we thought that perhaps combing that list down a bit might be appropriate. And there were some glaring omissions like use of psychoactive substances other than alcohol and nicotine, which are a very important part of the social history and dietary habits.

So, moving on, the…we're on the home stretch, just a few more comments here. There…the proposed rule asked for free-form feedback, didn't specifically propose a standard regarding industry and occupation, but did mention some options. We wanted to encourage a very close look at SNOMED for this because of its hierarchical and multi-axial capability because the implementation cost to EPs and EHs may be low, because they probably already are able to ingest SNOMED codes into their systems and because it does have very robust representation of occupation. There are over 3000 distinct codes for occupation in SNOMED.

They're…apparently NIOSH uses the CDC's occupation codes and we recognize that there may be benefit to being able to extract data from EHR systems and using those codes. But the same goals might be achieved by building a crosswalk between SNOMED and the CDC's occupation codes.

Moving to the next slide there, again with sort of an inquiry regarding military service and uniform service data; and in our opinion, this ought to be considered one and the same with occupational history. The…again SNOMED has a large number of codes to represent different types of uniformed service in the occupation hierarchy. The reasons given in the NPRM to capture this information were two; one is that individuals who serve in uniform may be at risk for certain health problems that others may not be and while that's certainly true, it's not necessarily unique to those occupations.

There may be individuals who are not in the uniform services such as first responders, law-enforcement officers, military contractors and so forth that have the same health risks. And those health risks again can be represented on the patient's problem list with SNOMED codes like, what's mentioned there, the SNOMED code for exposure to combat.

The other reason given to capture…potentially capture uniform service data is for coordination of benefits and the fact that veterans in particular may be eli…have certain benefits eligibility. And if that's the intent, then there are a whole host of requirements that really would need to be put into place for certification to support that use of that data.

So, moving on to the last slide…oh sorry, this is the last slide, my mistake. We didn't have any comment on encounter diagnoses. On medication dosing, there was a proposal to…that a system must enable…it must be configurable to disallow use of non-metric dosing instructions which refers to the fact that for oral liquids it's been proven to be safer to express dose in terms of things like milliliters instead of teaspoons, tablespoons, which…with which we agree. We just thought that it should be clarified to indicate it applies just to oral liquids because as the proposed rule is stated, it could be taken to apply to things like topical creams and lotions and inhalers and eye drops and so forth, which you can't really dose metrically. And that's it.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Okay, I saw David first, so I think we'll take…John did you want to go first or...

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
No, no, no, please go ahead.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
…we'll just take David first and go around.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
David.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
So I have a generic question and it reveals more of my ignorance than anything else but, that's never stopped me in the past so it won't stop me this time. Right at the beginning you made some calls to expand or harmonize the core clinical data set with a number of other things including the FDA data set and CDISC DASH, CDASH. What does that mean practically? And I'm thinking here of the work underway to create vendor coalition around the Argonaut DSTU 2 commitment to FHIR profiles which are fairly rigorously specified, reasonable chance that a swath of important vendors will in fact deploy services based on those decisions. Given where that stands and what it's likely to look like, how far apart is that from what you're proposing here and if it's way far apart, why are we proposing it? You know…you see where my question is…

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Yeah, so I do.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
…I mean, it seems like it could be a huge issue.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
And so let me address that and then see if the others have responses as well. I think we've consistently since the road…since the interoperability roadmap, commented that this data set needs more vetting and needs to have a more formalized vetting process and that not everything should have an equal priority within that data set. Now within that vetting process, I think what we're talking about now is looking at the longer-term objectives on the strategic roadmap for having a learning health system.

If the common…if this data set goes forward exactly as is, it may mean unanticipated costs to research and other dat…other clinical and other data systems outside of this particular program. And so that harmonization across the agencies and across the data sets should be part of the vetting process is I think is what we're saying. So I…and I don't know, I'm not part of Argonaut, so I don't know exactly what's being developed on that, but I do think that this is a good time to go through a better vetting process for this data set before carving it in stone.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And the Argonaut work has generally tried to inherit everything you guys have recommended in the past and so...

