

NATIONAL QUALITY FORUM

**Moderator: Value Set Harmonization
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OPERATOR: This is conference #: 22102501.

Welcome everyone. The webinar is about to begin. Please note today's call is being recorded. Please standby.

Ann Phillips: Hello, everyone. This is Ann Phillips and I want to thank you for joining for the Value Set Harmonization Project Committee Call. Today's agenda includes an update on our first harmonization out performed by the technical expert. A continuation of our governance, some policy discussion and just a little – we're going to talk about next steps.

We'd like to do the roll call right now but before the roll call, Jason Goldwater won't be joining us today. He's at an offsite and we have Chris Millet here today who is – can be joining us as the consultant on the project and working with us on some of the governance discussion that we'll be having.

Let's go ahead and go with the roll. Zahid?

Zahid Butt: Present.

Ann Phillips: I know Michael Lieberman is on vacation. Howard Bregman? Chengjian Che, Christopher Chute?

Christopher Chute: Present.

Ann Phillips: Cynthia Cullen?

Cynthia Cullen: Here.

Ann Phillips: Ellen Harper?

Ellen Harper: I'm here.

Ann Phillips: Yan Heras? Wendy Hofner?

Wendy Hofner: I'm here.

Ann Phillips: Stan Huff? Matt Humphrey?

Matt Humphrey: Here.

Ann Phillips: Rute Martins? Robert McClure?

Robert McClure: Present.

Ann Phillips: Marjorie Rallins?

Marjorie Rallins: I'm here.

Ann Phillips: Joseph Schneider?

Joseph Schneider: Present.

Ann Phillips: Ann Smith?

Ann Smith: Here.

Ann Phillips: James Tcheng? Nancy Walker?

Nancy Walker: I'm here.

Ann Phillips: Great. Thank you. Do we have any federal partners on the call?

Julia Skapik: This is Julia Skapik from ONC.

Ann Phillips: Hi, Julia.

(Rob Taylor): (Al Taylor) from ONC, as well.

Ann Phillips: Great.

Steve Emrick: This is Steve Emrick from the National Library of Medicine.

Ann Phillips: Excellent. All right. So, we're just going to briefly give you a project status on the pilot harmonization for medication that we did. I'm sure you're all interested in update on this.

And the test went through the first harmonization exercise in the beginning of July using modified form of the worksheet we've been discussing with you and the goal of the exercise, the first exercise was to ensure that medical intent and value set intent aligned and after examining any overlap duplication or potential admissions in the members of value set, the TEP would recommendation to harmonize or not.

There were test reviewed the three pairs of value set associated with AMI and VTE measures with significant overlap in value set members and NQF referenced RxNorms to identified drug classes in overlapping value set.

The TEP was evenly divided between harmonization and not harmonizing value set with significant overlapping of member and interestingly enough, the division in the TEP was between the (Inform) System and the clinician.

Simplification was the primary reason for harmonization and maintaining measure and value set intent was the primary thought to harmonize.

(Off-mike)

Ann Phillips: If somebody is streaming the audio from their computer, they might want to turn the volume down a little bit.

The first pair of value set we reviewed had Jaccard score of 0.71 which indicates the significant overlap and they were the other anticoagulant for AMI and the oral factor Xa inhibitor for VTE prophylaxis. One value set contains Dabigatran, I probably said that wrong – which has the different

function from factor X inhibitors and harmonization was not recommended in order to maintain the intent of this value set.

In comparing the low dose unfractionated heparin and value set for VTE prophylaxis and the unfractionated heparin value set, a Jaccard of 0.55 indicated significant overlap. Closer examination indicated the route of administration is different which factored into the decision not to harmonize in order to maintain the intent of the value set within the measure.

On the last pair of value set for the Jaccard for 0.51 indicated significant overlap and those were low molecular weight heparin for their VTE prophylaxis and parental anticoagulant. The low molecular weight heparin value set is more specific prevention of VTE while the parental anticoagulant value set have a wider range of medication used in treatment of VTE. And based on the harmonization was not recommended.

The next harmonization exercise will be quite a bit different because we're going to focus on encounters within a depression measures for Meaningful Use and we're in the midst of developing a methodology to evaluate this value set and develop intentional value set for the line with the intent of the measures and more for you on that shortly.

Is there any questions about the medication pilot?

Christopher Chute: Chris Chute. I know you said that some were more granular and some are more specific. Was there consideration given to explicit hierarchal nesting? I know that was suggested in our face to face meeting.

Ann Phillips: I believe it was but when you start looking at value set intent and measure intent, these were value set that were created for very specific goal for measure and I know that the test struggled with that and determine that not harmonizing was the best solution for that particular pair and that was just based on the measure logic, correct?

Joseph Schneider: Joe here, Schneider. Not sure that that answered Chris's questions. I understand that it's – I thought I was and I wasn't on the last call but I thought he was asking was there in the linking or subsetting between those two – say

two things whether decide not to harmonize but with the value, and if that's not was he asking, then I'll say never mind but wasn't quite sure whether your answer got exactly to what he wanted and I'll say that.

Christopher Chute: That is what I was asking. Thank you.

Ann Phillips: OK. As far as I understand, that wasn't the best solution and I will look into this further what their reasoning was and get back to you on that, Chris.

Christopher Chute: I mean, because I think clearly the sense of the room, at least as I recall it was to the extent that we can have semantic coherency between and among these, granted they have different applications and different levels of specificity and even application but to the extent that they are logical subsets one of the other then an explicit rendering of that, frankly, we'd go a long way toward, you know, demystisizing what is now a rather chaotic, at least, to some of us, spread of value set.

Ann Phillips: I think some of the problem with that might be the actual construction of measure logic when you're identifying populations, exclusions, and exceptions and I think some of this value set might be designed around that measure logic which makes the rules harder to create this very – this nested value set. What do you think, Chris?

Christopher Chute: Just ...

Cynthia Cullen: You can – this is Cindy Cullen, you can use groupings or the group or options to create value set for more granular – larger value sets for more granular value sets so that should not be an issue.

Joseph Schneider: And also, you know, whether all the logic is in the value set or not or this was another discussion we had on the face to face or it just starts to invoke phenotyping, algorithm type logic explicitly and leave the value set as the description, the semantic description of what is described then, you know, that would be another way to look at it.

Christopher Chute: Yes, this is Chris. Though to definitely thing to look at because the TEP did struggle with, we're trying to figure out these relationships between the

value set they are harmonize but I think from the discussion on reviewing the TEP result, they didn't come to the conclusion of any – of clear hierarchal relationships, I don't think they landed on specific ways slice that up that made more sense and the way the value sets were currently.

Ann Phillips: But Chris, do you agree with assertion that maybe people are utilizing the value sets for a purpose, I think (was) suggestion other than it's real, you know, native intent. So they're combining the logic of the value set instead of leaving the logic be a separate standalone thing.

Is that what you're saying Chris?

Christopher Chute: Well, I think even – I think we're looking at it, in both sense, on hand looking at it to consider the measure logic but also looking at what the value fit purpose as a standalone. Do they make sense to – how do this value set relate to each other? Are they clearly specifically in them? We know they overlap this on the grave but I think it's still a hard decision on how the whole value set relate to each other considering the measure purpose but also considering just the value of that purpose about the measures, the measure logic and intent of the measure.

Robert McClure: So, this is Rob McClure. I mean part of – there's a lot of factors here. And so, you know, one approach to identifying opportunity for harmonization is not going to be ever sufficient, you know, you're going to need to utilize a variety of inputs in order to be able to make those decisions because of all the issues that were just raised, I mean, you know, value sets. It is true that some value sets would take care of characteristics kind of heavy universal applicability.

But I think for some of the – somewhat turn out to be someone of a surprise that I'd even say the majority – the vast majority of value sets were actually very contextually bound. And in determining what those context or requirements are that led have keeping one code and another one. This is often time is hard and it's tide up in things that we – that right now are usually available for one, you know, this idea of describing very clearly the purpose of the value set and defect phrasing or scope of the intended concepts.

We don't have that in many of the value sets and although there's no question at – more and more of them are getting them but even then knowing what to actually put in there can be a little bit difficult and so for an external entity to kind of look and say, "OK, there is some description of what the intended scope of the concepts are." I mean I give you enough information. The other is, this idea of been how it was used inside the measure because we're using measure logic.

And there's lot of choices that the people have and we'll just talk about that, sometimes you can call out the individual value sets specifically inside the measure logic and that without knowing that, you know, how that particular value set is used. You can actually make incorrect assumptions about what should be in the value set. How it should align.

