National Quality Forum

Moderator: Ann Phillips
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OPERATOR: This is Conference #: 12879498.

Ann Phillips: Hi everybody. This is Ann Phillips and I'm here with Jason Goldwater and Kathy Streeter and we're here for our Value Set Harmonization Committee Meeting Call for today.

Next slide.

We're going to see who is here. We're going to talk about the project status for our pilot harmonization. I think you all should have a worksheet that we've sent out late last week.

The most – most of our call today is going to be dedicated to governance and policy discussion, and then we want to go over next steps with you. We've added one more – we've added two more calls to schedule. One more call to discuss harmonization and our post-comment call which we announced but they have not scheduled.

So, let's go to the welcome and roll call and as you know we've got myself, Ann Phillips, Jason Goldwater and Kathy Streeter. And I'm going to call roll for the committee. Zahid?

Zahid Butt: Yes.

Ann Phillips: Michael?

Michael Lieberman: Yes.

Ann Phillips: Howard?

Howard Bregman: Here.

Ann Phillips: Chengjian?

Chengjian Che: Yes.

Ann Phillips: Christopher Chute? Cynthia Cullen?

Cynthia Cullen: Cynthia is here.

Ann Phillips: Ellen Harper.

Ellen Harper: I'm here.

Ann Phillips: Yan Heras?

Yan Heras: Yes.

Ann Phillips: Wendy Hofner?

Wendy Hofner: Here.

Ann Phillips: Stan Huff? Matt Humphrey?

Matt Humphrey: Here.

Ann Phillips: Rute Martins? McClure? Marjorie Rallins? Joseph Schneider? Ann Smith? James Tcheng?

James Tcheng: I'm on the line.

Ann Phillips: Great. Nancy Walker?

Nancy Walker: Yes. I'm here.

Ann Phillips: Great. Is there anybody who's on the call, (or any from) the people who is presenting any of the people that we called and any of our federal partners?

Christopher Chute: I'm sorry. This is Chris Chute. I hang up rather than go on mute but I'm here.

Ann Phillips: Oh, great. Have any of our federal partners joined us? OK. All right, so we're going to jump right in with Jason and project status for the pilot harmonization.

Jason Goldwater: Thank you Ann and thanks to everyone for taking the time out today. Certainly, been looking forward to this conversation for a couple of reason, hopefully we're going to take a step towards finalizing the pilot test process and also have a rather robust discussion on governance. Attach to the invitation for this meeting was a worksheet for medication classes. So, hopefully you all have received and have opened up.

The last time I sent the – or we sent this – my apologies – it was a hypothetical document in which it was just comparing value sets that we have no idea whether there was actually a (Jaccard) score between them. We were just using it as a means of showing the type of worksheet we wanted to layout and also to get comments on the value set committee on the process and the methodology.

We greatly appreciate all of the comments from the last time we've incorporated all of them into this latest document in front you. This is not a hypothetical document. This is actually a (Jaccard) analysis between the AMI and the VTE measures and meaningful use and their value sets that are overlapping for this or at least the overlapping and the analysis that goes with that.

So, this is actually what the test we would be using for the pilot test for medication and what they would be using to be comparing the value sets, to determine whether they are (distinct), whether they need harmonization or whether there is too much ambiguity to actually make a decision.

So, what I want to do in the next few minutes is just walk you through this worksheet. Some of you that have seen it will notice that it's familiar to what we did the last time with some exceptions, and then I would like to have a discussion on this about what you think of the worksheet itself, what possible changes that you would like to see in it that for us to consider and then the other issues you might have with it.

I'm going to carry out that by saying that we want to limit the discussion to about 25 minutes because we will spend the next five minutes telling you about the process on how this pilot test is going to be conducted because it has changed a little bit since the last time we spoke. And I also need to tell you that it is important that we do finalize this today.

We cannot go and reengineer this worksheet another time because it will delay the technical expert panel from doing their work and that will delay the project. So we do need to move forward with this, the conclusion of today's call and because governance is in crucial issue that we really do need to spend a lot more time on in the time and for the other calls that we're going to be having. It's important that we turn our attention to that and just limit the discussion to this for 30 minutes.

So, what I want to do is just sort of quickly walk you through this. Some of these are going to seen very familiar. The worksheet designed to examine specific values that the (first dated) with AMI and VTE. Now, specifically we're looking at the following six measures which are in table one.

That table lists the measure number, the measure title and steward of the measure. You can see that CMS is steward for one, the joint commission is the steward for the rest.

When we did this and did an internally QA review, there was some discussion that perhaps having this table as the first would indicate to those who are reviewing and doing the analysis that they would be responsible for evaluating the measure which of course they are not. So, we did add some language in the next paragraph indicating that the measure (intends) provided to fits with the understanding of the value sets contained within these measures. It's not –

this exercise is not to evaluate the measures but rather the value sets that are contained within that and to determine whether harmonization is needed.

The second table really gets to the intent of the measure so it has the measure number, the measure title again, and then this timely intent of the measure. That came directly from the National Quality Forum's Quality Positioning System which lists all of the measures that we haven't or that have been endorse to the NOF process and all stat and part of the submission that they have to give us is what the intent of the measure is. So, that comes directly from the language within our QPS system.

So, you can see in the second table, it was again, the measure number, the measure title and the measure intent.

If you followed through to table number three, you will see the analysis that we were able to conduct and we thank the National Library of Medicine for giving us offering privileges in the VSAC so that we could do the (Jaccard) analysis.

We again use 0.49 as the threshold as we did with our pre-work analysis, and from that we came up with the following value sets that indicated some degree of overlap.

So, the next table lists, the 12 value sets that have a (Jaccard) set, (Jaccard) index of 0.49 or above. It lists the OID, the value set name and then who is the value set steward is. It should be noted that number seven and number 11 are draft value sets. They have not officially been publish but they are draft and they were indicating overlapping in the (Jaccard) and we thought it was important to include those because it does bring up questions of governance that we'll get to later.

Per year direction, the next table lists what the intent of each value set is which we got directly from the BSAC. So again, we have the value set object identifier, the value set description, the value set steward and then what the value set intent is, again, per year direction.

So, for each of these including the ones that are draft, we were able to find what the intent was. If you go all the way down, down to page – the bottom of page seven, then we sort of summarize all of these together. So, for this exercise we've identified the overlapping value sets. We've included the (Jaccard) scores so that they are able to ascertain the degree of overlap.

From these value sets, we need the technical expert panel to indicate based on the intent of a measure, based on the intent of the value sets, and how their value sets is use within that measure and this was again, (for your) analysis from the last call to indicate whether you think this overlap is acceptable based on the intent and the measure they come from, whether the value sets are redundant and need harmonization.

So, we have the last table. The first column is the (Jaccard) score. You'll see that it is not go lower than 0.49. The first value set, the measure that relates to, the second value set that they indicate there are some overlap with the measures that that value set relates to, and then what we want the TEP to do is to determine whether these value sets are distinct, whether these value sets need harmonization or whether there is not enough information or it's to ambiguous to determine.

We have (assessment) end of the language to ensure that this recommendation is aligned as supposedly with the possible, with the intent of the measure in which the value set is contained. And then as an appendix, and again, after some internal QA, we decided to add the value set data element but rather than having worksheet which I'll explain a little later, we just included this as a reference point.

So, for each one of those 12 value sets that indicated some degree of overlap, we have added the value set name, the object identifier, the type they're extensional, the definition I.D., the steward and the program in which the value set is contained and then we have the value set data elements. This will serve as reference point for the TEP as they are looking to determine whether they are distinct or whether harmonization is needed. Some of these you can look and see pretty much what the analysis may end being but we again decided to use this as a reference point.

There was some concern that this was a fairly long worksheet which it is, a much longer than I was hoping it's going to be. We're trying to (cram) all of this information in the table, so it's (proving) to be difficult to (read) and we wanted to create something that would take the TEP step by step and give them reference point for them to look at as they're doing their analysis.

So, the way this is going to go is that you're going to look at that last table and tell us and subsequently tell you whether these value sets that are indicating have a (Jaccard) score of 0.49 or above are distinct enough and essentially be left alone. We need harmonization or they are too ambiguous to make a decision.

The second part of this analysis involve that we would then go into RxNav after we knew the value sets and the intent of the value sets and determine the classes of medications that would apply to this specific data element and derive the (RxNav) codes from those.

That initially was going to be the work of the TEP. But in it – but after a kind of going through the first couple of iterations of this worksheet that was proving to be an incredibly lengthy task, and as such we didn't want to give that to the TEP because if we gave them something that was going to take potentially several hours to do the odds that that might not be completed and that would not provide the type of information or analysis be with me to proceed with this project. So, NQF staff along with its medical and clinical staff that we have here will be doing that part of the analysis. It will not be the TEP. It will be us.