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
But I don't any attention's been paid to CDASH…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
That's true.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
…and I don't think it's going to get paid to it anytime soon.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
And that's why I wonder about this recommendation which is hard to argue with on the surface, I don't know what the implications are for clinicians at the bedside doing routine care with respect to the learning health care system, because in general they're not actually driving towards feeding data into the learning health care system.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Right.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
They may all wish that that's a side effect, but the precision required is not there.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
So it may, I mean, I think it may end up that most of the changes have to happen on the research data set side…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Right.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
…or the safety data set side or, etcetera. But wouldn't it be nice to understand those gaps before fixing this and see if there are some small changes.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah and the difference between wouldn't it be nice and what we're actually doing is what I'm worried about.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Well…

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
I mean, it may be it's a com…it's a separate set of profiles that emerge in the future that would then, over time, supplant the existing profiles that…certainly the JASON Task Force recognized that there may be a different set of profiles needed for the research community. That was some of the testimony we got…

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
So, I think we have Becky on the phone and Becky, I wonder if you want to jump in on this one.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Yeah.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
Yeah, I mean I think this is really unfortunate because CDISC has been around since 2008 and it's now being recommended by FDA because they will require these elements in their submission. So for example, if you have a race code that's adopted by OMB and a different one by CDC and a different one by FDA and a different one through HL7, then why can't we look at harmonizing those before we set some of these things into stone? And so the FDA's getting ready to set theirs into stone, Argonaut is getting to set some others into stone and this should have been looked at when it first common data set came out, and I mentioned it when it was first presented a year ago. So I think it's time to look at it before we all go forward.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well maybe we could all agree to drop race, since it's a meaningless concept and then we won't have to harmonize that.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
Well I'm not just using, I mean, race was an example but we're talking about vital signs, we're talking about a number of demographics and I don't think it's too many elements to just take a look at what these are. I can tell you Mitra's right now in the process of mapping some of this because they don't fit and it would be really a lot easier if we could look at them now and see which ones could fit.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Well so Becky, just to help you out. As the Argonaut folks make any suggestions on vocabularies I'm happy to forward them to you for your comment and review. Because I think to data all we've done is said things like, you know, LOINC for labs, RxNorm for meds, you know, sort of the usual stuff.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics- Cerner Corporation
But I'm concerned John that the usual stuff isn't what they're talking about here. It's that there's in fact gaps.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
That's exactly right.

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration
Too, at the FDA we are...we have a…

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
(Indiscernible)

Mitra Rocca, PhD – Center for Drug Evaluation & Research (CDER), Office of Translational Sciences-Food & Drug Administration
…oh, sorry. We have a big interest on supplemental uses of EHR for clinical research, so we can just capture the clinical trial data from the EHR system.

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
But in general, that hasn't proven to be possible because there are so many specific things about specific trials that aren't captured in routine care.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
So this, I'm sorry but I disagree with that and it is something that's going to happen and the FDA is wanting to see it go forward, so why should we just write it off as being out of scope again as we have for the past 5 years?

David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation
Well, my question is, why isn't it in scope and if you're proposing it, but it's not anywhere else on anything that we've discussed, there's a disconnect that I'm just calling out and saying, you know, for the first time in recent memory, we've got an important coalition of vendors agreeing on an API standard that does not reflect this input. And I just want to say, that's happening, it's happening as we speak, the ballots have been submitted, frankly; they're being reconciled now; it's actually post-ballot. And it's just…it just strikes me as, I think it's a great suggestion but we're not paying attention to it. It's an anomaly.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
Yeah, yup; I think that's unfortunate and it's something I've raised at every HIT Standards Committee meeting I've been at for 5 years. And now the FDA is proceeding with binding guidance that means, it's required; so we're just building a chasm instead of a bridge here that we should be building.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So Becky, you know, I'll and I'll be the bridge here and I'll make sure you get a chance to review what we're working on and I look for your commentary. I have a feeling that as Jon White said, we're closer and probably more aligned than you think and, but look forward to any comments and feedback.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
If I can…

Rebecca D. Kush, PhD – Founder Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
Well I think it would be also proactive to look at what's in CDASH and not say, well, that's been out of scope and ignore it, because these are things the FDA statisticians are recommending.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
If I can just maybe close out this section of the conversation, in the interest of time; I do think that this is an area where our call for interagency harmonization might be especially important.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
Absolutely, thank you Jamie.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Next, Steve Posnack.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Ahh, so…

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
…follow that up.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Yeah, I know. Maybe with the easy question first and then I just wanted to give a slight 30 seconds of historical context on the data set issue. So the social, psychological and behavioral data certification criterion; so that's one of the certification criteria that is not applicable to meaningful use, it's not in scope for EPs or eligible hospitals, it was solely proposed as a voluntary certification criterion that was missing the punch line based on the actual, you know, substance of the recommended suggestions as to whether or not you think it should be in or out, and did the group discuss?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
So the consensus of our group is that in general structured data on what clinicians would call social history, which was what this section refers to, should be in. And that the list, like I mentioned, the list has two gaps that we would suggest filling; psychoactive substance use and dietary habits and has a bunch of stuff that we think are really superfluous, that they represent things that really…that are important to capture in a free-form conversation between clinician and patient, but that structured capture of the information is less than critical. At the same time we're saying drop all the specific code references.