So, I think this process of doing harmonization analysis, you know, it's going to be hard and it's going to require not only looking at what you see in the VSAC but also looking at how the measure is using a – how these value sets happen to being used in these measures because that's really their primary use point.

And then kind of collecting all of that and a human has to then decide, OK. Yes, obviously that's why we're getting that kind of results that we're seeing. Were many of them are not really harmonization targets because when you take all of those things into consideration, you just can't change them.

Zahid Butt: So I think – this is Zahid. I think Rob, that's a perfect segue into the next discussion which sort of gets into some of the process by which that context and the use and all of that could potentially be incorporated in some (sort) of a process.

Because I think you're correct that there is so much context to many of these value sets but I do also agree with the point that was being made earlier that to the extent possible as little of the sort of assumption or logic implications that one sort of assumes by being so and closely associated with the development process can be divorced from it wherever possible that would be ideal that sort of what I think Chris's main trust was a bit. This could be to the extent

possible sort of, you know, be just pure semantic description of exact membership, whatever.

Robert McClure: And guessing it what the next slide is going to be. But I think so having taking what we just talked about into consideration. It would be really valuable I think for this group to, you know, work to identify where harmonization you know, where the sweet spot is for things to be harmonized.

And also, I think along the way we'll be able to spin off suggestions and some of which are already incorporated in the VSAC for support that authors might need nor to, you know, identify opportunities from harmonization themselves, you know, and kind of do the best job they can do but it would be I think really variable for this group to say now having look at this and say "OK, well, this is this is actually complex and just blanket attempts to do harmonization without consideration" and I say, that would kind quotes, it's kind of a very difficult shot and miss thing.

So, where is it that we – can we characterize situations that we have a really high likelihood that its important for harmonization to occur and characterize the governances activities that occur around those places so that the result, you know, satisfies everybody who wants to use a value set like that. They'll be like "OK, great, yes. The governances on this meets my needs. I'm confident I can use it," those sorts of things.

In my mind I'm thinking things like they said that tackled general problems, you know, like my some of the classic ones. And there's nuances to this that's still I think fall into the category, we're talking about things like what are all those the concepts that should be used when I want to identify patients that have a particular disease process or particular procedure type, you know, things like that.

Those come up in the context of use and Meaningful Use and we forced our measure developers to kind of go off and figure out how can we get their expertise to figure out what are all the patients who should be diabetic. Well, maybe there's a better way to do those kinds of value sets as opposed to identifying those that are specifically used to treat a particular kind of VTE

which that actually I think is going to be unique because its going to be tied to a particular quality issue and the measure developers are probably the right people to do their own thing there.

Zahid Butt: So, I think Chris is going to sort of walk us through straw man for the governance aspect of a process I think but I think that's the intent of trying to spend some time today to sort of go through that straw man scenario and see what the committee feels about that.

Chris Millet: Right. Thanks, Zahid. So, why don't we get in to it because I think, I think we're going to get there anyway. Before I go over a sample straw man but we can look at one of the things we wanted to do is kind of reveal some general ground rules that sort of speak to – refer that we want to get out off out of this such governance of value that. This is going to play the part of a lot of our previous conversations from TEP and the committee, and just working to federal partners.

So, on this slide right now we have a few ground rules. Let us go through them. The first is how do we know we're dealing with value sets like the quality of value sets we want to see, so do we have all the information that we need to have in them so that we can maintain them appropriately. I think Rob spoke to that in some of the previous comments just now, having things like clear purposes and purpose statements and scope but what else of that entails them, for any proposal governance we should define what is a take two, what is a "high quality value set have so that we can effectively harmonized it and maintain it going forward." So that's the first ground rule.

The second is how do we come up with a way to maintain harmonization of value set? So, each proposal you look at, you want to make sure it kind of outlines some approach or maintaining the harmonization overtime.

The third is we would definitely want to make sure that we encourage youth of high quality and these harmonized value sets, so you go to work and find though, know that we have good value sets, good high quality value sets and know that they're harmonized, and they're not duplicative but how do we

really encourage their use. And that's just the three areas that, you know, we talked about. We decided that we want to outline in some way.

So, each proposal should speak to the relationship with measure development, that's was these value sets are used in measures. They said we should each proposals should have some kind of recommendation for how harmonized value sets or high quality value sets are relate to NQF endorsement, that's something that's important for NQF to sort out.

And last but not least what's the relationship between high-quality harmonized value sets in CMS programs. We should have some kind of recommendation or approach for how they're using these programs.

So, these three areas are not the only way to encourage adoption or use of high quality value sets but definitely big areas that relate to a lot of folks on the call today and part of the committee.

So, those are the general ground rules we came up with. It doesn't mean – there could be others but we wanted to have at least some framework for looking at the sample proposal we're going to go through.

And if we go to the next slide.

The idea is, you know, we'll have many – we'll have a few proposals not just one. And we can compare them to each other by this – using one set of criteria to kind of compare them, one raw set of criteria.

So, again, in the future conversations on this, we can certainly add to it if we're leaving out a key piece for what an effective governance of proposal is. But for today's discussion we at least outlined the initial set of ground rules to use.

So, before I jump in to the first proposal, does that kind of makes sense for everyone? Does anyone have any thoughts on the ground rules that I just went over before we start?

Christopher Chute: Well, I mean harking back to my original question. This is Chris Chute again.

Chris Millet: Yes.

Christopher Chute: You know, I'm surprised not to see a ground rule of trying to maintain, you know, semantic consistency with source classifications anthologies, vocabularies, whatever and insuring, you know, coherency between and among value sets.

Chris Millet: Sure. So, I think for at least for the first part of that, within semantic consistency with the underlying code systems, part of that is what I hope that – I hope any proposal (addressed) under what defines the high quality of value set.

So, in the proposal I go through, I suggest some ways to define that and part of that is or the value set they're using underlying code systems appropriately, semantically appropriately. And that kind of – but, you know, the proposal I go over might have the best way to do that and maybe there are other approaches of the committee has thoughts on how do we define high quality value set.

So, we hope that, you know, the proposal that we go for has a really good way of ensuring that – and anything else that we – what will make a value set high quality. But that's what we hope for that kind of issue to be addressed.

Steve Emrick: This is Steve – Steve Emrick from NLM. Just to kind of add to that – I'm thinking what, you know, when you construct the value set, you're often – it's going to be used to populate some kind of variable and, you know, done that value set. Is any of the members of that value set appropriate for that, the variable that you're trying to capture? And that's not on this list. I don't know if it should be, after discussion.

Chris Millet: Yes – No, thanks, Steve. That's another one that also I, you know, we intend for a high quality value set to do. To have them comment on how appropriate are the members of the value set to the purpose of the value set including, you know, what kind of variable it would help to describe.

Steve Emrick: So maybe then on high quality value set is to abstract for this list.

Chris Millet: Sure. Sure. That's certainly possible. Why don't – well, there's any other questions on this list but I – I want to go through how the first sample proposal defines high quality to see if it gets that some of those concerns. And maybe that, we'll make it a little more concrete so that we can see how these ground rules get apply. And if it's still too abstract, that's certainly possible then we can certainly come back to that.

OK. So, the first criterion it's high quality value, and what do we mean by it? In the first proposal, the idea of this first proposal will help to harmonize and kind of clean up existing values sets that are existing values sets that are out there that are in VSAC. And they're being used. We can get them up to a level that we feel these existing value sets are high quality.

And for the first criteria for defining, what do we mean by high quality? We're defining here in two ways. One is objectively where some of the check the VSAC already does on use, on technical use of codes that these things are automatically – that they're automatically checked.

So, and off there, it's creating a value set. Some of these they already have behind the scenes. I'm not sure how much opportunity in the areas to do it wrong in terms of picking the right actual code from and actual code systems. But this is really meant to say build on those things that VSAC already checks for as authors enter value set and select members of those value sets in the VSAC.

The second part of last bullet is really meant to build on some of the VSAC functionality that's also already there around kind of the optional purpose field for value sets. Where we also have the option to indicate what's the purpose of this value set, what kind of data elements to be use before the inclusion, exclusion criteria for creating – for picking codes for this value set.

So, objectively, the goal here is that any high quality value set, well, at least have that purpose statement present and complete, both fields are filled out and everything else VSAC check – what we check for all high quality value

set. That's some of the object of this slide which is more straightforward.
Why don't we go to the next slide for ...

