NATIONAL QUALITY FORUM

Moderator: Taroon Amin
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3:00 p.m. ET

Operator: Good afternoon everybody and welcome to the second call for the GI/GU Steering Committee Azure Evaluation Process. This is stage two of the project.

Thank you for joining us this afternoon.

This is Suzanne Theberge with NQF. And I am – I know, that we already did a roll call for the committee members on the private line but we're just going to do another roll call now that we're in to the main conference.

So, if you could just let us know that you are here again, that would be great. Thank you.

Andy Baskins?

Andy Baskin: Here.

Suzanne Theberge: (Chris Segal)?

(Chris Segal): Here.

Suzanne Theberge: (Miliana Bordna)?

(Miliana Bordna): Here.

Suzanne Theberge: Zahid Butt?

Zahid Butt: Present.

Suzanne Theberge: (Robert Ellis)?

(Robert Ellis): Here.

Suzanne Theberge: (Nancy Sower)?

(Edward Gill)?

(Edward Gill): Here.

Suzanne Theberge: (Johannes Cope)?

Suzanne Theberge: (Jennifer Lightdale)?

(Jennifer Lightdale): Here.

Suzanne Theberge: (Rick Blackmire)?

(Rick Blackmire): Here.

Suzanne Theberge: (Elaine Marklin)?

(Elaine Marklin): Here.

Suzanne Theberge: (John Martin)?

(John Martin): Here.

Suzanne Theberge: (Anne Cameron)?

(Stuart Reynolds)?

(Stuart Reynolds): Here.

Suzanne Theberge: And Phil Schoenfeld?

Phil Schoenfeld: Here.

Suzanne Theberge: Great. Thank you everybody.

I know we have some developers on the line as well. PCPI are you here?

Male: Yes, we are.

Suzanne Theberge: Great. And Active Health?

Male: Yes, we're here.

Suzanne Theberge: OK, great.

This again is Suzanne and I'm here with (Riva), (Evan) and (Ashley). We are all back here on the call today.

And then I'm just going to do a couple of quick housekeeping items and then we're just going to dive right in to the measure evaluation process.

Just as a reminder, if you're not speaking, please put your phone on mute, but please don't put the call on hold since we'll get your hold music.

You should all be seeing a slide with the Project Staff on it. If you have trouble voting, once we get to those slides, try first refreshing your browser and then let us know if that doesn't work and we'll take your vote verbally.

So, with that said, I am just going to turn this over to Andy to dive right into the measure discussion and we'll be starting up again with measure 658.

Andy Baskin: So, this was the GI measure which had to do with followup from colonoscopy and normal colonoscopy for 10 years now. My reflection is we voted at least on the non-eMeasure, the regular measure for reliability and validity already.

Are we going to continue on with that one and then go back to the eMeasure or are we going to do these parallel? Do you have any idea how we should do this?

(Riva): Yes. Andy, this is (Riva). They really are presented and submitted together as two versions of the same measures.

So, it will probably be best if you talk about them together in parallel.

Andy Baskin: OK. Well – all righty. Well we have presented the reliability and validities for the non-eMeasure. And we were going to have a discussion, then I guess for those same domains for the eMeasure. And Zahid I think you were going to help us out with that?

Zahid Butt: Sure.

Andy Baskin: As our resident eMeasure expert.

Zahid Butt: Well, I'll try my best.

So, I'm going to maybe ask the chair, I guess Andy. Should I dive right into the discussion or should I spend just a few minutes to sort of, you know, give everyone like a three-minute one-on-one on sort of eMeasures so that at least I can provide a context in the subsequent discussion?

Andy Baskin: And probably – it'd probably be helpful. It'd probably be helpful because there's this stake spreadsheet of which I reviewed it, but not being an eMeasure person, I'm not exactly sure what I've reviewed. So there might be others like that.

Zahid Butt: OK, great.

So, I think at the sort of the most basic level, an eMeasure is a performance measure that leverages EHR data, preferably collected by caregivers in the EHR as part of their routine care workflow.

So in that sense, the source of the data becomes the primary source of the truth in that context. And the use of the data in quality measurement or performance measurement is essentially a second reuse in that sense. And there is no additional abstraction required. Since there could be something lost in translation when an abstraction is done by a third-party, it is felt that the eMeasure is probably has a better chance of representing the care that was delivered.

However, the eMeasure themselves have additional sort of challenges in terms of their own accuracy. And critical in all of that, as one might already imagine, is the preciseness of the specification, the code sets that are defined, leaving aside the issues regarding how accurately something gets captured at the point of care, but at least from a definitional standpoint, there is not a human being in the middle to interpret what is in the chart. So you're going directly from the EHR documentation in that sense into a measure of performance computation.

So, another simpler way of looking at it is that the eMeasure needs to be specified in a way that a programer, without any domain knowledge, can program it according to those standards. And the computer itself should be able to compute the results without any human intervention in between.

So given those sort of parameters within which the eMeasures operate, it is critical to have very precise definitions of the data elements that would constitute the various denominators, the various numerators, the exception/exclusions. And it is very critical as well to have very precise logic that would go along with it.

So, in general, there are two sorts of types of eMeasures. One is what is commonly referred to as De novo eMeasure which is really an eMeasure that gets created from the ground up if you will, that does not have an existing sort of more traditional, for the lack of a better word, specification that's based on either claims data or abstraction data.

And the other is the concept of so called "retooling" because, obviously, there is a large body of measures that have been endorsed by the NQF. I think the last count – close to 800 measures have been endorsed. And so, clearly, there was an effort to try to retool many of them into an eMeasure specification.

You know, that's sort of the simple version. When you get into the detail there is an entire infrastructure that has to be built and is being built – much of it has been built and the NQF folks are quite front and center in many aspects of building that infrastructure. That affects really multiple areas. But the key

area is to have a sort of standardized way of defining the eMeasures and so forth.

So, without sort of getting into the details of that, for our purpose today, the two measures that are being submitted for eMeasures endorsement are actually existing measures that are going through their regular maintenance review, 0658 and 0659, and are also being looked at for endorsement from the eMeasure specification.

And NTS has provided actually some official guidance on measure testing and evaluation for scientific acceptability of these measures.

And the evaluation criteria are slightly different for de novo versus retooled measures. So the retool measure criteria are sort of if you want to get a high score, you have to have the eMeasure specification using the data elements from what it is referred to as the quality data model.

And this is a model that is designed to sort of allow all of the different parties within the measure development process to essentially speak the same language if you will.

The second component is to have really a well-defined crosswalk between the data elements and the code list and the measure logic that is selected for a specific retool, the eMeasures – eMeasure and also to have analysis of comparability of the score. So that would get you a high score if you had all three components.

If you wanted to have a sort of moderate score, then the quality data model needs to be available in a crosswalk between the original specification and the eMeasures measure set and logic needs to be present.

And a low score would be that if you had an EHR specification that does not comply with the quality data model or that the crosswalk showed that the specification as noted within the submission do not represent the original measure.

So those are sort of the criteria that would be used to rate the scientific acceptability as it pertains to validity and reliability.

And sort of for integrity, just as an aside, the validity in eMeasures are extremely important. And sometimes, you know, if you're using a computer, you can repeat the same thing fairly accurately over and over again. And in that sense it might be reliable in reproducing the results but it might not be valid.

So, therefore – so that's kind of how I used those sort of – those guidance criteria to try to do an assessment on behalf of the committee sort of – I don't know how many other people were able to sort of go through some of this. But I'll walk through some of this stuff just to – just sort of another housekeeping item which I think I should mention before I get into 0658 which is the first measure that we're discussing.

But in terms of the submission documents, the eMeasure code sets for 0658 are present actually towards the last couple of – last section of the full submission document.

So, in the 0659, there is actually a spreadsheet that is included. I didn't see that in 658. And maybe I wasn't looking for it at the right place. But I went to the SharePoint two or three times. But there is some communication between the NQF staff which actually evaluated the eMeasures part of it mostly for formatting compliance. And there was some missing codes from the 658 submission. And In response, I read the document. The developer mentioned that the spreadsheet of 659 which contains those code sets applied to both 658 and 659. And these have to do with the high risk for colorectal cancer definition code sets.

So really the key sort of code sets are for both of these measures, the denominator definitions, the numerator definitions, the exception definitions, especially how one defines a high-risk colon cancer, how one defines incomplete colonoscopy, how one defines inadequate prep, or how one defines the complications/contraindications.

So, in order for me to do that sort of evaluation, because there was not a sort of a crosswalk submitted as part of the submission, I had to pull the original specifications from the developer's URL that was submitted as part of the submission.

So, what I will now do is sort of go into the actual 658 codes that when I look at the spreadsheet and the submission, because part of it – part of the code sets are in that full submission document, and part of it is in the spreadsheet, but I'll try to walk through each one and explain what my findings are. And then perhaps we can have a discussion and have a conversation around that.

