

NATIONAL QUALITY FORUM

Moderator: Sheila Crawford
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11:00 a.m. ET

Suzanne Theberge: Good morning everybody and welcome to the G.I./G.U. stage II orientation call. Before we get started, if you are not speaking, if you could put your line on mute to reduce sound in the background that would be great.

So we'd like to get started by doing a roll call of the committee and then the developers and then we'll have the staff introduce themselves as well. And as we do the committee roll call, we're going to do a disclosure of interest. Since we are going to be doing some measure discussion on this call, we do need to start with a conflict of interest review.

So in the conflict of interest review just do a very brief introduction. Give us your name, where you are, and then any disclosure that you wish to make. Just because you make a disclosure does not mean you have a conflict of interest. It's just a disclosure. You don't need to go through your whole CV. We just want to hear about anything that might be relevant to the topics that we'll be discussing today.

In particular, we're interested in consulting, speaking engagements, grant money, research money, anything that's relevant to the discussion and we also want you to remember that conflict of interest and disclosure is not simply financial. Because of the nature of the work that we do many of your work may be volunteer. So we just want to hear about that as well.

And finally before we get started I just want to remind you that you serve as an individual not as a representative of your employer or the organization that may have nominated you. You're here because you're an expert in your field.

So with that said, I'm going to start reading off the steering committee list. I'll start with the co-chairs. We do know that several folks won't be on the call today as they were on Tuesday's call but I'm going to just go through the whole list in case anybody decided to dial in again for a second call.

Andy Baskin?

Andrew Baskin: Yes, hi, I'm here. So the only potential conflict of interest here is that ActiveHealth Managers a developer has a steward for two of the measures that are being reviewed. They are a subsidiary of my company Aetna and therefore I will not be voting on those measures but unless I'm told otherwise I believe I'm able to join in the conversation and discussion. But as I said I will not vote on those two measures.

Suzanne Theberge: OK, thanks, Andy. Chris Saigal? All right, Liliana Bordeianou? All right, Zahid Butt? Robert Ellis? Nancy Faller?

Nancy Faller: Hi, I'm Nancy Faller. And I have only one thing and that is that I'm on a journal which, journal editor which covers continents so.

Suzanne Theberge: Thank you. Edward Gill?

Edward Gill: Hi, this is Ed Gill, Euro Gynecology. I have no disclosures or conflicts of interest.

Suzanne Theberge: Johannes Koch? Richard Luetkemeyer?

Richard Luetkemeyer: Yes, good morning, I'm a general internists and I do have a disclosure of a potential conflict of interest. I was on the (inaudible) team that helped developed and implement the quality quest report that will be in front of you later today. I will not be voting and I will not be part of the conversation.

Suzanne Theberge: Thank you, Alayne Markland? John Morton? Anne Pelletier-Cameron? Stuart Reynolds and Phil Schoenfeld?

Philip Schoenfeld: Phil Schoenfeld, gastroenterologist at University of Michigan. Conflict of interest I'm the co-author of the American Society of Gastrointestinal

Endoscopy in the American College of Gastroenterology and American Gastrological Association physician statement on quality indicators in colonoscopy.

Suzanne Theberge: Perfect, thank you. Are there any committee members who didn't introduce themselves on the line?

All right great. And if we could just have the developers introduce themselves just your name and organization so we know who's on the call.

(Angie Veneti): This is (Angie Veneti) from the National Committee for Quality Assurance.

Gail Amundson: This is Gail Amundson independent consultant previously president and CEO of Quality Quest, developer of the colonoscopy quality index.

Katherine Ast: This is Katherine Ast at the AMA PCPI.

Suzanne Theberge: Anyone else?

(Sheila Mastic): This is (Sheila Mastic) with the American Society for Gastrointestinal Endoscopy.

Suzanne Theberge: All right, anyone else?

(Walter Park): Yes, this is (Walter Park) with ASG as well.

Liliana Bordeianou: Hi, are we introducing ourselves?

Suzanne Theberge: Yes.

Liliana Bordeianou: Sorry, I just plugged in. This is Liliana Bordeianou. I am a colorectal surgeon.

Suzanne Theberge: OK, we are having the steering committee members do a very brief disclosure of interest. So if you have anything to disclose that would be relevant to the measures that we're discussing today if you could do that that would be great.

Liliana Bordeianou: I don't have any relevant disclosures. I am a consultant for American Medical Systems but that is not pertinent to this discussion.

Suzanne Theberge: OK, thank you. All right, and if I could just ask folks again to put your phones on mute when you're not speaking that would be great. And is there anybody else who has not introduced themselves?

(Nancy): This is (Nancy) (Inaudible) from the (ASCE).

Philip Schoenfeld: How do we put it on mute again?

Suzanne Theberge: (Natalie), could you give instructions on how to put your phone on mute? Operator?

Operator: Please press star six to mute and un-mute your line.

Suzanne Theberge: Great, thank you. All right, so now I'll just do a quick staff introduction. This is Suzanne Theberge. I'm the project manager for the project in this phase. And I'm joined by my colleague, Ashlie.

Ashlie Wilbon: Hi, everyone. This is Ashlie Wilbon. I am backing Suzanne up on stage II. I'm looking forward to working with you guys again and wrapping up the project pretty soon. Thanks.

Taroon Amin: Hi, this is Taroon Amin senior director on this project. Happy to talk to you guys again.

Reva Winkler: Hi, this is Reva Winkler. I'm the senior director here at NQF. I will be taking over for Taroon on the second stage of this project.

Evan Williamson: And this is Evan Williamson, project analyst, looking forward to working with you all again.

Suzanne Theberge: All right, so on the agenda for the call we're going to go over the CDP and process and timeline for stage II of the project. And then we're going to go in for reviewing the stage I checklist and discussing that.

The measure developers are on the call to serve as a reference for committee members. So committee members if you have questions as we go through the checklist, please feel free to reach out to the developers and ask those questions.

After we have that discussion we're going to just talk about measurement, introduce you to our criteria for stage II and then we'll have time for questions and after that we'll adjourn. So I'm going to turn this over to Evan to talk about the CDP process for stage II.

Evan Williamson: Hi, everybody, we're going to do a quick overview of the contentious development process especially as it pertains to stage II here in this two-stage process.

So as you can see here we split it up into two stages where we went over the measure concepts in stage one and now for stage II we'll be going through the fully specified measures. So this will be a focus on the scientific acceptability, feasibility, and usability of these measures after we've focused on just the importance to measure and report during stage one.

You can see if the process will go through the steering committee approval, it will go into a comment period, and the difference between stage II and stage I is there will also be a two-week vote after the 30-day comment period. We're going up to the membership for a vote. After that it will go to our CSAC and then board ratification which will result in an endorsed measure.

Here we have it laid out in sequential order. We went through a technical assistance period again here for stage II. We have similar a process during stage I where measures, developers had to submit at least one of their measures for technical assistance.

They also – the developer must also demonstrate the checklist that was provided after stage I that the elements on there were addressed and on this call we'll be addressing that through the survey that was sent to you this morning.

So to go through the review process we have two conference calls scheduled to review the measures to go through the scientific acceptability, feasibility,

and usability and we'll compile a draft report. It will go out for comment, member voting and then again through CSAC and board approval.

So we'll be evaluating stage II. We'll have a checklist review and then we'll go through that today just to see if that, if the checklist was satisfactorily addressed. And then it will move on into the remaining evaluation for scientific acceptability, feasibility, and usability. So within the scientific acceptability you'll see we'll do a deeper dive on the measure specifications and the testing results. Are there any questions at this point about what will be evaluated in stage II?

Great, let's move on. So I want to go over the activities and timelines. You see we had an orientation call on Tuesday where many of your fellow steering members participated and the second of those orientation calls. We'll have two conference calls scheduled for April 3rd and April 8th where we'll be doing the bulk of the review. Please make sure you check and have those on your calendar. Those are very important.

Following that for the month of May will be the public and member comment. Member voting occurs in July and then August will be the review and board endorsement.

This will also be subject to a 30-day appeals period which will occur in September and we'll give you more information on that if we receive an appeal.

So starting today we have seven measures to evaluate. Again you saw all of these during stage I. They were approved as concepts and now the fully specified measures have been submitted by the developer for review. Five of them are maintenance measures meaning that they were previously endorsed by NQF and are going through the maintenance process. And two are new measures so this will be the first time we'll be looking at the specifications, the project acceptability and the remaining criteria. We have uneven split for this. We have six GI measures and one GU measure. But we'll need your expertise in this area for both elements.

Here is the list, these are the GI measures. We have measures from Access Health Management, the AMA PCPI, Quality Quest and ARC. And then for the GU measure it's from NCQA.

So this is the list of the measures. Do we have any questions about what we'll be going over today, the list of measures? Great.

Well at this point, I'll turn it over to Ashlie and we'll start reviewing the measure checklist.

Ashlie Wilbon: OK, hi, everyone. So just to kind of give everyone a little bit of background and as, you know, we had another orientation call earlier this week with the other half of the steering committee. So I'll kind of proactively address some of those things that came up as questions for that group as I give a brief introduction. But for the other concepts that were, the GU concepts particularly that were approved by the committee from the other developers those concepts were purely just concepts and the developers have opted to take some additional time to further stretch those out and test them before bringing them back for full review of the remaining criteria. So that's why we have somewhat of an uneven split and that the GU measures, I'm sorry GI measures were just a little bit further along in the development process and ready to bring back immediately back for stage II evaluations.