Steven Posnack, MHS, MS, CISSP – Director, Office of Standards and Technology – Office of the National Coordinator for Health Information Technology
Right. Yeah. I think it's just a, and this is more so as a participant and observer of the committee of, you know, not saying trim, trim, trim, pare, pare down, pare down, pare down, pare down and then also recommend that we keep a criterion. So I think there's just a balance of expectations in terms of what the committee would ultimately communicate.

And then the other one on just the common clinical data set and I think, and I'll speak for Erica on her behalf as well, I think we found based on the conversations that have occurred that there's been a little bit of blending and a…that was unintentional between the regulatory terminology that was used and the symmetry that we used in the Interoperability Roadmap draft that went out. The…and as the Argonaut work understands and think has alluded to already, we came out with what's called the common meaningful use data set to be a shorthand reference to a bun…a collection of a handful of data elements was an easy way to reference a bunch of data elements in the number of certification criteria. So then we didn't have to repeat all of these data elements.

That policy was set 3 years ago in 2012 and there's very little change, with the exception of a couple of extra data elements that got added to this newly coined or refreshed common clinical data set. So, I was wondering if, and I know, you know, Jamie kind of closed the issue of putting a pin in it, but I think it could be considered if the issue is on the data themselves which have largely been, I like to create English words like policyized, you know, 3 years ago or if it's an issue with how code set terminology values sets have of been assigned to that data now and in the future as we tried to add some more specificity. Because the debate over whether or not some of these things are in or out was already decided long, you know, 3 years ago. And then Jon wanted to go, but he knocked over his name tag.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
If I can just respond to that last point of yours; I think what we're saying is not whether it should be in or out, but that now because of the actions of other agencies, the lack of harmonization between this data set and the FDA's in particular is going to be a more serious problem and this is the time to look at it before going forward with the next final rule.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
I agree with Jamie. It's not the content; it's the exact code sets and the semantics, that's what our team was looking at.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Umm, so quickly. So wonderful presentation from all, Eric in particular, nice job; but also for specific questions, the vital signs question. Ahh, you know, I'm…In general I like the comment but I was trying to reconcile the roll back of, to a small degree of the specificity, with this push that we have for interoperability.

And I think the intent, I hope I'm not actually commenting on what's in there, but the intent is to try to make sure that blood pressure at place A means blood pressure at place B, right? So could you just comment on what effect do you think that may or may not have in terms of trying to roll back some of

this. But say don't require specificity in getting the vital signs with our ability to assure that semantic interoperability persists or is achieved?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
I think I understand the question. Umm, so I think it is possible to keep the certification requirements simple and straightforward and not overly burdensome and keep the more importantly the meaningful use objective because that's what the EPs and EHs have to adhere to. Simple and straightforward and not overly burdensome by simply saying, for instance, you have to be able to capture temperature. You have to be able to capture, as the proposed rule does, you have to be able to capture systolic blood pressure as a separate data element from diastolic blood pressure. There's nothing wrong with that and that data has to be captured…has to be encoded using LOINC.

Then you allow some differentiation. If I'm an EMR developer and I want to add the ability to indicate the mode of acquisition of body temperature because I know that my customers want it because it's clinically relevant and when John sees a newborn in the ER at Beth Israel Deaconess and knows and sees a temperature recorded, he needs to know whether that's axillary or rectal if it's on the borderline between when he needs to admit that kiddo for a sepsis workup. And so allowing that to be a differentiator, but not…the problem with the rule as it stands now is that it disallows full…it disallows implementers and developers from taking full advantage of the granularity that is present in the terminology in question, which is LOINC.

So, you know, for lab results the current certification rule appropriately says, if you, you know, you've got to be able to incorporate lab results in LOINC. If you get a LOINC code in, you've got to be able to store that and display the information to the user. So, there's no reason why that couldn't be the same for vital signs.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Okay, cool. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So we have Arien and then Kim and then public comments and then flights.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Kim first.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. Kim, go ahead.