Steve Emrick: Can I just say, can we go back to that slide?

Chris Millet: Sure.

Ann Phillips: Yes.

(Crosstalk)

Steve Emrick: I was going to say the VSAC – I don't think VSAC checks if your proper technical use of code systems. I'm not really sure what that means. VSAC make sure that you don't put a code, for example from SNOMED that doesn't exist in SNOMED or as what we call an invalid identifier.

Chris Millet: Right.

Steve Emrick: It also has some checks on obsolescence which, you know, I'm not sure how much of policing role we should have there but right now we do it. But it's very easy to make something in VSAC that could be completely wrong.

So, I just don't want the committee under the impression that VSAC prevents the world for making bad value sets because it doesn't.

Chris Millet: Yes. No, that's completely – when I say proper technical use, I do mean things like the invalid, picking invalid code from a code system. To my understanding – because VSAC kind of pre-populate that you chose SNOMED, it shows this SNOMED code, you know, you can't just enter a wrong SNOMED code like, you know, we would've done if we were just – I mean create a value set in Excel and I might have fat fingered or did something wrong and pick the wrong code.

So, that's a really basic check but still we want to make sure all high quality value sets at least have that.

Steve Emrick: I would characterize that, what you just describe as a check, you know, code system integrity, it checks ...

Chris Millet: OK.

Steve Emrick: ... via the coded entity, again, a version of a code systems and that's what VSAC does.

Chris Millet: OK. No, that definitely helps to frame it better. That what I was getting at.

Robert McClure: This is Rob. I want to highlight that. And you might want to – I want to highly another thing he just said which is what it does – what VSAC provides is code system version integrity.

Chris Millet: Yes.

Robert McClure: That's it.

Chris Millet: OK.

Joseph Schneider: Joe, here again, Schneider. You're going to – you're doing sort of slow reveal on – I suspect but words like, you know, value set purpose is complete. Presumably you're going – to have is like what you mean by complete? So, I can have two words and I've completed that field but it, it's the who is ...

Chris Millet: Yes.

Joseph Schneider: ... beyond the word complete there are, you know, there's other words that folks are better that than I am.

Robert McClure: Sure, yes, thank you, thank you, Joe. That's on for this is present without and complete because there's nothing about VSAC automatically checking that it's complete.

Chris Millet: Got it.

Female: Well, right, or did you mean Chris says is all four fields were completed which is different?

Chris Millet: Yes, that's really what I meant, but I guess present captures that that all.

Robert McClure: Yes it does.

Chris Millet: So, in terms of what's in the four fields that's what we're going to cover in the next slide. And that's we recheck things beyond the kind of basic thing – so your basic automatic things that we can check. So, yes, next slide, thank you.

So, subjective criteria, this is where we really need some human, you know, we need people to look at what's in there and at decide, you know, and to make some kind of judgment on what, what we see. So, let me go through all the concern of – concern of the feedback on them.

The first its called system fit. And what I mean by this is because that the value sets and the – and base on the purpose that provided for them, do they – do they match up with do you encourage the use of code systems from – I put in here as an example, the ONC Standards Advisory but this could be whatever – this could be guidance from some authority on, you know, we should use SNOMED for diagnosis. These kinds of – this kind of guidance I'm referring to what I mean for that first bullet.

We used RxNorm for medications. It's the code system that's that selected appropriate for, for the value set purpose. So, it's really among the same line. I think the example that the TEP has went through, when they're looking at the medication value sets. Those we're looking at different thing within RxNorm but it kind of gets to I think someone mentioned this just now on are the code system selected being used appropriately. So, not necessarily for the right code system but are we using the right components of the code system like are using drug classes that are brand name and that kind of thing.

All of that I'll kind of characterizing at code system fit and having people look at the value set and determine if that fit is there base on the value set purpose, which brings us to the second point if the value fit purpose clearly describes is not just started something in those fields, while are those fields descriptive enough to really communicate with the purpose of the value set is.

The third point, I guess this is not so much on, on which code system or which component of the code system but it's really similar it's, you know, when the actual member – the actual codes and concepts chose – selected from a code

system are they consistent with the – with the purpose of the value set provides, but on the code that actually were selected, are they the right codes based on what's the value set is describing that it wants to do. Again, that's something that it doesn't call the committee that kind of look at that and, you know, make some kind of determination on.

That's also where, you know, other factor outside of the value set purpose might be considered or even, you know, folks will bringing it up earlier. You know, that thing at the very least we're looking at or the actual members selected consistent with the value set purpose.

And the last is the value set conflict of other high quality value sets in terms of an – I think I look out where here I mean in terms of the state and purpose of the value set the that conflict, I think we can use the same criteria that the test been using because of overlap, but that's Jaccard index. But if any kind of proceed conflict between the (site) and others that's something that, again, it's not come through to automatically determine, so this part of the subjective criteria when reviewing value set, is this is a conflict with any other value set that's already being (high) quality.

I think there's more we have on (high) quality value sets when I know that was a lot so that's a good break here to see if there are any comments or questions.

Cynthia Cullen: This is Cindy.

Chris Millet: Yes.

Cynthia Cullen: Regarding the code systems set in your second bullet being used properly to the value set purpose and you're mentioning like drug class versus brand name, some of that, first of all there would need to be some guidance on it and second of – some of that is specific to a potential purpose for the values that, you know, some and I'm thinking in particular that some CMS quality reporting programs may have specific requirements for preferring none branded over branded or vice versa.

So, I think that's something we haven't talk about potentially uses of the value sets but something when they want to customer consideration for here.

Chris Millet: Yes.

Steve Emrick: This is Steve. Under code system fit, I would say maybe, maybe another bullet will be – is the right code system being used, because sometimes you have it under subjective criteria sometimes, you know, QDM kind of mandates, you know, if you have this type, you know, you know, tuberculosis diagnosis active you have to use SNOMED, so that's really I would say for in the context of QDM subjective but then if you're using some other data model it might be subjective, but I think – but I think the is the right code system being used another, you know, could be a – another potential bullet point under that.

Christopher Chute: Yes, this is Chris Chute, I agree with that. I mean you're saying that you sort of saying that it consistent with the latest ONC Standards Advisory but I think it somewhat weak and I certainly I'm troubled with it being subjective. I mean I would be much more direct and say is it concordant or it doesn't comply with Meaningful Use requirements. Meaningful use should trump QDM by the way.

Chris Millet: Actually I don't believe the QDM binds any specific terminology to its data types.

Christopher Chute: Then all the more reason to use Meaningful Use.

Robert McClure: Yes, this is Rob. I think that's – Chris, what you really mean is that this is – the sort of recommendations that you're eluding to here all from Meaningful Use not QDM. And I think what you're also getting a sense of this that there some other than this is a complex problem.

Some of these things could actually be not subjective that they could be more hard and fast and certain contacts, right? Now, part of what we've just ended up talking about here are guidance to authors that are creating value sets based on what in a context of the value set creation process is really outside of the VSAC but it's – but it's a sort of a thing that VSAC and value set creation needs. And that is if I'm going to use – here, I'm creating a value set. But I'm going to use this value set in a particular place.

I'm going to have it down in the QDM model to particular, you know, so-called data type and QDM, where that given this other external piece of information, guidance from, you know, Meaningful Use says "OK, if you're going to do it that that data type is looking for a type of diagnosis and Meaningful Use," in the (U.S.) says "You should be using SNOMED for that."

All of that's actually, you know, kind of symmetrical – regimented, and therefore you could it's really not necessarily a subjective activity. It could be more actively control than in fact, you know, Steve will confirm this. We've been thinking about how can we bring that to VSAC, because VSAC can have knowledge of this external constraints and can inform authors and inform a harmonization process t say, hey, you know, you if you're going to be associating this value set with a particular use binding and that that particularly use has constraints that we know about we can tell you about those constraints and we should apply those constraints in terms of our harmonization guidance.

So, it's a – so there's, you know, there's this – there's the ability to utilize external constraints that aren't necessarily embedded into the meaning of the value set like you talked about a minute ago.

Chris Millet: Right.

Robert McClure: To help us do objective things not subjective things.

Chris Millet: Yes. I think that's the intention behind code system fit. The only reason why I still kind of included this on this subject of was because which of these external constraints that were up high. I didn't want to prescribe that for all cases.

Certainly, you can imagine meaning use would be one where you, most of the time if all of these value sets ...

Robert McClure: Right.