So this measure as everybody knows is defining a denominator of people who have – who are age 50 and above, who undergo a screening colonoscopy which is negative.

And so the denominator code is very important in how it gets defined.

So, when I compare the denominator code in the spreadsheet to the original specification, it seems like there are differences in what was specified. So, the original specification says that a (CPTD2) code of GZO121 which is colorectal cancer screening – colonoscopy on individuals not meeting criteria for high risk. Along with a simple diagnostic colonoscopy, code 45378, are the only two codes specified.

But in the spreadsheet there are some additional codes which, some of them actually don't appear to be valid for this type of screening colonoscopy. For example, there's a code included 45381 which says, "This is a colonoscopy with directed submucosal injection, any substance.

Then there is a colonoscopy code that is, basically, a colotomy code that's specified.

So, I think there are some additional codes. Now, the guidance does provide that eMeasures can have code variance from the original specification. But in case there is a significant variance from the original specification, then that code set needs to be tested as an eMeasure itself.

So, my understanding, or at least from what I can see within the submission, that the eMeasures component of this was not directly tested in that sense.

Andy Baskin: All right. Zahid, maybe we just stop for a second here because I – so you've identified one area which is the screening colonoscopy codes in the eMeasure set are different than those in the non-eMeasure set.

Zahid Butt: Right.

Andy Baskin: So I guess, let's just go right to developer and try to understand why it's a different code set.

Zahid Butt: The AMA I think is on this phone. I don't know whether there's someone else who is also on the phone that's familiar with this measure.

Kendra Hanley: Yes, this is Kendra Hanley from the AMA. And actually, I'm wondering if I could clarify that, you know, we did submit an E-specification for 658. It didn't sound like Dr. Butt had received that or seen that document. And I guess I was just wondering if NQF staff might be able to…

Zahid Butt: Is that a PDF document, or is that a spreadsheet?

Kendra Hanley: That's a PDF document. The information in the spreadsheet is included as part of that PDF at the end.

Zahid Butt: That's what I'm referring to actually.

Kendra Hanley: OK, OK.

Zahid Butt: This is the PDF that I'm referring to.

Andy Baskin: Yes, in the full submission, there is a – there is a measure – there is a big list here of procedure codes.

Zahid Butt: Yes. If you look at that measure set, 000 – four zeroes, one, value set ID.

Kendra Hanley: Right.

Andy Baskin: The others says, 53 out of 50 – page 53 in the full submission out of 54.

Zahid Butt: Yes. 53 pages. You are exactly right, Andy. So you'll see that there is a code, 45355 colonoscopy, rigid or flexible transabdominal via colotomy, single or multiple.

I'm not sure if that qualifies for a screening colonoscopy. There are other codes that have directed biopsies and things like control of bleeding, like there's a control of bleeding code.

Now, these were not – these are not in – the original specification really only has the G0121 and 45378.

And the original spec actually also has an (N) with ICD-9diagnosis for patients who are getting the screening colonoscopy, and my guess is that's because if you use the 78 code, you have to use a diagnosis of screening colonoscopy, because the G code, by itself, is inclusive of that diagnosis in some sense.

But – so I'm not sure if the developers have, you know, once they look at this, they have further explanation of why these additional codes were included.

Joel Brill: So – may I speak?

Andy Baskin: Yes, please do. And who's this speaking?

Joel Brill: Hi Andy, it's Joel Brill.

Andy Baskin: Oh, hi Joel. Go ahead. Thanks.

Joel Brill: Hi there. So, as you see in the screen right now, 658 says percentage of patients receiving screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least years for repeat colonoscopy documented in their colonoscopy report.

So the issue is that some of these patients may be receiving follow up for an incident that occurred obviously 10 years or even 10 years after a previous – (inaudible) had initial lesion, then had a follow up. That follow up was negative then they're now coming back for a follow up. That's why I think a

number of (inaudible) policies as well as other circumstances address this question of whether or not one additional CPT codes versus the injection code that Dr. Butt referred to a few moments whether those should be included. And then two, also addresses why some of the additional diagnoses would be included within the eMeasure set.

Andy Baskin: Well, I guess, Joel, what we're trying to understand is why wouldn't the same codes be in the non-eMeasure set if they came in in a claim as opposed to through an eMeasure.

It's unclear why this – why the codes that are considered potential screening colonoscopies would be different. I understand why you'd have them here, or why you've been on the same codes in the non-eMeasure.

Joel Brill: I can't (inaudible) and the only defense that I have at this point is to say that there should consistency with those. And if there's consistency, obviously those of us involved in the development of the eMeasures have created an oversight to which we apologize and which we would rectify.

Andy Baskin: Thank you Joel. Any other comments? Someone else from the AMA – someone from the AMA that was speaking before, do you need to add anything to Joel, or is that the answer?

Kendra Hanley: I think that's consistent. You know, again, we originally developed this measure several years ago. And as we've learned about the different standards in place to incorporate and develop the eMeasure specification, it's kind of been an evolving work in progress.

You know, I think with every time we do this, we learn something new. But I thinks it's – you know, we would be happy to look at those colonoscopy codes again to determine if those are all applicable in this case.

Andy Baskin: OK. Zahid, is there any other mismatch in the codes other than the screening colonoscopy? What would be a screening colonoscopy?

I don't want to spend too much time on this particular measure 'cause we already have an issue…

Zahid Butt: Yes. There are several of these types of things which we could spend a lot of time going through these but I think…

Andy Baskin: Well, rather than go through all the detail – rather than go through all the details, Zahid, is there – can you give us maybe one other example of where there may be a mismatch in codes?

Zahid Butt: So, one example might be a sort of – in the original specification, some of the (CPT2) – I'm sorry. Some of the CPT modifiers are used for incomplete colonoscopy and those are not in here. So there is – I can't – I don't see incomplete colonoscopy code set here. So, again I don't know.

Andy Baskin: And there is such a data point in the electronic medical record that say – that it would say that the – it was an incomplete colonoscopy. In other words, there should be a data point for that, right?

Zahid Butt: In the report that a colonoscopy didn't complete and that's one of the exceptions I believe in the original specification.

Joel Brill: Again, this is Joel Brill. And I will point out that the CPT definition of a colonoscopy is that the colonoscope hasn't been advanced beyond the splenic flexure. That's what the CPT description of the colonoscopy is.

Yes, (inaudible) is going to address that any point in the future, but look carefully, and respectfully and look carefully in how a coloscopy is defined by CPT and has been defined by CPT.

There are modifiers 52 and or 53 which CPT defines for use as well.

Andy Baskin: That would come in on a claim but then there'd be no reason to have that in electronic record than you're saying the modifier because if the colonoscopy was…

Zahid Butt: But then there should be a comparable code here that describes a sort of incomplete colonoscopy because that's part of the definition of the original specification.

Joel Brill: Again, I don't think that the NFQ should be the point of discussion of how CPT defines what a colonoscopy is.

Zahid Butt: No, no, Joel, I don't think we are trying to do that. I think we're trying to see where the E-specifications are consistent with the original specification.

That's all the intent here is just simply to see where the specifications on the eMeasure site are at variance with the original specification. Because I believe that would have an impact on how the measure gets calculated.

Joel Brill: Perhaps AMA staff would like to address it.

Kendra Hanley: This is Kendra. And I just – just to clarify in looking at 658, we actually do not list an incomplete colonoscopy as one of the reasons for an exception. It is in fact a reason in 659, but it is not.

Zahid Butt: OK, so then, that's fine.

The other one that I think is worth mentioning is the code that are part of the medical reason for an exception. There are a whole bunch of medical reason codes that are an exception for the colonoscopy 10-year recommendation. And if you go down this list, I see things like drug resistance as one of the codes.

Kendra Hanley: So I can speak to that. This is the standard medical reason value set that the PCPI has developed and is used across all of our measures where we do allow for the medical reason.

Similarly, we have a standard list for patient reason and a standard list for system reason.

We can appreciate that from, you know, one measure to the other that not every single reason might apply in this case, but for parsimony of developing value sets to capture these medical reasons, we've landed on the approach to provide one general medical reason value set to account for some of these other reasons that may be applicable.

Zahid Butt: I see. So this is more like a generic value set that gets reused for everything where there is the medical reason involved.

Kendra Hanley: That's correct. And that's – this is also consistent with the value sets that are in use in the meaningful use program.

Zahid Butt: OK, that's fair enough.

Andy Baskin: That sounds reasonable. Yes.

Zahid Butt: Right, right.

Andy Baskins: So it seems that a really snafu here is that we may not be counting or seeing colonoscopies by the different CPT code – the variations of a colonoscopy. So that would have to be fixed.

Zahid, is there another reason why this would – that these two sets wouldn't match? I mean, it sounds like the exceptions are OK.

Zahid Butt: Yes, so I believe that the other one is, which is applicable actually to both of these measures, is the high risk for colon cancer. And so there is a value set called high risk for colon cancer.

