NATIONAL QUALITY FORUM

Moderator: Value Set Harmonization
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Katie Streeter: Hi, good afternoon everybody. Welcome to the Value Set Harmonization Committee Webinar. This is Katie Streeter speaking, I'm a senior project manager here at NQF.

Also joining us are Jason Goldwater, senior director, and Ann Phillips, project analyst.

Today, we'll be giving you our project status update, an update on our pilot harmonization process. We'll also be facilitating our governance and policy discussion and discussing next steps for this project.

Before we proceed, we'd like to take a quick roll call to see who's with us today on the call.

Ann Phillips: OK. This is Ann. And Zahid, are you here?

Zahid Butt: Yes, I am.

Ann Phillips: Great. Excellent. Michael Lieberman?

Michael Lieberman: Yes.

Ann Phillips: Howard Bregman? Chengjian Che? Christopher Chute? Cynthia Cullen?

Cynthia Cullen: Here.

Ann Phillips: Ellen Harper?

Ellen Harper: Yes.

Ann Phillips: Yan Heras?

Yan Heras: This is Yan.

Ann Phillips: Wendy Hofner?

Wendy Hofner: Here.

Ann Phillips: Stan Huff? Matt Humphrey? I know, Rute is not joining us. Robert McClure?

Robert McClure: Present.

Ann Phillips: Marjorie Rallins?

Marjorie Rallins: I'm here.

Ann Phillips: Joseph Schneider?

Joseph Schneider: Here for the first hour.

Ann Phillips: Great. Ann Smith?

Ann Smith: Here.

Ann Phillips: James Tcheng? And Nancy Walker? And is there anybody who's on the call?

Nancy Walker: This is Nancy.

Ann Phillips: That I haven't called. Great. Thank you, Nancy. Is there anybody else who's on the call that I have not …

Kevin Larsen: Hey, it's Kevin Larsen.

Ann Phillips: Hi, Kevin. OK.

Jason Goldwater: OK, thank you all very much. This is Jason Goldwater. And I thank you all very much for taking the time out again to be with us. We greatly appreciate your participation and taking the time off at a very, well, I'm sure, as hectic schedule, and through the beginning of the summer.

So, what we want to do today in the next two hours is to one, provide a status update on where we are now, which is always what we will do in this call. And then two, to sort of shift focus a bit.

The last time that we met, we really discussed the methodology for how the technical expert panel, which we've convened twice since our last meeting, would be evaluating the value set and looking at a way of potentially harmonizing based on the methodology that you all arrived at during our in-person meeting.

So we will provide a brief status on that, but then we want to switch focus a bit and spend a considerable amount of time talking about the governance issues that surround values for harmonization. That is a crucial topic. It really is one of the primary topics of this project and is incredibly important both to ONC, the National Library of Medicine, and other federal partners that are involved with value set.

So, the technical expert panel, which is independent of the Value Set Committee, was designed to perform analysis, suggest resolutions and provide feedback on our process that included resolving the definitional issues around the meaning of value set and the codes that are required to articulate that meaning, adjudicating was complicated and judgment dependent variances, and then assisting us in the development of an iterative process with (inaudible).

Next slide.

The project status at the moment. So, when we convened last month, we talked about moving from an extensional value set into an intentional one. And that we would look at a way of doing that through understanding the

intent of measures particularly AMI, VTE, and depression with AMI and VTE being looked at for medication and depression being looked at for encounters.

We would look at overlap duplication and omission within the measure and most importantly, between the measures by manually reviewing the value set and using the Jaccard analysis with a threshold of 0.49 is return on the degree of overlap.

In terms of classification, for medications, we would be using RxNorm. And in the RxNorm database are (Nav). They have two ways of classifying medications, the NDF-RT and the ACS.

And, then we would look at why – look at the recommendations from the TEP once they have looked at these measures and the recommendations, why is it changed recommendation – why is it changed recommended and what they believe, what are improvements or result from that particular change.

Next slide.

So, where we have started is this, we have clearly identified the measures that we're going to look at. And, we have identified all of the value sets with respect to medication for AMI and for VTE, and that's what we've started, we had not gone into depression yet, that's a little bit later down probably into the beginning of the fall.

And, we are still looking to do the Jaccard analysis. Now, the last time, NLM was very gracious and did the Jaccard for us. And they are actually now going to incorporate functionality into the VSAC which will allow us to do the Jaccard analysis ourselves. So, we'll be able to then look at all of the medications, see where they're cutting – where they're overlapping within themselves and then across measures, and being able to identify the measures where there's potential overlap and potential redundancy.

That functionality is expected to go live at any day. As of now, we're still waiting. We're hoping it will be this week. And once it is that week, then we will go in and do the analysis ourselves. And we'll be able then to identify the

degree of medications that potentially are overlapping and the measures that they're overlapping again.

Once that's done, then what we're going to do for the technical expert panel is to break out a worksheet. And we want to go to this approach because we think it's the easiest for them, given that much like yourselves, they have very limited amounts of time. We want to make sure that we're just giving them the medications that based on the Jaccard, we understand have possible overlap, the measures that are overlapping again. And then to give them the medication, the instructions for downloading RxNav which most of them already know.

And then looking at the intent of the measure, the intent of the value set as directed by you all. And then looking at the appropriate class of medication in RxNav and so we (met out) on the worksheet and sending it back to us.

So the worksheet, the sample worksheet looks a little bit like this. Now, I'm going to qualify this and say this is a sample, this is – some of this is real, the Jaccard analysis in here is a figment of my imagination, it's not in any way do this kind of analysis, I just – you made this out as a representative example. Unless you're going to hopefully be sending this worksheet out tomorrow based on your feedback.

So, one of the AMI measures where we indicated there could be potential overlap, we don't know the degree yet until we do the Jaccard, is the AMI measure, the statin prescribed at discharge.

Within the worksheet, we will look at the measure steward, which in this case, would be CMS, and then, at the measure intent which we extracted from the measure submission form. And here, I won't get into reading this, but this is the actual intent at this particular measure.

Next slide.

We would then also be looking at the parent value set, so this is really following the methodology that we use in our pre-work analysis.

So, we did some analysis and we looked at the parent value set, that it's supposed to be there was a AMI measure, and looked at potential overlap with measures from either stroke or the VTE families. And we provided description of this parent value sets, listing the object identifiers, the value set description and the value set steward.

We are in a process now of contacting the stewards per your instruction and looking for what the intent of that value set is. And once we have a description of that value set, we will include it in the worksheet, so we will have the measure, the measure steward, the intent of the measure, then we'll have the parent value set, a description of that, the value set steward and what the intent of that value set as – is as well.

So, as the TEP begins its analysis, they will have the intent of both the measure and the parent value set.

Next slide.

So, the way they will work this is, they'll identify possible medications that will replace these sub-value set listed below. So we'll have the parent value set, and then the sub-value set that go under that, again, very similar to the pre-work analysis.

It'll be broken out into several columns. The first column will be the Jaccard index number which indicates the degree of potential overlap that's, again, as a sample and is not representative of reality at this moment.

The second column is the name of the sub-value set. The third is the name of the parent value set that that sub-value belongs to. So in this case, it belongs to statin allergen.

The recommend – fourth column would be the recommended class of medication identified on RxNav so the type (would do). And then we would want to know whether they identified that through the NDF-RT or whether they identified that through ACS.

We would align the recommendation, we are – at least we're recommending that they align the recommendation as closely as possible with the intent of both the measure on the current value set, or classes that can be reheated across many sub-value set, they need to reenter the class and the worksheet as many times as needed. And then in some way, that would begin the harmonization process.

We don't know yet how much – how many – how much repetition there will be. And we don't know the types of classes they're going to discover yet, until again, we have the Jaccard and know exactly what they're going to be looking at. Nor do we know at this point how many value sets they're going to be looking at.

But just our preliminary analysis identifying all of the medication and some of the potential overlap, it's not asset – it's not a hugely substantial list, but it is sizable enough where we should be able to get a good idea of whether what you are proposing is actually moving us towards harmonization.

And again, NQF will also be filling out this worksheet, we will not be just letting the TEP do this. We're also going to conduct this analysis ourselves and let that be a baseline that will be evaluating the worksheets as they come in to see what comparisons, what similarities, what differences there are. And then when we convene the TEP again, which will be towards the end of June, we'll be able to get a much better sense of the types of classes of medication that they have been able to find. We'll be able to get an idea of whether they were able to take those classes of medication and harmonize the various differences and possible overlaps, again, between value sets and between measures.

Next slide.

So, this is sort of what that worksheet will look like a little bit. Again, you can see the Jaccard score in the left, the sub-value set, the parent value set that belongs to recommended class in the NDF whether it's NDF-RT or whether it's ACS.

And again, that will be only applicable to the measure that is listed at the time.

Robert McClure: Now, Jason.

Jason Goldwater: Yes.

Robert McClure: Are you asking for our input into this, or what is it that …

Jason Goldwater: Yes, absolutely. Yes, we were – I – we were just getting to the last slide, so. Then I was going to open this up for comment and I'd like to hear what you have to say about this, yes.