Chris Millet: ... supporting Meaningful Use measures but if – what if we're looking at values sets in the VSAC? They are not supporting Meaningful Use measures.

Robert McClure: Exactly, exactly.

Chris Millet: I feel (inaudible) advisory because I thought that was higher level and more – supposed to be, you know adopted more broadly than simple – than simply for reporting for Meaningful Use. But I think any guidance from any authority could be slotted in there and that determination, I don't think we'll ever know – I think that might change based on the context and I wanted the committee's reviewing to be able to determine what – based on the value set purpose and the committee's judgment on what guidance are – what objective guidance are we going to apply?

Both the value set mentioned – this is supporting some Meaningful Use stage 3 measures then the committee should say, "Let's look at Meaningful Use stage 3 guidance and stick to it."

Robert McClure: Right.

Chris Millet: And that's the kind of interaction I was hoping for a code system fit and external guidance outside of this process. But I didn't want to prescribe it in all cases because I think – I don't think we could cover all cases adequately.

Robert McClure: OK.

Nancy Walker: This is Nancy. I have a question that based on the last discussion we were talking about, object of – by way of VSAC. But some of the subject that needs to occur by way of the "Committee" whatever that may be. So, can we be clear about is this VSAC sits on this committee that includes the clinical people, is that what were talking about?

Chris Millet: So, are you getting who's committee and how does that ...

Nancy Walker: Kind of.

Chris Millet: Yes.

Nancy Walker: Maybe I'm getting a little too far ahead, but yes.

Chris Millet: I think it is (quite too) ahead.

Joseph Schneider: Hey, Joe here. If I could on this slide ...

Chris Millet: Yes.

Joseph Schneider: ... if that's all right? At the very end, you say does the value set conflict and you might have addressed this but the word conflict is the – or conflict. Chris, or Chris Chute was earlier talking about what is the relationship of this value set to other value sets? Is there an overlap? Are there linked? So, just conflict is a – might not be the best choice of words but it's really what is the relationship of this value set with other high quality value sets?

Chris Millet: Yes. I think that's broadens and get that come on the earlier comments.

Joseph Schneider: That's right. I think this – you know, I think relationship is fine but I do also think that we need to call out specifically the overlap issue because that's kind of what started this all effort to begin with, right? Your relationship can be an overlap but it could be broader and that's fine but I think it should be relationship and overlap or something like that which ...

Christopher Chute: Well, I agree and I don't know if it's a VSAC job or whether it's NLM's job or whose job it would be. But I mean, somewhere, somehow there should be an ontological framework of all value sets and if you will, for any given element of that value set, where it occurs in other value sets and what the relationships between the value sets are semantically.

You want to make a semantic network out of the value sets. Now, I don't know that that's QDMs job but that would be an ideal. And any approximations we can make toward having an explicit semantic network of value set contents which would make explicit their relationships, I think would be highly desirable.

Steve Emrick: This is Steve. Chris, that's an interesting idea. I see these – I think that was in the value sets. We absolutely want to achieve semantic consistency. I mean,

you don't want in general, you know, mix up SNOMED diseases and procedures of the same value sets but – so when you start talking about semantic relationship and value sets. I'm not sure – I'm not sure how people would view that and I – so that's one issue. And then how – to me, I see the semantic relationship more on the side of the variable or the data element and that's where you could have – you could assert these kind of semantic relationships. It's more on the element side of using that value set to complete it.

Ellen Harper: This is Ellen. I have a question on the choice of the words said. Is integrity a better word than fit, between not to be consistent? And then that – that plus I have a question. Are we ever going to come across a term that's going to be used in the value set that is in the process of being added to a coded system like LOINC or SNOMED? And do we need to account for that?

Chris Millet: Oh, well. Certainly, open to how we frame. So, this is the first part of your question on code system fit versus integrity. We're certainly open to better ways of framing that. Are we seeing in the objective of criteria there was a certain – because a better way to frame what was – what we have there in terms of code system version integrity. So, I think we have. We can probably find a better way to frame what we mean by code system fit and I think we had a lot good earlier suggestions on it.

I made to think on the second question that you asked. I'm not sure if others have thoughts on it.

Ann Phillips: Well, when you built a value set in the VSAC you have to pick codes that are in that version or other versions of the code system. You can't really type in your own code.

Nancy Walker: That would say then in order to get this approved or (inferred), I will need to do the preliminary work. So, could some of the social determinants in health, I think we're going to uncover some that need to be coded in SNOMED or LOINC. So, maybe that's the first step that would have to happen before it could ever come into here.

Ann Phillips: Right. Right, that's the process we view as we've some of this is the code request and then once it's been approved and the code has been added then we are able to pull it into the value sets.

Nancy Walker: OK. So it's assumed we don't met – there's no need to add it here. It's a prerequisite.

Chris Millet: (It was) my understanding. I didn't think it was possible to add a lift when you're offering a value set into VSAC to adding codes that haven't been added yet to a code system.

Christopher Chute: You cannot, right now.

Chris Millet: Yes. OK.

Male: Yes. And that's a use case where we're trying to handle a little bit better and there's lots of different ways to think about handling it. But right now, you can't do that although, you know, in the context of harmonization, I'd be interested in how that – the provisional code thing fits in.

Male: Yes.

Chris Millet: OK. Why don't we keep going on (this)? There's a lot of other aspects of this that we want some thoughts on, or that might spur up other proposals to handle them better.

So, just to continue on the subjective criteria the idea that the these criteria are evaluated by some kind of test, some kind of Technical Expert Panel similar to the one's that we're piloting right now that we're trying to definitely learn from the ones we're piloting now but see how that – how that can be used regularly in the future when we have governance established.

So, with this proposal, we're suggesting that we have what – meet monthly to review either existing value sets in the VSAC to determine if they're high quality, newly submitted value sets – so, I guess, newly created value sets in the VSAC. And then value sets that were previously created and the already

considered high quality and – but may have already "expired," and I say that in quote, because we'll talk about what expired means.

But the idea here is that we have a group that convened – that revived regularly to review and make the determination so that we have a lot of opportunities to review and rereview value sets to get this high quality – to be the high quality so that it can be used in other efforts like in eCQM measure development or in other new cases that might need to use these value sets so that, this is something that happens really rarely and when it does it's a big monster of attack. And it can't properly support other activities that needs to go on.

In terms of we had a question earlier on who's doing this, but the idea is that is the group meets regularly by the idea if we can – they gives better opportunity to plan out who's doing – who's on the TEP and kind of aligning who we want on the TEP versus which value sets we want to review at any time.

So right now, for example, you know, even with our pilot, we decided, at some point we're going to review the first that the medication value sets. And then we decided – no, half of that we're going to comeback and look at an encounter value sets. What this proposal or we're suggesting that in – we do something similar when we look at, OK, and we know we want talk about encounter value set that convene us, we'll do that and let's say September, lets scope between now and then we'll convene a group that has one member that are, you know, experts in the cons, the domain of the value sets or the kinds of encounters, the device that DOS but also in the code system that are used by the values that will be reviewed.

Those are the two like high levels criteria for who this test are intended to be and because they are meeting regularly that the hope is that is give some opportunities so practically plan for when we convene which task to review, which value set.

But we know we're going to tackle harder issues like some of the issues of diagnosis value sets, we know we might be doing in December we can pull together the experts and the domain areas for the diagnosis that value sets we

will be reviewing are, and we can pull together experts in ICD-9 and SNOMED, and ICD-10 whatever other code systems are being considered for those value set. So, that's kind of the rationale – that's the thinking behind who's doing this review.

If we go to the next slide, I'm going to see what else we have on subjective.

Ann Phillips: Hey, Chris, can I just add in there that if we are going to have a TEP – we're going to have to really consider how that fits in with the measure updates every year.

Chris Millet: Yes.

Ann Phillips: Because if I'm updating a measure and I need to create a new value set and my updates are due by March 15. I might have to jump ahead of the lists on a totally different expert panels and we've been thinking about for whatever subject is up for review.

Chris Millet: Right. So, curious to hear your thoughts and another measure developers thoughts on the call and folks that is involved in the measure development their feedback on this, the idea is it sound its like a balance between some kind of ad hoc review for measure developer needs because the value sets review because they measures are due in March, they have time to do it.