We will be looking at these value sets, identifying ATC classes that are aligned with those value sets. We have questions which I'm sure we're going to – that's when we will be employing our medical staff to help guide us through that and then we will derive the (RxNav) code from those. And we will show you that when we would have our next call, we start sharing the results with this analysis.

Before I open this up for discussion, I do want to point out that this is a pilot test. This is not meant to be perfect. I wish we could perfect it. I have no

idea what will work on this and what will not and that's why we're going to pilot it with the TEP and see what the successes with this and what things they would like to see corrected, and to see if we're actually getting something worthwhile out of this that helps us the long (problem).

And so, well, what I would like to do more in order to try to make this even better, I think realistically what we can expect the TEP to accomplish in the couple of weeks when they start doing this analysis and the information that we're actually going to need to help us this is probably as good as we might be able to get it. I think this contains all of the information that is needed and allows them to do the analysis necessary to determine what value sets actually need harmonization, and again, it is based up the direction of the last call that we had and the information that you all believe that that time is relevant for the TEP to be perfect.

So, with that in mind, I am happy to open this up to discussion for about the next 20 minutes. And then we will have to wrap it up and began our discussion on (top).

Christopher Chute: This is Chris Chute. This is an excellent document. I missed the last call but I – this is wonderful. My only question is with respect to the drug class and I do think that will be a crucial piece of information.

I – it really gets at what are – is there an understanding of the underlying quality and consistency of that within RxNav? I know when we look at these years ago, it wasn't ATC classes. It was actually NDF-RT classes but the same problem may persist and that is there was what was called a mono-hierarchy which means a drug (happened in) only one class. And (assignment) of the class was rather arbitrary.

For example, topical steroid creams, half of them, you know, half of cortisone, 1 percent were assigned to a topical agent and the other half were assigned to steroid kind of randomly. So, our – do we know that that drug class assignments for these agents are multiply inherited that is to say if there truly an antithrombotic, their code is antithrombotic rather than saying non-steroidal?

Jason Goldwater: So Chris, we don't know that yet but that is one of the discussion points that we're going to look at when we start doing this analysis. This will probably do after the 4th of July holiday and that's the line we're employing our medical staff to assist us with that to address that very questioned. I don't know at this point whether that's our case or not but when we do the analysis we will come to you and let you know what we found.

Christopher Chute: Excellent. Thanks.

(Crosstalk)

Jason Goldwater: You're welcome.

Male: Yes. I assume it's going to include group of (ESM) and/or not and what…

Jason Goldwater: Yes, correct.

Male: ... take advantage of that to address that issue.

Jason Goldwater: That's correct.

(Crosstalk)

Jason Goldwater: We've already had discussions with – not me but I think if, you know, Ann, and Kathy, and I have had discussions with Helen Burstin as our chief science officer and all of you know who she is, as well as, a couple of other doctors we have here on staff.

Just to go over some of these medications, to understand their relationship with the measure and how they would be using the measures so that way we get a kind of baseline understanding of what we're looking now and what we're looking at data element. And they brought up that very, you know, the question Chris just brought up which is, is there, you know, one class they're assigned to, how is it assigned, are there multiple and, you know, we didn't know the answer at that point but I suggest that we all get together and do the analysis and then we'll be able to sort of understand those issues and then bring them to you all once we undertake that.

But Michael is right. They're almost certainly will be and/or they're not, you know, similar to the quality measure, they'll be things look it in and things that went off.

James Tcheng: So, this is James Tcheng. I have a comment about the document which, again, I appreciate just to reflect Chris' comment. It's great that you put this together. But as I look at these tables one and two, have two of three identical columns which raises a question, couldn't you just make four columns, single table out of one and two, the same comment about tables three and four where three of the four columns and each of the columns are identical. So, therefore, just make one single five column table rather than having to go back and forth between two tables to get a different piece of information.

Jason Goldwater: So, Dr. Tcheng, we will try that when we did that initially been doing in landscape, you know, for the – when I say there's only half (jokingly) – for the younger people on our staff wasn't really an issue for them to read. Given that our staff is out of that age group, obviously, from a usability standpoint and I was thinking that they're hard to read, it is difficult to look at and some of the columns I get back were that it was a little both columns, a little too small but we are going to continue to try to play with them to see if we can play down these tables a bit.

I agree that we're being repetitive with this but it was seemingly the only way of keeping the font size at adequate enough for people to read without too much difficulty.

So, if we can try to convince it without comprising that we will. If not, you know, we may have to go with that. As much as again, I don't, you know, enjoy getting – distributing 16 pages worksheet but if that's what we have to do to get people to read them then that's what we have to do it.

James Tcheng: So, this is James again. I think a landscape work fine for the table.

Jason Goldwater: Right. You know, we tried that too and it was just causing, you know, I love Microsoft Word and I hate it because it causes some formatting issues but we're actually going to have one of our graphic editors to take a look at this

and see what they can do. I'm sure they're far more experience at this than I am but we will try.

Zahid Butt: So Jason, this is Zahid, the last table obviously is, you know, the potentially the most important from the way the TEP is going to work on it.

Will they just say yes or no need harmonization or will they be also providing some additional information based on the discussion that will take place? And is there some mechanism to capture some of that because that would be important to somehow see how…

Jason Goldwater: Right. So, in terms of this worksheet, all we're going to have to do is check (it back). But we're going to ask them to do a brief write up of their analysis on each one of these value set payers whether they can send it to us either or to an e-mail text or send it as a word document, whatever is going to be easiest for them. We didn't want to get overly prescriptive, without they were going to give us their comment because, again, I didn't want to add yet, another from to this, and make it longer. I mean this is the perception that it was going to be, you know, long with the – I was afraid it would deter people.

So, along with the Dr. Tcheng that is trying to make (took incentive) and make it a little bit smaller in terms of page length. When they send their comment, they can send it to whatever form they feel is – is works best for them, as long as we're able to receive them and analyze and appropriate.

Zahid Butt: Yes. So, that's what I was getting at that if they know that, you know, we are also interested in some of the reasoning behind this chat box but, however, is most convenient for the TEP to capture it.

You know, how sometimes when you get into this discussions and committees and so forth, we tend to forget that, you know, that maybe one of the goals to try to at le ast capture some of the essence of the conversation.

The other thing, I know that several suggestions have we made in reformatting in your graphics. People will look at it. The one that I found probably that would have been the most helpful, at least, when I was looking at this, would

have been to add the OID under the name in that value set one and value set two columns because my tendency was to take that OID and look up.

Jason Goldwater: I see.

Zahid Butt: I don't know if that would (cluster) this too much but, you know, you have to kind of – back and forth correlate the OID with the name.

Jason Goldwater: Right.

Zahid Butt: Potential reformatting recommendation that I may have.

Male: This question of…

Zahid Butt: Go ahead.

Howard Bregman: This is Howard Bregman. I'm going to just ask a question about the content of this (line sensor) the content and list they were dealing with. So, if I'm reading this correctly, seven out of 12 of these value sets are from the joint commission VTE measures, right?

Jason Goldwater: That's correct.

Howard Bregman: And one can assume – all these measures were developed in tandem to address the joint commission's efforts for VTE prevention and measures about prevention and treatment of VTE.

Jason Goldwater: Correct.

Howard Bregman: And then basically, we're developed with – I assume with the same group and the same expert panel. And therefore, when I look at them I assume that had they thought that any of these could have been condensed or were reused they would have done that at a time.

And then therefore, I would just make the assumption that they made them distinct for a reason. I mean they made a new value set for a reason.

(Crosstalk)

Rute Martins: This Rute. I can speak to that. But go ahead. Sorry, Jason.

Jason Goldwater: No. I didn't know that you're on the phone so go ahead.

Rute Martins: Oh, yes. Sorry. I joined in late and I apologize that I haven't been able to join the – I wasn't able to join the last call but that absolutely, right, Howard. And in fact, they are different for a reason.

They are in – this is actually speaks to one element that I'd like to bring up which is the notion of – there is actually two dimensions for harmonization. There's value sets that are concurrent in their intents and their meaning. And that they're separate for some reason. They may overlap fully or early partially but they're intent is the same.

And then, there is – there are value sets that while they overlap, they're not redundant. They may contain redundant content because the same medications are appropriate and meet the intent of both value sets but they're not necessarily redundant in its entirety. And this is something that I think it should be considered as two separate criteria for harmonization.

That is not to say that harmonization couldn't happen even within value sets of the same measure steward. So, for instance, the parenteral anticoagulant value set contains unfractionated heparin. That's part of it.

So, we could have potentially (reuse) the unfractionated heparin value set within the parenteral anticoagulant value set, just create smaller value sets that are medication class specific and in some cases could even get to medication specific value sets. The question is, how far deep do you go in this notion of reusing value sets? And then all of a sudden, there's a value set for each different medication and it's almost like you have a value set for each code.