And in the original specification, high risk for colon cancer is defined at a very high level. For example, it says inflammatory bowel disease as high risk for colon cancer.

Now, I don't know if there is additional guidance because the specification itself is not detailed enough to say whether there is additional guidance as to which inflammatory bowel disease constitutes high risk.

But if you look at the value sets that are – the codes that are here, as part of the high risk, which I guess mapped to that high risk category, the high level category on the other side, you have basically 140 codes which have all sorts and manner of inflammatory conditions of the GI tract.

So for example, you have here regional enteritis, unspecified. You have stuff like that which I don't think really map over to a high risk for colon cancer. On the other side I would think, I don't know.

Andy Baskin: So, developers, Joel or with the AMA, I'm sorry, I couldn't remember whom I was speaking but is the (inaudible) value set is – I don't even see in here, Zahid's (inaudible). I'm having difficulty finding it but...

Zahid Butt: That's the one that I mentioned it in the spreadsheet for both 659 and 658.

Andy Baskin: OK. So with that – so from the developer's point of view, is that what you're using as the best match for – I mean that's a pretty standard high risk set that you use for – built for colonoscopies?

Kendra Henley: So in looking further at – so in 658, the medical exception states the patients at above average risk.

In 659, we specifically say patients at high risk.

We did do some additional query of our expert work group to determine, you know, what would actually make up those characteristics of 658 of above average risk? And they were pretty consistent in terms of the clinical areas, pretty consistent with how we had defined high risk in 659.

Again, if we were developing these measures de novo today, we would make sure that we have similar language in both. But because we were working with an older version of the measure, that's why we have a little bit of difference in the exception examples. But after reviewing the reasons for above average risk, we felt comfortable using that high risk which included things like the inflammatory bowel disease. Other gastrointestinal conditions where you may have, you know, bleeding and other issues.

Zahid Butt: Well, I mean, you know, I think like for instance I'm seeing some codes here that say eosinophilic gastritis and gastroenteritis.

That is considered a high risk for colon cancer. So I don't know. We have other GI people on the line and I don't know if they've had a chance to look at

this. But, you know, there's Crohn's Disease of the duodenum, for example, is one of the codes. And I don't know if that qualifies as high risk for colon cancer.

Andy Baskin: In turn, Zahid, is the list maybe incomplete?

Zahid Butt: No, my concern is that this list is basically – see, I believe and the developers could clarify. I believe that the original specification is at such a high level of sort of non-specificity in terms of inflammatory bowel disease that – that's my concern that if there is no guidance on the other side, how is it being interpreted as what constitutes as a high risk for colon cancer, because they are very specific inflammatory bowel disease criteria for high risk of colon cancer.

And so, someone has interpreted that all inflammatory bowel disease as the entire 140 codes.

So, in other words, any one of these, if they are present in the HER, or a patient would qualify that patient as high risk for colon cancer. And I'm not sure if that's what these map back to – at that high level code on the original specification. But, you know…

Andy Baskin: So you're saying there's not – so you're saying there's not – you don't think it's – well, certainly not perfect, but it can't be perfect. But you don't think it's a close enough match as the best approximation that could be done through an electronic record as to reasonably close to the high risk…

Zahid Butt: No, I think that a Crohn's Disease of the duodenum is not high risk for colon cancer. And I'd like to hear from the other GI people, is that a high risk for colon cancer?

Andy Baskin: Anyone else on the committee that wants to comment?

Male: (Jennifer) (inaudible) going – I don't know if it is the truth, I have to go look at that.

Phil Schoenfeld: This is Schoenfeld. Can you guys hear me or not?

Andy Baskins: Yes. We can hear you, Phil.

Phil Schoenfeld: OK. Just – I think this comes down to an issue of, that may came up in the colon policy surveillance indicator even more so soon.

This is not perfect in terms of the E-specifications, but I would say that at this time it's close enough.

Andy Baskin: I appreciate that. Any other comment?

(Rick Blackmire): Yes. This is (Rick Blackmire). I think eosinophilic gastroenteritis isn't an increased risk for colon cancer. And therefore, you would – for either one, you might have increased frequency of colonoscopy and over-utilization.

Andy Baskin: OK, thank you. Joel, since you happen to be on the call, just to that one issue, are you familiar with what the risk of eosinophilic gastroenteritis with increased risk of color cancer? You may not be, but if you are.

Joel Brill: I would agree with the last comment that eosinophilic esophagitis where it's not been, to date, linked to an increased risk of colon cancer.

I think that the issue – the issue relating to inflammatory bowel disease is a question of whether the individual performing the examination hasn't provided specificity as to whether it is IBD for example, ulcerative colitis, whether it is Crohn's Disease, whether they've provided specificity as to the location of the Crohn's Disease.

And I believe that the reason that the specific of Crohn's Disease of the midgut such as Crohn's of the duodenum was included was to recognize the fact that there would people who might not have the proper specificity as Dr. Schoenfeld just mentioned, but have recognized that the patient has inflammatory bowel disease, and as such is at a higher risk than the population who doesn't have underlying inflammatory bowel disease.

Andy Baskin: OK. Thank you. (Riva), are you out there?

Zahid Butt: I think my concern again, Andy, is that if, you know, any of these codes are chosen, any of these codes would put that case in an exception.

Andy Baskin: Yes. No, I understand that.

(Riva) are you out there?

(Riva): Yes, I'm here. Yes, I'm here.

Andy Baskin: So, here's a concern, (Riva), I mean, there's no doubt that there's certainly a little bit of issue on the colonoscopy codes, maybe not being exactly right, and they need to do some tweaking. You know, it'll be hard for us to vote on a set we know as not perfectly right. And there may be some clinical argument about the exact set of codes for the high risk codes, not to say that most of them aren't fine, but there may be a couple of it that could be tweaked with agreement. But I don't think this is the place to do it. And I need to move this forward.

So, I guess my questions is, we have two choices. We either vote on the electronic specifications as is, and yay or nay, or is it possible to say yay with the idea that these issues would be worked out before this is finally settled?

(Riva): Yes.

Andy Baskin: Or can we not do that?

(Riva): Yes, we can do that.

I think that it's reasonable to suggest that a more specific crosswalk between the E-specifications and the coding for the original measure would I think help clarify it, make it easier for everybody to understand. And if indeed PCPI could produce that, you know, in a reasonably – in a reasonable period of time, I think that's certainly a reasonable alternative for the committee.

Andy Baskin: So what I'd like to put forth here is that, you know, by and large, the specifications are pretty good, but there are some issues here with exact match of – or as good a match as possible with the screening colonoscopy codes and possibly not as good a match as possible with the high risk codes that I would put out there that propose that we would vote for approval, reliability and validity on this with the idea that the folks from the developer and perhaps a

couple of representatives from this GI team, you know, agree on those tweaks at a later time, if that's a reasonable, (Riva) for that proposal to go out there?

(Riva): I think that this committee will have a chance to meet again. And so certainly after we take measures out for public comment, and so I would think it would be reasonable to require the developer to, you know, clarify those issues for you at least by the time you regroup after comment.

Andy Baskin: OK. So they'll sort it all today then, for the electronic (inaudible)?

(Riva): Well, you've already voted for reliability and validity of the measure. You've raised – for the original measure. You've raised some issues around the eMeasure specifications. We can kind of hold that for now if you want.

Andy Baskin: OK. I'm thinking that the (inaudible) of this is that the committee is, you know, mostly in favor of the eMeasure but would like to see these details work out before final vote. So, we'll hold off on the final vote and ask for those details which I'm sure, it can be worked out. It doesn't sound like anything insurmountable here, that that gets worked out before the final vote. So, then I'm going to (disable) the vote if that's fine…

(Riva): That's fine.

Andy Baskin: …to do that as co-chair. OK.

Then I think, Zahid, thank you very much. It's very helpful. I've learned a lot and it'll will make it a lot easier to vote for this, when this, you know, these few tweaks are made. So, thank you. And actually everyone that contributed.

Let's move on then to feasibility and usability.

Phil Schoenfeld: I'm not sure if I'm supposed to read this part since, (inaudible) is not on the call or somebody else is.

Andy Baskin: If you feel comfortable doing it, Phil, I thought you would be replacing him for that, but if you're not ready too, then I'll try Zahid.

Phil Schoenfeld: I'd like you to take the lead on this, Andy, as possible and I can supplement it.

Andy Baskin: OK.

Phil Schoenfeld: My impression from the feasibility and usability and based on the last discussion, the only other real issue was going to ultimately be around whether or not screening should be stopped at age 75 in terms of pure content.

That's not necessarily part of feasibility and usability which, I think, for this measure, are probably, relatively easy.