The hope of this proposal was that between now and March, you can work backward and say, we need to have a value sets, you know, reviewed for high quality by sometime before March. So, by December, or January, or November or sometime earlier to get that, that designation so that your – all your value set things your measure will be high quality by time, you know, you're measure development contracts done or timely measures are limited to NQF, or by the time they need to go to whatever the next step is. I don't know how well this monthly meeting will handle that but that's the goal that it can handle that so we're looking for feedback on whether or not that's true.

Joseph Schneider: It's Joe here, if I could so, I think the slides start out with the word governance but I think what this be – if I can be – to be honest I could say this is actually

sound like a gold star programs so quality – or for value set rather than the governance process for value set.

And, you know, from what you describe, I don't think monthly meetings will get there and I guess it with go back at early on, I pitched the concept that, you know, in accounting, we have the financial accounting standards board, (David's staff), they (inaudible) stuff. They made sure the standard fit part that are allowed to exists are all high quality. There is no such thing as a low quality standard or low quality value set.

There's a couple of thoughts there one is it takes some awful lot of efforts to do this and certainly in terms of, you know, its got some timeframes that were just mentioned. And then the second thing is I would suggest putting in a lot more keys like if you don't if you're not a high quality value that then you're not – then you're not a value set.

Chris Millet: OK.

Steve Emrick: This is Steve. Does that – what is not a value set means in the context of people publishing ...

Joseph Schneider: It means you don't exist. I mean, you're not allowed to call yourself a value set if you haven't pass this through this evaluation.

Now, that I'm being – I'm taking (inaudible) out on extreme, I understand but I think the – if you don't have that you're our little Technical Expert Panel here will rapidly get overwhelmed and some things will have gold stars, something won't and folks will ignore the advice of the Technical Expert Panel.

Chris Millet: So, let me before we get other thoughts on that, just really quickly. We're hoping – what they're trying to do with calling these value sets was the things we talked about as high quality versus, you know, what value set that don't meet this criteria which would be theses value sets are even low quality value set. That's meant to really provide flat for value sets they having gone through this kind of review already, like we know their value sets in the VSAC because now VSAC offers field for purpose. People are providing them. But we know there are existing ones that just didn't get there yet, and we still have

to deal so we don't want just say we don't use them. We need a plan to transition though into looking like how we want them to look.

So, the goal with this proposal is the kind of create that path. So, if any new value set, value ideas that they are being prompted for all of these things, the things that the purpose fields the code system version integrity that we talked about. And that, you know, value set have created will get reviewed to see if all those other, you know, "objective criteria" are met and are appropriate.

But for the existing ones we want to process, that regularly gets those review in a practical feasible way as well, and the piece is later in proposal we get to how these high quality value sets relate to other processes. And the goal there is that other processes should encourage only using high quality value sets and the low quality ones aren't picked up.

So, you know, we'll get to that in a few slides with ideas that, you know, CMS program of measures that you high quality value sets, NQF endorsement strongly factors in using high quality values that and so on. We can go on to other processes as well but that's the general thing to we will get during the later slide is supposed to be some of the drivers for why we want – or for drivers who are getting this high quality designation. But again, you know, definitely here your points on is this is not strong enough. That's what we want to review. And maybe we will come up with proposals, alternative proposals to add better (fee) for that.

So, I just thought I'll put that context in.

Robert McClure: So, this is Rob McClure. Maybe I got lost in terms of the value sets that we might run through this process. And I'm going to highlight – I forgot who said about this focus on governance versus – and I'm going to use a word that probably will get me in trouble in the space but endorsement kind of sounds of like there is an endorsement process here.

There are certainly values in doing all of that stuff overtime but I'm a little worried that we're trying to eat the elephant. And I think that there's a possibility of not getting into the middle of the really difficult fast moving stream of producing value sets across the entire set of requirements needed for

Meaningful Use of eCQMs. That's one thing. I worry about standing in the middle of that stream.

Two, we have to acknowledge that with very good reason, there's a lot of value sets across the spectrum of health care and not – and actually I could use a little reminder as to what constraints to this particular community needs to work within in the context of its charge because I sense it's just Meaningful Use and VSAC is actively and will continue to actively pursue the use of this tool, VSAC tool by a wide-range of value set authors, not just those creating eCQMs and although that's clearly the majority of the current VSAC content.

So the sort of things that are going to be in VSAC that could benefit from guidance will grow beyond what's, you know, those value sets that are just focused on meaning the needs for eCQMs.

So I asked, you know, if we focus on governance – if we focus and I kind of alluded this before, I think there are value sets that there's qualities, characteristics, there's characteristics of value sets that in my humble opinion lend themselves to targeted harmonization because there should be consistency with regards to their use independent of context and, again, air quotes a little bit that as a starter process it certainly can be true.

And lend themselves to kind of universal guidance recommendations in terms of approach. They would benefit from the sort of things that Chris's continued to highlight about oncologic knowledge and consistency and completeness and that sort of thing that won't so often run into nuances that, you know, require a particular kind of concept ingredient whatever. They don't need to be in there because it has a very specific context of use.

And so if – and I don't want to drag this in a totally different direction so I'm asking if that's part of where we're going here because I could imagine value in this group with some, you know, kind of efficiency getting to saying, "OK, here is our some – here some criteria characteristics of value sets that, you know, in terms of what the purpose would be and that sort of thing where, you know, we would give recommendations with regards to a process that should

be followed that could even potentially lead to endorsement because the governance process was followed.

And it would be a smaller percentage of the overall stream and wouldn't, you know, kind of get into this. OK, well then, you've got a gold star and you don't, what does that mean across the entire spectrum which given the timelines and stuff I worry about.

So am I talking about what you're talking about or did I throw a wrench into the game?

Chris Millet: No. I think they're all valid and that's actually what we'll look for so from alternative approaches to governance, the things you mentioned sound like just the difference proposal for what governance looks like and definitely with the concern of it being more practical.

So, I mean that's – just as aside, I know we're looking at this, this one proposal right now with the idea of that as folks react to it and they have thoughts on different really different models of governance, the value sets that we can look at those side by side and we'll see, you know, here are the ones that we really want to go with based on the different strength and challenges.

So that's not far off, Rob. We do and to others they're bringing up these kinds of concerns that is what we want. But we just want to be able to have a way to look across different models of governance and hoping that lead us to what we eventually recommend on an approach forward to governing value sets so that's a key goal of this whole entire project.

Steve Emrick: This is Steve. I do agree with Robert essentially on the, you know, the idea of this, you know, moving towards the, you know, the gold star approach. I don't – I'm not sure, you know, when we update these things it's a very fast nimble process and there's a lot of back and forth and I'm not sure that that process could be kind of – it's not just of the maturity where, you know, kind of stuffing value sets along the way could be useful or even happen in anytime in efficient manner so I would kind of caution things in that direction as well.

Chris Millet: Yes. That's helpful.

Zahid Butt: So I think the discussion. This is Zahid, the sort of scope of this governance and the word governance imply to certain amount of sort of something more than just simple guidance I would think so the scope at least as far as I can think of are sort of this large and small overlapping circles and the three that I think of are sort of the CMS controlled Meaningful Use type of circle which is a very well-defined circle and in the eCQM world at least that's where the rubber is meeting the road right now.

The other which is sort of the NQF endorsement which certainly is beyond certainly Meaningful Use but again it's still not the entire circle. So the entire circle is sort of the universe of all these things and so I would think that the more limited scope of any kind of governance would be the smaller circles which would be sort of a Meaningful Use endorsement kind of circles other than sort of the global measure development that goes on not perhaps just nationally but internationally.

But I do agree that the process that we're undertaking is still in its very early formative stages and it shouldn't be something that gets in the way of even annual updates of Meaningful Use by having some kind of mandate thrown in their prematurely.

Robert McClure: Yes. So this is Rob. You know I want to kind of really caution this. I'm surprised that, you know, what we heard with regards to, well, I would need to move to the frontal line is I think a very polite small voice that would be a torrent of pain if we were to get in front of the way that the current process functions. It's just not as Steve was alluding to, it's not as efficient as we would like to see it that still kind of getting its feet under itself and no way am I suggesting and I – well, I think the measure developers are doing an extraordinary job that is been improvement on certainly on a yearly basis and really on a monthly basis.

Nobody feels comfortable that they have this thing really nailed down and so one, no one is going to say, "Oh yes, we would just absolutely don't need any input," but they're also going to tell you that they have requirements that they have to meet in terms of timing and all kind of things that for some the, you

know, responsible stewards are hundreds of value sets. And without giving guidance about which ones might have to meet a process that would benefit in a timely way there is going to be a chaos.