I don't the answer to that but that would be interesting to get out of this pilot is to see where that happy medium of creating small enough value sets that they can be reuse even in the harmonizing value sets that are not necessarily concurrent or speak to the same meaning and intent. But how to do that harmonization at the level of smaller chunks that can be group into larger value sets and promote reuse that way.

Jason Goldwater: So, I think that there's sort of comment about, one is that's why we're having a technical expert panel do this but it is independent from the values that committee and have not offered the values that are being considered. When we carefully selected that's have for that reason to give an independent objective (assessment) of the value sets that they're looking at to see whether they are distinct, to see whether they are overlapping but not redundant, where to see if they are overlapping and redundant and can be combined.

So, I think that analysis would be interesting. It doesn't mean that's what we have to go with but it would certainly would be interesting to see what the results of that analysis be.

As to, you know, whether some of this can be combine or whether or not we can create classes, that would make this perhaps easier so we're avoiding what could just describe which is a value set for each medication which if you look at this draft one, the two draft one I mentioned that's exactly what they're doing, which I thought it was interesting and would be interesting as part of the analysis that if we, you know, continue moving forward with this and try to avoid that, at least we can have a expression about, you know, whether or not this process can be include, if there's a possibility for improvement.

And like we said this is a pilot test. It not meant have final result. It meant to just test the process, to see what the results are, and to see what if any changes need to be made.

Howard Bregman: And whether the point I was making and this is really for the whole group comment on is that I think that value, the bank for the bucket to begin by this effort is when you've got eight different – I'm just picking the number eight at random – you got eight different organizations who create eight different measures independently. They basically use a – their own expert panels to come up with their value sets. And essentially, they all appoint to the same thing. They all say, statins, for example.

And the description statement is basically equivalent to that. They are all saying we wanted to come up with the value set for statins. And that's what needs to harmonized.

As opposed to this situation where, I mean, I would bet the experts at the joint commission or whoever they recruited for this effort basically knew what they were doing when they made this independent value sets and did it for a very good reason because they, you know, every value set was done by them. And they were all done in a (cancer).

Cynthia Cullen: Yes. Building on that – Howard, this Cindy Cullen – really the only relevant one on the (Jaccard) table, that would be the first one because that's the only one that shows the comparison between two value sets that do not have the joint commission as the original developer. And just – I know you identify two that were in draft status when I did review with the OID on this, I identified four that were need to draft to propose status.

In addition (from the Paranox) and the Factor X inhibitor, rivaroxaban and oral factor X inhibitors were all in draft status.

So, the comparisons about two, four and then the last two on the table, really are – I don't quite understand why comparisons are being made to draft status, right.

Rute Martins: Yes, and this is Rute, I completely agree. First I agree with Howard that the bigger your harmonization is having duplicate content that is in fact redundant versus the overlap issue which is a good, good harmonization discussion to or perhaps in the 80/20, it's the 20. And then for draft values that they also wondered why are we comparing to draft. I understand this in your rational behind it but values that can be in draft mode for multitude of reasons including values sets that have been abandoned in favor of values sets that's has been published and therefore reused.

The other item that I wondered in terms when I saw two different value sets next to the same measures, I started wondering about value set versioning and harmonization efforts that have already happened and also measures of version – I'm sorry – versions of measures.

So, is it possible that one value set is being used with one version of the measure than a harmonization effort occurred and to the measure started using

another values set. So, in that case it wouldn't – the harmonization has already happened and we're missing it all together.

Cynthia Cullen: Yes, and that's indicated in the draft statuses. I'd checked them against the current versions to the measures. The most four that were interacted proposed that are not included in the version to the measures that are listed here which is the most current.

Howard Bregman: I see, the answer is that…

(Crosstalk)

Howard Bregman: Go ahead, Jim

Jame Tcheng: Sorry. So, this is Jimmy Tcheng at the risk of moving forward to quickly in this conversation, as I was thinking about the task that we are faced with, it's interesting that the ANOVA or anticoagulant class comes up as part of this exercise here, because in fact, the comment about versioning actually holds through here. There's basically four members of this class, the dabigatran, rivaroxaban, apixaban and edoxaban. And they're all approved for DVT and PE prophylaxis yet, none of the value sets include edoxaban to the values that's only include rivaroxaban and then the third value sets includes three of the four agents.

And so, we actually not just have a versioning problem here but based upon the intent of the measure itself like we'd argue that the value set is already outdated, and again, at the risk of jumping too far forward, I do want to raise that as one question and if I could at the same time, the second question that I would raise, is that the measure that's in number one, CMS 100 version of (the four) is about aspirin at discharge in patients who have coronary disease, neither of the value sets have anything to do with that particular measure.

And so, my question is, how did the measure get matched to these value sets because the value sets do – none of them contain aspirin at them. And that's really what the measure itself is pointing towards.

Howard Bregman: I think the answer to that is – that's not really our job to be evaluating these value sets or looking at the intent and the quality of them. I think the answer is where this is just for the purposes of an exercise, right? And we're looking at this to say, can they use these value sets in whatever state they're in, whether they're completely updated or they're – where it's an older version that hasn't been updated and basically say that this can be used in an exercise, is that correct, Jason?

Jason Goldwater: So, that's partially correct that, yes, the first part of the exercise is to look at the pair value set to determine whether or not harmonization is needed based on their analysis – measure of the measure intent, the value sets, the value set intent.

We may come up with that decision. We would like to know why they reached that. So, it is very possible that they will then provide the analysis that is similarly with Dr. Tcheng just said which is harmonization is needed because the quality of the value sets is not consistent with the intent of the measure. And so, is there a way that taking what is already there, harmonizing it with the elements of that particular value set or eliminating elements of that value set, you create one that is more consistent with what the intent of the measure is.

I don't know with that analysis is going to be. I don't know what they're going to say, I can't predict that but it's not out of the possibility that that's something that they may provide. I do want to get this question of why we're doing draft value sets because we did talk about this internally. If you don't think that we need to be doing that we're happy to redo so.

But my understanding was when we're doing the analysis and then was popping up in the (Jaccard), indicating that it was overlapping with another value sets that this was interesting point of analysis because yet, they're finding that there are elements in that draft value sets that are redundant with elements as another pair of values sets. Do we need to publish that draft value sets or do we need to harmonize it into something else? I don't know any answer to that.

James Tcheng: (Do you think). Its two different questions though, I think that we want to think about how you promote a value sets from draft to approve or whatever. And of course, in that process you would want to look for overlap and we'd want to make sure it's harmonize before it gets there. I think the issue here is that some of that is kind of confusing the issue and even then, you know, I think that it would it might be OK to use to include draft if you want to but they should be (slug) at such because I think again it's a different problem, it means that maybe that either it's an abandoned or it has to, yet, gone through that harmonization process that would occur internally with an organization or something of that nature.

Christopher Chute: In a related question – and this is Chris Chute again. I maybe out of scope. I tend to live in out of scope places. But in terms of overlap and redundancy the original value set discussions that occurred in HL7 probably 15 years ago, and I think we're continued to through a lot of the value set standard organizations and related issues on how you manage and manipulate value sets.

We're very clear that value sets could contain another value sets. And so, whether we're in the position to make this recommendation or not, I'm not sure. But one of them would be, gosh, why don't we just, you know, make fairly atomic value sets and then have value sets explicitly contain those other value sets. You get, you know, simple classes of drugs, I'm not frankly familiar with a lot of this new anticoagulant that are used for VTE and the like but nevertheless they appeared to be in discrete classes.

And making value sets of those classes and then having other value sets, include those value sets would make the overlap and redundancy not only acceptable but explicit, in a way that people could understand them and make sense of. And that raises the related question of intentional versus extensional value sets. This again is something that's been debated in the community. You know, these things may be out of date, partly because clearly enumerated.

Male: I'm sorry.

(Off-mike)

Jason Goldwater: Hello.

Christopher Chute: I'm sure what that…

(Off-mike)

Christopher Chute: I thought somebody was trying to shut me up but, you know, it raises the obvious question of whether you can specify and maybe you were going down this pathway looking up the drug classes. You know if you specify a drug class and have that constitute a value set by intention. Then, you know, to the extent that you live within versions of RxNorm. It can't become expired or redundant but I hear more buzzing so I'll shut up.

James Tcheng: Chris, I get through your point and what we wanted – I don't know if it's in scope or out of scope but you also don't want to recreate another anthology within value sets, so it's where do you make use of, like you said what's up there RxNorm or SNOMED or whatever, to define your concept and then attach a value set toward instead of, you know., like somebody said earlier creating a value sets for every atomic medication and then having value sets to combine value sets. And I would tend towards saying that that we should do less of – we should not create another anthology that we should try to keep value set, you know, fairly – we should use anthologies to create these concepts and then attach the value sets.