So we recognize that it is somewhat uneven but the developers have – it's up to them and to their discretion to decide whether or not they would bring it directly back for stage II or if they were going to take some additional time to further specify the measure.

So just to give a little bit of background on how we got to this point. I mean obviously you guys were there with me so but it's been a while, so I'll just refresh everyone's memory.

If you recall at the steering committee meeting in August that we had last year as you were going through each of the concepts staff was taking note of the various recommendations and concerns that you guys brought up during the evaluation of the measures of the concepts. And what we did as a follow-up to that meeting was to document each of those and provide them to each of the

developers in the form of a checklist. So while there was some standardized items on that checklist reminders about testing and all that stuff each of the checklists were really specific to the measures to each measure and to the developers based on the input that you provided during the evaluation of the concept. And so that's what we're reviewing today.

The checklist as this process was developed was set up to be somewhat of an entry point into stage II such that developers would have to respond in some way to each of the items on the checklist to describe either how they were able to address and implement the recommendations from the committee or rationale for why they were not able to do that.

And so the purpose of this section of the call is really to review those checklists with the steering committee and determine whether or not the responses from the developer are adequate or whether you feel like their responses are adequate and you would like them to move forward to the next stage of the evaluation in which you would really dig much deeper into the measure specifications and apply the remaining criteria.

So what we're asking for in the survey you should have received this survey via email from I think it came from Evan. In there is a link from SurveyMonkey in which you will be asked two questions about each of these measures.

The first is has the developer adequately responded to the committee's recommendations and concerns indicated on the checklist. And if you indicate no we'd just like a brief explanation as to why you believe that.

And then the next question would be should this measure be considered in stage II and evaluated against the remaining criteria. And again there I believe we ask you if you say no that we would just like a brief explanation as to why you believe that as well.

What we will do after this call is take the results of the group that was oriented earlier this week and the results of you guys votes today, compile them and that will determine which measures we will be evaluating on the call in April for the full evaluation against the remaining criteria.

So what we'd like to do if possible is if you are sitting at a computer we'd like you to pull up the SurveyMonkey and be, you know, entering your votes on each of these measures as we go along. And hopefully by the end of the call you can submit your votes and we'll have it by the end of today so we can have a quick turnaround on that information for you.

So I think I'll pause there. Does anyone have any questions about kind of the process, the purpose of this section, the purpose of this exercise or anything like that?

Richard Luetkemeyer: This is Rich Luetkemeyer, if you're not voting on a specific metric do you just leave it blank?

Evan Williamson: Yes, that would be great.

Ashlie Wilbon: Yes, you can do that. All right, so this portion is going to be primarily led by Andy but I did want to give just a brief introduction to this portion of the call. I will also note that in our first memo, our very first memo I know you guys have gotten quite a few emails from us, we apologize for that. But in the very first email that describes stage II process there was a table at the end that indicated lead discussion. If any of those lead discussion are on the call and you would like to kind of give, you know, an opinion or your assessment of the checklist for that particular measure we welcome you to do so and Andy can open that up for you.

I will also briefly as you guys begin to review each checklist item just give a really high level summary of some of the points that came up in the group from earlier this week and I think that will be it.

So Andy if you want to take it away. I will also say we're going to start with the quality question index for I think that will be the last measure on your SurveyMonkey so you'll have to kind of forward through to get to the end. And then we'll go back to the beginning. It's second to last sorry. It's number 20 ...

Evan Williamson: Fifty six.

Ashlie Wilbon: Fifty six.

Andrew Baskin: OK, thank you, Ashlie. This is Andy. So I didn't know we were going out of order but I'm happy to go out of order. Are you going to be displaying the checklist comments? I mean I'm looking at them as I do this but the recommendation and responses while we're doing this on the web?

Suzanne Theberge: Yes, we're going to pull that up right now so.

Andrew Baskin: OK, there it is good.

Suzanne Theberge: Just a minute.

Andrew Baskin: So if you pull down to the page for the call in the index that would be helpful. So when we do this first of all it's a virtual meeting it's obvious I don't recognize everybody's voice over the phone. I apologize.

So if you can remember to say who you are when you're speaking that would be great. I'm hoping that we'll do this in a very systematic way meaning, you know, we'll look at each particular checklist item, discuss that one, move on to the next one, discuss that one.

We don't actually come to any individual decisions necessarily because that comes out in your vote. But I guess you'll get a sense of how others feel. Hopefully people will feel comfortable speaking up.

We'll try our best not to talk over each other. So just wait until somebody stops and maybe some gaps in the conversation while I wait to see if someone is going to the next person is going to speak up. That's how we'll do it.

I really urge everybody to not be tempted to go beyond this particular checklist item. Don't go to a separate checklist item and don't go outside of the checklist. Because frankly all of the other discussions occurred at stage one and there will be plenty of discussions at stage II for all the other related issues to these measures.

Frankly at this point our real job is to either say yay or nay to move on the measure and it's based on the additional responses to these checklists that

we're going to make that decision and what we've already decided about those measures to get them this far.

So we don't need to rehash old stuff and we don't have to bring up new stuff because that will happen in stage II. So I thank you, or we'll never get done.

So let's go to the first one. Ashlie, are you there? And what I'll do is I'll ask the lead discussion if they're on the call, if they have any comments, they don't have to have comments, they may not even be on the call. And then open it up to anyone else there.

So oh boy that's, I'm sitting there trying to enlarge the size of that on my screen so I can read it. OK so this one will be the most difficult because it's the most composite measure and therefore there's multiple components and once again let's try and talk about each component individually.

Got it where you want it, Ashlie? OK so item number one is not an issue. There were no recommendations so that's an easy one.

So item number two and this was the standardized risk assessment was performed and documented and we had some the initial comments were that this is basically in some people's words one of these check the box things. It's a standard of care should be done at every procedure it's unclear why this in and of itself is considered a quality metric.

Now looking at the response here I'm thinking that the thought here being that this is part of, part and parcel of a larger set and that may be individually it will not have withstood its own quality metric but it didn't need to because that's not how composites are created.

But that it is essentially linked to the other components and as part of a complete assessment and that's how I kind of read this. Is there a lead discussion Phil were you the lead discussion on this one?

Philip Schoenfeld: I was the lead discussion on this one.

Andrew Baskin: So would you like to comment first and open it up?

Philip Schoenfeld: Sure, and I could potentially go through the items if that's OK Andy?

Andrew Baskin: Well let's do one at a time and see if there's other comments because I, because on this one what happened is this time we jumped all over the place and there was no sense of what we decided on each item. So just let's stick to item two for the moment.

Philip Schoenfeld: Absolutely that's fine. That's fine. OK, so, you know, bottom line is the committee gave a fairly blunt or straightforward recommendation saying it should be removed from the composite and the sponsor agreed with that and chose to keep it in there.

And I would just note that, you know, this is a process measure not a measure of measuring the quality of whether or not somebody has done a good colonoscopy per the opinion of the committee based on the extensive additional discussion we had after we initially rejected this in stage I and the sponsor appealed.

Andrew Baskin: Thank you. Are there other comments from folks on the committee regarding this issue? That's the pregnant pause I'm going to give so hopefully people aren't uncomfortable with that little bit of wait.

Not hearing any I would actually like to make a comment here. I mean I certainly realize that had this come out as a single measure in and of itself I would not have passed this along as a measure. I would not have approved it.

In the context of the larger composite I look at this as yes it should be performed. It is probably being performed regularly. But I'm assuming that there is certainly there may be some gaps in that it's not being documented that it's been performed otherwise it wouldn't have been included in this and I didn't look at the performance gap information right this second to check that. But I'm sure that will occur at the next stage anyway.

And I look at this as is kind of do no harm kind of doctrine. So what even if it doesn't stand as a quality metric on its own what is the harm, who's being harmed by putting this in the metric if the expectation is it should be, it should be performed on every as part of every colonoscopy and every other procedure for that matter. But, you know, why would this be harmful to patients by having this continue in the measure. And I'm looking at also is the

idea that in my mind it doesn't do harm to patients. And to have this prevent the other parts of the measure which do meet more robustness in terms of component of an actual being a quality measure each component why risk them not going forward because of this piece that is not hurting anybody.

So does anybody have a comment about that? But that's certainly my personal feeling?

Ashlie Wilbon: Hi, Andy, this is Ashlie. I'm sorry I just briefly before we go forward I just want to make sure that we're clear like really the discussion should be about the developer's response to the recommendations.

Since the committee has already made a recommendation about this component I don't want us to go back to wavering and changing recommendations in stage I since we've already made that recommendation. So really let's keep it to the developer's response to what the committee has already decided.

Andrew Baskin: No I understand that. But at the end of the day we're going to be voting on the entire composite and each of us has the option of saying yes this is, you know, I accept this explanation, they want to keep it for whatever reason they want to keep it and I'm just pointing out that I think the explanation is reasonable in my opinion and that I'm accepting of this.

That's the kind of discussion I'm looking for. I'm not looking for a debate as whether it's a quality metric or not a quality metric. It's is this response, could someone consider this acceptable. I do consider this acceptable.