So that's why I think if we really focus on identifying characteristics of value sets that would benefit from a process like this as our first step and maybe again, that's why I'm not sure that I'm really off field from where you were going Chris but I just want to highlight that I really think that would be a good place to go first knowing that we want to sip from the stream and not stand in the middle of it.

Female: Yes. And Rob, you also made me think of something because we run all of our codes to past technical committee of our own and in NCQA. And so then my question is what if my technical experts disagree with your technical experts as to what should be on the value set? Where do we get a tie breaker?

Joseph Schneider: Joe here, actually one of the grenades started this. I think that sort of the crux of the governance issue that you either have governance or you don't. And I do agree that it has to be a steady process for getting there. But somewhere along the line, it has to be somebody who can say yes and no, the buck stops here. And I think that's in – and we, we as a group may not be able to identify exactly who that is but it's got to be somebody because otherwise we – I don't think they make – they can make progress certainly by saying what's good and what's necessary and so on, but we can't get the true governance without it.

Zahid Butt: Rob, can I go back to I guess some of your approach when you're mentioning focus on identifying characteristics that, you know, the advice that we'll benefit from? Is that more of a – let's come up with – well, let's continue to improve on guidelines for developing value set or that's something or there's something else more to that.

Robert McClure: That's not what I had in mind. It doesn't mean that it is not part of it. But what I had in mind were that value sets that are, you know, I kind of mentioned this before and just made – this is kind of a small set particularly in terms of what we use in our current value set.

But, things that are general groupings, you know, they have a scope that's more general and reflect the expertise of things of – they reflect a need for expertise that may not be driven by the nuances of a particular youth.

So in that context I think of things like, you know, some of these that you just may seem too general to even be useful, but they're in my mind. So, like I said, all of the codes that represent diabetes.

So, when one looks at that, one of the things that the process has taught us and some of the measure developers have followed, they're saying, OK, well diabetes is actually somewhat diverse entity.

And so, you know, it makes sense for example to think about codes that represent conditions that are insulin dependent, non-insulin dependent. Pregnancy induced, you know, has a separate category.

Things like, OK, subsets of disorders that, you know, and I wouldn't kind of blindly go out and find these things, obviously they're going to be driven by the needs of a particular, you know, our current measures.

So, you know, things like disorders that affect the metabolism of drugs. You know, that – those kinds of general things and I won't know that that one is in there, but it could be where if we identify criteria that whatever those criteria are that I used to come up with this list, then that kind of sips from the stream.

And I think it's a sort of thing and I'm really being presumptuous here but measure developer said, "Yes. You know, if you can help provide guidance on that, bring in the right individuals into a TEP that can reliably, you know, identify how you determine what concepts along in a value set like that." Get it endorsed even.

Then, we'll use it. We may not – actually, we may say, "Well, you know, we're going use it or we're going to have to take a few codes out," but it's a starter. And then our TEP, our technical panels because of the specific needs of our particular use, we'll build from that or modify from that, but at least we'll always start from your thing.

That's what I have in my mind.

Zahid Butt: So, Rob, I think just to kind of generalize the concept that you are proposing I assume you're sort of implying based on what you were saying that the – perhaps the initial patient population and denominator definition is kind of what you're referring to more than the specific numerator type things or the specific negations that pertain to numerator value sets. Those pertain to those very precise things. Is that kind of what you're ...

Robert McClure: Right. I am. I'm also as you can sense that I'm not focusing – that's not to say that we – this can be brought to us, but I'm not focusing on, gee, we just need to look and see what's there and attempt to harmonize.

That's what – that was certainly in people's mind when this process first kind of came to be because we had a lot of those and because they're all created independently. And there are few that still exist.

But, I think that managing that first half of harmonization requirement was an initial set of work that on an ongoing basis because of the capabilities that VSAC has provided in terms of kind of universal viewing and all that sort of stuff, the – will become less and less of an issue.

And I think that where we can build a foundation for harmonization as a de facto activity is by doing what I just described or – and then the people who are coming in to create value set see either something they can use or see something that has, you know, high quality that they can build from and make some minor modifications to.

Female: Right. And to build on that Rob, if you made your value sets granular and up like diabetes if you did insulin dependent, non insulin dependent, you know, gestational, secondary whatever, I would be more than happy to combine those into what I need to say that, you know, this is what I mean by diabetic in this measure.

And then maybe somebody else will combine those in a different way to say this is diabetic for this measure. But we're all starting with the same foundational value set.

Male: So ...

Robert McClure: Yes. I apologize if I've drive you into a different direction. But ...

Zahid Butt: No. I think it may not be more a different direction, but maybe just that's stage issue that maybe in the first stage you pack all those. I think personally that defining the initial patient population denominators should be theoretically easier than the ones that have to do more within numerators and precise sort of negations that ...

Robert McClure: Right. And I mean not to interrupt but one comes to mind that's even, you know, the sort of things that are really quicksand but, you know, this group could potentially at the right people could tackle. And it seems like, OK, what are the right encounter concepts that identifying counters?

I mean these are very troubling, very difficult. I can't imagine any measure developer who wants to actually have to figure that out and certainly not many universal way. So, you know, these are problematic areas that do need harmonization, do need consistency in terms of approach.

And that consistency in terms of approach and I wouldn't really get caught into the study because it's an easy place to spend a lot of time, but it needs governance. What are the rules that creators of value sets need to follow in order to make sure that they do this right thing?

I mean we've already addressed some of these things. That horrible way issue around how do we identify encounters, you know? You know, I'm worried that I'm using that as an example because it's a good one, but also because it's a bad one and that we need to be careful about trying to spend a lot of time thinking about what's really the right model for this.

But that being said, you can't create good value sets without understanding the model. And that's how – that's part of what we need to describe in the governance. So, you know ...

Zahid Butt: But, Rob, you wouldn't be opposed to it if the governance process starts there but eventually needs to – the full sort of harmonization semantic relationship that Chris was describing throughout the process, right? Eventually ...

Robert McClure: Oh yes, no I agree. I think, you know, I mean my understanding of what, you know, I assume Chris still here. He can certainly speak from herself but there's a lot of knowledge in code systems that at times is hard to tease out from – I mean now VSAC provide access to view things and the context, in the that code system context that's really useful but I'll say to some but it's foolish to create value sets without understanding the code system.

Chris Chute: You know, I would agree enforce that, you know, I am still here and, you know, it turn – some code systems are smarter than others. Let's be honest. SNOMED has a lot of depth, a lot of symmetric coherency, you know, LOINC and RxNorm not so much so. These things are relative but they are enhancing, I mean the class infrastructure within RxNorm just got a complete revamp about a year ago. And so now, you know, you can actually talk about the beta-lactam penicillin where as that was a hard thing to do three years ago.

Chris Millet: So, I mean we're kind of already into this looking at alternative approaches. I'll just going down that path. Rob, I will make sure I'm getting a good graph for what you're describing. Are you saying a good model for governance is having a TEP or a group responsible for creating – initially creating high quality value sets for problematic areas that are hard to harmonize and then the governance is how people should create value sets or how people should use this value sets that this group creates?

Robert McClure: Not exactly.

Chris Millet: I was worried about that.

Robert McClure: I'm not discounting that but what I was describing was that this group could – again when I think of governance in this context, I mean that's a pretty kind of general phrase but it's guidance. I'm thinking about guidance about how those value sets should be crafted. It could be that we would then having then done that, again, you know, they'll be easy to get stuck in that for a long time and I wouldn't want that to happen.

But once you kind of got some general framework about how you build a good value sets and what are the characteristics of value sets were we want to do this kind of more general, you know, apply this approach initially then you – and then we need to go and find, you know, some real needs i.e. based on our current, you know, Meaningful Use requirements around this and the eCQM and associated Meaningful Use requirements I would say because there some like go that aren't eCQM based but are, you know, CCDA and (HQMF) and QRDA based. And then we might say for example, I mean part of this I'm going to say things that I think might be true and I've been wrong so many times. I hesitate to say but, you know, talking to specialty societies, talking to organizations that have knowledgeable clinicians who also understand coding.

And working with them to figure out, you know, in the context of the sorts of use we expert value sets to be use in particularly in the idea of creating quality measures and decision support. What subsets of codes, what kinds of information, scopes – a scope or a purpose for the value set are necessary in order to meet the needs of value set users? And then how do we, you know, how is it that you best pull those concepts into a value set?