Kim Nolen, PharmD – Medical Outcomes Specialist – Pfizer, Inc.
I just wanted to reemphasize our comments from the Content Standards Workgroup on pharmacogenomic information also. You all had mentioned that it was increasing in the FDA approved drug labels and we actually had some conversation in our group around that also. And what we really wanted to know is, we know there's a lot of pharmacokinetic information in there that helps with decisions with drug interactions, but we weren't sure how that correlated with pharmacogenomic

information. So we would like for there to be some thought around that correlation before applying the pharmacokinetic information as pharmacogenomic information.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. Arien.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Thank you. So again, really good, very detailed. Steve answered or asked and answered one of my questions which is, regarding the social, psychological and behavioral health whether you're actually making a recommendation that those things be included or excluded. I…given that they're certification only requirements, I just wonder whether there's enough EHR practice in use to include and understand what should be included there? So I don't have enough experience there to comment one way or the other, but I guess that would be the metric that I would use is, is there enough EHR usage in practice to collect this data to justify inclusion of the criteria.

I lost the thread on smoking status. It sounds like you were both saying, include any SNOMED terms related to smoking and limit the measure to two questions. And I'm just trying to understand how to reconcile that thread and I wonder, I think the proposal of the magic eight was to improve the level of interoperability so that if I say it this way and you say it this way, we can say it together. And it sounds like what you're proposing is, I can say it any way as long it's SNOMED and you can receive it any way as long as it's SNOMED and that requires me to have my SNOMED and your SNOMED the same version and reconcile the map to my local terminology. So I just wa…maybe as you to comment on that.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Well, taking the easy question first; the mention of the…sounded like the committee recommended something about two codes, that actually…that bullet point was included in the slide by mistake, so good on you for reading it closely. But that was actually a…came from a set of background information referring to an IOM committee that had issued some recommendations about smoking status.

The problem with these eight SNOMED codes which according to folklore, I'm not sure if this is true, actually date back to a paper form used by British Public Health workers in the 1950s going door-to-door, made it into read codes and then made it into SNOMED through there; is that they…not only are they restrictive but they're also ambiguous. They use things like, I think, heavy smoker, things like that without defining them.

So the issue Arien about reconciling different versions of SNOMED is a real one, because SNOMED codes never get deleted, but they do get, I believe the term is retired or deprecated and that is true for any SNOMED coded information. So it goes for a problem list and procedures and whatever else we choose to use SNOMED for; but it seemed…it just seemed to be unduly restrictive to limit the use to just those eight.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Okay, so yeah, just understood; want to make sure people understand that the interoperability context it may be that that list of eight is a bad list, but the value of a defined value set that's at least mappable to sub-concepts is high value with regard to interoperability and it sounds like we're missing that…value set that is a high-value value set.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
So I would just point you again back to the overarching comment that we think that the rule should not specify specific enumerated code values, but rather the coding system. And then point to a source of guidance…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
That's right.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
…like the Value Set Authority Center that can tell you what are the appropriate value sets to use for the different elements.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And that I completely and strongly endorse. With regard to vital signs, just a super detailed sub-question given that I'm not an ambulatory medicine doctor. But the certification requirements call for collection of…or require collection of O2 sat and mean arterial pressure, and to my knowledge for many settings of care, that's not a routine standard of care or routine value that's collected; clearly is routinely collected in an acute care context.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Well, so O2 sat, most physician offices are able to…have equipment to measure O2 sat; it's not measured at all visits, but it is a piece of data that is frequently collected in ambulatory as well as, of course, in inpatient and acute care. And it…I think it's appropriate for there to be a requirement to be able to record it. Mean arterial pressure tends to be calculated, so it's an example of one of those…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
…calculated measures, sure. And then with regard to CDASH, I would submit very respectfully that the higher value harmonization would be, for example, NDC to RxNorm, MedDRA to SNOMED, some of these sort of foundational things where clinical trials do it one way and clinical medicine do it a vastly different way. Those are some of the high-value activities where if only we could get, you know, another one would be analyte machines expressing in LOINC; those are some of the high-value FDA to clinical medicine reconciliation work that probably is preparatory to any precision medicine activity relating to better harmonizing clinical trials and clinical medicine.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…I sent Becky all the implementation guides…

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
…comment.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes, go-ahead Becky.

Rebecca D. Kush, PhD – Founder, Chief Executive Officer, President & Director – Clinical Data Interchange Standards Consortium (CDISC)
I just said that was an excellent comment. Thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Yes, and I sent you all the implementation guides so you can, per the discussion that we had earlier, tell us if there are gaps or things that we've missed. It's not that much reading, it's in your email box. Did I miss Stan Huff?