Robert McClure: OK. So, when …

Jason Goldwater: Go ahead.

Robert McClure: … you're ready.

Jason Goldwater: Yes, go ahead.

Robert McClure: OK. So, this is Rob. I'm trying to follow – first off, I think you mean ATC not, whatever the other.

Jason Goldwater: I'm sorry, yes.

Robert McClure: Right? You do mean the ATC?

Jason Goldwater: That's correct. My apologies.

Robert McClure: OK.

So, and this is really kind of the meat of the things. So, imagine that gets stay here. So just trying to get a sense of – so the – your – the Jaccard is comparing what you're calling a sub-value set, help me understand how you – what do you mean by sub-value set, right? Is it a value set that's just smaller than the parent? Why do you – why are you calling one thing a parent and one a sub?

Jason Goldwater: Because, Rob, there's a – the parent value set or there's a statin allergen value set, and then underneath that, there are a number of values that comprise that statin allergen value set.

Robert McClure: Oh, you mean what they're group together, is that – so the parent – a parent, you mean the grouping?

Jason Goldwater: That's correct. Right, so the value set with the OID and then underneath that, the statin allergen, for example, it's got its own unique OID. And then when you go into that value set, then there's a list of all of these values.

So we just clarify that as being the parent value set was statin allergen. And then these are the sub-value sets that fall under that.

Male: But aren't they actually just values, not a sub-value set, aren't they the values that are members at the set?

Jason Goldwater: Yes, those would be the values that would be comprising the value set, but if you think that terminology is confusing, we can get rid of that. But, that …

Robert McClure: Yes, it is confusing, because what you just said, I was – I'm looking. So, it isn't what I just suggested.

So, there – the – I'm not sure who just spoke but they spoke the truth.

Jason Goldwater: OK.

Robert McClure: What you're – because I'm getting this issue about what the Jaccard is trying to actually say. So, the – so what you – what appears is, is that where you have this parent value set is the value set itself. And there's this whole issue about grouping value sets and the value sets they group. But, I don't believe that's coming into play here although it might. But I think we could assume on first pass that the value sets that you're looking at certainly in the medication ones, whether they have been crafted as a grouping value set or not, can just be ignored. So there's a value set that has a whole series of members.

And then, or you have a sub-value set, it's not a sub-value set, it's a concept that is in that value sets of, you know, whether statin (sodium) is that concept that exist inside the statin allergen value set, the same thing for atorvastatin, calcium and then atorvastatin and Lipitor, right, those are – because I'm looking and I see them so they are concepts inside that value set.

Jason Goldwater: Right.

Robert McClure: Is that right? OK.

Jason Goldwater: Right.

Robert McClure: So, part of – and then the fact that you've got in this list a variety of value set. So one of them is statin allergen. And another one is statin. And then statin ingredient specific. And then – so, we have at least three different value sets in which concepts can occur across in any one of those three, one, two or three, right?

Jason Goldwater: That's correct.

Robert McClure: That's right. So then – so atorvastatin, and they're second to last one, so help me understand the Jaccard score in the context of now, you know, that we have – I'm assuming that it said – that the Jaccard is in some way, you know, trying to give us an assessment of whether atorvastatin is showing up in all three. Help me get that.

Jason Goldwater: What the Jaccard is doing is that what it's showing, Rob, is that that particular value in that value set is showing up in this AMI measure, but it's also showing up in other measures.

Robert McClure: So it's a …

Jason Goldwater: Right, so …

Robert McClure: … class measure. Got it.

Jason Goldwater: Correct. That's correct. So, what we're seeing, the Jaccard is indicating the degree of potential overlap between that value in AMI and other measures that are also taking that value.

Now, you know, does that value belong in those other measures? Would it be easier to look at it from a class standpoint instead of a specific medication? That's the analysis that we're having the TEP undergo.

Robert McClure: So atorvastatin, the third one down, is the same concept that's in statin allergen, as atorvastatin, the second one from the bottom …

Jason Goldwater: Right.

Robert McClure: … statin ingredient specific.

Jason Goldwater: That's correct.

Robert McClure: And, the fact that they have different Jaccard scores, help me understand that.

Jason Goldwater: So, they have different Jaccard because the – a degree of potential overlap or correlation between what's an AMI and what are these little measures is reflected in that score.

So, you know …

Robert McClure: So where is – for this table we're looking at, what is the – you know, for Jaccard, you've got a base and then you compare, right?

Jason Goldwater: Correct.

Robert McClure: So – and it sounds like Jaccard is talking about comparing across measures. So what's the base measure, where you're starting and then doing in comparison?

Jason Goldwater: We're starting with the AMI measure that was listed above.

Robert McClure: So the AMI …

Jason Goldwater: The direction was to start with AMI. And so, when we look at the – now, Rob, we haven't done the Jaccard yet. I mean, this is …

Robert McClure: No, I get it, I get it. Those are made up numbers is what I'm saying.

Jason Goldwater: Right, because this is just – when we talk to the TEP, they asked specifically if we're going to send the worksheet, because they felt that would be easier, that we would list the Jaccard score and then we would also – we would submit an explanation of what that Jaccard score is, which we're doing.

So – but this is not real. So, what the degree of that …

Robert McClure: All right.

Jason Goldwater: … I don't know yet.

But, we started with the AMI measure, and what we have done today because we haven't been able to do the statistical analysis is we looked at all of the medications that we're in each of these AMI measures in meaningful years, because that's the first measure we've started off with.

And when we look at the medications, we also saw other measures where these medications were appearing at. So, when we look at the Jaccard, we do the Jaccard analysis, and we do it on this measure, it will show us the degree of overlap between that particular value and the other measures that it is appearing in.

Now, is it going to be a one to one, is it going to be 100 percent correlation? It might be, if they have – if it's sustained sort of parent value set that it's raining under, but I don't know, I mean, and I don't know how – what that correlation is going to be. And when we did the pre-work analysis, some of the – what we were finding in depression and what we were finding the VTE had very high Jaccard and some of them had very low one.

So …

Robert McClure: Yes, no, I kind of get it now. I'll stop in a second here. I'm – I don't want to – I just – I'm not – I am completely lost as to how this is going to be, where this is going. And …

Michael Lieberman: Right, and this is Mike …

Robert McClure: … I mean, really, totally completely lost.

And so, I'm trying to figure that out and I – not only this second, because part of this is I'm very familiar with these particular value sets. And the fact that a concept would show up in the statin allergen, in statin and in statin ingredient specific, are all – well, it's like atorvastatin, it should be in statin allergen because all the statin allergen concepts are ingredient-level concepts.

It should be in statin ingredient specific because that value set, obviously, is also specific to ingredients. The fact – so, one question one might add – ask is, well, the fact that you have a value set that is ingredient specific that was a set that is restricted to particular kind of, it's called the term type, and RxNorm, is their overlap with those things that are – the allergen value sets because they have also been limited but they're not exactly the same.

I mean, that – when you know the meaning, the reason why and you kind of got to that on the prior side where you're looking at the intent of the value set, the intents, I think, you might have had to guess it's some of them, and some of the wording was a little bit, I think, not reflective of some of the, you know, the nuances of why those value sets existed.

But when you, know, using that, that's going to be an important part, I think, of doing this analysis. And then, the overlaps, you know, as I'm sure you're aware of, some overlaps are absolutely expected and required in terms of the needs of those particular value sets.

Female: So this is – Rob …

Robert McClure: And then separately, this thing about, OK, then, when you've got a value set in three different measures, maybe there's – you know, that would be expected but the question is, "Oh, but you've got different names or something that look

very similar." And that's, I think, where you're getting. And I'm just – I'm not exactly sure how that's going to fall out in these tables.

And then the last thing, which is really a separate thing, is this issue about recommending class in the NDF-RT ATC column, and I don't know how they're going to get used. But, I'll stop and let others comment because …

term type: Yes, this is …

Robert McClure: … really lost.

Marjorie Rallins: This is Marjorie because – Rob, I'm glad you identified that, for me, I guess the question is, is when you use the same example of atorvastatin. What's different about those two – the two rows here is the context of use for the value sets. And I think we have to think about that when we're evaluating whether, you know, harmonization is warranted, because you can have two identical value sets where the context of use or the name of the value set is different because the context is used as different. And should those exist separately.

But that was kind of my question. And Rob, is that where you're going also?

Robert McClure: Yes, that's exactly part of this, this issue – again, I'd actually have to go back and look. But just looking at the fact that we have statin allergen and statin ingredient specific, I have to go back and see why.

Marjorie Rallins: Well, you have …

Robert McClure: Surely, those are different context of use.

Marjorie Rallins: Right.

Robert McClure: But it could be that there's – they could be the same value set, but I'm not convinced of that because I have a feeling there are some things in statin allergen – I'm sorry, in statin ingredient specific that, you know, that the are some nuances differences. And it certainly possible to do Jaccard scores against that to help us seize that out, that's exactly where that would be beneficial.