Again, this gets to a Chris's issue, I mean some folks mean, you know, some of those more clinically orient post may not be as aware of what code system capabilities they could utilize but SNOMED like hierarchies and things like that. And then, yes, you could even say that having then created those – having then identified those characteristics on that process, you would apply it against the code system, you know, sorry the value sets that are in play. And, you know, this is sort of stuff that we've already that lead to some of the initial work that was done, Olivier Bodenreider at NLM did were they said, OK, let's look at this value sets and see and lay them on top of the code system structure and say, "Why he's got this one code from this hierarchy and then the other code. Is that a miss or not?"

And so some of this processes that, you know, that we could say are important processes to apply, you know, we would presumably actually do for some test value sets and yes, it's possible that a TEP could end up through that activity

come up with the actual content. But I'm more interested in us defining the process that could be followed by any entity and necessarily just doing the work and not telling people how to do it in another place.

Chris Millet: I see.

Robert McClure: You know, again I am – this is – I'm not an, you know, I was about to say I'm not an expert in this. I'm actually an expert in this but I'm not – we don't know how all of this works really well yet. And so we have to test some of these things out. That's my understanding what this group could help do is begin the test some of these waters in order to – because as I noted there's a – we're already in a rapidly moving stream in terms of creating thousands of value sets to support Meaningful Use in eCQM.

And we want to give guidance to those measure developers who are responsible for doing this but we can't tell everybody just wait until we get it done.

You know, there's another part to this is obvious but ask – I mean, you know, we have some measure developers here on committee and there are certainly others and, you know, once we kind of decide this might be something that we want to follow, we can go out to them, after they say, tell us what value sets you want external support and understanding how to better do? What are the characteristics of value sets? You know, do they follow the sort of things as Zahid was mentioning?

Chris Millet: So the other portion we want some feedback on and keeping in light, you know, approach you're describing or even with the gold star approach that the proposal of how they're going through that has its practical challenges, any approach for governance, one of the things we're looking for is how to relate to other, in this other key activities whether it doesn't relate at all or it relates in some small way but just understanding what that looks like and how do this process intersect.

So particularly the ones we went over earlier, measure development in general which we've been talking about, we've been doing the job of keeping in mind

but also how they're use in program, Meaningful Use and even other program that eQMs decide Meaningful Use and measure endorsement. These are things we're trying to figure out how do they relate to this kind of activities for somehow harmonizing value sets.

So any thoughts out that's, I mean I don't want to this have to only be limited to Rob because it kinds of addressing you were just talking to but – from anyone are there any suggestions on the kind of relationship that seems practical for governing life, how that might relate to some of this other key activities?

I can take that off. I can go over how this approach that we have on the slide relates to other activities but, you know, we don't limit it there once – both kind of broadly on in general how should governance of value set relate to these other activities. So why don't we go through a few of this just to kick off, why don't we go to the slide.

So some of these slides again we're just carrying out (inaudible) I described it already which, you know, it doesn't address the challenges folks have been bringing up because it's – this is this continuing the same approach but the idea that in a way you're kind of sampling value set is high quality and value sets that (inaudible) high quality will be compared to each other, part of that process is comparing them – comparing value sets being considered for high quality to other already high quality values sets.

So we heard the challenges of that already but the idea of this approach is that, once the value set is considered high quality then we want to pick those value sets and prioritize the way they're used in other places. So if we go to the next slide and lot as we go forward.

Joseph Schneider: Can we go back to the previous slide? This notion, I was looking at something about a value set expiring automatically even if it's intentionally defined or at least it's a high quality approval expiring.

Are you really sure you want to do that? I mean you know, pharmaceuticals are a good example. Let's say you want to include a whole class of either anti-

hypertensives or antibiotics or something like that as and part of a quality metric. Well you know they had these things like candy.

And are you – you know just because they add a new anti-hypertensive and the quality metric is about you know blood pressure management, are you sure you want to automatically expire the quality status just because a new, you know, antibiotic is at the formulary or to the to RxNorm.

Chris Millet: Yes, so that's a really good question. The thinking behind that is, if the members of the value set changed even in the situation just described where it's intentional, the value set intentionally described and the code system change leads to different – hold being hold into the value set when it's expanded.

The idea is that we want to "expire" the value set so that it triggers it to be reviewed so that we can check again to see that the purpose of the value set still matches what the members are, now that the members are different. And the reason why we thought this would be – we compose this as a trigger because we figure there's no way to know whether or not that change would be something we want to – whether or not, we know, that that change is small enough to say, no it's probably OK. It still meets, this intention – this change that happened because the value set potentially the final be in lined with the values set purpose.

We figured out the – we assume, it will be a subjective determination but yes we'll definitely hear your thoughts on that focusing in most cases or in all cases. Intentional changes like the one you described are – should still meet values sets purposes. That definitely useful feedback on that and then maybe it should be a trigger.

Joseph Schneider: Well I mean if the authors choose to use an intentional definition they make that choice deliberately and I would think that just because you're adding a new drug to that class or whatever, it would – I think you got bigger fish to fry than to review every darn twiddly little code that gets added to unintentional class.

Nancy Walker: This is Nancy, you know I am – I really understand what you're saying but on the other hand when it comes to the – if we're talking about Meaningful Use and quality reporting, when it comes to that kind of detail, it's the physician in hospital A that is now using that new measure that new drug that is he no longer meets the measure because it's not in the list. So, you know I can see both sides of it. That's a difficult issue.

Steve Emrick: Yes, this is Steve. I mean I think there's a lot we're talking about here in this slide. This is kind of packed slide in terms of the issue. And, you know, one of the thing is this issue of automatic expiration and I think that's a really, that could be kind of a dangerous thing. There are – you know, a lot can talk about this but the idea of a value set definition having effective date and even in expiration date as metadata that can help the author determine, you know when it's appropriate for that values set to no longer be used in terms of a creating an enumeration or a value set expansion. And I think that if we get in the, you know, this committee or VSAC gets into, you know, auto expiry of things that could be a big problem.

I think that even we may have gone even a little too far and letting people add or include inactive or what some code system called obsolete codes and their value set, that's not that easy to do right now and I think we should consider making that easier for purposes of look back. You know you might need those codes for a very good reason. And, you know, we'll always provide the tools for people to know whether a code within, it was created at in certain value set a certain time is still active or not within the context to the code system. But we might want to make it easier to meet those use cases.

And then the next thing we're talking now with drugs, it's you know, I've sensed that there's kind of a divide on this issue in terms of the measures and the values sets are – we're not to the point yet where a value set can update because of the new you know – has a new drug, it doesn't matter. That value set is statically bound to that version of that measure and therefore yes, the doctors not going to get credit for that but then the implementer community I think is sensitive to too many updates at once and the impact on have workload and then quality in any kind of safety issues that could come from that.

Robert McClure: And so this, this is Rob, Steve is right there's a lot in here and again I highlight the importance of giving governance and recommendations with regards to the guidance from this committee in terms of how measure authors and value set creation interact. But I think all going all the way to just kind of saying auto you know, auto X, auto something probably is something that we want to eventually get to maybe but not start as our goal.

I'll finish by just saying that, again my humble opinion, this issue around the utilization of value set expansions, you know what you actually use in a context of a particular implementation is – the offering processes, one of trust, right.

So, the idea you built, that you define a value set using an intentional statement and expression and then you get the set of codes out of that, when you run that expression. Whether that set of codes that you get by running that expressions are could be "trusted" is a complex issue but that's really what it's about. It's whether the author trust that the resulting expansion set meets the intent of the definition.

And I think we can again give guidance to authors and there in also the use of value sets so to measure developers about characteristics and criteria that will help them decide whether they in fact trust that expansion or not. Whether it was reviewed, you know, in the context of the situation may not have been reviewed.

And so these are really important things I think that this committee could really bring value to the overall activity by looking at the nuances in that particular set situation and saying here, given our, you know, our knowledge, we would give guidance about trusting expansions in these situations but probably not in these other situations.

Zahid Butt: Instead of – this is Zahid, instead of sort of the auto cancel which implies that it just automatically gets disabled, would there be more tolerance for some kind of an alert system that goes in and there's the 30-day preview period or something after which it becomes automatically disabled.

Steve Emrick: I think why – sorry.

Robert McClure: Yes. I think – sorry, Steve. But we are talking in metaphors and don't take that wrong, Zahid but the practicality of our situation, I think what you – this idea of auto anything, just doesn't exist.