Philip Schoenfeld: OK, well Andy I guess I would just say two things. I certainly agree with you this is a do no harm part of the index. And second that there are multiple things like that that we could then make recommendations about like documenting that an informed consent was signed, documenting that a timeout was performed prior to beginning the colonoscopy. I mean all those things are part of a standard medical practice that then we potentially could discuss including.

Having said that though I would note two major things. First, that the committee gave a very precise recommendation to remove this from the composite and the response from the sponsor was that no we disagree OK.

The second part that I would just emphasize is that let me try and just remember, I lost my train on thought on that one. We gave them a specific recommendation not to do it. They chose not to go on set, oh and but having said that Andy if this was the only thing where there was a disagreement on I'd totally go along with it. But we're ultimately going to find that virtually every recommendation we made they just disagreed with and didn't change anything so I agree with you. If this was the only thing ...

Andrew Baskin: OK, but our point is that they don't necessarily have to agree with all of our recommendations if they give a rationale and we can accept the rationale you're saying that some don't accept this rationale and so do and that's fine and that's fine. I was just saying that I accept it but if there's no other comments.

Liliana Bordeianou: I have a question.

Andrew Baskin: Go ahead.

Liliana Bordeianou: This is Liliana Bordeianou. So when we reviewed other measures and they were not composite measures if we said that this measure should not pass then this measure didn't pass and we didn't go into looking at what other commentary the developer had. Is that correct?

Andrew Baskin: Yes, if it didn't pass stage I it didn't pass. But some of them passed stage I with recommendations. These are the one's with recommendations right.

Liliana Bordeianou: So we decided that doing this composite measurement we will look at each individual and task them or not task them. So this item did not pass the committee so we shouldn't be discussing the commentary to the items that did not pass the committee.

Andrew Baskin: Well I beg to differ in that. We make a recommendation on the checklist and it's absolute only in the sense that the recommendation must be addressed. It

doesn't mean that they have to do exactly what we said if they can come up with an explanation that satisfies us as to why they don't do what we ask for.

What we're deciding here individually each of us for each component so that you can add it up at the end and decide how you're going to vote is do you think their answer, and you don't have to say it out loud but I happen to say out loud what my feeling is if you think their response to the recommendation is such that they gave a good reason as to why they're not following the recommendation and it's acceptable to you. If it's not acceptable to you the reason then you should say hey it's not good enough for me and move on. And that's fine, that's each of our decisions to make.

Liliana Bordeianou: And what I'm saying then is we're treating this developer differently from all the other developers that were rejected in stage I who only had one measure and we didn't give them an opportunity to speak up. Why are we giving them special treatment?

Andrew Baskin: Well I don't think we are. See this is, first of all this is the only composite measure with this difficulty. So what we said was there were parts of the composite measure that we felt made it through and there were parts that we felt that as individual items wouldn't have made it through and we would, we would we gave the impression that we would look favorably upon the composite if the recommendations were addressed with that individual components.

This component the recommendation was remove it and the rest of it, you know, well we said that about several of them. But, you know, if they follow those recommendations that we would feel comfortable. That's, we've made recommendations about other ones too and if we don't find the other recommendations were satisfied then we're going to reject those measures. This one just happens to have multiple components to it.

So it just makes this discussion a little bit more complex as to how you want to handle the fact that if six of the seven components you say they've addressed wonderfully you like the response you got and one you don't at the end of the day you're going to have to say yay or nay on the entire measure.

And that's going to be you have the you can say yay or nay and that's OK.
And if your feeling is one component doesn't address the way I want I'm
going to say nay you have the option to do that.

Philip Schoenfeld: OK, but Andy just to be clear it's the exact opposite of the example you gave.
Where for six out of seven for what we recommended they disagreed and then
we changed it.

Andrew Baskin: Well we're going to get there. So let's go to the next one.

Philip Schoenfeld: OK.

Andrew Baskin: We're going to go through each one. I mean this is due process. You know
we made a recommendation and we should talk about each of the
recommendations and the response as to whether we think the response is
adequate.

It may turn out our answer is going to be the same one every one. But we're
going to do it because it's the only way we can do this and be complete.

Philip Schoenfeld: OK, that's fine, that part I totally agree with.

Andrew Baskin: OK.

Philip Schoenfeld: I'm just saying based on the example you gave if it was one out of seven I
understand your rationale and I'm just explaining that ultimately it's going to
be six out of seven except the one that they just gave.

Andrew Baskin: We'll find out when we get to the end.

Philip Schoenfeld: OK.

Andrew Baskin: All right, so if there's no other comment from the committee on item number
two we'll move on to item number three. And I'll give a second to see if
anyone else has a comment.

OK so this next one was regarding the bowel prep indicator as to whether it
was this is whether the bowel prep was adequate or not. And you can see the
categories of preparation here. And our recommendation was that this once

again should be removed as a component and Phil go ahead you were taking the lead.

Philip Schoenfeld: No we said very precisely to the sponsor that simply documenting what the bowel prep was, the quality of the bowel prep was is a process factor. It does not tell you anything about the quality of the colonoscopy being performed. And that goes back to the idea that, you know, you grade the quality of your bowel prep based on how much effort you put in during the colonoscopy to suction out all the stool so you get a good look at everything. That's the assessment of quality.

So we gave them a precise comment saying that simply documenting what the bowel prep was is not an assessment of quality and we recommended that it be removed from the composite. And the sponsor basically said we disagree. So we're not going to remove it.

Andrew Baskin: Any other, thank you Phil. Any other comments regarding this particular item?

Gail Amundson: Andy, this is Gail from quality.

Andrew Baskin: Yes, Gail, let me ask the committee first, Gail. Because this is, I actually do have a question for you about this particular one but I'd like the committee to have their option to speak.

Anyone on the committee have a particular comment here or a question? I do have a question Gail and it's going to be specifically for you because I have a understanding of how this particular component works and tell me if I'm right or wrong here and explain how I'm wrong if I am.

My understanding is if there was an inadequate bowel prep that the case is actually removed from the measure and that it's not it doesn't actually the case doesn't count in the denominator because when they would come back with an inadequate bowel prep is when the case would be entered into the denominator of the measure. Do I have that wrong, is it an exclusion criteria?

Gail Amundson: The answer, yes you have it partly correct. The majority of the procedures have a bowel prep that's sufficient to assess presence or absence of findings. Some don't. Those that don't that have inadequate bowel prep are excluded from the denominator of the measure calculation. The ...

Andrew Baskin: So based on the excellent, good, fair, and poor which ones would be excluded from the denominator?

Gail Amundson: Poor and unsatisfactory.

Andrew Baskin: Poor and unsatisfactory. So I guess what I'm trying to understand Gail and help me with this is it seems to me that this is not actually a component of the scoring it's an exclusion criteria from the, it's a criteria from being in the denominator at all and that if you have a poor bowel prep you're not dinged on the score. The case doesn't count. It's not even measured. So that's why I'm wondering why would this particular part of it why wouldn't this be included as a criteria in the denominator for the eligible population as opposed to a component of the, component of the measure. I don't understand why it's a component.

Gail Amundson: So the reason it's a component the logic behind that is that this is a procedural composite which means that the whole procedure is done well and it was needed and there weren't bad outcomes from it.

Part of the process of doing a high quality colonoscopy is specifying the adequacy of the bowel prep. The answer to that is then used to identify cases that shouldn't be fully scored because the prep is not sufficient to actually answer all the rest of the questions in the composite. And those are removed. But the process the factors like it's like other elements that should be standard and actually aren't. Excuse me, you can see the citations from (Morota) there that ...

Andrew Baskin: No I understand that. We've seen the citations so I don't want to get back into that story. So I still don't understand that every case that's counted in the denominator will have passed the bowel prep. If you didn't pass the bowel prep you're not in the denominator.

Philip Schoenfeld: Andy, Andy I think the point is if because I had a pretty detailed discussion with Bonnie Paris from Quality Quest. You fail in your score on the entire composite if you don't record.

Andrew Baskin: So that's the point. It's only the recording that actually makes any difference to the score.

Philip Schoenfeld: Correct.

Gail Amundson: It's the actual assessment of the prep. So did you do it yes or no? That's what's called ...

Philip Schoenfeld: Well no, no did you document it. Did you put excellent, fair, good or poor. Did you put that in your report? You have to, you're documenting it. You lose out and get a negative like you did not do your colonoscopy quality index composite if you don't document.

Gail Amundson: Right, and that ...

Philip Schoenfeld: Inaccurate.

Gail Amundson: That's correct. So if someone is looking at a procedure note and trying to determine what intervention should be taken for a patient given some subsequent finding and they look to see the adequacy of that examination if there's no mention of what the bowel prep was like they are left without the information that they need to take clinical action at a subsequent point. So this is ...

Philip Schoenfeld: I don't know what clinical action you're talking about because you don't change when you did your clinical action if it's a fair, good, or excellent prep. The only action that's different if it's a poor prep and you reschedule it. But if you think you have a different opinion about that I'd be pretty happy to hear it.

Gail Amundson: I think ...

Liliana Bordeianou: Liliana Bordeianou. I have another comment.

Andrew Baskin: All right, well Liliana let me give Gail just a chance to say, to respond directly to what Phil said and then Liliana I'd like to hear your comment.

Gail Amundson: I don't think I have a response to that. I'm just saying it's an important procedure, it's assessing the prep, that's how people know what's the, how much validity can I attribute to this examination findings and that's just the reason it's in there.