Jason Goldwater: Right. So, I need to (interject) for a minute because I think we're starting to get into (governance) type of questions, which definitely – absolutely need to be discussing both in five minutes, because I do want to wrap this in five minutes.

Are there any recommendations or changes to this worksheet other than Dr. Tcheng trying to consolidated tables to make it a little shorter that we need to do before we've sends this out to the TEP?

Howard Bregman: Yes, I would say that we flag provisional or whatever they write, you know, the value…

Jason Goldwater: The value.

Howard Bregman: …not accepted. That would be a key part of this as well.

Jason Goldwater: OK will do. And…

Rute Martins: And it seems that the values set one, values set two table as Cindy pointed out. The measure versions that they're attached to, if it's a draft value set, I'm not sure how it can be attached to a measure. And specifically I doubt that they're all attached to the same version so I would check that.

I also noticed that in some of the value set in tens there were some errors. So, specifically, I was looking at the Oral Factor Xa – I'm sorry Injectable Factor Xa Inhibitor there was an error there.

And then it seems like in the appendix, not all of the value sets that are mentioned in the tables are there. I wasn't able to find from the paranox or rivaroxaban for instance.

Jason Goldwater: So I'll – we'll double check this. I do want to say to this team directly from the VSAC. This was all…

Rute Martins: Right. So that's the problem is that when I look at VSAC I don't see the same.

Male: I think because they're draft in some…

Rute Martins: Not really. So, this specific example Injectable Factor Xa Inhibitor for VTE Prophylaxis, it includes…

Jason Goldwater: It's not draft.

Rute Martins: … in additional statement that is not part of – yes, that's not draft and the statement is just not correspond. It may just has been a copy paste or – but I mean, that was the one that I really noticed. I didn't check all of them.

And I found it really confusing in the appendix that we're calling the value set members data elements. Because from a measure perspective the expression

data elements usually speaks to your QDM Element that is represented by a value set rather than having the members of the value set we did on the elements themselves, so…

Jason Goldwater: OK, so we initially call them sub value sets and everybody hated that, understandably. And then…

Male: Value set members.

Jason Goldwater: … call them data…

Cynthia Cullen: Members or content?

Jason Goldwater: What's that?

Male: We call them value set members.

Cynthia Cullen: Members or content?

Jason Goldwater: All right.

Male: We call them members. It looks like – so that's what I would use.

Marjorie Rallins: This is Marjorie, I just want to tell you I've been on for a while and I agree with the last statement about calling them members.

Male: All right.

Rute Martins: And then I just have one final comment. I'm sorry, and then I'll shut up after that. That is, you know, some have brought up the notion of what's in the value set versus what isn't and why isn't it there.

And when I look at the AMI value set, when I see other anti coagulants I wonder what the other are that aren't in this value set if that makes sense. And I think that's some of the critical information that whoever is going to be looking at this is going to need because it's not just what's defined in the value sets, it's also what isn't.

And the same goes for instance for the Oral Factor Xa Inhibitor value set. And the (bigotry) isn't there for instance because it's used, it's modeled in a separate value sets, that's the direct thrombin inhibitors. So, that missing information may actually lead to a different recommendation in terms of harmonization just because the other, the rest of the context around the value set and the other pieces aren't here.

Jason Goldwater: OK. So, we will retitle value set data elements into value set members. We will do some double checking in terms of the VSAC to ensure that the intent that's listed in the VSAC is what is copied directly into the table.

We'll run through that again to make sure that it's correct. And again, when I brought up the draft value set in the VSAC it was associating with the measures that we have listed. I will double check that as well if that is not or I read that incorrectly which is possible, we'll take those out.

And we will also note the ones that are draft or proposed. And offer a footnote into the table as to what is meant by that description.

Anything else?

OK, that had been said, we will make those changes, we will probably send this out to the TEP beginning next week. And as we get to the end of this call and Ann tells you when we will meet again, we'll have the results to share with all of you.

Before we begin our discussion on governance, thank you all very, very much for all of your assistance and guidance in those, this has certainly been quite a journey to get a worksheet done. But obviously, this is not the easiest exercise to be doing. So, we are very appreciative of all of your help and (guide).

Ann, let's go to governance and policy, thank you.

All right, so, when we left, we were talking about – and I realized some of you were not on the call. So, we'll spend a little bit of time on going over this for those that didn't have a chance to contribute.

But we started of with what is the criteria for high quality values that which sort of goes to what Howard and Dr. Tcheng were saying earlier. We wanted to define what we mean when we say a high quality value set and there were five elements that came out of that from the discussion.

It was a high quality value set describe – perfectly describe the intent of the specific data element, or I guess at this point, member that it's associated with, this for purpose. Correct identifications of patient population based on the value set. I guess value set members that match the meaning and have no false negatives and no false positives.

Intentional value sets allow for unambiguous description and regular analysis with regards to the value sets defined skilled or purpose. So, in looking at that, for those – does anyone have any additional comments to either of those that were unable to be on the call the last time around?

Female: You used data element correctly in the first bullet.

Jason Goldwater: All right.

Female: It should be data element.

Jason Goldwater: Right.

Female: Because the lines which starts or…

Jason Goldwater: OK.

Female: … measure developers understand it.

Jason Goldwater: Looks like – this is like…

(Off-mike)

Jason Goldwater: All right. OK. Anything else? Any other comments on this?

Male: No, looks good.

Jason Goldwater: OK, next one. Next slide.

So again, continuing with the criteria for high value sets verification of the codes, and the value set are present both in the EHR and used in practice and testing. Review of the codes systems and internal with it, there are concepts inside those code systems that fall within the scope on a regular basis.

Any comments on this?

Marjorie Rallins: Yes, so this is Marjorie, I have one comment about verifications that the codes are present. Was it more that the codes can be accepted because – say, there's a new code that doesn't currently exist? It seems to me that if the code system already exist within the EHR, that new code can be present, it's just not there yet. Should we make that clarification or…

Jason Goldwater: What do you all think?

Marjorie Rallins: What do you think?

Male: Yes, that statement is a little problematic for me as well. And that, you know, it really depends, different systems use different code sets. And for example, you know, RxNorm is not used directly in a lot of systems, is my guess but if used this is kind of a translation to other systems that people use.

Jason Goldwater: OK.

Male: So, I don't – you know, that – I don't know that you would find RxNorm codes in a lot of EHRs that are used in practice right now. You know, I'd…

Jason Goldwater: Right.

Howard Bregman: Well, I would strike that first sentence entirely. I don't think it's a requirement for high quality value set.

Male: So, how was their verification, their codes, that sentence?

Howard Bregman: Yes. I mean I think that was what Mike was alerting to.

Male: OK, sure.

Marjorie Rallins: Yes, I would agree. I think that – and maybe the second bullet. This is Marjorie, again.

(Crosstalk)

Jason Goldwater: Take the second bullet out too?

Male: Well, let's think about it.

Rute Martins: I don't understand the second bullet.

Marjorie Rallins: I think we should talk about that some more.

Male: OK.

Male: I think what that's trying to say is that if you have an extensional value set that over time it's going to need revision. So that – and that actually, yes, the idea behind the intentional versus extensional, so if you say beta blockers. And over – so, if your intentional is beta blockers over – but you have an extensional listing of all the beta blocker concepts in RxNorm overtime, you're going to need to update that as new beta blockers come to market and some beta blockers fall off. Is that the idea behind that?

Jason Goldwater: I believe so.

Rute Martins: That is – that doesn't make a lot of sense to me just because the quality of the value set shouldn't be tight. I mean the – obviously, if there are changes in the value sets needs to be maintained but the value sets maybe high quality at one point in time and then move quality so, it's not a property of values that it's a function of time, right?

Christopher Chute: Well, I mean – This is Chris again. I would say frankly that a high quality values at the way I look at it is an intentional value set that's linked to specific version or versions of a source system such RxNorm. And all these other things sort of go away in terms of review and what not because it is what it is.

Male: That sounds like several votes for striking both of these requirements.

Jason Goldwater: Right. What I've thought of them (I'd say). OK. All right, Ann, next slide.

OK, again, so, criteria for high quality value sets. So, we left off the discussion with this. Which body, is it National Quality Forum, is it CMS, is it some other organization now? And now and perhaps that will define and choose high quality value sets. What are your thoughts on what sort of becomes the prevailing organization that examines and determines this?

And then as such, if it's not NQF which is fine, what will the role be for us with regard to identifying high quality value sets within measures? eMeasures (in particular).

Christopher Chute: Well, I would say that the one criteria that I would – the criterion that I would look at very closely is how many organizations are doing it. Frankly, I don't care deeply who does it whether it's NQF, CMS or NLM or somebody else, but I am deeply discomforted by the fact that many organizations are doing it.

I think if you're going to have quality there are needs to be consistency and coherency. And very hard to achieve when you have lots of chiefs, so to speak in the process.