But boy, I had only know to look at that, because I know it separately from this table, and I'm really worried that if we throw this table and, you know, please – but this is not an entity throwing stones, this is hard and your first task. But, I'm not sure that if I just would handle this table, I can guarantee you I'd have no idea what to do with it.

Michael Lieberman: Yes, this is Mike. So I think the – I mean, one issue here is that, a Jaccard score is a comparison between two sets, I had to look at that. But …

Robert McClure: Right.

Michael Lieberman: … so it's basically the intersection over the union. And so that's where – what you'd want to – where you actually want to do and I think, Rob, and I think you've point this out, if you want to do the Jaccard between statin and statin allergen, or the statin ingredient.

And the other thing that we want to do is look for similar value sets across measures, and I just looked, there are – you know, there are two statin value sets, one for the statin at discharge for stroke and one for statin at discharge for acute M.I., for AMI. That seemed to be very similar, and I think that's exactly where you want to look to see …

Robert McClure: All right.

Michael Lieberman: … you know, what the Jaccard analysis there is. And those are the types of value sets that we've – that we want to harmonize.

Female: Right.

Michael Lieberman: You want to discover those. And I just – you know, I just looked for statins. But there might be other ones that are more hidden that don't – with the names not exactly the same. So, I think that's kind of where we want to go.

And then the question that you got at about, you know, do you really need – do you need a separate statin ingredient specific and a statin value set, I think that's what – you know, once we have the Jaccard score, you could actually

then look at the intent, you can talk to the measure developers and then – I think we're going to get to this part next, is then how do you actually decide whether you need two value sets or not. But, that will be the question.

Nancy Walker: And this is Nancy.

Speaking of the intent, I think that is the key point to this whole thing, what is the measure intent in the first place. And, when you – are we going back to, like the human readable definition in National Library of Medicine, the whole set? Are we looking to that as the intent, or are we literally going back to the measure steward and asking for the intent of each one of these, basically, value sets, because you can use medication – well, clearly, you know how you can use medications in a different way. So, let me stop there.

Jason Goldwater: The intent is to contact the value set steward and to ask them what's the meaning of this value set, so that was the instruction given.

We are going to look at the human readable for the intent of the measure. I don't think we need to go to the steward for that. But, the instruction was to contact the steward of the value set and to ask them to describe what the intent was.

And then we would write that down onto the worksheet, so that as this analysis is going forward, whoever is conducting the analysis, that was the intent of both the measure and the value set.

If you think it would be easier to go the human readable for the value sets, then

Nancy Walker: Well …

Jason Goldwater: … you know, I'm willing to do that but the instruction was different when we met.

Nancy Walker: Yes, no, I don't recommend just using the human readable because it's the intent of the entire measure. You have to get to the value set intent, really, in order to get the right information.

Zahid Butt: So this is Zahid. I think this is a great discussion, and I think that the intent that is being mentioned really is the intent not just of the measure, but also the intent of the use of that value set. And I think Marjorie pointed that out.

So, for example, in this specific measure, the statin value set is, I believe, for use in the administered context, so it's the codes in that are the lowest or at the most granular level including the dosage.

And I believe that the intent of the statin ingredient specific, in general, the places where I've seen it used, is mostly where it's being used for negation of certain drugs. So, you don't want to negate at that administered levels. You want to negate it at a much higher level so that if it's negated within the order set, then the physician is only given a few choices.

And then the alert – the allergen is somewhere in between, I guess it's a little bit more granular. And I think the question really would be whether the allergen and the one that's used for the negation, whether the used case is different enough that they have to be separate value sets, or whether they could potentially be the same value set in terms of …

Robert McClure: So this is Rob, let me jump in.

So he's actually right, and I'm actually looking at the history value sets and they all have different scopes and there's no way that they can be exchanged or one can use the other. So let me just – if this makes sense, we can use this as an example of the kind of thing that either …

Male: A context of the use of …

Robert McClure: … discover when you look at Jaccards across common things and then you say, "Well, this seem pretty close, oh, now I can't", kind of thing.

So, the, you know, we're just saying so statin, that value set is exactly as Zahid is saying, and that is intended to – and this is described in the purpose, the value set purpose as reported in the VSAC. So that's meant to be values that contain statin medications that are prescribed for therapy. At hospital

discharge, I think that that actually shouldn't be there quite honestly, the hospital discharge part.

But, it is – it includes inclusion criteria are single and multiple ingredient prescribable statin medications, all those forms should be included generic only, right, that's what it says.

And so that is the whole series of RxNorm codes but it doesn't include those things that are kind of, as we say, higher level things that don't have the – that aren't literally prescribable otherwise, in other words, they have a form and a strength.

The statin – all the statin ingredient specific, again, so he's exactly right. I wasn't remembering this and I can't believe since I was the one that suggested it, but I forgot. But that is used when we want to do represent something that wasn't done when it was expected to be done. It's not – it's kind of a usable phrase hack, but had a very specific intent, and it includes statins and independent ingredient.

So, only single ingredient concepts, no multi-ingredient concepts, because when that's different in the statin allergen, again, and you can see this when you look at the VSAC on the (authoring) side. Unfortunately, we don't show it on the general search side.

And that's – it actually has a clinical focus that is actually poorly worded because it says it identifies patients with an allergy with statin medications and clearly this value set does nothing of the kind. It doesn't identify patients at all. It's a list of ingredients.

And – but it is a list of statin medications from – that have turn (pikes), MIN, PIN, IN and BN. And that MIN and PIN are important ones because they're multi-ingredient things, which is specifically excluded from the statin ingredient specific that we use for that negation thing.

So what I'm saying is, is that now we have three different purposes that are understood, at least kind of relatively well described in VSAC. They

absolutely will have some overlap, particularly statin allergen and statin ingredient specific will, there's no question about that.

In fact, interestingly, probably the statin one may not, but we've changed that overtime because as I think many of us have been participating found out that there's a need to have concepts that aren't as fully specified, don't have strength and forms in order to support sub-drug ordering systems in hospitals.

So there's going to be a lot of overlap between them and that's expected and that's a sort of thing that, OK, you can do Jaccard scores against that. But it's not going to lead to anything because once you understand the meanings of the uses of the value set, you're – you know you're going to see overlapping doing a Jaccard score is really use with.

What would be useful is to go back again as you had originally discussed statin, you said we're going to look across measures and find value sets that keen to have the same names, but they aren't exactly the same, right?

And that's hard and Jaccard scores can help you to begin that, assess that, but you got to pull these kinds of expected high Jaccard scores out from those which are telling you something that's useful.

And how this sheet does that, I think, has to be worked on a little bit so that when you hand the sheet to folks, they have enough information on the worksheet to kind of do some work. Again, coming back to this issue about the last (inaudible), I still – I don't know if that helps. But anyway, now we have some background.

Jason Goldwater: So let me ask a question then, which is, how could we construct this worksheet to get at what you're looking for?

Robert McClure: Well, one thing that comes immediately to mind is putting the – unfortunately, this is not straightforward, by putting the, you know, the value – on VSAC, it's called the purpose, in the sheet, would help.

I'm not sure that people who aren't as involved as some of us had been will be able to read that and immediately know that, oh, yes, these things, you know,

they have a – you know, they are correct, they have unique needs and there should be overlap. And so I'll just ignore the high Jaccard scores. But without that, they'll never know that so I would definitely add the purpose now. It's four fields. And so it's kind of clutter your (sheet) a little bit, but there you go.

Nancy Walker: Rob, when you say purpose is for four different fields, there's more – there's a really valuable or extensive description for purpose, is that what you're saying?

Robert McClure: Yes. And so if you have authoring privileges and if in fact, you can see that it needs to be …

(Crosstalk)

Nancy Walker: Item.

Robert McClure: … to others.

But the general idea of a purpose or scope of intended set of ideas instead of value set has been broken into four sections in order to make it easier for people to really kind of think about the things that they should put into this idea of a purpose, and for our clinical focus which is just kind of a general statement as to the sort of concepts that belong in there.

Inclusion criteria, exclusion criteria, so those are two kind of specific things like yours. What did you really want to make sure you hit in and what are the things you're going to pull back out?

And then the last one is data element scope which is intended to describe the sort of model element that the value set is intended to be attached to.

Marjorie Rallins: And this is Marjorie. I think that last one is really important that the point that I was getting at earlier. You got to understand the data element and the scope of that in order to …

Robert McClure: Right. But that means, Marjorie, that it's been filled out correctly.

Marjorie Rallin: Right, right, I mean, yes.

Robert McClure: And I'm looking and there's variability just even among those three value sets we just talked about …

(Crosstalk)

Marjorie Rallin: Yes, and that's what – that's what makes me the most nervous as a, you know, someone from a hospital and next to the clinical users. Because the clinical focus is the key for, you know, the care that the patient is given so – and that means what the patient needs from an evidence-based provision of care, and that means what the physician is going to decide to do on behalf of the patient.