Andrew Baskin: Understood.

Philip Schoenfeld: Let me just be precise then because this is what the committee talked about during the appeal process. What, whether or not I write down a good prep or a fair prep does not say anything about the quality of the colonoscopy that I actually performed.

I could write down I got a poor prep in 40 percent of my colonoscopy patients. 40 percent of the time I got a poor prep. All 40 percent of those people with a poor prep I still do fine on my colonoscopy quality index because I wrote down it was a poor prep.

Or 40 percent of the time I get a fair prep. I still get a perfect score on my colonoscopy quality index as long as I put down it was a fair prep.

But that does not associate itself with whether or not I perform a quality colonoscopy because one of your jobs as an endoscopist is to do the best possible job to clear out stool during the procedure. And that is why it when we had a prolonged conference call about this we said that merely documenting bowel prep did not relate to the quality of performing the colonoscopy.

Andrew Baskin: Thank you Phil. Liliana you wanted to make a comment? I appreciate it Phil that clarification. This conversation has been helpful for me but I think we need to move on.

Liliana does want to make a comment. We need to have all committee members a chance to speak.

Liliana Bordeianou: I'm sorry to be belaboring this point but original recommendation that we made when we discussed this composite measure in stage I was to reject the measure. And then we had an appeal and there was a conversation about going to each individual measure one by one and looking at each individual measure and deciding whether or not each point within this composite is a go or a not.

So my understanding was that when we said it's a non go that part is removed from the composite. And what we're left with is what we're left with and that's the one's that we want them to comment on.

Andrew Baskin: No we actually asked them to comment on whether on our statement that we think it should be out. They do have the right to address that and if they decide not to do it we have the right to say too bad then. We're not going to move the measure on. But they, when we put out, when we put out the checklist it is to enable the measure developer to reply to that even though this we happened to have an appeal in between they still have the right at this level to respond. We may not accept their response but that's what we're choosing today to accept it or not accept it. And you're saying it's not good enough.

Liliana Bordeianou: I think we're giving them a different treatment from every other developer on every other measure that was rejected. And we're discussing the issue that we discussed in the conference call last time. We already rejected the measure of bowel prep. So why are we now looking at the answer that they are giving in step two. This should go back to step one next year. They can give us all the data. We can have a real meeting eye to eye not on the phone where half of us are not listening which is, you know, a handicap for this committee. I just think this is inappropriate. We should only review the measures that we thought were worthwhile pushing forward.

Andrew Baskin: Well, well I appreciate that Liliana and I but we did put it on the schedule to be as we thought was due process to do. So I don't think we're going to go back on that decision at this moment in time. I do think we should just go through the list and we do our final vote and that's the way it should be.

At some other time if we want to discuss the process of why the process you may or not feel was followed for this measure differently from others I think that's a different issue and one that we can't undo at the spur of the moment here. But I do appreciate your comment.

Liliana Bordeianou: I just wanted to ...

Andrew Baskin: I understand yes.

Gail Amundson: Andy this is Gail I have a question for you. Is that comment is that, you know, it is really challenging as a measure developer on this because we submitted a measure that's fully tested and it's been in use since the year 2008. It was developed by GI doctors and surgeons ...

Andrew Baskin: We understand that Gail but this is not the time to present the measure.

Philip Schoenfeld: Christ.

Gail Amundson: OK, please let me finish. Is that when you, this committee is not a measurement development committee. And so, you know, just saying that a measure a composite measure should be re-configured when it has been in use for five years and tested is measurement development work.

Andrew Baskin: The committee ability to say yay or nay.

Philip Schoenfeld: Why do we have a committee, stop come on ...

Andrew Baskin: Please Phil stop, Gail stop we're not going down this conversation. This committee has the ability to reject or not reject. If the committee chose to say here are some things that you could do that would make it more likely for us to accept we can say that. If you don't have any interest in changing the measure that's fine too. But this committee either rejects or not rejects the measure going forward. And we're not going to have this debate over again and we're not presenting the whole measure again.

So let's go to the next item on the list. I think we've discussed this item as long as was necessary to see whether the committee felt that the response met our needs or not.

There is nothing for item four, there's nothing for item five. We did, we did make a comment about item number six about the essential polyp information being recorded.

And there was a comment made a recommendation made that whether there was detection or not detection not just of the information about polyps that were detected. There is a response here.

Phil, do you have any comment about the response as to whether that response addressed our issue not addressed our issue?

Philip Schoenfeld: It's very straightforward as a committee we said you have to document among the polyp information. If the polyp was an adenoma precancerous polyp that is actually the goal of doing a colonoscopy. The developer chose to disagree with that and to not include that in the composite.

Gail Amundson: No, that's not accurate. The polyp information is the information recorded at the time that the polyp is removed. That adenoma yes or no is not a known piece of information at that time.

In the last item of the composite whether or not the pathology comes back as adenoma is included, incorporated into the measure in terms of appropriate follow-up. So in a sense what you are looking for is in a different part of the composite. It's not in this part.

Philip Schoenfeld: Gail, I understand exactly what you're saying. But the decision of the committee was that you needed to go back and include as part of the colonoscopy index everything you're documenting when you include that information whether or not it was an adenoma.

I understand what you're saying; you have a separate measure on that. The conclusion of the committee was we need to document it as part of the colonoscopy quality index after you get pathology back.

Gail Amundson: No it is in the quality, it is in the index, sir.

Philip Schoenfeld: Oh my gosh.

Gail Amundson: It's in the last ...

Philip Schoenfeld: Your last line is therefore we do not include whether or not an adenoma was detected in this component.

Gail Amundson: It's in this component. I'm saying it's in a different component the adenoma.

Andrew Baskin: Well we'll get to that component. So is there a comment about this particular item number six not we'll get to a future item and see if our recommendations were addressed or not. Any other comment on item number six?

Philip Schoenfeld: I'm just saying down the checklist we said our recommendation and I'm just going to quote this specifically. The information recorded about whether the information recorded about the polyp should include whether or not the adenoma was detected.

The last sentence of their response is therefore we do not include whether or not an adenoma was detected in this component. And it stops there.

Andrew Baskin: Right in this component. I got it. So we've heard that and we have no further comments on that.

We're going to move on and I do think that there is some information about pathology that will come up in a different component. But we'll see what that says when we get there.

Item number seven withdrawal time was recorded. And our point here was withdrawal time in and of itself was not an indication of quality. And that the other components of information that would make it an indication of quality would have to do I believe with adenoma detection rates which are not part of this particular measure.

I understand it is measured elsewhere as a separate quality measure. But measuring our recommendation I believe was it measuring withdrawal time in absence of that. And it doesn't, doesn't pass muster as a component. Phil, I hope I said that properly.

Philip Schoenfeld: I will, I will at this point I am just going to start directly quoting what's on the checklist. The recommendation from the committee was getting credit for simply documenting the withdrawal time is not an indication of a quality colonoscopy as the colonoscopist could get credit for a withdrawal time that is outside the timeframe that is shown to produce higher adenoma detection. Further without any linkage the colonoscopist adenoma detection rate within the measure the relevance of this component is greatly diminished. The committee recommends that this component be removed from the composite.

The response of the sponsor was ultimately that failure to record withdrawal times diminishes colonoscopy quality so that they chose to leave it in without making any attempt to quantify whether the endoscopist has a withdrawal time of six minutes or greater or not. So bottom line is we recommended they remove it in its current form and they chose not to do it.

Andrew Baskin: Any committee comments that anyone wants to make? And I have no particular comment either as a member of the committee. So let's go to item number eight of the series ...

Gail Amundson: Andy, I need to respond to this one. This is Gail.

Andrew Baskin: Well it wasn't actually a question, Gail. But I will allow you to give a very brief comment if you want to respond to that.

Gail Amundson: OK, so just like in adenoma detection rates is an average of multiple procedures the colonoscopy withdrawal average time of six minutes or greater is typically recorded on multiple procedures. And so that's the reason that this is very similar to a surgical checklist. This is an important perspective on colonoscopy quality. It's part of the literature base and it's recommended in the geo guidelines.

Andrew Baskin: OK, and thank you. We've heard that presented before though. But thank you for being brief on that.

Gail Amundson: I just ...

Andrew Baskin: I think the committee is aware of that.

Gail Amundson: OK.

Andrew Baskin: If we go on to item number eight free of serious complications. If you scroll up a little bit there thank you. This one here not sure I understand the response. We agree to include in the timeframe the component, oh OK our issue was if there were complications, right, our issue was if there were complications some complications occur soon after there is a different set of complications that occurred at a later time. Phil you wanted to make a comment?

Philip Schoenfeld: Right they agree to, so the sponsor, hey I don't mean, I'm not being flippant here I'm being positive. The sponsor agreed with this recommendation so they changed the title of this component to free of intra procedural complications. So I'm happy about that. They changed the component.

Andrew Baskin: OK, so you're accepting of the response there. Any other comments regarding this? And I think we can move on to item number nine which is the appropriate follow-up to the recommendation. Phil you wanted to comment on this one?

Philip Schoenfeld: I'll just quote again directly. We said that the appropriate follow-up recommendation that the sponsor needed to "clarify the time range" specified to when the follow-up recommendations can be given to the patient. And their response was we have not specified a time frame for providing the patient with the follow-up recommendation nor do we collect information on the number of days given. The ultimate bottom line is they chose not to adjust their composite in response to that recommendation.