Jason Goldwater: OK, anyone else?

Ann Smith: This is Ann…

Nancy Walker: This is Nancy, I really agree with that comments. Who else – well, first of all I would not recommend CMS because they are also up there.

Jason Goldwater: Yes.

Nancy Walker: And so, they – I don't think that's a comfortable role to have a payer setting those standards. What is a quality high value set, you know, but that would be the governance agency. So, it is a good question. Who else besides NQF has the (threats) of this type of function?

Marjorie Rallins: Yes. This is Marjorie. You know, organizations, I worked for the (AMA) and we convened the PCPI, the Physician Consortium for Performance

Improvement. And we also convened, you know, professional societies. I'm not necessarily meeting towards one or another, I think there are – and there are others beyond, you know, NQF and PCPI that do that. I think that – I think the reason why this bullet is here, participation from professional societies with clinical perspective is the important one.

Jason Goldwater: Right.

Zahid Butt: All right. So, Jason, this is Zahid. When I think of criteria for – criteria for something, it sort of the what? First is the who? So, I think perhaps, you know, all the criteria that we were talking about before would be the criteria that defined a high quality value set. And then, the next question should be, well, how should a determination be done which is your – these last two bullets which is either yes or no versus a greater scale or some sort. And the third question is, who should do it? Should we sort of organize this in that sort of way, rather than all of these now being listed as criteria for high quality value sets?

And the other part, maybe you're getting to that is, what is the impact of that designation? So – And I think that kind of relates to who does it. And because if we – that would be implicit in that who question as to, you know, who, they, whether you say a voluntary process or a involuntary or a mandatory process and, you know, what's the mechanism to accomplish. But, that separate from defining a set of criteria whoever does it would really follow those criteria to define that this is a high quality value set.

Christopher Chute: Yes. And I think you would have to work into the endorsement processes. And then do you say that the NQF will only endorse measures that have a value sets that meet a certain level or, you know, what is the, you know, what's the forcing function on that.

James Tcheng: This is Tcheng from (inaudible). So, I just want to raise a point. When we talking about, you know, the body and who created a value set, I think we shouldn't forget the end user, the providers or the EHRs, you know? Because they are the – I mean they have been using the code to codify patient records. And a lot of times, you know, it will be good idea to take this bottom up

approach. Look at what has been used? What's commonly used? And then to create, you know, a harmonized or universally great upon value set.

So, I just want to raise, you know, we should involve, you know, end users.

Zahid Butt: So, Tcheng, this is Zahid. I want to make sure I understand what you were just suggesting. I think the prior slide we discussed which would be sort of generally lumped under feasibility as in presence and as in normal workflow usage by end users and so forth, are you referring to the feasibility which we sort of carved out of quality in the prior discussion or are you referring to the end users involvement in quality somehow per se?

Are you referring more to feasibility versus quality which seems to be sort of a distinction were somehow trying to make?

James Tcheng: I am referring to I think more of the quality or I think also, you know, the feasibility because when we create a value set a lot of times some codes are never being used and some codes are used more often to the others. So, I think, you know, to select a codes into a value set, you know, it's better to consider, you know, what's the frequency and how they are used in real world.

Zahid Butt: I guess the fine point here is that should feasibility be a component of quality or should it be a separate thing. In other words, you could have a really high quality value set, it meets all the criteria for a high quality value set, but it's infeasible. You could have that situation potentially, but should those two be kind of separate things as opposed to feasibility be a component of quality itself? And that's kind of a group discussion how the group feels about it.

Male: Actually we're getting back into the definition of value set of a high quality advice which I thought we already moved to passed.

James Tcheng: Right, right, right. I agree, I agree. So feasibility I think is kind of – I think what was being implied in this last comment.

Male: The issue here is who's going to do it? And I think the overwriting factor is who can do it, not like who has the knowledge to do it, but who can actually get the job done? It's very easy to say end users should do it, providers should

it, but good luck actually getting them to – I don't even know the mechanism that you could come up with. They could…

Jason Goldwater: It's already very difficult.

Male: … come to an agreement and then, of course, the cardiologists are going to argue with internist et cetera, et cetera. So, you know, I wouldn't even consider something like that. You need somebody. Do we have to identify a body or can we just (punt)?

Jason Goldwater: I mean I think it's – I think we can set along. It needs to be an overwriting thought. And that's a discussion on who that will be, can be discussed later and hope if there's anything wrong with that. How we're – I mean, you know, I think your point is well made and I think that it even applies to organizations like NQF which is, you know, how would we incorporate that into our process of evaluation eMeasures.

Remember, it's not the job with NQF and all of you know this which is to endorse measures. That's not what we do. We evaluate them for feasibility, validity, reliability, scientific accessibility and then we pass them on a standing committee and they infer, decide whether that measure needs to be passed on for endorsement. And then that has to be approved.

So, do we incorporate? Really, if NQF is going to be the body of choice to evaluate high quality values, does that become part of the evaluation we do with measures or does that become part of this (consensus) development process that the standing committee looks at the values and determines whether or not it's feasible and reliable to be put into a – it's appropriate to be put into the measures that's under review.

And again, we don't have to answer that today, but those are the questions that we have to discuss. If NQF is going to be the body to do this and I have no idea whether that's what you all are thinking or not that it's not just – it's how NQF would do this.

Zahid Butt: So, Jason, this is Zahid. I think that the – if the NQF were to be the body scope, I believe what we are intending here would have to be beyond just the endorsement process.

Marjorie Rallins: Yes. I think this really deserves – this is Marjorie again. A separate discussion as Jason said because there's probably lots of other issues you have to consider…

Jason Goldwater: Right.

Marjorie Rallins: … when you think about NQF. How do you create a firewall between the endorsement site and then, you know, because you can fetch yourself up for situations that, you know, don't work best for the process overall. So, I think that's something we need to think about. And you know, are there – are there – and keep ourselves neutralize to what the body is or who the body is that does the review.

Jason Goldwater: OK.

James Tcheng: And this is Tcheng again. So, right now the situation, the steward is kind of the body controlling them reading the methods and the monitor and the quality and also the maintenance. So, I mean maybe we're – if we're thinking into create or the federal kind of that type of (own edition) to, you know, become the body to maintaining and monitoring body. That may – that may seems, you know, impossible. But, we see – I mean pro and cons for each, probably which, I mean maybe just ask the steward to be conscious and be responsible of, you know, managing these value sets from the creation to the maintenance and maybe, you know, so.

Jason Goldwater: OK.

Rute Martins: Yes. This is Rute. I share Tcheng's concerns in terms of having an entire process been around the value sets and having this single entity who would be able to wrap their arms around all the values that's in existence because let's not forget the values maybe used for constructs other than measures, right?

So, from an NQF perspective what I would say is that, the same way that you now say, well, in order to submit an NCQM, it has to be specified in (NQMF) it has to meet certainly. It has to use the quality and all of these things which I'm guessing will be refined moving forward from the measure part. I'd say that those would apply to the values sets as well.

I wouldn't necessarily create an – a process in which a value set would need to be – there would need to be justifications around the purposes of the value sets as compared to other value sets or competing value sets and go very deep into that, but perhaps making sure that there's a checklist or a really good set of criteria that the value set would need to meet. For instance there's a purpose statement, it's intentionally to find it possible and the developer would then specify that for not to reach value set but for the group of value set listed in the measure. I think that's the most feasible approach.

Male: OK.

Male: But, Rute, I think the issue here is that there has to be some checkpoint in there to make sure that people have actually followed that process. So, it's the idea that if you are creating a value set for statin and since somebody else has already created one and either, you know, you haven't done your due diligence to see that somebody has created one and that you're creating a duplicate or that you feel yours is significantly different, different and needs to be separate. How do we educate that – adjudicate that?

You know, there's – and that's where I think it probably has to be the NQF. I don't know. I mean we've kind of heard many times that the NLM does not want to do that. And you need somebody to be able to look at that and say, "OK, these are actually different (enough)" or, you know, that "Yes, we agree that there is no current statin value set and we do need a new." But, there has to be – some has to be invest that time and effort into doing that.

Cynthia Cullen: This is Cindy. The NLM in particular, the tool that's available, the VSAC now has additional tool that allow you to check for overlap and things like that. So, there are mechanisms our there for stewards to self-regulate in a sense that they can look for that. These tools were not available even as much

as – just a couple of weeks ago these are a relatively new. But, that capability is out there. I do agree though that there should be some responsibility put on the stewards to look to see if there are existing value sets that could be used.

Jason Goldwater: OK.

Zahid Butt: So could I just for discussion sake, could this be sort of a two-tier governance process where there is at the NLM level that the stewards and developers typically use would voluntary agree to whatever, you know, the sort of harmonization processes – recommended harmonization processes might be. And then NQF would incorporate some of the criteria during the endorsement either new measures or existing measures.