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
Yeah, I think we have Stan and then Floyd.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
…Stan.

Stanley M. Huff, MD, FACMI – Chief Medical Informatics Officer – Intermountain Healthcare
Just a quick comment; it just follows on some of the things that were said. And I agree just to expand a little bit on the reason to not put specific codes in regulations. You know, going back to the earlier discussion, you know relative to FHIR and other things where we said, this is a direction we want to go, but there's work to do to get to see how that is implemented and how it works in real systems. We're in exactly that situation with the things we're doing, I mean, assuming that we want to get to true interoperability; the things that are specified in the common data set are woefully underspecified in terms of getting to true interoperability.

And so you don't want to stick codes in there that people haven't used in real systems or they haven't tried out. So it's, I think, a very important principle that we not put, you know, codes into the regulations but in fact, we have other forums, either as Jamie noted at the National Library of Medicine or at HL7 or, you know, with CIMI and HSPC and the Argonauts, where we get real world experience with trying to create truly interoperable services. And that's where we, after we've had a chance to implement these things in real systems, then we can say, this is the way we'll use those codes and that stands as the body of work that's publicly available through an authoritative source. But it's not what you want to put in regulation, so, thank you.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And Floyd.

Floyd Eisenberg, MD, MPH, FACP- President – iParsimony, LLC
I think Stan said more eloquently what I was hoping to say so ditto.

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
And I want to move that we include Jamie's really important clarification that what we're actually calling for is, in regulation, pointing to defined value sets with a value set authority as the way to achieve interoperability in practice.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
I think what we said in the workgroup was to point to a source of guidance and, you know…

Arien Malec – Vice President Strategy & Product Marketing – RelayHealth Corporation
Sure.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
…but whether it's for specific codes or value…you know so.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
The way I analogize this it's like Dixie pointing to FIPS, right, instead of enumerating what's in FIPS, it's a pointer to FIPS and you're going to do a pointer to whether it's the Value Set Authority Center or other guidance.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
Although guidance sounds awfully morally relative…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Indeed.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
So…

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
So where we are here, we are at time. It sounds to me like the only what I'll call reconciliation that needs to be done is, you know, Becky I sent that stuff to you if looking at that stuff you see that there is significant deviance from CDASH, I think Arien's guidance was excellent. If there's mapping that we should enumerate should be done, then that would certainly be a recommendation that Jamie's group would want to include. But other than that one, other items of disagreement or editing or revision?

Anne LeMaistre, MD – Senior Director Clinical Information Systems and CMIO – Ascension Health
Kim's not in the room, but what about the other point about the pharmacogenetics? I think there's a little clarification.

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
I don't think there's disagreement on that.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
I mean, I think we're all kind of saying the same thing here but, I mean, is there a friendly amendment we should add?

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
(Indiscernible)

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
We'll clarify with Kim if there's something, but it sounded like it was relatively…

Jamie Ferguson – Vice President, Health Information Technology Strategy & Planning, Fellow, Institute for Health Policy – Kaiser Permanente, Institute for Health Policy
I thought that was a friendly comment with no recommended changes.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay. So with that, it sounds like there are no objections. So Michelle, we have a body of work but of course we'll await some input from Becky. And I think we are now ready for public comment.

Public Comment

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Thank you. If there's anyone in the room that would like to make a public comment, please come up to the table. As a reminder, public comment is limited to 3 minutes. And Alan, please open the lines.

Alan Merritt – Interactive Specialist – Altarum Institute
If you'd like to make a public comment and you're listening via your computer speakers, please dial 1-877-705-6006 and press *1. Or if you're listening via your telephone, you may press *1 at this time to be entered into the queue.

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
And while we wait for public comment, just a reminder that we have our virtual meeting on June 11. As we've discussed earlier, we will talk about some prioritization of the certification rule and then we have our in-person meeting on June 24 where we will say goodbye to a lot of loved and beloved members of our committee. Hopefully it won't be good bye, hopefully you'll still want to participate in some of these exciting task forces that we talked about earlier; but, we'll see.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
And then in July and August, we will have virtual meetings and then the fall meetings are to be determined. If they in your calendars say they're all virtual, but of course, we are going to get together again probably at least twice, September through December…comments?