So, if we are saying this is the "quality of care" that we need to follow, then we need to be really clear not just about the scope, but also the clinical focus. What does the clinical person need to do to follow this evidence correctly?

Robert McClure: Right. And it just – so, there's nuances here but, for example, on that one that I was kind of throwing stones at, the statin allergen value set, which as its clinical focus says identifies patients with an allergy to statin medication. This value set does not do that.

The measure use of the value set might. And so in fact, what's in the clinical focus field for this really is more a description of the data element scope. It's how this value set should be used.

The clinical focus of the value set is, you know, ingredient-level concepts where there is a HMG-CoA reductase by a concept as one of the ingredients in that product. So that's the – and that's why clinical focus is actually a, you know, perhaps not the best phrase to describe the idea but it's really the scope. It's the scope of concepts that belong inside there.

And then as you've noted, I think it is really important though to figure out how is this set of values intended to be used? And that gives a better sense of, oh, yes, there's – then makes sense that there's overlap with that other one that has a slightly different intention of its use.

Jason Goldwater: So, I guess I'm just trying to conceptualize the – because we'll start retooling this later. But, are you looking for then the purpose to be on the top, you know, when we describe the value set. Then in addition to having this steward and the intent, then we will also be lifting the purpose broken out by those four categories?

Robert McClure: Well, what I would suggest is that not the row level information for the sort of thing that we're talking about would be value sets. And you're doing – you know, Jaccard again is doing set comparisons and so they're comparing, you know, value sets to other value sets, I would presume. I mean, I know that you can do this, obviously, when you're taking that concept, you know, sort of like, you know, there's a statin sodium, and they're comparing it across all of these other value sets and you're finding how often is it showing up, right?

But, the sort of thing that we were just talking about would be a value set level comparison. And, you know, I'm not exactly sure how to set this up, but one thing I would do is, I would put the purpose in. And I'd suggest you could just probably not have to break that out into four columns. You might just jam it all into one, I don't know.

But – and then do comparisons at a value set level to value set level and see the overall – all the concepts aligned across those different value sets. That's the one thing that I'd be trying to get at.

Ellen Harper: This is …

Nancy Walker: This is Nancy …

Ellen Harper: … Harper.

Nancy Walker: Oh, go ahead, Ellen.

Ellen Harper: I wasn't with you at face to face so I've read the transcript so I hope the questions that I'm proposing here haven't been discussed in detail previously. But, honestly, I'm getting very confused with the use of the word value set.

I think that you're – when it's used, it's not always at the same level because you have a data harmonization attempt to order statins at discharge and then you have another parent value set, but really what you're trying to do is look at the overlap at the most discrete level, which is the med or the multi-ingredient med or even the dose, 40 milligram oral tablet.

So, is the column heading sub-value set, could it be renamed to be discrete value that's used in a parent value set of statin allergy which is – see, I'm not sure if it's parent, because you'll have crossover between other statins used across other AMI, VTE stroke?

Male: Yes, I think that's – I think again the – we should rename – sub-value set should be value set member and parent value set should just be value set.

Jason Goldwater: Right, that's what I have written down.

Male: Yes.

Ellen Harper: OK. OK.

Male: Yes.

Ellen Harper: And then, when you're evaluating the crossover, you're going to do it at the most discrete level. So, in the example, and I know it was just to have conversation around, isn't the Jaccard score would be the same regardless of which value set it resided in?

Because the overlap is measured by the Jaccard score. So, you have at the statin listed twice with the score of 80 and another one at 97, even though they're used differently in each value set. Wouldn't that …

Male: I think also these aren't real scores, I think Jason was just trying to give an idea of what it would look like.

Ellen Harper: Yes, I'm trying to get this so that it's meaningful for people to understand and not ask the question.

Male: Right, right. And I think we decided too that, that really we wouldn't – it wouldn't look like this with the value set members in the …

Jason Goldwater: Right.

Male: … and that it should be a comparison of value set to value set with the Jaccard score.

Jason Goldwater: So probably when it would start looking like – just to speculate on the problem I had, is that we still have the column with the Jaccard score, but then we would have the OID, the value set, and then the OID and the value set that it eventually overlaps against. And then, the description of those two value sets would include the steward, the intent and the purpose.

And I'll – you know, we'll have to talk, Rob, to how we're going to break out the purpose, so that it reflects each one of those elements. And I'm not sure jamming that all up to one column …

Robert McClure: Yes, I agree, it might be difficult. But unfortunately, (you got four because).

Jason Goldwater: I understand. And I also don't want to shrink that the, you know, 8.1 …

Robert McClure: Yes, I know, I hear you.

Ellen Harper: Thank you.

Jason Goldwater: Yes, you're welcome.

So I understand that and I appreciate what you all are saying and I do think that that would probably lead to much more (cogent) analysis.

What I'm still stuck on is – again, going back to the discussion which was the idea was once we find value sets that are essentially overlapping based on the Jaccard score that you would go into since our RxNorm is the standard that's been promulgated by CMS as the one for medication that you don't use the RxNav database and find an appropriate class to represent that value set.

Is that still what you all want to do, or are we …

Robert McClure: Oh, because you're – I finally – a light bulb just went off.

Good. So that's the – because the idea is, and you were trying to say, "Oh, OK, having now found – this is really a totally – in my opinion, a totally separate activity. But now, having decided there's a value set that's needed, is there a, you know, what traditionally would be called an intentional, we call definition an intentional query that would generate the set of members for that value set, i.e., can we say that there's a class concept, assuming classes are linked to all the different parts they're supposed to be.

That if we said this concept and all of it's, you know, it's subclass elements, all of its descendants, we would get the value set, instead of having to pick each individual item one on one on one, right? That's why …

Jason Goldwater: That's right.

Robert McClure: you've got that in there.

Jason Goldwater: Correct.

Robert McClure: Holy cow, OK. That's a – I see that as a totally separate activity that I would do the harmonization thing first.

I understand that there's nuances of overlap there because you might say, "Well, this thing should actually do the same", and you look at the class and, you know, "Well, maybe they're meant to be different."

But, I really would separate them because you've got enough hard things to do and I would do that second activity.

Once you've looked at your value sets and you say, you know, here's five value sets, they really need to exist, they may or may not overlap, but they are obviously needed, you know, for the measures as we've described, defined them. We can't kind of toss one because, you know, because just similar, it actually needs to be different.

Now, I have this five, OK, now can I, in some way, use that class – a drug class structure to generate the members of this list. Then I would say, having then done that and that's a separate task and it – you know, it'll have a whole series of kind of associated parts to it. And I absolutely agree, you could then come back to that original question and say, "Now, that I've done that, do I have additional information that I want to apply to this original value set, the value set comparison." That might bring, you know, new information (or like that).

I know that, in fact, when this – there is work that was being done, I'm sure you're aware of that wasn't – that was done by the NLM by (Olivier). And there was that attempt, that was an important part of their analysis, they tried to kind of backward chain up to create a "intentional" definition.

And they did that not to necessarily do Jaccard comparisons, they did that primarily as a way of trying to identify whether the value sets were complete or not. They were trying to assess, "Oh, well, you know, all of these concepts in this value set are a descendant of concept A except for this three."

So, that seems odd, why didn't you include those three, and so that may indicate a gap. And so – or another – and then they flip it too, they said, "So here's the value set that has 50 members, 45 of those members are a descendant of concept A", and then you got this four that are over here maybe those are mistake.

So that's what they were doing at and that's what (Olivier's) PhD students were doing. It's an interesting question, those of you who understand these code systems realize that some of them lend themselves to this kind of analysis better than others.

I think it's a good second activity. I think the first one, I'm doing this analysis across value sets to see if the similarities is the higher payoff.

(Crosstalk)

Jason Goldwater: OK.

Zahid Butt: So, yes, so this is Zahid. So I think I agree that, you know, this two-step approach where you first try, you harmonize existing extensional value sets and see how much of an overlap is, again, keeping the context of the use of the value set in mind.

And then the second step is to see if you could create an intentional. One, if there is agreement that there is too much overlap. And potentially the Jaccard could be run with the value sets – set that's a part of that intentional set that you could see if there is a very high Jaccard between that and the extensional ones, then that would imply that potentially they could be reconciled in that fashion.

The other thing to keep in mind also, again, context of use, especially I think some people have mentioned the clinical usage. And in these three examples, they were talking about, obviously, the statin whether it's at the ordering level or the administration level or prescription level, certainly, has that granularity.

The question that's clinically relevant would be that allergies are generally captured in a sort of, you know, centralized fashion, hopefully, through the meaningful use mandates. The question might be, is there a preferred or a standardized terminology that would be binding in that context that could flow through into this value sets because I think that's where we need to tie this sort of the allergy capture is not a separate function, that has to take place within the measures themselves.

Nancy Walker: Interesting you mentioned that, this is Nancy. I actually was thinking before, right, that was this group at all, was thinking that that's what we were really looking to do in terms of harmonization was, looking to the multiple code sets for this different – and then allergy is a good example.