Andrew Baskin: Anyone on the committee have a comment regarding this one? And I believe that was, is that the last item?

Ashlie Wilbon: That was the last item.

Gail Amundson: Andy this is the one where the pathology results actually are part of the calculation for appropriate follow-up. An appropriate follow-up is when is the next procedure recommended. And so they adenoma yes or no is part of this

item the one where, you know, on the earlier item it was at the time of the procedure documentation.

And the other thing I would say is that they're in the process of collecting the data for this measure. There's a time window for submission of data and all the surveillance screening colonoscopies. And if this were to not have been communicated to the patient within that window of time which is I'm going to base it on my memory here but I think the centers have it's either 15 or 30 I think it's 30-days within close of the quarter to submit the data that it would be scored as a negative but that does not happen. We don't see that happen.

Andrew Baskin: OK, thank you for that clarification.

Liliana Bordeianou: I have one comment. I am sorry, I just wanted to say one more comment about how we're treating this particular measure as opposed to the other measures and then I'll shut up.

So when we're looking at any other measure whenever the developer even opens their mouths and try to say something after they've presented their measure for the allotted of five seconds during the stage I they were asked not to speak unless spoken to. This particular measure is being discussed in very, very much detail and the developer is given the opportunity to respond to every, every comment that we're making and I feel like they're being treated differently from everybody else. Why is that?

Andrew Baskin: Well I don't have an easy answer for you and this is something that will be evaluated after all the events. There was, I understand on today's call that's an issue somewhat and I tried to hold it back but I agree I have not been holding the line here because this was not meant to be a discussion. But if we have specific questions developers are here for help and actually I think some of the comments I thought were trying to address our specific questions even though they may have been later on the same question may have been addressed. But I appreciate your comment about that.

One of the issues here was that there was extreme difficulty in being able to review a composite measure. There is actually a lot of issues even with NQF in general about what constitutes review of a composite measure versus a non-

composite measure which created a lot of the extra work that's gone into this one. I appreciate that some people would think that maybe it's been too much. Others would say it's been too little.

That would be part an evaluation of the process but at this point we've completed this review and we'll take your comments into account when we do kind of the post mortem or the after the fact of, you know, how in general did this stage one, stage II process go. So thank you for sharing that.

But at this point I'm going to take a moment to ask everyone to vote. I'm literally going to give people a few seconds to vote so we don't do it during the next conversation. And I'm sorry someone is trying to break in with a comment.

Philip Schoenfeld: Yes, I just want to, I just feel like I have to make this comment and actually ask a question. Ashlie or Evan at stage I when we voted on this as a committee what was the vote? I believe it was 80 percent of people on the committee voted against moving this forward to stage II. Do you have precise numbers on that?

Ashlie Wilbon: This is Ashlie. I don't have them in front of me but it was something like that. It might have been more total like three, because we did a component like a component vote and then we also did an overall composite. But it was close to that yes.

Andrew Baskin: I mean it made it to the checklist review I don't know why but it did.

Ashlie Wilbon: Well every developer got a checklist and we did track everything that the committee discussed on the checklist and I ...

Andrew Baskin: OK, so our process is that even if one doesn't make it through the first vote if there are checklist items we allow that to come back to see if those checklist items were addressed and that would change our decision.

Ashlie Wilbon: No, actually the checklist that they received for those items that were not recommended there was it was grayed out and they put a response in. So we have just been asked to pass everything to the committee for discussion. Even

though that wasn't necessarily what the committee put forward we felt that was ...

Andrew Baskin: So that's an issue, that's an issue that will be addressed. That's an issue that's addressed outside of this committee as to whether this process was followed or not followed but at this point we put it on the checklist for discussion of the response to the checklist and we've done that and apparently whether the process is, I'm not sure whether the process is correct or not.

It is included on our voting SurveyMonkey so we are going to vote. I mean if someone doesn't want to vote out of because they don't think the process we followed you have the right to do so. But at this point we've listened to the checklist results, we do a vote and we move on.

Philip Schoenfeld: So Andy, so stage I 75 percent of us rejected that we're moving forward to stage II. We provided the checklist responses with specific advice. We made changes to the index and six components. Five out of the six components the sponsor chose not to make those changes and provided a rationale for why they felt like they should not make changes.

Andrew Baskin: And if you're not, and if those rationales don't change your opinion then I presume you would vote the way you did previously.

Philip Schoenfeld: Correct.

Andrew Baskin: And that's what we do as individuals make that vote.

Taroon Amin: Andy, this is Taroon. I just wanted to give you a quick time check here. We have a number of other concepts that deserve an equal amount of time.

Andrew Baskin: Yes, that's why I'm trying to vote and move on, Taroon.

Taroon Amin: So let's just vote and move on and, you know, I know that many people have some concerns about the process and to be honest we especially the staff will take a lot of them to heart because many of them were very appropriate. But in the spirit of what we have to cover today we have to get through the rest of

these concepts and we have orientation to stage II. So if we can just keep moving it's critically important.

Andrew Baskin: OK, take a moment.

Evan Williamson: Before we move on to vote when you go the checklist to vote the first one that comes up at least on mine is not the one we're talking about. It's 0098.

Andrew Baskin: Yes, we went out of order. So just flip through the pages until you get to this one.

Evan Williamson: So just click all the way through.

Andrew Baskin: Click all the way through and just click back for the next one we're going to review.

Evan Williamson: Got you.

Andrew Baskin: We went out of order on purpose yes.

Evan Williamson: Got you.

Andrew Baskin: And I'll give everybody a few seconds to do that while Ashlie we'll key up the next measure on the let's see have you done that already on the web here so that we can see which one we're going to review?

Suzanne Theberge: We're pulling up 0098 now and the committee wants to start discussing that that would be great.

Andrew Baskin: Yes, let's go ahead and start discussing that. So do we have a lead discussion for this one on the call? I'm sorry did someone say yes?

Philip Schoenfeld: Yes, that was me.

Andrew Baskin: Who is that?

Philip Schoenfeld: I'm not sure if that was me or not.

Andrew Baskin: OK, well you can feel free to make comments. This one I don't think is, so this one we did make some recommendations that e-measures, understand that e-measures is a separate, you know, additionally to put to make something an e-measure requires considerable additional work. They basically the developers have basically said here that yes they're interested in making this an e-measure and that work is yet to be done and yet to be funded and that's the direction they're going to go.

But for now we're putting they are asking to put through the measure is not an e-measure and that a separate e-measure would come along at some later time hopefully at least that would be the plan. Is there any particular concern about that particular response? I personally think it's a fair response.

Hearing none let's move on to the second one. Consider the option of a patient choice if no treatment and I think the answer the response we're getting here is that really is already an option because one of the options is to just reassess at follow-up visit.

I understand that that may mean that no particular active treatment occurred other than passively, well a passive treatment. In other words no active treatment is actually going to occur and this follow-up would occur.

I'm OK with that. It would be nice if the wording were such so that it would be clear to somebody that, that no active treatment and just following along is considered a valid option. I'm just not so sure that a reader would say when they saw the words reassess at follow-up that they could check that box if they were just saying, you know, everyone has discussed, we decided not to do anything and we're just going to reassess. It's not just going to reassess there was an active decision not to do any other treatment. But I think it's, I understand that that option is there. I just wish the wording made it easier for the, for the provider to know that that's what's meant by that. But that's my point. Any other comments about that?

Richard Luetkemeyer: This is Rich Luetkemeyer; I think, you know, if we're really trying to get to the outcome measure that that response is unacceptable because the physician might have recommended any of the active things for the patient.

And the patient refused it. So to me one of the choices ought to be the physician recommended X and the patient chose not to follow the direction.

Andrew Baskin: Well I think that I mean what the measure is measuring is whether there's a plan of care and a plan of care could be in conversation with the member we've agreed not to. I mean this is a patient centered measure. I mean the patient does have a choice of saying no I don't want medication, no I don't want surgery, I would like to, I'm OK with doing nothing. I don't think that it should be a ding that that patient chose to do that. I mean that's acceptable.

Richard Luetkemeyer: Yes, it's only your measuring process. But if you're looking down for this to change behavior or to measure outcomes I think it is an important option. I see no harm in adding it. I don't understand why they didn't to say OK that's a legitimate choice. That's my personal opinion.

Andrew Baskin: OK, so you're saying separate then reassess at follow-up meaning the ...

Richard Luetkemeyer: Correct. I think, I think patient choice is different than a reassessment and follow-up.

Andrew Baskin: Any other comments on that one other people feel? I mean here's one where you're truly going to have to decide yay or nay based on these total responses so each of us will have our own.

Female 1: This is the measure developer and if I have an opportunity to comment I'd like to. But I understand there's no time.

Andrew Baskin: Let me see if the committee has any comments first and then if you want to address that one issue I will let you.

Female 1: OK.

Andrew Baskin: Any comments from the committee? OK then please if you would keep it brief though and just to that point. Thank you.

Female 1: Yes, completely. One reason we didn't make the change was because we wanted to bring it to stage II and the short timeframe didn't allow

us to retest this measure with the numbered response choice. We additionally don't have the funding to retest this measure with that additional option.

The other thing is that, you know, this is consistent with I completely understand the patient centeredness of that particular option but this is consistent with many other measures where patient refusal of treatment is often abused in terms of gaining of measures. And we don't allow that option for many measures such as blood pressure monitoring, hypertension control, diabetes control and other monitoring of chronic conditions. So that's our rationale and I completely understand if you disagree.