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
The operator's asking for a moment. Somebody might be dialing in.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
While we are giving the operator the moment, because we are past time, you know, I think again as this NPRM gets reviewed, our role here is by June to enumerate for all of our ONC colleagues those standards which are fully baked and ready for prime time, those that are not baked for prime time and those that have the potential to be ready for prime time so that as the regulation writers finish their paring down, they will be able to weed out those that we think will do more harm than good. So today was a great first step and look forward to the final reports from our groups in June. So…

Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology
Our commenter decided to not make a public comment, so, we're all set.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Okay.

P. Jonathan White, MD – Acting Deputy National Coordinator – Office of the National Coordinator for Health Information Technology
We won't bite, I promise. So it's Jon, I just want to make a few quick closing points. First of all, substantive, chewy, excellent feedback, thank you for both the specific recommendations back in the discussion today. To bring us back full loop to the beginning of the day, also in addition to saying loved and beloved, I want to say respected members of the committee, very much so. We are grateful both for your feedback and your ongoing input. We're going to be looking forward to reaching out to you perhaps after we walk out the door, about how we go about structuring the work as we go ahead.

On the point of the exciting new task forces, I do want to preview for you. Many of you are aware of the President's Precision Medicine Initiative; there have been some very active NIH workshops and internal workgroups and I am looking forward to inviting you all to participate in a workgroup on Precision Medicine and standards that can be used for that. Some of those obviously we've begun to address in some of the recommendations we've got, so we've got a great basis to build on.

But, you know, the funding for that is 2016 and that initiative is taking structure and they are quite interested in the feedback of this committee in what standards can be used in our information systems to help support that. So I will be looking forward to sending you an offline invitation for that. So thank you again for all your great feedback today and I look forward to the next time.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center
Thank you. And Michelle, any final administrative closing issues?

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

Umm, well we announced the Standard Advisory Task Force at the previous meeting, so, and there are a few folks who have indicated that they were interested, but if anyone else is, we welcome that. And it's…you're able to apply through the FACA database as well.

John Halamka, MD, MS – Chief Informatics Officer – Harvard Medical School/Beth Israel Deaconess Medical Center

Very good, well thanks and safe travels everybody. See you next time.

Public Comment Received During the Meeting

1. The Data Provenance Task Force in January 2015, was among the most efficient and most productive. Scope was very well managed. This subject matter is key to stakeholder adoption and trust. The work produced from this Task Force served as the basis for a number of my comments to both the ONC and CMS NPRMs.
2. I agree with Dr. David McCallie. One should have an "outcomes" construct; rather than a "process" construct. In this manner, we can all point to the goal, and know that we arrived.

Meeting Attendance								
Name	**05/20/15**	**04/22/15**	**03/18/15**	**01/27/15**	**12/10/14**	**11/18/14**	**10/15/14**	**09/10/14**
Andrew Wiesenthal	X	X	X	X	X		X	
Anne Castro	X		X	X	X	X	X	X
Anne LeMaistre	X	X	X	X	X	X	X	
Arien Malec	X	X	X	X	X	X	X	X
C. Martin Harris		X	X	X	X	X		X
Charles H. Romine	X	X	X	X			X	
Christopher Ross	X	X	X	X			X	X
David McCallie, Jr.	X	X	X	X	X	X	X	X
Dixie B. Baker	X	X	X	X	X	X	X	X
Elizabeth Johnson		X	X	X	X	X	X	X
Eric Rose	X	X	X	X	X	X	X	X
Floyd Eisenberg	X		X	X	X	X	X	
James	X	X	X	X	X		X	X

Ferguson								
Jeremy Delinsky	X		X	X		X	X	
John Halamka	X	X	X	X	X	X	X	X
John F. Derr		X	X	X	X	X	X	X
Jon White	X	X	X	X	X			
Jonathan B. Perlin			X					
Keith J. Figlioli	X		X		X		X	X
Kim Nolen	X	X	X	X	X	X	X	X
Leslie Kelly Hall	X	X	X	X	X	X	X	X
Lisa Gallagher	X	X	X	X	X	X	X	X
Lorraine Doo		X	X	X	X	X		X
Nancy J. Orvis		X	X	X			X	X
Rebecca D. Kush	X			X		X	X	X
Sharon F. Terry		X					X	X
Stanley M. Huff	X		X	X	X	X	X	X
Steve Brown		X			X			X
Wes Rishel	X	X	X	X	X	X	X	
Total Attendees	**21**	**22**	**26**	**25**	**22**	**20**	**25**	**22**