Andy Baskin: Yes. That actually did come up, but I guess at the end of the last call. I mean, certainly feasibility and usability maybe easy on this – outside of the test – outside of the limitations of age only because this measure's already been in use. And, as far as I know, there have been no reason – it's obviously, that it is feasible. And, I think, obviously usable but I'll certainly entertain comments on that. On the age issue, I think, we went back to some recommendations, somebody shared me. I think it was you Phil or somebody did. There is an age limit on some recommendations out there for colonoscopy.

Phil Schoenfeld: I think it's somebody else who did it. I just wanted to help you out with that.

Andy Baskin: Yes. I think it was, Phil – I'm sorry, it was some – yes, somebody else had been…

Phil Schoenfeld: Yes, I know. I remember now who did it but I…

Zahid Butt: (inaudible) kind of agreed that it hasn't made it into the guidelines yet?

Phil Schoenfeld: That is correct. The USPSTF said at least colon follow up surveillance should stop after age 85, not between the ages of 75 and 85. The potential for benefit should be individualized based on comorbidities in the findings of any prior colonoscopy.

Andy Baskin: Right. And so the question is should there be…

Phil Schoenfeld: Yes. It's not really made a comment about certainly 75 and younger.

Zahid Butt: I think we sort of agreed last time, Andy, that maybe we will just leave the specifications as they are for now until…

Andy Baskin: OK, I was just wondering if there was an interest in the developer in stopping at 85, where there is probably evidence out there that is not even discretionary at that point in time.

But if people are in favor of that, I'm OK leaving it as it is until that…

Phil Schoenfeld: I would leave it as is for this time, and that would by my comment.

Andy Baskin: OK.

Zahid Butt: So…

Andy Baskin: (inaudible)

Zahid Butt: The only one question I have, and that might be possibly in the usability, or potentially in a different discussion, but I think it might affect usability and that's the – the original specification actually has – in the same measure, two different calculations, one for reporting of the measure and one for the performance.

And there is some reference to whether that reporting calculation is more for PQRS type of thing. And my – I guess my only concern is that how would we know when the measure is in use from the description or from whatever, in which context this measure is being used because the two calculations are quite different and would yield very different percentages.

Andy Baskin: And the differences whether the exceptions are included in the numerator or not, so that's the difference?

Zahid Butt: That is correct. So, these…

Andy Baskin: My understanding is that that – whoever is using it would define which calculation is being done. I mean, I can't imagine it being done any other way. Any comments from the developer on that?

Kendra Henley: Yes. This is Kendra Henley.

The sample of reporting and performance calculations that are included in the document on our website are really there to demonstrate how the measure is being implemented in PQRS. And as everybody is probably aware, PQRS is a reporting program currently and not necessarily, you know, a true performance program.

And so there have been certain modifications needed for CMS to be able to come up with whether or not an eligible professional is reporting on the appropriate percentage of their eligible patient to qualify for that incentive payment or, you know, now we're looking at penalties. So…

Zahid Butt: Right. Right. But, you know, it's sort of sometimes easy to lose that sort of distinction because I believe that in the next measure, the PQRS data that's (inaudible) for performance actually may actually be reporting...

Kendra Henley: Yes.

Zahid Butt: … data.

Male: CMS does provide – they do do a performance calculation. But it's the reporting calculation that is used for any incentive payment. But the data that we've reported has been based on the performance results.

(Riva): Andy. This is (Riva).

Andy Baskin: Yes. Yes. Go ahead (inaudible).

(Riva): I just wanted to say that the measure submitted by PCPI is the measure that you have in your documentation, and there really is only one version of it. And that is the percentage of patients aged 50 and older receiving screening colonoscopy with or without biopsy or polypectomy with a recommended follow up of at least ten years. So that is the measure that you all are evaluating.

Andy Baskin: Hey (Riva), does that mean though the exceptions are given credit in the numerator or they're separately – or two separate rates that's reported?

(Riva): They, including the specifications of the denominator exclusion.

Zahid Butt: So if (Riva), that's the case, then when CMS puts it on their website, that this is measure 0658 and these are the performance numbers, or these are the rates for measures 658. It doesn't look like they say it's only a reporting rate and not a performance rate. So, will they be able to use the NQF endorsement for reporting their reporting rates?

(Riva): I never will speak for CMS, but the measure that NQF is evaluating for endorsement is the one with the specifications you have in front of you, and that's what you need to be focused on.

Zahid Butt: So that's the..

Andy Baskin: Yes, I think…

Zahid Butt: That's just performance rate then.

Male: Yes.

Zahid Butt: OK, got it. Yes?

Andy Baskin: OK. Any other comments before we vote here? All right, I think we're OK to go ahead and vote on the feasibility.

(Riva): OK. Voting is – the slide is available for you all.

Suzanne Theberge: Is there any committee members who are unable to vote or unable to see the voting slide? You can vote either by emailing (Evan) or by just voting verbally. I noticed a couple of folks who were having trouble earlier.

Andy Baskin: How many people do we have voting? Do we know?

Suzanne Theberge: I think, 12, maybe 13.

(Evan): Those who weren't able to vote online, so if they want to verbalize or email me, that will be good.

Male: Yes (inaudible) go ahead.

Male: Yes, I have to vote verbally 'cause I can't see it. I'll give it a moderate.

Phil Schoenfeld: I would – this is Phil Schoenfeld, I would give it a moderate for feasibility and usability.

Male: OK.

(Jay Morgan): This is (Jay Morgan). I'm giving moderate for both.

Andy Baskin: So the feasibility is completed then.

Male: Yes.

Andy Baskin: You have to call out the vote before we move on to the usability vote.

Suzanne Theberge: Yes. So we have 12 moderate – or, sorry. 13 moderate.

Andy Baskin: OK, let's move on to usability then.

We heard from two of the people on this phone already that they said usability was moderate. One person I don't think spoke for usability was on the phone.

(Stuart Reynolds): This is (Stuart Reynolds). I'll give it a moderate for usability.

Andy Baskin: OK. So the three of you have moderate. And now we – are you putting it up here for us?

Suzanne Theberge: Sure. Get ready to vote, I will pull that out.

Andy Baskin: Yes. Yes, yes. So everybody please vote (inaudible) kindly do so.

I think we're still waiting for one more vote. We have nine online, there should be 10.

Suzanne Theberge: There we go, OK. So we have 13 moderate.

Andy Baskin: OK. Then we could move – it's the next vote, I'm sorry.

All right, so this is, "Does the measure meet NQF criteria for endorsement?" Remember this is not the eMeasure part that's being worked out between.

So just yes or no. Those of you who want – if you're comfortable speaking up and voting the three but can't vote online, please do so. If you're not comfortable, just say so and you could email the result of it.

Phil Schoenfeld: This is Phil Schoenfeld. I feel comfortable saying, yes.

Andy Baskin: OK.

(Stuart Reynolds): (Stuart Reynolds), I say yes.

Andy Baskin: Thank you.

One more.

Who is the third person on the phone that needs to vote?

Suzanne Theberge: (John Martin).

Andy Baskin: (John)?

(John Martin): I'm (inaudible) moderate, please?

Andy Baskin: No, no, it's a yes or no.

(John Martin): I'm sorry, yes.

Male: OK.

Andy Baskin: Yes, it's tough when you can't hear. I'm sorry.

Suzanne Theberge: We have 13 (inaudible) votes.

Andy Baskin: OK, thank you everyone and for that. And Zahid, once again, thank you.

Hopefully the difficulties we had there will help us with 0659. So why don't we move on to that one straight away? Phil, is this one that you're supposed to present?

Phil Schoenfeld: Yes, this is Phil.

Let me preface my statement by giving the ultimate bottom line here, which is that this measure is not optimal. But if we do not send it forward again because this is already being used in PQRS, then it may be more detrimental not to send it forward than to send it forward at this time.

Here is what I mean by that. The current measure simply says that if you have polyps found on a colonoscopy, that you should not get a repeat colonoscopy for at least three years, as long as you don't meet one of the exclusion criteria.

For example, that you had inadequate bowel preparation, or that the polyps wasn't totally removed.

Having said that, that is not optimal. Optimally, you should be able to say that you determine that somebody has an adenoma. And if they meet the criteria in terms of the number or adenomas or size of adenoma that you recommend a repeat colonoscopy in either three years or five years or 10 years if the polyp is hyperplastic.

But, if we do not put this forward, we confirmed it since they're already being used in PQRS, then, we don't have any quality measure in people who choose to repeat a colonoscopy at one year or two years after finding a polyp, are allowed to do that without having any evaluation in the quality of care.

So, my bottom line is that I would – I want to continue to see this put forward but on a limited time basis, in order to give the sponsor time – in a limited time basis to come back with a more appropriate quality indicator.

And I just note that, you know, two of the databases they refer to, the AGA's Digestive Health Registry as well as (GI quick) which is a combined effort from the American College of Gastroenterology and the American Society for Gastrointestinal Endoscopy.

Those databases do include data that could be used for that type of (inaudible) more optimal quality indicator I just mentioned.