Andrew Baskin: Thank you. Let's move on to the next one which is expanding the age group. And the answer here is it sounds like it's something that they would consider in the future. Obviously their point is they can't just change the age group without further evaluation and testing going forward. But they'll consider that change going forward. Is there any comment from the committee regarding that?

OK so those being the checklist items and the responses at this point you can go to your SurveyMonkey and this is number 0098 and you have two questions to answer. If you can take a moment to do that now.

And Ashlie you'll pull up the next one in the GERD one 622022. And where is it. Oh I'm flipping, trying to flip back and forth between two things here, OK.

So there's a lot of things here I will try and help lead this conversation but I once again would want to reiterate to people that I will not vote on this one as this is a subsidiary of my company. So I won't be a voting member. Is there a lead discussion for this one on the call? No.

Suzanne Theberge: They were on the other call.

Andrew Baskin: That's fine. That's fine. That's what I figured. So this is a measure of, you know, an upper GI study in somebody with GERD so the denominator includes those with GERD who happen to have alarm symptoms and therefore, you know, go ahead whether an upper GI study is done or not.

The measure should include chronic GERD patients and their answer is that's how the denominator is defined as GERD patients is the denominator and then obviously the numerator is did you get the study or not get the study. Is there a particular comment on that this clarification?

OK, I'm not sure I understand this one. The exclusion should be clarified as previous malignancy and the exclusion they're saying that it say metastatic malignancy.

If I'm not mistaken the way the measure reads today is metastatic malignancy is a exclusion. And I'm not sure what our comment was. Were we saying that just whether it would be metastatic or not should be an exclusion? Even I'm not clear of what our recommendation was. Does anyone know?

Ashlie Wilbon: Hi, Andy, this is Ashlie. I think the in the if you look at the numerator and denominator statements and the actual measure submission form there was some confusion over what they had specified in the numerator and denominator as it appeared that they added in a numerator and then excluded a denominator I believe. And so I think the committee just wanted some clarification on what type of malignancy was excluded versus included.

Andrew Baskin: OK, well if I'm not mistaken from reading it the exclusions specific to metastatic malignancy. I don't know if that's ...

Ashlie Wilbon: They clarified that in there.

Andrew Baskin: OK, OK unless there's a comment that Barrett's esophagus should be included and I think they're saying it is being included they're removing it from the denominator exclusion list and Barrett's will be included so I'm thinking that's pretty straight forward. Any comment on that?

The measure should include patients under 18 as well. And their responses it sounds like that's fine that they listed the age span on this. I don't know whether they went to I guess no age bands at all I guess they're saying. I don't know whether anybody feels that there's a lower cut off point but I'm thinking GERD symptoms how would you even figure that out in a 1-year-old. I guess I'm not worried about that.

Any comments regarding this? It sounds like they did what we asked them to. If you're having separate conversations please mute your phone if you're not going to speak here because we're hearing that side stuff. Thank you.

The next one additional evidence should be provided for evidence criteria and they apparently did submit, was it additional evidence or they're just pointing us to the evidence Ashlie? I'm seeing here evidence submission form in section 1C28 was that additional evidence because I didn't get a chance to read it.

Ashlie Wilbon: Yes, I don't have it directly in front of me. But the committee had asked for some expansion on the evidence that was provided there. I think the committee felt like there was more out there than was provided in the submission form. And so there was just some additional some additional items added and we were just asking for the committee to review that to see if what they provided was adequate based on the initial ...

Andrew Baskin: But the committee, the committee did feel that the evidence was out there whether it had been submitted or not. But it should be for completions sake should be included in the submission.

Ashlie Wilbon: Right, correct.

Andrew Baskin: OK, all right and I presume we'll all have the ability to review that evidence. But it doesn't, it sounds like we were OK with this just wanted more evidence to be there. But we knew the evidence existed.

Ashlie Wilbon: Yes.

Andrew Baskin: Performance gap stuff I think that will get reviewed at the time of stage II right?

Ashlie Wilbon: No.

Taroon Amin: No evidence isn't important, Andy, and performance gaps. Also operator can you mute Gail's line. I think we can hear some background.

Operator: Gail's line is muted.

Andrew Baskin: I'm sorry, Taroon. What were you saying about evidence and performance gap?

Taroon Amin: Performance gap should be evaluated in stage I.

Andrew Baskin: Oh OK.

Taroon Amin: So that's why we want to make sure it's complete in responses to the committees request to make sure that the information was provided.

Andrew Baskin: OK, well Taroon, do you or anybody have any information about this performance gap stuff with submitted. I mean I looked at it previously but I haven't looked to see if anything has changed.

Taroon Amin: I can't point to it specifically but maybe we can ask the developer to point out exactly what was added in.

Andrew Baskin: Is the developer on the phone? Anyone from ActiveHealth on the phone? I don't think they were initially. I don't think they joined the call. They didn't speak up when we first took roll call.

OK, if I'm not, OK well I guess I don't want to guess here. If I'm not mistaken though this was a measure where there was the measure was on a population and not necessarily on a provider level which makes performance gap difficult because there's nothing to compare it to. But that it did show that this was not being performed at a high rate, high percentage rate of patients. You'll have to each of you have to recall or go back to the initial information to see if it's satisfactory for you to have this measure move on.

Any comments though from the group specifically about the evidence criteria additional information and the performance gap in terms of our recommendation?

OK, and the next one is sort of the same issue. It's about defining the procedures and numerator more clearly and I don't have whether they've defined it more clearly or not.

Now the last one I, even I'm a little puzzled by this. I read through their answer. It seemed to me the answer addressed the issue of patient populations and that they're looking at two patient populations. One is the denominator the general population that has GERD and one is the numerator, I mean a numerator denominator combination that deals with those GERD members with high risk, at high risk and the high risk I think is the well it doesn't say it here what the high risk parameters are but I, but that it would be calculated separately, separated the denominator into the two populations right. Does that help people in terms of what they were looking for here? I think they were unclear as to why somebody would want to do that but nevertheless they certainly were willing to do it.

Richard Luetkemeyer: This is Rich Luetkemeyer again. Would you interpret that as the high risk is still part of the general population or are they two separate groups?

Andrew Baskin: I interpreted it as the general population included high risk and not high risk. But that they were separately calculate a number of the subset of the general population that is high risk to see what the compliance is and that population specifically.

Richard Luetkemeyer: Thank you.

Andrew Baskin: But frankly, you know, you could calculate the other way around by just removing them if you had, if you knew the numbers, you know, what I mean.

Richard Luetkemeyer: Yes.

Andrew Baskin: You could subtract one set from the other. So I think you can get all combinations of calculation this way if you chose to do that. Any other comments? OK then let's move on and vote on 622.

I have to remember not to vote. Sorry. OK then next go to the next one where am I here, chronically received hepatitis A vaccination. So this was, so they decided there was a question here about the title of vitamin A, vitamin A, hepatitis A vaccination because it was when you measured the numerator it was those who were vaccinated and those who were tested. Not necessarily those who tested positive by the way. It was only those that were tested which

was one of the issues here. And what they chose to do is remove those that were tested out of the numerator and really only accounting vaccinations of hepatitis A for those with chronic liver disease. So rather than change the title they actually decided to remove those from the measure so that the title is now accurate with what is being measured which is hepatitis A vaccinations and chronic liver disease and actual vaccine.

The second issue was of course that very same issue which was if you tested them you didn't know whether they got vaccinated or not. And their point is then if we remove those from the, those folks from the numerator of just being tested is counting then that essentially removes recommendation number two here.

I think the issue comes however that there will be folks that will have been tested, will have been tested as immune but you don't get credit for them. And I think that's my thought on this one is a concern. But I don't know how often that happens or whether that's just some background noise and in reality, you know, the measure really measures the activity we want is that having somebody with chronic liver disease and they got vaccinated. So I'm just pointing that out.

The harmonization issue there has been contact by the way between the AMA just recently and ActiveHealth and there will be some future discussions. It hasn't occurred yet. The AMA measure is those with hepatitis C getting vaccinated with the hepatitis A vaccine and obviously this is the denominator that people with chronic liver disease there's obviously overlap there and the question is whether there is some way to harmonize the denominators for this.

I will point out however that 3999 also allows credit for positive testing of immunization with antibody testing as credited in the numerator. Obviously you wouldn't vaccinate those folks.

So, any comments regarding these recommendations? They're kind of all related that's why I kind of went through them together.

Richard Luetkemeyer: This is Richard Luetkemeyer again. If they're removing the antibody testing from the numerator shouldn't they remove the those with the positive antibody from the denominator?

Andrew Baskin: Well that was my point that I was making. The problem I can tell you that the issue they have is they don't know the result of the test. This is done with administrative data and they can only tell that a test was performed. They can't tell whether the test showed immunity or not immunity and that's their limitation and why they're doing it this way which is why they chose to put it in initially with their recommendation, with their reasoning being that if they got tested they thought there was a high likelihood that the physician would appropriately treat vaccinate or not vaccinate based on the result of that and they would trust that and they thought that was the lesser error to make than removing it. But they removed it at the request of this committee I think they'd be happy to go back the other way. But that's exactly the issue.