Because currently at the measure level, NQF does have a harmonization framework that is inexistence where it does try to do the concept of best in class and harmonization, I mean it doesn't do the work itself but it does require the folks who are taking measures through endorsement to address those issues and show that they have been addressed.

And so, similar framework could be established for value sets including both harmonization as well as the quality of the value set as part of the endorsement or maintenance endorsement process. That's within the NQF's purview within the endorsement process whereas there could be some kind of voluntary framework that would fit into that that's at the VSAC level.

Jason Goldwater: Right. I mean I think this is something that we can probably slash out in detail a little later, perhaps another call, but the – I think our thinking was very similar to yours that if there is going to be a role for NQF that was not in overarching body which, you know, I don't think it's a (fully our envision) for the organization, but that would be incorporated into the evaluation process of that where they're submitted on.

So, the whatever standing committee based on, you know, with the clinical and constant of measures that we would look to the stewards to be initially validating the value sets to ensure that there was, you know, limits, (decrease) of overlap. It was high quality, whatever the standards of that are. And then whatever the criteria is that this committee comes up with we would then

potentially incorporate it to our evaluation process which is – that's a lot more feasible to do and if you ask them then, you know, assign an entire body to be reviewing every value set which runs into just not logistical and bandwidth issues in terms of your resources, but as Marjorie pointed out, there's also firewall issue as well.

So, let's go to the next question which we haven't addressed yet. And I think that we've, you know, already looked at how at least initially have a measurement endorser process would account to this with high quality value sets. And we would probably work based on what criteria are established in our evaluation of these value sets or evaluation with eMeasures.

I think I'm going to – but the next question is, you know, will there be exceptions to find – this is kind of where we left off to the last question we started discussing before we had to end last time. But are there going to be exceptions defined? And how are those exceptions and appeals be managed into measure endorsement?

And so, I think where I want to start with this is, you know, what would be the exceptions to the rule here? We set up a criteria for high value quality value sets. What – and we, you know, say this is the criteria, the measure comes in, NQF goes through evaluation process, we have the criteria that was recommended by this committee. We've examined the values that's based on that criteria and then we do a write up before it's passed along to a standing committee.

Are there exceptions to that? Do you foresee there being exceptions to that process. And why would those occur? Anybody?

Male: Well, as long as those criteria are public and given, you know, enough lead time or head time so that authors are aware of them. Then I would be hard pressed to understand why you would entertain exceptions.

Male: OK.

Male: Well, I think it depends on exactly what you mean by exceptions as well. Because is that same sort of thing where – so in the analysis that you did there

was a value set for fondaparinux and there's a value set for Injectable Xa Inhibitor. And it looks like right now the only Injectable Xa Inhibitors are fondaparinux.

So you get you get into this issue of, well, what is the appropriate value set? Should it be the specific medication, or should it be the class of medications and should we have two, should we have both. And should we have one measure using fondaparinux and another measure using Injectable Xa when they actually have exactly the same members.

And who is going to make that decision, you know, are they both high quality value sets by the definition of high quality value set? They probably are. But how do we – who says, OK, yes, that is a little different, you're doing one for fondaparinux and you're doing one for this general client.

So do we need two value sets there? Who – Is that an exception and who makes that decision?

Male: Well, that's a good question, like who does make that decision?

Male: Yes.

Male: Don't say me because it's not going to be me.

Male: OK. So there's information called – out there called the Value Set Authority Center. So in report he sounds really good as somebody to make that. But it probably is and from what we've heard earlier.

But there is a – you know, it gets to almost, you know, a style guide or a – you know, a Value Set best practices that kind of need to be determined and developed. And I think that's the type of thing that would probably be developed under the – you guys in the NQF and then, again, you know, I think there needs – it's that multi-stakeholder organization that likely needs to make that sort of decision.

Male: (Inaudible) you want to go to the next slide?

Male: So perhaps you need another standing committee in the NQF to oversee that. And when those – when these issues arise make those decisions.

Male: OK. All right. So we're focusing quite a bit on the criteria for value sets. So now we're going to move towards value set development endorsement and use. So I think where I want to start with this is…

Male: (Inaudible) still there?

Male: Yes, (inaudible).

Male: Hello.

Female: Yes.

Male: Yes. So I guess it's sort of gets to the same question, who would enforce the requirement for the development of value set…

Male: Hello.

Male: … assuming we get a, you know, I guess documented criteria, documented best practices of what to follow. That would of course be reached through consensus of everyone on the phone.

But who would enforce those requirements? I think CMS sort of – is a nonstarter as it was raised earlier because there are payer and that would be potentiality problematic. I also don't particularly see CMS flying to take on that role.

Do you thing that NQF takes on that role by, again, when eMeasure comes in applying the criteria to the value set, examining to make sure that it is thorough and complete based on that criteria, the use of best practices that we would be creating. And that we would then be – if it's not, if it doesn't meet that, then we send the measure back. And say you have to fix this in order for us to consider that measure to be passed on to the standing committee.

Is that a – I mean, that generally how it goes now. As, you know, Cynthia and Rute and Marjorie and others are well aware off that when measures are sent

in – any measure and it's evaluated, if it's not passing the criteria that we've established our evaluation, it gets sent back to the measure developer and we have to work with them on fixing that before it gets passed on to the committee. So if you see that process being similar for this.

Marjorie Rallins: Yes. So this is Marjorie. And I actually think that some of that process happens already when you look at claims measures and the committee sort of, you know, is evaluating, they'll look at the code that are associated with a claims pay for measure.

Male: Right.

Marjorie Rallins: You know, this is really not different. What I'm a little been uncomfortable with is the word enforcement, I know what you mean. But when (inaudible) enforced it kind of has a regulatory kind of…

Male: Right, right.

Marjorie Rallins: … role to it. And I don't think that's where we're going here, right? And I do think the roles for NQF is similar to what it has now, I mean, they don't – if the codes that are associated with the claims measures don 't match the intent et cetera, then they'll let you know that. And I think that, that's similar to what you would want in evaluating a measure that happens to have an electronic specification.

I think what we see now is that the steering committees are not as familiar with the format of the eMeasure. And they are not necessarily reviewing the value sets themselves when they evaluate the measure. You know what I'm saying?

Male: Yes.

Marjorie Rallins: So I think there isn't – you know, it's all about messaging and I don't think there would be a change in the perception if we communicate it in that way as it relates to NQF's role. It's really no different than what they do now.

But I don't necessarily see NQF as being the one also to determine the quality of the value set if you're actually reviewing them as part of the endorsement process.

Male: Right.

Female: Yes, I think this is good. When I think of this, I think about regular (inaudible) measure data element, let's say. And for the scientific acceptability of that data element one is going to provide reliability data. By this elements, right?

What I see as the risk here is that if one value set has a problem or requires harmonization or something like that, would that be sufficient for NQF to send an entire measure back. And how does that relate to the other criteria where a whole set of testing processes have been put in place. I mean I would imagine that NQF look at the value sets as a set and not at the each individual value set, although, I mean, of course you would check for a minimum qualities values such as purpose statements or that sort of thing. But not go into each individual value set and make a aye or nay decision.

Jason Goldwater: No. And I don't think that that's how we perceive that. I think that sort of beyond the scope of the organization. It's – I think it's more of what criteria do you all feel is essential. And then how do we fit that into evaluating the measure in totality with the value sets being a part of that.

So it's not looking into each value set individually going yes or no, it's looking at the value sets as a whole. And say, it doesn't meet the criteria that was established during this project that people that worked on value sets feel as appropriate to have. And then if it does, then, you know, it meets that check mark like it would with reliability or validity.

If it does not, then, you know, we have to ask the questions as to why and figure out what can be done to meet that criteria so the measure can get passed on as it would with, you know, any other part of the criteria that we used to evaluate and measures from. I don't – I guess I'm not envisioning this as being any different than what we do with eMeasures along those other components. It's just that its focus is value set.

So I mean in the criteria it will be – you know, it could be something as, you know, did you validate in the VSAC that there's that overlap between the value set and anything else, is the value set published, which is something we ask now, you know. Is the – You know, it could be questions as detailed or the questions as broad as we think is appropriate.

As long as we have some process in place by which to ensure that there is some degree of consistency in value sets in the same way that we, you know, work to ensure that there's some consistency and reliability of the measure or validity of the measure and so forth.

Male: Yes, so I think…

Jason Goldwater: … today but that sort of what our line of thinking is.

Zahid Butt: So, Jason, so I agree with what you're saying. This is Zahid. That for example currently, when you go through endorsement there is check box that the measure steward has to say that, yes, we have harmonized this measure with other measures or something like that and you have to provide evidence that's – so in that sense, you know, the president is already there even before the concept of harmonization.