And what would be the more appropriate terminology classification system, whatever, in the clinical realm in the, you know, in use today with the clinician to describe it because that's what they're going to use.

Male: Maybe Howard can weigh in on that question. Howard, do you have any thoughts on that?

Howard Bregman: Oh, no, I have nothing in particular to say in response.

Male: Anyone else on the EHR side if they have any ideas along those lines?

Marjorie Rallins: So I don't – I'm not from the EHR side, right? I'm a measure developer. But, I would say that as I mentioned before that the value sets have been developed, you know, in accordance with a certain set of – or guidelines that guys at the development have the value sets.

And the basis awhile ago, and I think it's in the notes was that, the value sets primarily should be comprised of vocabularies that have some kind of structure to capture clinical information in detail and have some kind of ontology structure to promote interoperability, et cetera.

That said, it doesn't mean that we can't continue or refine, you know, the certain set of criteria for the vocabularies and make up the value set.

Zahid Butt: Right, that was just Marjorie pointing out the sort of specific instance here where the used case overlaps the clinical capture, and if there is a potential harmonization, if there is general agreement on what the level of granularity should be for allergy capture on the EHR side, then potentially that could be the one that could be harmonized with the ones that are used for allergy within the eCQMs to keep it consistent.

Marjorie Rallins: Oh, I see, thank you.

James Tcheng: So this is Jimmy Tcheng, I'm representing, I think, the clinicians perspective here, and I just want to raise two points. One is to reemphasize that we don't think of the statin allergy in isolation, we actually manage patients from the standpoint of their medications, allergies, list to require documentation specific to statin intolerance for allergies as a separate data element is not really congress with the clinical workflows.

So, I would just ask us all to keep in mind that, ultimately, it's the clinicians who were doing this documentation.

The second point I'll raise is that statin allergy actually is not an allergy, it's an – it's a sensitivity. And without trying to be too sensitive to the terminologies as I've been listening to this discussion, the question has been percolating in my mind, why do we use of the word allergy to begin with because statin allergies are exceedingly rare, but statin sensitivities are exceedingly common. And that's actually what this is trying to capture is the concept to sensitivity or intolerance to the statin, not the allergy.

Male: That's a good question, and …

Robert McClure: So this is Robert McClure.

I mean, this whole area is – well, first off, you're exactly right. And the – as much as I would like to see this group have an impact on that, there's good work that's happening in HL7 to try and begin to change the direction of this gigantic aircraft carrier of health care, and how it thinks about intolerance and allergies and sensitivities and that sort of stuff. It was, unfortunately, kind of simplified early in the process of creating electronic health records, and that simplification is causing a straight pain.

Male: Yes.

Robert McClure: And so, I just want to acknowledge what you just said and note that it's really important, but I don't know that this project can solve that problem.

And, I mean, so, what it's trying to do is fit into the constructs that we currently have to absolutely pay attention to the clinician workflow and data capture in the context of empowering sensitivity, allergy, data capture. And that's one of the reasons why you see a value set that's specific – specifically, and I'll put air quotes around this, design to support that.

Originally, when these things were put together, people thought, oh, you just, you know, whatever drugs you order, that's what you're going to identify as the allergy and we found out to be problematic.

Michael Lieberman: Right.

Yes, I think that whole issue of allergen, I think that is going to be on the scope of this. I think what we're trying to get at here is that this has been documented in some way as a discrete piece of information within the EMR whether it's – you know, each EMR system, I have slightly different way of doing that. But the idea is that for, you know, especially for kind of quality measurement, that we do know that a patient – there's a good reason for the patient not to be on this medication.

I think we probably need to move on …

Male: Yes.

Michael Lieberman: … to the other part.

But I wanted to just – before we do, you're using my co-chair status to get the last word in here.

What we really want to do is say, I think it does get into this NDF ATC issue because what we're really looking for, you know, under statin is, you know, we want all the medications that have an ingredient that is a – that is a HMG-CoA reductase inhibitor.

And really – so it's pretty simple to state in a – even in, you know, in somewhat of a logic statement and then what you would hope is that you can have various instantiations of what that looks like depending on which codes that you want to model it in, which EMR system you want to use, but really it's kind of – it evolves from that, you know, very clear and precise definition.

Michael Lieberman: OK.

Well, I do thank all of you for this discussion. It certainly provided a lot of valuable inputs.

So, I think what we're going to do is probably take the next couple of days, reengineer the worksheet. We'll probably reach out to Mike and Zahid to get their initial feedback and then we'll see if we need to send it to you all as a part of a larger group.

And then we'll talk to the TEP, again, because we're going to be changing this a little bit and that there'll be two parts to this, instead of essentially the one part which is what we have.

But, overall, I think if it's going to lead to a better result and get sort of the end of what we were looking for in terms of this project that, you know, I think this certainly has a lot of value recognizing, of course, that as well as others that thought that this is a challenging project because just the nuances that have already been discussed now and I'm sure we're going to find a lot more, particularly when we get into encounters.

And I'm very thankful we're not doing diagnosis at the moment, no offense, (Steve).

So, next slide, Katie.

So, I do want to spend, I guess, the next 15 minutes talking about governance and policy.

And so, really, this is sort of a major component of this project. It is, as I've said before, very crucial to ONC, NLM, CMS and others, and HHS.

And, it really goes to this sort of fundamental question of when we get to a point where we are harmonizing or we've discovered a harmonization process that works and is effective, how are we going to sort of govern this process, and/or to ensure that we are maintaining a high value of harmonized value sets that we are able to update the value sets on a somewhat regular basis and probably, more importantly, that we are – I don't want to say forcing, but that we are strongly encouraging measure developers to use these harmonized value sets so that we do not end up back in the problem that we are very diligently trying to work our way out of.

So, sort of this has a long – a different level to it, and I'm not going to pretend that we're going to solve or answer all of these questions today. I don't expect that we're going to.

But what I do want to do is to get through some of the issues and have some discussion in determining now what the follow-on points are to continue to have these discussions throughout the next few calls in addition to updating you on progress of the TEP. And then when we meet again in the fall, to sort of try to finalize a draft governance process for ONC to consider and to give, you know, their thoughts on and then work through that. I could see how NQF can incorporate that into its endorsement process.

So, sort of the first element of this is really establishing a criteria. And this has always been, and I know there's a lot of us that have been at measure development for a long, long time. And we're always searching for what is the criteria for a high quality value set and what constitutes a high quality value set.

So, I think when we get to the point of harmonization and we have started to renew some of these overlap and (variant), that we are going to be doing this under the offices of that we're going to create these high quality value sets that will be used and repeatable and (measurable) as needed.

So, we have to then sort of set forth a criteria about how we're defining that, and what do we constitute as a high quality value set, what body is going to define and choose what those value sets are. Is the quality defined as a yes or no proposition, or are we going to have some sort of graded scale that determine the level of quality? How will the NQF measurement endorsement process account for the use of quality value sets?

Our process now, if you're not aware of it, is when an eMeasure is submitted and we receive that information, we check to ensure that the value sets that are part of the measure are listed in the VSAC, that they are recognized in the database.

And if they are and we can see them, then they're passed on. If they are not in the VSAC, then we have to go back to the developer and ask why they were not. And because there's the possibility that they submitted a value set to an O.M. and it's in draft status and this is waiting to be published that have found in a couple of times, or they just created a value set and it's not in VSAC, it's

either draft or final, and then we have to look and see is there a similar value set in the VSAC that could be substituted for that.

So, that's all we do at the moment. And I would be the first to tell you that that is probably not a comprehensive process, but based on what we have now, that is what we can do.

So, if we're going to change this where we're going to look at high quality value sets and that's going to be part of endorsement, then how do we account for that? And more importantly, and as we start to move into where eMeasures are really becoming far more prevalent and certainly there's the hope that they're going to be dominant after a while, you know, again, from our experience in reviewing and approving eMeasures, of course, NQF does not endorse them. We – it's an external process. But there are always exceptions to the policy guidelines that we make for a variety of reasons because there – we can't account for every feasible scenario.

And so, as those scenarios come up, we have to then sort of look at that and see where our policy is. If we can stick to our policy and say, "This is sort of the threshold and we need to adhere to this for the measure to be considered," great. But there are times where we had to look at them and say, "Well, we're going to have to make a few exceptions because these situations have presented themselves, and so our criteria is not fitting, or it's not appropriate for this so we have to then rethink this."

And I have no doubt that as we move towards this new era of creating high quality value sets that are harmonized and that we then are, again, strongly encouraging measure developers to use these, that they're going to be scenarios that we have not considered.

So, where I want to start with this discussion today is, and if – this may be the only slide we get to today, and that's OK, is how would you all constitute and define what a high quality values that would be?

I can't believe that none of you have any opinion, but.

Nancy Walker: Oh, this is Nancy.

And that – pardon my description, but one way to describe it and this is certainly not all encompassing, but that a high quality value set perfectly describes the intent of the specific data element that its associated with or that it defines or whatever.

Jason Goldwater: OK. Anybody else?