So, Andy, I'm sorry, I didn't get a chance to – and (Chris) that I didn't get a chance to go over this picture in more detail previously.

Andy Baskin: That's OK. That feedback actually – this will be the not the first time that that feedback has gone back to the developer. And I appreciate it you bringing it up again.

So the point here being three or more years is not wrong, but there is a better measure that could be developed and perhaps not that difficult to develop, that we would – we'd like to once again send a strong message back to the developers that we would hope and expect that that would be done because this measure isn't one that we want to continue on forever, but I appreciate that. But I think now we need to get into the reliability of this particular measure.

Phil Schoenfeld: So in terms of – I mean, everybody can see the data that was submitted.

I mean, in terms of reliability and validity, I would say it's moderate. I mean, they can show based on using those endoscopic databases appropriate reliability and validity for the marker that's specified or the indicator that's specified.

Andy Baskin: And essentially they did the same analysis or the same type of analysis that was done on the previous one. So that we're familiar with how that was done. So I guess there's no reason to go through the explanation of how that was done.

Are there any particular questions or concerns about the reliability and validity testing of this particular measure?

Zahid Butt: I have one question on the opening remarks, this gentleman stated adenoma or a hyperplastic, what I interpret it as, I thought it only applied to adenomatous polyps and not hyperplastic. The concern…

Phil Schoenfeld: As I read this, it only says polyps. It does not say adenoma. If I'm mistaken, I would be happy to be corrected.

Zahid Butt: Yes. This is Zahid. That's my understanding too. It's just polyp. That's – those are the codes that are being used. It's not adenoma, just polyp.

So that really, you know, it opens up a whole can of worms for me at least is that the hyperplastic polyp (inaudible) which is distal and which is really common and – will be justified at three years, and all the (inaudible) has – should not be done…

Phil Schoenfeld: There's a big difference here. What we're saying is not that you're justified for doing it three years. What this is saying is that if you have a polyp, you're not justified at repeating it at one to two years.

Again, the issue is trying to make sure, as currently stated, and this has been an issue in the past. If somebody had a polyp found, that you couldn't repeat the colonoscopy in one to two years. And that overuse is eliminated. The problem is, there is other overuse that has to be eliminated in a indicator in the future. But if we don't put this forward, well then actually, if you do want to repeat your colonoscopy at one year, there's nothing in PQRS to prevent you from doing that.

Andy Baskin: Yes, can I just ask the developer to comment because I have thought that this was for adenoma polyps, especially adenomatous polyps especially because that language was used in many of the answers to the questions.

Is it just that the description is not as accurate or as precise as it was intended to be, or is the intent that it only be polyps, that this hyperplastic polyps be included in here?

Can someone from the – or how does it actually function today is well I guess – someone from the developer who can comment on that?

Male: Kendra, do you want to start?

Kendra Hanley: Yes, sure. So, it is in fact as the title indicates, adenomatous polyps.

(John): So it eliminates the issue around – this is (John). It eliminates the issue around the hyperplastic polyp. And I think it was unfortunate that that became, in this last five minutes or so of conversation, add confusion or confounding issue.

Andy Baskin: OK, so I would just ask her if there's any place in the measure description where polyp is used without the word adenomatous in front of it which may or may not be, that the word adenomatous be put in there so that nobody would be misled into thinking that a hyperplastic polyp would count.

And I haven't gone back to check – I haven't gone back to check that, so it may already be true, to be honest with you. But I'm just saying.

So with that – with that clarification, Phil, any other comment or anyone in the committee around the reliability or validity?

(Audio Gap)

Andy Baskin: I'll give that "Umm" a chance to (inaudible). I'm sorry? Was someone going to comment?

(Audio Gap)

Andy Baskin: Hello?

Phil Schoenfeld: I don't think you have any other comments, Andy.

Andy Baskin: OK, I know I just I didn't know whether my phone went silent. All of a sudden I (inaudible) noise.

OK, then I think we're ready to go ahead and vote then. So if we can get the voting up for reliability, please?

Zahid Butt: So, Andy, are we including the E-spec issues here as well, or is that what we're going to discuss?

Andy Baskin: I'm sorry. I guess we decided we were going to talk about E-Spec at the same time. So why don't we – before we vote on reliability and validity, let's go to E-Spec.

And, Zahid, let me ask that if this is a similar issue to the last one, if we could just stay to this such an – and deal with it the same way. If you feel there is something different that this measure is fine from an eMeasure point of view, or there's a different problem here, and please just try and direct us. 'Cause I don't want to get back to a half-hour discussion about the eMeasure.

Zahid Butt: Sure. And I think it's similar issues and part of the – it's similar issues in definitions, basically. And part of the definitions, the code sets or the codes that are selected may pertain to the discussion that we just had because it includes codes that would be not specific for adenoma polyps but could be, you know, any polyp.

And so, you know, that's one issue. The other issue is that the screening for high risk colonoscopy code is different. The CPT2 code is different from what is specified here.

This code, the CPT2 code that's specified in this measure is the one that's for – not a high risk but this one is by definition a high risk colonoscopy because it has a previous adenoma.

And actually, in the original specification, it is specified as a high risk colonoscopy by definition.

Andy Baskin: Wait, I think you lost me on that one. So you're saying that…

Zahid Butt: There is a code G0105 for high risk colonoscopy…

Andy Baskin: Right

Zahid Butt: …versus the average risk which is G0121.

So I believe that the original specification calls out for the high risk colonoscopy because this is a colonoscopy that is done in patients who have had a previous adenoma which by definition is a high risk colonoscopy.

Andy Baskin: That's right.

Joel Brill: Zahid, this is Joel Brill.

I (inaudible) again just recognized that the G codes were established by Medicare. That's a pre-date (inaudible) that were just – they were established by Medicare because Congress directed the agency to cover colorectal cancer screening. And the further one looks carefully at the way that G0105 is constructed, that really talks about a congressional description of when colorectal cancer surveillance, which is, toward, you know, within 48 months.

So, I would be a little bit cautious about trying to pull in congressional intent and mix that in with, you know, multi-society guideline recommendations.

Andy Baskin: All right. So in the eMeasure then, are you proposing that – or have you proposed then that whichever colonoscopy code came in, if it came with the high risk value set of code, an ICD-9 code that that would be – could not be considered – that would be how you would define high risk rather than the description of the CPT or HCPCS code.

Zahid Butt: So Andy, the issue, this is Zahid again, just to make sure I stated clearly. In the original specification, G0105 is part of the original specification. So if what Joel just said is true then we should remove it from there, because otherwise we'll approve it with that in place.

Kendra Hanley: Yes.

Zahid Butt: And…

Andy Baskin: Oh, so your point is we're not using the same code set for the procedure codes in the regular measure versus the eMeasure set?

Zahid Butt: Yes.

Andy Baskin: And I can't think of a reason why they wouldn't be the same set of CPT codes or HCPCS codes – procedure codes.

Kendra Hanley: This is Kendra Hanley from the AMA. I – I'm actually looking at the detail and I'm realizing that that's an error. The G code that's included in 659 should in fact be the colonoscopy for higher, patient at high risk.

Andy Baskin: OK. So it sounds like what we have here is very similar issues to the previous one, that there may be some screening colonoscopy codes that have to be matched up better.

We've already dealt with – we've already dealt with the medical reasons, codes, values that that was OK. But we're concerned about the high risk set of codes as to whether all the codes are specifically high risk or not, such as the eosinophilic esophagitis, the same issue as before.

So I would think that the same work to be done to harmonize, essentially, the code set with the eMeasure and the regular measure should happen with this one as well. And probably, it would almost be identical work being done if not identical.

Zahid Butt: Yes, I agree. I mean, the only thing that I'll comment on is that there are colon polyp codes that are specified in the E-spec with SNOMED and ICD-10 but not ICD-9. And I think that needs to be added.

Kendra Hanley: This is Kendra from the PCPI, if I can speak to that. The reason is that in ICD-9, we don't actually have the level of granularity to capture the concept that we're looking for.

Zahid Butt: OK. That's fine.

Andy Baskin: That's fair. OK, so I would think that this will, once again, table the eMeasure portion of it because I think it will exact – we'll come to the exact same situation with this as the prior code. And, in fact, the, you know, the fix will be almost identical and we can just do them both together, rather than have it not passed at this point, when I think it will pass in the future.

So let's go half that and let's then go back to the voting on reliability and feasibility on the regular spec measure not the eMeasure. And go ahead and vote on reliability here.

And once again, we have three folks on the phone – Phil, (Stu), and, oh my gosh, I'm (inaudible) oh, (John), there's a (John)?

Male: Yes.

Andy Baskin: OK. I just wanted to remember who the three people are going to vote out loud if they want to.

Philip Schoenfeld: That's right. This is Phil, I vote moderate for reliability and validity.

(Stu Reynolds): (Stu Reynolds). I also give it moderate for both those ratings.