Richard Luetkemeyer: Right but, this is Rich Luetkemeyer again. I'm afraid though I'm making the score look for the individual doctor who got the positive result saying I'm not going to vaccinate you. So maybe it's going to look like his rate is lower and he's actually following the right path. So to me the solution would be anybody with an antibody testing be removed from the numerator and denominator if you don't know the results.

Andrew Baskin: OK, I appreciate that. That is a good response. And that's another way to do it. So barring any comments you'll have to decide now whether this recommendation, whether the developer response, you know, based on the conversation and your own thoughts here whether they were responsive to our checklist and whether this should move forward.

Once again I'm not voting on this one but if you please vote now and then we'll move on to the next measure. Ashlie, why don't you pull up the next one?

All right, so as you're doing that voting the next one is the endoscopy polyp surveillance. Phil are you the lead on this?

Philip Schoenfeld: I believe I was.

Andrew Baskin: OK, so this was the one where they the measure was to recommend if you had a essentially a normal or negative screening colonoscopy that in the plan or whatever it is the in your notes and your, oh gosh I can't get the words out today, your recommendation to the patient that the plan is to repeat the colonoscopy in 10 years and it's so documented.

And our response to this was well gee whiz wouldn't it be a better measure to see if he performed one that wasn't performed before 10 years after a prior one because that would be an outcome as opposed to saying you did it doesn't mean it actually didn't occur before 10 years. Phil what do you think about that response?

Philip Schoenfeld: Well and I just want to make sure again precisely there here the quality indication is after you do a colonoscopy if it's a normal screening colonoscopy you make the recommendation to repeat it in 10 years. Is that correct?

Andrew Baskin: Yes, I believe that's what it is but there's certainly no measurement that you actually follow through with that or not.

Philip Schoenfeld: Right, so here's, here's where it's a different issue. As a committee we felt we want to measure whether or not the indication for a colonoscopy when you're beginning, when you're scheduling the colonoscopy when you're beginning it whether or not you're documenting that yes I'll talk to the patient, I've gotten medical records, I know that their last normal screened colonoscopy was 10 years ago.

And that's absolutely important. But what the quality measure here is to say is if I do a colonoscopy and it's normal am I recommending to repeat the colonoscopy in 10 years.

So that's really a different quality measure. And both are very important. But what we suggested is we want you to add on this additional quality measure not that we're disputing that the issue that you're measuring whether or not after a normal screening colonoscopy whether or not the recommendation is there to repeat in 10 years. We're not disputing that that's important we're just saying we want you to add on another one.

And they basically said, you know, at this point we don't have the data to add on that other one.

So I actually feel OK about this one moving to stage II to the extent that I mean we didn't say anything that what they're measuring is unimportant. We just said boy we would really like another measure to assess the indication part to. Because frankly I mean this goes off a little bit on a tangent the current data suggests that up to 30 percent of the time after a normal screening colonoscopy a patient gets a recommendation to come back sooner than 10 years. So that's kind of my take on it.

Andrew Baskin: Other comments? OK let's move down to the other recommendations on this same measure then quickly because I think these other ones are a little bit easier. Phil do you just want to do it rather than have me repeat them or?

Philip Schoenfeld: I'm sorry. Say that again, Andy.

Andrew Baskin: The other lines here of the recommendations on the checklist do you want to do it so that I don't do it and then you repeat in a better way than I do.

Philip Schoenfeld: Actually it would be helpful for me if you did because I have to admit on this one I'm actually driving now.

Andrew Baskin: Oh OK, that's OK.

Philip Schoenfeld: I thought we were only going to be on the call (for a little).

Andrew Baskin: So the next one was had to do with folks who had an inadequate or poor prep and who had a recommendation to repeat the colonoscopy in a year or less. And they're basically saying that's kind of built into it and that there's a medical exception out on this one so that those folks are essentially you're not dinged for this and in fact, you know, if, it's basically saying if you recommend in a less than 10 years and then specifically here in a year or less because of a poor prep that you get credit for making the correct recommendation. In other words it's the same credit as if you had told them to come in 10 years with a normal one. It's one way, it's not the only way to get at it but I think it's reasonable.

Philip Schoenfeld: Yes, this one is different because it's not totally clear to me. If it's an inadequate prep you should just like if it's a normal screening colonoscopy you should say come back in 10 years. If it's an inadequate prep you got to say come back in one year or less. It can't just be you were told to come back sometime shorter than 10 years.

Andrew Baskin: Oh no, no, no, yes, so specifically getting credit for this particular exception right.

Philip Schoenfeld: And that part is fine. Then that's appropriate. Failure ...

Andrew Baskin: And it's reported separately so ...

Philip Schoenfeld: Right, failure to do that, failure to do that would be inappropriate.

Andrew Baskin: Yes, so it's a reason right, right, so it's just a group of patients that the right recommendation is one year or less then this is separating them out of as by the way can be calculated separately in the numerator if you choose to right.

Philip Schoenfeld: Right.

Andrew Baskin: So I think this addresses the issue. Any comments on that? Consider it just in the upper age limit and including inflammatory bowel disease and defining above average risk they're basically saying that above average risk is defined by the clinical guidelines. I don't know if they actually in the measure. I can't recall. Their recommendation for the upper age limit they will take into review for the next time that of this measure. They can't do it now obviously but they appreciate that there maybe should be an adjustment there.

And once again the inflammatory bowel disease they're OK with considering that. They just can't do it, you know, they just can't change the measure. It would require, you know, additional review and enhancement and they chose, they said they will do that at some time. Clarification, specification where the exceptions are included in the denominator. Oh wait I'm not saying this, no the exceptions are not included in the denominator if there is a valid medical reason.

Well here I don't understand because frankly the exception of a poor bowel prep which is a medical reason is included. Maybe there's someone from the AMA here that can help out because the other one said the PC recommends exceptions to be reported alongside the performance rate.

So are they being, so is the exception for the poor bowel prep being removed from the denominator as well as every other medical reason for not recommending 10 years being removed from the denominator or are they being counted as an exception in the numerator?

The AMA can help me on this if there's some one on that knows this or ...

Katherine Ast: Hi, it's Katherine from the AMA. First I want to ask if any of my specifications colleagues are on, (Kendra) or (Autumn). OK, I guess that's a no.

So my understanding is that they go through the whole measure so the patients are in the denominator. And if they do not meet the numerator then you go back and look to see if an exception was noted and is valid. So if the exception is inadequate prep for example then that patient will be removed from the denominator and not counted. So then the exception rate however many people have been removed we recommend they report it alongside the performance rate.

Andrew Baskin: Oh OK.

Katherine Ast: Does that make sense?

Andrew Baskin: OK, so the one year unless recommended for bowel prep will be taken out of the denominator but they will be included in that group of people who have a medical exception and will be counted alongside.

Katherine Ast: Correct.

Andrew Baskin: I got it, OK all right that's one way to do it. There is various ways to do this and, you know, appreciate the response to how you're doing it. Anybody have any questions about that?

Richard Luetkemeyer: This is Rich Luetkemeyer again. I assume if the person is 70 years old and the opinion of the colonoscopists is they don't have a 10 year life expectancy they're not going to say follow-up in 10 years. Would they also be counted like an inadequate prep?

Andrew Baskin: I think that's a medical reason. I think that's included as a medical reason for not recommending. So you don't know the actual reason because there is a code for just medical reason. But I think that's an acceptable medical reason. But if the AMA thinks otherwise but I believe it is.

Katherine Ast: No, that's correct.

Andrew Baskin: Yes.

Richard Luetkemeyer: Thank you.

Andrew Baskin: And the last one has to do with some harmonization with another measure. And I presume this means they'll look into it.

So any other comments about this particular measure? I think we need to vote. I know Taroon is probably sitting there going we're never going to finish which is possible.

And then I guess we need to move on to the next measure while everyone is voting. The problem is I can't vote and talk about the next measure at the same time. But I'll try.

So this is the other colonoscopy one and this has to do with basically I believe, you know, that if the patient had a polyp or history of polyps that required them as normal guidelines we'd say return in three to five years. That the, that the, this is that they waited at least three years.

So this is the after the fact. That you're doing a colonoscopy and did you wait at least three years since the prior one where they had a recommendation to come back in three to five years or whatever it was. But there is no reason to do it in less than three years.

So this is, this is the look back one as opposed to recommending going forward. And I think the feeling was here that you can look back three years

although looking back 10 years was a difficulty. It was mentioned in the other one.

The evidence expansion and details I'm not sure what here is, during the committee satisfied with the evidence and details supplied in the submission. So that was the response. So I'm presuming that we didn't get any additional information.

Philip Schoenfeld: I think the big deal here Andy is this. The committee felt that if at all possible it should more precisely reflect looking back for three years versus five years. Here's what I mean by that. It's very clear cut in the recommendation that if you have one large adenoma or three or more small adenomas that you should repeat the colonoscopy at three years. But if you only have one or two small adenomas you should repeat it in five years.

Now if you say you have to make sure that it's been at least three years I mean that's good. But really it should be expanded to say, you know, if you look back and the person only had one or two small adenomas you really should be saying we're only going to do it again if it's five years. And the response, I'm paraphrasing here was that it was felt it would really be hard to get that five-year data.

Having said that, you know, I think that this is something where the AMA could work a little bit harder on it because I do think it would be better if we expanded it to really say you're going to try not just three years or more but three years if it meets the criteria that you're going to repeat at three years and five years if it meets the criteria to repeat at five years.