Howard Bregman: And this is Howard Bregman. I would say that the value set comes with a meaning, and a perfect value set has data elements that match the meaning and have no false negatives and no false positives, which is essentially the errors that are – we have to deal with the bad value set.

Howard Bregman: Right. Right. Right. Anybody else?

Marjorie Rallins: So, this is Marjorie, and I would agree with those two descriptions. I think what we might end up with is maybe a value set – maybe this is future thinking, but value sets may look different than they do today based on those very specific goals. Meaning, maybe an intentional value set allows you to get to that sort of unambiguous description in use as opposed to extensional value set which we use now.

Jason Goldwater: OK.

Robert McClure: So this is Rob. And I also agree with those things. But, I – we need to also figure out some actionable things and as important as the criteria that we just heard are, and having kind of been in the swamp for a while.

I'm not sure how actionable if I was handed that task to figure out whether one value set was better than another, I could tell would be based on the figuring out the specific kinds of things that are actionable, things like the code systems, code system and systems that are use to describe the, you know, to populate the value set and how those align with code systems that are in use today inside of EHRs.

And I would add as a corollary to that or can be mapped.

So, you know, and things like that, I would even extend this to expectations with regards to stewardship. So, the value set has regular, I'll say, attention, you know, regular analysis with regards to its defined scope or purpose. And those code systems to determine whether there are concepts inside those code systems that fall within the scope on a regular basis.

So it's one thing to say that there is a value set that seems to – and the word that I use is fit for purpose so that the value set is, in fact, fit for purpose of, you know, conception. But then code system is changed and the clinical knowledge is changed and nobody looks at it again, it's not a good value set because the process of stewardship is not being followed.

So it's – some of those kinds of things because those actually are measurable objective things that you can begin to assign, you know, whether you want to make them binary response or not, that's a hard question.

Joseph Schneider: Yes, hey, this is Joe Schneider and I'm going to have to get off quickly, but a couple of quick thoughts.

First, that this reminds me of the ABCD evidence type thing that we use clinically. You could probably set up some criteria then and use something similar to that.

The second concept, just want to reiterate, as I understand it was talking there, that these things will – unlike – well, maybe with the guidance – guidelines, these things will change overtime. So, A today might be a C in five years. And then the one other concept and then they try to bring in from other organizations, American Academy – I'm sorry American Institute of Certified Public Accounts, so in a formal life.

There are certain sanctions standards, things that the governing body says, "These are valid sets", and I would probably not look for the NQF not look for the world's biggest insurance company, AKA, CMS. But probably, the National Library of Medicine or something like that. Those are my quick thoughts. I appreciate everybody's efforts. Going to get off. Thanks.

Jason Goldwater: All right, Joe, thanks so much.

Robert McClure: Actually that – this is Rob, that reminds me a couple of things I wanted to say.

So, one is the – I would hope that NQF has many years of experience in the process of its quality measure analysis that it also analyzes the sets of codes that are used to define patient populations. So whatever, you know, I would hope that you have a process already in place, and I would have expected you to bring that process to us for a discussion because it should – you know, we should build upon that, just for the same reason that measure developers, they have a process by which they sit down and say – because that's what value sets do by and large, I mean, you know, where you kind of the edges are a little soft but they are used to define patient populations.

And, so, in the – particular in the context of the quality measure analysis, that's a good value set, that's true.

So, that's that core of what we're asking or asking when we look at a value set and determine whether it's good. This gets to what Howard was saying. You are correctly identifying patient populations based on that value set. And, you know, I think NQF should have some ideas about how they assess that in the context of their accreditation of quality measures, and I would bring that to bear here.

The other thing I was going to say is that we – the process of testing, which is somewhere to that point I was just making about the accreditation process. I don't – you know, I don't know how much we can really hold to that ideal.

But, in it's – without a question, Kevin knows this very, very much, that it's a desire that we can reach in terms of, you know, creating value sets and creating measures to be able to say, "OK, there's a set of concepts that we need in order to define a patient population." And we analyze them, you know, as a human, let me go and look in code systems. But, you know, and Howard definitely knows this. But, no EHR collects them.

So, some kind of way of beginning to test us and then that's where I would join this test data bid that we've talked about would be a really important, if

not, today criteria. Here's where one of the places that we would want to put that in stone so that it can be a future criteria.

I guess I've one last thing, and that is there's different kinds of value sets. And again, Howard and others on this call, I think, are familiar with this. And that aligns with what I was just talking about.

Some value sets – and the medication value sets are a good example, need to be inclusive, they have to be broad, have a lot of concepts in them because the patient population that you're looking for literally could have any of those concepts. Those concepts exist in systems or something that could be directly mapped to them to have – and so there's data in patient records that line up and you need to make sure that you have all the different representations of that data in your value set in order to make sure you get the good sensitivity for your value set you're collecting all of your patients.

There are other value sets that are describing the intended expectations, but may not actually represent data already collecting. And this is a nuance difference, but again, here, we're talking about how do we define good value sets, so a place to talk about it.

And in those cases, you know, kind of on one end of that scale, literally, that value set could have one concept in it because we're telling people this is what we want you to capture and you really probably don't capture it right now.

Or if you do, it's going to be some mapping anyway. So why give you 15 different things you could map to, unless we're going to (tease) those things apart some other place. If we really have one thing that we want to really capture.

And so, there is a very interesting subtle question of the complexity of value sets and whether they should, in fact, be small, discrete, specific (things), or whether they should be big broad complex things. Do you see what I'm saying?

Jason Goldwater: Yes, I do.

James Tcheng: So, Rob, this is Jimmy Tcheng. I just wanted to echo in, perhaps, in a little bit of a repetitious way, reinforce some of the content that it's just been forwarded.

But, as I was looking at that question, and that is, what is a high quality value set, I was thinking actually initially in terms of technical qualifiers or technical specifications, and then it really struck me that the applicability qualifiers are probably just as relevant in defining what a high quality value set is. And that is – and again, this is echoing others' comments, but that value sets are built to and they're fit for purpose.

So, at least in my mind, I kind of just restate that the high quality value set would be one that's built in service of the high quality or high value quality measure that we will not be doing anybody a service if we are just building value sets rather than recognizing the intent – intended use of those value sets in service of the, what I would call, a high value quality measure.

I would also state that the value set components of the members of value sets, really do need to be defined in clinical terms with clinical stewardship. There is a bit of a disconnect between the ontologic approach and the clinical realities of defining what's going on in clinical practice.

And the component that then that brings forward is, is that whatever is created as a value set really needs to be able to be captured in clinical care processes. It has to be reasonable and practicable. It can't just be something that sits out there in isolation almost, if you will, in a clinical trials model, but we – I believe need to be thinking about the used case, the clinical used case context as we're defining high quality value sets.

Jason Goldwater: That's great. Thank you both.

Male: Yes.

Jason Goldwater: Go ahead.

Stan Huff: This is Stan Huff. I apologize for being late, but.

Male: Sure.

Stan Huff: Yes, I would just second some of those ideas. I mean, we're – in terms of quality, it really is completely about fit for purpose. In other words, we're not – we're not defining some universal truth. What we're doing is defining collections of things that cause software to behave in the ways that we want it to.

And so, yes, you want, you know, the definitions that came out very first are great, but what we need to do is have some way to test whether this thing is, in fact, causes a software to behave the way that we want the software to behave. And the ties to the clinical data are essential to make it workable. And then in terms of process, it's essential to have a way to retest and maintain and as Rob said, give attention, make sure that it receives attention so that it stays fit for purpose overtime, and as medicine and as our own purposes evolve.

Jason Goldwater: So, given all these, you know, different – I don't want to say different, but this large number of interpretations and definitions and concepts over what constitutes the quality value set. Let me get to sort of the third bullet then, which is, how are we defining that. Is it yes, it's a high quality value set, or no, it – that's used to be just given what you all stated, that'd be far too atomic of the – of any value. No pun intended.

But – or do we use a sort of graded scale to determine the degree of quality. Or do none of those work, either this work.

Nancy Walker: This is Nancy. Somebody already addressed utilizing something similar to the way medical evidence is graded in ABCD and then has a subset even to A, B, C and D. That intuitive – although I don't really have a good example other than that, intuitively, I just can't imagine that we can say this is a high quality value set with just a yes or a no. I'm having a hard time.

Jason Goldwater: I agree.

Nancy Walker: You know, coming to that.

Jason Goldwater: Right.

Michael Lieberman: Yes, and it's not even – I'm not sure high quality is quite the right word. I mean, you can have value sets that meet all of the purposes that we've talked about that you wouldn't necessarily want somebody to use as their first choice. And you wouldn't want somebody necessarily creating an additional high quality value set for another, you know, yet another statin value set that isn't significantly different than the one we already have.

Even if it could be – even if it's very fit for purpose and that sort of thing, it's – I think what you were getting at is you want people to use a standard value set, kind of a preferred value set, vetted value set, something of that nature, when possible and then you need to – I think it's done in a, you know, further bullet, it's an exemption process around it. But, basically, you don't want people creating new value sets when there's already one out there that you feel will meet their purpose.