(John Martin): (John Martin). I agree with moderate for both.

Andy Baskin: OK. And we have 10 votes already in for reliability electronically, so if you want to call out the results, then we'll move on to the validity.

Suzanne Theberge: Yes, that's one high and 12 moderate for reliability.

Andy Baskin: OK.

Suzanne Theberge: And are you ready to…

Andy Baskin: Move on.

Suzanne Theberge: …to vote. OK.

Andy Baskin: Yes, we're ready to vote on validity.

We already have the three votes as moderate for the folks on the phone who are voting on the phone. So now, we're looking for 10 electronic votes.

And we have seven so far – eight.

My gosh, I feel like it's election. We're up to nine. Oh, 10 (inaudible) are in. All right. Thank you. So you want to call out that vote please.

Suzanne Theberge: We have 11 moderate and two low.

Andy Baskin: OK. Let's move on to feasibility.

Phil, I don't know whether you have anything specific to say about feasibility on this one.

Philip Schoenfeld: (Inaudible) feasibility and usability. My comments really reflect what I already said for reliability and validity with respect to the fact that this is a measure that's already been approved in the past as in PQRS and we're looking to re-approve it.

So, that with respect to the measure, is defined. I think the feasibility and usability is moderate with the caveats I already mentioned.

Andy Baskin: And no evidence that this measure has ever caused any harm – or anybody – I forget what it said in the submission. But let's go back to look. But I think there was no such evidence.

Zahid Butt: So…

Andy Baskin: Any comments from anyone on the committee?

Go ahead, someone was trying to speak up. I'm sorry I didn't mean to interject.

Zahid Butt: Yes. This is Zahid. Are we discussing feasibility for the eMeasures component as well or we're going to do…

Andy Baskin: No, I think we should not, because frankly that's tied to the code set to be honest with you. 'Cause once we agree on that, feasibility and usability in electronic form, it takes a whole different meaning.

I don't want to vote half of the eMeasure and not the other half. I don't think that makes much sense for us.

Zahid Butt: OK. Because there are some feasibility issues that are unique to the eMeasure side of it in this.

Andy Baskin: Well, then maybe just bring them up because I'm not sure whether we're going to do the votes – final vote over this electronically through email or whether we're doing it with a – I guess we're doing it on-call meeting, but if you have a few comments about feasibility and usability through electronic, go ahead and comment now so we'll have it on record and can use that when we meet again.

Zahid Butt: So I think in terms of the feasibility, the sort of history of colon – adenomatous colon polyp is just a history of the colon polyp end. So, somehow the recommendations are tied specifically to a report. And in many cases within EHRs, the history of the pathology report, if it is codified, might not be in the report itself.

So, I believe that that really needs to be looked at and tested to make sure that it will perform, you know, as intended within an EHR environment, or, you know, within the eMeasure environment.

Andy Baskin: Thank you.

Any other comments regarding feasibility or usability for this measure before we go for a vote?

Then let's go ahead and vote on feasibility. Remember this is the non-eMeasure spec. This is just the regular spec.

And we'll ask the folks from the phone. So, Phil?

Phil Schoenfeld: Yes, a moderate. You'll see that all the way through I'm moderate on all the markers and I'll vote yes in the end.

So, sorry to jump ahead. I'm just saying that 'cause you're getting a voice vote from me.

Andy Baskin: Yes, that's OK. (Stu)? (Stuart)?

(Stuart Reynolds): Yes, I'll do a moderate for both. And I guess I'll throw up my yes as well, just remind me.

Andy Baskin: OK, thank you. And (John)?

Are you out there on mute somewhere?

(Audio Gap)

Andy Baskin: Am I missing a voter?

Suzanne Theberge: We seem to be missing John's vote. So we can try to collect that from him later if necessary.

Andy Baskin: OK.

Suzanne Theberge: We have 12 moderate for feasibility.

Andy Baskin: All right, and let's move on to usability then.

Suzanne Theberge: Just straight to the vote?

Andy Baskin: Yes, 'cause we already discussed and there were no more comments about it. So, I think we can vote on usability and we've already had two on the phone say moderate. And John, I presume is not available.

(Audio Gap)

Andy Baskin: And one more.

(Audio Gap)

Andy Baskin: Did everyone online vote 'cause we had 10 votes before, and we only have 9 online?

There we go.

Suzanne Theberge: All right.

Andy Baskin: OK. You want to get ahead and poll it?

Suzanne Theberge: Yes. We have 12 moderate for usability.

Andy Baskin: All right. And then the endorsement, we've already had two, say yes. And then everyone else is online, they should say yes or no.

And we're waiting for one more vote.

I'm sorry. I want to give people adequate time to think. So, think.

OK. All the votes are cast.

Suzanne Theberge: All right, we have 11 yes and 1 no.

Andy Baskin: Thank you everybody. Thank you Phil. Thanks for all for that. And then we'll move on to the next measure which I don't know which measure it is.

Phil Schoenfeld: Before we go on, Andy, I just want to ask this part quickly though.

In some way, can we reflect either in limiting the time for this quality indicator and are there, some other way to make it clear that, you know – I'm trying to find the right words here. Basically -

Andy Baskin: I know what you're saying, Phil.

Phil Schoenfeld: We get this stacked in two years. That's not going to fly.

Andy Baskin: Right. So, I think we've made it pretty clear that the next go-around which would naturally be three years would be extremely difficult for this measure to make it through. And I can't say it in another – anymore and we set it off.

Phil Schoenfeld: OK. That's fine.

Andy Baskin: I don't think we necessarily have the option at this time to give less than a three-year – less than a full up or down on this.

Phil Schoenfeld: OK. OK.

Andy Baskin: But it would take that long probably for the developer to, you know, retool the measure and test it anyway. So, I think it's reasonable to give that strong message, not that we have to vote on that but we've stated it abundantly clear.

Phil Schoenfeld: OK. Thank you very much.

Joel Brill: Then, Andy, on – this is Joel. On behalf of the measure developers. Yes, we have heard that measure. Probably we've heard those comments quite loud and quite clearly and we will respond as appropriate.

Andy Baskin: Thank you. Thank you, Joel. And thank you to the developer (inaudible) AMA as well.

All right, the next one is not - I'm not leading that discussion. And in fact, I believe, I just want to reiterate to folks that I will not vote, participate because of conflict of interest.

(Chris Segal): OK. So, I think, I am going to do that one. This is – we're doing 635 now, or 622?

Suzanne Theberge: 622.

(Chris Segal): OK. So -

Suzanne Theberge: And Chris, it's a little hard to hear you. If you could speak up or move closer to you phone.

(Chris Segal): OK. And I'll let Suzanne know that I have to hop up right over on 155 or so. So, we may have (inaudible) to this measure but we'll try.

So this is Active Health measure, looking at whether upper GI (inaudible) patients with alarm systems since we have GERD. And I'm not sure who is it the - discuss it for this.

Suzanne Theberge: It's (John Martin).

(Chris Segal): Oh, John. Could you take a swift jump, please?

(John), are you there? That John got (inaudible)…

Andy Baskin: Yes, we've lost – yes, we have any lost (John) with the voting on the last one. I wonder what's happened with him.

(Chris Segal): Oh, well, who is discussing this, the other measure, 635?

(Rick Blackmire): (Rick) – this is (Rick Blackmire). I was assigned that task.

(Chris Segal): (Rick), would you mind – maybe we should just do that one since (John) is not available right now, regarding Hepatitis A Vaccination in patients with chronic liver disease interactive health management measure.

(Rick Blackmire): OK. This is 635 and the title is Chronic Liver Disease - Hepatitis A Vaccination. It's a maintenance review. It's Active Health is (inaudible). And the – it's a process measure at the population level.

A brief description is that it's measuring the percentage of adult patients with chronic liver disease who have received at least one Hepatitis vaccine – vaccination.

The developer originally defined the numerator as folks with chronic liver disease who either had at least one Hepatitis A vaccination or had a document in neurologic testing for HAV.

They've dropped the latter for – due to – it was raised in stage one and they've elected to drop it. And now they define it as the percent of chronic liver disease, adults with hepatitis A vaccination.

The numerator is adult with chronic liver disease who have received at least one Hepatitis A vaccination. The denominator is adults with chronic liver disease. And they have (inaudible) solutions.

The data sources are quite diverse. It includes administrative claims, E-clinical data that includes the electronic health record and electronic lab testing.

If they weren't able – under electronic lab testing, my understanding is that they could test whether Hepatitis A antibody test was performed but they did not have the results of whether the results were positive for susceptible – positive for non-susceptibility, or negative for susceptibility.

And really that's why they dropped it off the numerator.

They also used a healthcare provider survey and patient self-report supplemented by if the patient is going to do the management program, RN questioning and reporting.

All the data is processed through a clinical rule engine. There is feedback to both the provider and the patient, and there's opportunity to correct the provider and patient feedback.