Now it will be defined differently potentially for value sets because it's – you know, eCQMs have a sort of unique set of needs. And so I think that's really where the gap as I see it is that those things that are very sort of unique to – eCQMs are not as well defined within the NQF process.

Jason Goldwater: Right.

Zahid Butt: And so the community outside thinks that any eCQM that's been endorsed by NQF has been gone through a fine-toothed comb. And I think that's sort of the missing component and I agree with Marjorie's comment earlier. And my experience on being on a steering committee is a couple of years old but I do remember that out of the 12 or 14 physician members I think I may have been one of two members of that committee that any idea of eCQMs. So there's a general lack of understanding of the concept.

Jason Goldwater: Right. That's good.

Zahid Butt: So I think all of those things doing the endorsement process will have to be addressed from the type of members that are on steering committees if eCQMs are coming for endorsement as well as some of these criteria that are very specific to eCQMs but are addressing similar type of concepts that you're already addressing for the claims order, the other measures.

Nancy Walker: This is Nancy. That is an excellent suggestion because it is a different animal. Just talking about aspirin discharge and the particular measure that we're looking at right now other anticoagulants. Well, you know, in the eMeasure you need that to identify the medication. You wouldn't – I'm sorry. The medication that you're going to give instead of aspirin. I think that's the reason for that particular detail.

So it really does take – it's really important to have the expertise of not just the clinical but also the understanding of how that heart of the value set, subset number, whatever, will really work to meet the intent of the measure.

Jason Goldwater: All right. So let's shift to a similar but somewhat different question which is, you know, while we are proposing to engage in is changing the process from the way it's currently done now and that we would be developing criteria and guidelines and then in some manner, evaluating whether there was some degree of conformance to sort of managing the process (inaudible) rather than forcing it.

But how is it – How do you think this is going to impact the work of measure developers? And what kind of ripple effects is this going to have and more or less just to understand and to anticipate them, especially, you know, there are measures that are used that are not NQF endorsed, and the passage of HR2 states that that's not necessarily something they have to have. I think a lot of people will still continue develop forward with it but it's not a mandatory required. So we have people who still be developing eMeasures and they'll still be using value sets.

So how will the change in this process impact the work of measure developers with particular consideration as those that are developing or we are looking at non-NQF endorsed measures. What do you think that – what do you think will – well – or what do you believe those ripple effects will be?

Rute Martins: This is Rute. I don't think the value set should go to NQF if it's not part of the measure that's being submitted for endorsement period.

Jason Goldwater: OK. OK.

Male: I would agree with that statement as well.

Jason Goldwater: So really we should just be looking at value sets for measures they're getting pass to the standing committees for potential endorsement and those that are not NQF endorsed measures we should just leave alone which, you know, again, perfectly fine.

Zahid Butt: Well, I think unless we agree upon that earlier sort of concept that there could be a voluntary sort of agreement that the criteria that eventually NQF will also be using that could be sort of incorporated within the VSAC along with the tools and guidance for folks who are taking their value sets to the VSAC to, you know, follow those best practices in a voluntary sort of way as opposed to not doing anything. I would think that that would be at least the start and then we can reevaluate in a year or two to see how well it's working.

Marjorie Rallins: This is Marjorie. I agree. Maybe I'm repeating this again. But I think regardless of endorsement, there needs to be a criteria we agree with that, right?

Jason Goldwater: Right.

Marjorie Rallins: That's (inaudible) NQF in reviewing measures for endorsement would also apply.

(Off-mike)

Jason Goldwater: So following to that question, you know, not in the – even when we developed guidelines and criteria it's, you know, clearly I think we all understand that

will not – that's not going to be done in a vacuum and we're going to assume that they're non-changeable and there wont be adaptations that are done as eMeasures and value sets continue to evolve which they almost certainly will.

So how would – So it's not out of realm of possibility that developers will make recommendations on how the guidelines and criteria should be changed. And I would even assume at the moment that those were published people are going to have suggestions on how they could change.

So how do you recommend those changes be met and again who should do that? Is that something that the steward should do? Is that something NQF should do? Is that something that the standing committee of NQF should do? Is that something another entity should do? I mean who – is that something (inaudible) should do? Is that – Who would manage the changes to this criteria and policy guidelines as they evolve?

Zahid Butt: Are you asking for this committee to become permanent forever?

Jason Goldwater: Well, that's not what I have in mind, Zahid. But since you brought it up, I don't know. I mean that's certainly within the realm of possibility, just become a standing committee that, you know, has a term like other standing committees of three years and then changes and that's certainly something that we could do if that is something that you all think is reasonable and something you would want to do, or you'd want to participate on that. Because that will be the first question we get if we even propose this. Is that something they all want to do and commit to this, which is what we ask everybody that wants to be on a standing committee.

Ellen Harper: This is Ellen Harper. One of the things that I've heard consistently over the last couple of calls is we want to move the thoughtfulness of is it a value or is it duplication move that to the right level. So that might be the knowledge developer or it may be the value set evaluator or whether it's the library of medicine that houses tools that allow people to go check for the harmonization pieces. Seems like we want to move things to the levels where the highest amount of knowledge-based resides to make good avoidance of needing harmony at a higher level.

Jason Goldwater: Right.

Ellen Harper: If we could get those processes in place with the tools and move things to the right level, it would certainly make the work of this higher level committee less and less because the work would have done – happen prior.

Jason Goldwater: Right. Good point. Very good point. Any other comment on this?

Zahid Butt: I mean…

Jason Goldwater: Go ahead.

Zahid Butt: I would imagine you would probably need some sort of committee or whatever you want to call it that at least would assist with some – you know, changes as things go along because I'm sure that criteria or whatever we come up with will potentially in need of refinement. I don't know what the length of that time is but I would imagine that at least there is some level of that type of activity that would be needed even providing that type of multi-stakeholder input into the NLM and the same type of criteria than being also used by the NQF during the endorsement process. I think it will be – we have some group that is sort of doing this on a somewhat regular basis. Not too frequently but, you know, once a year review or something like that. I don't know, after sometime.

Female: Yes, I agree with that, Zahid. I think are multi-stakeholder perspective is important. I do go back to my firewall concerns. Jason, I really do think that's going to – that will eventually be an issue but…

Jason Goldwater: Yes. I agree.

Female: If we are – if we're, you know, focusing on this is being a committee of NQF, it could certainly belong to another body if that's where we want to – but I don't know if we're there yet. I just think that that is something to consider.

Jason Goldwater: Agree.

Female: You know, you need a Switzerland group, you know.

Jason Goldwater: Right, yes. Completely (inaudible).

Rute Martins: And this is Rute. I would (inaudible) the – I think it was (Kara's) comment in terms of making sure that the tools are in place. I think those are going to be a critical piece. Cindy I think you mentioned earlier on the call, we've just now had access to tools that enable us to compare the content of value sets easily. So, part of it is just a missing tools and NLM has done a lot of progress in providing those and I really think that there's a huge knowledge-based at the NLM from the terminology perspective, their terminology management experience that could lead into these best practices.

And I understand – my understanding is that NLM doesn't want to be the arbiter of deciding if this value set is a good one or not. But I do know that they know what a good value set looks like. So, I think having that perspective is critical for this whole process in maintaining those criteria.

Jason Goldwater: OK. (Inaudible) the next one.

OK. So, looking at value set update and maintenance which you know is an issue we came up with earlier when we're looking at the worksheet. So, you know, I think it was pointed out by Dr. Tcheng, it seems initially that there were some values that may have been outdated or the science has evolve and that the values, the members have not evolve with it. But what is going to be sort of the incentive, I guess, to encourage update and maintenance at the value set. I mean, what – (inaudible) develop values that's personally although quite familiar with what they are don't develop them.

So, there's several of you on this call that do. So, I guess how – what is your process for updating and maintaining the value set and how do we apply that consistently once we start having these processes and tools in place to help people develop high quality values that's for inclusion that to be measured.

So, I guess starting off is like what do you do now to update and maintain value set? And when you do it? What's the catalyst for doing it?

Rute Martins: This is Rute. I can start. So I don't think that there's any roadblock in perceiving the value set or I think measure develop those – I believe that value set should be maintained.

Jason Goldwater: Right.

Rute Martins: Some value sets are currently out there are actually bound to certain maintenance schedules like once every year. And that causes value set sometimes to be outdated right at the outset of the example that was given today on this call because of the version that is supposed to be used with that particular update which is a problematic requirement is the aversion that's become obsolete eventually. And then (inaudible) norm we're talking about monthly releases, right.

I think the bigger question in terms of value set maintenance and not only on going maintenance of value sets but management of value sets in general is ownership because right now value sets are – have a steward. They may have an officer who's different from the steward. So, the hands that go and actually update the value set maybe different. That may include terminology experts for instance.

But the bigger question to me is these value sets that are high value value sets that could be used with across a lot of measure, for instance, is it first come first serve so that the first person who come over the first organization who comes up with – comes up with a value set that they now on the concept forever, that sort of thing. I think that's going to be the challenge.