Zahid Butt: I think – this is Zahid. I think also since it appears that there will be multiple components of whatever we called this that would go into the calculation, so some sort of scoring which is implicit in your relation methodology potentially would be, you know, a useful way to look at it.

And then, of course, at some point, you'd have to – whatever scoring methodology you use, you'd have to have some sort of a cut off below which is unacceptable and above which, potentially, is acceptable which is not dissimilar to a lot of the grading that occurs in the NQF endorsement process beyond the scientific applicability of measures. I think there is, you know, that specific relation methodology that's incorporated.

And you have to have a X number of criteria that if our – if they're met, then it goes forward. If they're not met, then what needs to be done, more work needs to be done on it.

Jason Goldwater: Right.

So what – you know, what sort of – and I know Zahid and Mike briefly talked about this last week, but what sort of organizational body that sort of oversees this, I mean, defines and chooses high quality value set, is that still within

NLM do you think, or does that need to be us, does that need to be CMS, does it need to be a wholly independent body?

You know, there's somebody that's going to have to govern this in terms of, you know, what is the high – or what's the quality value set, the level of quality that meet the criteria or standards that we would hopefully establish, and these are the kinds of sets that we would look to ask you to choose from in the development of the measure. So, what body sort of oversees that, do you think?. What would be the most appropriate one?

Zahid Butt: So again, this is Zahid. I think there are two separate sort of scenarios in which that governance works.

One, obviously, is through the endorsement process which is within the NQF's control. So, I think that endorsement related, whatever criteria, hopefully the same criteria that are used for developing these would be the ones that would be used as part of the endorsement process.

I'm really not sure what happens at the NLM level. That's a much tougher question and certainly, we've already heard some comments as to who it should not be.

Jason Goldwater: Right.

Zahid Butt: And so, I think that is the trickiest one as to, you know …

Zahid Butt: So this Rob. I mean, I can speak a little bit to that. I'm not going to speak officially for the NLM here. But, the NLM is not in the business of endorsing anything. And so if it was to take on an endorsement role in the context of value sets, that would be a strange departure, I'll say, from its current presumed focus. It's providing a service with regards sort of VSAC and in the context of that service that's, you know, providing tool, anything like that.

So it's providing – it definitely sees its role as one where it would provide the infrastructure to support an analysis that could result in grading, but it wouldn't do the grading, and then – and I believe it likely wouldn't even take on the role of the sort thing that we're talking about in NQF doing. So I would

agree that's where NQF had some experience in this kind of activity and, you know, using criteria that we're being asked to think about would then be able to – in some way, good for a process. It could be something like endorsement.

I also want to say though that, and this was mentioned before, and I'd very strongly believe this is an important thing to consider and that is to bring in the professional societies.

You know, there's – those professional societies along way of other knowledgeable folks, you know, right now, clinical professional societies are not stuck with lots of people understanding EHRs yet. And so they're going to need some help.

And not all value sets, I think, perfectly fit with the idea of bringing in active professional clinicians in terms of deciding what belongs and what doesn't belong. But many do. And so there's, you know, a role for an organization that is a convener that make sure that those sorts of entities are involved in the process using, perhaps, tools like those that could be produced by NLM, particularly once NLM – the VSAC collaboration sites up and running. That's the way I see this potentially operating.

Nancy Walker: This is Nancy again. I do agree with Rob about the importance of a clinical voice and that there – you're right even in the – even when you get down to the specifics of individual hospitals, do you think that they are not evaluating their own care and providing suggestions for care maps, or quality maps, or whatever you want to call them. But, you know, support for the evidence-based – I'm sorry, support in the EHR tools for evidence-based care of the patient.

And so, that reality or that day-to-day reality is an important part of making sure that this is going to be useful and valuable to move the health – the whole health care business forward.

Jason Goldwater: OK.

If we get to the point, and I know we're going to. We know we hopefully have a harmonized set of value sets that are used in the development of

eMeasures coming forward, and as they cut to NQF for review, you know, we will, you know, establish a criteria for a high quality value set, but it certainly goes back to this point Mike made earlier, which is there may be a value that is graded as being a good quality or high quality and certainly, it's something that on base value would be encouraged in the use of a quality measure.

But, Mike – as Mike pointed out, even if it's high quality, you may not want to use it, or there may be people encouraging they're not to use it because it's not representing the intent of the measure in the way that it should be.

So, you know, that's one of the exceptions that's going to come up, which is we're going to have this, you know, hopefully a criteria of this is what constitutes a high quality value set, and then this is how we come up with this decision, this is how we're grading them. This is part of the endorsement process, is that you have to have high quality value sets because it's the best representation of the values that go into this measure and it provides, perhaps, hopefully the best indicator of quality and this would be implemented and actually being used, but then there are going to be exceptions.

So, how do we – how do you think we handle those exceptions? What – how …

Zahid Butt: So, Jason, this is …

Jason Goldwater: Go ahead.

Zahid Butt: Yes. This is Zahid. I think that we should do whatever is necessary to reduce the need for exceptions as much as possible because I think as was mentioned, the intent of the measure was mentioned first by more than one person.

So, if the criteria provide sufficient weights to that very important criteria, that's the best way to reduce the need for exceptions. But …

Jason Goldwater: OK.

Zahid Butt: … you know, I agree that there may be those rare cases when that happens. But I think as long as the criteria are developed in a way with the proper

weighting of the components, that one aspect is, you know, is weighted appropriately enough that it reduces the need for exceptions.

Jason Goldwater: OK. Anyone else?

Nancy Walker: Yes, I agree with that. It's the fit for purpose again. That was well put, but I think there really will be – there will be exceptions. There's always exceptions because something – something that's odd. So, I think we do have to have some type of mechanism for exceptions and the end appeals because, you know, clarity is – in appeals practice, clarity might even provide that it is not really an exception. It's not – or it fits, so it is appropriate for those exception, sorry.

Michael Lieberman: Yes, I think ultimately, you're going to need – this is probably – in terms of an organization, it sounds – it seems like the NQF as a convener of, you know, multiple stakeholders is probably the best organization to do it. And whether you can incorporate it into the current – into your current measure process or not, I don't really know. I kind of doubt it. I think you're going to probably need a separate committee to kind of anoint certain value set as the preferred ones, and again, I think maybe a various levels there. And probably that same committee would then need to be the one to take on appeals when people don't want to use those particular value sets.

And I think you all would – we'll have to figure out how it fits into the whole system because, you know, measure developer also have the choices to whether or not they will accept that or not. If they – you know, if they choose not to use a preferred value set, they can still develop a measure. It's just the question of whether it will be endorsed or what level it will be endorsed and who will use it, if that's the case.

Jason Goldwater: Yes.

Nancy Walker: This is Nancy again. I have a question about the National Library of Medicine. There – don't users or stewards right now review with the National Library of Medicine, or don't they have a mechanism to deal with value sets that are out there right now?

Jason Goldwater: So again, this is Rob. So the NLM provides this tool that is a repository for value set content. And there's also a place where value sets can be created. But it doesn't provide any – it doesn't for the NLM specifically and VSAC specifically, it doesn't provide any oversight.

There is – you know, I'll say it. So we does not involve, working to try and provide tools within the context of creating the value sets that will make it more evident that, you know, there is another value set, for example, that's very similar to the one you're creating. You really want to create another one. That's not available yet, but it's on the drawing board.

There is a desire to, you know, well, they actually exist now, the ability to see codes within the context of the code systems. You can do a better job of identifying line codes and bring those in, so there's tool functionality. But, in terms of actual oversight and the actives of stewardship, that's a responsibility of the organization that's actually putting the value set in totally on their own.

Kevin Larsen: Yes, Rob. This is Kevin Larsen from ONC. Totally agree, and the kind of way we've been thinking about at the HHS, the National Library of Medicine or library, that's where you file books (stay) and they're terrific at building a Dewey Decimal system and an (indexing) for you to find all the right books. But they don't say when two books are 99 percent the same. They put a new Dewey Decimal number on the next book that comes in.

What we've been doing with these tools is trying to give people all – as much information so they don't inadvertently create value sets that look like some other value set because they can't see it, because they can't know, they couldn't find the value set that was fit for purpose. So we want to continue to build really good tools to make it easiest to use the best value set. And ideally, the best value sets are ones that have been well created and well curated.

But, what we're – what the National Library of Medicine doesn't do and I don't think ONC wants to do either is pick the winners.

Nancy Walker: And did – so then did we say that as part of the criteria for a high quality value set that they – that the steward does due diligence with the National Library of Medicine existing tools?

Male: Yes.

Nancy Walker: Make sure that they …

Robert McClure: Well, again, I think the expectations that there is some review of existing value sets …

Nancy Walker: OK.

Robert McClure: … is something that this process would put in place the fact that there is a tool that supports that is something NLM can put in place.

Nancy Walker: Yes. OK. Thank you.