The denominator exclusions are pretty standard. The – if the history of viral Hepatitis, and I presume that they mean viral Hepatitis A, and that's via the diagnosis by claims data or health HIE, anytime in the past, or self reported average data to the vaccine – Hepatitis A vaccine, data reported via in the personal health record or via telephone RN assessment.

And then the general exclusions include somebody with a history of evidence of metastatic, malignancy or disease, somebody with cancer who's received chemotherapy within the last six months, and patient in a skilled nursing and they'll have three months. And the rationale for adding that is the exclusion was to avoid holding the physician who cared for the patient during the care – transitional care from skilled (inaudible) so they would not be – I guess, they have – they didn't give the Hepatitis A vaccine.

This is at the population level and it's not at the physician level so I'm not so certain of that exclusion.

The scientific acceptability-reliability, the measure is really quite specific and inclusive for hepatitis, chronic hepatitis B or chronic hepatitis C patient. However, I really couldn't find the specificity for other chronic liver diseases such as alcoholic liver disease or nonalcoholic fatty liver disease. The others, I believe, are identified by – through claims for chronic liver disease and I think that's a little bit ambiguous to me, and I'm not sure if that includes non-alcoholic fatty liver disease or the chronic liver disease.

(Chris Segal): Rick, do you know where they specify the specificity and sensitivity of their new (inaudible) drug in this document?

(Rick Blackmire): No, I don't. I don't have that in front of me. I'm sorry. Oh, it's--we went over the specificity of the four, I thought.

(Chris Segal): Yes, I don't see it on the document. Maybe – oh, I see. Maybe it's in the bottom part of this. OK, go on.

(Rick Blackmire): I think it's – for hepatitis C and B, it's really outstanding. For non-hepatitis D and C, chronic non-hepatitis D, chronic non-hepatitis C, it's just – I interpreted it as just two general diagnostic point claims with other diagnosis. And I never saw what they considered as chronic liver disease. Others have been chronic hepatitis A – excuse me, B and C.

(Chris Segal): OK, is the developer going to give comment about that?

(Bonnie Vair): Yes, hi, this is (Bonnie Vair) from Active Health. So you know, we apologize for the ambiguity. We are in the rule algorithm. We actually identify the name of our sort of elements which is the label that we give to a set of codes. So in the liver disease, chronic, excluding hepatitis A element that you're seeing in the rule, using the present, the requirement is that they need two of these diagnoses from claims or HIE in the past year. Embedded in that element are the exact codes that you're referring to.

We have chronic hepatitis C, we have hepatorenal syndrome, we have other chronic hepatitis. We have pleural hypertension, alcoholic liver disease, et cetera, and the sort of the legends for those, for each element is in the code sets that we've attached.

(Chris Segal): OK.

(Rick Blackmire): So you do consider as a chronic liver disease, nonalcoholic fatty liver diagnosis?

(Bonnie Vair): Yes, yes.

(Rick Blackmire): OK. I'll get into that in the validity then. But the preliminary evaluations for reliability were 3 high, 4 moderate, and 1 low with no imposition.

(Chris Segal): OK, all right. So that…

(Rick Blackmire): I'll stop here and open it up for the reliability.

(Chris Segal): Any questions? OK, so hearing none, let's move on to the next section, usability.

(Rick Blackmire): The vote – Are we going to vote on reliability? OK.

(Chris Segal): I'll do this at the end I think.

(Riva): (Chris), it's (Riva). It's probably easier if after you discuss it then vote on it then move on to validity and go right through them in order.

(Chris Segal): OK, all right, let's go then to reliability. Slide 6.

(Stuart Reynolds): Oh, (Chris) are we voting? This is (Stuart Reynolds).

(Chris Segal): Yes.

(Stuart Reynolds): I have to vote. I vote moderate.

(Chris Segal): OK, makes that nine.

(Miliana Bordna): This is (Miliana Bordna), I'd like to switch to (inaudible) on voting and it's moderate on me.

(Chris Segal): OK, that would be ten.

(John Martin): I vote moderate, (John Martin).

(Chris Segal): Oh. Hey, John, OK, great.

(John Martin): Hey, (Chris).

Suzanne Theberge: And Phil, we need a vote from you as well.

(Riva): Is Phil still on the on line? Is Phil still on the line?

Suzanne Theberge: All right.

(Chris Segal): I think he might dropped off. So, I think that Phil dropped off. I counted 11 votes then.

Suzanne Theberge: Yes, that's correct.

(Chris Segal): OK, that's sufficient for us to move on?

Suzanne Theberge: es, so we have 11 moderate.

(Chris Segal): OK. Hi Rick, validity.

(Rick Blackmire): OK, for validity, here's where I have some concerns. The measurement for sure is consistent with multiple expert consensus guideline that people with chronic liver disease be vaccinated against hepatitis A.

The concerns I have is most of the datasets where fulminant hepatitis was found was in patients with chronic hepatitis C and chronic hepatitis B and everybody referred to the (inaudible) article in '95 or '98. It was a really small set but both of those conditions is they get some infection with hepatitis A.

I did have fulminant hepatitis, especially if that was chronic hepatitis C and (inaudible) actually in hepatitis C. So the metric being proposed is consistent with the literature – with the guideline recommendations. There are no outcome studies that vaccination actually will decrease.

And my concern is if you open it up for all people with fatty liver, the evidence for vaccination even though the vaccine is safe, it seems like without any outcome data that definitely large population of people out there, that it would be endorsing hepatitis A for – with all your metabolic syndrome patients and things like that. So that's one of my personal concerns on this.

The validity also, the second concern I have on validity is without knowing the susceptibility of the person that you're going to vaccinate, there will be over utilization of hepatitis A vaccine. The DA looked at 33,000 patients with chronic hepatitis C, two-thirds of those were tested for antibodies to hepatitis C, and of that group, one-third of the two-third tested or approximately 20

percent were susceptible to hepatitis A. In other words, they either had had previous vaccination or previous infection.

There is a large group of people who are – who have – especially in children who have hepatitis A that are asymptomatic. And what we end up doing the validity of this is just giving hepatitis A to people who really have no benefit from it.

I think the risks are low and really, that's a concern I have.

(Chris Segal): Thank you, (inaudible).

(Rick Blackmire): I'll stop there.

(Chris Segal): Yes. I think it's helpful to hear from other experts about those concerns. So, anyone else have any comment about that? Or Zahid?

Zahid Butt: Yes, I think that was the one aspect that I've been sort of pondering over myself. But I'm glad that numbers were presented, so that really would be the concern there. This would sort of, I guess, mean that everybody with chronic liver disease whether they had previous exposure or not.

But I think they sort of initially try to get at that, but it seemed like it was difficult for them to address that when they were testing for whether somebody have been tested and assuming that that meant that maybe they should be excluded. But I suppose the way this is being presented now is that you would literally have to, you know, the question I have is that – I don't know what the answer to it, is that if you do test someone who has chronic liver disease and not give them vaccine, how would they get treated in this measure?

(Rick Blackmire): Well, it's the way the current – the current exclusions include anybody with the history of previous hepatitis A.

Zahid Butt: No, not a history of but let's say that a provider tests somebody for hepatitis A, you know, they test for the antibody and someone is found immune and they decide not to give the vaccination. Now that patient will be in the population

if they are being measured. If that patient has a diagnosis of chronic liver disease. But in that scenario, would that patient fail the measure?

(Rick Blackmire): I think that patient would be excluded because in – either you'd have history of the previous vaccination or history of previous hepatitis A infection. And they do exclude people who have had previous hepatitis A infection.

Zahid Butt: Right, right. But by history though, right? Not by testing or is it by testing at all?

(Rick Blackmire): The health information exchange, if they have had previous hepatitis A anytime.

Zahid Butt: No, no, not the history.

I'm saying that the patient who does not have a known history of hepatitis A but test positive for the antibody.

(Rick Blackmire): Right. I think the only two ways you can get that is previous vaccination or previous infection. I'm not sure…

Zahid Butt: But the infection could be clinical. You don't have to have a history of hepatitis A sometimes.

(Rick Blackmire): No. And that's the problem. In the pediatric population, 75 percent – 70 or 75 percent of people with documented hepatitis A infection are asymptomatic and not diagnosed obviously.

Zahid Butt: Right. So my question is that how does that patient that does not have a "history of hepatitis A" was tested by a provider and found to have hepatitis A antibodies. Would they – how would they sort of be excluded in this measure?

(Rick Blackmire): I think their problem was or their diagnostic or their electronic record would state previous history of hepatitis A, and that would exclude them.

Zahid Butt: OK. So that that's…

(Rick Blackmire): That's my interpretation.

Zahid Butt: The testing would have to lead to a specific diagnosis of a history of hepatitis A.

(Rick Blackmire): Correct.

Zahid Butt: OK.

(Rick Blackmire): Or a previous vaccination.

Zahid Butt: OK.