Andrew Baskin: You're segmenting it out to more specific recommendations so that some recommendations are more than three years. And they're saying for simplicities sake it would be very difficult. They included all that as certainly nobody more than three years but they can't get to that other level without some difficulties and they're pointing out what those difficulties are.

Philip Schoenfeld: And our feedback ...

Andrew Baskin: So they don't disagree. It's a good idea. It's just hard to do.

Philip Schoenfeld: And our feedback was well sometimes things are hard to do but they're important to do.

Andrew Baskin: Right. So, so this group has to decide whether that's adequate, whether it's worth having this measure go through as is with the, with the less specificity but nevertheless not clinically incorrect because at least five years does include five years. At least three years does include five years. But that there was an opportunity to make this better and perhaps it wasn't ceased and or whether and would we accept this with the idea that maybe a better one would come along later to enhance this one or we just don't want to let this go.

Philip Schoenfeld: Exactly.

Andrew Baskin: So that's your choice.

Philip Schoenfeld: And that was, and that was not clear to me and this is where I thought the AMA folks might respond. I mean is there a more definitive plan to refine this to get us to the five mark as well.

Katherine Ast: Hi, it's Katherine. I'm sorry someone else ...

Richard Luetkemeyer: Yes, this is Rich Luetkemeyer again. I would just raise the issue that if they're doing it at three years and one or two small adenomas that they're accepting inappropriate overutilization. In five years is the recommendation.

Philip Schoenfeld: Correct.

Richard Luetkemeyer: And it's title is avoidance of inappropriate use. So they're promoting it.

Philip Schoenfeld: They're certainly not doing enough to limit it.

Richard Luetkemeyer: Correct.

Andrew Baskin: I'm sorry Katherine you were going to say something or somebody else was aware of this measure and what the future may lie, where the future may lie.

Katherine Ast: So yes this is Katherine from the AMA. And whereas I do not know where the future may lie I can tell you our current philosophy of, you know, developing performance measures is to set the floor not the ceiling. So we often times differentiate between measures and guidelines and we don't try to mirror the measure exactly on the guideline but rather what's, you know, balanced with the measure that can be most applicable and apply across most settings and in that case as you described at least three years.

Now that said I can understand what you're saying and I can certainly bring this back to others here at the AMA and also our partners on these measures. And make that recommendation that they can reconvene the work group. At this time there are no plans to reconvene the work group. So we'd have to get together with our specialty society partners and discuss this.

Philip Schoenfeld: OK, and Katherine just so I can make sure though and Andy you can correct me. This is a pre approval of an existing measure. Is that correct?

Katherine Ast: Yes, that's correct.

Philip Schoenfeld: OK, and Katherine, I agree with you totally when you're initiating a measure you kind of set the floor not the ceiling. But now that we're in the re-approval process I think, I think the floor is rising. The tide is rising and that's why I kind of emphasize that I think at this point for re-approving it that's why we emphasize that yes back when we first approved this this three-year mark was an appropriate floor. But, but we're getting better and doing it for five years for two small adenomas is a threshold that we should be striving to meet now.

Katherine Ast: OK.

Philip Schoenfeld: So, so I understand your perspective I really do.

Andrew Baskin: Any other comments from the committee? I think we need to move on and vote. I appreciate the comments and the clarification from the AMA. Thank you.

And let's move on to the next measure then as you're voting.

Are we done or did we have to? I thought there was one more, OK.

This one I'm a little confused with so I'm hoping there's someone on this call that in the committee here that is better than I at this. I mean I can certainly read what's here. But I'm not so sure I understand it all. Any of our GI folks on the committee that have a better insight to this answer than I do?

Suzanne Theberge: Liliana, are you still on?

Andrew Baskin: It's the primary, you know, diagnosis issue versus the secondary diagnosis. I'm sorry someone was going to speak.

Suzanne Theberge: Is Liliana still on the call. I believe she's the primary reviewer for this measure. She may have stepped off.

Andrew Baskin: I mean I always have issues with ...

Operator: Liliana is connected.

Andrew Baskin: Liliana are you out there on mute somewhere? She may be connected and walked away for a moment.

Suzanne Theberge: All right, just go.

Andrew Baskin: I think I'm sorry go ahead.

Suzanne Theberge: Just go on.

Andrew Baskin: OK, I mean this is a coding issue. And I guess in general my worries about coding is there's not a lot of consistency in what's a primary and what's a secondary diagnosis. So I guess I'm not understanding how this works. Is there someone from the developer here, oh well certainly not, I don't know that there is who can explain their answer, response?

Suzanne Theberge: No, the developer is not on the call.

Andrew Baskin: OK, and this is I presume a maintenance measure?

Suzanne Theberge: No, it's a new measure.

Andrew Baskin: Oh this was a new one, OK. Well, you know, they try and go through the explanations why they use primary diagnosis versus secondary diagnosis. And in a perfect world I certainly understand that. One could argue that I guess we shouldn't be approving or disapproving based on the likelihood of good coding or bad coding. That may be one way to look at this. And I'm not sure what population, was this meant to be a population level measure. Do we know the level of the measurement on this one? I'm not; did it list it as a measure for individual providers or in a different level?

Suzanne Theberge: We think this is a facility level measure. I'm just double checking but I'm pretty sure it's facility level.

Andrew Baskin: OK, because I would have had issues more issues with this at a provider level than I would be at a higher level. That's why I'm asking. I doubt this is an institution level.

Taroon Amin: If there aren't really any questions on the committee really related to it, I mean its fine to just kind of move on because these were sort of minor issues by the committee.

Andrew Baskin: OK, then we don't have to address it.

Taroon Amin: So I won't, don't ...

Andrew Baskin: Well we do have to address. I mean everyone has to make a decision regarding it. So I've read it and I've come to the best conclusion I can and presumably others have as well. So go ahead and vote and then I believe we've completed the review in record time, I might add. And Ashlie and Taroon, you've got 12 minutes.

Taroon Amin: OK, great.

Andrew Baskin: So go for it.

Taroon Amin: I'll turn the floor over to Suzanne.

Suzanne Theberge: So we're actually going to have to skip the rest of the orientation section since we're out of time for that. So I'm just going to ask Evan to jump forward in the slides to the next steps which is at the very end.

So what we would like for you to do is complete your preliminary checklist votes. If you have not already voted please complete that by 9:00 a.m. Eastern Time on Monday morning. And on Monday, at some point Monday, we will send out a list of which measures will be going forward to stage II based on the results of your checklist vote. And a staff notes memo that has some notes and comments on the measures and that memo will also include the comments that we received from NQF members during the recent member comment period.

Now please note if you vote that a measure should not move forward to stage II, it will remain an approved concept and it can be and will be brought back if the developer wishes to at some point within the 18 months that they were allotted from the board endorsement date. So if you decide not to move a measure forward now, it can be brought back in the future.

So our next steps as I said please complete that checklist review vote. Following that we'd like you to review all of the measures that are going to be moving forward to stage II. Again we'll let, you know, what those are on Monday. And please complete a preliminary evaluation survey of those measures. We'll send a link out to that survey on Monday as well. And that's going to have you look at the criteria.

Unfortunately, we didn't have time to go over the remaining criteria on this call. This criteria our scientific acceptability use and usability and feasibility. What we'd like you to do instead is just review the slides that we have sent earlier and that has kind of a summary. And then if you have questions once you start looking at the measures, please give us a call or email and we'll be happy to talk you through anything you want to know. Really what we want you to focus on is scientific acceptability that's really the big must have criteria for stage II and that's really where your time in preparing to evaluate measures and then your evaluation time should be focused on that. And again just call us once you've looked at the slides if you have any questions.

I think and then following that we will be holding full committee calls on April 3rd and April 8th. Those are both from 3:00 to 5:00 p.m. Eastern Time. And at that time we'll be reviewing the remaining criteria and having the committee decide which measures they're going to recommend.

We need you to be at a computer during those calls because we'll be doing online live voting and the measures will, we need to know your votes as we go. So please be at a computer to access that online voting toll which we'll be sending out in advance of that call.

So with all that said, do folks have any questions?

Andrew Baskin: No, but I'd like to make a quick comment. I wanted to thank the committee members and appreciate your openness and honesty about some of the issues in this type of review. That was very well appreciated and I'm glad everyone felt comfortable speaking up. That's the right thing to do.

I will take responsibility for failure of not getting us done quicker. But, you know, time goes and I apologize for that. And thank you for those developers who came on to the call, your being there was helpful and answering our questions when needed but just being available is a tremendous help to us. So thank you to all for that.

Suzanne Theberge: All right, thanks, Andy. So again, please really don't hesitate to call or email us if you have questions as you start to look at the rest of the criteria. I would really like to help you out there. There is information in the slides.

And now we need to do a public comment since this was a measure discussion call. So operator, if you could open the lines and see if there's any public comments.

Operator: At this time, if you would like to ask a question, please press star then the number one on your telephone keypad.

You have no questions or comments from the public.

Suzanne Theberge: All right, thanks everybody for your time today. And we look forward to speaking with you in a week or so on the April 3rd and April 8th committee calls.

Andrew Baskin: Great, thank you, guys.

Suzanne Theberge: Have a great weekend, everyone.

Evan Williamson: Thanks everyone.

END