Zahid Butt: Right. And the question is that, what – if there is going to be a body that governs that NLM piece of it which, by definition, will be a larger set than those that will go through the endorsement process, so it almost looks like they're, you know, two different avenues in which this governance could work and NLM one is the trickier one as to which body should – and how they should govern that.

Jason Goldwater: Right. Zahid, I'm not following you. What is it that you're assuming the NLM would do?

Zahid Butt: So, I just used NLM in the sense that, for example, you mentioned that the existing value sets would need to be harmonized, and I agree with that and they don't necessarily – some of them have already gone through some sort of semi-endorsement but this type of review was not done at the NQF endorsement level, perhaps, the new measures – not all measures get endorsed but, you know, hopefully the majority of the ones that come to national performance measurement programs would be endorsed.

But, my only question is that, what is the role of a – even if it's a third party, what is the authority that somebody has at the VSAC level to say that, you

know, if there is a dispute or if there is a, you know, steward who is not harmonizing their existing value set at a certain pace, or whatever, there are many different scenarios in which somebody would have to come in and say that, you know, you either need to do this or this goes away, or et cetera.

I mean, I'm just trying to think out loud here …

Robert McClure: Right, so …

Zahid Butt: … mechanism would be.

Robert McClure: Yes. And the way we – you've kind of thought about this, again, is NLM can provide tools for that activity, someone else will need to take on the responsibility of doing it.

Zahid Butt: Right.

Robert McClure: With that being said, one of the driving forces behind the idea of the VSAC collaboration, the VSAC collaboration tool is to create a tool that makes review and discussion and input into, I think some might say, the quality of value sets open and simple, that's what's striving the creation of that tool.

So, the VSAC collaboration, it's not out yet, still under development. When it comes out, it's still not going to be perfect.

But, you know, with that tool then, even if an organization like NQF wasn't – let me – before I – to where that's been happening so far is ONC and the various workgroups, you know, meetings that are happening where the discussions occur among the measure developers and implementers and stuff like that.

So, right now, it's not like these things are completely not reviewed. I mean, they're reviewed, obviously, by the measure developers but input comes from implementers and others who review the things and one of the activities that ONC take on is to, you know, look at concerns about value sets typically through (Gerry Bells) or elsewhere and look for the harmonization and then

attempt to do that. That's one of the activities that I do along with some of the other ONC folks.

But, the bottom line is, is that a lot of times and particularly all these things that are aren't involved with measures, we still want this to happen. And that's why the VSAC open collaboration tool, the hope is, is that, you know, our ever present current love with the air quotes, "social (curation)" might solve some of those problems.

So as long as there's a place where people can go in and see things and comment on them and get feedback, we might work towards, you know, harmonization through comment and select the views of good stuff.

Zahid Butt: So, that's still a voluntary-user community driven framework.

Robert McClure: Absolutely.

Zahid Butt: I think the question, if I understand Jason is posing is that should there be a voluntary framework within – which the tools are available and there's an active user community giving input and there's a self-correcting mechanism, or should there be an external body that should govern that process.

Robert McClure: Right, I for one – yes, (inaudible), yes.

Male: Yes.

Robert McClure: Because I'm saying that there's always going to be something that's falling outside, and that's why I'll push hard for VSAC collaboration to exist. And – but I strongly believe that there's a role certainly for the quality measures that are associated with government programs that we establish an oversight mechanism that can lead to the creation of best of breed value sets, that in particular, I'm very, very much actually in support of or concern about, and desires of specialty society participation. And I can't imagine a way that that happens effectively unless there is a convener.

Marjorie Rallins: This is Marjorie. I would agree with that.

In – Zahid, back to your question that you post when you summarized Jason's question, I don't know if those two things from the voluntary perspective and the non-voluntary or the governance perspective are necessarily mutually exclusive.

Male: Right.

Marjorie Rallins: You know, I think you might need both so you need the tools for evaluation, tools for curation which are pretty much voluntary, and then some type of body to convene. I don't know if it's necessarily to pick the winners as Kevin described, but, you know, there are some type of oversight there.

Zahid Butt: So Marjorie, thanks for clarifying, that sort of what I meant, really …

Marjorie Rallins: Yes.

Zahid Butt: … that in addition to the voluntary mechanism, should there be an additional governing body that could arbitrate disputes or that could facilitate certain aspects that – or gaps in the voluntary process.

Jason Goldwater: And Rob, are you advocating for somebody other than the NQF, or when you say a convener, is that in professional society participation, are you thinking through the NQF?

Robert McClure: Well, you know, I'm saying that the NQF in its role within this particular activity, certainly, could fulfill that responsibility, but I don't know how long and how far.

Marjorie Rallins: Yes. And this is Marjorie. I think that is true. I think what we need to consider now is – I mean, we weren't necessarily picking, were we, or weren't we looking at …

Male: No.

Marjorie Rallins: Yes, and I think that's exactly we want to go …

Male: Right

Marjorie Rallins: … at this point.

Michael Lieberman: Right.

Now, can I just have one more question, though, about the role of the VSAC and, you know, I'm so – for example, if we do define – I'll go back to our statin one. If we do give it the three intentional definition of, you know, all drugs with a, you know, and ingredient that is a statin, you know, defined via NDF-RT or whatever that – these codes are. Would – and then – would VSAC – could VSAC play the role of then, OK, given that definition, select all of the RxNorm codes that comply with that definition. So that – you know, so that you – because I think that's one concern is that if you have lots of people using it and you have one measure steward that's responsible for keeping it up, you want to – I mean, you want to make sure that the instantiation of it reflects what the definition is and perhaps that is something that could be done by the VSAC.

Robert McClure: Yes. So, I mean, it sound like a broken record. But the – absolutely, in ONC is it's role in standing up the VSAC to provide, you know, all the tools, all the sophisticated tools that they can master, that could support individuals doing work of creating value sets. But responsibility of the content of the value set will always lie in the steward's hands. And the reason for that – but I'm not saying that to be, you know, to kind of dock the issue, it is a fundamental fact of value sets. And the reason I say that is, is that value sets describe – the reason the value set exist is that it exist in order to describe a collection of concept representations drawn from a code system that have some common scope.

And as I mentioned before, that the expectation there is there's really two primary uses there. One of them is, I don't know if we're trying to be thinking about for quality measures is that they describe a variety of nuance differences that when taken in the context of the measure, are considered equivalent, right? That's what a value set does.

Another kind of value set that I see and we can just set aside is those that are used to create dropdown list and things like that.

Still has some fundamental similarities but, obviously, it does – there's a core difference there.

So, these value sets that we use in eMeasures, those things absolutely will, you know, the intention of that scope is described by a human. Here is what I want. And then we have to go to a value set, I'm sorry, go to a code system and find the codes that fit that intention, fit that scope, fit that purpose.

And you're right, it's absolutely important that the tool, like VSAC, provide some help in being able to do that, like things for medication as we say, "Let's go take a drug class, because I know that's kind of part of what I'm defining, let's just go." And let's find all the specific concepts that fall within that drug class and then – and the VSAC should support that. Right now, does it do it? Not well, but it will.

But, the idea that all of the concepts that belong inside that value set based on the idea that the human has kind of crafted, there's always the responsibility of the steward because code systems are funky. Anyone who's looked at SNOMED will know that picking root codes and assuming that all of the descendants of that root code will meet fit for purpose as a full variant. And the only way to do it right is to go in there and hand pick out the bad ones if you're going to start with, you know, one of this thing and all of its descendants. That's even true of more rigorously constructed things like RxNorm and stuff like that.

So, you know, I understand the desire to have that functionality and believe me, it's on the agenda. I am a strong believer that tooling is how you get people to adhere to good practices. Sending them to read a book and admonishing them when they screw up just doesn't work. Giving them a great tool is the right thing, is the solution and we're very much interested in doing that at NLM.

Jason Goldwater: OK. Guys, I have to break this conversation up, but we are just past our time. And we do need to open it up for a public comment if there are members who would like to comment now.

So Katie, let me turn it back to you and you can ask for public comment.

Katie Streeter: Hi, (Nan), at this time, can we please open up the line for public comment?

Operator: Thank you. At this time, if you have a comment, please pres star then the number one on your telephone keypad. We'll pause for just a moment.

And there are no public comments at this time.

Katie Streeter: Thank you.

Jason Goldwater: OK. Thank you very much. Thanks, Katie, and thank you to all of you. This has been a very encouraging and certainly very in-depth conversation. Really did enjoy it and certainly appreciate all of your feedback. I think we will take the time now to reengineer our worksheet. And we'll have an initial discussion with Mike and Zahid on our revisions and we will look to go to all of you if they feel that's necessary to do. And I appreciate this initial discussion on governance. It is a very long topic. There are a number of things we have to consider, so we will certainly pick up this discussion when we convene again.

Thank you all very, very much. Have a great beginning of the summer and we will talk to you all soon. Thank you.

Male: Thank you.

Female: Thank you.

Male: Thank you.

Operator: Ladies and gentlemen, this does conclude today's conference call. You may now disconnect.

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