(Chris Segal): Maybe added to the MR, I guess is what you're saying. So, but the other issue about vaccinated people that have fatty liver disease, I don't know about the risk-benefit ratio of that. Maybe someone else can comment about how big a deal that is.

Male: So, I mean I think that there's no serious adverse events that are really associated with the hep A vaccine and so they're quite safe so that's number one. I mean, this event, you know, safety and benefits of the vaccine are good. I think what gets interesting with advanced liver disease in general is the more advanced it is, the less you are likely to zero convert with vaccination. So, there's this issue of getting ahead of the patient liver disease, try to, you know, immunize them before they become more advanced.

(Chris Segal): All right. OK.

Male: And I think that's across all chronic liver diseases.

(Chris Segal): OK. Anyone else…OK, go ahead.

(John Martin): Just, it's John Martin with a comment about fatty liver disease. I think everybody knows that there's potential for it to advance on to even cirrhosis and hepatitis A, maybe some additional risk factor and like the previous speaker mentioned, there's no downside to giving it and it may be a protective factor along with, you know, the other recommendations about protecting

your liver when you have fatty liver disease. I think it's an appropriate measure.

(Chris Segal): OK.

(Rick Blackmire): The only real downside actually is the cause and effect in the efficiency. And then, if you take it the next step, I think that all people with chronic liver disease, it's also recommended that they have chronic (inaudible) that they be immunized for hepatitis B and now we're talking about a lot of money.

(Chris Segal): OK. (Inaudible)

(Rick Blackmire): This metric is specific I should say to hepatitis A only.

(Chris Segal): Right. Right. OK, any other comments about validity? So, should we vote? They voted five up there. OK. Let's vote on this issue.

Male: (Inaudible)

Suzanne Theberge: I think we're up to four voice votes now.

(Stuart Reynolds): Yes, this is (Stu), moderate.

(Miliana Bordna): (Miliana Bordna), I'm voting low.

(Chris Segal): It's three to seven. There's one more I think.

Suzanne Theberge: John, are you…

(John Martin): (John Martin) and moderate.

(Chris Segal): OK.

Suzanne Theberge: And is Phil still on the line?

Male: No, we lost Phil.

Suzanne Theberge: OK.

(Chris Segal): OK. So it's eight to three, I think in moderate if it's all right.

Suzanne Theberge: Yes. That's eight moderate. Three low.

(Chris Segal): OK. All right.

(Rick Blackmire): And moving this feasibility, this metric is already in operational use and there are data from stage 2. The results are very consistent with the similar data published in the VA and it's a sophisticated engine that they're using. The – I think it's feasible and the – in other words, on the preliminary, there were four high feasibility, three moderate, one low. No insufficient.

(Chris Segal): OK. Great. Let's vote – Any comments about feasibility or concerns?

Zahid Butt: So, in the feasibility, I know that we have a sort of large variety of data sources for that were used. I assumed those would be feasible even outside some of this sort of controlled settings for wider use.

(Chris Segal): Well, you know, that's a good point. They you have a proprietary analytic engine that is doing this measurement from my understanding. So, I think, to reproduce this if you weren't part of a health plan that Active Health is serving, you would have to recreate that rule then. Is that correct of our (inaudible) Active Health because I mentioned that?

(Bonnie Vair): Yes, this is (Bonnie) from Active Health. Yes, they could reproduce it. Our measure specifications are publically available for anyone who would like to use our measures along with the code sets. We make them publically available as well. And additionally, we've had several organizations contact us about using our measures and we've allowed them to be modified as long as they are aligned with the guidelines and the evidence and they are not straying from that, they can modify it to suit their capabilities as long as they remain true to the measure.

(Chris Segal): OK. So, an open source basically put.

Zahid Butt: Also - I mean, that does raise other issues though. I mean, if they modify the specification, are they truly - I mean, what are those parameters of the

modification because this measure with all the specification is going to be very rigorous process. If others can modify and claim that they are doing this measure, would that still be valid?

(Bonnie Vair): Should I respond to that?

(Chris Segal): Go ahead.

(Bonnie Vair): So, we really ask organizations to allow us to review if they're modifying in any way to make sure the measure is still very much aligned with sort of the, you know, the heart of the measure. We definitely don't say that it is an NQF endorsed Active Health Measure if they are straying too far from measure specification. So, we're definitely not allowing for a huge, you know, wide interpretations of the measure.

(Chris Segal): Yes. We're approving or voting on a very specific proposal and if anyone else represents a different set of measures as NQF endorsed, that would be incorrect, bottom line…

Zahid Butt: But would they then be able to claim that this has been approved by the measure developer/steward?

(Bonnie Vair): Not as an NQF-endorsed measure.

Zahid Butt: I see. So the NQF-endorsed measure is then only limited to Active Health or where Active Heath may be used to use this measure.

(Chris Segal): Right.

Thanks for clearing that up.

Anyone else?

OK. Let's vote on this.

Suzanne Theberge: So, that - folks, you need to vote by voice.

(Stuart Reynolds): Moderate for me, that's (Stu).

Suzanne Theberge: (Miliana)?

(Miliana Bordna): Moderate.

Suzanne Theberge: And (John)?

(John Martin): Moderate.

(Chris Segal): OK.

Suzanne Theberge: All right. So that's two high, six moderate, and three low.

(Chris Segal): OK. And then the next is the vote.

Male: (Inaudible).

(Rick Blackmire): Next is usability Active Health plans reports that they are planning on a year on year results making it available for public review at their website and the only unintended consequence I could see was a potential over vaccination of non-susceptible individual. Preliminary voting was high three, moderate three, and two low. I'll stop there.

(Chris Segal): Thanks. Any questions about that or concerns? OK then, hearing none, can we vote on that?

Zahid Butt: So I have a clarifying question, Chris. Is this usability for Active Health or for the general public at large?

(Chris Segal): I think it's for as described by Active Health. I mean, I don't know that we're – You mean in terms of is this usable by people that – think this way. If you were a third party and when you use Active Health process would be, you know, available for you to use and, you know, you know accountability in a sense in the same way.

Zahid Butt: Right. So, the usability is in the context of its usability for Active Health or Active Health related?

(Chris Segal): I think it's really across the entire healthcare spectrum of people.

Zahid Butt: But then the healthcare spectrum can't use it unless it's through Active Health from the previous conversation.

(Chris Segal): They could adapt the same rules and (inaudible).

Zahid Butt: They would have to be exactly the same thing, right?

(Chris Segal): Correct.

Zahid Butt: OK.

(Chris Segal): Voice vote.

(Riva): Voice vote folks say.

(Stuart Reynolds): Moderate for me. That's (Stu).

(Riva): Miliana.

(Miliana Bordna): Moderately.

(Riva): And (John)?

(John Martin): Moderate.

(Riva): OK.

(Miliana Bordna): So looks like we have one high, eight moderate, and two low.

(Chris Segal): OK. And then the last vote. Overall vote. Any final comments or concerns? OK, so let's vote on an endorsement for this or non-endorsement. And I guess the people that are on the phone don't want to do a voice vote, you can email (inaudible).

(Stuart Reynolds): Chris, this is (Stu). I vote yes.

(Chris Segal): OK.

(John Martin): (John) (inaudible).

(Miliana Bordna): (Miliana), I'm saying yes.

(Riva): John, was that a yes?

(Miliana Bordna): Yes, please.

(John Martin): Yes.

(Miliana Bordna): Yes.

(Riva): Thank you. Nine to one.

Suzanne Theberge: All right, so that's ten yes, one no.

(Chris Segal): OK. So I have to hop off now. So I guess there's one more measure. And I don't know if you want to continue on or want to do it a different time.

(Riva): Yes. I think we're going to have to reschedule and do it at different time. This is (Riva). Thank you very much (Chris).

(Chris Segal): OK.

(Riva): Just because we're almost at time, we do want to provide any opportunities for public comments from anyone. But just I think to give the final measure it's due time with everybody available. I think we'll need to reschedule the time to discuss it and so we'll be in touch with doing that. Any comments from the committee? OK.

Male: This is measure 0622, right?

(Riva): Correct.

Male: OK.

Suzanne Theberge: This Suzanne. I'll send out an email tomorrow morning to get your availability for our call following all the committee.

(Riva): Is there any comment from anyone in the audience, operator?

Operator: Thank you.

(Riva): Or everyone?

Operator: At this time, if you have a question or a comment please press star then the number one on your telephone keypad.

And again, that's star one to ask the question.

There are no questions or comments at this time.

(Riva): Thank you operator. All right, Andy, it looks like we're going to finish up. Did you want to have any concluding?

Andy Baskin: Just thank you everybody, I apologize that we couldn't get it done in time but I think the eMeasure thing is something we need to learn a lot about so it does take some time, so. Thank you and we look forward to the next call which will hopefully be the last call to do this level review.

(Riva): Thank you everyone.

END