So far so good. I would say that all measure developers has been extremely collaborative and relinquishing these and not even going into this ownership questions we're using whenever possible. But I think moving forward that will certainly be an issue.

Jason Goldwater: OK. Thank you very much.

Zahid Butt: So, Jason, this is Zahid.

I think the two main areas that where we see this kind of get out of sync is when – and I think Rute alluded to the RX norm issue that a new branded drug comes on the market that does exactly the same thing is the existing value set. And the hospitals starts using it or the physicians at the hospital start using it and, you know, how do you incorporate that into the value set that's usually one sort of scenario in which there is this lag.

And the other is that sometimes these process measures key off of certain guidelines and these are national guidelines that inherently have a slow process of being changed based on the type of guideline and sometimes the science has shifted quickly and the guidelines are still lagging and then the measures lag even still.

So, I think it's those kinds of things where you get into this lag that is sometimes difficult to deal with when you're dealing with clinicians who were insisting that they're doing the right thing.

Jason Goldwater: Right. OK. I mean I guess Rute and others, I mean, is there – I clearly can understand that there's a fine mean schedule for, you know, some value sets because they're tied into national measures.

Do you think that there's some general framework that can be created or perhaps guidelines, again, for maintenance and updates to value sets that could be published right along with guidelines creating the value set or do you think there's just too many intangibles to actually sort through that?

Female: I actually think we've been talking about one that would actually relieve some of that maintenance burden and that's the intentional definition just run a rule against the next version. And if there's tooling that enables you to compare with the result the – resulting expansions are then you can actually see exactly what's happening and it should be a terribly onerous processes. The tooling is really, really lacking. I don't want to understate that.

Jason Goldwater: Right. I understand that.

Female: And so that will definitely be – that is where I think the barrier is from your technical perspective and then there's the ownership aspect of it.

Jason Goldwater: Right, right. OK. Are there any other thoughts on this?

OK. Next slide.

So – And this is sort of brought up in some discussions that we were listening (inaudible) when people were talking about. And I'm not sure how much understanding they have at this project, but it was – to talk about the value set contents or value set harmonization and the effect that it would have on clinical documents beyond just this eCQM.

So in your mind and maybe the answer to this it's not going to affect anything. But in your mind and given all of your experience, what clinical documents are potentially affected by changes in value set content besides eCQMs? So, are there any other things that harmonize the value sets (inaudible) other than just measures? And what were those effect? What were those impacts be?

Nancy Walker: This is Nancy. Well, from a user's perspective, if – I hope I'm answering this. I hope this is useful. But from a user's perspective the – if the measure, if the values, you know, value set are modified and therefore changes the quality measure, that works backward to what needs to be captured in the electronic environment. And that means what's front-facing to a user.

So, that means do we add something to the EHR that we didn't have before? Do we now need to use clinical decision support to help support capturing that information? It goes all the way back to the user. Does that help?

Jason Goldwater: It does.

Male: Yes. I mean I think in theory, it's – you know, when you look at a clinical guideline that really is, you know, behind a clinical quality measure so around – you could think around, you know, patient's status for some, are they discharged on a beta blocker? So, that's the measure, but its' really also, you know, best practice. And that's why it's a measure.

And so, you would ideally like to use the same value set to drive your decision support in your EHR system. So at the time of discharge, has the patient been

prescribed it? And you get an alert if you they haven't or something of that nature.

So – And as they change overtime, you know, the easier you can make it to keep your decisions for current the better.

Jason Goldwater: Right, right. OK. (Inaudible) thank you…

Female: This also – go ahead.

Jason Goldwater: No, no, no, go ahead.

Female: This is actually been a discussion that's been had a couple of times at the VSAC user forum. And it's an old – age-old issue. And that is that document – (inaudible) documents like the clinical – like the CDA. OK. For some reason I'm blanking on what it stands for. Clinical Document Architecture, there we go. That it uses value sets and uses terminologies extensively.

And quality measures don't necessarily always align in the – for instance when you transmit a CDA doc and you assume a problem is going to be based on the value set that is a list of extensive list of (normal) codes but the problems that are – problem value sets for specific problems that are being used in the quality measures don't necessarily align with that super set that is defined for CDA. So that's just an example.

And I'm really not sure what the underpinnings and maintenance of those value sets are. But I would suspect that they move in even more slowly than the eCQM value sets. But that's been – that's going to be an ongoing challenges to harmonize what's – what people and implementers have to use for information exchange, help data exchange and what they would need to use for reporting quality measures. Those shouldn't be separate requirements. So, I see that as another layer of harmonization that's never been addressed

Jason Goldwater: Thanks (inaudible).

Zahid Butt: I think the changes in the value sets from an implementation standpoint that have the highest impact are the ones where the value set is used for surveying

up outside the clinical decision support because I agree that that's a very important use case. But outside that there are certain value sets that are used as part of documentation. In other words, you know, nurse goes into document whether they applied a device and there were a list of devices that is available.

And so, that typically they try to match to the specification and the value set. That's – So, any type of value set that has members that are used as part of a build process as it's referred to on the application side has a big impact. Even one code change requires a significant effort on part of incorporating it inside that built process as well as the education that has to go along with it. So that has a huge impact from the clinical workflow standpoint.

And the other is where there's already some documentation that is going on, but then it is not in the native code or terminology and there's a mapping involved. And so, that has a very big impact because then you have to map the local term, whatever is being captured to the code.

And so, those have – those two areas are the biggest impact in addition to what has already been mentioned.

Jason Goldwater: Right. This is very, very helpful. Thank you. Anybody else?

Rute Martins: Not anybody else, but somebody. So, sorry. That actually is a – that creates a question for me in terms of the impacts of value sets and how they change over time because – I'm going to take your example and say that another device comes on to market and let's say a bunch of hospitals start using it, so I would assume that they would build that additional device into their documentation processes.

So, adding that device as a value set may actually be a result of it being used already, for instance, but it wouldn't necessarily be a requirement that all hospitals have it as an option if they don't use it.

So, I think part of this is a really interesting interplay between what a value set means. S it everything that is in a value set, is it a requirement, or is it outlining a bunch of options to meet a requirement?

Zahid Butt: Right. So, that's a good question actually, Rute. I think we're almost out of time, but I'll just quickly say a couple of words on that.

So, there are two scenarios that in your comment there. One is that they have a new device that they have added and it's perhaps a local term that they have used. So, if it shows up in a value set then there's got to be a mapping done to the code, whatever code system is chosen for that device.

The other is actually an even more important and you would think that people would take a value set that by definition will have more than they need and pair it down, but in practice we see this all the time that they'll just take the whole thing and put it in there whether it is applicable to them or not.

In many cases, a lot of – I will say that a lot of them do try to make it as they gain more experience try to narrow it down to the choices that apply to them, but it has been a long educational process for people.

Jason Goldwater: Right. All right. Well, thank you all very, very much.

We're actually at the point now where we need to open up the call for public comments if there are any. So Ann do you want to lead that?

Ann Phillips: Is there anyone on the line for public comments?

Operator: At this time, if you would like to make a comment, please press star one.

And there are no public comments at this time.

Ann Phillips: OK. Well, let's talk next step then.

We have added a one more – a conference call for September 24th, 2015. Hopefully, that works with everyone's calendars. We'll be discussing more of the harmonization testing and continuing the governance call.

We've also chosen the date for our post comment call that's January 21st, 20 – sorry, 16. I should not say 2015. We are not going back in time, we're going forward.

And our next in-person meeting will be November 10th. And travel information will probably be sent by the travel office I would say the beginning of October for that.

You know where to reach me if you have any questions via e-mail. You can e-mail the value set harmonization box for me direct – me, myself, Katy or Jason directly. And thank you so much.

Male: Is that (inaudible).

Female: Ann, can I ask?

Ann Phillips: Yes.

Male: 24th call, tentatively scheduled for 1:00 p.m. eastern or not?

Ann Phillips: Is that a Thursday?

Male: Yes?

Ann Phillips: I believe we tried to schedule it around the value set harmonization group.

Male: (Inaudible) it would be useful to send that out.

Ann Phillips: Yes. Yes. It's 12:00 to 2:00 because there's a value set group call. And we'll be sending that appointment out, I would say, probably by tomorrow.

Male: OK.

Ann Phillips: We just selected that date and we're waiting for the conference call information to be assigned to it.

(Off-mike)

Male: All right. Thank you all very, very much for this highly productive call. Thank you again for your guidance and instruction on the worksheet. And thank you for a lot of very valuable thoughts on governance. We certainly look forward to discussing with you the results of the first pilot test.

Male: OK.

Female: All right.

Female: Thank you.

Female: Thank you.

Female: Buh-bye.

Male: Buh-bye guys.

END