Zahid Butt: Yes, yes. Just having a discussion trying to balance what the measure developers, you know, because as we heard there's – there are two sides to the argument. I'm not partial to one or other. I truly understand the complexity issue and trust me I would be the last one to even suggest that we had any more things that are going to become, you know, difficult to handle more so than things are difficult to handle as it is.

Robert McClure: Yes.

Zahid Butt: So, I'm not suggesting any – I would just trying to ...

Robert McClure: Yes, that's why I think there. I can – someone said ...

Zahid Butt: Auto process that at least accomplishes what potentially the measure developers could still have some issue with even though I understand perfectly what Chris is saying that ones to have elected to do the intentional but that that's what their intention is. But, you know, again, you get this exceptional situation where is something could potentially slept through that was unintended.

Robert McClure: Yes. So, again, I want to dominate but it – I think this is an important thing but my – when I read this, what I'm thinking is sort to stuff that Steve is kind of alluding to it too is that is – let's think about what are criteria by which certain code systems or value set scopes would lend themselves to supporting consistent value in the expansion set.

And others need more close attention in order to be confident that anything that occurs in the context of an intentional statement would lead something that any user the value set would be comfortable with. Because really what this is, it's about the measure – sorry, the value set offer providing confidence

to users of that value set that the expansion set, the set of codes that are the result of the expression analysis is exactly what they're telling the users it was going to be, right? Because the user or the value set comes in and says, they – I know there's some practical. Well we don't really do it because build the whole thing, we don't care.

But the reality is a user value set is going to read the purpose, going to look at the set to the definition. And right now, we don't have complex definition, you know, so that can look at the expansion set. And say, "This is what I want." And the next time that expansion could change, they have to have a trust with the author's extent that the measure – that the expansion is going to continue to perform in the way that they expected to.

This is a complex thing; I think we can give guidance, a governance guidance, about the criteria by which authors could promote that, you know, in essence do the right thing so that user of value sets can have that trust. And then, this issue of auto expiring or not really isn't the critical thing. That's, you know, that's not a good focal point. It's better to talk about what's going on in the context of the – sorry, the value set. What are the code systems? You know, if you're doing drug code systems in your definition of the way you get the codes into the value set are depending on things that you can trust then me as a user of that value set, I'm not going to wanted it to ever expire because I trust that every expansion set is going to be useful.

But, in another situation like if I'm depending on the hierarchy of SNOMED, I maybe less trusting that any future expansion is always going to meet my needs. So, right? And the same thing with the author, the author is going to want review it too because you have two players. This is, you know, this is kind of a relationship. The author's building something but it doesn't matter which in the value set, it's what you, the user point to and say you want to use, right? You bind that value set. And you can buy bind the value set in a way, like we currently do with Meaningful Use and releases. It doesn't matter what's happening in the value set expansions because the Meaningful Use only uses a – one single expansion for a release.

So, I don't really care whether they did a good a job and what's going to happen with the expansion because I know that the next time I'm going to have to look at it because it's going to get a new release. So, this is a complex thing.

Zahid Butt: So, Chris, you got 15 more minutes to wrap up the rest of this. And there lots of obviously very good discussion and a lot of food for thought which is really the purpose of the straw man to elicit this type response.

So, I think you want to finish the rest of your slide now?

Chris Millet: I'll see what I can I do next five minutes or so and then I know – if I had a few wrap up slides for the next steps.

Zahid Butt: OK.

Chris Millet: So, yes, this is defiantly really complex. The whole expiration was meant to – well, it was meant to help distinguish between, I guess level so we have value sets that are – we know they're high quality and they've been reviewed actually "recently."

There are some that may have been challenged, some of (inaudible) value set and feel like they want to challenge the – whether or not they think it really represents this intention or we kind of discuss the automatic, the rationale between automatic expiration where the value set change due to just the underlying code system changes. But the point is if the value set is either high quality for – it was high quality but then something change, the idea that can be use in subsequent processes.

So, I think I spoke to maintaining harmonization really what I want to get to in this slide is that, if value set meet this bar for being high quality then we can compare their purpose statements. If we know they have complete and descriptive purpose statement, we can compare them, if we know we have much more to use in our comparison if they meet high quality as we described it earlier.

So, let me – I know this so long, a lot of the slides. So, I'm sure there are things in here that we could discuss more but we are getting good feedback which we can use to create some alternative, so we can use for alternative proposals. Let's actually skip this one too. We did just talked about how to (meet) the measure development.

I guess the last two slides are really on how – how could governance and value set mean for processes like endorsement and processes like how measures are selected for rule making and use in programs.

If we have a way to identify value set that are high quality slides that they have harmonized, whether they're starter value set and measure developers are building on them or we are reviewing value set and sort of consolidating them. If there are way that these different level, the different types of value set can be incorporated into the other processes.

So this proposal, we just have an example for what some recommendations could like for endorsement for example or the e-measure trial approval and queue updates for viewing e-measure that don't go through all of the endorsement criteria. These are opportunities where endorsement can look for either value set that are currently company high quality. They could look at value set that used to be high quality but maybe they expired but because they did pass that bar and maybe it was something that has a small change based on the code system change, they're still be considered and then the committee can kind of review the status of where the measures are. Not reviewing all the codes in the value set but simply reviewing its high quality status and factoring that into their review for the measures for either NQF endorsement or NQF trial approval.

So those are the kind of example for how this could relate to endorsement but we want the group to kind of think about this kind of relationship. And if it's simply we don't thing governance or value set should relate to this processes, I want to hear that too, we definitely want to pull that out there because it's something that, you know, definitely we end up thinking about a lot of our other discussions, how do we factor these things and then probably the group

to help us think it through. So we don't have a ton of time for discussions, so we'll kind of – we'll think about that.

Please go to next slide. For the use in programs, we talk about a good bit whether – the idea is the same, we should come up with some idea or approach for how whatever high quality and harmonized values has looked like and the governance of them looked like. How does that relate to – you know, how do we expect or how do we want CMS to use those value sets in programs. We talked about a number of issues like the fact the programs only tied to one version of one release of the value set so we're coming up with guidance on how should that change or how does that look in the future. I think it'll do the right things for us to be talking about. And then, I think that might be that we have on this proposal.

So yes, next steps, (so then I'll) ...

Ann Phillips: Thanks, Chris. So for next steps, we will be reconvening via webinar September 24th and October 19th and we will continue discussions around the governance and put together possibly new proposals for us to review with you.

We will be having an in-person meeting with the Value Set committee on November 10th, and I know a couple of you have reached out about – with questions about travel arrangements for that and our meetings department will be in touch with you probably some time in September with details on making those arrangements.

Staff will be preparing a draft report that will display your recommendations from this project and that report will be posted for public comments on December 1st for 30 days. We will then be reconvening the committee on January 21st to review comments and that will be for now, the last TEP for the committee as part of this project.

Again, please don't hesitate to reach out to us with any questions. We will continue to communicate with you all by next steps and provide you with

details for the upcoming webinars but here our e-mail addresses if you have any questions in the mean time.

Before we close today's webinar, today's webinar, I would like to see if we have any members of the public that would like to make public comments?

Operator: At this time, if you would have a comment or question, please press star one.

And there are no public comments at this time.

Ann Phillips: Great, thank you. Before we end today's call, do we have any other questions or comments from committee members?

OK.

Zahid Butt: No, I just – this is Zahid. I just want to say Chris did a great job. I know he just recently joined but I think he sort of hit the ground running and did a great job framing this discussion. I personally think it was a very nice feedback and a very nice discussion about all the different topics that were covered.

Robert McClure: Yes, this is Rob McClure. I want to welcome Chris to the fray and I'm very happy to hear that Chris is participating and I expect good things.

Chris Millet: Well, thank you. I feel like I've been hazed but it's good to be here.

Marjorie Rallins: So this is Marjorie and I agree with Rob's comments.

Zahid Butt: Oh we all do.

Male: Thank you, Chris

Zahid Butt: The hazing shall continue.

Robert McClure: Yes. I'm the one holding the paddle, so I get to say I guess, I apologize.

Chris Millet: Yes. Well thank you everybody for the feedback. It definitely helps and we'll try to – we may reach out to some folks as we try to come up with some new – some different approach as based on the feedback because you know, as the

call went you guys all heard that they found it pretty different than the proposal we walked through today. So yes, thanks for the feedback and just look out for – when we reach out in the future.

Female: Thank you, everybody.

Female: Thanks, everyone.

Male: Thanks a lot.

Male: Thank you.

END